

# A feasibility study to assess the role of pharmacists in lung cancer diagnosis compared to current pathways

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| <b>Submission date</b><br>09/07/2020   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>10/07/2020 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>13/10/2022       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

The study aims to find out what people think about using pharmacists to refer people with lung symptoms for a chest x-ray to check for lung cancer. We will see if this could be something that could be used in the future, and what we can do to improve it.

### Who can participate?

Members of the public attending pharmacies with some lung symptoms e.g. a cough, who are smokers or ex-smokers.

### What does the study involve?

The pharmacist will ask you some questions about your health. If they feel you need a chest x-ray they will send you for one. You will be referred to the hospital for a chest x-ray. The hospital will send you a letter or ring you to let you know your results. You might be asked to go to the hospital for further tests if needed. The pharmacist will give you a short questionnaire to fill in when you get home. Some people will be invited to take part in an interview and the researcher will be asking questions to get a better idea of what you thought about the service, why you went to your pharmacist for advice and how we can help other people to access this help in the future.

### What are the possible benefits and risks of participating?

The results of the research will help us to understand what services can make the most difference to patients. This can help other patients like you in the future. It may also mean that you can get the appropriate treatment for your symptoms.

The symptoms that you have described to your pharmacist mean that a chest x-ray is recommended in guidance from the National Institute for Health and Care Clinical Excellence (NICE). We would recommend you have a chest x-ray even if you chose not to participate in the study. A chest x-ray is a form of ionising radiation that allows images to be made of your body. Exposure to large amounts of ionising radiation can carry risks to the body, for example, it can cause cell damage that may, over many years and decades, turn cancerous. The amount of

radiation that a chest x-ray will expose you to is very small and is the same amount of exposure as 2 days natural radiation from the environment. This has less than 1 in 1 million chance of causing cancer.

Where is the study run from?

There are 16 community pharmacies participating in the study, all based in the Llanelli or Burry Port area of Hywel Dda University Health Board.

When is the study starting and how long is it expected to run for?

May 2018 to August 2020

Who is funding the study?

Health and Care Research Wales (UK)

Who is the main contact?

Dr Rachel Gemine

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Mrs Sarah Rees

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## Contact information

### Type(s)

Public

### Contact name

Mrs Sarah Rees

### Contact details

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

231842

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

IRAS 231842

# Study information

## Scientific Title

Pharmacy referral for Lung cancer Symptoms: a feasibility study to assess the role of pharmacists in lung cancer diagnosis compared to current pathways

## Acronym

PLUS1

## Study objectives

To monitor numbers of patients suitable for referral/willingness to be referred for chest x-ray by community pharmacies and subsequent lung cancer diagnosis rates.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 23/11/2018, Wales REC6 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB; +44 (0)1874 615950; Wales.REC6@wales.nhs.uk) ref: 18/WA/0215

## Study design

Observational mixed methods

## Primary study design

Observational

## Secondary study design

Case series

## Study setting(s)

Community

## Study type(s)

Diagnostic

## Participant information sheet

## Health condition(s) or problem(s) studied

Lung cancer

## Interventions

Members of the public presenting at community pharmacies with symptoms of lung cancer will be offered a consultation with the pharmacist and if required, direct referral to the local hospital for a chest x-ray. Participants will also be asked to complete a questionnaire and invited to a qualitative interview with a researcher, following their x-ray.

## Intervention Type

Other

**Primary outcome measure**

1. Number of patients referred via the pathway measured using case report forms at the end of the study
2. Number of patients referred with a lung cancer diagnosis measured using patient records at the end of the study

**Secondary outcome measures**

Assessed using a novel questionnaire and interview at a single time point:

1. Acceptability of the pathway to patients and healthcare professionals
2. Perceived impact on pharmacy workload and radiology referrals
3. Patient and professional views and experiences of consulting the pharmacist

**Overall study start date**

31/05/2018

**Completion date**

31/08/2020

**Eligibility****Key inclusion criteria**

1. Individuals over the age of 40, who are current or ex-smokers with a history of 10 or more smoking pack-years, and have had 1 or more of the following, for more than three weeks:
  - 1.1. Coughing up blood
  - 1.2. High pitched audible wheeze
  - 1.3. Neck vein engorgement/facial swelling
  - 1.4. Cough
  - 1.5. Chest and/or shoulder pain
  - 1.6. Unexplained weight loss
  - 1.7. Shortness of breath
  - 1.8. Hoarse voice
  - 1.9. Finger clubbing
  - 1.10. Swollen nodes in the head or neck
2. Community pharmacists and respiratory physicians involved in patient care

**Participant type(s)**

Mixed

**Age group**

Adult

**Sex**

Both

**Target number of participants**

228

**Key exclusion criteria**

1. Unable or unwilling to provide written informed consent
2. Patients who have a diagnosed cognitive impairment will be excluded from the evaluation/

follow up element of the study

3. WHO performance status 4

**Date of first enrolment**

01/05/2019

**Date of final enrolment**

31/03/2020

## **Locations**

**Countries of recruitment**

United Kingdom

Wales

**Study participating centre**

**Prince Philip Hospital**

Hywel Dda University Health Board

Bryngwyn Mawr

Dafen

Llanelli

United Kingdom

SA14 8QF

## **Sponsor information**

**Organisation**

Hywel Dda University Health Board

**Sponsor details**

2nd Floor

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**Sponsor type**

Hospital/treatment centre

**ROR**

## Funder(s)

### Funder type

Government

### Funder Name

Health and Care Research Wales

### Alternative Name(s)

Health & Care Research Wales, Ymchwil Iechyd a Gofal Cymru, Health Care Research Wales, HCRW

### Funding Body Type

Government organisation

### Funding Body Subtype

Local government

### Location

United Kingdom

## Results and Publications

### Publication and dissemination plan

The results of the study will be disseminated via peer reviewed scientific journals, internal reports, conference presentations and website publications.

### Intention to publish date

31/08/2021

### Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

| Output type                                   | Details      | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|--------------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> | version V2.1 | 22/01/2019   | 07/08/2020 | No             | Yes             |
| <a href="#">Protocol file</a>                 | version V2.0 | 23/08/2018   | 07/08/2020 | No             | No              |
| <a href="#">Results article</a>               |              | 09/08/2021   | 11/11/2021 | Yes            | No              |
| <a href="#">Plain English results</a>         |              |              | 13/10/2022 | No             | Yes             |

