A REAL WORLD STUDY TO DESCRIBE THE PATIENT PATHWAYS AND NHS RESOURCE USE ASSOCIATED WITH THE MANAGEMENT OF IRRITABLE BOWEL SYNDROME (IBS) IN UK CLINICAL PRACTICE

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Introduction

- Irritable bowel syndrome (IBS) can be painful, debilitating and can cause anxiety and embarrassment. It has been shown to significantly reduce the quality of life of sufferers.
- The prevalence of the condition in the general population in the UK is estimated to lie somewhere between 10 and 20%[1]. Women are twice as likely to be affected with IBS symptoms as men[3]. It has been estimated that only about half of those affected by IBS will seek medical help and that, of those, approximately half will receive medication with some patients seeking alternative complementary/dietary approaches[2].
- Although there is national clinical practice guidance on the diagnosis and management of IBS[1,3], there is little evidence to show whether this is being followed in the real world. As a result patient care pathways are thought to vary and may involve inappropriate or unnecessary and costly investigations and treatments with associated risk to patient safety.
- There is a need by GPs and other healthcare professionals looking after people with IBS to understand current patient pathways of this potentially lifelong condition and to quantify current resource use.
- Data relating to the full study is intended to be used to identify opportunities for ensuring that people with IBS are diagnosed and managed more effectively in the NHS both acutely and long-term.
- IBS is often considered a diagnosis of exclusion, with poor diagnosis coding in primary care. This makes identification of eligible research participants particularly challenging.

Objective

- We present the methodology development of a multi-centre, observational, retrospective research study ongoing in primary care, designed to overcome the challenges of IBS patient identification.

Methods

Study Feasibility

- Study feasibility was conducted by pH Associates (research consultancy; study coordinators) for Almirall UK Ltd (Sponsor) using medical opinion, clinical coding searches and National Institute for Health Research (NIHR) Clinical Research Network expertise.

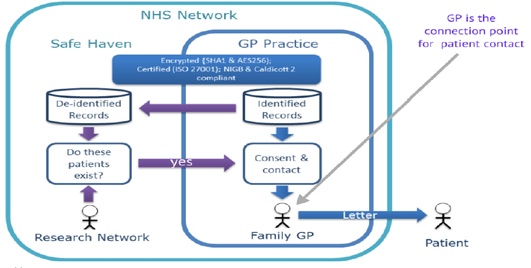
FARSITE Patient Recruitment Tool

- The NIHR Greater Manchester Comprehensive Local Research Network (GM CLRN) recommended FARSITE, (Feasibility And Recruitment System for Improving Trial Efficiency), an electronic software tool purposely designed to facilitate the anonymised searching of patient medical records to identify eligible patients for research purposes. The FARSITE application has been developed by the GM CLRN and North West eHealth consultancy in partnership with, and for use by, Salford Primary Care Trust and General Practitioners in the Greater Manchester area in the UK.
- FARSITE is a rapid 'search and find' tool designed to preserve patient confidentiality. The FARSITE software provides a safe, convenient and effective way for the GP to control the recruitment of their patients into clinical research, whilst allowing NHS-based researchers to run complex and powerful searches over anonymised population level health record data (Fig. 1).

FARSITE Search Criteria

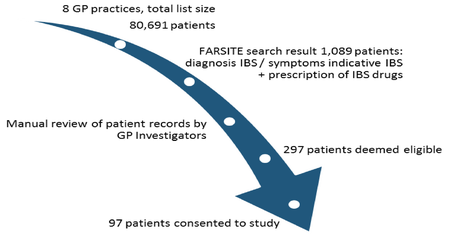
- **Initial FARSITE search criteria:** patients aged 18-60; with Read code for IBS or a combination Read code symptoms indicative of IBS and prescription of IBS drugs between 01/01/2009–31/12/2011. GP Investigators reviewed clinical records of the FARSITE-generated list of patients to apply full eligibility criteria for final patient selection.
- **Full study inclusion criteria:** medical diagnosis of IBS or meeting ROME III criteria[4]; provision of consent. **Exclusion criteria:** diagnosis excluding IBS; IBS symptoms secondary to other condition; IBS medications for non-GI symptoms.
- The study was NHS peer-reviewed and supported by the NIHR GM CLRN and the NIHR Primary Care Research Network and received Research Ethics Committee approval (13/LO/0692). The study is ongoing in 8 GP practices in Salford & Greater Manchester region.

Fig. 1 FARSITE Patient Recruitment Tool



Results

Fig. 2 Study Participant Eligibility



- During the feasibility search, just using the Read code specific for IBS identified only 50 (0.02%) patients across the whole FARSITE network–linked GP practices. When combining Read codes for IBS with symptoms indicative of IBS and prescriptions from 01/01/2009–31/12/2011, FARSITE selected 4714 (1.9%) patients aged 18-60. From these, 3 GP pilot practices each screened 10 random patient records to confirm whether the patient did have IBS and 12/30 (40%) were found to be eligible. The study eligibility Read codes were revised following this pilot.
- Following study design confirmation and approvals, the FARSITE search was conducted at all 8 participating GP practices using the criteria: patients aged 18-60; combination Read code of IBS/symptoms indicative of IBS and prescription of IBS drugs 01/01/2009–31/12/2011.
- FARSITE identified 1089 potentially eligible patients, of which 297 (27.3%) patients were deemed eligible by manual review of the patient records by the study Investigators. Main reasons for non-eligibility were symptom characteristics not meeting ROME III criteria or not confirmed as IBS by medical opinion. All potential participants were subsequently approached for study consent; with 97 providing their consent for participation (Fig. 2).

Conclusions

- **Identification of patients using only Read diagnosis codes specific for IBS is sub-optimal in primary care.**
- **A combination search of Read codes with symptoms and prescription data via FARSITE has enabled potential participants to be identified in primary care with a reasonable screening failure rate.**
- **FARSITE is a valuable research tool aiding study feasibility by reducing the need for manual patient identification.**

References

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Disclosures

I. Caldwell: None declared; J. Collins: None declared; M. Rance: Employee of Almirall UK Limited; R. Dew: Employee of pH Associates, commissioned by Almirall to provide research design, conduct analysis and provide scientific editorial services.

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