Host department:

Southampton (in collaboration with Oxford)

Title:

Can we sensibly use cancer risk scores for lung and colon cancer in primary care?: using the CANDID cohort.

Proposed supervisory team:

- Professor Paul Little (clinical and quantitative expertise)
- Professor Geraldine Leydon (sociology and qualitative expertise)
- Dr Beth Stuart (Southampton) and Dr Richard Stevens (Oxford) (statistical expertise)
- Professor Lucy Yardley (Health Psychology/behavioural expertise)

Project description:

The proposed project is aligned closely with the £2.5 million CANDID cohort, a flagship prospective diagnostic cohort for two of the commonest cancers in clinical practice (lung and colon), funded by the NIHR through the School for Primary Care Research (SPCR), and is a collaboration across 8 departments of the SPCR.

For lung cancer, NICE guidelines suggest that any haemoptysis, or cough lasting longer than three weeks should be investigated with a CXR but we know that for the commonest acute infection presenting in primary care (chest infection) the median duration of symptoms is 3 weeks so this guidance arguably is setting much too low a threshold for investigation. There is also evidence from secondary care settings that a normal X ray may not be helpful in excluding cancer. If clinicians in primary care acted on the NICE guidance for X rays this could dramatically increase the number of CXRs performed for the primary care population, which is likely to increase the dangers of iatrogenesis, and may not be cost-effective. A clinical prediction rule based on prospective clinical data collection and assessing the place of simple investigations in primary care (full blood count, CXR) is the most robust way to better inform thresholds for such investigations and for referrals.

For colon cancer, NICE guidelines recommend a suspected cancer referral for different combinations of abdominal pain, abdominal masses, rectal bleeding, change in bowel habits, and/or weight loss depending on patients' age. Recent studies suggest that only 9.1% of such referrals detected colon cancer. Therefore, similar considerations about efficient referral and limiting iatrogenesis also apply to colon cancer.

There is suggestive evidence that clinical prediction rules (CPRs) for diagnosing both lung and colon cancer can be developed in primary care. However, current prediction rules 'weight' each variable based on routinely collected observational data i.e. what a GP happens to record, and not based on structured and consistent data collection. Such scores have the great advantage of efficiently identifying possible 'signals' for cancer but given the major limitations due to differential recording of clinical data by GPs, they make it difficult to adequately quantify the importance of individual variables and their possible weighting – and so make it extremely difficult to develop valid CPR risk scores.

There have been no sufficiently powered prospective primary care cohort studies to develop CPRs, nor to test and validate such rules in primary care cohorts. We also have limited information about the key issues for doctors and patients in engaging with using risk scores, and unless we do understand the issues CPRs will not be used effectively in practice.

The objectives of CANDID are:

1) To use prospective diagnostic cohorts to develop and validate Clinical Prediction Rules for lung and colon cancer
2) To assess the incremental utility of incorporating additional measures (e.g. genetic, inflammatory and lifestyle information including smoking and alcohol status) in the prediction models.

CANDID has now finished recruiting more than 20,000 patients who are currently being followed up in the cancer registries and also in GP records to see if cancer develops. The whole of the CANDID data set will be available to the fellow. A range of PhDs are possible for the doctoral fellow, on lung cancer or colorectal cancer or both, and using either quantitative or qualitative methodologies or both (mixed methods) depending on the preference and interests of the fellow, and to be agreed with the supervising team.

Qualitative methods: the fellow would explore the key issues among both patients and doctors in using clinical scoring systems (both existing clinical scores and the scores developed from CANDID) with a view to developing

an effective training package, working with both clinicians and patients. The theoretical framework for the PhD would include theories of behaviour change, including Protection Motivation Theory (for patients) and May's Normalisation Process Theory (NPT) (for clinicians). The work with clinicians will address key questions such as do practitioners agree about the usefulness of CPRs?; are they viewed as a legitimate part of their work?; how are they implemented and which methods do clinicians favour/use?; and how is the 'work' of using CPRs understood? The work with patients will address questions such as what are the benefits and problems associated with communicating personal risk based on CPRs? how best should this risk information be communicated?;

Quantitative methods: the fellow would use the CPR based on prospective data collected in CANDID, and also scores based on the existing CPRs, and compare how well each score compared with the observed risk of cancer. An extensive range of other baseline measures have also been collected in CANDID (such as satisfaction with life; life orientation, cancer fatalism, illness behaviours, attitudes to doctors, attitudes to medical threats, diet, physical activity, continuity of care, multi-morbidity) which will allow the fellow to explore the way bio-psychosocial variables determine both the presentation of cancer related symptoms and also the risk of developing cancer.

Training plan:

Formal training:

The training programme will be tailored to meet the needs of the individual and the project, based on a learning needs assessment in the first week. The formal taught postgraduate research training programme at the University of Southampton includes epidemiology, statistics, research governance and study design. Qualitative training for new doctoral candidates is provided by Dr Leydon, and NVivo training is also provided centrally. In addition, transferable skills courses are offered including Good Clinical Practice, time management, leadership, grant writing, and presentation skills. There is also the opportunity to attend the highly regarded annual Epidemiology for Clinicians course jointly run by the Southampton MRC Lifecourse Epidemiology Unit and the University of Cambridge. The Fellow will also be able to access free on-line masterclasses on systematic reviews and meta-analysis, research governance, ethics, patient and public involvement and engagement, developed by leaders in the SPCR.

Informal training:

The Fellow will also be offered mentorship from a senior primary care academic working in an external institution, meeting twice a year. Mentors receive formal training, developed by the Society for Academic Primary Care, to ensure independence and appropriate support. This relationship will continue after completion of the doctorate (if appropriate) to support continued career development. The Fellow will also have access to informal mentoring from senior members of the collaboration at an annual training meeting, and to participate in doctoral exchange programmes.

We have close links with the Southampton NIHR Collaboration for Leadership in Applied Health Research and Care, through Michael Moore's co-leadership of the CLAHRC, providing the opportunity to form strong collaborations with NHS organisations and to help implement research findings into clinical practice.

PPIE:

We have a dedicated member of staff for PPI/E support and strong and proximate relationship with PPI/E experts at the RDS. We have approached two PPI collaborators to develop the plan for the fellowship and will also generate PPI panel as we have done in our ongoing programmes in cancer, and have excellent links with major cancer charities.