Protocol

Cancer Diagnosis in the Acute Setting (CaDiAS)

A study on behalf of the London Cancer Alliance

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1 BACKGROUND

1.1 Early Cancer Diagnosis
It is well recognised that the United Kingdom has poorer cancer survival than other countries (EUROCARE 3 and 4 studies). Furthermore, for some tumours such as colorectal cancer, the stage at diagnosis is more advanced in the UK, and relative survival is particularly poor in older age groups. Delays in diagnosis are associated with poorer survival, and factors in this include non-attribution of symptoms to cancer, deprivation, ethnicity and older age. Indeed public awareness of the signs and symptoms of cancer remains poor.

The National Awareness and Early Diagnosis Initiative (NAEDI) was launched in 2008 with the aims of promoting earlier diagnosis of cancer, improving cancer survival rates and reducing cancer mortality. Prioritisation of early diagnosis is supported in the Cancer Reform Strategy (Department of Health, DoH, 2007) and Improving Outcomes: A Strategy for Cancer (DoH, 2010).

1.2 NCIN Report: ‘Routes to Diagnosis’
In 2010 the National Cancer Intelligence Network (NCIN) published a report as part of NAEDI, Routes to Diagnosis, which attracted considerable interest from both the medical and media communities. The key findings were that 23% of newly diagnosed cancer patients presented as emergencies. The tumour types most likely to present in this way, as opposed to other routes, were acute leukaemias (61% diagnosed as an emergency), brain tumours (49%), pancreatic cancer (45%), chronic leukaemias (45%), myeloma (44%) and lung cancer (38%). Emergency presentations of new cancer were more likely in older patients, and those from a more deprived background. Perhaps most important of all, the relative one-year survival was significantly lower across nearly all tumour types for those patients presenting as an emergency.

1.3 Routes to Cancer Diagnosis in Primary Care
In 2009 a study of lung cancer diagnosis in primary care, produced for NAEDI, used significant event audits (SAU) and began to identify opportunities for earlier diagnosis. Two years later, a National Audit of Cancer Diagnosis in Primary Care (Royal College of General Practitioners, 2011), also undertaken as part of NAEDI, was published. This involved all patients with a new cancer diagnosis and collected information on demographics and the nature of the assessment process in primary care.
Emergency presentation of cancer occurred in 12.9% (range: 3.7% [breast] to 39.3% [brain]) of all cases, and was found to be associated with worse outcomes. Fourteen percent of patients who had their cancer diagnosed during an emergency presentation had never seen their GP. In 6% of cases the GP believed that better access to investigations would have reduced delay in diagnosis. Amongst the several recommendations put forward by the authors was the suggestion that primary and secondary care data should be combined to generate more detailed understanding of factors influencing the pathway to cancer diagnosis.

1.4 Clinical Commissioning and Emergency Cancer Diagnosis
The importance of patients presenting with an emergency cancer diagnosis in clinical commissioning has been recognised. The King’s Fund How To Improve Cancer Services report (2011) report, published in partnership with Cancer Research UK, explored what is needed to achieve the aspiration that “cancer outcomes in the UK are compatible with the best in the world”. The most plausible drivers for this were thought to be diagnosis at an early stage, effective screening programmes, access to optimal treatment and improvement in the management of older patients with cancer. It was recommended that measuring emergency presentations of new cancers would be an important metric in assessing the quality of cancer pathways.
This opinion is supported by conclusion from The Intelligent Board Clinical Commissioning Report (Dr Foster, 2011) which states that assessing emergency admissions for cancer diagnosis is one of the key measures in fully understanding cancer services.

1.5 Acute Oncology
In 2008, the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report into deaths within 30 days of receiving systemic anti-cancer therapy identified significant concerns regarding the quality and safety of patient care both at an organisational as well as clinical level. This paved the way for the National Chemotherapy Advisory Group (NCAG) report on chemotherapy services in England (Ensuring Quality and Safety, 2009) which highlighted the need to improve both elective chemotherapy and Acute Oncology Services (AOS). AOS was seen as including the management of the complications of cancer and cancer treatments, but particular note was also made of patients who present as emergencies with previously undiagnosed cancer, and of those with a diagnosis of carcinoma of unknown primary.
Acute Oncology represents a fundamental change in the provision of oncology services within the UK since every Trust with an emergency department (ED) and/or chemotherapy service are required to have an AOS. This offers significant benefits in terms of the quality of care given, but also provides opportunities to audit Acute Oncology presentations in an attempt to understand the nature and scale of the problems, and to reduce the number such cases.

1.6 London Cancer Alliance

In 2009, Healthcare for London published the Cancer Case for Change report which focused on the need to improve cancer services in the capital. In 2011, this was strengthened by evidence from the National Cancer Patient Experience Survey, in which London performed very badly, and the Improving Outcomes: A strategy for Cancer report.

This culminated in the January 2011 publication of the Cancer Model of Care. Authored by more than 45 lead cancer clinicians and endorsed by Professor Sir Mike Richards, it sets out the expectation that providers work together in ‘integrated cancer systems’ to deliver seamless cancer care. Two integrated cancer systems have been established. The London Cancer Alliance encompasses South East, North West and South West London, has a population base of almost 5 million and comprises 17 NHS Trusts including 2 Academic Health Science Centres.

Acute Oncology has been designated as one of the five first wave priority area for the nascent London Cancer Alliance, as it is an area that is relevant to every hospital and is an exemplar of collaborative working and seamless cancer care. Central to the Acute Oncology work-plan, which itself is based on the Model of Care recommendations, are a number of areas directly related to the emergency presentation of new cancers: the establishment of AOS in all hospitals in to ensure their early assessment; the use of outcome data to improve and develop cancer services; and collaborative working with primary care to reduce emergency admissions.
2 AIMS OF AUDIT

The importance of emergency new cancer diagnoses is recognised at both a clinical and strategic level. Addressing each factor at every level – from patient to primary care to secondary care – that leads to such presentations and developing methods of tackling these, is key to improving cancer services within the UK. Previous work has been limited by looking separately at primary care or secondary care. There is therefore a unique opportunity to carry out a project that spans all aspects of the patient journey.

Through collaborative working between secondary care, primary care and the cancer networks, we will undertake an in depth study of patients presenting as an emergency with a new cancer diagnosis.

The aims of this audit are:

1. To understand the whole diagnostic pathway, from primary to secondary care, for patients presenting as an emergency with a new cancer diagnosis.
2. To gain an in-depth understanding of the events that lead to a cancer patients receiving their diagnosis as a result of an emergency admission.
3. To identify the clinical and organisational factors that contribute to an emergency new cancer diagnosis.
4. To produce an action plan to target these factors, with a view to working closely with the relevant national, regional and local bodies to implement the necessary changes. It is envisaged that awareness campaigns and access to early diagnostics will be amongst the areas targeted in order to reduce the proportion of new cancer diagnoses presenting as an emergency.
5. To improve the cancer diagnosis pathway between primary and secondary care to facilitate earlier cancer diagnosis.
3 STRUCTURE OF AUDIT

3.1 Stakeholders
The audit is being run by the LCA in collaboration with primary care, North West London Cancer Network (NWLCN), South West London Cancer Network (SWLCN), South East London Cancer Network (SELCN) and the Institute of Psychiatry, King’s College London.
The project also involves the Trusts listed in section 3.3, the current lung and colorectal tumour working groups of the respective Networks, and the LCA lung and acute oncology groups.

3.2 Patient Groups
Adult patients (>18 years) with lung cancer (LC) or colorectal cancer (CRC) will be involved with this audit. These tumour types have been chosen for the following reasons: They represent amongst the commonest cancers in the UK, a high proportion are diagnosed in the emergency setting, there are well recognised signs and symptoms yet diagnosis in primary care is a challenge, there are investigations available to primary care that can aid diagnosis, diagnosis at an early stage may allow potentially curative surgery, they are subject to current public awareness campaigns, and there is now a CRC screening programme.

3.3 Hospital Trusts
The following Trusts will be involved in the audit:

- Chelsea & Westminster Hospital Foundation NHS Trust (C&W)
- Hillingdon Hospital NHS Trust (HHT)
- Guy’s and St Thomas’ NHS Foundation Trust (GST)
- Croydon University Hospital (CUH)
- St George’s Hospital NHS Trust (SGH)
- University Hospital Lewisham NHS Trust (UHL)

They have been chosen as they all have an ED, represent each of the current cancer networks (North West, South West and South East London), are a mix of district general hospitals, teaching hospitals, and cancer units, and include a broad socioeconomic mix of population.
3.4 **Timescale**

The audit will run for one calendar year to ensure consistency of data and avoid any bias during certain times of year. It is anticipated that the project will start in October 2012, with interim results available in March 2013 (as requested by DH), and the final report produced by the end of 2013.

3.5 **Scale**

It is felt that to undertake an audit of every patient, with any tumour type, presenting to all of the 19 Trusts within the LCA is too unwieldy, requires substantial investments both financially and in terms of professionals’ time, and runs the risk that the datasets are so large that information is omitted or inaccurate. Consequently we propose a focussed, streamlined audit targeting specific tumour types and involving a pro-active group of hospitals. By doing so we expect to generate clinically important results which will be applicable to the broader patient population, and we will do so quickly and in a cost-efficient manner.

The expected number of emergency new cancer diagnosis patients involved in this audit has been based on 38% of LC and 25% of CRC (as per NCIN report) of the number of new total new diagnoses per trust:

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Total Number of New Cases*</th>
<th>Expected Emergency Diagnoses*</th>
<th>Total Emergency Diagnoses*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CRC</td>
<td>LC</td>
<td>CRC</td>
</tr>
<tr>
<td>C&amp;W</td>
<td>77</td>
<td>61</td>
<td>19</td>
</tr>
<tr>
<td>HHT</td>
<td>78</td>
<td>120</td>
<td>20</td>
</tr>
<tr>
<td>GST</td>
<td>60†</td>
<td>120</td>
<td>15</td>
</tr>
<tr>
<td>CUH</td>
<td>83</td>
<td>134</td>
<td>20</td>
</tr>
<tr>
<td>SGH</td>
<td>84</td>
<td>194</td>
<td>21</td>
</tr>
<tr>
<td>UHL</td>
<td>85</td>
<td>113</td>
<td>20</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>467</strong></td>
<td><strong>742</strong></td>
<td><strong>115</strong></td>
</tr>
</tbody>
</table>

All numbers represent cases per annum. Data from NBOCAP and LUCADA databases; † Estimate

If patient recruitment is below that which is expected, additional hospitals will be invited to join the project. The first such site, which has already been approached, is Epsom and St Helier NHS Trust.

3.6 **Inclusion Criteria**

- New diagnosis of LC or CRC made during an admission which followed presentation via ED or the Acute Assessment Unit (AAU) in the hospitals above.
• Patients who have been referred by their GP to secondary care with suspected cancer, but who have not received or attended the appointment.

• Patients in whom cancer is diagnosed incidentally during an emergency admission for an unrelated medical problem.

• Age >18 years.

3.7 Exclusion Criteria

• <18 years old

• Any cancer other than CRC or LC

• Patients who are unable to understand, consent for and participate in the patient interview component of the study. The decision whether a patient is competent to take part will be made the Trust Project Lead. Interviewing the patient’s next of kin or carer, as a substitute for the patient themselves, is not acceptable.

• Patients with lung metastases from a primary tumour that is not CRC or LC

• LC or CRC diagnosed and treatment started prior to their emergency admission

• Relapsed disease

• Emergency admissions from LC or CRC site-specific specialist clinics

The location of the GP within the UK is not an exclusion criterion and so GP practices outside the LCA are still included in the audit. Similarly, overseas patients not registered with a GP in the UK will be included as they may represent a distinct group with unique reasons to account for their late presentation and absence of primary care input.

3.8 Identification of Patients

Each Trust involved in the audit will nominate a clinician as Audit Lead whose responsibility it will be to ensure all correct patients are identified and that a complete dataset is collected.

The most efficient and effective method of identifying patients is through the established lung and colorectal multidisciplinary teams (MDTs) and clinical nurse specialists. Each week the MDT coordinators will compile a list of newly diagnosed patients who have attended hospital as an emergency as part of the diagnostic process. This information will normally be available through the MDT records, but where necessary patient records will be interrogated.

The list of patients will be passed to the Trust Audit Lead and, to ensure completeness of the data, the list will be cross-checked with the AOS (who should have received referrals for all emergency
presentation of new cancer) and the local palliative care team (in case patients not suitable for active treatment have been omitted from the MDT lists).

The weekly patient lists will form the basis of the data collection, which will be done prospectively wherever possible. The patient will be contacted to determine if they are willing to undertake a patient interview. Secondary care data will be obtained from hospital records. The patient’s GP will be written to by the project team to establish whether they are prepared to participate in the primary care data collection. Contact with the patient will be done by members of the multi-disciplinary team who are known to patient which, depending on the trust, will include site-specific CNSs, AOS CNSs, research nurses, or physicians. Most patients are expected to still be inpatients at this point, and so such requests will be in person. For those who have already been discharged, contact will be made at home. A flow diagram summarising the patient identification, data collection and data processing is below:
It is recognised that collection of the data entails additional work for the project team, site-specific CNSs, AOS CNSs, and (when relevant) research nurses. The Trust Leads for each hospital have been consulted in the design of this project and the above proposal has agreed as being practical and feasible. The precise format of data collection will vary from site to site reflecting the individual configuration of local services, and this will be agreed between the Trust Leads and the Project Lead. This project is supported by the LCA Acute Oncology Group.
4 Collection of Data

Each patient’s route to diagnosis will be analysed from three perspectives: secondary care, primary care, and the patient.

4.1 Secondary Care

The material to be examined includes ED records (‘Cas Card’), admissions clerking, inpatient notes, and results of relevant investigations. The data to be collected (which includes fields recommended in the NCIN report) will include:

- Patient demographics
- Nature and timing of attendance to emergency services
  - Self referral or referral by GP
  - Timing: date, day and time
  - Including if bank holiday / public holiday
- Tumour type and stage
  - Stage of cancer may only be available later
- Route to emergency presentation
  - Self-referral, referral via GP, referral via another healthcare professional
- Where admitted from
  - Home, nursing home, another hospital
- GP name and practice (if registered)
- Consultations specifically related to new cancer diagnosis
  - Number of visits, if any, to hospital
o Results of any previous investigations

- Symptoms at presentation
  o Nature, duration, severity
  o Reasons for this emergency admission
  o Performance status

- Medical history
  o Cardiac: ischaemic heart disease, hypertension, hypercholesterolemia, other significant cardiac condition
  o Respiratory: chronic obstructive pulmonary disease, asthma, other significant respiratory condition
  o Endocrine: diabetes mellitus (type I or II)
  o Any other relevant medical co-morbidity
  o Smoking history

- Concurrent medications

4.2 Primary Care

The GP for each patient eligible for this study will be invited to take part in this audit by one of the audit research team. They will be contacted on the same day the patient is contacted. If they agree to participate, the GP will be asked to review the patient’s clinical file and complete a significant event analysis (SEA). The purpose of this is to understand the patient’s route to diagnosis from the primary care point of view, and to obtain the GP’s opinion on the patient’s case. It is important to emphasise that this will not be used as an opportunity to criticise the management in primary care, nor an attempt to focus on missed diagnoses and mistakes.

Data fields would include:

- Further demographics
  o Including ethnicity and Post code
- Date registered with the practice
- Corroborate co-morbid medical conditions and risk factors for cancer
- Family history of cancer
- PCT / CCG
  o Total number of 2WW referrals (if any) over last 5 years
  o Number and nature of previous appointments to any hospital in previous 5 years
Consultations relevant to new cancer diagnosis
  - Date and number of visits, if any, to GP (or OOH/WIC/A+E)
  - Reason for visits (including symptoms)
  - Results of relevant investigations
  - Action taken by GP (and compare to two-week wait criteria)
  - For CRC screening: invitations / results / attendance for any screening

- Reasons for emergency referral (if referred to ED / AAU by GP)
- Number of missed GP and hospital appointments
- Dates last seen in the practice

The GP would receive a ‘zip’ file, named by the relevant audit code for ease of identification, containing the Primary Care audit data set (in Excel file format), an SEA template and a FAQ sheet (both Word documents). A short introduction training video will be hosted on the NWLCN / LCA website.

The primary care data set is based on the Royal College of General Practitioners National Audit of Cancer Diagnosis, has been amended for the purpose of this study, and will still aim to identify any avoidable delays in patient pathway. The use of the SEA template supports the activities that promote the earlier diagnosis of cancer and will provide a valuable understanding of the circumstances surrounding the emergency presentation, diagnosis and referral for cancer symptoms in primary care.

To encourage participation, GPs will be paid in part when they agree to participate in the audit and the SEA, and paid in full when their patient record and subsequent SEA has been submitted. The records and templates will be reviewed by the audit team (GP Leads) and if all the relevant information is available, the final payment will be triggered. If some information is missing, members of the audit team will be available for telephone advice and will also visit those GPs who are finding it difficult to complete the questionnaire before triggering the payment. Further encouragement is that the SEAs will be suitable for inclusion in QOF returns and for GP Revalidation. Individual practice profiles (produced in association with NCAT) will be studied in order to gain a more rounded view of the cancer activity of the practice and the demographics of the local population.

Findings on the learning points will be fed back to participating practices together with their practice profiles and relevant resources for earlier diagnosis. The process of completing SEAs would facilitate practice identification of relevant learning points, with associated changes to practice. A particular
benefit of the SEA process would be its potential impact on improving clinical practice, not least in relation to re-review of referral guidelines and pathways.

If a GP declines to participate in the project, but if the patient themselves is happy to take part in the interview, the patient’s data will still be included in the project.

The incentives for primary care are the same whether or not practices are within existing London cancer networks / proposed LCA. Consequently it is not anticipated that any addition incentives or resources will be needed for more distant GPs.

4.3 Patient Interview

We propose to invite all patients identified as eligible for the study to take part in an interview, in the few days after diagnosis. This work will be led by Professor Amanda-Jane Ramirez, a liaison psychiatrist with more than 20 years experience of collecting data from cancer patients, and will draw on her expertise in the psychological and psychosocial aspects of cancer. If a patient declines to be interviewed, but their GP agrees to participate in the study, then the patient’s data will continue to be included in the study.

A semi-structured interview schedule will be constructed to identify the pathway to diagnosis in the months leading up to the admission. In particular, the schedule will collect data on:

- Patient demographics
  - Including socioeconomic status
- The nature of symptoms
- The onset dates and duration of all identified symptoms. Where patients are unable to give precise dates we will collect as much data as possible to be able to estimate duration of symptoms. To supplement this we will also ask patients how long they have experienced symptoms for
- Details of consultations with health professionals (both primary and secondary care)
- Actions taken by health professionals (from the perspective of the patient)
- The patient’s beliefs about the cause of the symptoms and what led them to present (or not) to a health professional
- Risk factors for cancer, including occupational risk factors
- The patient’s beliefs about screening for cancer

For the symptoms, we will focus on, in particular:
Cancer Diagnosis in the Acute Setting

4.3.1 Interview Details

When a patient agrees with their clinical team to participate in the interview process, their details will be passed onto the patient interview team who will contact the patient or their carer to arrange an interview date. These will be conducted as soon as possible, either as an inpatient or in the community.

The interviews will be carried out by the project research nurse, supported by the project manager. Where facilities exist, the Trust Lead is in agreement, and the individual concerns is happy to participate, site-specific CNSs or AOS CNSs will be involved in collecting patient interview data. If the application for adoption onto the national cancer research network (NCRN) portfolio is successful, local NCRN research nurses will also be involved in patient interview data collection.

The interviewer will use an iPad application to collect the data, based on one previously developed by Professor Ramirez’ team to interview young women with cervical cancer. The application allows data to be directly entered onto a database during the interview. The patient may look at the screen with the interviewer. A key advantage of this approach is that the data can be represented on the iPad screen on a timeline ‘real time’ during the interview and shown to the patient; this means that they can check that the sequence of events is as they remembers it. Calendar timelines have been used previously to facilitate data collection from patients on sequences of events in a health setting.

The interviewer will use additional techniques to maximise accuracy of recall:

- Rapport and pace: the interviewer will establish a rapport and allow the patient to describe the events at his or her own pace.
- Approach to data collection: the interviewer will first ask the patient to describe the events leading up to diagnosis using open questions. They will then probe for further, more detailed information, using open directive questions, followed by closed questions.
- Checklist: when the patient has described all their symptoms, the interviewer will read out a list of possible symptoms of the relevant cancer, asking whether he or she had experienced

- Trigger symptoms: the symptom or cluster of symptoms that, from the patient’s perspective, led to them presenting and in turn to being diagnosed with cancer
- ‘First attributed’ symptom: the earliest symptom that the patient believes were due to the cancer at the time of the interview. This may or may not have led to presentation
- Earliest relevant symptom that led to presenting to a doctor but which did not lead to diagnosis
- Earliest relevant symptom that did not lead to presentation
any of these in addition. Symptom checklists have been shown to elicit symptoms occurring earlier in the history of presentation among cancer patients.

- Calendar anchoring: if the patient cannot remember dates, the interviewer will ask about dates of other memorable events around that time such as birthdays, summer holidays or job changes, and will ask the patient to identify when the symptoms or consultations occurred in relation to these.

With the patient’s permission, interviews will be recorded so that the data can be checked later, and to allow quality assurance and assessment of inter-rater reliability.

4.3.2 Training and quality assurance

All those involved in patient interview data collection will be trained by Professor Ramirez, who will also listen to all early interviews and a proportion of later interviews to check interview quality and provide performance feedback to the interviewer to ensure accuracy, consistency and sensitivity.

A different researcher (a post-doctoral fellow) will enter data from 1 in 10 recorded interviews onto the iPad app to allow us to assess inter-rater reliability.

4.3.3 Research and ethical approval

Although the primary and secondary care data collection and analysis will be service evaluation and audit, there is a clear research component to the patient interview and the interviewing will be carried out by research nurses. Consequently formal research and ethical approval will be sought through the integrated research application system (IRAS) and adoption onto the NCRN portfolio requested.

4.4 Data Collation and Storage

All those involved in data collection, collation and storage will have received training of information governance and data protection. All data will be collected and stored electronically in keeping with local Data Protection standards. Data will be only be stored on Trust and other approved electronic devices, all computers and documents will be password protected and only available to authorised members of the audit team, and all databases will be saved on central servers to prevent data loss.

Use of portable memory devices such as USB sticks will be avoided wherever possible, but if absolutely necessary will only involve encrypted devices.

To maintain patient confidentiality, each patient will be identified by a unique audit number comprising a hospital code and patient number (e.g. C&W1234; HHT0025) which will be used for primary care, secondary care and patient interview data collection. Once data collection is complete.
and whenever data is transferred to the central database, only the audit number will be used as a patient identifier.

All primary care data will be collected locally (either via on-line questionnaire or by interviewer in person) and then entered directly into a secure central database. All secondary care data will be collected locally in keeping with Trust information governance guidelines on data protection, and then forwarded to the central database. The patient interview data will be collected by Professor Ramirez’s team and, once processed, added to the central database.

4.5 Support and Training

Given the six different hospital sites involved, and the three different sources of data collection, support for dedicated project staff is requested:

- Project manager: responsibilities would include acting as a central point of contact, making contact with GPs, receipt of data from individual hospital and GPs, maintenance of the central database, supervision of data returns, regular contact with hospital audit leads, contacting and supporting GPs.
- Research nurse: responsibilities include contacting and carrying out interviews with patients / carers, contacting and supporting GPs.

All staff involved in patient interviewing will be trained as described. All those involved in data analysis will receive training in root cause analysis.

4.6 Pilot Audit

A one month pilot audit will be carried out at C&W and UHL hospitals in order to test the primary and secondary care data collection techniques and assess the patient interview format. Results will be discussed with the governance team, changes made as necessary (see below), and the resulting revised methodology used for the formal 12 month audit. The specific items to be addressed and targets to be met include:

- Number of patients recruited (as percentage of expected numbers)
- Percentage of suitable patients missed by proposed MDT-based identification pathway
- Percentage of GPs agreeing to take part in study
- Percentage of patients agreeing to take part in interview
- Completeness of secondary care data (as percentage of expected data fields)
- Completeness of primary care data (as percentage of expected data fields)
In addition, any problems in the following areas will be focussed on:

- Time taken to identify and contact patients, and to contact GPs
- Ease of data entry and transfer to data to central database

If any percentage falls below 90%, the protocol will be reviewed. If the governance team feel that the quality of data collected during the pilot is inadequate, and if it is felt that there is insufficient time to change to protocol in time to provide sufficient interim data by Spring 2013, the project will be temporarily halted whilst fundamental changes are made. The DH will be contacted immediately in such an event.
5 DATA ANALYSIS AND OUTPUT

The fundamental questions to be answered are:

- **Who** are the patients whose cancer is diagnosed during an emergency admission?
- **Why** do they present as an emergency with their new cancer diagnosis?
- **What** can be done to prevent emergency cancer presentations in future?

5.1 Profile of LC and CRC Patients Whose Cancer Is Diagnosed As An Emergency?

The following will be described for the LC and CRC populations separately:

- **Patient demographics**
  - Especially gender, age, ethnic group and socioeconomic status
- **Presentation and symptoms**
  - Whether the presentation was initiated by the patient or by the GP
  - Time of presentation: out of hours, weekend, bank holidays
  - Nature experienced in lead up to admission: trigger and first attributed
  - Duration
  - Beliefs about symptoms: what they are due to, what they signify?
- **Cancer details**
  - Type, stage and pathology
  - Relevant risk factors
- **Medical history**
  - Extent of medical co-morbidities
  - Performance status
  - Prevalence of psychiatric co-morbidities
- **Primary care**
  - Proportion attending primary care during lead up to cancer diagnosis
  - If relevant, reason for not attending primary care
  - If relevant, record of events in primary care (from patient and GP perspective)
  - Profile of primary care practice
  - Screening behaviour
5.2 Why Do Patients Present As An Emergency With Their New Cancer Diagnosis?
The LC and CRC populations will be divided into two groups: those who did not seek healthcare advice about their cancer prior to the emergency presentation, and those who did seek such advice. Separate hypotheses will be generated about each group to help understand the events.

5.2.1 Patients Who Do Not Seek Healthcare Advice Regarding Their Putative Cancer Diagnosis
The LC and CRC patients in this group will be described in terms of their characteristics listed in section 5.1. It is hypothesised that the following factors will be among those relevant when patients have not sought medical advice:

- Demographic group: older patients, those from a lower socioeconomic background, those from more isolated ethnic/social groups.
- Symptoms: lack of recognition of sinister nature of symptoms, failure of patient education regarding symptoms.
- Patient approaches and views of healthcare: a reluctance to engage, a suspicion of doctors, fear of results of investigations, negative views of screening.
- Course of disease: rapid onset of severe symptoms denying the opportunity to seek help elsewhere.

5.2.2 Patients Who Sought Healthcare Advice Regarding Their Putative Cancer Diagnosis
Again, the LC and CRC patients in this group will be described in terms of their characteristics listed in section 5.1. In addition, there will be focus on the details of all primary and secondary care consultations relating to the cancer diagnosis. This will involve both GP and patient perspectives, and any disagreements between patient-derived and healthcare-derived data will be dealt with non-judgementally with the acceptance that the real sequence of events may never be absolutely clear. Specific questions to be addressed are whether symptomatic patients are not being referred quickly enough to secondary care, whether access to investigations and/or secondary care is a factor, and why two-week-wait (2WW) appointments not prevent emergency cancer diagnoses.

Data from this patient group will be correlated with the relevant GP’s Practice Profile, to identify any other consistent themes in primary care that may be contributing to such presentations. These practice profiles, compiled by NCAT / NCIN, contain a broad array of cancer related data including local population demographics, cancer screening uptake, cancer waiting times (including 2WW referrals) and information on presentation and diagnostics.
5.3  **Root Cause Analysis**

Root cause analysis (RCA) will be used as a framework to ensure a comprehensive and wide-reaching study, to report results and develop an action plan. The RCA format as developed by the National Patient Safety Agency (NPSA) will be used, but adapted for our purposes. The RCA will be undertaken by the audit team, and will always include representatives from both primary care and secondary care. All those involved in the RCA will receive appropriate training.

The RCA will comprise the following steps and processes:

5.3.1  **Gathering and Mapping Information**

Individual cases will be scrutinised, and for each one a Tabular Timeline will be created which will detail, at all relevant time-points, what should have happened, what actually happened, any notable practice, all care and service delivery problems, contributory factors and the root cause.

5.3.2  **Identifying Care & service Delivery Problems**

A Change Analysis tool will explore further what is current accepted practice, what was actually practiced at the time, whether there was a deviation from accepted practice. If there was deviation, it will be investigated whether a care or service problem contributed to the situation.

All identified care and service delivery issues will then be grouped and ranked in order of their importance and influence regarding the eventual emergency cancer presentation.

5.3.3  **Identifying Contributory Factors and Root Causes**

A comprehensive list of contributory factors will then be examined to establish those relevant to each patient’s case. The list will be tailored to our patient group, and will include patient factors, staff factors, task factors, communication, equipment, work environment, organisational issues, education and training, and team factors.

Analysis of all the above information will be undertaken using the Fishbone tool and other techniques such as ‘The 5 Whys’.

5.3.4  **Generating Solutions and Recommendations**

Barrier Analysis will be carried out to identify current controls / safe-guarding, their fail-safe level, what additional improvements / measures are required, their cost, and whose responsibility for these it is.
A Preventative Action Plan will be written, using established templates, to identify specific actions and solutions. Examples of the areas covered include physical equipment, task design, physical environment, leadership and administration.

An Options Appraisal will then be undertaken to demonstrate the risk before intervention, the strength of intervention and its impact on other services, the time required for the intervention, and finally the risk reduction potential.

5.3.5 Report Writing and Solution Implementation

A report will be written and distributed as described in section 8. The audit team will work with all bodies to assist in the implementation of any solutions. If the audit were to be repeated, a risk assessment after implementation of the solution would allow for a subsequent Impact Analysis.

5.4 Additional Questions

5.4.1 Previous Cancer Screening

Uptake of CRC screening (if applicable) will be looked at. Although we will not attempt to make an analysis of the effectiveness of this programme, it would be informative to identify any patients who screened negative, but who were subsequently diagnosed with CRC during an emergency admission.

5.4.2 Cost of Emergency Diagnosis

The cost of the route to diagnosis in patients presenting as an emergency will be compared to the estimated costs of a patient being diagnosed electively as an out-patient, in order to understand the financial consequences of emergency cancer diagnoses. For each Trust, the following costs will be obtained:

- Cost per 24 hour in-patient stay
- Cost per radiological investigation (plain x-ray, CT, MRI, nuclear medicine)
- Cost per pathology investigation (blood tests, cytology, histopathology)

The overall cost of the emergency cancer diagnosis will be calculated by going through individual cases and adding up all tests and costs. These will then be compared to the cost of an outpatient diagnosis. The project group will establish the latter by agreeing a representative number of outpatient appointments and investigations that a typical LC and CRC patient would undergo.

5.4.3 Acute Oncology

The emergence of the field of acute oncology represents a significant change in the provision of cancer services in the UK, and all hospitals are required to have an acute oncology service. The
potential for acute oncology services to facilitating early diagnosis through fast-track outpatient clinics and so prevent emergency presentations is not known. This is of relevance to primary and secondary care across the country, and so we will carry out the following:

- Compare diagnostic pathways for patients in whom there was acute oncology involvement, to those in which it was not available or was not sought, to establish whether admissions shortened or prevented by acute oncology involvement.
- Centrally review each case to identify whether an earlier referral to a fast-track acute oncology appointment (where that to be available) could have prevented the emergency admission.

This analysis will be carried out by the project team and no additional costs for this are expected. The results will be of relevance to all those involved in acute oncology as they will demonstrate whether acute oncology services produce costs savings and whether there is a significant opportunity for rapid-access acute oncology clinics to prevent emergency admissions.

5.5 Recommendations To Reduce And Prevent Future Emergency Cancer Presentations

Based on the finding of the analysis above, a series of practical and feasible recommendations will be produced to tackle the problem of emergency cancer diagnoses. These will be targeted any aspect of the diagnostic pathway which was found at RCA to have contributed to the eventual emergency presentation.

All results and analyses will the compared and contrasted to relevant previous work, in particular the 2011 RCGP survey and the 2010 NCIN report.
6 GOVERNANCE

The following members of project team are proposed:

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Lead</td>
<td>Dr Tom Newsom-Davis</td>
<td>Consultant Medical Oncologist</td>
</tr>
<tr>
<td>C&amp;W Audit Lead</td>
<td></td>
<td>Chelsea &amp; Westminster Hospital</td>
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<tr>
<td>Lung Cancer Lead</td>
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<tr>
<td>LCA Lead</td>
<td>Professor Arnie Purushotham</td>
<td>Director, Integrated Cancer Centre</td>
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<td></td>
<td>King’s Health Partners</td>
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<tr>
<td>Primary Care Group</td>
<td>Dr Pawan Randev</td>
<td>Primary Care GP Lead</td>
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<td></td>
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<td>NWLCN</td>
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<tr>
<td>Primary Care Group</td>
<td>Sarita Yaganti</td>
<td>Primary Care Improvement Lead</td>
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<td></td>
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<td>NWLCN</td>
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<tr>
<td>Patient Interview Group</td>
<td>Prof Amanda-Jane Ramirez</td>
<td>Consultant Liaison Psychiatrist</td>
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<td></td>
<td></td>
<td>Institute of Psychiatry</td>
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<tr>
<td>Patient Interview Group</td>
<td>Dr Lindsay Forbes</td>
<td>Senior Lecturer</td>
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<tr>
<td></td>
<td></td>
<td>Kings College London</td>
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<tr>
<td>CRC Lead</td>
<td>Mr Muti Abulafi</td>
<td>Consultant Colorectal Surgeon</td>
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<tr>
<td>CUH Audit Lead</td>
<td></td>
<td>Croydon University Hospital</td>
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<tr>
<td>SGH Audit Lead</td>
<td>Dr Anna Mary Young</td>
<td>Consultant Medical Oncologist</td>
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<td></td>
<td></td>
<td>St George’s Hospital</td>
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<tr>
<td>GSTT Audit Lead</td>
<td>Dr Sarah Rudman</td>
<td>Consultant Medical Oncologist</td>
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<td></td>
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<td>Guy’s and St Thomas’ Hospital</td>
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<tr>
<td>HHT Audit Lead</td>
<td>Dr Amy Guppy</td>
<td>Consultant Medical Oncologist</td>
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<td>Hillingdon Hospital</td>
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<tr>
<td>UHL Audit Lead</td>
<td>Dr Naheed Mir</td>
<td>Consultant Haematologist</td>
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<td>University Hospital Lewisham</td>
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<tr>
<td>Project Manager</td>
<td>TBA</td>
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<tr>
<td>Research Nurse</td>
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The team will meet regularly throughout the course of the project to ensure progress is monitored closely. In addition two independent experts, who are in no way connected with this project, the LCA or any hospital involved, will be appointed to provide external review.
The project team will report back to the NAEDI Public Awareness and Primary Care Support Steering Group, and the Cancer Programme Board. At a local level, it will report back to all stakeholders listed in section 3.1 and all trusts listed in section 3.3. An interim and final project report will be produced.

The following people have also been consulted and have contributed to this work:

Nicola Beech, Acute Oncology CNS, Croydon University Hospital
Dr Tony Brzezicki, GP Lead, London Cancer Alliance
Dr Cathy Burton, Associate Director SELCN and Macmillan GP Advisor
Chipo Chirewa, NWLCN
Sarah Colley, Patient Representative, London Cancer Alliance
Claire Dowling, Project Director, London Cancer Alliance Integrated Cancer System
Harry Hall, Patient Representative, London Cancer Alliance
Louis Kleiman, Patient Representative, London Cancer Alliance
Kate Kavanagh, Service Improvement Facilitator, SELCN
7 COSTS

A full set of costs is attached separately.

8 RISKS AND MITIGATIONS

The following risks and mitigations have been identified:

<table>
<thead>
<tr>
<th>Risk</th>
<th>Mitigation</th>
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<tbody>
<tr>
<td>Insufficient number of patients recruited from hospitals</td>
<td>Addition of Epsom and St Helier Hospitals to project</td>
</tr>
<tr>
<td></td>
<td>(Agreed with Dr Bohsle, Consultant Oncologist)</td>
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<tr>
<td></td>
<td>Consideration of adding further tumour sites</td>
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<tr>
<td></td>
<td>(primary central nervous system tumours best candidate)</td>
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<tr>
<td>Poor GP involvement / return of primary care data</td>
<td>Individual GPs to be contacted by primary care group</td>
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<tr>
<td></td>
<td>Explanation of financial and QOF incentives</td>
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<td></td>
<td>Individual practices attended by project team to assist</td>
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<td></td>
<td>data completion and return</td>
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<tr>
<td>Emergency Cancer Diagnosis patients missed / inappropriate patients included in audit</td>
<td>Scrutiny of weekly LC and CRC MDT lists by Trust Audit Leads</td>
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<td></td>
<td>Cross checking of selected patients by project team</td>
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<td></td>
<td>Close liaison with AOS and palliative care teams</td>
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<tr>
<td>Too many patients recruited. Project teams overwhelmed by patient numbers</td>
<td>Greater involvement of local acute oncology and tumour-site specific teams</td>
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<td></td>
<td>Seek additional funding to appointment additional project team members</td>
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<tr>
<td></td>
<td>Consider shortening project to 9 month period</td>
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<tr>
<td>Poor recruitment to patient interview component</td>
<td>Discussion about study to be initiated by clinical nurse specialist or medical team known to patient. Patient interview team available to discuss project with patient / relatives</td>
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<tr>
<td>Loss of confidential patient data</td>
<td>All electronic storage of records to be protected</td>
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<tr>
<td></td>
<td>according to local data protection rules</td>
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<tr>
<td></td>
<td>No patient identifiable data to be transferred</td>
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<tr>
<td></td>
<td>between organisations. Project numbers to be used as patient identifiers.</td>
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</tbody>
</table>
9 RECOMMENDATIONS, DISTRIBUTION OF FINDINGS, AND FUTURE WORK

An interim report will be produced in time for the end of March 2013 deadline. It will contain data and analysis for the first 5 months. It will also be distributed to all stakeholders listed in the protocol.

A formal report will be produced once the planned 12 months data collection is complete and analysed. It will be distributed to all the stakeholders, all hospital trust, all primary care practices within the LCA, and any other bodies and practices that have been involved in the project. The reports will be completed by the group leads, with input from all members of the project team.

The work will also be submitted for presentation at relevant national and international conferences. It will be the responsibility of Tom Newsom-Davis and Arnie Purushotham to ensure timely and correct distribution of the findings.

A repeat audit in 2-3 years time is proposed in order to assess the impact of the recommendations from this work and, it is hoped, demonstrate further improvements in the early diagnosis of cancer. It is not included in the current proposal however.

10 SUPPORT

- Chelsea & Westminster Hospital Foundation NHS Trust
- Hillingdon Hospital NHS Trust London Cancer Alliance
- Guy’s and St Thomas’ NHS Foundation Trust
- Croydon University Healthcare NHS Trust
- National Cancer Action Team
- North West London Cancer Network
- St George’s Hospital NHS Trust
- London Cancer Alliance
- South East London Cancer Network
- South West London Cancer Network
- University Hospital Lewisham NHS Trust