YORKSHIRE AND HUMBERSIDE HAEMATOLOGY NETWORK REGISTER

PROTOCOL

Introduction

In the Yorkshire and Humberside region approximately 2000 people are diagnosed with a haematological malignancy each year. These patients are served by the haematology departments across the 14 hospitals in the region, all of which belong to a single network group, The Yorkshire Cancer Network and Humber & Yorkshire Coast Cancer Network Haematology Group. The network is well supported by its members and is active in promoting trials, developing guidelines and audit systems.

The diagnostic services for the region are centralised in the Haematological Malignancy Diagnostic Services (HMDS) (Richards and Jack, 2003), which is based at St James's Hospital, Leeds. HMDS uses a sophisticated custom-designed web database, HMDS Integrated Laboratory Information System (HILIS), to manage clinical diagnoses and for audit purposes. Since 1999, at the point of diagnostic confirmation, basic information on newly diagnosed patients are transferred to the Haematological Oncology Network Group (HONG) database. Through the HONG database more detailed information are collected on important prognostic factors from network clinicians.

This combination of an active clinical network serving a large population and collection of high-quality data on haematological malignancies not only informs clinicians and audit, but in collaboration with the Epidemiology & Genetics Unit (EGU) based at the University of York, also has the potential to be developed as a resource for population-based epidemiological study and clinical research.

Aims and Objectives

We aim to construct a comprehensive register of patients diagnosed with haematological malignancies whilst resident in the (former) Yorkshire Regional Health Authority. This

valuable resource will contain clinical, prognostic and outcome information encompassing both health services needs and a wide range of research:

Specific objectives of the study are:

1. To further develop data collection in the network region in line with the Haematology cancer dataset requirements for haematological malignancies. http://www.nhsia.nhs.uk/cancer/pages/dataset/haematology.asp

2. To develop a tissue bank using samples sent to HMDS for diagnostic purposes.

3. To obtain long term follow-up – date of death and subsequent primary cancers – on all patients in the region.

Access to the above resources gives potential for the following research in the area of haematological malignancies:

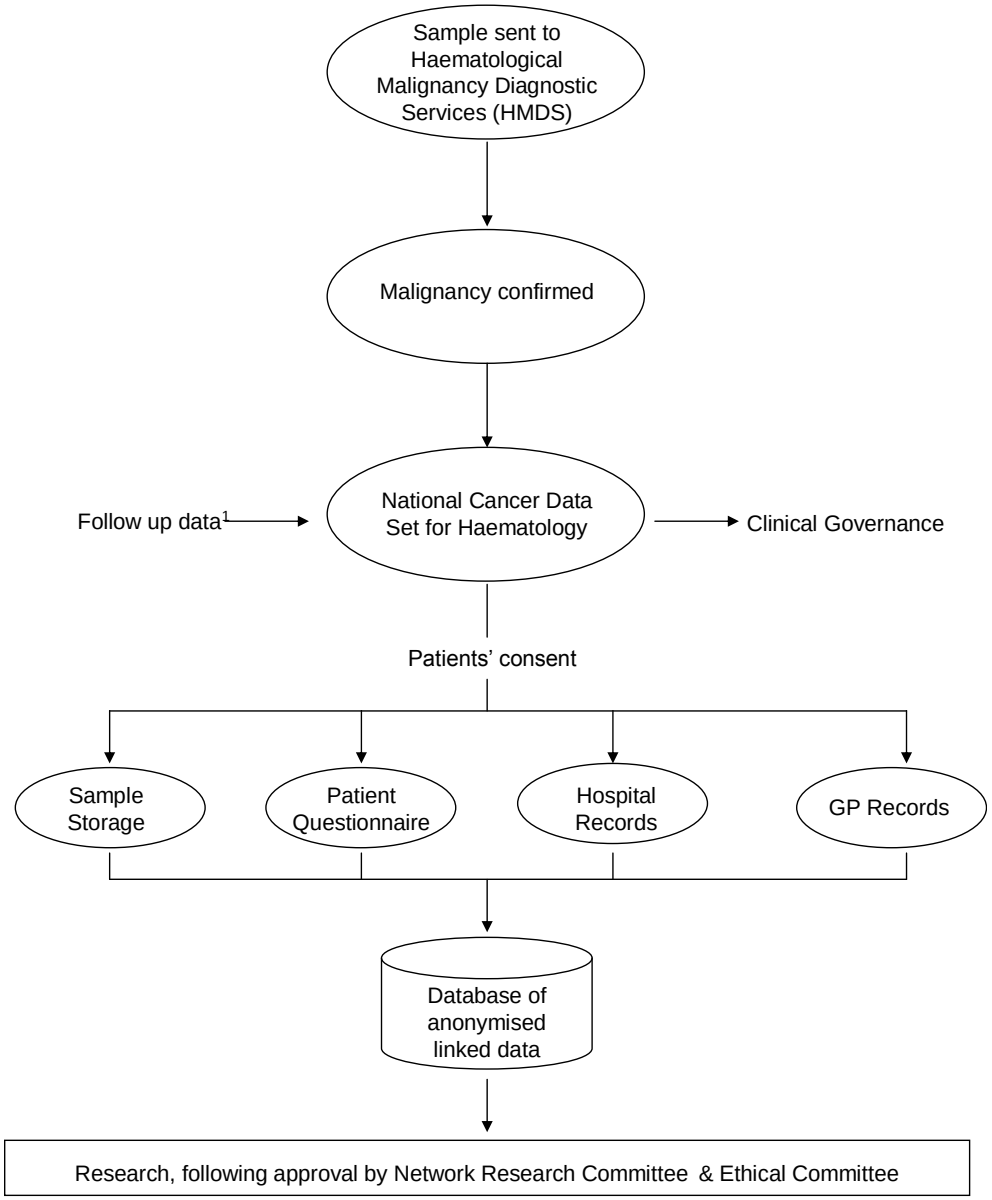
- Descriptive epidemiology
- Aetiology, initiation and progression of disease
- Defining the disease trajectory, which includes referral patterns and diagnostic delay, as well as factors affecting decision to treat and issues surrounding palliative care
- Treatment details including clinical trial entry
- Subsequent health and quality of life
- Long term follow-up including survival and future cancer registrations.

Ascertainment of Cases & Data Collection

The patient population will comprise of adults (aged 18+) and children (aged 0 to 18) newly diagnosed with a haematological malignancy on or after 1 September 2004 resident in the (former) Yorkshire Regional Health Authority.

We plan to build on an existing structure implemented for clinical governance (see figure 1). All patients will have prognostic, treatment and outcome data abstracted from their hospital records to comply with the national cancer data set. This will occur at two time-points (4 and 12 months after diagnosis) and will be undertaken by research nurses employed by the Epidemiology & Genetics Unit at the University of York As an associate member of the UK Association of Cancer Registries (UKACR), we will receive long-term follow-up on all patients - date of death and any future cancer registrations - and are currently preparing a PIAG application for permission to hold patient identifiable data from the Cancer Registries.

Figure I: Schematic view of data collection



[1] As an associate member of the UK Association of Cancer Registries (UKACR) data on date of death and subsequent primary cancers will be available

As part of the patients' clinical care, patients will be asked to provide written consent granting permission to:

- complete a brief questionnaire about their background and current illness;
- the storage of routine diagnostic samples by the Haematological Malignancy Diagnostic Service (HMDS);
- the storage of DNA, extracted from routine diagnostic samples, by the Haematological Malignancy Diagnostic Service (HMDS);
- allow a researcher to access, examine and record information from their hospital records;
- their GP being notified of their involvement in the study;
- allow a researcher to access, examine and record information from their GP records;
- allow any information or material they provide to be used anonymously for teaching purposes;
- agree to be contacted again should any further research be considered.

Soon after diagnosis all patients will be given by a member of their clinical team the patient information leaflet to read describing the work and inviting them to participate (See Appendix I). The mechanism to obtain consent will be dependent on whether the patient is being treated as an in-patient or an out-patient. In-patients are generally approached by a member of their clinical team (clinical nurse specialist/treating consultant), the timing of which will be at the discretion of the clinical staff, whereas out-patients are consented either by a member of the clinic team at their second or later clinic visit; or at the discretion of the clinic team, by posting the patient information pack to the patient's home address. There are separate patient information sheets for patients under the age of 18 with different versions available for young children, older children and another version is available for their parents. A separate consent form is available for patients under the age of 18, allowing a parent to provide consent instead of the child. The need for parental consent will depend

upon the child's age and level of understanding of the study. If a patient agrees to participate they will be given a code number, which will be used to anonymously link information from the questionnaire, medical records and diagnostic samples.

Soon after diagnosis all patients will receive a patient information leaflet to read describing the work and inviting them to participate (See Appendix I). The mechanism to obtain consent will be dependent on whether the patient is being treated as an in-patient or an out-patient. In-patients will be consented by a member of their clinical team (clinical nurse specialist/treating consultant), the timing of which will be at the discretion of the clinical staff. Out-patients will be consented either by a member of the clinic team at their second or later clinic visit; or at the discretion of the clinic team, by posting the patient information pack to the patient's home address. A witness to the consent procedure will be required if the patient is considered 'vulnerable', for example an adult with learning disabilities or a patient who is severely ill. The witness would ensure that the subject is able to provide informed consent. In the first instance it will be presumed that all patients are capable of being able to make a decision with regards to participation in the Registry. If a member of their clinical team advises us that a patient does not have the capacity to understand what the study involves and to make a decision a close relative or friend will be approached to act as 'consultee' and to inform us what the patient's wishes would be.

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If a patient agrees to participate they will be given a code number, which will be used to anonymously link information from the questionnaire, medical records and diagnostic samples.

Stakeholders (the network, HMDS and EGU) will have access to anonymised descriptive data for audit via NHSnet to a secure server. Clinicians/researchers wishing to access the Register for research purposes would have to apply to the Network Research Committee for approval and if successful, the appropriate ethics committee.

Confidentiality and Data Security

1) The Data Protection Act applies to all information stored on computer as part of this research. In addition, all information will be stored in a secure building and on computer systems designed specifically to prevent outside intrusion.

2) All biological samples will be kept in secure locked refrigerators/freezers and stored separately from personal data via a linked anonymised system.

3) Data and biological samples will be processed by a restricted number of staff working on the projects at HMDS and the University of York who are respectively bound by the NHS or University's confidentiality guidelines. Research nurses employed by the University of York all have honorary contracts with the appropriate NHS trusts.

4) No personal information is ever released to unauthorised individuals, groups or companies. No individual is ever identified in any published material.

Data Analysis

It is estimated that around 2000 new haematological malignancies are diagnosed in the region each year and we aim to recruit approximately 20,000 patients over ten years. Under this current protocol, data will only be collated for audit and descriptive purposes. Any

future research will require Network Research Committee and ethical approval and these applications will be required to include calculations of the power of the study.

References

Richards,S.J. and Jack, A.S. (2003) The development of integrated haematopathology laboratories: a new approach to the diagnosis of leukaemia and lymphoma. *Clin Lab Haematol.* 25, 337-342.