Anglia Cancer Network

Agenda Item: **11a**

From: **Mary Emurla (Associate Director, Programme Manager)**

BOARD REPORT – Haemato-Pathology IOG

1 Purpose

This report is further to previous updates provided to the Network Board and has been written to:

1.1 Inform the Board of the outcome of the national review of the Improving Outcomes Guidance around haemato-oncology diagnostics.

1.2 Recommend the implementation of a single diagnostic service for haematological malignancies for the Anglia population (2.4 million) in 2011/12.

2 Background

2.1 The Improving Outcomes Guidance in Haematological Cancers (NICE, 2003) emphasised that 'improving the consistency and accuracy of diagnosis is probably the single most important aspect of improving outcomes in haematological cancers'. 75% of Cancer Networks, including the AngCN, have not fully implemented the haemato-oncology diagnostics aspects of the guidance.

2.2 The Network team were advised in 2009 that NCAT would be co-ordinating a review of the haemato-oncology section of the IOG. NCAT anticipate the revised guidance will be published in 2011. A draft of this document ("Haematopathology Redraft Guidance Clarification") has been shared with SHAs and Network Directors. The draft guidance is attached to this report at *Appendix 1*.

3 Key Points

3.1 The draft guidance confirms that Network Boards should agree a single named provider of Specialist Integrated Malignancy Diagnostic Services (SIHMDS) for the Network which should cover a catchment population of at least 2 million.

3.2 In light of the redraft guidance, there are several issues to note:

- Under the current Network configuration 6 Trusts are providing some level of specialist pathology service for haematological malignancies. Some modalities (such as immunohistochemistry) are provided at all 6 Trusts whilst others, such as molecular genetics or cytogenetics are only provided by CUHFT or NNUHFT. In addition some samples are referred outside of the Network.
- There is no specific requirement within this guidance for a Network to provide a local SIHMDS service. Networks have the option of accessing any compliant service nationally, although the impact of taking this approach on local services would need to be carefully evaluated. It should be noted however that if an out of network provider was considered, this would be with a view to commissioning a single Network-wide service.
- None of our current service providers are compliant with the redraft guidance in terms of population base.
- If any one of the Trusts within Anglia should go on to be a SIHMDS provider, it is likely they would face significant capacity and investment issues.

3.3 The Network has considered the above issues and the various options in terms of an implementation process. It is vital that the process we follow to identify a single service provider on behalf of the Network is equitable and does not discriminate against service providers. The process should also be transparent and provide clear accountability.

3.4 In order to achieve this, the Network are recommending a procurement mechanism for securing a SIHMDS provider. The implementation plan attached to this report (*appendix 2*) has therefore been developed in accordance with the Department of Health *"Procurement Guide for Commissioners of NHS Funded Services"* (30 July 2010) and the *"Principles and Rules for Co-operation and Competition"* (30 July 2010).

Implementing this guidance will enable the Network team to work with commissioners and providers to develop a service specification before we evaluate our procurement options. The basis for this specification will be the elements laid out in the redraft guidance (*please see appendix 1*).

3.5 The Network has considered the impact of the East of England Transforming Pathology Services project on this piece of work. At this stage we do not believe that the implementation process we are recommending will be adversely affected by the Pathology Review, however the Network has written to the SHA to formally request that the Transforming Pathology Services project considers this.

4 Future Action

4.1 The Network will work with commissioners and providers to implement the attached implementation plan.

5 Recommendations

5.1 The Network Board are asked to consider the attached implementation plan, which has been developed to ensure that we follow an equitable and transparent process for designating a SIHMDS provider for the Network and to ensure we are working towards providing/accessing a compliant haemato-oncology diagnostic service.

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APPENDIX 1: Redraft Guidance

20.10.10 Haematopathology Redraft Guidance Clarification; Post Discussion on 11.1.2010. (A Newland, A Jack, R Ireland, C Dalley, C McNamara, I Manifold)

Responsibility of the Network Board:

1. The network board should agree a single named provider of specialist integrated haematological malignancy diagnostic services for the network (the SIHMDS) which fulfils the requirements specified in this guidance.
2. The agreement should specify which pathology laboratories in the network are part of the SIHMDS and which are not.
3. The agreement should specify a single named host trust as having overall managerial, operational and financial responsibility for the service.
4. The SIHMDS should cover a catchment population for the service of at least 2 million but there should be no new SIHMDS services set up as a result of this guidance, where none previously existed. In fulfilling this requirement the network may obtain this service from another network.
5. The simplest and the recommended configuration is for the whole of the service to be provided by one laboratory, but where it is agreed that more than one may contribute, then where a given laboratory is providing a certain investigational modality (see 'components of the SIHMDS para. 3'), it should be the only laboratory providing that modality for the whole service/catchment.
6. The agreement should specify the location and host organisation for each of the investigational modalities.
7. The network board should agree pathways with laboratories outside the SIHMDS to ensure that:
    a. Specimens taken for a suspected diagnosis of haematological malignancy are transferred immediately to the reception point of the SIHMDS. The pathway should specify methods of sample handling and transport.
    b. Specimens found to be suspicious of haematological malignancy during the course of the pathology investigation of a more general clinical problem, are transferred immediately to the reception point of the SIHMDS. The pathway should specify methods of sample handling and transport.

Responsibility of Network Site Specific Groups:

1. The NSSG should agree binding investigational protocols for the network with the SIHMDS and the MDTs which fulfil the following:
    a. They should be aimed at disease categories and relevant presenting haematological clinical problems.
    b. They should use multiple investigational modalities to confirm a given patient's diagnosis, so that the results of one modality may be used to corroborate those of another, thus providing a degree of internal QA to the process.
    c. The option should be available to make choices between investigations and redirect the investigational pathway if necessary during the diagnostic process, depending on results so far.
    d. They should include investigational protocols for prognostication, minimal residual disease monitoring and follow up using the principle of multimodality investigations where relevant.

Components of the SIHMDS. (Responsibility of the Host Trust):

1. There should be a single lead for the service who should be a consultant pathologist, consultant haematologist or clinical scientist with equivalent professional status.
    They should have agreed a list of responsibilities with the cancer lead clinician of the trust and should have agreed specified time for the role in their job plan with the cancer lead clinician and their relevant line manager.
2. There should be a single reception point for all specimens sent to the service, even if some tests

are performed at a different location.

3. There should be facilities and equipment for the provision of the following investigational modalities:
    a. Cytomorphology
    b. Histology
    c. Immunocytochemistry
    d. Immunophenotyping
    e. Cytogenetics
    f. Molecular genetics

4. The service should provide the investigations needed for the diagnosis of haematological malignancy using *systematic and integrated methodology.* The key components of this are:
    a. Working to protocols agreed with the haemato-oncology NSSG.
    b. The use of multiple investigational modalities to confirm a given patient's diagnosis, so that the results of one modality may be used to corroborate those of another, thus providing a degree of internal QA to the process.
    c. The ability to make choices between investigations and redirect the investigational pathway if necessary during the diagnostic process, depending on results so far.
5. The service should also provide the investigations needed for prognostics, minimal residual disease monitoring and follow up protocols using the same systematic, integrated principles specified above.
6. There should be a quality assurance system for the investigational process consisting at least, of:
    a. An audit trail showing the pathway followed by each sample.
    b. Participation in all relevant and current NEQAS schemes.
7. The investigation of a given case should result in a *final integrated report,* which means it should fulfill the following key requirements:
    a. It should be compiled entirely within the SIHMDS.
    b. It should summarise the results of all investigations performed, contain interpretative comments and a final diagnosis using the categories and terminology of the current WHO classification for haematological malignancy.
    c. It should be authorised by a single pathologist, one of a group within the SIHMDS, authorised for this by the service lead.
8. The report should be produced within a time limit agreed between the SIHMDS and the NSSG.
9. There should be a single IT system for the SIHMDS which covers the investigational pathways, report generation, diagnostic coding and communication of results with users and which meets the following minimum specification:
    a. It records patients' demographics and clinical details on reception.
    b. It records specimen types and tracks them to the laboratories to which they have been sent and through the tests they have been sent for.
    c. It allows choices between tests and redirection of the pathway during the diagnostic process, depending on results so far, and can track this process.
    d. It can show all test results of a case on the same screen.
    e. Interpretative comments on and review of all results can take place on the same occasion to allow final authorisation of a report by a single pathologist.
    f. Authorisation of reports by designated personnel only, is made possible by password protection of the system.
    g. It is linked to all subsections of the SIHMDS.
    h. It allows users to obtain reports electronically.
    i. It records diagnoses using the categories and terminology of the current WHO classification of haematological malignancy.

APPENDIX 2: HAEMATO-ONCOLOGY PATHOLOGY IMPLEMENTATION PLAN – January 2011

Key Milestone	Specific Action Required	Target Date	Lead	Progress	RAG	Next Steps	Complete
Develop network-wide operational arrangements							
Initiate project	Set up project Steering Group	Jan-11	ME	First meeting has been set up	C	Set up group, schedule meetings for next 12 months	
	Ensure Network Board agreement to implementation plan	Feb-11	ME	On Board forward plan	Green	Submit to 02.02.11 Network Board for approval	
Develop a method of selecting the single Specialist Integrated Haematological Malignancy Diagnostic Service (SIHMDS) provider for the Network **PLEASE NOTE:** This structured process for selecting a single provider is line with DoH Procurement Guidance. Please refer to Appendix 1 for a flow chart summary of this process and a link to the guidance in full.	Ensure development of the SIHMDS is in line with PCT commissioning strategies	Apr-11	ME/LD		Green	Commissioners should publish commissioning intentions on their website and via Supply2Health	
	Perform commissioning needs assessment	May-11	ME/LD	Provision was mapped July 2009, to be validated as part of this assessment	Green	Assessment to gauge patient and population need against current capacity	
	Develop a specification for the SIHMDS	Oct-11	ME/LD	Specification being developed in South West, being shared nationally Spring 2011	Green	Specification to include all recommendations within national guidance (currently in draft)	
	Engage current service providers to develop and refine service specification	Oct-11	ME/GF/ VS/RH		Green		
	Evaluate procurement options	Dec-11	ME		Green	To make a decision whether or not to competitively tender or singly tender	
	Ensure Network Board agreement to method of procurement	Jan-12	ME		Green	Board meeting January 2012 not yet booked, exact date TBC	
	Advertise procurement and notify contract award	Mar-12	ME		Green	If procurement is the chosen method this will be notified to providers via Supply2Health	
Confirm Network SIHMDS service provider	Ensure Network Board agreement to configuration of SIHMDS, including: ➢ A named trust to host the SIHMDS for the Network ➢ Name which laboratories are part of the SIHMDS and which are not	Apr-12	ME		Green	Board meeting April 2012 not yet booked, exact date TBC	
	Confirm a minimum 2 million population base for the service	Apr-12	LD	Anglia Cancer Network population 2.6 million	Green	Dependant on configuration proposal	

Success Measure: Operational policy for the service agreed by Network Board, service level agreements between the host trust and all other trusts in the Network

Initials key: LD: Louise Dale ME: Mary Emurla GF: George Follows VS: Virginia Sams RH: Rory Harvey

NHS Suffolk represents Suffolk Primary Care Trust.