Newsletter

UK NEQAS
International Quality Expertise

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OGGETTO: Raccomandazioni e linee-guida NICE sull'organizzazione dei Servizi di diagnostica oncoematologica

Gentile Partecipante,
abbiamo il piacere di mettere a vostra disposizione due significativi documenti pubblicati da NICE e UK NEQAS.
NICE (National Institute for Health and Care Excellence) è un'istituzione governativa del Regno Unito dedicata alla raccolta di dati epidemiologici e alla formulazione di linee-guida basate sull'evidenza per il miglioramento e l'omogeneizzazione della qualità delle cure sul territorio inglese.
Nel 2017 NICE ha pubblicato un impressionante documento circa l'incidenza delle neoplasie ematologiche e sui provvedimenti da intraprendere a livello nazionale per evitare il rischio che larghe fasce della popolazione siano escluse da diagnosi e trattamenti di elevato standard (Snowden JA et al. J Clin Pathol 2017 Jun; 70(6): 461-468).
In breve, l'incidenza di nuovi casi di linfoma di Hodgkin, di linfomi non-Hodgkin e di mieloma è andata aumentando nel periodo 2001-2010, e nello stesso periodo nessuna patologia ematologica maligna ha mostrato rallentamenti di incidenza. Condizioni socioeconomiche sfavorevoli in certe aree hanno inoltre avuto un ruolo peggiorativo nella prognosi delle più comuni patologie oncoematologiche.
Da questi riscontri e da un'imponente meta-analisi di dati pubblicati, NICE ha concluso che le migliori prestazioni diagnostiche e terapeutiche si ottengono dove i servizi di ematologia sono concentrati e coordinati, rispetto alla recente tendenza di dissociare in sedi distaccate la localizzazione delle varie linee analitiche specialistiche (in primis la diagnostica molecolare). Si conclude inoltre sulla necessità di dotare queste strutture di staff numericamente e professionalmente adeguati, di curare il miglioramento continuo della qualità e di operare per emettere referti multidisciplinari integrati. Tenendo conto della complessità nell'implementare queste linee-guida, è comunque evidente il miglioramento degli esiti clinici per i pazienti là dove le istituzioni sono state in grado di adottarle.
Sembrano ovvietà, ma la realtà in molte aree pare purtroppo ancora molto arretrata (senza parlare di ciò che accade nel nostro Paese).
Uno studio UK NEQAS LI pubblicato molto recentemente ha voluto analizzare l'effettivo livello di implementazione delle raccomandazioni NICE, con l'invio di un questionario (Cartwright A et al. J Clin Pathol 2022; 0: 1–6. doi:10.1136/jclinpath-2021-208075).
Risposte sono state ottenute dal 59% dei centri di ematologia inglesi. A distanza di 5 anni dalla pubblicazione delle linee-guida nessuno dei centri responsivi le ha ancora integralmente applicate. Molti centri sono ancora nella condizione di dovere inviare campioni a strutture distanti fino a 150 chilometri. La media di applicazione nei centri responsivi sembra quantificabile al 73%, ma l'alto numero di mancate risposte dai centri reticenti fa pensare ad una situazione di mancata applicazione, che farebbe scendere il dato al 43%, in un contesto generale di grande variabilità. La raccomandazione più rispettata è quella del referto integrato, messo in pratica da 9 su 10.
Questo studio mostra come il 'mondo reale' fatichi non poco a adottare linee-guida, in ultima analisi dirette a beneficio dei pazienti, anche in un paese aduso alle regole e ben organizzato. Le spiegazioni sono le solite: il non ritenere le linee-guida rilevanti nella pratica quotidiana, il considerarle non raggiungibili perché troppo difficili, troppo avanzate o per la cronica mancanza di personale.
Riflessioni importanti, che ci stimolano ad un confronto costruttivo con la realtà del nostro Paese, ancora poco orientato all'applicazione di regole e raccomandazioni valide a livello nazionale.
Restando a disposizione per qualsiasi chiarimento, con l'occasione Vi saluto cordialmente

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Referente scientifico UK NEQAS for Leucocyte Immunophenotyping

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Article:
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Best Practice

Haematological Cancers: Improving Outcomes. A Summary of Updated NICE Service Guidance in relation to Specialist Integrated Haematological Malignancy Diagnostic Services (SIHMDS)

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Abstract

Haematological malignancies are a diverse group of cancers that affect the blood, bone marrow and lymphatic systems. Laboratory diagnosis of haematological malignancies is dependent on combining several technologies, including morphology, immunophenotyping, cytogenetics and molecular genetics correlated clinical details and classification according to the current WHO guidelines. The concept of the Specialised Integrated Haematological Malignancy Diagnostic Services (SIHMDS) has evolved since UK NICE Improving Outcomes Guidance (IOG) in 2003 and subsequently various models of delivery have been established. As part of the 2016 update to the NICE IOG, these models were systematically evaluated and recommendations produced to form the basis for quality standards for future development of SIHMDS. We provide a summary of the systematic review and recommendations. Although the recommendations pertain to the UK NHS, they have relevance to the modern delivery of diagnostic services internationally.

Definitions

Local reporting: service models in which haematological cancer diagnosis is made within a local laboratory of an associated clinical department.

Co-located: service models in which haematological cancer diagnosis is provided in dedicated, purpose-built and localised laboratories.

Networked: service models in which established laboratories work on the same information network, but are geographically separate and not dedicated solely to haematological cancer diagnosis.

Integrated report: A single report summarising all elements of laboratory diagnosis for a specific patient episode i.e. based on available haematological cytology, histopathology, immunophenotyping by flow cytometry, cytogenetics, FISH and molecular genetics and in accordance with the current WHO diagnostic classification.

Integration: The process of producing an integrated report.

Introduction

National Institute for Health and Care Excellence (NICE) service guidance is based on the best available evidence of clinical and cost effectiveness, and is produced to help commissioners, NHS Trusts, managers, healthcare professionals and patients make informed choices about appropriate healthcare to improve the effectiveness and efficiency of healthcare services.

Haematological malignancies include leukaemias, lymphomas and myeloma and originate mainly in the bone marrow and lymph nodes. They are a diverse group of diseases affecting people of all ages, but with highest incidence among the elderly. Prognosis and responsiveness to treatment of these conditions also varies widely. Haematological malignancies accounted for 8.4% of all malignant disease (excluding non-melanoma skin cancer) diagnosed in England in the years 2001 to 2010[1]

Accurate diagnosis of haematological malignancies involves haematological and histopathological cytomorphology, immunophenotyping by flow cytometry and/or immunohistochemistry, cytogenetics and molecular genetics, including cutting edge technologies, such as next generation sequencing (NGS). Clinical information is also essential, both at the time of specimen analysis and when discussing diagnostic reports in a multidisciplinary team meeting. This approach is built into the World Health Organisation (WHO) classification for all haematological malignancies and updates of this classification[2-4] provide a diagnostic framework that emphasises the importance of integrating all these modern diagnostic tests.

Historical evidence, based principally on lymphoma, supports between 5% and 15% of haematological malignancies being misdiagnosed, sometimes with major clinical consequences[5-7]. Such errors can be difficult to detect after a patient has been treated and so it is very important that the initial diagnosis is correct and supported by strong evidence from several independent investigative modalities.

In the United Kingdom (UK) the 2003 NICE Improving Outcomes Guidance (IOG) for Haematological Malignancies emphasised the importance of an integrated diagnostic

approach to haematological malignancies[8]. The original guidance defined two levels of haematological malignancy diagnostic service - a local service, which provides initial assessment of specimens and a specialist laboratory service. A specialist service uses predefined diagnostic pathways to analyse specimens using a variety of diagnostic modalities, then validates and correlates the results to produce an integrated diagnostic report. This approach has been gradually adopted across the country and the specialist laboratories are now known as Specialist Integrated Haematological Malignancy Diagnostic Services (SIHMDS).

Despite the 2003 NICE IOG for Haematological Malignancy recommendations that all diagnostic technologies should be provided by a single laboratory ('co-located' services), the adoption of a single co-located SIHMDS structure has been variable across England with little progress beyond local reporting by separate laboratories in some regions.

In 2016 the IOG was revised and included an economic appraisal of SIHMDS as well as additional guidance relating to these laboratories[1]. The original IOG was limited to adult patients (age 16 years or more) despite a similar requirement for integrated diagnostic technologies in the diagnosis of haematological cancers in childhood in accordance with the WHO classification. The updated NICE IOG applies to all ages.

The aim of this best practice review is to summarise the evidence and recommendations for SIHMDS laboratories included in the revised IOG for Haematological Malignancies. Although the NICE guidance will be most relevant to SIHMDS in England, the general principles will be relevant to specialised laboratory practitioners and healthcare providers who work in the field of cancer internationally.

Methods: Evidence review during NICE Improving Outcomes Guidance development in relation to SIHMDS

a) Service configuration

Most of the published research on cancer topics focuses on clinical evaluations of treatment; little direct research has been carried out on the organisation and delivery of services.

b) Epidemiology

This was key to the review in order to understand the routes through which patients with haematological malignancies might present initially or at relapse to healthcare services, to inform the shape of these services.

Accurate capture of information on haematological malignancies nationally, despite recent improvements, is still challenging. Haematological malignancies are diverse, ranging from highly aggressive types to incidentally identified indolent conditions. Certain chronic leukaemias rarely produce symptoms, and the recorded incidence of these conditions depends on whether blood samples are examined and on the criteria used for deciding whether there is a malignancy. Even when it is clear that there is a malignancy, identifying the specific type requires sophisticated diagnostic techniques and the integration of information from clinical and laboratory sources. These results are not always available to the Cancer Registries and so some registrations fail to capture the precise diagnosis. This is particularly true of non-Hodgkin lymphoma (NHL), a large and varied group of conditions, for which the ICD-10 coding may be inadequately detailed to separate distinct entities or present other challenges for accurate classification in routine practice.

Data sources for the guideline included the National Cancer Registration Service (NCRS), which is part of Public Health England (PHE), the National Cancer Intelligence Network (NCIN), the Office for National Statistics (ONS), the Patient Experience Survey, National Audit of Cancer Diagnosis in Primary Care, Hospital Episode Statistics (HES), National Cancer Data Repository (NCDR) and regional data taken from the Haematological Malignancies Research Network (HMRN).

Population-based national incidence rates for England (as estimated by cancer registrations) rose over the period 2001-2010 for some haematological cancers: Hodgkin lymphoma, non-Hodgkin lymphoma (NHL) and myeloma. There are no haematological cancers for which incidence rates declined over that period. Registration rates for haematological cancers may have changed because of better ascertainment of new cases and developments in both diagnosis and classification; therefore the changes seen may not represent true changes in incidence[1].

Relative survival improved for individuals in specific age groups who were diagnosed between 2000 and 2010 for a number of haematological cancers: acute lymphoblastic leukaemia (0-14 years males and females; 15-64 years males), acute myeloid leukaemia (15-64 years), chronic myeloid leukaemia, non-Hodgkin lymphoma, and myeloma. For the most common forms of leukaemia in older people (adults aged 65 years or more), namely acute myeloid leukaemia and chronic lymphocytic leukaemia, there was no evidence of significant change in the outcome for patients over this time period[1].

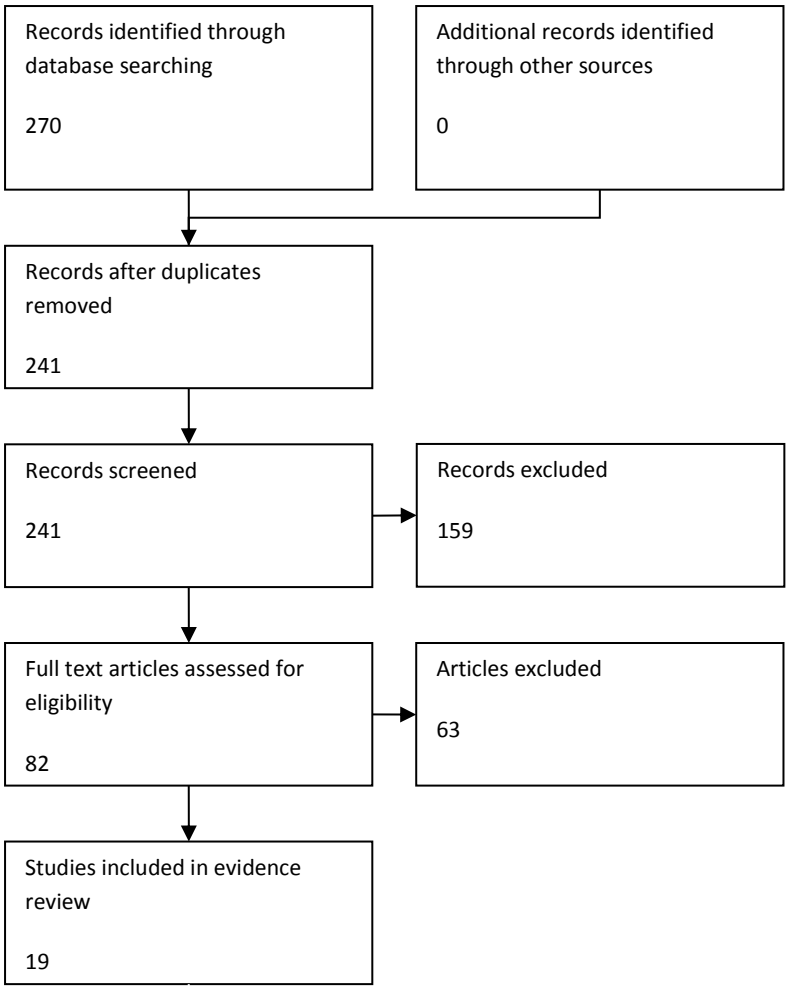
The incidence of haematological malignancy does not generally vary between areas with different levels of deprivation, apart from acute myeloid leukaemia (AML) and Hodgkin lymphoma. Deprivation was also associated with poorer relative survival for chronic lymphocytic leukaemia (CLL), chronic myeloid leukaemia (CML), Hodgkin lymphoma, myeloma and NHL[1].

For the majority of haematological malignancies, GP referral was the most common route to diagnosis, with the exception of AML and ALL, in which over half of all patients presented to hospital as an emergency. CML and myeloma had similar proportions of GP referral and emergency presentations. All haematological malignancies with the exception of Hodgkin lymphoma had a significantly higher proportion of emergency presentations than malignancies in general. Relative survival was significantly poorer for emergency presentations for most haematological malignancies. The exception to this was ALL, where one-year relative survival for emergency presentations was similar to that from all other routes. For some acute haematological malignancies emergency presentation may be the most appropriate route to diagnosis[1].

c) Evidence review and quality grading

Searches were carried out in Medline. Premedline, Embase, Cochrane, LibraryWeb of Science (SCI & SSCI) and ISI Proceedings, HMIC, PscyInfo, CINAHL, Joanna Briggs Institute EBP database, OpenGrey, HMRN (Haematological Malignancy Research Network) and British Committee for Standards in Haematology from January 2000 until April 2015. Results of the searches are detailed in Figure 1. In total 19 studies were included in the review (table 1)[5-7, 9-24].

Figure 1: Search Results



The evidence was considered to be of low quality overall as all the identified studies were retrospective case series and none of them directly compared integrated diagnostic services with other forms of diagnostic service. There was a high risk of bias based on the potential lack of blinding and the possibility of selection bias.

One study (Engel-Nitz et al, 2014) however compared diagnostic outcomes between specialist haematology laboratories and other commercial laboratories, reporting that patients in the specialist laboratory cohort were more likely to undergo more complex diagnostic testing with 26% of patients undergoing molecular diagnostics compared with 9.3% in community based hospital laboratories. Patients in the specialist laboratory cohort were 23% more likely to reach a final diagnosis within a 30 day testing period when compared with community based hospital laboratories.

Table 1: Studies included in Evidence Review

Study		Study Type/Setting	Aim	Population	Intervention	Comparison	Outcomes
1	**Bowen et al (2014)**	Retrospective Study	To determine the rate of revised diagnosis and subsequent impact on therapy following a second review	N=1010	Second Review Diagnosis	Primary referral diagnosis	Diagnostic Discrepancies
2	**Chang et al (2014)**	Retrospective Study	To review the final diagnoses made by general pathologists and analyse the discrepancies between referral and review diagnosis	N=395	Expert Review	Initial Diagnosis	Diagnostic Discrepancies
3	**Engel Nitz et al (2014)**	Retrospective Study Laboratory	To compare diagnostic changes, patterns of additional testing, treatment decisions and health care costs for patients with suspected haematological malignancies/conditions whose diagnostic tests were managed by specialty haematology laboratories and other commercial laboratories.	N=24,664 patients Genoptix N=1,387 Large Labs N=4,162 Other Controls (community hospital labs) N=19,115	Initial interim diagnosis	Final Diagnosis	Diagnostic Uncertainty Stability of Diagnosis
4	**Gundlapalli et al (2009)**	Survey	To address the hypotheses that clinical providers perceive composite laboratory reports to be important for the care of complex patients and that such reports can be generated using laboratory informatics methods	N=10 clinical staff	Survery and interview	None	End user survey opinions

Study		Study Type/Setting	Aim	Population	Intervention	Comparison	Outcomes
5	**Herrera et al (2014)**	Retrospective Study	To evaluate the rate of diagnostic concordance between referring centre diagnoses and expert haematology review for 4 subtypes of T-cell lymphoma	N=89	Review of primary diagnosis at an NCCN centrte	Primary diagnosis at a referring centre	Concordance
6	**Irving et al (2009)**	Report	To show that the standardised protocol has high sensitivity and technical applicability, has good concordance with the gold standard molecular based analysis and is highly reproducible between laboratories across different instrument platforms.	No details	Standardised protocol for flow cytometry	Gold standard molecular technique	Internal and external quality assurance testing of flow minimal residue disease Sensitivity and varibility of the standardised method Applicability of the standardised method in prospective samples Comparison of minimal residual disease as measured by PCR and by flow cytometry
7	**LaCasce et al (2005)**	Retrospective Study	To determine the rate of discordance for 5 common B-cell NHL diagnoses in five tertiary centres participating in a large national lymphoma database The determine whether additional information was obtained at the National Comprehensive Cancer Network (NCCN) centre To estimate the likely impact of a change in diagnosis on treatment	N=928	Pathologic diagnosis from the referral centre was compared with the final WHO diagnosis at the NCCN centres Etiology of the discordance was investigated along with the potential impact on treatment.	No Details	Pathologic Discordance

Study		Study Type/Setting	Aim	Population	Intervention	Comparison	Outcomes
					A random sample of concordant cases (10%) were also reviewed		

Study		Study Type/Setting	Aim	Population	Intervention	Comparison	Outcomes
8	**Lester et al (2003)**	Retospective Study	To establish the impact of the All Wales Lymphoma Panel review on clinical management decisions	N=99	Cases submitted for central review	Actual management plan received by the patient	Change in management
9	**Matasar et al (2012)**	Retrospective Study Laboratory Setting	To test the hypothesis that increased familiarity with the WHO classification of haematological malignancies is associated with a change in frequency of major diagnostic revision at pathology review.	N=719	Diagnosis and review in 2001 using the WHO classification of haematological malignancies	Diagnosis and review in 2006 using the WHO classification of haematological malignancies	Agreement between the submitted and review diagnosis (most recent diagnosis was considered the submitted diagnosis) Factors associated with the rate of major diagnostic revisions
10	**Norbert-Dworzak et al (2008)**	Prospective Review	To investigate whether flow cytometric assessment of minimal residual disease can be reliably standardised for multi-centric application	N=413 patients with acute lymphoblastic leukaemia (Centre 1=110, Centre 2=88, Centre 3=61, Centre 4=154) N=395 patients with blood and bone marrow samples received at diagnosis and from follow-up during induction treatment: PB at day 8, 15, 22, and 33; BM at day 15, 33 and 78).	Flow Cytometry according to a standard protocol	Results from each centre following standard protocol	Qualitative Concordance of Analyses of Exchanged List-Mode Data Quantitative Concordance of Analyses of Exchanged List-Mode Data Concordance of Risk Estimates upon Analyses of Exchanged List-Mode Data Reproducibility in Inter-Laboratory Sample Exchange Agreement of MRD Results from independent patient cohorts
11	**Norgaard et al (2005)**	Retrospective Study	To examine the data quality and quantifying the impact of any misclassification of the	N=1159	Danish Cancer Registry (DCR)	North Jutland Hospital Discharge	Degree of completeness Positive Predictive Value Survival

Study		Study Type/Setting	Aim	Population	Intervention	Comparison	Outcomes
			diagnoses on the survival estimates			Registry	
12	**Proctor et al (2011)**	Retrospective Study	A large scale assessment of expert central review in a UK regional cancer network and the impact of discordant diagnoses on patient management as well as the financial and educational implications of providing a centralised service.	N=1949	Expert Review	Initial Diagnosis	Concordance
13	**Rane et al (2014)**	Retrospective Study	To evaluate the ability and interobserver variability of pathologists with varying levels of experience and with an interest in lymphomas to diagnose Burkitt Lymphoma in a resource limited set up.	N=25	Consensus Diagnosis	Initial Independent Assessment	Initial Independent Assessment Interobserver variation in morphological features Parameters used to differentiate between classic CL, atypical BL and B-cell lymphoma intermediate between DLBL and Burkitt lymphoma. Consensus Diagnosis Concordance with consensus diagnosis Effect of tissue fixation, age group and provision of additional information on revision of diagnoses Accuracy of pathologist's Sensitivity and Specificity to diagnose Burkitt Lymphoma

Study		Study Type/Setting	Aim	Population	Intervention	Comparison	Outcomes
14	**Siebert et al (2001)**	Retropsective Study	To compare diagnoses made at a community and an academic centre to evaluate the reproducibility of the revised European-American Classification	N=188	Review of community hospital assessments at an academic centre	lymphoid neoplasms subtyped according to revised European-American classification criteria at a community hospital	Concordance
15	**Stevens et al (2012)**	Retrospective Study	To observe concordance and discrepancies between local findings and the specialist opinion.	N=125	Central Review	Regional/Community Hospital Review	Pathology Staging Therapy
16	**Strobbe et al (2014)**	Retrospective Study	To investigate whether implementation of an expert panel led to better quality of initial diagnoses by comparing the rate of discordant diagnoses after the panel was established compared with discordance rate 5 years later To evaluate whether lymphoma types with high discordance rate could be identified	N=161 referred to the expert panel N=183 reviewed at a later date	Expert Panel review	Initial Diagnosis	Discordance rate in 2000-2001 Discordance rate in 2005-2006
17	**Van Blerk et al (2003)**	Retrospective Study	To report first experiences from Belgian national external quality assessment scheme (EQAS)	N=17	External quality assessment review	N/A	Stability Intralaboratory reproducibility Homogeneity Interlaboratory reproducibility Single vs. Dual Platform

Study		Study Type/Setting	Aim	Population	Intervention	Comparison	Outcomes
							Influence of Gating strategy CD4+,CD3+ and CD8+CD3+ cells versus total CD4 and CD8 cells Abnormal Samples
18	**Van de Schans et al (2013)**	Retrospective Study	To evaluate the value of an expert pathology panel and report discordance rates between the diagnosis of initial pathologists and the expert panel and the effect on survival	N=344	Expert review of diagnosis	Initial Diagnosis	Discordance Rate
19	**Zhang et al (2007)**	Retrospective Study	To compare similarities and differences in results from participating laboratories and to identify variables which could potentially affect test results to discern variables important in test standardisation	N=38 laboratories	Quantitative testing for BCR-ABL1	Results from different participating laboratories	Test accuracy at different dilutions

d) Cost Effectiveness Analysis

No previous studies of cost effectiveness were identified as part of the evidence review. An economic model was therefore developed to inform the guideline. The economic model considered the cost effectiveness of two overall models of haematological malignancy diagnostic service delivery: (a) local reporting of diagnostic results with a proportion of tests being referred to SIHMDS for review and (b) referring all samples immediately to SIHMDS for suspected haematological malignancies. When considering the SIHMDS itself, two comparative configurations of SIHMDS were considered: (a) networked and (b) co-located. Health outcomes were calculated as lifetime Quality Adjusted Life Years (QALYs) and all costs to the NHS and Personal Social Services (PSS) were considered. Costs were predominantly taken from accounting data of one networked and one co-located SIHMDS. Health outcomes were based on the Guideline Committee's assumptions on the impact of misdiagnoses informed by clinical evidence of treatment for haematological malignancies. In the absence of strong evidence differentiating the two SIHMDS approaches their health outcomes were assumed identical. A range of sensitivity analyses were performed to test differing assumptions and to assess the robustness of and uncertainty around outcomes.

In the model, both approaches of SIHMDS had a lower cost per diagnosis and higher QALYs per patient compared to local reporting with subsequent referral of a proportion of cases to the SIHMDS. When comparing SIHMDS structure, a co-located approach was estimated to be £19 cheaper per diagnosis compared with a networked approach, although this was not robust during sensitivity analysis.

Change in staffing, capital and set-up costs were not considered as part of the economic modelling with this varying widely across England. It was acknowledged that there may be a significant initial resource impact on some centres around obtaining laboratory accommodation, implementation of integrated IT systems and the appointment of dedicated SIHMDS staff.

There was no evidence to directly compare outcomes from co-located and networked haematology diagnostic services and strong conclusions regarding the

preferred configuration of SIHMDS could not be drawn solely from the results of the economic model. One study[11] reported significantly better clinical outcomes for a specialist haematology diagnostic laboratory, but it was unclear from the information provided, whether this study directly compared co-located and networked services. Communication with the author of the study added extra information about the comparisons made and the Guideline Committee debated whether this warranted a recommendation for a co-located diagnostic service to optimise integration of the increasingly complex range of tests involved in the diagnosis of haematological malignancies required to fulfil WHO specifications. There was consensus in the Guideline Committee that a co-located service was the optimal approach and that, because it allowed more effective processes and procedures to be put in place, better communication between laboratory personnel and better quality control, it should be recommended, despite the lack of strong evidence.

The Guideline Committee agreed that there were a number of geographical and infrastructural barriers to establishing a co-located service and that the priority in any diagnostic service was delivering a high quality service that produced timely integrated reports. Although this was likely to be best met through a service with all the component parts located on a single site, this would not always be feasible and so a networked service might be a more appropriate option for certain parts of England. To clarify the key service requirements, the Guideline Committee developed a set of consensus-based recommendations outlining the key organisational, structural and managerial parameters, which should be fulfilled by any SIHMDS, whether co-located or networked. No specific evidence was identified about paediatric diagnosis but the Guideline Committee considered that diagnosis of paediatric patients would follow the same diagnostic pathways as that of adult patients and so the recommendations should cover all age groups.

Recommendations

The following is a list of the new, updated recommendations for 2016. For all recommendations, the quality of the evidence was considered to be low.

The Guideline Committee considered that recommendations are most likely to be achieved if the component parts of the SIHMDS are located at a single site.

All SIHMDS should:

- have clearly defined organisational structures
- have a formally appointed SIHMDS director who is responsible for the operation of the service, including the design of the diagnostic pathway, resource use and reporting standards
- have a single quality management system
- be formally accredited as a SIHMDS by a recognised independent organisation
- be managed by a single trust/organisation
- assess the clinical benefit and the financial and resource impact of new diagnostic and therapeutic technologies before introducing them
- have a central reception point for all specimens
- have a full range of age-appropriate specialist haematology and haematopathology input for diagnosis and the authorisation of integrated reports
- have a full range of protocols covering specimen handling, diagnostic pathways and compilation of integrated reports
- ensure that their location, organisation, infrastructure and culture allow effective day to day and *ad-hoc* communication for rapid resolution of diagnostic uncertainty and accurate diagnosis
- have clear and reliable systems for communicating with relevant healthcare professionals outside the SIHMDS
- produce integrated reports that include all information needed for disease management, and share these with the relevant multi-disciplinary team.
- report diagnoses sub-typed by the current WHO classification.

All SIHMDS should have a predefined diagnostic pathway that is followed for each specimen type or clinical problem. The pathway should ensure that:

- the most appropriate diagnostic platforms are selected for a particular clinical situation to avoid unnecessary duplication
- tests for each specimen are used to provide maximum levels of internal cross-validation, using the current WHO principle of multi-parameter disease definitions

- there is a robust process for report validation, including double reporting.

All SIHMDS should have an IT system that allows:

- specimen booking and registration at source
- input and update of clinical information
- integrated reporting
- two-way communication between SIHMDS and healthcare professionals using the SIHMDS.

The SIHMDS director should be responsible for the overall quality management system, including:

- laboratory processes and the quality of diagnostic reporting
- ongoing assessment of staff competencies
- training provision
- communication within the SIHMDS and with relevant healthcare professionals
- audit and quality assurance
- research and development.

If an urgent treatment decision is not needed, local diagnostic laboratories should send all specimens (including lymph node and other tissue material) directly to a SIHMDS without any local diagnostic workup:

- as soon as a haematological malignancy is suspected
- during active investigation of a suspected haematological malignancy
- if patients with an established or previous malignancy have suspected relapse or disease progression.

If an urgent treatment decision is needed and local diagnostic workup will not reduce the speed or quality of the SIHMDS assessment and integrated reporting, local diagnostic laboratories should process and report on blood film, bone marrow aspirate and cerebrospinal fluid cytology specimens.

SIHMDS should release individual laboratory reports before the integrated report is produced, if there is an urgent clinical need.

SIHMDS should be responsible for specimens that are sent to external labs and should integrate the results into the relevant report (unless there are exceptional arrangements in place for clinical trials).

Disease monitoring

When flow cytometry, molecular diagnostics or cytogenetics are needed for disease monitoring, local diagnostic laboratories should send all relevant specimens directly to a SIHMDS without any local diagnostic workup.

Discussion

The concept of SIHMDS is not new and was a result of recognition that haematological malignancy diagnosis is increasingly complex and dependent on new sophisticated laboratory technology. Separate laboratory reporting and reliance on clinicians to interpret and synthesise each result and stay up-to-date with ongoing revisions in classification is likely to compromise diagnostic quality despite the dual clinical and laboratory training and certification achieved by the majority of haematologists in the UK. This is due to the complexity of current diagnostic methods and the requirement to internally validate and cross-check information, at source, in order to preventing reporting of erroneous results.

From the late 1990s, some UK centres adopted an integrated approach which was incorporated into the NICE IOG in 2003 and subsequent cancer peer review standards. Despite this, many services did not progress integrated reporting beyond an elementary stage, consistent with local reporting. Additionally, although modern diagnostic technology and classifications are relevant to all age groups, patients under 16 had a different standard of care to those over 16. Others developed different models; some using co-located facilities and others using networked but geographically distinct laboratory facilities to produce integrated reports. As there were pros and cons associated with both models, the Guideline Committee considered an economic analysis as well as clinically important aspects in formulating their recommendations.

A fully co-located service is a logical and convenient means of delivering SIHMDS. It permits consolidation of expert diagnostic staff and expensive technologies and is more likely to result in reduced turn-around times, improved diagnostic accuracy, reduced need for repeat sampling and greater cost efficiency. This should in turn lead to more effective treatment and less anxiety for patients. However, there are a number of potential barriers to setting up co-located SIHMDS services, in particular the need to restructure services. Some laboratories such as histopathology and molecular genetics have a broad remit across all cancer and non-cancer specialities, which prevents separation of their haematological services into a co-located SIHMDS. In rural regions, geographically isolated and disparate units with relatively

small populations may find this restructuring a challenge with particular regard to recruitment, job satisfaction and ability to effectively communicate and attend MDT meetings: although modern telecommunications and developing digitalization could mitigate some aspects.

Balancing potential benefits against challenges around service reconfiguration, staff satisfaction, haematology training provision and recruitment, there was agreement that these recommendations were in the best interests of the service and the patients.

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OPEN ACCESS

Implementation of the updated NICE haematological cancers (NG47) improving outcomes guidelines across Specialist Integrated Haematological Malignancy Diagnostic Services (SIHMDS) in England: a UK NEQAS LI survey

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ABSTRACT

Aims Haematological malignancies represent a diverse group of diseases with complex diagnostic requirements. National Institute for Health and Care Excellence (NICE) Haematological Cancer: Improving Outcomes Guidance was published in 2003 and updated in 2016 (NG47), providing recommendations for service delivery including Specialist Integrated Haematological Malignancy Diagnostic Services (SIHMDSs). This survey assessed the implementation of NG47 guidelines, with a specific focus on implementation in relation to laboratory SIHMDS delivery.

Methods A survey was issued to the 17 SIHMDSs identified in England. The questionnaire covered laboratory configuration, information systems, integrated reporting and multidisciplinary team (MDT) working recommendations.

Results In the 10 responding SIHMDS, full implementation of recommendations was not achieved. Higher levels of implementation were reported in 'colocated' services compared with 'networked' SIHMDS. Increased guideline implementation was reported with longer duration since initial establishment of a SIHMDS and for laboratory based as opposed to clinical (MDT) reporting recommendations.

Conclusions Our survey highlights variable implementation of NICE guidance across SIHMDS, with likely inequity of access, standardisation and quality in haemato-oncology diagnostics. Provision of a more structured framework for guideline implementation could assist in increasing compliance to meet the goals of quality and equity of access to harmonised haemato-oncology diagnostics across the NHS in England. This would provide a basis for evaluating the clinical benefits and health economic impact of the SIHMDS model on patient care and outcomes.

INTRODUCTION

The National Institute for Health and Care Excellence (NICE) produces evidence-based guidance, based on clinical research and cost-effectiveness analysis in collaboration with healthcare professionals and end service users. The aim of NICE guidance is to provide health professionals, commissioners and regulators with systematic appraisals, expert consensus and quality standards for high-quality, equitable, harmonised and cost-effective care within the NHS in England. These outputs often have implications for the broader NHS and healthcare systems outside of the UK.

Haematological cancers represent a diverse group of diseases that involve the blood, bone marrow and/or lymph nodes, affecting individuals across all age groups. In 2018, haematological malignancies represented 8.5% of all malignancy diagnoses in England.[1] Diagnosis of haematological malignancy is complex and usually involves multiple pathology disciplines including haematology, immunophenotyping, histology, cytogenetic and molecular genetic services. Analysis and interpretation of results across multiple disciplines serve as the basis for the WHO framework for haematological oncology diagnostics and classifications.[2]

NICE Improving Outcomes Guidance (IOG) in Haematological Cancers was first published in 2003.[3] The original guidance outlined information relating to organisation of the specialist haemato-oncology laboratory service, treatment recommendations and continued management to enable long-term follow-up, all of which specifically related to adult haematological malignancy services.[3] However, timelines for the implementation of recommendations were not outlined. The aim was to improve the overall standard of care provided to patients by reducing the variance in diagnostic approaches.

Updated IOG was published in 2016, which developed the original recommendations under the term Specialist Integrated Haematological Malignancy Diagnostic Service (SIHMDS).[4 5] Supporting evidence for the updated guidelines included cost-effectiveness analysis of SIHMDS in comparison to single-pathology disciplines.[4 6] The guidelines aimed to promote harmonisation of testing pathways available to patients diagnosed with haematological malignancy across England and provided the basis for the NICE Quality Standard (QS150)[7] relating to SIHMDS provision across all ages.

Implementation of clinical guidelines can be impacted by educational-level, financial-level and organisational-level barriers[8–10] rarely allowing complete adoption. The implementation and

uptake of NICE guidance have been previously reviewed in relation to cancer diagnosis preguideline and postguideline implementations.[11] Despite the barriers faced, the study suggested that implementation of guidelines led to a reduction in the cancer diagnostic interval (duration from symptomatic presentation to diagnosis). This finding indicates that while implementation of guidelines is complex, patient-based clinical outcomes can be improved with their implementation. Levels of guideline implementation have also been assessed across other healthcare services within the NHS, including schizophrenia[12 13] and cardiac investigations in primary care.[14]

Despite NICE IOG in haematological cancers being available for 18 years and updated 5 years ago in NG47, an external review of implementation of these guidelines at the service level is lacking. UK National External Quality Assessment Service for Leucocyte Immunophenotyping (UK NEQAS LI) provides external quality assessment for a range of molecular and flow cytometric haematological malignancy testing pathways. UK NEQAS LI promotes harmonisation and standardisation of laboratory approaches to testing, values that align with the NG47 guidelines. The aim of this survey was to use the UK NEQAS LI network to assess implementation of the NG47 guidelines across SIHMDS in England, with a specific focus on the technical logistics, operation of the SIHMDS laboratory hub and the clinical multidisciplinary team (MDT) meetings.

METHODS

A survey questionnaire was designed by UK NEQAS LI to cover 32 recommendations outlined in the NG47 guidelines relating to the logistical and technical configuration of the laboratory (information technology (IT) capabilities, laboratory configuration, sample processing and reporting) and MDT meetings. Recommendations relating to clinical aspects of haematological malignancy service provisions, including levels of care, ambulatory care, staffing and clinical policies, were not assessed as part of this questionnaire.

All participants from England enrolled within molecular and flow cytometry programmes from UK NEQAS LI were emailed and asked to complete the questionnaire. SIHMDSs represent multiple pathology disciplines. As such, it was recognised that multiple services would be contacted within an SIHMDS; however, the SIHMDS director/senior lead was requested to complete the questionnaire.

Data returns from the questionnaire were anonymised, with duplicate data returns removed. The data were analysed and converted into quantifiable, binary classifications, that is, compliant or non-compliant with the diagnostic recommendations as a way of determining specific guideline implementation along with overall levels of implementation of recommendations assessed as part of the study.

RESULTS

In total, completed questionnaires were returned from 10 SIHMDS services out of a potential 17 SIHMDSs within England.

Three SIHMDS returning results operated as a single-entity SIHMDS (colocated disciplines with accreditation as a single service), with seven operating as a networked SIHMDS (operating as multiple disciplines to deliver a service, with accreditation as individual pathology modalities). Of the seven networked SIHMDSs, three reported working across a single NHS site for service delivery, with one SIHMDS operating across two sites, one operating across three sites and two operating across five sites. The physical distance reported between laboratories operating as networked SIHMDS varied from 0.2 to 100.0 miles (median=14.6 miles).

Overall compliance with the 32 recommendations assessed ranged from 46.9% to 84.4% when considering individual SIHMDS, with 73.1% average compliance observed across the 10 SIHMDS providers. When considering the implementation of NG47 guidelines across the two types of SIHMDS models, implementation in single-entity SIHMDS was 83.8%, with networked SIHMDS having 68.8% guideline implementation. Results of implementation rates across individual recommendations for single-entity and networked SIHMDS are detailed in table 1.

Further breakdown of the results showed that there were slight differences in overall implementation when considering the number of years an SIHMDS had been established. For SIHMDS established for 5–7 years, implementation was 70.3%; for SIHMDS established for 8–10 years, the implementation was 74.2%; and for SIHMDS established over 11 years ago, the overall implementation was 76.6%.

The SIHMDSs returning results all met the minimum population for providing a diagnostic service (>500 000), with two out of three (66.7%) of single-entity SIHMDS and six out of seven (85.7%) networked SIHMDS providing services for children (<16 years), young people (16–24 years) and adult (>24 years) populations. The two SIHMDSs that do not deliver a service across all age groups do not provide haematological malignancy diagnostics for children. All SIHMDSs are accredited by a recognised independent organisation (United Kingdom Accreditation Service (UKAS)); however, networked SIHMDSs are only accredited as individual specialist pathology disciplines and not as a single accredited service providing haematological malignancy diagnostics.

The highest rates of overall implementation were observed with respect to assessment of the reporting recommendations. All single-entity SIHMDS services reported implementation of IT systems set up for integrated reporting, issuing final reports, containing all relevant information for disease management and send-away results being integrated into the final report. For networked SIHMDSs, these specific areas of the reporting recommendations returned a range of implementation rates. Five out of seven (71.4%) have a dedicated IT system for integrated reporting, with four (57.1%) issuing final integrated reports and incorporating send-away results into the final reports. Most importantly, only three of seven (42.8%) networked SIHMDSs issued final integrated reports containing all the relevant information for disease management.

Lowest rates of implementation were observed when reviewing clinical recommendations related to MDT meetings, particularly in relation to reviewing all newly diagnosed and all newly relapsed patients. Only one of the three single-entity SIHMDSs (33%) reported the implementation of recommendations reviewing all newly diagnosed and newly relapsed cases. Furthermore, one of the seven networked SIHMDSs (14.3%) reported the implementation of recommendations reviewing newly diagnosed cases, and none reported implementation of recommendations requiring review of all relapsed patient cases. In addition, low levels of implementation were observed when reviewing all SIHMDSs for cases of lymphocyte or plasma cell proliferation of uncertain significance (which overlap lymphoma and myeloma), with 33.3% of single-entity SIHMDSs reporting implementation and 42.8% of networked SIHMDS. The review of all external quality assessment exercises and outcomes is not routinely discussed at MDT meetings, with 33.3% of single-entity SIHMDSs implementing this recommendation compared with 28.6% of networked SIHMDSs.

Table 1 Summary of implementation rates across individual recommendations for single-entity and networked SIHMDS

NICE NG47 recommendations assessed	Compliance among single-entity SIHMDS (%)	Compliance among networked SIHMDS (%)	Overall compliance among all SIHMDS (%)
Laboratory configuration recommendations			
Should serve child, adolescent and adult populations	2 (66.7)	6 (85.7)	8 (80.0)
Should serve a population of >500 000	3 (100.0)	7 (100.0)	10 (100.0)
Should be managed by a single trust	2 (66.7)	3 (42.8)	5 (50.0)
Should have a central reception for all specimens	3 (100.0)	5 (71.4)	8 (80.0)
Should have an IT system set up for specimen booking at central reception	3 (100.0)	6 (85.7)	9 (90.0)
Should be accredited by recognised independent organisation	3 (100.0)	7 (100.0)	10 (100.0)
Should have an IT system enabling two-way communication between SIHMDS and other healthcare professionals	1 (33.3)	4 (57.1)	5 (50.0)
Overall implementation for laboratory configuration	***80.9%***	***77.6%***	***78.6%***
Reporting recommendations			
Should have an IT system set-up for integrated reporting	3 (100.0)	5 (71.4)	8 (80.0)
Should have a full range of age-appropriate specialist haematologist and haematopathology input for diagnosis and report authorisation	3 (100.0)	6 (85.7)	9 (90.0)
Should issue final integrated reports	3 (100.0)	4 (57.1)	7 (70.0)
Final integrated reports should contain all disease management information.	3 (100.0)	3 (42.8)	6 (60.0)
Diagnostic pathways should have a robust process for report validation including double reporting.	3 (100.0)	6 (85.7)	9 (90.0)
Should issue and release individual reports prior to final integrated report if there is an urgent clinical need	3 (100.0)	6 (85.7)	9 (90.0)
Send-away results sent to external laboratories should be integrated into the final report.	3 (100.0)	4 (57.1)	7 (70.0)
Integrated reports should contain disease subtype reporting based on WHO guidelines.	3 (100.0)	6 (85.7)	9 (90.0)
Overall implementation for report recommendations	***100%***	***71.4%***	***80%***
Multidisciplinary meeting recommendations			
MDTs should be undertaken at least once per week.	3 (100.0)	7 (100.0)	10 (100.0)
MDTs should discuss all cases and integrated reports.	2 (66.6)	3 (42.8)	5 (50.0)
MDTs should review of all new diagnoses for integrated reporting.	1 (33.3)	1 (14.3)	2 (20.0)
MDTs should review of all newly relapsed patients for integrated reporting.	1 (33.3)	0 (0.0)	1 (10.0)
MDTs should review of all cases of diagnostic uncertainty for integrated reporting	1 (33.3)	5 (71.4)	6 (60.0)
MDTs should discuss response to treatment during and completion of therapy.	3 (100.0)	5 (71.4)	8 (80.0)
MDTs should assess disease extent (staging and prognosis) and probable course.	3 (100.0)	7 (100.0)	10 (100.0)
MDTs should work out treatment plans for all new diagnosis and relapsed patients.	3 (100.0)	7 (100.0)	10 (100.0)
MDTs should review treatment decisions made in the interval between MDTs.	3 (100.0)	4 (57.1)	7 (70.0)
MDTs should discuss discontinuing treatment when effectiveness has become limited.	3 (100.0)	5 (71.4)	8 (80.0)
MDTs should agree on dates for discussing patient progress.	3 (100.0)	4 (57.1)	7 (70.0)
MDTs should discuss clinical trials and audit results.	3 (100.0)	5 (71.4)	8 (80.0)
MDTs should review all SIHMDS reports of lymphocyte and plasma cell proliferation of uncertain significance (which overlap with lymphoma and myeloma).	1 (33.3)	3 (42.8)	4 (40.0)
MDTs should review all SIHMDS reports of borderline conditions such as aplastic anaemia and other non-malignant bone marrow failure syndromes which may overlap with hypoplastic myelodysplastic syndrome.	2 (66.6)	5 (71.4)	7 (70.0)
MDTs should record the minimum dataset for all cases of haematological malignancy within its specified catchment area, in line with the cancer registry.	3 (100.0)	6 (85.7)	9 (90.0)
MDTs should discuss all EQA exercises and outcomes.	1 (33.3)	2 (28.6)	3 (30.0)
GPs should be given information about their patients' illness, treatment, changes in management and the names of MDT members responsible for their patients' management.	3 (100.0)	7 (100.0)	10 (100.0)
Overall implementation for MDT recommendations	***76.5%***	***63.9%***	***67.6%***
Overall compliance with recommendations assessed	**83.8%**	**68.8%**	**73.1%**

EQA, External Quality Assessment; GP, general practitioner; IT, information technology; MDT, multidisciplinary team; NICE, National Institute for Health and Care Excellence; SIHMDS, Specialist Integrated Haematological Malignancy Diagnostic Services.

DISCUSSION

When the 'Improving Outcomes in Haematological Cancers' guidance document was first published in 2003, the NHS Cancer Plan[15] was set out to reform approaches to cancer diagnostics[15] with a view to delivering better prevention, detection and treatment in cancer care and reducing inequalities with standardisation.[15]

In our survey, data returns were received from 10 out of 17 SIHMDSs identified. While this may have been a limitation or a reflection of the reluctance of some individual SIHMDS

to respond to the survey, it may reflect the general picture of variable degrees of implementation of the NICE NG47 guidelines and quality standards. Our survey identified several key findings from the responding centres. Levels of implementation across the recommendations assessed within NG47 guidelines have not been fully achieved by any SIHMDS. Across the 10 SIHMDS providers that responded, overall compliance with the 32 recommendations assessed was 73.1%. However, it could be hypothesised that SIHMDSs returning data have the highest rates of implementation, and that non-returners have limited to no compliance. Given the proportion of data returns (58.8% of the identified SIHMDSs in England), overall compliance with the 32 recommendations could be as low as 43.0% when considering the whole SIHMDS cohort. When assessing laboratory set-up recommendations, compliance could be as low as 46%. For reporting recommendations and MDTs, the levels of compliance could be as low as 47% and 40.4%, respectively.

Furthermore, across the 10 responding SIHMDS providers, compliance with the recommendations ranged from 46.9% to 84.4%. Such variability has not been previously reported and is important in a number of respects. Equitable delivery of high-quality diagnostics has not been assured and may be at least inconsistent and possibly not adequately provided in some regions. With such variability, it is challenging to evaluate clinical benefits and health economic impact of the SIHMDS model on patient care and outcomes.

Additionally, findings from the survey suggest that implementation across single-entity or 'colocated' SIHMDS is more achievable than 'networked' SIHMDS. Our survey has highlighted that implementation of NG47 guidelines in single-entity SIHMDS was 83.8%, with networked SIHMDS having 68.8% guideline implementation. This was anticipated, that is, NG47 states recommendations are 'most likely' achieved if the pathology disciplines within a SIHMDS are located at a single site. However, NG47 does not state that SIHMDS 'should' be located at a single site, based on recognition of the barriers of providing a colocated service due to geographical and restructuring logistics, and most pathology disciplines having remits beyond haematological malignancy diagnostics.[5] Networked SIHMDSs reported operating between physical distances with a median of 14.6 miles, ranging from 0.2 to 100.0 miles, potentially explaining the differences in implementation.

Since the publication of NG47, NHS England has developed its genomics services via genomic laboratory hubs within the NHS England regions. The newer sophisticated high-throughput genomic technologies have justified increasingly centralised service models. NG47 anticipated these developments, which are accommodated via networked models. Haemato-oncology genomic tumour advisory boards maintain operational links for integrated reporting with the regional SIHMDSs and thereby close links with clinical MDTs. As previously, some SIHMDSs straddle NHS regional boundaries, and local arrangements apply in these settings to ensure continuity of links between component services. Concurrent major service delivery model changes such as NG47 and the redesignation of genomic services have inevitably led to conflicting priorities and ultimately compromised complete implementation of either. Moving forward, further evolution of the SIHMDS model is required due to this rapidly changing diagnostic landscape that may impact colocated SIHMDS delivery.

Our survey reflects that integrated reporting across SIHMDS has improved with implementation of NG47, with 8 of 10 SIHMDS IT systems designed to enable integrated reporting and 7 out of 10 issuing final integrated reports using these bespoke IT systems (despite some also issuing individual reports). Overall, local reports may be issued in these SIHMDSs in cases of clinical urgency, with a final integrated report issued at a later date, once all results have been obtained in order to meet the WHO framework for disease diagnostics and classifications.[2] However, while integrated reporting has improved since the publication of NG47 guidelines, there has been no full implementation of recommendations across all SIHMDS, despite the inclusion of reporting recommendations in 2003 guidance.

Low implementation rates across review of some disease-stage categories in MDT meetings are recognised in our survey, with low implementation of recommendations suggesting review of all cases, all newly diagnosed and newly relapsed patients. The reasons for the low levels of implementation are not within the scope of this study, although integrated diagnostic reports from networked services contained all disease management information in only three out of seven (42.8%) services. It has previously been recognised that accuracy of diagnosis through a multidisciplinary approach is an important factor in improving patient outcomes in haematological malignancy,[5 16] ensuring correct treatment and prognostic pathways. As such, review of all cases, newly diagnosed and relapsed cases should routinely be performed as part of an MDT to ensure diagnostic accuracy and certainty, with all reports containing information relating to disease management.

Diagnostic reports should also contain disease subgroups based on evidence outlined in WHO framework for disease diagnostics and classifications. While 9 out of 10 SIHMDSs reported implementing this recommendation, SIHMDSs are using two different editions of the WHO Classification. Seven SIHMDS are using the most recent edition of the guidelines (WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues, Revised Fourth Edition, 2017). However, two SIHMDS reported the use of the fourth edition, published in 2008. The difference in the guidelines is based on updated genetic information available as a result of the increased application of high-throughput genetic testing. Reporting of disease subtypes using the most updated classification system is important to ensure harmonisation of diagnostic provisions and prognosis for patients, aiding therapy selection and improving overall quality of care.

Low levels of implementation were also observed for the recommendation for MDTs to review all reports of lymphocyte and plasma cell proliferation of uncertain significance (which overlap with lymphoma and myeloma), with 4 out of 10 (40%) SIHMDSs reviewing these cases. While the reasons for implementation were not sought as part of this study, it has previously been recognised that accuracy in lymphoma diagnostics is problematic, with historical rates of diagnostic concordance ranging from 64% to 80%.[17–19] In 2018, lymphoma was the most commonly diagnosed haematological malignancy, representing 50.5% diagnoses, with myeloma representing 18.0% of newly diagnosed haematological malignancies.[1] Our findings suggest that improving the review of this disease subtype by MDT is required to aid in the prevention of incorrect diagnoses, particularly given the incidence of these diseases. In addition, 30% of SIHMDSs do not review all reports relating to borderline conditions such as aplastic anaemia and other non-malignant bone marrow failure syndromes which may overlap with hypoplastic myelodysplastic syndrome (MDS) complicating their diagnosis. Improving review of this disease subtype may improve diagnosis as, for example, approximately 10% of patients presenting with MDS have decreased marrow cellularity,[2] suggestive of aplastic anaemia as a differential diagnosis. Accurate diagnosis with differentiation between MDS

and aplastic anaemia has important prognostic and therapeutic implications.

To facilitate guideline implementation, NICE have introduced tools to allow healthcare services to monitor and track guideline implementation within a specific service. For the NG47 guidelines, these include provision of a baseline assessment tool that allows determination of whether practice is in line with the recommendations and assimilation of evidence to show that clinical practice is in line with guidelines.[4] NICE also provides general guidance regarding the practical steps to improving quality of care based on guidelines. However, the low rate of implementation of certain recommendations within NG47 guidelines suggests either that individual SIHMDS centres have deemed certain recommendations irrelevant to clinical practice, view certain recommendations as unachievable or have had to prioritise implementation of key recommendations. Although our survey was not designed to identify the barriers to implementation, these aspects require further exploration, but there are likely to be multiple factors, including NHS organisational aspects and financial restraints in delivering an appropriate operational structure, suitably trained personnel, laboratory facilities, advanced technologies and equipment, and integrated quality management/IT systems. While NICE states that it is not mandatory to apply all recommendations within guidelines, the overall aim of improving the quality of care through implementation suggests that increased guideline uptake results in improved quality of care and as such NICE could provide further assistance to aid increased implementation.

Several studies have previously identified issues with guideline implementation including the financial costs of implementation, personnel required to appraise guidelines and coordination of multidisciplinary groups necessary for implementation.[8 9] Previously, attempts have been made to ensure implementation through development of guideline implementation planning checklists and reviews of implementation methods and approaches.[20–22] Review of the barriers and strategies for guideline implementation has shown that providing a structured plan can improve implementation,[23] and it is possible that this should be recommended for SIHMDS elements of NG47. This could be a framework-based outline, providing key recommendations requiring implementation in year 1 and then additional recommendations for services to focus on implementing for each subsequent year, with a view to having full implementation within 5–10 years. Although the findings in this study demonstrated that even SIHMDSs established >10 years are not fully implementing the guidelines, a framework-based approach could increase overall implementation.

Given the observed differences in the accreditation of SIHMDS in single-entity and networked services identified in this study, a framework-based, yearly outline could also provide a secondary purpose by acting as a basis for independent audit and accreditation bodies, such as UKAS, to perform assessments against agreed minimum standards. This would also drive SIHMDS to become accredited as a single service, as recommended in NG47 (but only partially implemented herein) rather than as individual specialist modalities. SIHMDS review of the outcomes of such accreditation assessment could identify factors for non-compliance with the NICE guidelines and quality standards and, where necessary, make a case (internally or externally) for additional resources to meet recommendations.

In conclusion, we have surveyed SIHMDSs in England and in the responders, complete NG47 guideline compliance has not been achieved by any SIHMDS. There is variable implementation of NICE guidance across individual SIHMDSs, with likely inequity of access, standardisation and quality in haemato-oncology diagnostics. Provision of a more structured framework for guideline implementation could assist in increasing and monitoring compliance through accreditation to meet the goals of quality and equity of access to harmonised haemato-oncology diagnostic and prognostic services across the NHS in England. This would provide a basis for evaluating the clinical benefits and health economic impact of the SIHMDS model on patient care and outcomes.

Key messages

⇒ Implementation of NG47 guidelines was assessed among Specialist Integrated Haematological Malignancy Diagnostic Services (SIHMDS) within England, specifically relating to laboratory configuration, information systems, integrated reporting and multidisciplinary team working recommendations.

⇒ There was variable implementation of guidelines across individual SIHMDS, with likely inequity of access, standardisation and quality in haemato-oncology diagnostic and prognostic services across the NHS in England.

⇒ Provision of a more structured framework for guideline implementation could assist in increasing levels of implementation.

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