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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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Received 30 November 2021

Accepted 13 April 2022

Published Online First

4 May 2022

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 barriers⁸⁻¹⁰ rarely allowing complete adoption. The implementation and



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To cite: Cartwright A, Snowden JA, Whitehouse H, et al. *J Clin Pathol* 2023;**76**:618–623.

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 Plan¹⁵ was set out to reform approaches to cancer diagnostics¹⁵ 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 haematology 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.

Handling editor Mary Frances McMullin.

Contributors AC and LW initiated the study. AC, LW and HW designed the survey. JAS reviewed the survey. AC analysed the data and wrote the paper. LW and SS were involved in the drafting and review of the paper. JAS and HW reviewed the paper. All authors approved the submitted and final versions of the paper. LW is the guarantor for this work.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Disclaimer This work is based on information within the public domain and has not been performed on behalf of the National Institute for Health and Care Excellence (NICE) nor does it represent the views of NICE.

Competing interests JAS served as Clinical Lead for the 2016 Update of NICE Haematological Cancers: Improving Outcomes Guideline Committee (NG47).

Patient consent for publication Not applicable.

Ethics approval Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article.

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