Haematological cancer

Consultation on draft guideline - Stakeholder comments table
[30/11/15 to 14/01/16]

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British Society for Haematology	Full	38	General	'Unless blood film and/or bone marrow aspirate assessment is needed so that urgent treatment can begin, local diagnostic laboratories should send all specimens directly to a SIHMDS without any local diagnostic workup' In the absence of any good quality evidence, we believe it is potentially harmful to patients to introduce this recommendation using the current wording. Immediate morphological review of blood film and/or bone marrow aspirate appearances is part of any haematologist's initial clinical assessment of a presenting patient, and is discouraged only to the potential detriment of patients. It does not need to (nor should it) delay the simultaneous sending of material to the SIHMDS. The initial review informs and adds to all of the other clinical details relevant to the SIHMDS referral. We are extremely concerned that the guidance may be interpreted to imply that local reporting is unnecessary in many cases. Whilst it is clearly unnecessary and impossible for every haematologist to be an expert in all elements of diagnostics, we need to ensure that emergencies, especially amongst patients presenting out of hours, can be properly managed. A system of initial local review of material alongside referral to SIHMDS will reduce the risk of deskilling. We would ask the panel to consider a change in wording such as: Immediate morphological review of blood film and/or	Thank you for your comment. We recognise your concerns and have modified the recommendations to now read: '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 **[new 2016]'** AND '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

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				bone marrow aspirate appearances is part of any haematologist's initial clinical assessment of a presenting patient. It is necessary in order to assess whether any urgent immediate treatment is required. Local diagnostic laboratories should however simultaneously send all relevant specimens directly to a SIHMDS without any additional local diagnostic workup. The local morphological opinion, together with a summary of the history, examination and any imaging information or related biochemical/immunology results inform the clinical details which accompany the diagnostic material to the SIHMDS. The availability of this information should not delay specimen transport. An IT system which supports local booking of specimens directly in to the SIHMDS from referring institutions, including the possibility of updating additional clinical information as it becomes available, is potentially advantageous.	report on blood film, bone marrow aspirate and cerebrospinal fluid cytology specimens. [**new 2016**]'. Thank you for your helpful suggestions. We have expanded the recommendation about IT systems on page 38 to give more detail on what the IT system should provide to those working in the SIHMDS.
British Society for Haematology	Full	46	20	We are concerned by the levels of care designated by NICE which are somewhat in conflict with those published by the BCSH. We agree that 'intensive chemotherapy' encompasses a number of different treatment and of course treatment sequelae. The current model highlights those patients most at risk of complications of neutropenia by selecting those at highest risk of prolonged (>1 week) neutropenia (<0.5x109/l or lower). There can be little argument that this represents the highest risk group. We are however concerned by the designation of all	Thank you for your comments. The guideline has been modified following consultation. Definitions of high-intensity chemotherapy, as well as low- and intermediate-intensity chemotherapy are now provided in Table 19 and elsewhere in the text. Based on an appraisal of the data in table 20, the GC considered the risks of high-

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				other chemotherapy as being non-intensive. This includes R-DHAP, R-ICE, R-IVE and high dose methotrexate for instance. Whilst these regimens may not result in such significant neutropenia, they are more difficult to give and to support patients through than most outpatient regimens. They require exactly the same input from pharmacy as those regimens designated, in this draft guidance, as intensive. We would ask the panel to consider whether delivery of inpatient chemotherapy should be a criterion of the extra support services designated as being required for an intensive chemotherapy facility. We feel these regimens need to be better distinguished from the likes of oral chlorambucil and R-CHOP with which the vast majority of units are very familiar. We are very concerned that patients receiving high dose chemotherapy regimens (currently excluded from the intensive category in this current draft) as an inpatient will be significantly disadvantaged if appropriate facilities such as access to consultant-level specialist medical staff 24 hours per day, appropriate on-site medical cover, access to suitable ambulatory care facilities, access to central venous catheterisation provided by an experienced specialist, an appropriate level of nursing support including haematology trained specialist nurses 24 hours per day and access to on-site advice from a specialist haematology pharmacist etc are not considered an essential element of that treatment delivery. These are	intensity chemotherapy regimens (as defined) to be higher than R-DHAP and similar regimens, which were reasonably classified as intermediate-intensity regimens based on their shorter duration of neutropenia, generally lesser risks of risks of febrile neutropenia and infection and/or induction mortality (of less than 1%). The GC also considered that the safe administration of high-intensity chemotherapy for induction and re-induction of acute leukaemia and other aggressive haematological malignancies routinely requires inpatient administration and supportive care, whereas DHAP and similar intermediate-intensity regimens, although complex and associated with non-haematological toxicity, are routinely given in an outpatient/day case setting for re-induction of remission induction. The GC recognised that high-dose methotrexate requires special consideration but would normally be given in association with high-intensity chemotherapy. However, the GC considered that individual decisions have to be made on the basis of

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				of course the measures put forward in the draft for other patients who need inpatient chemotherapy. We cannot agree that duration of neutropenia is the only important priority in designating the intensity of treatment and strongly urge the committee to consider the mode of delivery of the treatment as well as its potential sequelae.	other potential organ toxicities, co-morbidities and frailty. In order to address your concerns this additional detail has been introduced into the appropriate sections of the guideline. i.e. the facilities and staffing recommended routinely for high-intensity chemotherapy to be extended to selected patients receiving intermediate-dose chemotherapy where there are anticipated toxicities, co-morbidities and frailty. The GC did not anticipate the majority of patients receiving intermediate-dose regimens would require such facilities or even inpatient admission. The scope of the guideline did not permit the consideration of low-dose chemotherapy, nor of other intermediate intensity regimens. In summary, by using duration of neutropenia as a primary definition of intensity, and also accommodating other toxicities, co-morbidities and frailty, the GC has been able to provide recommendations for facilities, staffing and minimum unit activity for the inpatient and ambulatory care management of patients receiving a well-defined group of chemotherapy regimens. We hope these complement and update

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					rather than replace the BCSH guidelines written in 2009.
British Society for Haematology	Full	61	General	We do not consider that the evidence presented is sufficient to support guidance that patients be placed in a single occupancy room with bathroom if they fulfil the criteria for 'high risk'. The main evidence seems to come from a meta-analysis which by our reading suggested that there was no impact on mortality for any intervention tested unless combined with prophylactic antibiotics: 'Protective isolation, including air quality control, prophylactic antibiotics, and barrier isolation (29 studies), brought about a significant reduction in all-cause mortality: risk ratio 0·60 (95% CI 0·50–0·72) at 30 days (number needed to treat [NNT] 20 [95% CI 14–33]) and 0·86 (95% CI 0·81–0·91) at the longest follow-up (up to 3 years; NNT 12 [95% CI 9–20]). Inclusion of prophylactic antibiotics in the intervention was necessary to show the effect on mortality.' It would seem, in the absence of good quality data, more logical to leave this decision to individual units and individual patients. Some will have HEPA filtered wards, some HEPA filtered rooms and so on. It is clearly most important to audit rates of infection, including use of antifungal therapy at a local level. Whilst the panel clearly are aware of the impact of long term isolation on patients psychological well being, we are concerned that this has been overridden by infection control concerns, the	Thank you for your comments. We are not sure where the evidence statement quoted in your comment originates from as it is not in the guideline evidence review nor is it in the original meta analysis. The risk ratios you quote appear to be the same as those in the meta analysis. These refer to protective isolation by any combination of means that included control of air quality. The meta analysis did not suggest that this effect was only seen in combination with prophylactic antibiotics. We recognise that the evidence was of low quality however the primary benefit of isolating patients is to reduce infection rates and mortality (although some patients experience short and long term psychological effects of being isolated from health professionals and family). The GC believed that there was a benefit to the patient in terms of a reduced risk of serious infection and death which outweighed the

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				evidence for which is not strong, as above. The considerable psychological impact of weeks of isolation for a vulnerable patient, often newly diagnosed and being treated at a centre some way from home must not be underestimated.	risk to the patients' psychological well-being. And despite the lack of high quality evidence the GC agreed to make a strong recommendation because isolation is a basic principle for avoiding infection in immuno-suppressed patients. We have also revised the LETR paragraph for clarification.
British Society for Haematology	Full	63	General	Whilst it is absolutely correct to maintain that there should be enough nurses in specialist haematology centres to provide care for the patients, based on severity and clinical status, we can find no evidence to support the assertion that specialist haematology centres should have the same level of nursing staffing as an HDU. Presumably this means 2 patients per nurse. This is, in our view, both unnecessary and unattainable and should be reviewed or omitted.	Thank you for your comments. This recommendation was in the original Haematology Improving Outcomes Guidance (NICE, 2003) and although there was no new evidence identified the GC felt it was appropriate to retain this recommendation especially in light of the new definition of intensive chemotherapy (see table 19).
British Society for Haematology	Full	73	General	The panel should consider whether the SACT dataset should be stipulated as the vehicle of data recording	Thank you for your comment. The SACT dataset is already mandated for use in England. The prescription of chemotherapy was not within the scope of this guideline update and therefore we have not looked at the evidence in this area and are consequently unable to make recommendations on this issue.
British Society of Haematology Nursing	Short	11		**1.2.19 There should be enough nurses**. This statement is meaningless. How does it help? Not defined. Not explained. 100% subjective. More concerningly for patient safety, the statement is of more use to an accountant who can apply any criteria wished than it is to	Thank you for your helpful comment. We have edited the recommendation to emphasis both the need for adequate numbers and to ensure there is the right skill mix to manage this vulnerable group of

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				a Ward Sister.	patients. We have removed references to the specialist haematology nurse because it could be misinterpreted as a clinical nurse specialist. Further clarification is provided in the supporting linking evidence to recommendations paragraph.
British Society of Haematology Nursing	Short	11		**1.2.20 Specialist haematology centres for patients with neutropenic sepsis 21 should have the same level of nursing staff as that in a high-22 dependency unit. [2016] 23.** The term 'level' is ambiguous. Even if there are nationally accepted HDU guidelines that are explicit on staff /patient ratio the SKILL MIX is critical as is the level of expertise a typical haem ward requires.	Thank you for your helpful comment. We have edited the recommendation to emphasis both the need for adequate numbers and to ensure there is the right skill mix to manage this vulnerable group of patients. We have removed references to the specialist haematology nurse because it could be misinterpreted as clinical nurse specialist. Further clarification is provided in the supporting linking evidence to recommendations paragraph.
British Society of Haematology Nursing	Short	11		**1.2.21 There should be at least 1 trained specialist nurse on the ward in 24 the specialist haematology centre at all times, and they should be 25 able to deal with indwelling venous catheters, recognise early 26 symptoms of infection, and respond to potential crisis situations.** The above 'Guideline' – describes the minimum competency of what every haematology ward nurse should have. NICE effectively implies that a haematology ward only needs 1 such nurse.	Thank you for your helpful comment. We have edited the recommendation to emphasis both the need for adequate numbers and to ensure there is the right skill mix to manage this vulnerable group of patients. We have removed references to the specialist haematology nurse because it could be misinterpreted as clinical nurse specialist. Further clarification is provided in the supporting linking evidence to recommendations paragraph.

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				Sorry to be blunt, but this is a truly awful standard of guidance for what is a critical aspect of patient safety; nursing staffing. Totally ambiguous. It doesn't provides Ward Sisters and Senior Nurses with any help at all. There is no understanding or acknowledgement of the fundamental principles that a haematology ward nursing establishment must be based upon to be safe.	
Children's Cancer and Leukaemia Group	Full	General	General	The Consultants of the UK paediatric haematology community were surveyed via the Childhood Leukaemia Clinicians Network (CLCN) which includes consultants responsible for the care of children with both malignant and benign haematological disorders. Although the group recognised that a co-located SIHMDS may offer some benefits to individual centres, the vast majority of paediatric haematologists have considerable concerns about its implementation nationally without a rigorous review of strength and weakness of current configurations and there are several specific concerns which risk compromising care for the majority of children with haematological disorders. In general there was a concern that there was no evidence presented about how and why this guidance would improve diagnostics for childhood haematological malignancy. Summarised below are the concerns and perceived benefits of a co-located SIHMDS for paediatric haematology. Following this summary are further specific comments raised by	Thank you for sending us the results from your survey of colleagues within the UK paediatric community. We have addressed each of your concerns below. The guideline covered the following two topics. In each topic different age ranges were applied. The GC and NICE took the view that the topic on laboratory services should cover all age groups as these services will be using the same technologies. • Integrated diagnostic reporting for the diagnosis of haematological cancer in adults (over 24 years), young people (16 to 24 years) and children (under 16 years). • The staffing and facilities (levels of care)

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				individuals who were consulted as part of the wider CCLG consultation. Concerns: •Diagnostics for malignant and benign paediatric haematology is different for paediatrics. In the first place there is a paediatric cancer IOG that put the responsibility for paediatric cancer diagnosis and management onto the relevant MDT at the regional paediatric oncology primary treatment centre (PTC). Thus, no paediatric malignant haematological diagnosis is allowed to be made 'locally' in a DGH (much of the argument for SIHMDS in the guidance). Services are already 'centralised', at least in terms of responsibility, to paediatric haematologists. Note, importantly, that not all paediatric PTCs are co-localised with or in the same trust as an SIHMDS, and there will be many SIHMDS that will not have a co-localised paediatric PTC or paediatric haematologists. •The variety of tests required for paediatric haematological diagnosis extends well beyond the capacity of any one SIHMDS. These critical links and sample pathways (for example for minimal residual disease testing, supra-regional molecular genetics, cell banking) get minimal if any mention in the guidance. •No mention in the guidance is made at all about the difference between paediatrics and adults. There is no requirement for a paediatric haematologist to be involved in the process at all (unlike the explicit requirements in	needed to treat adults (over 24 years) and young people (16 to 24 years) with haematological cancer. We have amended the recommendation on page 38 of the full guideline to ensure that age appropriate specialist haematological and histopathological advice is available both for discussion and for authorisation of integrated reports. We agree and there will be an occasional need for some specialised tests to be referred to other diagnostic facilities. We have amended the recommendation on page 38 of the full guideline to ensure that age appropriate specialist haematological

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				the paediatric cancer IOG), and no requirement for adequate volumes and experience of paediatric samples in the various subspecialist laboratories (flow cytometry, genetics etc). It should be noted that many of the paediatric malignancies are individually rare and few overlap with adult disorders. Under this model sample flows from a DGH would go (without local review) to the regional SIHMDS without reference to the paediatric PTC or a paediatric haematologist, potentially adding both delay and clinical risk and in direct contradistinction to the paediatric cancer IOG. •No mention is made of the rapid turnaround times required in paediatrics. There was concern that the exclusion of local diagnostics in the pathway could adversely affect the care of children presenting to a PTC that is not co-localised with the relevant SIHMDS. Typically, paediatric haematological diagnosis comprises two phases. Firstly enough accurate information to start urgent treatment (typically within 24 hours of presentation), followed in due course by very detailed characterisation of the disorder to allow for accurate prognostication and precision medicine. This is overlooked entirely in the guidance. Possible benefits of a co-located SIHMDS: •Physicians from two large centres where an SIHMDS responsible for both adult and paediatric diagnoses already operates were positive about the proposed	and histopathological advice is available both for discussion and for authorisation of integrated reports. We have added the following recommendation to address this issue: '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.' Thank you for your comment. We agree that that a SIHMDS should not provide a service for non-malignant paediatric haematology.

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				guidance as the service that they receive from the SIHMDS is regarded as excellent, including communication links and turnaround times. However, they did comment that SIHMDS should not provide a service for non-malignant paediatric haematology, a sizeable proportion of the workload for most paediatric haematologists. An additional smaller centre also had no concerns to date with the service from their local SIHMDS. Summary: There was a strong view from all but 3 centres that paediatrics should not be included in this guidance and that due consideration of its unique needs had not been made and that a one size fits all approach is not appropriate. Rather, as is current, responsibility for accurate, rapid and clinically relevant haematological cancer diagnosis should remain with the haematological cancer MDT of the relevant PTC. They should be responsible for ensuring that the quality of inputs (clinical and laboratory data) and outputs (formal reports) meet	However, as highlighted in several points throughout the guideline, there are some 'borderline' conditions that need specialist facilities for diagnosis and treatment and in which a careful distinction between malignant and non-malignant disorders needs to be made. A similar situation may apply to the distinction between haematological and non-haematological malignancy. Importantly, these issues apply throughout all age groups and the evolution of modern diagnostic technologies is increasingly important in these respects. This guidance does not preclude locally agreed working and commissioning arrangements based on effective service provision and economies of scale in these respects. Access to high quality diagnostic service provision should be equivalent irrespective of age group. The scope, which was subject to a consultation with stakeholders, reflected this remit and the constitution of the guideline committee reflected the requirement for appropriate paediatric input/expertise. We believe that the changes we have made

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				the requirements of the paediatric cancer IOG. In those centres where there is a co-localised SIHMDS, this may well be through the auspices of an appropriately skilled SIHMDS, which clearly can provide an excellent service for paediatric haematological cancers, but there was much resistance to this model being forced onto local situations where it does not fit.	to the guideline, in response to your comments, should address your concerns.
Children's Cancer and Leukaemia Group	Full	General	General	Concerns about the guideline development process: •There was a single paediatric representative on the committee who voiced significant concerns about the recommendation for co-ordination of paediatric haematology-oncology diagnostics by an SIHMDS. There is also an acknowledgement in the guidance that no evidence exists to support the recommendation for paediatrics. Having ignored paediatric expert input, the only basis we can see for the recommendation is "what's good for adults (on the basis of limited and weak evidence) must be good for children". •An alert about the consultation does not appear to have been sent to potential paediatric stakeholders. As far as we are aware, none of the following received such an alert: RCPCH, Childhood Cancer Leukaemia Group or specialist paediatric hospital trusts. We became aware of the consultation from an informal alert through our professional networks. Also, the timing of the consultation with a six week deadline including the Christmas holidays	Thank you for your comments. Paediatric expert input was not ignored. It was actively sought and a consensus reached in the committee on what recommendations should be made. In addition there were a number of other guideline committee members from centres with a great deal of experience in the management of haematological malignancies in children whose day to day work involves diagnosis and management of paediatric and teenagers and young adult cases alongside adult patients. All registered stakeholders would have been informed by NICE (via email) that the consultation version of the guideline was available for comment. Both the RCPCH and CCLG were registered stakeholders. It is not part of NICE process to send out alerts in advance of consultation. The timetable for the whole guideline

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				raises questions about the validity of the process.	development process, including the date of stakeholder consultation, has been available on the NICE website, since development of this guideline started. The consultation was extended to six weeks, instead of four weeks, to account for the consultation period occurring over Christmas.
Children's Cancer and Leukaemia Group	Full	General	General	Specific concerns Concerns about recommendation to require a SIHMDS for paediatric haematology-oncology diagnostics: 1)It's unclear why NICE have decided to separate diagnostics for paediatric haematology-oncology from other childhood cancers and produce a recommendation that is in conflict with its Children and Young Person Cancer IOG(August 2005) which states:	A core principle of this guidance was to ensure that all patients whatever their age have access to high quality diagnostic services for haematological malignancies. It is anticipated that this will be delivered by laboratories that comply with the generic standards and have sufficient throughput, quality assurance and economies of scale. We are aware of the recommendations in the CYP IOG (NICE, 2005) on specialist teams and feel that the most appropriate arrangements need to be agreed locally by commissioners. This guidance does not prevent there being a separate diagnostic paediatric service as long as these new recommendations are followed and

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					implemented. Given the national variation in practice the recommendation for a SIHMDS could be either a combined service covering all age ranges; an adult only service; or a children only service.
				Pathology and histopathology services for children should be provided in the long term only by paediatric pathologists and those with relevant specialist expertise. This is a matter of training, experience and governance. •Paediatric pathology should be concentrated at selected specialist paediatric surgical/oncological and tertiary referral maternity sites. •Paediatric pathology cannot be subsumed by general or other specialist pathologists without a further major reduction in both service and quality. •Haematologists are responsible for the morphological diagnosis of leukaemia and for the reporting of bone marrow aspirates and trephine biopsies from patients with solid tumours. The spectrum of leukaemia in childhood is different from that in adults, so diagnosis and the ongoing assessment of response to chemotherapy are best provided by a paediatric haematologist with specific expertise. Children are at greater risk of CNS involvement with leukaemia, which requires specialised input for the preparation and assessment of specimens.	All the bullet points opposite that you have quoted are taken from the introductory section of the care pathway chapter on pages 31-32 of the CYP IOG (NICE, 2003) and are not recommendations. We believe that the recommendations we have made in this update are fully consistent with the recommendations made on page 33 and 34 of the CYP IOG (NICE, 2005). We have added a further recommendation about the involvement of age appropriate haematologists and (histo) pathologists on page 38 of the full guideline.

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				2) The CYP IOG recommendations were translated into diagnostic standards for all childhood cancers within the 2009 CYP childhood cancer peer review measures. The standards require that a specialist integrated report is agreed by a PTC diagnosis MDT which includes paediatric haematologists, paediatric histopathologists and laboratory geneticists. These recommendations have been implemented by childhood cancer PTCs in a variety of ways and no concerns about their effectiveness or reporting standards were raised during peer review inspections. Has there been a formal audit of the diagnostic accuracy of the reports produced by the PTC MDTS to raise concern? If not, would it not be better to audit the present arrangements and develop paediatric specific guidance covering all childhood cancers as an update to the 2005 CYP IOG?	Thank you for this information. It is likely that the existing cancer peer review measures will be updated in light of the recommendations presented in this updated NICE guidance. It is not the responsibility of NICE or the guideline developers to carry out formal audits of the diagnostic accuracy of the reports produced by the PTC MDTS to raise concern. A surveillance review conducted by NICE in November 2014 concluded that an update of the children and young people with cancer service guidance was not necessary at this time. Further information can be found at - https://www.nice.org.uk/Guidance/CSG7/Evidence
				3) In practice, SIHMDSs whether co-located or networked will be adult focussed and led with a pre-dominantly adult repertoire and expertise. No paediatric competence or specialist input is specified for them within the guidance.	We have amended the recommendation on page 38 of the full guideline to ensure that age appropriate specialist haematological and (histo) pathological advice is available both for discussion and for authorisation of

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				The governance arrangements ensuring the diagnostic accuracy of reports produced by individual laboratories is reviewed during UKAS inspections and accreditation status provides some reassurance in that regard. Paediatric clinical competency is more important in integrating those reports into a specialist diagnosis and treatment management plan than an adult laboratory driven process. The latter will disrupt the current clinically driven process and de-skill paediatric haematologists thus increasing the risk of diagnostic errors. Furthermore, there is a risk of much longer turn-around times for producing an integrated report through an SIHMDS as it will add an extra node within the process.	integrated reports.
				4) There are several precision medicine initiatives embedded within childhood leukaemia trials that require integration of reports from a variety of national reference and research laboratories to guide an individual patient's treatment. An SIHMDS will merely add to the complexity of the pathway resulting in diagnostic confusion and an impact on turn-around times.	This issue is not unique to paediatric clinical trials. The recommendations in the update support clearly define the organisational structures and protocols, which should include the timely management of clinical trial samples. Use of a quality management system will mean that pathways for trial and non-trial samples will be frequently and easily be updated according to changes in clinical practice.
				5) There will be significant impact on education and training of paediatric haematologists and histopathologists if the current paediatric centred and clinician led diagnostic pathway is replaced by an adult	We don't agree that the current pathway is being replaced by an adult laboratory centred pathway. Laboratories will provide expert integrated advice to clinical teams

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				laboratory centred pathway.	wherever they are and however old their patients are. Depending upon the local service model adopted, we acknowledge that training arrangements may need to change. However it is not the responsibility of this guidance to consider the training implications and how these will be delivered.
Children's Cancer and Leukaemia Group	Full	General	General	There are some fundamental principles described in the 2005 NICE IOG (which the current cancer measures are based): •The reporting of paediatric malignancies is undertaken by specialists (pathologists and haematologists) trained specifically for the diagnosis of paediatric cancers in the wider setting •More specifically paediatric haematologists are responsible for the morphological diagnosis of acute leukaemia and other haematological malignancies in childhood – this is a highly specialised area. •Paediatric haematologists must be on site (within the paediatric services) delivering care directly to / for children with haematological malignancies •Paediatric haematologists are part of the core multidisciplinary team caring for children with haematological malignancies.	Thank you for your comments. The 'fundamental principles' you describe are related to the recommendations on page 33 and 34 of the CYP IOG (NICE, 2005), although the wording has been changed by the stakeholder organisation. All the bullet points opposite that you have quoted are taken from the introductory section of the care pathway chapter on pages 31-32 of the CYP IOG (NICE, 2003) and are not recommendations. We believe that the recommendations we have made in this update are fully consistent with the recommendations made on page 33 and 34 of the CYP IOG (NICE, 2005). We have added a further recommendation about the involvement of age appropriate haematologists and (histo) pathologists on

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					page 38 of the full guideline. We believe that the recommendations we have made are now fully consistent with the recommendations made on page 33 and 34 of the CYP IOG (NICE, 2005).
				Therefore the requirement that a single (SIHMDS) site is responsible for the diagnosis of haematological malignancies (etc) in children (unless they are part of a larger adult/ paed integrated organisation) raises a significant concern.	Our recommendation (on page 37 of the full guideline) does not specify that the SIHMDS must be on a single site.
				Whilst it is clear that the specialist integrated haematology and malignant diagnostic service (SIHMDS) are needed to meet certain criteria, the relationship between the referring SIHMDS and the paediatric haematology MDT needs to be clarified and service specification defined. The assumption that these are all on one site should be challenged – the safe multidisciplinary care for children with leukaemia is paramount – and (I assume) it is not feasible to have a fully accredited SIHMDS at all paediatric sites? If that is correct then the statement p 36 'local diagnostic laboratories should send all specimens directly to an SIHMDS without any local diagnostic workup' is also not feasible or desirable within the paediatric setting.	Our recommendation (on page 37 of the full guideline) does not specify that the SIHMDS must be on a single site. We agree that safe multidisciplinary care for children is important. However it is the responsibility of commissioners to set up safe and effective services based on the recommendations made in this guideline. The GC was very aware of this concern (based on the input of the GC paediatric representative) and therefore the recommendation has been amended to read

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				There is currently an evidence based infrastructure of clinical services for children with leukaemia. These comply with the children's Measures (at least in England) and service standards in the devolved nations. The guidance for the laboratory support of these services should be defined and integrated within the context of the paediatric NICE service guidance for haematological malignancies, (not as an add on to the adult guidance).	'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...' The following extra recommendation has been added to help clarify this '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'. We believe that the recommendations in this updated guidance comply with those in the CYP IOG (NICE, 2005).
Children's Cancer and Leukaemia Group	Full	37-39		1) The local immediate morphological review of blood/marrow aspirate material by adult or paediatric haematologists is highly important and is part of the clinical assessment of any haematologist's patients. It does not need to (nor should it) delay referral of all	Thank you for your comment. We recognise your concerns and have modified the recommendations to now read: 'If an urgent treatment decision is not

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				relevant material to the SIHMDS. We are concerned that it may be discouraged by the phrase "Unless blood film and/or bone marrow aspirate assessment is needed so that urgent treatment can begin, local diagnostic laboratories should send all specimens directly to a SIHMDS without any local diagnostic workup". 2) It is critically important (and well recognised and	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 **[new 2016]'** AND '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. [**new 2016**]'. Depending upon the local service model adopted, we acknowledge that training arrangements may need to change.

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				acknowledged in the 2003 guidance) that local morphology assessment and reporting continues to occur, both for trainees continuously throughout their training (whether or not they are co-located with an SIHMDS for all or part of their training) as well as career grade staff. The SIHMDS then has an educational and audit role in correlating initial morphological opinion with final diagnosis, which it cannot otherwise provide. If in the future morphological skills are not learned by trainees continuously over a longer period of time than is practical for SIHMDS attachments, or maintained by career grade staff in referring institutions, then patients whose material needs to be referred to an SIHMDS will not always be recognised. 3) From the paediatric point of view it is important that haematologists with a subspecialist interest in paediatric malignancy diagnosis are involved in the SIHMDS authorisation of paediatric reports and are present at MDTs. 4) For paediatric haematology as a speciality, it is extremely important to ensure that this guidance does not separate clinical and diagnostic haematology, nor harm well established and effective local training and working practices.	However it is not the responsibility of this guidance to consider the training implications and how these will be delivered. We have amended the recommendation on page 38 of the full guideline to ensure that age appropriate specialist haematological and (histo) pathological advice is available both for discussion and for authorisation of integrated reports. Thank you for your comment. We are confident that this guidance will prevent this from happening and ensure high quality services are developed and maintained.
Department of Health	Full	General	General	Thank you for the opportunity to comment on the draft for the above clinical guideline.	Thank you.

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				I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	
Leukaemia Care	Full	General	General	Following our conversation last week, we have reviewed the draft guidelines and have, on this occasion, decided not to comment due to time restrictions on our part. Thank you for getting in touch to remind us of the consultation deadline.	Thank you
Myeloma UK	Full	General	General	Myeloma UK welcomes the opportunity to comment on the revised NICE guideline on Haematological Cancers: Improving Outcomes. From speaking to a range of clinicians who work in the treatment and care of patients with myeloma, these guidelines form vital evidence-based guidance on best-practice structures for haematological services and how to improve standards of care across the NHS. As the guidelines have not been updated since 2003, given the reforms to the NHS through the Health and Social Care Act 2012 and advances in treatment since this time, Myeloma UK very much support the work that is being done to update the guidelines to improve their relevance to clinical practice. Whilst the guideline is very comprehensive, the topics it covers are quite narrow and specific. There is the potential to cover wider issues such as stem cell transplantation and end-of-life care provision or even	Thank you for your comment. Unfortunately stem cell transplantation and end-of-life care provision were not included within the scope for this updated guidance. However NICE has recently published a

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				reference other relevant guidance to where this flows on from Haematological Cancers: Improving Outcomes. In addition, the treatment and needs assessment of people from black and minority ethnic communities and in the elderly population could potentially be covered in more detail.	guideline on the diagnosis and management of myeloma which included topics on stem cell transplantation. End of life care for cancer patients is covered by NICE Improving supportive and palliative care for adults with cancer (2004) cancer service guidance and by the NICE guidance on 'Care of dying adults in the last days of life' (2015) The GC ensured that guideline recommendations were formulated so as to avoid unlawful and other harmful discrimination and promote equality of opportunity across the protected characteristics. Consideration of equality issues has been documented in the Linking Evidence to Recommendations table that accompanies the recommendations for each clinical question. However, the GC did not identify any potential issues. An equalities impact assessment has been carried throughout development of this guideline.
Myeloma UK	Full	General	General	There are a number of overlapping pieces of guidance in the NHS that focus on standards and service requirements/set-up in cancer treatment and care provision. These impact and align with Haematological Cancers: Improving Outcomes. For example, there is the	Thank you for your comment. We are aware of these documents and have taken them into account during development of this updated guideline.

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				NICE Myeloma Clinical Guideline and the NHS England Chemotherapy Service Specification and Manual for Cancer Services that also cover issues such as minimum staffing requirements for multi-disciplinary teams (MDTs). Whilst focusing on slightly different topics, NICE and NHS England need to ensure that their guidelines support each other. It also needs to be made clear which guidance takes precedent and which guidance clinical staff should be using to guide service development. This can be done through clarifying this within the guidance and through communication with haematological clinicians.	Thank you for your comments. It is anticipated that NHS England takes into account published NICE guidance.
Myeloma UK	Full	28-37	General	We welcome the detailed discussion of NHS diagnostic services for haematological cancers, particularly given the importance of early diagnosis and diagnostics for the development of stratified medicine. The coverage on the SIHMDS is comprehensive. The wider issue of late diagnosis in haematological cancers could potentially be covered. For example, the National Awareness and Early Diagnosis Initiative (NAEDI) run by Cancer Research UK and the former National Cancer Action Team (NCAT) undertook a number of projects auditing "significant events" in primary care (for example, where diagnoses had been missed and had impacted on patient care). The guideline could	Thank you for your comment. Thank you. The issue of late diagnosis in haematological cancers was not included within the scope of this update therefore we are unable to make any recommendations in this area. However NICE has recently updated its guidance on suspected cancer (NG12) which should cover the issues you raise.

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				include a recommendation on communication between secondary and primary care, when diagnosis has been significantly missed in haematological cancers. This would ensure that lessons would be learned in primary care following significant events.	The guideline committee has modified the recommendation on written policies to include communication with primary care and other clinical teams because they considered it was an important part of ensuring coordinated care for patients who may be treated by different teams, including primary care.
Myeloma UK	Full	63	7	We welcome the addition of recommendations covering ambulatory care in the guidelines and agree with the content. This is particularly important given DH policy statements relating to increasing the extent of community and home-based care in the NHS. Whilst outpatient based care is important, the IOG guidelines should serve to safeguard patients and to ensure that the Government is not moving care in the community to cut costs at the expense of patient care and interaction with clinical staff and other patients in the hospital setting. It is crucial that where community and home-based care is provided, this takes into account patient preference. This is outlined in the guidelines, however, it would benefit from further information on the types of information sort from patients about their preferences and who should be responsible for seeking this information. There is evidence to suggest that whilst home-based care improves independence and the ability to lead normal day-to-day lives, some patients prefer to receive	Thank you for your comment. Patient preference is addressed and acknowledged in the ambulatory care section of the updated guideline. The following recommendation has been added at the end of the ambulatory care section of the guideline: 'For more guidance on providing information to patients and discussing their preferences with them, see

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				hospital based treatment as they feel safer being treated in a hospital environment.	the NICE guideline on patient experience in adult NHS services'. The further information you require on the types of information sought by patients about their preferences was not considered a priority area for recommendations during scoping of this guideline but a cross reference has been added to the NICE patient experience guideline.
Myeloma UK	Full	63	7	The ambulatory care section outlines that patients need "written and oral information for patients and their family members or carers". Further information is required to define what this means and who would be responsible for providing this information.	Patient preference is addressed and acknowledged in the ambulatory care section of the updated guideline. The following recommendation has been added at the end of the ambulatory care section of the guideline: 'For more guidance on providing information to patients and discussing their preferences with them, see the NICE guideline on patient experience in adult NHS services'. The further information you require on the types of information sought by patients about their preferences was not considered a priority area for recommendations during scoping of this guideline but a cross reference has been added to the NICE patient experience guideline.
Myeloma UK	Short	11	1.2.15	We agree that there needs to be written policies in place	Thank you for your comment. A review

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				for all clinical procedures, however, this should be supported by a review process to ensure that these remain accurate, relevant and up-to-date.	process to ensure that written policies remain accurate, relevant and up-to-date is an implementation issue. However we would hope and expect that those responsible will regularly review and update these policies.
Myeloma UK	Full	61-64	General	From speaking to myeloma patients who use the services that Myeloma UK provide, there is a disparity between people who receive expert care in large cancer centres compared to those who receive care in smaller community hospitals – in terms of available expertise and access to CNS. In the guideline, there is the potential to expressly outline provisions to cover coordination of care between different hospitals that patients may attend for consultation and treatment. In addition, coordination between stem cell transplantation centres and other elements of secondary care.	Thank you for your comment. We recognise that this is an important issue and have amended the recommendations in the guideline to reflect this. Further clarification is provided in the LETR on page 65.
Myeloma UK	Full	71	7	We welcome the recommendation that all hospital MDTs have a coordinator. One potential barrier is that some MDTs will have dedicated administrative staff to coordinate the MDT and others will not. The guideline could potentially suggest ways of overcoming this barrier.	Thank you for your comment. This recommendation was published in chapter 4 of the original 2003 Improving outcomes in Haematological cancer guidance and has been included in this section of the updated guideline as it is still relevant to staffing and facilities (levels of care) for adults (over 24 years) and young people (16–24 years) with haematological cancer. However the evidence for this recommendation has not been reviewed as part of this update and so we are unable to make any changes.

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Myeloma UK	Full	71	7	In the section on extended members of the team, the guideline could better cover emotional and psychological support and include occupational therapists.	Thank you for your comment. Unfortunately the emotional and psychological support (including occupational therapists) for people with haematological cancers was not included within the scope of this update. The membership, role and responsibility of the MDT are specified as part of the Cancer Peer Review measures in England.
Myeloma UK	Full	70	7	Define what "sufficient" members of MDTs mean.	Thank you for your comment. This recommendation was published in chapter 4 of the original 2003 Improving outcomes in Haematological cancer guidance and has been included in this section of the updated guideline as it is still relevant to staffing and facilities (levels of care) for adults (over 24 years) and young people (16–24 years) with haematological cancer. However the evidence for this recommendation has not been reviewed as part of this update and so we are unable to make any changes. However the numbers are specified in the MDT recommendations on pages 72 and 73 of the full guideline.
Myeloma UK	Full	73	7	Define what "adequate information, advice and support" for patients means.	Thank you for your comment. Unfortunately the amount of adequate information, advice and support for people with haematological cancers was not included as a topic within the scope of this update. However more

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					detail on this recommendation, including the holistic needs assessment and information for patients and carers, can be found in the Cancer Peer Review measures in England.
Myeloma UK	Full	73	7	The MDT should also discuss the holistic needs of the patients	Thank you for your comment. Unfortunately the holistic needs of people with haematological cancers were not included as a topic within the scope of this update. However more detail on this recommendation, including the holistic needs assessment and information for patients and carers, can be found in the Cancer Peer Review measures in England.
NHS England	Short	5	7-8	The phrasing is potentially misleading; the full guideline (A.3.5) is unable to identify evidence to recommend a co-located over a networked SIHMDS and co-located SIHMDS. We suggest that more appropriate wording would be: "A managed SIHMDS co-located, or networked with a clear hub with management responsibility, should be identified as suitable solutions for provision of the service".	Thank you for your comment. We disagree. Our recommendations do not mandate that the service has to be located at a single site.
NHS England	Short	5	16	The costing modelling for a SIHMDS is largely based on one publication. This reports a service for a 2 million population size, as was recommended in Additional Best Practice Commissioning Guidance For developing Haematology Diagnostic Services, Gateway Number: 17241. In the Full Version the cost per test modelling indicates SIHMDS remain cost effective over a range of	Thank you for your comments. The figure of 2 million was first recommended in the following publication 'Additional Best Practice Commissioning Guidance for Developing Haematology Diagnostic Services' published by The National Cancer Action Team and the Royal College of

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				cost and perhaps therefore sizes. It would be helpful to have an advisory comment about size of service/population served likely to be served by an efficient, effective SIHMDS. Or is this considered implicit from 1.1.6 which indicates the service SIHMDS should run flow/molecular diagnostics/cytogenetic and therefore implies a limited number of service providers form the current portfolio of providers. Or is the idea that local services should set up flow/molecular/cytogenetics to fulfil this measure?	Pathologists in 2012 and was therefore not included in the original NICE haematological cancers IOG (2003). The GC was reluctant to specify a particular population base because of the variability of population distribution and felt it was more important to specify the SIHMDS for Commissioners in terms of the quality requirements and capabilities. The economic analysis makes clear the difficulties in recommending a minimum population base (see Appendix A of the full guideline). As we only had cost evidence for two centres, one of each configuration, we were unable to do any analysis around any potential 'economies of scale' of running a service for a larger population or optimal population size for each configuration of SIHMDS. The implication of recommendation 1.1.6 is that there would need to be centralisation of these services.
NHS England	Short	8	22-23	By "at risk of more than 7 days of neutropenia" the guidance presumably mean "are likely to experience more than 7 days of post chemotherapy neutropenia". Patients with haematological malignancy with conditions	Thank you for your comment. We have clarified that the recommendation relates to post-chemotherapy neutropenia

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				such as myelodysplastic syndrome may be chronically neutropenic; they are therefore at risk of neutropenia of more than 7 days.	
NHS England	Short	8	19-23	The definition is fine: but it is unfair to some patient groups to exclude them, as we believe them to be at risk of the complications of neutropenia following chemotherapy - treatment of hairy cell leukaemia, MDS / AML with lower intensity chemotherapy may also satisfy the criteria. And the Full guideline does not provide any evidence for "a minimum of 10 cases per year", in fact there is historical evidence that the caseload does do impact on outcome in intensive AML therapy. The arbitrary identification of a 10 cases per year here is inconsistent with the approach to SIHMDS where there is some evidence to support recommending a service size but the guidance does not.	Thank you for your comments. On page 6, lines 20-26 we list the groups that all these recommendations are relevant for. We believe that the groups you cite in your comment would be covered by lines 25 and 26 (bone marrow failure caused by other haematological malignancy, such as plasma cell leukaemia or other lymphoproliferative disorders). However we have amended this text to include other lymphoproliferative disorders. The figure of 2 million was first recommended in the following publication 'Additional Best Practice Commissioning Guidance for Developing Haematology Diagnostic Services' published by The National Cancer Action Team and the Royal College of Pathologists in 2012 and was therefore not included in the original NICE haematological cancers IOG (2003). Although no evidence was identified, the GC agreed that a recommendation on centre size was important. The induction death rate from the use of intensive chemotherapy

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					regimens exceeds those of high-dose therapy with autologous stem cell support for which the JACIE standards stipulate centres should manage a minimum of 10 new patients a year. In addition the GC considered that there were potential benefits from care in a larger centre including better access to clinical trials, the ability to audit outcomes, increased patient confidence, and better access to resources and expertise including the use of dedicated isolation facilities.
NHS England	Short	9	22-23	Why comment on cytotoxic drug reconstitution, but not prescribing? Consider: competency assessed prescribers; use of computer-aided prescribing. Any comment on monoclonal antibody reconstitution?	Thank you for your comment. This recommendation was in the original Haem IOG (NICE, 2003) and although there was no new evidence identified during this update the GC felt it was appropriate to retain this recommendation. These are broader issues about the prescribing and dispensing of anti cancer therapy which are covered by other guidance and peer review measures.
NHS England	Short	11	4-5	Should the Full or Short guideline specifically mention the SACT database as an audit of process and outcome?	Thank you for your comment. The SACT dataset is already mandated for use in England. The prescription of chemotherapy was not within the scope of this guideline update and therefore we have not looked at the evidence in this area and are

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					consequently unable to make recommendations on this issue.
NHS England	Short	11	12-13	As in point 4 – where is the evidence?	Thank you for your comment. This recommendation was in the original Haem IOG (NICE, 2003) and although there was no new evidence identified during this update the GC felt it was appropriate to retain this recommendation.
NHS England	Short	11	21-23	Why should other places caring for neutropenic sepsis not have the same level of nursing staff?	Thank you for your comment. Specialist haematology centres will be dealing with patients who have more severe and prolonged neutropenia and therefore are at greater risk of severe complications.
NHS England	Short	14	3-4	The cancer strategy published in 2015 recommends that all patients with cancer have access to a cancer clinical nurse specialist. The statement in this guideline could be strengthened to support the strategy recommendation. Access to clinical nurse specialise is the key factor associated with a good patient experience (from Cancer Patient Experience Data) however access to clinical nurse specialist is poorer for people with haematological cancers than for solid tumor cancers.	Thank you for your comment. We have not updated recommendations shaded in grey and so we can only accept comments on these where stakeholders feel that the meaning has changed.
RCGP	Full	General	General	Specialist guidelines – little or no reference to General Practice . Clear guidelines should be provide by specialist units on referrals for patients particularly if neutropenic sepsis is identified. (IR)	Thank you for your comment. The scope of this update was specifically about issues related to specialist hospital services. However we have added the following recommendation on page 64 to address your concerns: 'communication with primary

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					care about the care of the adult or young person is receiving, and their need for direct re-admission'. The NICE guideline on neutropenic sepsis (2014) provides clear guidance for patients identified with neutropenic sepsis in primary care.
RCGP	Full	General	General	Generally the document is secondary care focused and makes no significant reference to primary care other than in number of consultations in primary care before a patient with a haematological cancer has been referred and the communication back to the MDT. This document has disappointingly has not addressed primary care needs and the tools need to help GPs differentiate symptoms and signs. Palliative care should also be included as In other cancers outcomes have been improved by early involvement of palliative care.(MH)	Thank you for your comments. The scope of this update was specifically about issues related to specialist hospital services. Primary care was not within the scope of this update and therefore the evidence for managing patients in primary care was not reviewed. As a result no recommendations can be made. The tools needed to help GPs differentiate symptoms and signs of suspected cancer can be found in the NICE guideline on suspected cancer (2015). Palliative care was not included in the scope of this update therefore we are prohibited from making any recommendations in this area. However advice on supportive and palliative care for people with cancer can be found in the NICE guidance on Improving supportive and palliative care for adults with

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					cancer (2004).
RCGP	Full	General	General	GP need cancer decision support tools such as Qcancer, Risk assessment tools (RAT) as in Cancer Prediction in Exeter (CAPER) studies and other electronic cancer decision support tools such as MacMillan. (MH)	Thank you for your comment. The scope of this update was specifically about issues related to specialist hospital services. Decision tools needed to help GPs differentiate symptoms and signs of suspected cancer were not within the scope of this updated guidance.
RCGP	Full	20	3-7	Early diagnosis for haematological cancers present considerable challenges to present day General Practice. General practitioners will see patients every day with symptoms that could be attributable to cancer, but are only likely to see eight patients a year with a new cancer diagnosis. Similarly GPs are under considerable work pressures with a significant UK shortage of the primary workforce. In 2015 the Scottish Referral Guidelines Steering group produced a reference guide for GPs. and NICE published its updated guideline for England and Wales on Suspected cancer: recognition and referral . The suspicious symptoms and results highlighted for Gp to refer quickly and action may not may a significant impact on early diagnosis especially in the difficult condition of myeloma which appears to need several consultations before diagnosis. Gps and their staff need better tools to diagnosis suspected haematological cancers and research resources in primary care to	Thank you for your comments. The topics you refer to are outside of the scope of this update and therefore we have not been able to make any recommendations in these areas.

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				achieve this outcome. (MH)	
Royal Surrey County Hospital MDT	Short	9	6	We are concerned that the recommendation for provision of direct ward admission implies acutely ill haematology patients should come directly to the Haematology Ward. Our experience is that this can be unsafe and that patients are better off having an initial assessment in an acute assessment area where care needs can be assessed, resuscitation and medication started immediately (rather than waiting for a bed) and appropriate ward for patient's needs arranged. We agree elective admissions should be direct to the unit and that emergency admissions should be prioritised for swift transfer to the unit to access the haematology specialist staff/facilities.	Thank you for your comment. We have amended the recommendation on page 63 of the full guideline to account for the situation you describe. It now reads 'Ensure that there is provision for direct admission to the haematology ward or other facilities equipped to rapidly assess and manage potentially life-threatening complications of chemotherapy (such as neutropenic sepsis or bleeding), according to agreed local protocols.' We have also added supporting text to the LETR paragraph on page 68.
Royal Surrey County Hospital MDT	Short	12	24	We are concerned that this recommendation could be interpreted as suggesting that all patients with haematological malignancies should be cared for in a hospital setting as opposed to be seen and discharged back to primary care when appropriate eg: Stage A CLL, MGUS etc	Thank you for your comment. We have not updated recommendations shaded in grey and so we can only accept comments on these where stakeholders feel that the meaning has changed.
Royal Surrey County Hospital MDT	Short	13	12	We feel it important that referrals are directed at individual members of the MDT rather than to the MDT generically. This is important so that the referral is owned by an individual MDT member so the case is properly understood, making the consequent MDT discussion as useful as possible.	Thank you for your comment. We have not updated recommendations shaded in grey and so we can only accept comments on these where stakeholders feel that the meaning has changed. We do not think that the meaning of this recommendation will be misunderstood.

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Royal Surrey County Hospital MDT	Short	13	5	We are concerned that, as MDTs often work across several different trusts, making the MDT 'responsible' for treatments, delivery of treatment and support could make lines of responsibility blurred. We agree the MDT should oversee it and endeavour to make care equitable.	Thank you for your comment. We have not updated recommendations shaded in grey and so we can only accept comments on these where stakeholders feel that the meaning has changed. We do not think that the meaning of this recommendation will be misunderstood.
Royal College of Nursing	Full	General	General	Please note that there are no comments to submit on behalf of the Royal College of Nursing for the above draft guideline consultation. Thank you for the opportunity to comment.	Thank you.
Royal College of Paediatrics and Child Health	Full	General	General	We think that it would be very reasonable to comment that, given that the document states it should be read in conjunction with the CYP guidance, it should highlight in particular from that CYP guidance the points about discussion at TYA MDT at time of diagnosis (all new cases aged 16-24 inclusive) and about place-of-care age ranges (under 19s to TYA PTC for treatment; 19-24 informed choice).	Thank you for your comments. The section of the original guidance on MDTs was not included within the scope for updating and therefore cannot be changed. However these recommendations were retained in the updated guidance as they are still relevant to clinical practice and are thought to be fully implemented in many parts of the country.
Royal College of Paediatrics and Child Health	Full	General	General	In general the document does not acknowledge the fact that children are treated in Children's Hospitals through different pathways to adults. For lymphomas, many paediatric pathology centres report locally, but due to the previous IOG guidance,	Thank you for your comments. We recognise that there is scope for local variation in the way these services are commissioned across all age groups. However we believe the recommendations in this update will lead to improved services

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				have formed a link with local HODS, with cases sent on for a second opinion. Centres on the same site as HODS use the consultants for a second opinion which is logged in the report. Off-site HODS centres do not repeat immuno (many paediatric centres also members of Haematopath NEQAS scheme). Charge is thus as a second opinion, not a full HODS case. Turnaround is faster and all report attending the Paediatric Solid Tumour MDT, where paediatric lymphomas are discussed, because Paediatric Oncologists treat these children, not Haematologists. For leukaemias, local paediatric pathologists are reporting that local adult HODS do not have the panel specific for childhood leukaemias, they do not possess any expertise in these cases, their TAT was too long, they were not treating the patient, and they had no links to the labs performing MRD analysis (important for AML and ALL prorocols). Centres thus report no HODS links for leukaemia reporting.	through clearly defined organisational structures, pathways and quality management systems. Specifically, we believe that this will improve the quality of reporting of lymphoma, including distinction from solid tumours, and will be welcomed by paediatric oncologists. We agree that MRD is important in paediatric leukaemia but it is not unique and also has a growing importance irrespective of age group. We had already incorporated MRD analysis in our considerations of monitoring, but have clarified that other laboratories can be involved with the provision of specialised tests. We believe that this should address the issues in your comment.
Royal College of Surgeons	Full	General	General	We are unable to assist with this request.	Thank you for letting us know.
Sheffield Children's Hospital NHS Foundation Trust	Full	General	General	We were concerned to learn that there was a single paediatric representative on the committee who voiced significant concerns about the recommendation for co-ordination of paediatric haematology-oncology diagnostics by an SIHMDS. There is also an	Thank you for your comment. Paediatric expert input was not ignored. It was actively sought and a consensus reached in the guideline committee on what recommendations should be made.

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				acknowledgement in the guidance that no evidence exists to support the recommendation for paediatrics. Having ignored paediatric expert input, the only basis we can see for the recommendation is "what's good for adults (on the basis of limited and weak evidence) must be good for children".	
Sheffield Children's Hospital NHS Foundation Trust	Full	General	General	An alert about the consultation does not appear to have been sent to potential paediatric stakeholders. As far as we are aware, none of the following received such an alert: RCPCH, Childhood Cancer Leukaemia Group or specialist paediatric hospital trusts. We became aware of the consultation from an informal alert through our professional networks.	Thank you for your comment. All registered stakeholders would have been informed by NICE (via email) that the consultation version of the guideline was available for comment. Both the RCPCH and CCLG were registered stakeholders. It is not part of NICE process to send out alerts in advance of consultation. The timetable for the whole guideline development process, including the date of stakeholder consultation, has been available on the NICE website, since development of this guideline started. The consultation was extended to six weeks, instead of four weeks, to account for the consultation period occurring over Christmas.
Sheffield Children's Hospital NHS Foundation Trust	Full	37	17	It's unclear why NICE have decided to separate diagnostics for paediatric haematology-oncology from other childhood cancers and produce a recommendation that is in conflict with its Children and Young Person Cancer IOG(August 2005) which states: •Pathology and histopathology services for children	Thank you for your comments. A core principle of this guidance was to ensure that all patients whatever their age have access to high quality diagnostic services for haematological malignancies. This is likely to be delivered by laboratories that comply

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				should be provided in the long term only by paediatric pathologists and those with relevant specialist expertise. This is a matter of training, experience and governance. •Paediatric pathology should be concentrated at selected specialist paediatric surgical/oncological and tertiary referral maternity sites. •Paediatric pathology cannot be subsumed by general or other specialist pathologists without a further major reduction in both service and quality. •Haematologists are responsible for the morphological diagnosis of leukaemia and for the reporting of bone marrow aspirates and trephine biopsies from patients with solid tumours. The spectrum of leukaemia in childhood is different from that in adults, so diagnosis and the ongoing assessment of response to chemotherapy are best provided by a paediatric haematologist with specific expertise. Children are at greater risk of CNS involvement with leukaemia, which requires specialised input for the preparation and assessment of specimens.	with the generic standards and have sufficient throughput, quality assurance and economies of scale. We are aware of the recommendations in the CYP IOG (NICE, 2005) on specialist teams and feel that the most appropriate arrangements need to be agreed locally by commissioners. This guidance does not prevent there being a separate diagnostic paediatric service as long as these new recommendations are followed and implemented. Given the national variation in practice the recommendation for a SIHMDS could be either a combined service covering all age ranges; an adult only service; or a children only service. Ultimately, commissioning arrangements based on local service provision and economies of scale will be relevant. All the bullet points opposite that you have quoted are taken from the introductory section of the care pathway chapter on pages 31-32 of the CYP IOG (NICE, 2003) and are not recommendations. We believe that the recommendations we have made in this update are fully consistent with the recommendations made on page 33 and 34

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					of the CYP IOG (NICE, 2005). We have added a further recommendation about the involvement of age appropriate haematologists and (histo) pathologists on page 38 of the full guideline.
Sheffield Children's Hospital NHS Foundation Trust	Full	37	17	The CYP IOG recommendations were translated into diagnostic standards for all childhood cancers within the 2009 CYP childhood cancer peer review measures. The standards require that a specialist integrated report is agreed by a PTC diagnosis MDT which includes paediatric haematologists, paediatric histopathologists and laboratory geneticists. These recommendations have been implemented by childhood cancer PTCs in a variety of ways and no concerns about their effectiveness or reporting standards were raised during peer review inspections. Has there been a formal audit of the diagnostic accuracy of the reports produced by the PTC MDTS to raise concern? If not, would it not be better to audit the present arrangements and develop paediatric specific guidance covering all childhood cancers as an update to the 2005 CYP IOG?	Thank you for this information. It is anticipated that the existing cancer peer review measures will be updated in light of the recommendations presented in this updated NICE guidance. It is not the responsibility of NICE or the guideline developers to carry out formal audits of the diagnostic accuracy of the reports produced by the PTC MDTS to raise concern. A surveillance review conducted by NICE in November 2014 concluded that an update of the children and young people with cancer service guidance was not necessary at this time. Further information can be found at - https://www.nice.org.uk/Guidance/CSG7/Evidence.

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Sheffield Children's Hospital NHS Foundation Trust	Full	37	17	In practice, SIHMDSs whether co-located or networked will be adult focussed and led with a pre-dominantly adult repertoire and expertise. No paediatric competence or specialist input is specified for them within the guidance. The governance arrangements ensuring the diagnostic accuracy of reports produced by individual laboratories is reviewed during UKAS inspections and accreditation status provides some reassurance in that regard. Paediatric clinical competency is more important in integrating those reports into a specialist diagnosis and treatment management plan than an adult laboratory driven process. The latter will disrupt the current clinically driven process and de-skill paediatric haematologists thus increasing the risk of diagnostic errors. Furthermore, there is a risk of much longer turn-around times for producing an integrated report through an SIHMDS as it will add an extra node within the process.	Thank you for your comments. We have amended the recommendation on page 38 of the full guideline to ensure that age appropriate specialist haematological and haematopathological advice is available for diagnosis and authorisation of integrated reports. NICE is unable to specify a specific provider of services.
Sheffield Children's Hospital NHS Foundation Trust	Full	37	17	There are several precision medicine initiatives embedded within childhood leukaemia trials that require integration of reports from a variety of national reference and research laboratories to guide an individual patient's treatment. An SIHMDS will merely add to the complexity of the pathway resulting in diagnostic confusion and an impact on turn-around times.	Thank you for your comment. This issue is not unique to paediatric clinical trials. The recommendations in the update clearly define the necessary organisational structures and protocols and these should include the timely management of clinical trial samples. Use of a quality management system will mean that pathways for trial and non-trial samples will be frequently reviewed and updated appropriately according to changes in clinical practice.

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Sheffield Children's Hospital NHS Foundation Trust	Full	37	17	There will be significant impact on education and training of paediatric haematologists and histopathologists if the current paediatric centred and clinician led diagnostic pathway is replaced by an adult laboratory centred pathway.	Thank you for your comment. Depending upon the local service model adopted, we acknowledge that training arrangements may need to change. However it is not the responsibility of this guidance to consider the training implications and how these will be delivered.
Sheffield Teaching Hospitals NHS Foundation Trust	Full	21	29	The source of the data for the incidence tables is not clear	Thank you for your comment. We have added additional text on page 17 of the full guideline under 'Data sources'.
Sheffield Teaching Hospitals NHS Foundation Trust	Full	38	17	The statement that a business case should be in place for the adoption of new diagnostic and therapeutic technologies is inappropriate as this is not in line with how business planning processes work. Business plans are made as development needs arise and, in practice, are not standing documents, as inferred by this recommendation. What is more important is having a method for assessing needs of the service users and to use public money wisely (i.e. having a method to introduce relevant OPERATIONAL testing and not to feel under pressure to offer ASPIRATIONAL testing on the NHS when there is no proven clinical benefit. Such testing needs to be funded separately.	Thank you – we agree. Therefore we have modified the recommendation in light of your comments to read 'Assess the clinical benefit, and the financial and resource impact of new diagnostic and therapeutic technologies before introducing them'.
Sheffield Teaching	Full	38	17	It is not clear what is 'a recognised independent organisation' which needs to formally accredit a	NICE is unable to specify a specific provider of services.

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Hospitals NHS Foundation Trust				diagnostic service as a SIHMDS – this should be defined.	
Sheffield Teaching Hospitals NHS Foundation Trust	Full	38	17	There needs to be more clarification related to the SIHMDS director being responsible for the quality of diagnostic reporting and with SIHMDS being able to release individual reports before the integrated report is produced, if there is an urgent clinical need. Does this mean that the director is responsible for the quality of the integrated report, whilst individual reports may be released (authorised) by designated /delegated individuals?	Thank you for your comment. It is our view that the SIHMDS director is responsible for the overall quality of the management system (including the quality of diagnostic reporting and staff competencies). But the responsibility for the quality of individual reports rests with the healthcare professional signing them off. We believe our recommendations adequately cover this issue.
Sheffield Teaching Hospitals NHS Foundation Trust	Full	38-40		There is the statement that 'The GC agreed that the main benefits of a co-located diagnostic service included reduced turn-around times, improved diagnostic accuracy, reduced need for repeat sampling and control costs and such a service would therefore provide a viable and sustainable service and improved patient experience'. There is no available evidence to support this statement that criteria for a SIHMDS 'are most likely to be met if the component parts of the service are located at a single site'. It should be made clear that the recommendations around centralised services represent the professional opinion of the GC based upon untested assumptions, so that it is clear that this is a recommendation based on class C evidence.	Thank you for your comments. The evidence statements on page 29 make it clear that the overall quality of the evidence was low for all outcomes. In addition the economic modelling concluded that both the networked and co-located SIHMDS were likely to be more cost effective than local reporting. We believe that the sections on p39-41 summarising the quality of the available evidence (trade of between clinical benefits and harms and resource use) clearly describe the way in which the decisions were reached by the GC.
Sheffield	Full	74		The mention of 'copies of case notes' being available for	Thank you for your comment. We agree and

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Teaching Hospitals NHS Foundation Trust				the MDT is not applicable for trusts with electronic records. It would be better to mention 'relevant clinical details supplied by the responsible clinician'	have modified the recommendation on page 76 to say 'relevant clinical information'.
Sheffield Teaching Hospitals NHS Foundation Trust	Full	61 and 38		It is considered inappropriate that personal communications have been allowed such prominence in a document such as this, particularly where evidence based information has been used to good effect in other areas. Other NICE documents have definite statements that 'there is not sufficient published material to make a conclusion' etc. There is only one published document and even that has identified limitations. This NICE document does recognise the limitations and mention how its not possible to make direct comparisons, but follows with paragraphs of interpretation and gives a summary extrapolating from the costs mentioned in a personal communication which is not publicly available. Reference to, and use of, this personal communication should be removed.	Thank you for your comments. Information derived from personal communications was used to inform the health economic model in the absence of relevant published data. This is acceptable in NICE methodology and we have discussed the limitations of using unpublished data in the analysis. This information is publicly accessible by applying to NICE for access to the economic model, but the key data are in the full report.
Teenagers and Young Adults with Cancer (TYAC)	Full	General	General	We think that it would be very reasonable to comment that, given that the document states it should be read in conjunction with the CYP guidance, it should highlight in particular from that CYP guidance the points about discussion at TYA MDT at time of diagnosis (all new cases aged 16-24 inclusive) and about place-of-care age ranges (under 19s to TYA PTC for treatment; 19-24 informed choice).	Thank you for your comment. We agree, the NICE guidance on children and young people with cancer guidance (2005) is already cross referred to within the update and the guideline committee do not consider it appropriate to make more detailed cross references to this guidance.

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The Royal Marsden NHS Foundation Trust	Short	General	General	As managerial lead for RMH SIHMDS I have reviewed the sections relating primarily to the SIHMDS. The proposed updates to the guidelines provide more clarity and remove ambiguity, especially around the need to refer all specimens to a SIHMDS without any local diagnostic workup for diagnosis, disease assessment and suspected relapse or progression. We were wondering whether this will be audited as part of any peer review	Thank you. Thank you for this information. It is anticipated that the existing cancer peer review measures will be updated in light of the recommendations presented in this updated NICE guidance.
The Royal Marsden NHS Foundation Trust	Short	General	General	Apart from the items detailed above there is nothing that will result in any major issues for our current SIHMDS	Thank you.
The Royal Marsden NHS Foundation Trust	Short	7	11	We feel that the clear directive that SIHMDS should be responsible for specimens that are sent to external labs is helpful. We have been considering whether to implement this for a while now as we feel that it is important to integrate ALL results relevant to a suspected diagnosis into the integrated report. However, given that this was not part of the previous guidelines we didn't have this driver to feed into a business case to obtain administrative resource to implement this. This clear directive will help us to implement this. It will also help us to persuade referrers to engage with this practice	Thank you for your comment.
The Royal Marsden NHS Foundation	Short	36		Amended section: at each meeting, 'the MDT should ensure that all new diagnoses have had SIHMDS review and integrated reporting'; we were wondering how this would be audited and how the MDT discussion and the	Thank you for your comments. The issues you raise will be a matter for implementation of the guideline. The GC did not recommend a turnaround time for an integrated report

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Trust				availability of the integrated report would be synchronised given that some tests within SIHMDS have an extended turnaround time. The Turnaround time for an integrated report has not been suggested within the guidelines, just that clinically urgent results should be available before the integrated report is produced which is what we do and is important	because there was no evidence, and because of the variability of diagnostic workup between different diseases.
University Hospital Birmingham NHS Foundation trust	Full	37	17	In 'Recommendations', we were concerned that there was no recommendation on a minimum population size required for an SIHMDS. Whilst we appreciate the scantiness of evidence in this area, with the previous recommendation of 2 million now no longer be reiterated, there is the potential for disruption to service development and planning when population size is no longer a factor. We also note that there were no such reservations in a recommendation on centre size (p61 line 7 'Recommendations') despite there also being no quoted evidence to support this recommendation.	Thank you for your comments. The figure of 2 million was first recommended in the following publication 'Additional Best Practice Commissioning Guidance for Developing Haematology Diagnostic Services' published by The National Cancer Action Team and the Royal College of Pathologists in 2012 and was therefore not included in the original NICE haematological cancers IOG (2003). Although no evidence was identified, the GC agreed that a recommendation on centre size was important. The induction death rate from the use of intensive chemotherapy regimens exceeds those of high-dose therapy with autologous stem cell support for which the JACIE standards stipulate centres should manage a minimum of 10 new patients a year. In addition the GC considered that there were potential benefits from care in a larger centre including better

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					access to clinical trials, the ability to audit outcomes, increased patient confidence, and better access to resources and expertise including the use of dedicated isolation facilities.
University Hospital Birmingham NHS Foundation trust	Full	70	7	In 'Recommendations' we are concerned that 'some medical oncologists' is seen as equivalent to Haemato-Oncologists; in 2016, we would expect that the vastly different specialist training required for clinical Haematology reflects the different diagnostic and therapeutic skills required for the management of Haemato-Oncology patients. We would therefore not regard 'some medical oncologists' as equivalent.	Thank you for your comment. We have not updated recommendations shaded in grey and so we can only accept comments on these where stakeholders feel that the meaning has changed. For this recommendation the GC does not consider that the meaning has been changed by these edits.
University Hospital Birmingham NHS Foundation trust	Full	70	7	In 'Recommendations', it is not clear why a clinical oncologist is mandatory for lymphoma patient discussions, but not for myeloma patient discussions.	Thank you for your comment. This recommendation for clinical oncology input into the lymphoma MDT from the original Haem IOG (2003) is unchanged in this update.