Sarcoma – 2nd consultation − Stakeholder comments

9 September 2005 – 7 October 2005

National Institute for Health and Clinical Excellence

Stakeholders	Document	Section number Or General	Comments	Developer's response
Addenbrooke's NHS Trust			This organisation was approached but did not respond.	
Anglesey Local Health Board			This organisation was approached but did not respond.	
Association for Palliative Medicine of Great Britain and Ireland			This organisation was approached but did not respond.	
Association of Hospice and Specialist Palliative Care Social Workers			This organisation was approached but did not respond.	
Association of Surgeons of Great Britain and Ireland			This organisation was approached but did not respond.	
Association of the British Pharmaceuticals Industry (ABPI)			This organisation was approached but did not respond.	
Association of Upper GI Surgeons of Great Britain and Ireland			This organisation was approached but did not respond.	
Bard Limited			This organisation was approached but did not respond.	
Bath and North East Somerset PCT			This organisation was approached but did not respond.	
Baxter Oncology			This organisation was approached but did not respond.	
Bedfordshire and Hertfordshire NHS Strategic Health Authority			This organisation was approached but did not respond.	
BNMS	Manual	General	The document states that a minimum of 100 new cases should be seen by a soft tissue sarcoma unit.	This issue was addressed extensively by the guideline development group (GDG) following stakeholder

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			No evidence appears to have been produced to support this statement why is 50 patients not a suitable number? This appears to be a number plucked out of the air since the referenced papers seem to show that smaller numbers are managed appropriately. This smacks of a political agenda by a factional group	comments received during the first consultation. The GDG considered at length the optimum number of patients that a sarcoma treatment centre should manage per year. We believe that a patient's care is best managed by a sarcoma MDT ***[spell out*** multidisciplinary team***?]***, and that MDT must be of sufficient size and have sufficient members to be able to work effectively and have in-depth experience. We do not believe that a properly constituted sarcoma MDT is likely to be viable unless it treats the number of patients we have identified in the guidance. We feel that the numbers we have suggested are realistic. For a centre treating both bone and soft tissue sarcomas, the requirement for them to treat on average one new patient with bone sarcoma per week is not unrealistic, given the huge variety of bone sarcomas that exist. If a centre were treating fewer than 50 cases per year, it is unlikely that the surgical team, the pathologist or the back-up team would have sufficient expertise to give those patients optimum treatment. We feel that the same argument applies for soft tissue sarcomas, which is why we have stipulated a figure of 100 new cases per year, which correlates with a population base of approximately 3–4 million.
BNMS	Manual	General	There does not appear to be any mention of nuclear medicine imaging other than PET in GIST tumours – is this an omission? or review of the data suggests there is no contribution to soft tissue and bone	We agree that the role of PET (positron emission tomography) in primary imaging, staging and follow-up of sarcomas remains to be resolved. Our review of the evidence base found no conclusive documentation for

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			sarcoma evaluation – this needs to be stated.	the role of PET apart from in assessing response in GIST.
BNMS	Manual	General	A comment on the role of PET in assessment of response or research required in bone sarcomas should be inserted	We agree that the role of PET in primary imaging, staging and follow-up of sarcomas remains to be resolved. Our review of the evidence base found no conclusive documentation for the role of PET apart from in assessing response in GIST.
Boehringer Ingelheim Ltd			This organisation was approached but did not respond.	
Brighton & Sussex University Hospitals Trust			This organisation was approached but did not respond.	
British Association for Counselling and Psychotherapy	Manual	96	Whilst we appreciate that nice considers it has covers the issue of psychosocial interventions and counselling by cross referencing the NICE guidance on *Improving Supportive & Palliative Care for Adults with Cancer* in paragraph 77 (previously paragraph 73), we still believe that mention of psychological support should be included in Table 4: The Information Pathway.	Thank you for your comments, but we do not feel this fits particularly well into table 4.
British Association for Counselling and Psychotherapy	Manual	Appendix 5	The Glossary needs to include the term 'psychological therapy' or 'psychological support'. We would suggest the following: 'Professional support which can help people with a wide range of psychological problems such as anxiety and depression, and can provide emotional assistance during times of distress'	We will include a definition of psychological support in the glossary.
British Association for Counselling and Psychotherapy	Manual	Appendix 5	The Glossary also needs to include the term 'counselling'.	We will insert a definition of counselling in the glossary.

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			The glossary within the *NICE Clinical Guideline CG23 for Depression (2004)*, defines counselling as: 'A time-limited psychological intervention (regular planned meetings of usually 50 minutes or 1 hour in length). The intervention may have a facilitative approach, often with a strong focus on the therapeutic relationship, but may also be structured and at times directive.' In addition, the Department of Health's publication *Evidence Based Clinical Practice Guideline: Treatment Choice in Psychological Therapies and Counselling (2001)* uses the definition: 'The British Association for Counselling and Psychotherapy defines counselling as a systematic process which gives individuals an opportunity to explore, discover and clarify ways of living more resourcefully, with a greater sense of well being. Counselling may be concerned with addressing and resolving specific problems, making decisions, coping with crises, working through conflict, or improving relationships with others.'	
British Association for Dermatological Surgery			This organisation was approached but did not respond.	
British Association of Art Therapists			This organisation was approached but did not respond.	
British Association of Head and Neck Oncologists			This organisation was approached but did not respond.	
British Association of Oral and Maxillofacial Surgeons			This organisation was approached but did not respond.	
British Association of			This organisation was approached but did not	

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Otolaryngologists, Head and Neck Surgeons			respond.	
British Association of Plastic Surgeons			This organisation was approached but did not respond.	
British Bone & Soft Tissue Tumour Panel	Manual	General	Most of the guidance seems logical and reasonably well thought out. I do not agree, however, on the option of a diagnostic sub-centre serving a treatment centre. Those of us working in a treatment centre know how intimately involved we are in each case in terms of diagnosis and management at every stage. Any case sent on from a diagnostic centre is always going to need full review anyway thus delaying the diagnostic process. The individuals in such a position would be de-motivated and demoralised and would in effect be just triaging the cases. The pathologist calling the shots HAS to be involved at the MDT and management stages in every case.	We have thought through the proposed structure of diagnostic clinics and sarcoma treatment centres very carefully. We accept that there may be problems in running diagnostic clinics, but the likely advantages in terms of earlier diagnosis seem to outweigh the disadvantages at the present time.
British Bone & Soft Tissue Tumour Panel	Manual	General	Basically, I support this document and its aims. The definition of an SSP is a difficult one - I do not personally see how the CPA accreditation status of one's lab is in any way relevant to one's competence as a sarcoma pathologist. As well as participation in the EQA, I would also advocate active participation in the Panel as a criterion. It is also not clear to me whether an SSP must be a member of a functioning sarcoma MDT - surely this should be the case. My main problem is with the numerical thresholds. We will probably just about make the 100 case threshold by scrabbling around for GISTs, cutaneous sarcomas etc. But, supposing we only have 90 cases a year - should a fully-staffed and fully-functional MDT be	Laboratory accreditation enrolment is mandatory (Department of Health (DH), England and Wales) and it is usually CPA. Accreditation of a laboratory ensures that there is active audit of the service and that all work undertaken is of a certain standard. Wrong immunohistochemistry or a mix-up in specimens can result in wrong diagnoses and therefore wrong treatment. Laboratory accreditation is one of the cancer standards for all cancer networks. We feel the guidance makes clear what the criteria are for recognition of an SSP and that this would form the basis of a peer review standard at a future date. The guidance also makes clear in paras 211 and 212 that an

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			kicked into touch for the sake of 10 cases per year? I would therefore recommend that the Panel challenges the potential reduction in the number of SSPs that is likely to occur if the effect of these guidelines is to close down some of the smaller centres.	SSP should be part of a functioning sarcoma MDT. The main aim of this guidance is to ensure that we have properly constituted MDTs. They will need to do an appropriate amount of work to justify their existence.
British Bone & Soft Tissue Tumour Panel	Manual	General	This guidance will be helpful to commissioners, although it would be helpful if the scope of the guidance (range of tumours) as listed in Appendix 1, section 4.1.1, were also to be provided in the main text of the manual. A major omission is the complete absence of evidence to justify the inclusion of borderline tumours and those of uncertain behaviour in the guidance for sarcomas. If the guidance is intended to cover these other tumours, some indication of the incidence would be helpful to gauge the likely workload.	Thank you for your comments, but we do not feel that it would be useful to have a complete list of tumours covered by this guidance in the main text of the Manual. The decision to include borderline tumours in this guidance was made at a very early stage and was published in the Scope, which was circulated widely for consultation. The particular challenges posed by borderline tumours mean that they should ideally be treated by the sarcoma MDT, both for accurate diagnosis and for appropriate treatment. The incidence figures we have at the moment will include borderline tumours, giant cell tumour of bone, fibromatosis, etc.
British Bone & Soft Tissue Tumour Panel	Manual	General	The guidance highlights the benefits to patients. This could be emphasised as trying to ensure that wherever a patient presents, they are diagnosed and treated to a consistently high standard.	Thank you. We agree.
British Bone & Soft Tissue Tumour Panel	Manual	142	The guidance highlights the creation of designated diagnostic centres and diagnosis and treatment centres. In some circumstances, particularly to make the best use of skilled health care professionals who may not wish to work in the major centres, it might be	This guidance recommends that diagnosis and surgery should be carried out at a sarcoma treatment centre by the MDT, but that chemotherapy and radiotherapy may be carried out at local centres by nominated oncologists. It is not envisaged that surgery of sarcomas would be

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			useful to consider an intermediate option of delegated treatment options to diagnostic centres where staff meet the appropriate standards. This would reduce the substantial increase in workload that would otherwise fall on the main D+T centres, and should speed implementation of this guidance.	carried out at diagnostic clinics as this would be outside the remit of the MDT.
British Bone & Soft Tissue Tumour Panel	Manual	153	While we agree in principle that rapid referral for osteosarcoma and Ewing's sarcoma in children is often possible on the basis of simple imaging studies, it may well be possible for diagnostic clinics to undertake the imaging and biopsy (according to protocols) of many adult bone sarcomas (and of borderline and other tumours).	The evidence currently available indicates that the best outcomes are achieved when biopsies of patients with bone sarcomas are carried out at bone tumour treatment centres.
British Bone & Soft Tissue Tumour Panel	Manual	211 + 247	In these paragraphs, "All malignant bone tumours" should be replaced by "All primary malignant bone tumours" for clarity	These amendments have been made to the text.
British Bone & Soft Tissue Tumour Panel	Manual	216 + 217	These paragraphs refer to The Royal College datasets – these are no longer referred to as 'minimum' datasets. 'Histopathology datasets' would be preferable.	This amendment has been made to the text.
British Bone & Soft Tissue Tumour Panel	Manual	217	In this paragraph, the text should be corrected to indicate that The Royal College of Pathologists commissions the writing of datasets. The dataset for soft tissue sarcomas is being written (as acknowledged in para. 216), so this paragraph should presumably indicate that the College should commission the writing of a dataset on bone sarcomas.	We feel that this paragraph is clear as it stands.
British Bone & Soft Tissue Tumour Panel	Manual	218	This paragraph should be changed to read '…at least conditional accreditation for the laboratory…'	We were informed by the DH that conditional accreditation is not the correct terminology and were advised to use 'conditional approval'.

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British Bone & Soft Tissue Tumour Panel	Manual	229	While we agree in principle that the storage of tissue for future research is essential, a single national tissue bank for sarcomas may not be the best way to make progress due to practical difficulties. Each treatment centre should have its own tissue bank and be willing in principle to share material with other centres for ethically-approved research.	We do not feel that para 229 implies that there should be a single national tissue bank in one place (see para 224).
British Bone & Soft Tissue Tumour Panel	Manual	305	While we agree in principle that limb sparing surgery for osteosarcoma and Ewing's sarcoma in children should be performed at designated sarcoma treatment centres, it may well be possible for other centres to treat adult sarcomas (if requiring amputation, for example), as well as borderline and other tumours according to agree protocols after MDT discussion, provided that appropriate staff are in place.	The evidence currently available indicates that the best outcomes are achieved when biopsies of patients with bone sarcomas are carried out at bone tumour treatment centres.
British Bone & Soft Tissue Tumour Panel	Manual	334	This paragraph should include head and neck in the list of more common STS.	Head and neck sarcomas are included under 'sarcomas requiring shared management'. These are dealt with in more detail in paras 384 and 386.
British Bone & Soft Tissue Tumour Panel	Manual	387	This paragraph should include the work of thoracic surgeons in resecting intrapulmonary metastases from sarcomas at other sites – this work will need to be covered by commissioners.	The text has been amended to include pulmonary metastases.
British Bone & Soft Tissue Tumour Panel	Manual	525	This paragraph should be rephrased, as EQA schemes are not usually considered to be audit; they are a means of professional development. Also, networks should ensure that all sarcomas are reviewed by a pathologist participating in an EQA scheme (this could be the bone and soft tissue EQA or the gastrointestinal EQA). Most histopathologists should be capable of writing a preliminary diagnostic report on a sarcoma and it is unrealistic and unhelpful	Thank you for your comments. We feel that audit of the work of SSPs and nominated pathologists is already covered in para 219. We also believe that paras 212 and 215 clarify that any histopathologist **is** able to write a preliminary report but that all sarcomas should be reviewed by an SSP. Para 525 has been amended to clarify that 'SSPs

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			to suggest that reports can only be written by EQA-participating pathologists. The review for accuracy and consistency of diagnosis is what should be emphasised.	should undertake the existing EQA scheme'.
British Bone & Soft Tissue Tumour Panel	Manual	554	This paragraph is meaningless. The EQA schemes do not assess the pathology department's performance. They are means for professional development of individual pathologists. Other mechanisms should be put in place to collect pathology data (the completeness of these data could then be audited).	Para 554 has been amended.
British Bone & Soft Tissue Tumour Panel	Manual	General	I believe that the definition of a sarcoma specialist pathologist needs to be tightened. A mere interest in sarcomas is meaningless if you are not regularly reporting these tumours. Participating in an EQA scheme is helpful and shows good intention but surely a sarcoma pathologist needs to be regularly reporting sarcomas. I would therefore add a third criterion for sarcoma specialist pathologists :- 3) *To regularly attend and actively report cases discussed at a CPC or MDT*	The definition of an SSP was amended during the last consultation to include being a member of a sarcoma MDT (see paras 211 and 212).
British National Formulary (BNF)			This organisation was approached but did not respond.	
British Oncology Pharmacy Association			This organisation was approached but did not respond.	
British Orthopaedic Association			This organisation was approached but did not respond.	
British Psychological Society, The			This organisation was approached but did not respond.	

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British Psychosocial Oncology Society			This organisation was approached but did not respond.	
British Society for Dermatopathology	Manual	214/215	If the case has been initially reported or reviewed by a SSP-soft tissue, it is unclear whether the mandatory review in these paragraphs should be by a second different SSP-soft tissue or the original SSP-soft tissue. This requires clarification in both paragraphs.	Thank you for pointing out the slight lack of clarity in these two paragraphs. This issue has now been resolved. We do not recommend there should be dual reporting and one SSP-soft tissue reporting on a malignant tumour is sufficient in the vast majority of cases.
British Society of Paediatric Radiology			This organisation was approached but did not respond.	
British Society of Skeletal Radiology			This organisation was approached but did not respond.	
BUPA			This organisation was approached but did not respond.	
Cancer and Leukaemia in Childhood (UK)			This organisation was approached but did not respond.	
Cancer Research UK			This organisation was approached but did not respond.	
Cancer Services Collaborative 'Improvement Partnership' (CSCIP)			This organisation was approached but did not respond.	
Cancer Services Coordinating Group			This organisation was approached but did not respond.	
Cancer Voices			This organisation was approached but did not respond.	
CancerBACUP			This organisation was approached but did not respond.	
Chartered Society of Physiotherapy	Manual	262	The CSP feels that a specialist sarcoma physiotherapist is an important member of the Core Sarcoma MDT, particularly in large, complex cancer units where the physio will be present with the patient	The GDG does not underestimate the very important role that physiotherapists have to play in managing patients with sarcoma. In some units a physiotherapist will be a key worker, and will thus be a core member of

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			at all stages of their journey and thus very much a core member of the team. In addition the key worker could also be a physiotherapist (or any other professional) and the wording of this paragraph needs to be changed to reflect this. The CSP is most gravely disappointed that NICE has chosen to ignore our recommendation that was submitted in the first consultation. The role of a specialist physiotherapist can be central in the management of such patients. The view of NICE that we are not key member of the MDT appears to reflect a lack of understanding of the breadth and depth of the abilities of specialist physiotherapists by NICE rather than a reasoned argument as to why they should not be there. The CSP vigorously asserts its opinion that physiotherapists SHOULD be a key member of the core MDT	the MDT. In many other units the physiotherapist will be an invaluable member of the extended MDT, and their attendance at MDT meetings would not be necessary for all patients. We would also like to stress that the distinction between 'core' and 'extended' MDT members is not made on the basis of how 'key' their role is in the management of patients, but on the basis of how often they will be required to attend MDT meetings. The GDG felt that attending weekly, and sometimes lengthy, MDT meetings would not always be a sensible use of physiotherapists' important clinical skills unless they were involved with the care of specific patients, and therefore listed them as extended MDT members.
Chartered Society of Physiotherapy	Manual	263	It is good to see that a specialist sarcoma physiotherapist is a member of the extended MDT but they should also play a key role in the core MDT where treatment decisions are made for the reasons given above. NICE's view that physiotherapists are unlikely to play a key role in the core MDT is at best misguided, so please take this opportunity to be guided by the national body representing physiotherapists who practice daily in his area and who are in the best position to advise as to whether or not they have a role in the core MDT.	The GDG does not underestimate the very important role that physiotherapists have to play in managing patients with sarcoma. In some units a physiotherapist will be a key worker, and will thus be a core member of the MDT. In many other units the physiotherapist will be an invaluable extended team member, and their attendance at the MDT would not be necessary for all patients. We would also like to stress that the distinction between 'core' and 'extended' MDT members is not made on the basis of how 'key' their role is in the management of patients, but on the basis of how often they will be required to attend MDT meetings. The GDG felt that

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				attending weekly, and sometimes lengthy, MDT meetings would not always be a sensible use of physiotherapists' important clinical skills unless they were involved with the care of specific patients, and therefore listed them as extended MDT members.
Chartered Society of Physiotherapy	Manual	420	The CSP strongly feels that the key worker could equally be a specialist physiotherapist rather than a nurse. We would like to see the wording in brackets changed to say 'specialist nurse or other clinical specialist such as a physiotherapist'. The feedback from NICE was that in most cases a nurse would take on this role; thus the wording reflects only the prevailing conditions. The CSP feels this is erroneous in that it may lead centres to assume that only a nurse can fulfil the role. NICE indeed acknowledges that the role could be performed by an allied health professional, and thus the CSP AGAIN requests that the wording of this paragraph is changed to reflect this possibility in a future date. We would hope that the reluctant to change the wording is not as a result of the fact that the key worker must be a member of the core MDT and at present NICE idoes not feel thsatphysios have a plca eint he core MDT>	We have amended para 420 to 'Key workers are individuals (usually a specialist nurse or allied health professional)'.
Chartered Society of Physiotherapy	Manual	433	The CSP is unsure as to why clinical nurse specialists are specifically mentioned under the heading of physiotherapy and rehabilitation. Nursing and physiotherapy are completely different professions and it is unlikely that any specialist nurse would have the depth and breadth of understanding of physiotherapy and rehabilitation to provide better solutions to issues than a physiotherapist could. We	We have changed 'clinical nurse specialists' to 'AHPs'.

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			understand the sentiment of this paragraph but suggest it is moved to a chapter focussing on the role of nursing or key working to avoid confusion, which we hope is unintended, that may suggest that the roles of specialist nursing and physiotherapy are in any way interchangeable.	
Children's and Adolescent Cancer Partnership (CACP)			This organisation was approached but did not respond.	
Chugai Pharma UK Ltd			This organisation was approached but did not respond.	
College of Occupational Therapists	Manual	General	The College thanks the NCC for their consideration of comments submitted at the previous consultation stage. However, there are a few points that we feel still require clarification.	Thank you.
College of Occupational Therapists	Manual	437 and 449	In order for the best outcomes to be achieved regarding quality of life and function as detailed as being key outcomes of Supportive and Palliative Care, a specialist Occupational Therapist needs to be involved.	We have emphasised earlier in the guidance the importance of occupational therapists as members of the extended MDT. Para 437 covers anticipated benefits and para 449 is a review of the available evidence.
College of Occupational Therapists	Manual	263	At present Table 6 reads as if a specialist physiotherapist is necessary and some of the other 'AHP's (of which OT are included) may also be required. Specialist Physiotherapists and Occupational Therapists (both AHP's) should form part of the extended (if not core) MDT if best rehabilitation outcomes are to be achieved.	We accept the extremely valuable role that occupational therapists and other allied health professionals have in improving outcomes for patients with sarcomas. The skills of an occupational therapist are, however, generic and not specific to sarcoma patients.
College of Occupational Therapists	Manual	430 and 434	There is the potential for the importance of the role of occupational therapy being overlooked in service	We have modified paras 430 and 434 to include other allied health professionals.

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			planning as paragraphs 430 and 434 (which discusses the rehabilitation team) only names the physiotherapist and does not mention the occupational therapist. We would suggest that these paragraphs would benefit from being amended, especially given that the presence of the Specialist Occupational Therapist is listed in paragraph 443.	
Coloplast Limited			This organisation was approached but did not respond.	
Countess of Chester Hospital NHS Foundation Trust			This organisation was approached but did not respond.	
Department of Health	Manual	Paragraphs 6 & 257	Thank you for the opportunity to comment on the consultation document for the above guideline. The Department of Health has the following specific comments on paragraphs 6 & 257 of the document. *Paragraphs 6 & 257* We are grateful for the explanation of the thinking behind the requirement for minimum volumes for the MDT and we do not dispute the need for considerable expertise in the management of bone sarcoma. However, the choice of 50 new cases per annum as the minimum requirement is evidently somewhat arbitrary and this particular choice of cut-off has significant implications for the current pattern of NHS services. We are also led to believe that a number of	The decision to make a requirement of 50 new cases per annum for primary malignant bone tumours was based on consensus. It was a pragmatic decision on the basis that an MDT treating bone sarcomas will need considerable expertise and it was felt that seeing anything less than an average of one case per week would not justify the existence of a bone sarcoma MDT. We are not aware of any comparative studies looking at outcomes between centres in the UK, Germany, the Netherlands and Scandinavia, but we feel that the infrastructure required by the MDT would be difficult to sustain if only 30 cases per year were treated. We are aware that there are some examples currently in existence of two surgical teams being based at different sites but being members of a single MDT. We would have some reservations about the relative expertise of

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			Germany, the Netherlands and Scandinavia have volumes of about 30 new cases per annum but achieve outcomes as good as those in the UK. We would therefore be grateful for specific comment on a threshold of 30 new cases per annum of bone sarcoma (rather than 50 as currently recommended). We would also be grateful if the recommendations could tease out whether the key requirement is for the MDT to consider this number of cases: can two surgical teams, based at different sites, be members of a single MDT?	these two teams. If one team is treating a disproportionately low number of cases, they might not be retaining sufficient expertise. Ideally, the two surgical teams would work as one, with crossover of surgeons between institutions as and when required, so that expertise was retained by all. All of the surgical members of the sarcoma MDT should be meeting the criteria as laid out in table 5, i.e. having at least 5 PAs dedicated to managing sarcomas.
Eisai Limited			This organisation was approached but did not respond.	
Faculty of Public Health			This organisation was approached but did not respond.	
Guerbet Laboratories Ltd			This organisation was approached but did not respond.	
Healthcare Commission			This organisation was approached but did not respond.	
Help Adolescents with Cancer			This organisation was approached but did not respond.	
Hinckley & Bosworth Primary Care Trust			This organisation was approached but did not respond.	
Hull and East Yorkshire NHS Trust			This organisation was approached but did not respond.	
Institute of Biomedical Science			This organisation was approached but did not respond.	
Intra-Tech Health Care Ltd			This organisation was approached but did not	

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Joint Committee on Palliative Medicine			This organisation was approached but did not respond.	
Leeds Teaching Hospitals NHS Trust			This organisation was approached but did not respond.	
Limbless Association			This organisation was approached but did not respond.	
Macmillan Cancer Relief			This organisation was approached but did not respond.	
Marie Curie Cancer Care			This organisation was approached but did not respond.	
Medical Research Council Clinical Trials Unit			This organisation was approached but did not respond.	
Medicines and Healthcare products Regulatory Agency (MHRA)			This organisation was approached but did not respond.	
Middlesbrough Primary Care Trust			This organisation was approached but did not respond.	
National Alliance of Childhood Cancer Parent Organisations			This organisation was approached but did not respond.	
National Cancer Alliance			This organisation was approached but did not respond.	
National Cancer Network Clinical Directors Group (Merseyside and Cheshire)	Manual	General	This guidance will be helpful to commissioners, although it would be helpful if the scope of the guidance (range of tumours) as listed in Appendix 1, section 4.1.1, were also to be provided in the main text of the manual. A major omission is the complete absence of evidence to justify the inclusion of borderline tumours and those of uncertain behaviour in the guidance for sarcomas. If the guidance is	Thank you for your comments, but we do not feel that it would be useful to have a complete list of tumours covered by this guidance in the main text of the Manual. The decision to include borderline tumours in this guidance was made at a very early stage and was published in the scope, which was circulated widely for consultation. The particular challenges posed by

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			intended to cover these other tumours, some indication of the incidence would be helpful to gauge the likely workload.	borderline tumours mean that they should ideally be treated by the sarcoma MDT, both for accurate diagnosis and for appropriate treatment. The incidence figures we have at the moment will include borderline tumours, giant cell tumour of bone, fibromatosis, etc.
National Cancer Network Clinical Directors Group (Merseyside and Cheshire)	Manual	General	The guidance highlights the benefits to patients. This could be emphasised as trying to ensure that wherever a patient presents, they are diagnosed and treated to a consistently high standard.	Thank you. We agree.
National Cancer Network Clinical Directors Group (Merseyside and Cheshire)	Manual	142	The guidance highlights the creation of designated diagnostic centres and diagnosis and treatment centres. In some circumstances, particularly to make the best use of skilled health care professionals who may not wish to work in the major centres, it might be useful to consider an intermediate option of delegated treatment options to diagnostic centres where staff meet the appropriate standards. This would reduce the substantial increase in workload that would otherwise fall on the main D+T centres, and should speed implementation of this guidance.	This guidance recommends that diagnosis and surgery should be carried out at a sarcoma treatment centre by the MDT, but that chemotherapy and radiotherapy may be carried out at local centres by nominated oncologists. It is not envisaged that surgery of sarcomas would be carried out at diagnostic clinics as this would be outside the remit of the MDT.
National Cancer Network Clinical Directors Group (Merseyside and Cheshire)	Manual	153	While we agree in principle that rapid referral for osteosarcoma and Ewing's sarcoma in children is often possible on the basis of simple imaging studies, it may well be possible for diagnostic clinics to undertake the imaging and biopsy (according to protocols) of many adult bone sarcomas (and of borderline and other tumours).	The evidence currently available indicates that the best outcomes are achieved when biopsies of patients with bone sarcomas are carried out at bone tumour treatment centres.
National Cancer Network Clinical Directors Group	Manual	211 + 247	In these paragraphs, "All malignant bone tumours" should be replaced by "All primary malignant bone	These amendments have been made to the text.

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(Merseyside and Cheshire)			tumours" for clarity	
National Cancer Network Clinical Directors Group (Merseyside and Cheshire)	Manual	216 + 217	These paragraphs refer to The Royal College datasets – these are no longer referred to as 'minimum' datasets. 'Histopathology datasets' would be preferable.	This amendment has been made to the text.
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National Cancer Network Clinical Directors Group (Merseyside and Cheshire)	Manual	305	While we agree in principle that limb sparing surgery for osteosarcoma and Ewing's sarcoma in children should be performed at designated sarcoma treatment centres, it may well be possible for other centres to treat adult sarcomas (if requiring amputation, for example), as well as borderline and other tumours according to agree protocols after MDT discussion, provided that appropriate staff are in place.	The evidence currently available indicates that the best outcomes are achieved when biopsies of patients with bone sarcomas are carried out at bone tumour treatment centres.

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National Cancer Network Clinical Directors Group (Merseyside and Cheshire)	Manual	334	This paragraph should include head and neck in the list of more common STS.	Head and neck sarcomas are included under 'sarcomas requiring shared management'. These are dealt with in more detail in paras 384 and 386.
National Cancer Network Clinical Directors Group (Merseyside and Cheshire)	Manual	387	This paragraph should include the work of thoracic surgeons in resecting intrapulmonary metastases from sarcomas at other sites – this work will need to be covered by commissioners.	The text has been amended to include pulmonary metastases.
National Cancer Network Clinical Directors Group (Merseyside and Cheshire)	Manual	525	This paragraph should be rephrased, as EQA schemes are not usually considered to be audit; they are a means of professional development. Also, networks should ensure that all sarcomas are reviewed by a pathologist participating in an EQA scheme (this could be the bone and soft tissue EQA or the gastrointestinal EQA). Most histopathologists should be capable of writing a preliminary diagnostic report on a sarcoma and it is unrealistic and unhelpful to suggest that reports can only be written by EQA-participating pathologists. The review for accuracy and consistency of diagnosis is what should be emphasised.	Thank you for your comments. We feel that audit of the work of SSPs and nominated pathologists is already covered in para 219. We also believe that paras 212 and 215 clarify that any histopathologist **is** able to write a preliminary report, but that all sarcomas should be reviewed by an SSP. Para 525 has been amended to clarify that 'SSPs should undertake the existing EQA scheme'.
National Cancer Network Clinical Directors Group (Merseyside and Cheshire)	Manual	554	This paragraph is meaningless. The EQA schemes do not assess the pathology department's performance. They are means for professional development of individual pathologists. Other mechanisms should be put in place to collect pathology data (the completeness of these data could then be audited).	Para 554 has been amended.
National Cancer Research Institute – Sarcoma Clinical Studies Group	Manual	General	TheGDG have made clear recommendations on restructuring the service for sarcoma management. If fully implemented this will be of major benefit to sarcoma patients.	Thank you.
National Cancer Research	Manual	General,	There is repeated reference to treatment DECISIONS	Thank you for your comment. We have amended the

Stakeholders	Document	Section number Or General	Comments	Developer's response
Institute – Sarcoma Clinical Studies Group		table 4, 215, 338	made my MDTs. This is incorrect. MDTs can only make treatment RECOMMENDATIONS. These are OFFERED to the patient, along with discussion of the alternatives. A treatment decision is made by the patient.	text accordingly.
National Cancer Research Institute – Sarcoma Clinical Studies Group	Manual	72, key points	The statement that "most bone tumours occur in children and young people" contradicts figure 2. The incidence of bone tumours is higher in young people, but more tumours occur in the over 40s.	We have amended the text to 'The peak incidence for bone tumours…'.
National Cancer Research Institute – Sarcoma Clinical Studies Group	Manual	80	"MOST patients wish to receive the best possible treatment… and will cope with the travel issues as a secondary issue. "	We have made this amendment to the text.
National Cancer Research Institute – Sarcoma Clinical Studies Group	Manual	90	When there is a SPECIFIC AGREEMENT with a patient to provide confirmation of the diagnosis by phone, AGREED PROTOCOLS should be followed to ensure that the patient can phone an individual whom they have already met face-to-face, at a time when the patient is comfortable, quiet and their carers are present (if desired), to discuss the implications of their diagnosis and onward management plan.	Individual centres are likely to have their own protocols about divulging information, and are required as part of this guidance to audit these.
National Cancer Research Institute – Sarcoma Clinical Studies Group	Manual	94	Paragraph 108 states that there is good evidence of the value of offering patients audiotaped or written copies of consultations. This should therefore be specifically recommended.	This is already recommended in para 92.
National Cancer Research Institute – Sarcoma Clinical Studies Group	Manual	100	Patients should also be offered support in returning to school/work, and help with social/sexual relationships resulting from functional impairment following surgery, radio- or chemo-therapy.	We feel that the list under para 100 is likely to be sufficient to offer patients help with school/work, social/sexual relationships. The key worker is likely to pick up the nuances.
National Cancer Research Institute – Sarcoma Clinical Studies Group	Manual	262, table 5	There is inconsistency in stating that sarcoma surgeons should devote >50% of their time to sarcoma work, but oncologists 3PAs. The same	The text has been amended to state that surgeons should spend 'at least 5 PAs of their time in managing sarcomas.'

Stakeholders	Document	Section number Or General	Comments	Developer's response
			currency should be used for both.	
National Cancer Research Institute – Sarcoma Clinical Studies Group	Manual	516-570	Co-ordinated training, audit and research are particularly important for rare tumours asuch as sarcomas. This section deserves full support. It is particularly important that NCRN networks allocate sufficient resource to this. The role of research could be strengthened by recommending that all MDTs include a research lead and a research nurse.	Thank you for your suggestion. Not all sarcoma MDTs will be able to obtain a research nurse, although they should be striving towards this. We agree, however, that there should be a designated research lead, and this has been clarified in para 537.
National Cancer Research Institute (NCRI) Clinical Studies Group and National Cancer Research Network (NCRN)			This organisation was approached but did not respond.	
National Council for Disabled People, Black, Minority and Ethnic Community (Equalities)			This organisation was approached but did not respond.	
National Patient Safety Agency			This organisation was approached but did not respond.	
National Public Health Service – Wales			This organisation was approached but did not respond.	
NHS Direct			This organisation was approached but did not respond.	
NHS Information Authority (PHSMI Programme)			This organisation was approached but did not respond.	
NHS Modernisation Agency, The			This organisation was approached but did not respond.	
NHS Quality Improvement Scotland			This organisation was approached but did not respond.	
Northumberland Care Trust			This organisation was approached but did not respond.	

Stakeholders	Document	Section number Or General	Comments	Developer's response
Novartis Pharmaceuticals UK Ltd	Manual	7	Site-specific MDTs *do* treat sarcomas and therefore fall within the remit of this guidance. The GDG's response to Novartis' comment on Chapter 3 of the first consultation clearly acknowledges this. The GDG's response states that they "have amended para 351 of the first consultation to clarify that the primary responsibility for GIST tumour management should be with the upper GI MDT". In order to make provision for GISTs, this key recommendation should be amended as follows: "A key worker who will be a member of the sarcoma or site- specific MDT should be allocated to each sarcoma patient."	Thank you for your comments. We are still unable to make specific recommendations about key workers for other site-specific groups. The wording of para 7 has been changed to 'All patients managed by a sarcoma MDT should be allocated a key worker.'
Novartis Pharmaceuticals UK Ltd	Manual	11	Site-specific MDTs *do* treat sarcomas and therefore fall within the remit of this guidance. The GDG's response to Novartis' comment on Chapter 3 of the first consultation clearly acknowledges this. The GDG's response states that they "have amended para 351 of the first consultation to clarify that the primary responsibility for GIST tumour management should be with the upper GI MDT". In order to make provision for GISTs, this key recommendation should be amended as follows: "All sarcoma and site-specific MDTs should participate in national audit, data collection and training."	It is outside the remit of this guidance to make recommendations for site-specific MDTs.
Novartis Pharmaceuticals UK Ltd	Manual	141	Patients with GISTs will not be diagnosed unless GPs and hospital doctors are aware of diagnostic pathways for GISTs and therefore refer their patients accordingly.	The NICE guideline 'Referral for suspected cancer' deals with sarcomas but also with upper GI symptoms that might indicate a potential diagnosis of GIST. GPs will already be well aware of this guideline.

Stakeholders	Document	Section number Or General	Comments	Developer's response
			In order to make provision for GISTs, this key recommendation should be amended as follows: "Networks should ensure that GPs and hospital doctors are aware of the diagnostic pathways for patients with features suggestive of bone or soft tissue sarcoma, or GISTs."	
Novartis Pharmaceuticals UK Ltd	Manual	149	Service provision will be affected by the way patients are managed, therefore guidelines for the management of GISTs would be useful to inform the service provision outlined in this sarcoma guideline. A copy of the guidelines developed by a panel of UK opinion leaders (including pathologists, radiologists and oncologists) in collaboration with Novartis on the management of GISTs can be provided on request.	The guidance is not giving guidance on management of patients, but on service provision.
Nuffield Orthopaedic Centre NHS Trust			This organisation was approached but did not respond.	
Pfizer Limited	Manual	36 390 and General	New agents are being developed for GIST. These include sunitinib (SU11248) a multi-targeted agent that is anticipated to be specifically licensed for the treatment of patients with imatinib resistant GIST, prior to the publication of these guidelines. Guidelines should therefore refer to the potential role of sunitinib in the treatment of imatinib resistant GIST (further details are included below).	This level of detail is not possible in service guidance.
Pfizer Limited	Manual	400 405	We support the increased role of PET scanning in the management of GIST. PET scans are more accurate than CT at diagnosing metastatic disease and can be used to monitor response to imatinib and newer	Thank you for your comment.

Stakeholders	Document	Section number Or General	Comments	Developer's response
			agents such as sunitinib.[1]	
Pfizer Limited	Manual	Appendix 5 Glossary of terms	Definition of sunitinib should be included… Sunitinib = a drug that will be available for use in the treatment of patients with GIST, whose disease is resistant to imatinib	The glossary only covers those terms used within the guidance.
Pfizer Limited	Evidence Review	Page 91 and Table 3b	Evidence for pathology and GIST There is evidence to suggest that mutational status of KIT may be important in predicting outcome with sunitinib therapy. Clinical benefit (response rate + stable disease for > 6months), time to tumour progression and overall survival is significantly higher for exon 9 KIT compared with exon 11 KIT mutations.[8]	This is too much clinical detail for service guidance.
Pfizer Limited	Evidence Review	Table 8	There is evidence that FDG-PET scanning can be used to monitor response to sunitinib therapy[1]and this should be included within this review of evidence.	We have highlighted that PET scanning can be used to monitor response to therapy for GIST. In view of the rapidly changing clinical treatment options for this disease, it would not be appropriate to mention specific drugs other than imatinib, which was the first one to become available and has been part of a NICE technology appraisal.
Pfizer Limited	Evidence Review	Appendix C and General	A section reviewing the evidence for sunitinib for the treatment of imatinib refractory GIST should be included. Sunitinib is an oral, small molecule, multi-targeted tyrosine kinase inhibitor that has demonstrated both direct antitumour activity and antiangiogenic action. It	It is not appropriate to include this evidence as we are not making recommendations about treatment.

Stakeholders	Document	Section number Or General	Comments	Developer's response
			produces this integrated effect by targeting vascular endothelial growth factor receptor (VEGFR) -1, VEGFR-2, VEGFR-3, platelet-derived growth factor receptor (PDGFR) -α, PDGFR-β, c-Kit and fms-like tyrosine kinase (Flt-3).[2,3] Approximately 20% of patients exhibit primary resistance to imatinib.[4] Patients who experience initial response to imatinib can show secondary resistance, typically after more than one year of therapy.[5] Phase I – III trials have been conducted to evaluate the use of sunitinib as second-line therapy in patients with imatinib-resistant or imatinib-intolerant metastatic GIST.[6-12] Phase III data were presented at the 2005 Annual Meeting of ASCO.[9,12] In a randomised, double-blind, placebo-controlled trial, sunitinib was evaluated for efficacy and safety in patients with GIST following documented failure of imatinib.[9] Patients were initially randomized 2:1 to sunitinib (50 mg once daily for 4 weeks followed by a 2-week break in each 6-week cycle) or placebo. Treatment of patients who exhibited RECIST-defined progression of GIST were unblinded and crossed over to unblinded sunitinib therapy. The primary study endpoint was time to tumour progression (TTP). Secondary	

Stakeholders	Document	Section number Or General	Comments	Developer's response
			endpoints included overall survival (OS), objective response rate (ORR), time to tumour response, duration of response, duration of performance status maintenance and clinical benefit-related parameters.[9] 312 patients (SU11248: n=207, placebo: n=105) were enrolled and equally balanced with regard to patient characteristics and prior imatinib therapy. Median dose of prior imatinib therapy was 800 mg/day. At the first planned interim analysis in January 2005, the primary endpoint (TTP) was statistically significant between SU11248 and the control. Therefore, following a discussion with the Independent Data and Safety Monitoring Board, treatment was unblinded.[9] At this time, median TTP (95% CI) was 6.3 months (3.7, 7.6) for SU11248 versus 1.5 months (1.0, 2.3) for placebo, corresponding to a hazard ratio (HR) of 0.335 ($p<0.00001$). The HR for OS was 0.491 ($p=0.0067$). A comparison of ORR in patients administered SU11248 vs. placebo revealed: PR (8% vs. 0%), SD (58% vs. 50%), progressive disease (20% vs. 39%), and not evaluable (14% vs. 11%). Sunitinib was reasonably well tolerated.[9] In summary, results from this phase III trial revealed statistically significant improvements in both TTP and OS in patients treated with sunitinib compared with placebo. The median OS has not been reached in either treatment arm. It should also be noted that the protocol driven crossover of patients from placebo to active treatment following progression may have	

Stakeholders	Document	Section number Or General	Comments	Developer's response
			resulted in an underestimation of the survival benefit of sunitinib.[9] As sunitinib represents an active treatment for patients with GIST who are resistant to or intolerant of imatinib[9], this should be indicated in the treatment strategy, particularly in figure 2.	
Pfizer Limited	Manual And Evidence Review	General	The future provision of sunitinib for imatinib refractory GIST should be included, particularly in the absence of any planned NICE appraisal for sunitinib. Access to sunitinib will improve the outcome for patients with refractory GIST and in the absence of any guidelines access may be inequitable and patchy.	This level of detail is not possible in service guidance. We have, however, stressed the importance of research in GIST in para 390.
Pfizer Limited			References 1. Van Den Abbeele, AD, Imaging target kinase inhibition with SU11248 by FDG-PET in patients with imatinib resistant GIST, presented ASCO 2005 2. Sakamoto KM (2004) Curr Opin Invest Drugs; 5(12): 1329-1339 3. Mendel DB et al (2003) Clin Cancer Res; 9: 327-337 4. Sawaki A, Yamao K (2004) Cancer Chemother Pharmacol; 54(Suppl 1): S44-S49 5. Fletcher JA et al Mechanisms of resistance to imatinib mesylate (IM) in advanced gastrointestinal stromal tumours (GIST). Oral presentation at: American Society of Clinical Oncologists (ASCO); May 31 − June 3, 2003;	

Stakeholders	Document	Section number Or General	Comments	Developer's response
			Chicago, Ill. 6. Demetri GD et al (2003) Clinical activity and tolerability of the multi-targeted tyrosine kinase inhibitor SU11248 in patients (pts) with metastatic gastrointestinal stromal tumour (GIST) refractory to imatinib mesylate. *Proc Am Soc Clin Oncol* 2003; 22: 814 (abstract 3273) 7. Demetri GD et al (2004) SU11248, A multi-targeted tyrosine kinase inhibitor, can overcome imatinib resistance caused by diverse genomic mechanisms in patients with metastatic gastrointestinal stromal tumour (GIST). Oral presentation at: 40st Annual Meeting of American Society of Clinical Oncology (ASCO); June 5-8, 2004; New Orleans, LA. 8. Maki RG et al (2005) SU11248 in patients with imatinib-resistant GIST: results form a continuation trial. Oral presentation at: 41st Annual Meeting of American Society of Clinical Oncology (ASCO); May 14-17, 2005; Orlando, FL. 9. Demetri GD et al (2005) Phase 3, multicenter, randomized, double-blind, placebo-controlled trial of SU11248 in patients following failure of imatinib for metastatic GIST. Oral presentation at: 41st Annual Meeting of American Society of Clinical Oncology (ASCO); May 14-17, 2005; Orlando, FL. 10. Davis D et al (2005) Pharmacodynamic Analysis of Target Receptor Tyrosine Kinase	

Stakeholders	Document	Section number Or General	Comments	Developer's response
			Activity and Apoptosis in GIST Responding to Therapy with SU11248. Oral presentation at: 41st Annual Meeting of American Society of Clinical Oncology (ASCO); May 14-17, 2005; Orlando, FL. 11. Norden-Zfoni A et al (2005) Levels of Circulating Endothelial Cells and Monocytes as Pharmacodynamic Markers of SU11248 Activity in Patients with Metastatic Imatinib-resistant GIST. Oral presentation at: 41st Annual Meeting of American Society of Clinical Oncology (ASCO); May 14-17, 2005; Orlando, FL. 12. Demetri GD et al (2005) Phase 3, multicenter, randomized, double-blind, placebo-controlled trial of SU11248 in patients (pts) following failure of imatinib for metastatic GIST. *Proc Am Soc Clin Onc* 2005; 23: 308s (abstract 4000).	
Princess Alexandra Hospital NHS Trust			This organisation was approached but did not respond.	
Richmond and Twickenham PCT			This organisation was approached but did not respond.	
Robert Jones and Agnes Hunt Orthopaedic and District Hospital NHS Trust			This organisation was approached but did not respond.	
Royal College of Anaesthetists			This organisation was approached but did not respond.	
Royal College of General Practitioners			This organisation was approached but did not respond.	

Stakeholders	Document	Section number Or General	Comments	Developer's response
Royal College of General Practitioners Wales			This organisation was approached but did not respond.	
Royal College of Nursing	Manual		Thank you for the opportunity to comment and for the developers' responses to the comments submitted on behalf of the Royal College of Nursing in the 1st draft consultation.	Thank you.
Royal College of Nursing	Manual	104	Add to 104 - Cancer network managers should be responsible for patient process mapping - Patient process mapping means examining the referral pathways for patients.	We imagine that cancer network managers will already be aware of their responsibility for patient process mapping. We feel it is important, however, that the MDTs also audit the appropriateness of referrals, and this has been highlighted in para 265.
Royal College of Paediatrics and Child Health			This organisation was approached but did not respond.	
Royal College of Pathologists	Manual		The Royal College of Pathologists have no comments to submit at this stage of the consultation.	Thank you.
Royal College of Physicians of London			This organisation was approached but did not respond.	
Royal College of Psychiatrists	Manual	75	The Patient Support section refers to possible psychological and social needs of patients with sarcoma. It identifies that some patients may need support of patient and carer groups or specialist nurses. This is helpful advice but is not sufficient as a significant number of patients will require a higher level of support. NICE guidance 'Supportive and Palliative Care for Adults with Cancer' recommends that the psychological and social needs of persons with cancer	We have extensively cross-referenced the NICE guidance on 'Supportive and palliative care for adults with cancer', particularly in chapter 8.

Stakeholders	Document	Section number Or General	Comments	Developer's response
			should be formally assessed at diagnosis, treatment, recurrence and palliative stages of the cancer journey and that a range of levels of support should be made available according to a 4-tier model. The Sarcoma guidance should reflect this previous guidance either by referring the reader to the Supportive and Palliative care for people with cancer recommendations or by incorporating these recommendations into the current guidance. A significant number of people with sarcoma will suffer from clinical disorders of mood, anxiety, adjustment which will require specialist assessment and treatment at 'level 3' or 'level 4' i.e. liaison psychiatry or mental health services. It is essential that, when planning services, account is taken of this need which cannot be met simply by patient support groups and information alone.	
Royal College of Radiologists (Faculty of Clinical Oncology)			This organisation was approached but did not respond.	
Royal College of Surgeons of England			This organisation was approached but did not respond.	
Royal College Patient Liasion Groups			This organisation was approached but did not respond.	
Royal Liverpool Children's NHS Trust			This organisation was approached but did not respond.	
Royal Marsden Hospital NHS Trust			This organisation was approached but did not respond.	
Royal National Orthopaedic			This organisation was approached but did not	

Stakeholders	Document	Section number Or General	Comments	Developer's response
Hospital NHS Trust			respond.	
Royal Pharmaceutical Society of Great Britain	Manual		Please note that the Royal Pharmaceutical Society of Great Britain will not be commenting on the above.	Thank you.
Sarcoma UK			This organisation was approached but did not respond.	
Scottish Bone and Soft Tissue Sarcoma Network			This organisation was approached but did not respond.	
Scottish Intercollegiate Guidelines Network (SIGN)			This organisation was approached but did not respond.	
Sheffield Teaching Hospitals NHS Trust			This organisation was approached but did not respond.	
Society and College of Radiographers	Manual	263	There is a role for a nominated specialist therapeutic radiographer, who is expert in the practice of radiotherapy treatment for sarcomas and patient care across this particular often, complex radiotherapy pathway. They have expert skills and knowledge pertaining to sarcomas and will work closely with the clinical /medical oncologists. They will also link the radiotherapy pathway to the surgical and chemotherapy pathways for patients via close liaison with the clinical nurse specialist.	While we accept that in units with a large sarcoma practice some radiographers will become more specialised in dealing with sarcoma patients, we feel that this should not be a part of this guidance but should be resolved locally.
Society and College of Radiographers	Manual	309	We continue to stress the need for identification of a 2nd supporting clinical oncologist with expertise in the treatment of sarcomas. We would also recommend the need for a specialist therapeutic radiographer, who is expert n the practice of radiotherapy treatment for sarcomas and patient care across the radiotherapy pathway. This person would be responsible for the overall co-ordination of the patient pathway and patient care during the radiotherapy treatment, they would have high level specialist skills and would have	The GDG has recommended that there should be at least one clinical oncologist. The need for additional clinical oncology support would be a matter for any one MDT to come to a view about locally. While we accept that in units with a large sarcoma practice some radiographers will become more specialised in dealing with sarcoma patients, we feel that this should not be a part of this guidance but should be resolved locally.

Stakeholders	Document	Section number Or General	Comments	Developer's response
			detailed technical knowledge and skills about external beam radiotherapy options which are often extremely complex for this group of patients.	
Society and College of Radiographers	Manual	344	Same comment: as 309 identification of the need of a specialist therapeutic radiographer	While we accept that in units with a large sarcoma practice some radiographers will become more specialised in dealing with sarcoma patients, we feel that this should not be a part of this guidance but should be resolved locally.
Society and College of Radiographers	Manual	420	Key workers are individuals (usually a specialist nurse-.by stating this other AHP's with specific expertise may be excluded?) Therefore we would suggest adding specialist nurse/AHP.	We have made this amendment to the text.
Society and College of Radiographers	Manual	GLOSSARY	AHP section; Radiographers are Diagnostic and/or Therapeutic (could this be added please, as there is different education and training as well as roles)	The text has been amended.
Society and College of Radiographers	Manual	GLOSSARY	A definition of Diagnostic Radiographer and Therapeutic Radiographer must be added: We believe that it is vital to understand how the radiographers' role has developed since radiography became an all-graduate profession more than a decade ago, if the most effective use of their diverse skills is to be made. We believe that your definition for both diagnostic and therapeutic radiographers are too narrow and very out dated. As such we would wish to see this new definition of a Diagnostic Radiographer be used, "Diagnostic radiographers are responsible for	We will include a definition of diagnostic and therapeutic radiographers in the glossary.

Stakeholders	Document	Section number Or General	Comments	Developer's response
			providing safe and accurate imaging examinations and, often, resultant reports in a wide range of clinical environments, using a variety of imaging modalities and techniques so that appropriate management and treatment of patients and clients can proceed. The identification, evaluation and monitoring of systemic diseases, skeletal and soft tissue abnormalities and trauma are the major focus of diagnostic radiography. Significantly, radiographers provide this service throughout the 24-hour day, often working alone or in inter-professional care teams. Hence they need to be prepared to deal with medical emergencies which may arise during examination and treatment." Similarly the following definition adopted when describing a therapeutic radiographer " Therapeutic radiographers are responsible for providing safe and accurate high-energy radiation treatments to individual patients with cancer and for the patient's physical, psychological well being prior to, during and following radiotherapy. This is a continuum of care, which, involves complex technical skills in pre-treatment localisation, target delineation, planning and dosimetry, technique development, management and verification of the treatment process."	
South Warwickshire General Hospitals NHS Trust			This organisation was approached but did not respond.	

Stakeholders	Document	Section number Or General	Comments	Developer's response
South West Cancer Intelligence Service	Manual		Comments from Tumour Panel Clinicians	
South West Cancer Intelligence Service	Manual	8 & 9	Part of the key recommendations: items 8 and 9 stress the importance of a surgeon, chemotherapy and radiotherapy as part of the sarcoma MDT. We feel that a Pathologist and a Radiologist with a special interest and expertise in soft tissue sarcoma, should also be specified as a necessary part of the MDT	We have modified para 5 to cover this.
South West Cancer Intelligence Service	Manual	54	1/We agree with the benign to malignant ratio stated by the NICE GDG. It is important to recognise the number of lumps falling within the NICE guidelines for suspicious lumps that require MDT assessment. This is not a ratio of 100:1 and these cases need to be included in the number for assessment by an expert MDT meeting. 2/ Are these suspicious lumps included in the MDT costing as suspicious bony lesions included in NSCAG costing up until a firm diagnosis is made?	Thank you for your comment. These figures have been taken into account in the costing.
South West Cancer Intelligence Service	Manual	145	Is a one stop diagnostic clinic an ideal or a requirement which NICE feels is realistic? We would be unhappy with a diagnostic clinic run by a non core MDT member especially a CNS.	We feel that a one-stop diagnostic clinic is ideal and is also realistic. We believe that there will be a variety of different options for staffing a diagnostic clinic, based on whatever expertise is available. All staff at diagnostic clinics will need to be approved and trained by a sarcoma MDT.
South West Cancer Intelligence Service	Manual	262	We do not feel that it is necessary for a surgeon to spend more than 50% of his/her time in managing sarcoma to remain competent nor do we feel it is necessary for 2 oncologists each to spend more than 3PAs a week. These requirements should be removed from the guidelines.	The GDG does not agree that, in a properly constituted MDT seeing the requisite number of patients, the recommendations that we have made are incorrect.

Stakeholders	Document	Section number Or General	Comments	Developer's response
South West Cancer Intelligence Service	Manual	265	We disagree that weekly MDT meetings are necessary and we feel that fortnightly meetings are sufficient.	Given the volume of patients being seen by a properly constituted MDT and the requirements of the cancer waiting time targets, we do not feel that a fortnightly MDT meeting is appropriate.
South West Cancer Intelligence Service	Manual	General	.The criteria should be for 'a good MDT' and *not* 'more than 100 cases per year'. • If each centre covers 4 million population, with a total population of 60 million, there would be only 15 centres. This means long travelling distances for patients and families. • Long travelling distances = stress = increased risk of poor outcome. • More *informed* GPs and clinical staff plus clearly defined referral procedures would ease the problem area I see as most important - that of recognising the possibility of a sarcoma. Further handling of cases by those with an interest can surely be done by specialists who also deal with other types of medical problems. They need not be solely devoted to sarcomas	Thank you for your comments. The GDG deliberated at length about the issues of travelling versus local treatment and felt that overall the benefits of being treated in a specialist centre outweighed the inconveniences of travelling, certainly for diagnosis and surgical treatment. We agree that early diagnosis is desirable and more informed GPs and clinical staff will be welcomed. We have made recommendations about this in paras 139 and 140. We have emphasised that except in a few circumstances there will be very few clinicians who do nothing but treat sarcomas, and most of the clinicians will have other interests as well.
South West Cancer Intelligence Service	Manual	chapter 2	In general I agree with most of the points covered in chapter 2. The following comments are, however, applicable:	Thank you.
South West Cancer Intelligence Service	Manual	80	States that patients needing to travel long distances for appropriate treatment will cope with this issue as	We agree that travel should be minimised, provided treatment can be carried out at an appropriate centre with sufficient expertise. We believe that diagnosis and

Stakeholders	Document	Section number Or General	Comments	Developer's response
			an additional pressure if necessary. In my own experience and talking to other friends who were cancer patients (of whom four have passed away in the last year), the stress of travelling long distances is high both for patients and family. Part of the problem is that treatment or travel sickness causes nausea which makes the patient miserable which lowers the patients willpower and pushes stress levels up. I strongly believe, based on my own experience, that an important part of a cure is to reduce all toxins, especially those introduced by stress, and to boost the immune system (where this is permissable depending on the treatment).	surgical treatment should be carried out in highly specialised units and that chemotherapy and radiotherapy can be safely carried out in hospitals nearer to patients' homes.
South West Cancer Intelligence Service	Manual	82	Primary source of information is specified as a printed leaflet for specific types of tumour. Many of the leaflets I have read did not contain sufficient information and I needed more. I agree that Internet access does not always provide accurate information and indeed, is sometimes misleading. Not all patients want the same depth of information. This is the reason I produced my own notes from all sources. It seemed to me that a good way to solve the problem was to put all the information together in the form of a web page but put the web page onto a CD. This way, selective links can provide as much or as little information as the patient needs, specifically for	Thank you for your comments.

Stakeholders	Document	Section number Or General	Comments	Developer's response
			different types of Sarcoma. Good on-line sites can be identified and links built in. A CD can hold a lot of information so that a patient using it is not restricted by the speed of download from an on-line site for most of the detail. Once a CD has been compiled, the cost of reproducing it is quite cheap these days. The patient could even make his own copy to save costs and the original could be returned. Leaflets and audio tapes would be preferred for patients who do not have computing facilities.	
South West Cancer Intelligence Service	Manual	84	I agree that not all Internet information is suitable quality and think this is a good reason for the CD mentioned in 82 above which will gives links to good sites.	Thank you for your comments.
South West Cancer Intelligence Service	Manual	88	Participating in clinical trials is not only a burden - it could also be a source of hope.	We have amended para 88 accordingly.
South West Cancer Intelligence Service	Manual	94	Again, include the possibility of a CD for web style information for those patients with computers.	Para 94 highlights that a variety of formats are suitable, but we do not think it is appropriate to specify any one format over and above the others.
South West Cancer Intelligence Service	Manual	96	Information pathway where referral to another treatment centre is necessary should also include the reason why this is necessary.	This has been added to table 4.
South West Cancer Intelligence Service	Manual	100	Support should include the possibility of 'complementary treatment' for those patients who could benefit from it and where no contra-indications exist.	Complementary therapies are likely to be available in different parts of the country. It has been discussed in the NICE guidance on 'Supportive and palliative care for adults with cancer'. We do not feel that specific recommendations about its role for patients with sarcomas is necessary.
South West Cancer Intelligence Service	Manual	103	Important to share information but without excessive meetings and paperwork.	Thank you.

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South West Cancer Intelligence Service	Manual	110	Agree but can be solved by an 'official' web site identified to the patient and by the CD solution referred to in 82 above.	Para 110 summarises the evidence. We are not aware of an 'official' website for patients with sarcoma at the moment.
South West Cancer Intelligence Service	Manual	113	To psychological and psychosocial support could also be added complementary support and hypnotherapy	This paragraph summarises the current evidence.
South West Cancer Intelligence Service	Manual	115	It is not clear what distance is implied that a patient is prepared to travel. A number of patients including myself would not agree to travel too far - indeed, I moved house to be nearer to my treatment centre as journeys of two hours were found to be too long. Half an hour journey is more than enough.	This paragraph summarises the current evidence. Further detail is available in the Evidence Review that accompanies the Manual.
South West Cancer Intelligence Service	Manual	116	Although effects of travel on patient outcomes is inconclusive, I am convinced that a detrimental effect will be identified due to increased stress as referred to in 80 above.	This paragraph summarises the current evidence. Further detail is available in the Evidence Review that accompanies the Manual.
South West Cancer Intelligence Service	Manual	117	Increased risk in order to receive treatment in local hospitals is completely understandable in my opinion. It has also largely to do with the trust a patient feels when talking to a consultant who is open with the patient. Fortunately most consultants are open these days, but a few 'arrogant' examples still exist who 'know best'. I would refuse treatment from such a character. Although there are patients who have little interest in their own treatment, the majority feel a *responsibility* to work together with the medical team to achieve the best results.	This paragraph summarises the current evidence. Further detail is available in the Evidence Review that accompanies the Manual.
South West Cancer Intelligence Service	Manual	129	The cost of compiling and producing information could possibly be reduced by patient involvement. They could assist in producing draft versions although expert editing would be needed to check accuracy and with copyright issues.	Virtually all information sources currently available have been produced in conjunction with patients.

Stakeholders	Document	Section number Or General	Comments	Developer's response
South West London Strategic Health Authority			This organisation was approached but did not respond.	
Tameside and Glossop Acute Services NHS Trust			This organisation was approached but did not respond.	
Teenage Cancer Trust, The			This organisation was approached but did not respond.	
Thames Valley Strategic Health Authority			This organisation was approached but did not respond.	
The Neurofibromatosis Association			This organisation was approached but did not respond.	
The Royal Society of Medicine			This organisation was approached but did not respond.	
The Royal West Sussex Trust			This organisation was approached but did not respond.	
UK Children's Cancer Study Group			This organisation was approached but did not respond.	
University College London's Hospital NHS Trust			This organisation was approached but did not respond.	
University Hospital Birmingham NHS Trust			This organisation was approached but did not respond.	
Welsh Assembly Government	Manual		Thank you for giving the Welsh Assembly Government the opportunity to comment on the guideline. We are content with the technical detail of the evidence supporting the provisional recommendations and have no further comments to make at this stage.	Thank you.
Wessex Cancer Trust			This organisation was approached but did not respond.	
West Lincolnshire PCT			This organisation was approached but did not respond.	

Stakeholders	Document	Section number Or General	Comments	Developer's response
West Midlands Cancer Intelligence Unit (individual comment – not stakeholder)	Manual	36	The West Midlands Cancer Intelligence Unit (WMCIU) registers all cases of gastrointestinal stromal tumours (GIST) that are submitted by pathology laboratories in the West Midlands region. A review of the registration of GIST has been undertaken which indicates that the incidence of GIST in the West Midlands was 3.94 per million (3-year rolling directly age rate for males and females combined) in 2001-2003. Our review shows that the complete ascertainment of these tumours relies heavily on how they are coded by pathologists. This is because GIST are often classified by pathologists as leiomyomas, leiomyoblastomas and leiomyosarcomas. These benign tumours would not normally be registered by cancer registries. This misclassification of GIST by pathologists may account for the relatively low incidence rate for GIST observed in the West Midlands compared to that in the Swedish study by Nilsson et al in 2005. Further details of the WMCIU analyses can be found in the supplementary document accompanying these comments.	Thank you for supplying this supplementary documentation, which was most interesting. We hope it will shortly be published.
West Midlands Cancer Intelligence Unit (individual comment – not stakeholder)	Manual	523	Cancer registries have considerable experience in the classification and registration of tumours, including the recording of detailed diagnosis and treatment information. In many registries, including the WMCIU, this information is currently abstracted from medical notes by trained clinical coding staff. These staff have considerable experience in consolidating information relating to a patient from a number of different sources. We would therefore suggest that the central repository of the agreed dataset for sarcomas (the 'national sarcoma register') should reside within a	Thank you for your comment.

Stakeholders	Document	Section number Or General	Comments	Developer's response
			cancer registry. The WMCIU would be pleased to act as that central repository.	
West Midlands Specialised Services Agency			This organisation was approached but did not respond.	