National Institute for Health and Clinical Excellence

Metastatic spinal cord compression

Guideline Consultation Table

23 May - 18 July 2008

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	1	3 Counties Cancer Network Palliative Care Lead Clinicians Group				This organisation was approached but did not respond	
SH	2	Anglia Cancer Network				This organisation was approached but did not respond	
SH	3	Arden Cancer Network				This organisation was approached but did not respond	
SH	4	ArjoHuntleigh				This organisation was approached but did not respond	
SH	5	Association for Continence Advice				This organisation was approached but did not respond	
SH	6	Association for Palliative Medicine of Great Britain and Ireland				This organisation was approached but did not respond	
SH	7.0	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	General		Much of the guideline relies on bony and neurological stability being confirmed. Who is responsible for doing this and how do they do this? Due to the nature of metastatic spinal cord compression most neurosurgeons and oncologists are reluctant to confirm stability and this makes the rest of the document difficult to implement. We accept this may not be solvable but feel the issue should be acknowledged. Is it possible for it to be described as low, medium or high likelihood of instability or something similar to make it more workable?	The GDG acknowledges the difficulties confirming spinal stability and has attempted a pragmatic description of current practice being a combination of clinical and radiological features, and careful observation in a multidisciplinary setting (see mobilisation section on p 84 - 86).
SH	7.1	Association of Chartered Physiotherapists in	Full	49	2	We feel strongly that it be made explicit that the co-ordinator role could be a physiotherapist for which	This role is already filled on ad-hoc basis (usually registrar on call). The guideline looks to formalise

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		Oncology and Palliative Care				these are core skills. Radiographers and nurses would need specialist training to do this. Therefore in all statements particularly in appendix C please list physios as a specific option for the co-ordinator role.	this but we do not feel that it is appropriate to explicitly mention specific specialties.
SH	7.2	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	General		Different sections are referenced differently, some use Harvard and some just make statements and list references at the end which is not as helpful and raises questions about evidence for certain statements.	We will standardise the references.
SH	7.3	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	General		Format is not very user friendly at present, easier to read if more box representation used throughout documentation	The full guideline will use more box representation.
SH	7.4	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	General		Is there room to acknowledge that higher level research in certain areas is not feasible due to ethical considerations	The GDG feel that the ethical difficulties of medical research are well established and apply equally in this area. We do not feel that we need to acknowledge this explicitly in the guideline.
SH	7.5	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full/N ICE	4		Rehabilitation should be included as a key priority for implementation in addition to supportive care and discharge planning in both documents and should be added as a section to the contents pages	The guidance is only permitted 10 key recommendations for implementation and of necessity these are wide ranging. We have amended key priority 10 to include "rehabilitation". We have amended the title for chapter 7 to "Supportive care and rehabilitation".
SH	7.6	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	6 and 99	13 and 3	What is IMRT? Need full wording and added to abbreviations list	We have made this change.
SH	7.7	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	66	11-13	This statement needs referenced – it is unclear where it has come from	We have now included a reference as suggested.
SH	7.8	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	66	23	The likelihood in certain cancers is higher e.g. lung, breast and prostate is nearer 20%. This needs acknowledgement.	We define these conditions and metastases in the guideline. It is explicitly acknowledges in the epidemiology introduction (see section 1.1 page 37 line 9-12) and the guideline discusses pts at high

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
							risk of developing bone metastases.
SH	7.9	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	66	32	It should be clear that the information leaflet should not just be handed to the patient but explained by the appropriate professional so as to reduce anxiety	We have amended these recommendations to include reference to both verbal and written information.
SH	7.10	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	67	17	Same point again, could be added "depending on site of primary" as not so rare with some cancers	We have amended these recommendations to include reference to both verbal and written information.
SH	7.11	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	67	40-42	We feel in an oncological emergency such as this anyone outside the acute sector should have rapid access into acute settings for MRI and not have to wait as treatment needs to be fast, every referral cant go through the co-ordinator for practical and time reasons. Agree co-ordinator should be made aware of all MSCC but cannot "discuss" every single case with them. Need clarification of what "discuss" means in this situation.	This is not an oncological emergency but needs urgent discussion with an MSCC coordinator whose role is to deal with these requests.
SH	7.12	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	68	16-17 and 27-28	Continues above point – surely every patient with cancer and spinal pain cannot be discussed with the co-ordinator? Particularly as an oncological emergency there is no time to wait to do this, particularly if patient is in the community/	These recommendations are designed to prevent paralysis and give appropriate levels of urgency to progressive symptoms and signs.
SH	7.13	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	68	31	Clarification needed of what "difficulty walking" means as this is rather vague and patients may have many reasons for having difficulty walking	New onset difficulty walking is the most frequent significant neurological symptom reported in the patients experience and needs rapid assessing by a clinician able to distinguish neurological cause from other less important causes. We do not think further clarification is needed.
SH	7.14	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	68	38-42	Why is this just about degeneration in lumbar spine? Surely it should just say "patients who develop spinal pain" as most MSCC is of thoracic or cervical origin and degeneration in those areas is common also.	Pain in the upper spine in patients with cancer is more predictive of metastases and is recommended for early investigation p68 19.
SH	7.15	Association of Chartered Physiotherapists in Oncology and Palliative	Full	77	32	Can the statement about halo jackets not being particularly effective be referenced	Than you. The sentence has been changed.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		Care					
SH	7.16	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	84	22-26	Can this be clarified about what the steroids are actually doing e.g. reducing oedema/tumour etc as opposed to structural failure	This is an introduction. Explained in more detail at p86, lines 28-32.
SH	7.17	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	85	23-28	This does not reflect functional management of those with mild/moderate pain and/or intact neurology. The necessity of being nursed flat and log rolled should be assessed by a rehabilitation professional and rather than "cautious remobilisation" a statement such as mobilisation with regular evaluation is more appropriate. These tasks should be carried out by a professional of level 3 or above. During this section there is no reference to relation to treatment e.g. has radiotherapy started or are they waiting – this will make a difference to when mobilisation takes place	It is not relevant for patients with mild/moderate pain or intact neurology. We do not think this change is necessary. All tasks should only be done by competent personnel. This is irrelevant. The recommendation is designed to briefly ensure that patients are safe and if both column and cord are safe, mobilisation is appropriate at any stage during treatment.
SH	7.18	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	85	30-33	Is there evidence for this gradual sitting over 3-4 hours and is this realistic to expect a physiotherapist to do this with every patient. There are serious implications for workforce levels if that is the case. Also is this appropriate for every patient? Even those with minimal pain and/or neurology. This seems extremely prescriptive with no room for individuality of patients. Also clarification needed of what is meant by "spinal shock"	We have amended this recommendation. It is appropriate for those patients as defined in the revised recommendation. This is defined in the glossary.
SH	7.19	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	85	35-38	This should not just be about blood pressure but about cardiovascular system. Also is not just about muscle power, perhaps better to state mobilisation can be carried out "as	This is about ensuring spinal cord perfusion when it is threatened by critical compression or hypotension. We have changed this recommendation.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						symptoms allow". Also some acknowledgement of those patients whose neurology is not stable but for whom there are no treatment options – can they be offered the opportunity to sit out etc if they understand the risks? More emphasis needed on quality of life.	We have added a new recommendation.
SH	7.20	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	99	18	There are issues of bias with the Patchell study that need acknowledged	This has been acknowledged in the evidence summary and review.
SH	7.21	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	100	34	The data from the Royal Orthopaedic Hospital – is there chance of bias due to selection of patients	The data from the ROH has been used to determine representative health care costs of a range of procedures, not clinical outcomes. These are likely to be similar between different units within the UK healthcare provision. It would be helpful if comparative date was to be available but this is not currently the case.
SH	7.22	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	103	18	What about patients with severe pain at end stage who may benefit but will go over the recommended dose. They will not be affected by side effects of high doses in long term.	The recommendation supports further radiotherapy and it supports exceeding the recommended dose when necessary (below 100Gy where possible.
SH	7.23	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	116	33	There is no evidence that passive leg movements reduce risk of thromboembolism – if patients can actively move they should be encourage to do active leg exercises. We feel strongly this line needs to be removed as it is not modern practice and there is no evidence for it.	Thank you for your comment. We have removed this from the recommendation.
SH	7.24	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	118	1-18	What is the evidence for 2 hourly turns? Patients with unstable spines could be at risk from this. This also has staffing implications. The line stating patients should be encourage to mobilise regularly may be better as "patients who are not on bed rest and have spinal stability confirmed	The GDG felt that for patients at particular risk of developing pressure ulcers, 2 hourly turn using the correct technique minimises the risk. This recommendation is based on GDG consensus. We have amended the recommendation.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						should be encourage to mobilise/sit out as symptoms allow"	
SH	7.25	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	118	8-10	It should be clear that only patients with spinal stability should be on pressure mattresses and only if necessary – if a patient is mobile and out of bed this may not be necessary	Thank you. We have amended the recommendation.
SH	7.26	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	120	2-7	This statement takes our profession back, is very prescriptive and not in keeping with current trends. Furthermore there is no evidence for preventative respiratory management such as this and it is not routinely done for other oncology patients. We feel strongly this paragraph needs rewording and it should be made clear respiratory management is only following appropriate assessment. We suggest "appropriate respiratory management should be provided following assessment by a physiotherapist for patients with MSCC with compromised respiratory function as a consequence of their MSCC or co-morbidities" Also throughout there is no acknowledgement that MSCC could ultimately be the start of a continued deterioration and the end of life – no mention of GSF of Liverpool care pathway, not all patients will be appropriate for intensive rehab.	We do not suggest that all patients will be appropriate for intensive rehabilitation. Only that they are entitled to be assessed for it. Much of the content from these recommendations relates to people's transitions to home with supportive care. However, at present those patients who would benefit from continued rehabilitation are often unable to access it. It is hoped that this element of the guidance will help to change that. The GSF is not relevant here.
SH	7.27	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	122	26	Suggest "should be assessed by" rather than "have access to"	Thank you. We have amended the recommendation.
SH	7.28	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	122	41-44	Suggest "start on admission" rather than "start early" Suggest palliative care should not be "as required" as most of these patients will have widespread disease and should have contact with their palliative care team. Suggest also include mention of the GSF and Liverpool care pathway for appropriate patients.	We have changed the recommendation.
SH	7.29	Association of Chartered Physiotherapists in	Full	35	Timin g of	Dex should be started as soon as MSCC suspected not after MRI?	We will discuss this with the GDG and change where appropriate.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		Oncology and Palliative Care			mobilisation		
SH	7.30	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	35	Box ongoing assessment	Suggest adding word "including" to read "including transfers, sitting, standing etc"	We will discuss this with the GDG and change where appropriate.
SH	7.31	Association of Chartered Physiotherapists in Oncology and Palliative Care	Full	35		Suggest add box before MRI to establish "fit for MRI?"	We will discuss this with the GDG and change where appropriate.
SH	8	Barnsley Hospital NHS Foundation Trust				This organisation was approached but did not respond	
SH	9	Barnsley PCT				This organisation was approached but did not respond	
SH	10	Birmingham Cancer Network				This organisation was approached but did not respond	
SH	11	Bournemouth and Poole PCT				This organisation was approached but did not respond	
SH	12	Brain and Spine Foundation				This organisation was approached but did not respond	
SH	13.0	Breakthrough Breast Cancer	Full guideline	General		Breakthrough welcomes the development of clinical guidelines for the diagnosis and management of adults at risk of, and with, metastatic spinal cord compression (MSCC). This condition is estimated to affect only a relatively low number of patients a year and it is therefore important that clinicians, Cancer Networks and Trusts are appropriately prepared to identify patients at risk and offer rapid and effective treatment in order to minimise the impact of this potentially very serious condition.	Thank you.
SH	13.1	Breakthrough Breast Cancer	Full guideline	General		We appreciate that many of the comments below relate to the need to provide patients with information and to involve them in decisions about their care, and that it may be felt such considerations are already embedded within general clinical practice and thus do	The patients experience of MSCC is made pre-eminent in this guideline. Deficiencies in communication are graphically illustrated and recommendations have been made to improve communication with patients and their families etc.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						not need to be specifically included. However, the involvement of patients in their care is of crucial importance and as such it may be useful to explicitly recognise and reinforce this throughout the guidelines.	(chapter 3).
SH	13.2	Breakthrough Breast Cancer	Full guidel ine	48	9-10	The development of local pathways for diagnosis and management which are documented, agreed and consistent across the cancer network is highly important but these arrangements should also highlight the need for guidelines to reflect best practice.	This guideline is based on the best evidence currently available.
SH	13.3	Breakthrough Breast Cancer	Full guidel ine	48	11-12	This point would benefit from greater clarity on when telephone contacts would be expected to be available, given the importance of urgent diagnosis and treatment for this condition. While the exact operating hours for each centre will be a matter for local Trusts, guidance on whether, for example, out of hours access is recommended would be beneficial.	The MSCC co-ordinator is a 24hour role as described on p49, lines 44-47.
SH	13.4	Breakthrough Breast Cancer	Full guidel ine	48	19-31	An additional responsibility of the lead clinician in each secondary or tertiary centre should be to ensure that clear and appropriate information is available within their centre to patients either at risk of, or with, MSCC. However, it will be important for all clinical staff involved in dispensing this information to be made aware of how to assess whether patients are at risk, in order to avoid causing distress unnecessarily in low risk patients.	We agree.
SH	13.5	Breakthrough Breast Cancer	Full guidel ine	59	29	Breakthrough believes it would emphasise the importance of clear communication with patients, in light of the patient feedback received by the GDG, to substitute "is" for "should be" in this line.	Thus change has been made.
SH	13.6	Breakthrough Breast Cancer	Full guidel ine	59	31	It should be highlighted that patients frequently have different information needs and those involved in their care should be adequately prepared to meet these needs. Particularly important points are that written as well as verbal information should be available, as	We agree. The provision of written information is recommended on p66.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						people affected by breast cancer tell us that the distress associated with diagnosis can often result in information given at the time being forgotten.	
SH	13.7	Breakthrough Breast Cancer	Full guidel ine	61	22	It may be helpful to consider providing a definition of "urgent," in line with the approach taken to other similar recommendations made in the guideline.	We will define timelines in the final version of the guideline.
SH	13.8	Breakthrough Breast Cancer	Full guidel ine	66	32-43	Breakthrough supports the recommendations regarding the provision of information to patients in order to help ensure rapid presentation of symptoms. However, a key point, highlighted in section 3 of the draft guidelines, is that often GPs can have difficulty in identifying potential cases of MSCC, particularly while symptoms are at an early stage. Much of the patient testimony reproduced in the draft guidelines demonstrates the difficulty patients can experience in obtaining a correct diagnosis. It may therefore be appropriate to consider including an additional recommendation to the effect that GPs should also be provided with information on the signs and symptoms of MSCC and the identification of patients at risk, together with details of who to contact if they believe a patient may have the condition. Early detection and diagnosis is of paramount importance and educating GPs in this way may help to improve the speed of referral to secondary or tertiary services.	Thank you. We agree and think that the guideline is one of the tools to increase general awareness.
SH	13.9	Breakthrough Breast Cancer	Full guidel ine	74	31-32	It is not entirely clear from the context of this recommendation whether targeted CT scans should be offered to all patients requiring an assessment of spinal stability or surgery, or just those where MRI is contraindicated. The preceding paragraph refers only to patients in whom MRI is contraindicated but then concludes that the imaging technique used should be selected with the help of the relevant treatment centre. We would welcome clarity in the following paragraph as it is currently unclear as it does not specify a patient group.	We have changed the recommendation.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	13.10	Breakthrough Breast Cancer	Full guideline	84	3	Breakthrough strongly endorses the recommendation that patients be involved in decisions regarding their care.	Thank you.
SH	13.11	Breakthrough Breast Cancer	Full guideline	90	44	While the opinion of the team planning the treatment, and the surgeon in particular, will always be essential in deciding on the most appropriate course of treatment, patients should still be involved in these decisions where appropriate, for example in discussion surrounding risk. Spinal surgery can carry risks even for those patients whose functions are beginning to be impaired and it is important patients are able to assess the risks and benefits of the proposed treatment themselves, supported by comprehensive and independent information. The recommendation could be amended to reflect this need. A full understanding of risk and benefit is an important part of patient consent.	Patient wishes are now explicitly included. It is implicit within patient consent that a full understanding of risk and benefit is achieved.
SH	13.12	Breakthrough Breast Cancer	Full guideline	93	39	The views of the patient are essential to the planning of treatment and this should be reflected in the list of factors to consider. It is important to recognise that some patients with late-stage metastatic disease who are otherwise fit for surgery may choose not to undergo further invasive treatment that may impact negatively on their quality of life and may wish instead to only receive palliative therapy.	Thank you for your comment. We have changed the recommendation.
SH	13.13	Breakthrough Breast Cancer	Full guideline	94	6-7	Breakthrough warmly welcomes the recommendation that treatment should not be denied on the basis of age alone.	Thank you.
SH	13.14	Breakthrough Breast Cancer	Full guideline	98	32-36	It is not clear whether the two factors listed in this recommendation are both required for emergency radiotherapy to be contraindicated, or whether the presence of only one is necessary. Clarity in this matter has important implications for the planning of patient treatment and the options available to different patient groups, and would therefore be welcome.	Thank you. We have changed the recommendation.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	13.15	Breakthrough Breast Cancer	Full guideline	123	6-9	The recommendation to offer referral to community-based rehabilitation and supportive care services to patients is positive, as this has the potential to help patients maximise their functional independence and the benefits gained from treatment. However, in order for this to be fully effective, referrals should be offered (and made where patients request a referral) as part of the discharge planning process before patients leave hospital, rather than following discharge as is currently recommended. This should help to minimise the time between being discharged from hospital and receiving community support and could help patients to make the transition from hospital to community-based care as quickly and smoothly as possible. It will also help to join up care and prevent referrals being missed, by helping to ensure that responsibility for making the referral lies with the secondary care team. To leave the referral process until after discharge risks responsibility falling between primary and secondary care and thus becoming the responsibility of neither.	Thank you. The recommendation has been changed.
SH	14.0	Breast Cancer Care	Full version	General		Breast Cancer Care is aware that patients with metastatic breast cancer of the bones involving the spine are a large population at risk of spinal cord compression and therefore, on behalf of these patients, we welcome this important comprehensive set of guidelines.	Thank you.
SH	14.1	Breast Cancer Care	Full version	47	41-43	We welcome the recommendation that Cancer Networks should ensure that there is access to urgent MRI for all patients with suspected metastatic spinal cord compression and that this service should be available outside normal working hours.	Thank you.
SH	14.2	Breast Cancer Care	Full version	49 and 50	2 and 44-46	We very much welcome the recommendation of the creation of the role of MSCC coordinator and the recommendation that the optimal care of patients with MSCC should be decided by senior professional	Thank you.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						advisers (SPA).	
SH	14.3	Breast Cancer Care	Full version	53	16-17	Given that GPs might be the first contact point for patients with suspected metastatic spinal cord compression and that there appears to be a lack of GP awareness of its signs and symptoms, it is important that there is a more comprehensive information tool available for GPs alongside the brief information given in the suggested information leaflet.	We agree and think that the guideline is one of the tools to increase general awareness.
SH	14.4	Breast Cancer Care	Full version	60	11-17	We welcome the emphasis given to the significant psychological distress MSCC can cause for patients and their families and carers.	Thank you.
SH	14.5	Breast Cancer Care	Full version	66	32-36	We welcome the recommendation of the creation of an information leaflet. We would like to see the inclusion of guidance stating that written information must be accompanied by a verbal explanation of metastatic spinal cord compression and that the patient must be given a contact number in case of any further queries. It is also important that this information is given in context of the implications of the overall diagnosis with other relevant information about metastatic cancer of the bones.	Thank you – we agree. We have amended the recommendation to include verbal and written information.
SH	14.6	Breast Cancer Care	Full version	122	41-44	We welcome the recommendation that discharge planning and ongoing care for patients with MSCC should be led by a named individual from within the responsible clinical team.	Thank you.
SH	15	Brighton & Sussex University Hospitals Trust				This organisation was approached but did not respond	
SH	16	British Association of Day Surgery				This organisation was approached but did not respond	
SH	17.0	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	47	33	Suggest NICE collaborate with Scottish National MSCC group who have developed a core minimum data set	Thank you we will pass this comment on to the implementation team.
SH	17.1	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	General		No mention of trying to obtain tissue diagnosis in patients not previously known to have cancer before starting RT...this is important so we don't miss a plasmacytoma which gets a much higher dose	We feel this issue is addressed by the recommendation on p93, lines 13-14, which has been amended to explicitly include vertebral biopsy.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	17.2	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full versio n	General		Use of surgery mainly restricted to single level in patients with good prognosis - not sure it explicitly states this - the Patchell trial took several years to recruit even for a small trial so they must have been very highly selected	The GDG agrees that it is this group of patients who are most likely to benefit from surgical intervention and we feel that we have defined them appropriately. Staging of tumours and performance status of patients are important determinants of appropriate care.
SH	17.3	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full versio n	General		There's an awful lot of surgery in document which will stretch the service, and may be inappropriate in many cases. There needs to be more emphasis on considerations of prognosis before this course of action. The median survival for patients with lung cancer and MSCC is less than 3 months, and intervening to improve the management of MSCC will improve quality of life not prognosis.	This guideline is to improve the service for patients who would otherwise become paraplegic with the intention of improving quality of life. Selection for surgery is complex, as described in recommendations (p 88-97) and includes senior professional advice, and excludes those with poor prognosis. Surgery is not appropriate for patients with limited or poor prognosis and this is supported by the health economic evaluation. Information about the importance of palliative care and recommendations for palliative care are in chapter 7.
SH	17.4	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full versio n	68	25	Suggest it might be useful to define what is meant by radicular pain or add glossary	We have added radicular pain to the glossary.
SH	17.5	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full versio n	7 and 47	8 and 38	Suggestion pathway should include out of hours pathway if different to in hours	Pathway includes contact with MSCC co-ordinator who provides 24hr point of first contact p8 15-16.
SH	17.6	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full versio n	9 and 61	23 and 32	Suggestion would be to change 'before any neurological deterioration' to 'before any further neurological deterioration'	We do not think that using the term "further" is appropriate because this implies potential acceptance of significant neurological compromise which would require earlier intervention."
SH	17.7	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full versio n	9 and 66	32 and 37	Suggest they are also given an information leaflet with contact details should they develop symptoms	We have combined this recommendation with the previous one so that patients with cancer who present with spinal pain are also given an

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
							information leaflet.
SH	17.8	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full versio n	13 and 85	16 and 30	Suggest it might be useful to define what spinal shock means or add to a glossary	We will add this to the glossary.
SH	17.9	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full versio n	13 and 85	19 and 33	Cost/resource implications for physiotherapists spending 4h with patients as they gently mobilise from flat to semi-sitting. Where will they come from?	Continuous monitoring is not required. The recommendation requires return to recumbancy if there is adverse change.
SH	17.10	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full versio n	13 and 85	10 and 23	Is there any evidence for log-rolling etc or against mobilisation. Since MCC is common in lung cancer pts who are already highly pro-thrombotic extra bedrest would be a concern.	Immobility is brief and intended to protect against unnecessary spinal cord damage until stability can be assured.
SH	17.11	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full versio n	13 and 86	28 and 40	Suggest "unless contraindicated" or similar caution be added Also consider "ensuring last dose given before 6pm to avoid sleep disturbance ". Pts who experience this side effect can become extremely distressed.	We have made this change. The recommendation states 16mg of dexamethasone daily. Dose fractionation and timing is not discussed. This is intended as a short course to protect cord and can be given in single daily dose.
SH	17.12	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full versio n	13 and 86	32 and 43	Suggest adding "reduced and stopped as appropriate in each case"	We feel that the text is adequately descriptive as is.
SH	17.13	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full versio n	16 and 103	32 and 22	Ref to 100Gy is wrong this is a BED not an absolute dose	Thank you for noting this we will correct the text to read "$100Gy_2$".
SH	17.14	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full versio n	18 and 121	22 and 2	Suggestion would be to include assisted ventilation as appropriate	Supplementary ventilatory support is part of this recommendation.
SH	17.15	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full versio n	61	21	Suggest it might be useful to define what is meant by spinal nerve root pain or add glossary	Included to glossary.
SH	17.16	British Association of	Full	32	1/2/3/	Question – In what circumstances would someone	When MRI demonstrates unsuspected extensive

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		euroscience Nurses and NHS Lothian (SCAN)	version		4	have an + MRI and then be discharged to supportive care? If not fit for treatment after MRI one questions were they fit for it in the 1st instance	spinal involvement.
SH	17.17	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	32	1/2/3/4	Suggest box's post positive MRI could be condensed into 1 – Referred to most appropriate centre for RT, RX, Surgery	We agree and will combine the boxes.
SH	17.18	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	32	1/2/3/4	Suggest line between Positive MRI and co-ordinator	We will make this change.
SH	17.20	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	32	1/2/3/4	Suggest definition in box of what signs and symptoms would suggest suspected MSCC	This is too much detail for an algorithm and is covered in the main text of the guideline.
SH	17.21	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	33	10/11	Suggest definition in box of what signs and symptoms would raise clinical suspicion	This is too much detail for an algorithm and is covered in the main text of the guideline.
SH	17.22	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	34	1 / 1) 2	No diagram	This will be corrected.
SH	17.23	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	33	1-54	This flowchart has pts lying flat having had dex then in last box suggests admission may not be felt appropriate straight away which for the patient may be very confusing and frightening	This algorithm leads to contact with the MSCC co-ordinator, further evaluation and further treatment. The order of the pathways will be revised.
SH	17.24	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	34	Box 1 If working box's top down then clock wise	Suggest this should be suspected unstable MSCC then define what unstable is If early symptoms and suspected MSCC but pt walking unaided should we really lie them flat?	We will discuss this with the GDG and change where appropriate.
SH	17.25	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	34	Box 2	Huge implications to log roll properly i.e at least 5 staff in addition the anxiety this is likely to cause a pt whose prognosis is probably limited is enormous	We will discuss this with the GDG and change where appropriate.
SH	17.26	British Association of	Full	34	Box 4	How will stability be assessed?	We will discuss this with the GDG and change

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		Neuroscience Nurses and HS Lothian (SCAN)	version			Diagram suggests that if spine is stable then no treatment is given?	where appropriate.
SH	17.27	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	34	Box 6	Guideline has already recommended on pg 32 that dexamethasone only be started if pt has pain and neurological symptoms	We will discuss this with the GDG and change where appropriate.
SH	17.28	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	34	Box 7	How is stability assessed?	We will discuss this with the GDG and change where appropriate.
SH	17.29	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	34	Box 9	Don't understand this box re spinal shock which by definition is "state of transient physiological (rather than anatomical) reflex depression of cord function below the level of injury with associated loss of all sensory motor functions" Up to 60% over 4 hours has manpower implications	We will discuss this with the GDG and change where appropriate.
SH	17.30	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	36	All	Group unsure how common this is in MSCC and has never been seen by any specialists in our group in relation to MSCC Implications if this is common or has a high risk of happening is we need to include in education for healthcare professionals, pts and carers on discharge	We will remove this algorithm from the NICE version and only include it as an appendix to the full version of the guideline.
SH	17.31	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	143		Agree raising awareness. A written document for patients and carers (and health care professionals) would be useful, but message should be cancer suspicion and radicular pain = MRI; we still see many patients whose first presentation of cancer is paraplegia however broader criteria here might apply in a system with excess MR capacity, but will break ours and might delay the diagnosis of patients who really do have MSCC.	This s only an example and can be adopted by local service providers.
SH	17.32	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	47	43	Suggest 'as appropriate' be added to the sentence	This is adequately addressed in text and this addition is not necessary. Treatment centres should provide 24/7 access. Acute hospitals should extend days if necessary.
SH	17.33	British Association of Neuroscience Nurses and	Full versio	48	1	Network site specific group would be difficult due to nature of range of cancers MSCC affects. Suggest it	It is recommended that the NSSG includes primary site champions.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		NHS Lothian (SCAN)	n			be part of the site specific groups in the form of a champion within the group	
SH	17.34	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	49	36 - 38	' As well as ensuring that patients requiring emergency admission are admitted in a timely manner, the coordinator will help to avoid inappropriate transfer of frail symptomatic pts at unsuitable times' The NICE (short) version fails to emphasise that it is not always suitable to transfer pts out of hours whilst this sentence covers it well	We have inserted a new recommendation on this into chapter 6.
SH	17.35	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	53	25 – 29	Would suggest these are more late than early symptoms	This list has been deleted.
SH	17.36	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version			Is it possible to get a copy of letters sent out to patients with the view to reproducing it in a Scottish population	We will forward a copy to you.
SH	17.37	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	60	26-27	Suggest guideline recommends/suggests a validated tool to assess distress	We have re-worded the recommendation and this comment no longer applies.
SH	17.38	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	61	22	Word urgently means different timescales in different areas suggest it should be 'the same day' or 'within 24 hours'	We will define timelines in the final version of the guideline.
SH	17.39	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	61	28-30	MRI out of hours would only be considered if treatment was also planned out of hours in our health board suggest adding in 'if condition dictates' or 'if appropriate'	Emergency MRI leading to treatment must be available 24h per day. Urgent MRI may be appropriately scheduled. We will define timelines in the final version of the guideline.
SH	17.40	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	66	37-39	Suggest pts should be given leaflet as in 1)32	We have combined this recommendation with the previous one so that patients with cancer who present with spinal pain are also given an information leaflet.
SH	17.41	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	68	22	Spinal pain aggravated by straining would benefit from definition e.g. coughing, sneezing	The GDG considers that straining is a term in common use. We have amended the recommendation to include examples.
SH	17.42	British Association of	Full	68	17	Like the way urgent is followed by (within 24 hours)	Thank you.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		Neuroscience Nurses and NHS Lothian (SCAN)	version				
SH	17.43	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	76	General	Suggest surgery 1st choice of treatment for a small number of pts In Scotland this is only considered suitable for a small cohort of pts	The guideline is intended to decrease the number of patients ending their lives paraplegic.
SH	17.44	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	74	4	Agree access to MRI scanning earlier on in the staging of patients rather than the use of isotope bone scanning would help in the prevention of MSCC and in its earlier diagnosis. Treating asymptomatic bone mets when the appearances on imaging suggest that the risk of MSCC is high.	Thank you. We have not made a recommendation to treat asymptomatic metastases or perform bone scans.
SH	17.45	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	79	42	The data on use of 8Gy in paralysed patient, though sensible is only based on retrospective series and a Ph 3 trial is planned so not sure advice should be so prescriptive	This recommendation is for the treatment of bone pain not for treatment of MSCC, and is based on a reasonable body of evidence. The current RCT is for treatment of MSCC.
SH	17.46	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	85 - 86	21-46 1-19	Recommendation to lie pts flat as soon as MSCC is suspected has huge implications for resources medical, nursing, AHP's and does not take into consideration the patients who present/detected early and is surprising given the lack of evidence and the findings from the Peace et al study Again gradual sitting over 3-4 hours will have impact of resources (most units will not have physio input for this amount of time) Interestingly the West of Scotland Cancer Network guidelines are due to be audited which will disclose if this is a sustainable practice Suggest decision to lie pt flat should be made according to patients condition in that if they are walking unaided with no signs of instability (would need defined) then pts position should be dictated by what is comfortable to them	We agree. Caution is only required if stability is questioned and until stability is assured. The algorithm and guideline will be amended to demonstrate that only those with threatened spinal cord function are required to be treated in this way until neurological safety is ensured. Constant supervision by physio was not intended The recommendation has been changed to require only interval assessment.
SH	17.47	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	84	General	No recommendation for referral to Occupational therapy which is just as important in the late presenting pt	This section is about the definitive treatment of MSCC. OT etc included in chapter 7.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	17.48	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	84	84	Suggest advice on use of hard collars for unstable necks.	These are not recommended.
SH	17.49	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	86	40	Suggest "unless contraindicated" should be added No allowance for the early presenting/detected pt who is mobile, investigated, diagnosed and treated within 24-48 hours	We have changed the recommendation.
SH	17.50	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	87	7	Suggest other side effect monitored such as mania, depression and sleep disturbance	Blood glucose is monitored because it can't be seen. The other side effects of dexamethasone are apparent. It is intended that this only be a short course to limit side effects. Therefore the recommendation is appropriate as is.
SH	17.51	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	88	38	Suggestion would be that pts with MSCC should be discussed with neurology surgeon	This is already covered by previous recommendations.
SH	17.52	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	118	5 – 6	Suggest pts who are unable to pressure relieve should only sit out of bed for short periods in line with pressure ulcer protocols	We have changed the recommendation.
SH	17.53	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	118	43 – 45	As no evidence reported in guideline group unsure how common autonomic dysreflexia is in MSCC and has never been seen by any specialists in our group in relation to MSCC Implications if this is common or has a high risk of happening is we need to include in education for healthcare professionals, pts and carers on discharge	Thank you for your comment. We have removed this from the guideline.
SH	17.54	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	121	2 -6	Suggestion would be to include assisted ventilation as appropriate	Thank you. We have changed the recommendation.
SH	17.55	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	122	34 – 36	Reality in Scotland is that within SCAN (1 regional network) specialist rehabilitation has an age restriction as well	The GDG disagree with this. The guideline does not cover Scotland.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	17.56	British Association of Neuroscience Nurses and NHS Lothian (SCAN)	Full version	131	1 - 2	Unable to view figure 1	Thank you.
SH	18	British Association Of Spine Surgeons				This organisation was approached but did not respond	
SH	19	British Lymphology Society				This organisation was approached but did not respond	
SH	20	British National Formulary (BNF)				This organisation was approached but did not respond	
SH	21	British Neuro Oncology Society (BNOS)				This organisation was approached but did not respond	
SH	22.0	British Nuclear Medicine Society	Full version		General	There is no mention of nuclear medicine in the initial diagnosis of MSCC and I think that this is appropriate.	Thank you
SH	22.1	British Nuclear Medicine Society	Full version	93	22	Extent of metastases – no specific imaging is mentioned but I think the role of radio-isotope scanning is minimal if at all. MRI would give the extent of vertebral metastasis and whole body CT would stage visceral disease and also allow assessment of the spine if MRI was contraindicated.	Radio-isotope scanning is mentioned on p 74, lines 4-6 but is not recommended.
SH	23	British Paramedic Association				This organisation was approached but did not respond	
SH	24	British Society of Interventional Radiology				This organisation was approached but did not respond	
SH	25	British Society of Neuroradiologists				This organisation was approached but did not respond	
SH	26	British Society of Rehabilitation Medicine				This organisation was approached but did not respond	
SH	27	British Society of Skeletal Radiology				This organisation was approached but did not respond	
SH	28	Calderdale PCT				This organisation was approached but did not respond	
SH	29.0	Cambridge University Hospitals NHS Foundation Trust	Full version	general		First I should like to congratulate the authors on making a substantial first step in improving the care of patients with MSCC. This is an impressive document which proposes a wide-ranging	Thank you.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						reorganisation of services and should see treatment improve and become more timely for these patients.	
SH	29.1	Cambridge University Hospitals NHS Foundation Trust	Full version	general		A weakness is the fact that there is reference to timeliness with the statement 'ideally within 24 hours of first presentation' but it is not make explicitly clear to whom this first presentation is. It is the GP, secondary care, or to an oncologist. I believe this it should be made clear that this refers to the first clinical presentation whether it be to primary or secondary care.	We have amended the recommendation.
SH	29.2	Cambridge University Hospitals NHS Foundation Trust	Full version	general		The need to establish a diagnosis is nowhere specified in this document. It identifies that 23% of patients have no pre-existing malignant diagnosis and clearly in them there will be a need for a biopsy to establish their management at some point, and indeed this may be an indication for surgical intervention.	We feel this issue is addressed by the recommendation on p93, lines 13-14, which has been amended to explicitly include vertebral biopsy.
SH	29.3	Cambridge University Hospitals NHS Foundation Trust	Full version	general		The possibility that a patient with MSCC is actually presenting with a curable lymphoma is not considered in this document. This is a dangerous omission, following on from the failure to emphasise the need for a histological diagnosis. The difficulty is compounded by the advice to administer steroids without considering the histological diagnosis. Steroids can make histology uninterpretable if the patient has a lymphoma.	This occasional circumstance is acknowledged but the frequency with which this occurs is insufficient to justify specific recommendations within the guideline.
SH	29.4	Cambridge University Hospitals NHS Foundation Trust	Full version	4	7	Define within 24 hours of first presentation to any clinical care whether in the primary or secondary sector (medical, nursing or other).	We have amended the recommendation.
SH	29.5	Cambridge University Hospitals NHS Foundation Trust	Full version	4	21	Add: pain radiating from the back around the thorax or abdomen.	We think this is encompassed within the term "radicular pain" but will include your text in the glossary definition for this term.
SH	29.6	Cambridge University Hospitals NHS Foundation Trust	Full version	4	27	Add: severe axial pain made worse by standing/movement and relieved by lying down "instability pain".	We feel this is addressed adequately in recommendation 7 (lines 32-37).
SH	29.7	Cambridge University	Full	4	30	Treatment should be undertaken within 24 hours not	Currently the management of patients with MSCC

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		Hospitals NHS Foundation Trust	version			merely planned.	takes between 6 weeks and 9 months. The guideline is attempting to limit the time this process takes by advising optimal timescales, all of which should be completed prior to neurological deterioration.
SH	29.8	Cambridge University Hospitals NHS Foundation Trust	Full version	5	4	Surgery should be planned to decompress the spinal cord and maintain or restore spinal stability.	We are not sure what this comment is referring to. We have amended the recommendation.
SH	29.9	Cambridge University Hospitals NHS Foundation Trust	Full version	5	7	It is unclear what this reference to 'daytime out of hours facility' means	We have changed this to "…daytime, 7 days a week…"
SH	29.10	Cambridge University Hospitals NHS Foundation Trust	Full version	6	20	Consider adding investigation of the role of bisphosphonates in the prevention of MSCC?	We are restricted to 5 key research recommendations. However we do have research recommendation to this effect on p79.
SH	29.11	Cambridge University Hospitals NHS Foundation Trust	Full version	9	17	I fully support displacement of routine patients to allow MRI of the patients with MSCC. You suggest displacing them to later in the day and making everyone else wait longer. The alternative would be to cancer one or two non urgent patients. I have never understood why this is not done (as it is common for surgery) and I would recommend it as an alternative	Thank you we agree and we have changed the recommendation to include alternative sessions.
SH	29.12	Cambridge University Hospitals NHS Foundation Trust	Full version	9	24	Within 24 hours of first presentation to any clinical care whether in the primary or secondary sector (medical, nursing or other).	Currently the management of patients with MSCC takes between 6 weeks and 9 months. The guideline is attempting to limit the time this process takes by advising optimal timescales, all of which should be completed prior to neurological deterioration.
SH	29.13	Cambridge University Hospitals NHS Foundation Trust	Full version	10	35	Change the wording to 'within 24 hours of presentation to any clinician'. Introducing a new term suspected diagnosis will create muddle	Currently the management of patients with MSCC takes between 6 weeks and 9 months. The guideline is attempting to limit the time this process takes by advising optimal timescales, all of which should be completed prior to neurological deterioration.
SH	29.14	Cambridge University Hospitals NHS Foundation	Full versio	11	22	There is a whole chapter missing here on establishing a diagnosis. Patients with pre-existing	We have made the requirement for diagnostic biopsy more apparent in the recommendations.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		Trust	n			malignancy are usually considered to have metastatic disease but even here if there is a very long interval from the primary diagnosis it will be prudent to insist on re-biopsy. My main concern is with the 23% of patients identified in this report as not having pre-existing malignancy. It is indeed possible that they do not have malignancy at all. They might rarely have another diagnosis, for example tuberculosis. A new section should include the need to consider to determine what the histological diagnosis is if it is not known previously. If a patient has metastatic disease in other sites then one of these can be biopsied after treatment of the spinal cord compression. It is particularly important to consider lymphoma here as spinal cord compression can be part of the curable presentation in these diseases. Similarly it is essential to ensure that steroids are not given before biopsy as they can make the material un-interpretable. I recommend a new chapter on this issue.	
SH	29.15	Cambridge University Hospitals NHS Foundation Trust	Full version	Page 13	Line 29	As soon as possible after assessment, once due consideration has been given to the nature of the histological diagnosis and the possible need for biopsy.	The issue of timing is contentious for the rare case of epidural lymphoma. We have added text to cover this. We have also included the need for biopsy in recommendation p93, lines 13-14.
SH	29.16	Cambridge University Hospitals NHS Foundation Trust	Full version	15	10	Anterior surgery should be considered not "performed" Properly planned and executed posterior stabilisation can last indefinitely in selected patients Mannion et al Br j of Neurosurg 2007 21:565-570	We will make this change.
SH	29.17	Cambridge University Hospitals NHS Foundation Trust	Full version	16	12	I do not understand what 'including daytimes out of hours facilities' actually means	We have changed this to "…daytime, 7 days a week…"
SH	29.18	Cambridge University Hospitals NHS Foundation	Full versio	16	32	The statement 'biologically equivalent dose of 100Gy' is incorrect. The key reference has been quoted in	Thank you for noting this we will correct the text to read "100Gy_2".

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		Trust	n			your document (Rades et al, IJROBP, 2006). The correct dose is $100Gy_2$ (with subscript 2) which means equivalent dose in 2Gy fractions.	
SH	29.19	Cambridge University Hospitals NHS Foundation Trust	Full version	67	17	The fact that 23% of patients with MSCC have no prior cancer diagnosis is not adequately dealt with in this guideline. There needs to be a new section on how to establish the diagnosis in these patients and the essential role of biopsy in their management.	The absence of primary malignant diagnosis is referenced 3 times within the guideline (p 38, line 33; p 67, line 17 and p73, line 16). We acknowledge the increased difficulty in making this diagnosis in the 1 in 4 patients who present without a prior cancer diagnosis. The recommendation on p93, lines 13-14, has been amended to explicitly include vertebral biopsy.
SH	29.20	Cambridge University Hospitals NHS Foundation Trust	Full version	76	37	The first essential element of treatment planning is to establish a histological diagnosis by biopsy if necessary.	Thank you for your comment. we have changed the recommendation.
SH	29.21	Cambridge University Hospitals NHS Foundation Trust	Full version	84	30-41	I find this section muddled. It refers to radio-resistant tumours but does not define which they are other than to say that surgery is the treatment of choice for them. As discussed elsewhere there is moderately good evidence that outcomes are improved by having surgery before radiotherapy in suitable cases. This is the evidence base and it should be stated at this point. Rather than referring to radio-resistant tumours it would be more helpful to refer specifically to identified radio-sensitive tumours such as myeloma, and lymphoma (not mentioned at all) which are probably best managed by radiotherapy unless there is spinal instability. Breast and prostate cancer should be at least considered for surgery. Lung cancer also needs to be mentioned in the review as does bowel cancer. It is also possible to manage lymphoma with initial chemotherapy. This has been completely omitted. These two paragraphs need completely redrafting.	The term "radio-resistant tumours" has been deleted. The backgrounds for sections 6.1 and 6.2 have been amended to include haematological malignancies.
SH	29.22	Cambridge University	Full	86	26	Corticosteroids have an important role but should not	Benefits of steroids for the majority of patients with

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		Hospitals NHS Foundation Trust	version			be given if a histological diagnosis has not been established either in the past or at this presentation. Lymphoma is a curable condition and needs to be histologically diagnosed before steroids are given. This should be emphasised at this point.	spinal cord compression by solid tumour, outweighs the potential detriment for the small group with cord compression associated with lymphoma. The recommendations have been changed to include histology. Timelines for steroid treatment will be considered.
SH	29.23	Cambridge University Hospitals NHS Foundation Trust	Full version	86	39	Suggest adding a new bullet point 'before steroids are given a histological diagnosis must have been established by biopsy either at this presentation or previously.	Benefits of steroids for the majority of patients with spinal cord compression by solid tumour, outweighs the potential detriment for the small group with cord compression associated with lymphoma. It is unreasonable to expect all patients to be denied steroids at risk of irretrievable neurological loss whilst biopsy is performed. The background and recommendations have been changed to emphasise the importance of histology and especially in the small number of patients where prior steroids might jeapordise diagnosis. Corticosteriods also have a role in the primary treatment of myeloma and lymphoma. However, steroids may impair the histological diagnoses of lymphoma. Timelines for steroid treatment will be considered.
SH	29.24	Cambridge University Hospitals NHS Foundation Trust	Full version	103	23	The statement 'biologically equivalent dose of 100Gy' is incorrect. The key reference has been quoted in your document (Rades et al, IJROBP, 2006). The correct dose is $100Gy_2$ (with subscript 2) which means equivalent dose in 2Gy fractions. In addition, that paper made no assumptions about recovery after the previous course and included	We will correct this.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						patients treated at an interval of 2-40 months.	
SH	29.25	Cambridge University Hospitals NHS Foundation Trust	Full version	141	20	It is unclear to me why non-urgent patients cannot simply be cancelled. The suggestion seems to be to make the whole list run late whereas cancelling a couple of patients might be a simpler solution. Cancellation at the last minute is not uncommon in surgery. Patients should be warned of the possibility.	The recommendation has been altered to reflect this point .
SH	29.26	Cambridge University Hospitals NHS Foundation Trust	Full version	143		This patient information sheet is offered as an example but I find it inadequate. I attach separately a document which we have used within the West Anglia cancer network for five years. It was intended for patients with known bone metastases, but even then it has proven difficult to get staff to issue it to patients. This will be an issue for you as well.	Thank you for submitting the document used within the West Anglia network. The GDG were happy with the example in the guideline, which can be adapted or developed by local service providers.
SH	29.27	Cambridge University Hospitals NHS Foundation Trust	Full version	143	16	Pain can also radiate round the abdomen and down the arms and down the legs.	This s only an example and can be adopted by local service providers.
SH	29.28	Cambridge University Hospitals NHS Foundation Trust	Full version	143	20	This advice is disingenuous. It is not useful to advise patients to speak to a clinician as soon as practical (certainly within 24 hours). We want them to act more rapidly. The consequences of not doing so should be more clearly spelt out – see attached WACN information sheet.	This s only an example and can be adopted by local service providers.
SH	30	Cancer Research UK				This organisation was approached but did not respond	
SH	31	Cancerbackup				This organisation was approached but did not respond	
SH	32	Cardiothoracic Centre - Liverpool NHS Trust				This organisation was approached but did not respond	
SH	33	Chartered Society of Physiotherapy				This organisation was approached but did not respond	
SH	34.0	College of Occupational Therapists	Full version	5 and 122	8 and 41	Rehabilitation is an essential priority at this stage. Suggests reads: *Rehabilitation, discharge planning and ongoing care for patients with MSCC should start….*	We have amended the text to include "rehabilitation".

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	34.1	College of Occupational Therapists	Full versio n	5 and 122	8 and 41	Need to define the term '*early'*. Suggests reads: …*should start upon admission…*	We changed the text to "…should start on admission…"
SH	34.2	College of Occupational Therapists	Full versio n	7 and 47	7 and 33	Will there be a specific prospective audit tool?	Creating an audit tool is not within the remit of the GDG but a tool is under discussion with the NICE implementation tool and the Cancer Intelligence Unit.
SH	34.3	College of Occupational Therapists	Full versio n	8 and 48	8 and 33	Should add rehabilitation at this stage, as many social services are reluctant to provide rehabilitation to such patients, particularly if rehab is viewed in the traditional and simplest sense of maybe walking again.	We have changed the text to read "…ensure efficient provision of equipment, and support including nursing and rehabilitation services to meet the…"
SH	34.4	College of Occupational Therapists	Full versio n	9 and 60	3 and 21	Concerned about the term '*end of rehabilitation*' as according to Dietz (1980) this can be ongoing even throughout the palliative and end-of-life stages.	We have changed the text to read "during treatment"
SH	34.5	College of Occupational Therapists	Full versio n	10 and 66	1 and 41	Need to clarify the difference between the spinal pain referred to here and the pain that is described under the '*Early Detection'* sections.	This information is appropriate for any patient with cancer who develops any kind of spinal pain. It is not specifically intended for patients with pain indicative of early metastatic spinal cord compression.
SH	34.6	College of Occupational Therapists	Full versio n	10 and 67	4 and 14	Would such patients not be admitted to hospital, as MSCC is '*oncological emergency*'?	These early symptoms are indicative of spinal metastases but not neurological disability and do not constitute an oncological emergency.
SH	34.7	College of Occupational Therapists	Full versio n	10 and 68	9 and 16	Should it not be stated that these patients are viewed as an '*oncological emergency*'?	These early symptoms are indicative of spinal metastases but not neurological disability and do not constitute an oncological emergency.
SH	34.8	College of Occupational Therapists	Full versio n	13 and 85	11 and 23	Suggest add about consulting carers for issues where there may be other malignancies/metastases that affect cognitive ability.	This would apply to all recommendations throughout the guideline and we do not feel it warrants explicit mention here.
SH	34.9	College of Occupational Therapists	Full versio n	14 and 88	13 and 41	Should the 'ability to walk' be clarified, for example adding change in usual functional mobility?	Your point is noted. However the evidence points to "the ability to walk" being an important prognostic indicator and therefore we feel that the text should be kept as is.
SH	34.10	College of Occupational	Full	15 and	26	How will functional status be measured?	A variety of methods are available and in use. We

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		Therapists	version	93	and39		have not assessed all these potential methods and are therefore not able to recommend specific ones.
SH	34.11	College of Occupational Therapists	Full version	17 and 118	22 and 1	Consider making '*safe turning*' more specific – would the recommended method not be log rolling?	This recommendation does not address spinal instability. It recommends pressure relieving turns to prevent pressure sores.
SH	34.12	College of Occupational Therapists	Full version	17 and 118	24-27 and 8	Should specify patients must have stable spine to be sitting out and carrying out weight distribution activity	This is addressed in the section on mobilisation (chapter 6).
SH	34.13	College of Occupational Therapists	Full version	18 and 122	29 and 26	Consider other members of the multi-professional team such as speech and language therapy and dietetics.	We feel it would be inappropriate to list all of the potential AHPs that could be involved. We have amended the recommendation to refer to AHPs instead.
SH	34.14	College of Occupational Therapists	Full version	18 and 122	31 and 30	To be truly holistic and client centred, goals should be short and long term not just short-term.	We have deleted "short term".
SH	34.15	College of Occupational Therapists	Full version	19 and 122	2 and 41	Clarify term "*early*"	We have changed this to "on admission".
SH	34.16	College of Occupational Therapists	Full version	19 and 123	6 and 6	Consider adding that rehabilitation potential is based on feedback from the multi-professional team	We have changed the recommendation.
SH	34.17	College of Occupational Therapists	Full version	19 and 123	8 and 6	Add members of the multi-professional team.	We do not feel that this is necessary.
SH	34.18	College of Occupational Therapists	Full version	33	23-23	'Pain and Neurological Symptoms and /or Signs' consider changing to '*Pain and/or neurological symptoms/signs*'.	We have made this change.
SH	34.19	College of Occupational Therapists	Full version	35		Consider adding transfers to ongoing assessment box	We will discuss this with the GDG and change where appropriate.
SH	34.20	College of Occupational Therapists	Full version	49	35	Add rehabilitation.	The MSCC co-ordinators role is to organise pre-hospital care prior to diagnosis. Rehabilitation is inappropriate in this context.
SH	34.21	College of Occupational Therapists	Full versio	50	23	Need to define '*best supportive care'.*	We have removed the word "best".

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
			n				
SH	34.22	College of Occupational Therapists	Full version	54	29	"Difficulty with bladder and bowl control" Should read *"Difficulty with bladder and bowel control"*	This list has been deleted.
SH	34.23	College of Occupational Therapists	Full version	61	23	Concerned about the term "end of rehabilitation" as according to Dietz (1980) this can be ongoing even throughout the palliative and end-of-life stages	We have removed this in the revised recommendation.
SH	34.24	College of Occupational Therapists	Full version	123	9	'(*often small*)' although these gains may be perceived as small, they may have significant implications for quality of life and such gains are the subjective experience of the patient.	We agree that it is possible, but that does not change the implication of this nackground information.
SH	34.25	College of Occupational Therapists	Full version	123	26	Not all patients with MSCC will need to be seen by OT/PT, however referral should be early. Suggest "*All patients admitted to hospital with MSCC should have access to both physiotherapy and occupational therapy services for assessment, advice and rehabilitation and this should be an early referral".*	This recommendation has been changed.
SH	34.26	College of Occupational Therapists	Full version	123	26	Referral to AHPs should also include other disciplines such as speech and language therapy, dietetics, and social work.	We feel it would be inappropriate to list all of the potential AHPs that could be involved. We have amended the recommendation to refer to AHPs instead.
SH	34.27	College of Occupational Therapists	Full version	123	30	Goals should not only be short-term but long-term also.	The recommendation has been amended.
SH	34.28	College of Occupational Therapists	Full version	123	34	The term '*explored*' rather than '*offered'* may be more appropriate as there are very few inpatient rehabilitation units in the community and patients with cancer may not be given priority.	This is something that we are trying to change as a result of this guidance.
SH	34.29	College of Occupational Therapists	Full version	123	42	Clarify term '*early'* or replace with '*upon admission'.*	Thank you. The recommendation has been changed.
SH	34.30	College of Occupational Therapists	Full versio	123	43	Rehabilitation team should be included here.	Thank you. We have included rehabilitation team in the recommendation.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
			n				
SH	34.31	College of Occupational Therapists	Full version	184	19	Add 'multi-professional team' here.	We have not mentioned 'multi professional team' in the guideline and therefore cannot include a definition in the glossary.
SH	34.32	College of Occupational Therapists	Full version	186	28	Consider adding definition of '*supportive care*' here.	We will include a definition of supportive care in the glossary.
SH	34.33	College of Occupational Therapists	Full version	197	37	As a stakeholder organisation we would ask that you insert *College of Occupational Therapists* here.	We will include the College of Occupational Therapists as a stakeholder.
SH	35	Coloplast Limited				This organisation was approached but did not respond	
SH	36	Commission for Social Care Inspection				This organisation was approached but did not respond	
SH	37	Connecting for Health				This organisation was approached but did not respond	
SH	38	Conwy & Denbighshire Acute Trust				This organisation was approached but did not respond	
SH	39	David Lewis Centre, The				This organisation was approached but did not respond	
SH	40	Department for Communities and Local Government				This organisation was approached but did not respond	
SH	41.0	Department of Health	Full	General		This document appears to make the assumption that vertebroplasty / kyphoplasty is performed by surgeons in theatre, under X-ray control. We would query whether it would not be unusual for this to be done in an interventional suite by a radiologist.	We disagree that the guideline makes the assumption that vertebroplasty/ kyphopasty are performed by surgeons in theatre and assume that you are referring to the need for good access to spinal surgery. We have addressed this by inserting text into the background information. Facilities for spinal surgery are required for complications but the site in which these procedures are performed varies with local custom and practice and is continuing to evolve, with an increasing number conducted by interventional radiologists.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						"Plain radiology /plain imaging/ plain x-ray" are all terms, used in the document. We feel that it would be better to pick one term and use consistently, and would suggest "plain X-Ray".	We will standardise the text to refer to "plain X-ray" throughout.
SH	41.1	Department of Health	Full	General		Regarding the organisations invited to comment, we would recommend that the College of Occupational Therapists and the British Dietetic Association are included. We feel that in the future, it may be useful for NICE to invite comments from AHP professional bodies, via the AHP Federation.	The College of Occupational Therapists are registered stakeholders. We will pass the British Dietetic Association and AHP Federation onto NICE for consultation.
SH	41.2	Department of Health	Full	32		In our opinion, the flowchart on should say "therapy radiographer", as distinct from "diagnostic".	This is not a role envisaged to be performed by a "therapy radiographer".
SH	41.3	Department of Health	Full		Gloss ary	Radiograph : This definition appears to refer to film, with no mention of digital. We consider that this needs to be revised, as CR and DR imaging are now much more common than plain X-rays. Radiologist and radiographer: in our view, 'creating and interpreting' could be re-phrased as 'acquire and in some cases interpret'. The definition of the role of a dietitian is included, but there appears to be no reference to the role of a dietitian in the main body of the report. We feel that dietitians can play a key role in ensuring optimum nutrition, which can contribute to (for example) prevention of pressure sores. With regard to the definitions of certain categories, we would recommend that the following are more appropriate: Occupational therapists assess, rehabilitate and treat people, using purposeful activity and occupation to prevent disability, and promote health and	We have changed "Plain film" to "Plain X-ray". We have made this change. We have removed this term from the glossary as it does not appear in the main body of the text. We have inserted this definition.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						independent function. Physiotherapists assess and treat people with physical problems caused by accident, ageing, disease or disability, using physical approaches in the alleviation of all aspects of the person's condition. Diagnostic radiographers produce high quality images on film and other recording media, using all kinds of radiations. Therapeutic radiographers treat mainly cancer patients, using ionising radiations and sometimes drugs. They provide care across the entire spectrum of cancer services. Dietitians translate the science of nutrition into practical information about food. They work with people to promote nutritional well being, prevent food related problems and treat disease.	We have inserted this definition. We have inserted this definition. We are not including this definition as the guideline does not refer to therapeutic radiographers. See response above.
SH	42	Department of Health, Social Security and Public Safety of Northern Ireland				This organisation was approached but did not respond	
SH	43	Derby-Burton Cancer Network				This organisation was approached but did not respond	
SH	44	East & North Herts PCT & West Herts PCT				This organisation was approached but did not respond	
SH	122.0	East Lancashire PCT	Full	47	38	We have developed an integrated care pathway document from suspected diagnosis through to rehab, which is based on the Network Guidelines and is being piloted across sites from July. This could be adapted in line of the full guidelines when published and used as a national tool.	We will forward this information to our implementation team.
SH	45.0	Essex Cancer Network	Full Versi on	General		The document is quite confused about timing - patients are supposed to be discussed with an MSCC co-ordinator within 24 hours, imaged within 24 hours,	Currently the management of patients with MSCC takes between 6 weeks and 9 months. The guideline is attempting to limit the time this process

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						planned within 24 hours, definitive treatment started within 24 hours ... which do you mean?	takes by advising optimal timescales, all of which should be completed prior to neurological deterioration.
SH	45.1	Essex Cancer Network	Full Version	General		There is no evidence that early surgery is associated with a better outcome - in the Patchell study surgery was performed within 48 hours of presentation. This is big surgery that is best performed on planned lists where the ideal anaesthetic, surgical and nursing teams are available. It is standard for patients who are not progressing neurologically to be scheduled in this way. Implementation of a treat within 24 hours guideline (without evidence) could quite probably result in substandard surgical treatment.	There is considerable evidence that surgery prior to paraplegia improves functional outcome and quality of life. The timing of surgery is primarily dependant upon patients functional status which may permit extensive planning or require emergency surgery (see p89, lines 18-26).
SH	45.2	Essex Cancer Network	Full Version	61	32	1.2.3.4 does not make sense - MSCC is a neurological condition; it presents as a neurological deterioration. To state that treatment should always commence before this is ridiculous. If it is intended to promote prophylactic surgery it is at odds with the very sensible statement in 1.5.1.13.	Thank you. We have changed the recommendation.
SH	45.3	Essex Cancer Network	Full Version	84	8	In the section regarding surgical guidance 1.5.2... Many of the sections are strongly worded but to my mind controversial or in evidence free zones. For example - 1.5.2.19 represents a controversial personal opinion without evidence.	Evidence on MSCC is limited but where it exists it has been appraised and considered when developing recommendations. Where no evidence exists we have come to a consensus view amongst the whole GDG as to what should be recommended Recommendation 1.5.2.19 has been reworded to use the term "considered".
SH	45.4	Essex Cancer Network	Full Version	General		I'm afraid that the radiotherapy details are beyond my expertise but the rest of the document seems sensible and should aid all our attempts to promote prompt, specialised attention to metastatic spine disease.	Thank you.
SH	46	General Chiropractic Council					

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	129.0	Guy's and St. Thomas' NHS Foundation Trust	Full version, and Appendices to full version	85 'general'	23-28	It would be extremely helpful to have a definition of or reference to diagnosis of spinal stability. This is mentioned frequently as being important and affects both the nursing care and early mobilisation of the patient. Whilst all patients should have an MRI, has the work been undertaken to demonstrate that CT scan/X-Ray is required to determine stability? Could it be that the references that relate to CT scanning and X-Ray are pre-MRI? The cost in additional scanning and workload for spinal surgeons to review every patient to ensure spinal stability would be immense and possibly not possible in many institutions.	We agree. Caution is only required if stability is questioned and until stability is assured. A definition of spinal stability will be added to the glossary. CT only required after MRI if stability questioned or if vertebroplasty is being considered. This recommendation has been changed to reflect these issues. This is for local dissemination at cancer network level.
SH	129.1	Guy's and St. Thomas' NHS Foundation Trust	Summary	116	38	Anticoagulation – is there evidence for the need for this?	Yes. Please refer to NICE clinical guidelines on Venous thromboembolism (April 2007)
SH	47	Harrogate and District NHS Foundation Trust				This organisation was approached but did not respond	
SH	48	Health and Safety Executive				This organisation was approached but did not respond	
SH	49	Healthcare Commission				This organisation was approached but did not respond	
SH	50	Heart of England Acute Trust				This organisation was approached but did not respond	
SH	51	Help the Hospices				This organisation was approached but did not respond	
SH	52	Hove Polyclinic				This organisation was approached but did not respond	
SH	53	Humber and Yorkshire Coast Cancer Network				This organisation was approached but did not respond	
SH	54	Institute of Biomedical Science				This organisation was approached but did not respond	
SH	55	International Myeloma Foundation (UK)				This organisation was approached but did not respond	
SH	56	James Cook University				This organisation was approached but did not	

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		Hospital				respond	
SH	57	Johnson & Johnson Medical				This organisation was approached but did not respond	
SH	58	Kirklees PCT				This organisation was approached but did not respond	
SH	59	Leeds PCT				This organisation was approached but did not respond	
SH	60	Leicestershire Northamptonshire and Rutland Cancer Network				This organisation was approached but did not respond	
SH	61	Leukaemia Research Fund				This organisation was approached but did not respond	
SH	62	Liverpool PCT				This organisation was approached but did not respond	
SH	63	Marie Curie Cancer Care				This organisation was approached but did not respond	
SH	64	Medicines and Healthcare Products Regulatory Agency (MHRA)				This organisation was approached but did not respond	
SH	65	Medtronic Ltd				This organisation was approached but did not respond	
SH	66	Mental Health Act Commission				This organisation was approached but did not respond	
SH	67	Midlands Centre for Spinal Injuries				This organisation was approached but did not respond	
SH	68	National Cancer Network Clinical Directors Group				This organisation was approached but did not respond	
SH	69	National Patient Safety Agency (NPSA)				This organisation was approached but did not respond	
SH	70	National Public Health Service - Wales				This organisation was approached but did not respond	
SH	71	National Treatment Agency for Substance Misuse				This organisation was approached but did not respond	
NCC	133.0	NCC Acute Conditions	Full version	General		Thank you for giving the guideline development group for the NICE guideline on the prevention of Venous Thromboembolism for hospitalised patients, an	Thank you.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						opportunity to review this draft guideline. As we have not yet completed the review of the cost effectiveness for patients who have not undergone surgery we are unable to provide firm recommendations for VTE prophylaxis for this population. However, members the guideline group did wish to say that they thought the guideline was excellent in general and to make the following comments:	
NCC	133.1	NCC Acute Conditions	Full version	116	General	Although the need for further research is stated in many of the sections of the guideline it is not stated for VTE prophylaxis. We believe more research is needed for these patients.	We do not think VTE prophylaxis is likely to be a suitable topic for randomised research.
NCC	133.2	NCC Acute Conditions	Full version	116	General	The new ACCP guideline has now been published and contains some useful advice for this population (Geerts et al. (2008) Prevention of Venous Thromboembolism: American College of Chest Physicians Evidence Based Clinical Practice Guidelines (8th Edition). Chest; 133: 381-453)	Thank you for your suggestion, however, this guideline was published outside of our literature search times. It will be considered as part of the update of this guideline.
NCC	133.3	NCC Acute Conditions	Full version	116	General	Although we welcome the inclusion of section on the provision of prophylaxis for venous thromboembolism some members of the group did not think that it should be in the supportive care section. They felt that it should be within section 6 (Treatment strategies/selection).	We disagree. This is about general care of patients with disability rather than definitive care of MSCC.
NCC	133.4	NCC Acute Conditions	Full version	116	23	The ACCP guideline (p.422) comments that 'although the period of greatest risk for VTE following spinal cord injury is the acute phase, symptomatic DVT or PE and fatal PE also occurs during the rehabilitation phase'. It might be useful to have an equivalent statement in your guideline.	Thank you for your suggestion, however, this guideline was published outside of our literature search times. It will be considered as part of the update of this guideline.
NCC	133.5	NCC Acute Conditions	Full version	116	27	The ACCP guideline (p.422) 'If there are major concerns about bleeding at the injury site or elsewhere, mechanical thromboprophylaxis should be initiated as soon as possible after hospital admission	Thank you for your suggestion, however, this guideline was published outside of our literature search times. It will be considered as part of the update of this guideline.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						, and anticoagulation thromboprophylaxis should be started once the bleeding risk has decreased'. It might be useful to have an equivalent statement in your guideline	
NCC	133.6	NCC Acute Conditions	Full version	116	33-40	The group felt that the first two recommendations were slightly confusing as it read as though patients who undergo surgery should not get mechanical prophylaxis. NICE guideline 46 (VTE prevention in surgical inpatients) recommends that patients receive both mechanical and pharmacological methods, and it is the opinion of members of the guideline development group that immobile patients admitted to hospital not undergoing surgery are still at high risk and should receive both methods. We suggest rewording: 'Unless contraindicated, all patients with MSCC admitted to hospital who are immobile or who are undergoing surgery should have: • Thigh length graduated compression/antiembolism stockings and /or intermittent pneumatic compression or foot impulse devices; and • Subcutaneous thromboprophylactic dose low molecular weight heparin, once primary haemostasis is evident. In patients who have undergone surgery this should be given 24 hours after surgery. The group member suggesting 'primary haemostasis' meant that clinical testing should show that the bleeding risk is low.	Thank you for your comment. We have changed the recommendation.
NCC	133.7	NCC Acute Conditions	Full versio	116	33	The group were concerned that 'immobility' had not been well defined and it was not clear why a three	Thank you for your comment. We have changed the

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
			n			day cut off for immobility was chosen. We would welcome help in defining this term.	recommendation.
NCC	133.8	NCC Acute Conditions	Full version	116	42	The group though that the final recommendation could include more scope for continued use of prophylaxis in this high risk population by rephrasing: • For patients with MSCC the duration of thromboprophylaxis should be individually assessed, and continuous use considered, based on the presence of ….'	There is no evidence to support any particular time period.
Peer Reviewer	72.0	NCCHTA (1)				Please comment on the validity of the work i.e. the quality of the methods and their application (the methods should comply with NICE's Guidelines Manual available at http://www.nice.org.uk/page.aspx?o=guidelinesmanual).	
Peer Reviewer	72.1	NCCHTA (1)	Full	24	25	In considering only published or accepted papers this review may be affected by "publication bias". This is to some extent unavoidable but the issue nevertheless should be acknowledged and discussed. Some comment as to the number of negative, positive and/or equivocal studies published may be sufficient. Publication bias is more of a problem in some research areas than others.	Refer to NICE technical manual which describes in detail the methodology that is used to develop NICE clinical guidelines.
Peer Reviewer	72.2	NCCHTA (1)	Full	16	26	I was a little surprised that the selection of papers for inclusion, critical appraisal and grading appears to have been done by one person. It is usual for at least a subset to be independently assessed in order to minimise potential bias.	The NICE Guideline programme at the NCC-Cancer designates one reviewer per guideline with a random sample of questions and studies reviewed by another reviewer. We acknowledge the deficiencies with this action.
Peer Reviewer	72.3	NCCHTA (1)	Full	25 - 35	26	I found this section a bit confusing. It read to me as though the full papers were critically appraised using some appraisal checklist (unspecified) and later graded in accordance with Table A. If this was so, it would be helpful to state which appraisal checklist was used. There are a number available but they vary in quality and appropriateness for use in this context. If the appraisal and grading were both	Refer to NICE technical manual which describes in detail the methodology that is used to develop NICE clinical guidelines.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						carried out using the SIGN checklist then this should be clarified.	
Peer Reviewer	72.4	NCCHTA (1)	Full	25 - 35	26	Personally, I would have preferred it if the critical appraisal had been carried out using the CONSORT checklists because these are, I believe, more detailed and more widely used, but the use of SIGN may be equally valid. The level of evidence, per Table A, is not the only outcome though. The critical appraisal information and level of evidence ought to have to be reviewed together to come up with an overall grade of recommendation (per the Sign 50: A guideline developer's manual http://www.sign.ac.uk/guidelines/fulltext/50/annexb.html).	Refer to NICE technical manual which describes in detail the methodology that is used to develop NICE clinical guidelines.
Peer Reviewer	72.5	NCCHTA (1)	Full	25 - 35	26	This is not mentioned here, which is quite a major omission. The grades of recommendation aren't reported either, in the qualifying statements and I feel, if done, they should have been.	Refer to NICE technical manual which describes in detail the methodology that is used to develop NICE clinical guidelines. NICE does not grade its recommendations.
Peer Reviewer	72.6	NCCHTA (1)				Please comment on the health economics and/or statistical issues depending on your area of expertise.	
Peer Reviewer	72.7	NCCHTA (1)	Full	43 – 46	40	I am not surprised at the low response rate to this questionnaire but it does undermine my confidence in the information obtained somewhat, particularly from the spinal surgery and palliative care units. The considerable number of respondents that were unsure in some areas adds to my concern. I have not reviewed the economic evaluations fully, as that is not my area of expertise, but I would hope that any costings based on the service provision information fully incorporates this uncertainty.	Costings were not based on service provision but on the cost per treatment for patient populations appropriate for treatment using published evidence of outcome. Although the response rate was low we are confident that these data are fairly representative of the service as a whole. All these data was sent to the health economists working on this guideline.
Peer Reviewer	72.8	NCCHTA (1)	Full	35	61	It would be helpful to readers, perhaps, to mention the strength of the evidence as well at the source and the consistency. (i.e. say that it is "moderately strong", or that the grade of recommendation was X,	Not sure what this is referring to.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						on average). Are the observational studies referred to solely case-control and cohort studies or are case series and other types included?	
Peer Reviewer	72.9	NCCHTA (1)	Full	44	68	As above. Since the evidence was graded and appraised it seems a pity not to use the result to justify/further explain the Qualifying Statement (It might be helpful to add that the average level of evidence /grade of recommendation was X per Table A, etc). This comment also applies to subsequent qualifying statements.	Refer to NICE technical manual which describes in detail the methodology that is used to develop NICE clinical guidelines. NICE does not grade its recommendations. We will acknowledge this point.
Peer Reviewer	72.10	NCCHTA (1)	Full	42	74	Again, I feel it would strengthen the Qualifying Statement to add the average Grade of Recommendation or level of evidence score since a reader may be unaware of the strength of evidence from an observational study, in general, and these ones, in particular.	Refer to NICE technical manual which describes in detail the methodology that is used to develop NICE clinical guidelines. NICE does not grade its recommendations.
Peer Reviewer	72.11	NCCHTA (1)	Full	10 – 30	92	I feel this whole section could be better written.	We have rewritten this section.
Peer Reviewer	72.12	NCCHTA (1)	Full	10 -13		Where is the justification for/explanation of the statement, "Given the extent of bias associated with this comparison"? If this is reference to the study design issues mentioned on page 91, lines 36-39 then perhaps that should be stated directly. Also, perhaps the wording should be altered because I found it a tad harsh to be honest (the same caveat could be applied to the majority of studies on which these guidelines are based – I wonder why this one, in particular, has been singled out? If it's completely untrustworthy then why is it included at all?)	Refer to the Full evidence review for further details about this issue (patient selection bias). The study was included because it is one of the most informative and relevant studies that this field has available. To exclude this study would be to ignore a seminal piece of work. Bias in other studies included in this guideline are indicated by the lower evidence level designated to it.
Peer Reviewer	72.13	NCCHTA (1)	Full	17 – 30		There is too much emphasis on significance here and too little on the magnitude of benefits. (i.e. "significant improvements" (line 17), "Significantly more" (line 21), "significantly longer" (line 23), "Significantly more" (line 24) and "significantly reduced" (line 26)). Line 17, for example, would be better if it echoed the	Refer to the Evidence Review for full details of the evidence.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						wording of the publication's abstract "Significantly more patients in the surgery group (42/50, 84%) than in the radiotherapy group (29/51, 57%) were able to walk after treatment.	
Peer Reviewer	72.14	NCCHTA (1)	Full	7	95	To say that the Tokuhashi score has "a significant effect on the length of survival" does not give sufficient information. Does increasing score imply longer or shorter expected survival? Similarly, as regards "significantly correlated" in line 9.	Thank you for your comments, we have addressed this issue.
Peer Reviewer	72.15	NCCHTA (1)				How far are the recommendations based on the findings? Are they a) justified i.e. not overstated or understated given the evidence? b) Complete? i.e. are all the important aspects of the evidence reflected?	
Peer Reviewer	72.16	NCCHTA (1)	Full	general		This is a general comment relating to the guidelines as a whole. Generally speaking, I'd say the level of evidence on which these guidelines are based is pretty poor but poor evidence is all we have and these guidelines do, in my opinion, make the best use of it. As mentioned above though, I do not think the results of the critical appraisal and grading have been presented as well as they might. I found it very difficult to compare the various Qualifying Statements. How much more trustworthy is "consistent evidence from well conducted observational studies" (page 71, line 30-31) in comparison to GDG consensus and "observational evidence" (page 68, line 45)? That is why I have suggested adding the overall "grade of recommendation" (or level of evidence if the overall grading was never done) to the Qualifying Statements	
Peer Reviewer	72.17	NCCHTA (1)				Are any important limitations of the evidence clearly described and discussed?	
Peer	72.18	NCCHTA (1)	Full	general		As above, I don't think the limitations implicit in the	

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
Reviewer						qualifying statements will necessarily be understood by all those reading the guidelines. (If they don't know that observational studies generally provide a low level of evidence they may not realise that the level of evidence on which these guidelines are based is generally quite poor (below what would be considered acceptable for other diseases/conditions)).	
Peer Reviewer	72.19	NCCHTA (1)				Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.	
Peer Reviewer	72.20	NCCHTA (1)	Full	26-35	70	Given that the evidence base is generally so poor, I found myself wanting more information on the size, quality and number of studies than was given in the Clinical Evidence or Qualifying Statement sections. Perhaps it is down to lack of space or deliberate policy but I would have preferred a summary of the more detailed information in the Full Evidence review to have been included with each relevant section.	This detailed information is available in the Evidence Review that accompanies this guideline. It is not practical to include this amount of information in the guideline.
Peer Reviewer	72.21	NCCHTA (1)				Please comment on whether the research recommendations, if included, are clear and justified.	
Peer Reviewer	72.22	NCCHTA (1)	Full	2 - 21	6	I feel the key research recommendations are pertinent, clear and fully justified.	Thank you.
Peer Reviewer	72.23	NCCHTA (1)	Full	1	8	Should read "at risk of and with" not "at risk or of".	Thank you. We have made this change.
Peer Reviewer	72.24	NCCHTA (1)	Full	32		What does Rx stand for? Rehabilitation?	Rx stands for treatment. This will be changed.
Peer Reviewer	72.25	NCCHTA (1)	Full	42	40	There is a space missing between the right bracket and the "do"	Thank you.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
Peer Reviewer	72.26	NCCHTA (1)	Full	103	7	Should read "radiotherapy" and not "radiotherapy"	Thank you. We have made this change.
Peer Reviewer	72.27	NCCHTA (1)	Full	92	13	There should be a "be" between the "to" and "considered"	Thank you we have made this change.
Peer Reviewer	72.28	NCCHTA (1)	Full	99-100	34 - 7	Are a verbatim repeat of a previous section (page 92, lines 10-30, although ordered slightly differently). I don't know whether this was intentional but it struck me as a little odd/unprofessional.	These papers compare radiotherapy and surgery and are appropriate for presentation in both sections. Please bear in mind that readers may only read sections in isolation.
Peer Reviewer	72.29	NCCHTA (1)	Full	100	34	This sentence is very poorly worded (and potentially offensive!) and should be corrected.	This sentence has been deleted.
Peer Reviewer	72.30	NCCHTA (2)				Are there any important ways in which the work has not fulfilled the declared intentions of the NICE guideline (compared to its scope – attached)	
Peer Reviewer	72.31	NCCHTA (2)	Full	General		The Guideline has covered the issues raised in the scope, although cost-effectiveness has not been assessed for the majority of recommendations. This is understandable given the number of separate issues and the resources and time available.	Thank you.
Peer Reviewer	72.32	NCCHTA (2)				Please comment on the validity of the work i.e. the quality of the methods and their application (the methods should comply with NICE's Guidelines Manual available at http://www.nice.org.uk/page.aspx?o=guidelinesmanual).	
Peer Reviewer	72.33	NCCHTA (2)	Full			The correct process appears to have been followed in general; see 2.2 for specific comments on the Health Economics methods.	Thank you.
Peer Reviewer	72.34	NCCHTA (2)	Full	5	Page 28-29	It would have been helpful if there were more documentation of the process by which the Group selected the topics for economic evaluation. For example, a tabulation of how the GDG rated each issue against the selection criteria could be included as an Appendix. The selection appears to have been	This information is covered by the economic plan which has been added as an appendix to the Evidence Review.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						made prior to systematic reviews of the economic literature. Surely the latter would have helped to determine the feasibility and desirability of particular economic evaluations? The number of titles to review would not have been great across all issues.	
Peer Reviewer	72.35	NCCHTA (2)				Please comment on the health economics and/or statistical issues depending on your area of expertise.	
Peer Reviewer	72.36	NCCHTA (2)	Full	64		Table 2 contains typos and does not match Table 5 in Appendix 1 which I think is correct.	Thank you.
Peer Reviewer	72.37	NCCHTA (2)	Full	75		The final sentence has a typo – clinical evidence should read cost-effectiveness evidence?	Thank you.
Peer Reviewer	72.38	NCCHTA (2)	Full	128		The explanation of the exclusivity assumption is not clearly presented. It is the proportion of all MRIs which is given to MSSC patients which is very small. The fact that sensitivity analysis was carried out on the unrealistic assumption in the base-case should be mentioned here.	The text in the paragraph has been altered to include a clear explanation of the exclusivity assumption.
Peer Reviewer	72.39	NCCHTA (2)	Full	136		In (e) the cost of radiographer time appears to be double-counted.	There was an error in the textural explanation of the calculation, rather than an error in the maths. This has been corrected.
Peer Reviewer	72.40	NCCHTA (2)	Full	138		The extended dominance of 2a and 2b over 3 presumably reflects the fact that in 3 patients are not transferred to the tertiary centre outside extended working hours?	Yes.
Peer Reviewer	72.41	NCCHTA (2)	Full	138	12	The costs go up for 1b and 3 as well as for 2a and 2b?	An error in the calculations for 1b and 3 has been identified, but was of little importance.
Peer Reviewer	72.42	NCCHTA (2)	Full	140		The results are indeed an artifact of the assumptions. The impact of in-patient stays to wait for scans should be explicitly modelled. Also, if treatment is to be given at a tertiary centre the overall cost of diagnosis and treatment for some options may be lower.	The impact of inpatient stays whilst waiting for a scan has been included as a separate sensitivity analysis. The results suggest that option 2b remains the most cost-effective option, but appears to be even more cost-effective (as everybody receives an MRI in this scenario).

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
							The second point may or may not be true, we did not find any specific evidence to suggest this either way.
Peer Revie wer	72.43	NCCHTA (2)	Full			This analysis appears to be well-conducted given the lack of good data, and the assumptions seem reasonable.	Thank you.
Peer Revie wer	72.44	NCCHTA (2)	Full	152		The cost of nursing home care for severely impaired patients will be much greater than the average of £81. Is this an opportunity cost or a charge?	This was the most detailed cost information that we could identify. However, if the unit cost is increased, the cost-effectiveness of the various treatments, relative to no treatments, also increases. Therefore we do not feel this is a particularly important issue.
Peer Revie wer	72.45	NCCHTA (2)	Full	156		The sense of bullet 1. is lost in the wording	The text has been changed to clarify the meaning.
Peer Revie wer	72.46	NCCHTA (2)	Full	160-161		The wording of the last sentence on p 160 is clumsily worded	Changes have been made to the text.
Peer Revie wer	72.47	NCCHTA (2)				How far are the recommendations based on the findings? Are they a) justified i.e. not overstated or understated given the evidence? b) Complete? i.e. are all the important aspects of the evidence reflected?	
Peer Revie wer	72.48	NCCHTA (2)	Full	General		Apart from the fact that economic evidence was not considered necessary for many recommendations.	Due to the broad scope of the guideline it was not possible to investigate the cost effectiveness for every topic. Therefore the topics were prioritised according to criteria set out in the NICE technical manual.
Peer Revie wer	72.49	NCCHTA (2)				Are any important limitations of the evidence clearly described and discussed?	
Peer Revie wer	72.50	NCCHTA (2)	Full	General		The limitations of the evidence in the economic analyses that were carried out were well documented in the Appendices.	Thank you.
Peer	72.51	NCCHTA (2)				Is the whole report readable and well presented?	

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
Reviewer						Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.	
Peer Reviewer	72.52	NCCHTA (2)	Full	General		Generally yes, but there were several typos which made reading difficult at some points.	Thank you.
Peer Reviewer	72.53	NCCHTA (2)				Please comment on whether the research recommendations, if included, are clear and justified.	
Peer Reviewer	72.54	NCCHTA (2)	Full	General		The need for economic analysis alongside the clinical trials should be made more explicit in the research recommendations	Ideally all NHS research should have economic analysis alongside but it is not the role of the GDG to prioritise this.
SH	73	Neurological Alliance, The				This organisation was approached but did not responc	
SH	74	NHS Lothian				Comments included with British Association of Neuroscience Nurses	Thank you.
SH	75	NHS Pathways				This organisation was approached but did not responc	
SH	76	NHS Plus				This organisation was approached but did not responc	
SH	77	NHS Purchasing & Supply Agency				This organisation was approached but did not responc	
SH	78	NHS Quality Improvement Scotland				This organisation was approached but did not responc	
SH	135.0	NHS Tayside (NOSCAN)	Full	General		Suggest collaboration with Scottish National MSCC group who have developed a core minimum data set. Working with ISD and all three regional cancer networks, we have put together a minimum dataset on E-case with options to add extra data wished by individual centres. It would be a good opportunity to collaborate on a UK basis to learn from each other. Pam Levack	Thank you. We will pass this on to the NICE implementation team.
SH	135.1	NHS Tayside (NOSCAN)	Full	General		Consider Early Detection and Diagnosis as separate pathway for management and treatment of patients. If patients are mobile and have malignant epidural	We acknowledge that this issue is difficult. However the GDG have debated this at length and feel that the guideline should differentiate

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						disease and impending malignant cord compression there is no need to treat as if spine is unstable. Better to have system flexible enough to allow these patients the easiest access to diagnosis i.e. walking out patient appointment within 24-48 hours. Agree that pathways shown for late presentation and for patients with loss of mobility and evidence of instability provide sensible caution. We should not think of MCC as a single entity. It is hoped that the diagnosis of epidural disease will be the priority – i.e. more upstream. Do not think that walking patients with impingement only should be managed in the same way as gross MCC. Analogy angina and MI are managed very differently. Pam Levack/Lynsay Allan	between the management of patients with early symptoms and those with clinical cord compression.
SH	135.2	NHS Tayside (NOSCAN)	Full	General		The guidelines attempt to standardise treatment for MSCC and raise awareness as to what might improve outcomes. There are a group of patients (probably the group we see in Palliative care) who present 'late', not because the diagnosis is missed but because it is a late complication in the course of their illness. The guidelines should offer recommendations about management, taking account of all relevant information, and instituting clinically appropriate treatment according to patients' overall condition and prognosis. This appears to be stated clearly in the treatment sections (i.e. surgery & radiotherapy) but less clearly in the supportive care section.	Thank you for your comment. The GDG attempts in its selection for treatment section (chapter 6) to distinguish patients who are too ill, too frail or otherwise inappropriate for active treatment of MSCC (such as those who present late). We do not feel that adding recommendations on this topic would be appropriate but will add background information about the importance of palliative care in chapter 7.
SH	135.3	NHS Tayside (NOSCAN)	Full	General		Everything depends on the setting in which MCC is diagnosed. Treating patients who are dying is not the aim.	We agree.
SH	135.4	NHS Tayside (NOSCAN)	Full	General		I agree with the indications for surgery and also would be interested to know what the spinal surgeons think about the following example in addition.	We feel this situation is recognised and surgery is recommended see p82, lines 29-37.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						A patient who has got serious "instability pain" in spite of efforts to control it. These patients are unsuitable for radiotherapy and surgery can provide almost instant relief. Medical/palliative treatment alone would also be unsuitable. In these unusual cases would surgery be considered even if the other criteria are not fulfilled?	
SH	135.5	NHS Tayside (NOSCAN)	Full Version	33	30-51	Consider separate algorithm for early cord comp which aims to maintain mobility and promote treatment of patients as out patients. ? Evidence to say admission necessary for all suspected cases. GPs really want someone to talk over the problem with. They are presented with a problem – rather than is this MCC and discussion [from our feedback] is a key part of the system	This algorithm leads to discussion with the MSCC co-ordinator, whose role is partly educational (see section 2.2).
SH	135.6	NHS Tayside (NOSCAN)	Full Version	47	41-43	Suggest when appropriate is added. If promoting early detection and patients are mobile a next day appointment should suffice. This system protects valuable resources rather than relying on their presence.	This is adequately addressed in text and this addition is not necessary. Treatment centres should provide 24/7 access. Acute hospitals should extend days if necessary.
SH	135.7	NHS Tayside (NOSCAN)	Full Version	48	1-3	Agree-Having a separate network gives it more profile and attention and not all the cancer sites are covered with existing cancer networks.	Thank you.
SH	135.8	NHS Tayside (NOSCAN)	Full Version	49	11-16	Agree this system is working well in Scotland and is crucial in providing point of contact for early referral and diagnosis with prompt commencement of treatment, which we know has more favourable outcomes for these patients.	Thank you.
SH	135.9	NHS Tayside (NOSCAN)	Full Version	49	11-16	MCC Coordinator – I'm not sure many areas have this person	The guideline is recommending that they should have this person.
SH	135.10	NHS Tayside (NOSCAN)	Full Version	66	19-25	Agree. Consider that breast cancer patients are routinely given information about lymphoedema and what symptoms to look out for, although it will not	We agree.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						affect all patients. Should MCC be thought of in the same way?	
SH	135.11	NHS Tayside (NOSCAN)	Full Version	66	27-28	Agree work needs to take place nationally to provide consistent levels of information given to patients.	Thank you.
SH	135.12	NHS Tayside (NOSCAN)	Full Version	66	32-36	Pts with bone mets should have an info leaflet	Thank you.
SH	135.13	NHS Tayside (NOSCAN)	Full Version	66	32-36	PIS for patients. Is there an evidence base for its use? Lots of patients have bony mets, few get MCC - if we use an information sheet are we at risk of either a. causing more anxiety than benefit b. "over-alerting" patients so that we are referred more than we can cope with. I'm all in favour of informing patients but it is difficult to get the level of information for rare conditions correct.	Thank you. The patient information sheet is based on GDG consensus.
SH	135.14	NHS Tayside (NOSCAN)	Full Version	66	32-36	Wonder whether since neuropathic pain is a key factor here – it is so awful and so poorly diagnosed, whether this is the opportunity to educate about that. The presence of neuropathic pain itself is suggestive of new disease	Broad education about neuropathic pain is outside the scope of the guideline. We have attempted to define the characteristic features of MSCC within this guideline.
SH	135.15	NHS Tayside (NOSCAN)	Full Version	66	41-43	Disagree, if being investigated urgently, relevant Health care professional will be involved from start. With a referral system in place patients will already have contact details if awaiting MRI the next day. Suggest that numbers are given to patients prior to any episodes, as part of patient information given at appropriate time during treatment or diagnosis of disease progression	We agree. We have amended the recommendation to include reference to the patient information leaflet in Appendix 2.
SH	135.16	NHS Tayside (NOSCAN)	Full Version	67	16-25	Consider treating all as oncological emergencies. Patients should be referred into system at soonest point, at which time experts can decide if patient meets criteria to be acted upon urgently or within	It is inappropriate to treat every patient as an oncological emergency. Timelines are being defined and will be included in the final guideline.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						48hours. With referral system in place (as in Grampian and Tayside) patients individual needs are met. Some will be transferred immediately to hospital for MRI and diagnosis, others will be given next day appointment.	
SH	135.17	NHS Tayside (NOSCAN)	Full Version	67	19-25	Suggest that criteria are very wide and any coordinator not of a medical background may find it difficult to screen large numbers that may come through. If the net is too wide then the sifting quality needs to be very good and someone with lot knowledge. e.g. low back pain ++ may become a really difficult area. Somehow got to sift into urgent [from symptom and ? underlying developing problem] and v urgent. Someone is going to have to sift all these indications – and we know how tricky this can be. No evidence for localised spinal tenderness on examination. Many types of pains prevent sleep. Focus has to be on neuropathic pain, or new progressive pain.	The evidence available demonstrates considerable overlap of symptoms between significant pathology and degenerative disease. This is described in Section 4.3.
SH	135.18	NHS Tayside (NOSCAN)	Full Version	71	27	Consider whether applicable for those detected with early MSCC Consideration should be made for geographically remote areas, e.g. Islands in North Scotland.	We will define timelines in the final version of the guideline. NICE guidance does not apply to Scotland.
SH	135.19	NHS Tayside (NOSCAN)	Full Version	71	27	I would agree the dogmatic "within 24 hours" MRI is a simple statement with great implications. In the past we have usually linked the availability of out of hours MRI resource to a level of neurosurgical/radiotherapist discussion centred on the linked availability of surgery and more specifically RT out of hours. Perhaps this aspect of the timing of the MRI can be agreed at local level. In essence MRI should be available within the 24 hour period prior to available surgery or RT planned for treatment?	We will define timelines in the final version of the guideline.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	135.20	NHS Tayside (NOSCAN)	Full Version	71	27	- local agreement is best option. What we found was that if the day time system worked – and we were confident that a scan could be done the next morning – OOH not really needed. However I don't know the English set up – and would have to defer to the radiologists.	We will define timelines in the final version of the guideline.
SH	135.21	NHS Tayside (NOSCAN)	Full Version	71	27	MRI within 24 hours of available radiotherapy would commit to a weekend MR service as radiotherapy planning and treatment is available at the weekend for emergencies (certainly in Highland)	We would expect radiotherapy to be available at weekends.
SH	135.22	NHS Tayside (NOSCAN)	Full Version	71	27	MRI availability within 24 hours is inevitable and we need to take these forwards to NHS Tayside to fund this service properly. There are other patients who may require emergency MRI where their treatment is dependant on MRI information, perhaps all that can be linked.	We agree. We will define timelines in the final version of the guideline.
SH	135.23	NHS Tayside (NOSCAN)	Full Version	73	27-37	Consider just STIR and T2. If only T1 & T2 and diagnosis is vertebral metastases only, then STIR ideally needed for additional information required for vertebroplasty. All three sequences in Sagittal plane lengthens scan time and for many patients with pain management issues this may render the examination abandoned. STIR will give as much anatomical detail as T1.	The recommendation is that you can do either a T1 or STIR and this is at the discretion of the supervising radiologist. This is in recognition that the scan time needs to be kept to a minimum for these patients. It also takes into account that there are different scanners in different units producing images of widely variable image quality. It gives the freedom for an individual cancer network to decide which sequence they wish to use, whilst still indicating that aT2 on its own is insufficient.
SH	135.24	NHS Tayside (NOSCAN)	Full version	80	40-41	8Gy single I would use in poor-prognosis patients. As we often dose to 100% or D-max. If the patient is very fat I'd consider treating to a certain depth instead. In some cases I might use 10Gy e.g. in a poor prognosis patient with radio-resistant disease	Thank you. The options you describe seem reasonable and appropriate in specific circumstances. However this is not a reason to change the recommendation.
SH	135.2	NHS Tayside (NOSCAN)	Full	85	23-28	Out of context if promoting early detection to keep	We agree. Caution is only required if stability

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	5		Version			and maintain mobility.	is questioned and until stability is assured.
SH	135.26	NHS Tayside (NOSCAN)	Full Version	85	23-28	Assuming spinal instability and log rolling in all, would burden fast track referral system where objective is to have maximum number of patients mobile out patients. In many cases 5 members of staff are not available in MRI departments, especially if out of hours is being considered. Examination times would be markedly increased, impacting on waiting times overall. Out patients presenting will require only one member of staff and on average have shorter scan times.	We agree. Caution is only required if stability is questioned and until stability is assured.
SH	135.27	NHS Tayside (NOSCAN)	Full Version	85	23-28	This is a difficult area – in fit, alert patients who are walking I normally do not advise bed-rest. I advise them to be careful and avoid anything that entails the risk of falling or jolting and anything that brings on pain. Problems of course can occur when for example a wheelchair-bound patient is transferred awkwardly for transport or when a patient who is already partly immobile is put on the commode from bed. Provided the patient is alert then pain on movement can indicate instability.	We agree. Caution is only required if stability is questioned and until stability is assured.
SH	135.28	NHS Tayside (NOSCAN)	Full Version	85	23-28	Spinal stability is the issue here, therefore if the paragraph read 'Patients with severe mechanical pain suggestive of vertebral bony structural instability or any neurological impairment suggestive of spinal cord functional instability, should be nursed flat with neutral spine alignment ( ) until bony and neurological stability is confirmed.' If confirmed then the patient will require some form of brace to achieve stability and cannot mobilise until it is in place. If the spine is ultimately deemed stable then cautious mobilisation can occur. As per 1.5.2.2. And 1.5.2.4. The flaw in it is that it does not take into account the	We agree. Caution is only required if stability is questioned and until stability is assured.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						early detection cases who are diagnosed early, and present walking, who should therefore remain walking, Pam's and CRAG work.	
SH	135.29	NHS Tayside (NOSCAN)	Full Version	85	23-28	From the physio point of view the most important thing we need to know at the point of diagnosis, after confirmed cord compression or not, is spinal stability, because this heavily influences whether or not we can mobilise the patient. I feel the flow chart at page 36, apart from not fitting with early diagnosis walkers, sums it all up very nicely. Perhaps two flow charts are needed, walking at diagnosis, and non-walking at diagnosis, likewise if paragraph 1.5.2.1 was split the same way it would be clearer.	Caution is only required if stability is questioned and until stability is assured. The algorithm is being altered to make things clearer.
SH	135.30	NHS Tayside (NOSCAN)	Full Version	85	23-28	a guideline – can not be dogmatic without evidence	We do not know how this comment relates to this particular section of the guideline.
SH	135.31	NHS Tayside (NOSCAN)	Full Version	86	40-41	Out of context if early malignant cord compression referred and diagnosed within 24-48 hours	We agree and the recommendation has been altered. Timelines for steroid treatment will be considered.
SH	135.32	NHS Tayside (NOSCAN)	Full Version	86	40-41	It sometimes works very well for pain relief (and so it must be doing something?) I cut down more rapidly than it says in the table. As well as initial pain control I understand steroids help prevent the acute worsening in response to radiotherapy esp. the first dose or a single. After that I often cut it to half although would be more cautious in doing this if the patient responded extremely well to initial steroids. If I don't think the steroid has helped I cut it out as speedily as possible. I always give cover at the dose of 16mg daily and continue it until stopped or a small dose is reached. I	We agree. Duration of dexamethasone is not recommended, only dose for best effect and least side effects.

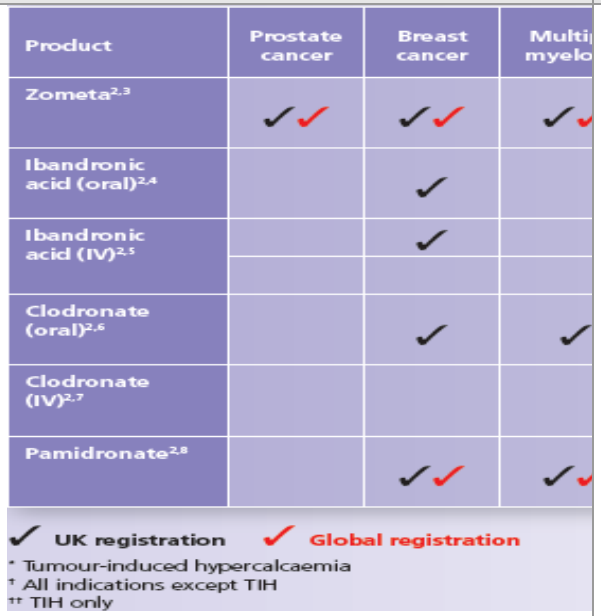
Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						have seen gastric perforations in other cases. Perhaps I'd say "in some cases it is appropriate to reduce steroids in a shorter time than this table"	
SH	135.33	NHS Tayside (NOSCAN)	Full Version	86	40-41	Don't really have evidence to be so dogmatic. As a pain/oedema measure it is useful – the analogy is a brain swelling – so seems reasonable without being dogmatic	There is evidence that a loading dose improves outcome.
SH	135.34	NHS Tayside (NOSCAN)	Full Version	86	40-41	Re routine steroid cover - I don't think we have a clear answer to this question. Practice will be guided by the need to provide adequate analgesia and steroids may provide a means to achieving this although the evidence base is poor.	Evidence that a loading dose and low dose (16mg) short course improves outcome. High dose (100mg)does not improve outcome further and causes significant side effects.
SH	135.35	NHS Tayside (NOSCAN)	Full version	86	40-41	Where is evidence for treating all suspected MCC patients in this way?	Evidence presented p87 13-25 (and in more detail in the Evidence Review that accompanies this guideline.
SH	135.36	NHS Tayside (NOSCAN)	Full version	86	40-41	This seems a counsel of perfection and unlikely to be carried out in primary care or even in smaller hospitals	This guideline is intended to improve practice and reduce paralysis.
SH	135.37	NHS Tayside (NOSCAN)	Full Version	118	43	Not known about across North Scotland centres. We do not educate about it. Is this widely known about in relation to MCC or more applicable to Spinal trauma?	Thank you for your comment. We have removed this from the guideline.
SH	135.38	NHS Tayside (NOSCAN)	Full Version	118	43	What is autonomic dysreflexia – must be stupid have lived so long and don't know	Thank you for your comment. We have removed this from the guideline.
SH	135.39	NHS Tayside (NOSCAN)	Full Version	118	43	I've only ever seen this condition twice in patients with long term paraplegia (I think from spinal injury or MS) – never in malignant cord compression. On those two occasions the diagnosis was obvious. The blood pressure is always checked if the patient is admitted of course. I don't know whether autonomic dysreflexia can present with more subtle signs that I could have missed.	Thank you for your comment. We have removed this from the guideline.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	135.40	NHS Tayside (NOSCAN)	Full Version	118	43	Autonomic dysreflexia is not a problem I have encountered in patients with MSCC.	Thank you for your comment. We have removed this from the guideline.
SH	135.41	NHS Tayside (NOSCAN)	Full Version	120	39-41	Initial assessment and routine monitoring of all patients with MSCC should include HR &BP measurement.....Again this must be judged according to the stage of the patient's illness and their prognosis. If this is a preterminal event then routine monitoring is not appropriate.	Thank you. We have changed the recommendation.
SH	79	Norfolk Suffolk and Cambridgeshire Local Specialised Commissioning Group				This organisation was approached but did not respond	
SH	80	North Bristol NHS Trust				This organisation was approached but did not respond	
SH	81	North East London Cancer Network				This organisation was approached but did not respond	
SH	82	North Yorkshire and York PCT				This organisation was approached but did not respond	
SH	123.0	Nottingham University Hospital NHS Trust	full	98	16	Why should fractionated radiotherapy be used for patients receiving RT alone (not suitable for surgery)? The guidelines say 'for all pts with good prognostic features' . Tumours response is quickest after single fraction RT (in chest/lung RT symptom control fastest after single fraction 10Gy cf 30Gy/10# - MRC lung cancer studies). This would be of paramount importance when the cord is compromised. I do not know of any evidence that fractionated RT is more likely to be effective, although by analogy with other sites, fractionated higher dose RT may possibly be effective for longer. This is unlikely to be an issue for the majority of MSCC pts,	The use of hypofractionated radiotherapy to treat patients with MSCC is the subject of a current RCT. In the absence of reliable evidence for the safety and efficacy of single or two fraction radiotherapy for treating MSCC, the GDG felt it was appropriate to recommend what is current standard practice. There is a theoretical risk (supported by some evidence from studies of hypofractionated radiotherapy in lung cancer) that large fractions may be associated with oedema and worsening of symptoms.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						particularly lung cancer pts for whom the prognosis from the disease is poor. If this is the justification for suggesting fractionated treatment, then the guidelines should state 'only where prognosis is thought to exceed 6 months'. If there is no good evidence on the value of fractionating the RT then it should not be included in the recommendations as it will have a considerable impact on the elective RT pts receiving curative treatment (e.g. breast adjuvant RT). Similarly there is no evidence to recommend fractionated post-operative RT, or RT in epidural tumour without neurological deficit (1.5.4.3). Your guidelines specifically state (4.4) that there is no evidence for the use of different fractionation regimens.	In the absence of evidence about the most appropriate dose fractionation regimens for post-operative radiotherapy or for the treatment of patients with epidural, it was felt that it was more appropriate to recommend standard, fractionated radiotherapy especially as some patients may have quite long survival.
SH	123.1	Nottingham University Hospital NHS Trust	full	96	16	The recovery from surgery is likely to be longer than 3 months – why do the guidelines state a prognosis of over 3 months is indication for surgery rather than radiotherapy? We surely have to aim for a <u>useful</u> period of symptom control?	The requirement for 3 month survival is supported by health economic evaluation, which demonstrates the satisfactory cost-effectiveness ratio for this group of patients. Below 3 months survival, surgery is not recommended.
SH	123.2	Nottingham University Hospital NHS Trust	full	general		Is there any evidence that in the presence of established neurological deficit (complete cord paralysis of over 24 hours duration) there is any value in giving RT in a pain free patient? Or within 24 hours (except for pain relief when the RCR guidelines on good practice would suggest 2 working days)?	There is no evidence on either of these topics. The GDG does not recommend giving RT to pain free paraplegic patients. The guideline states that patients who are paraplegic for more than 24 hours and without pain should not have radiotherapy (p98, lines 32-36). The GDG recommends access to radiotherapy 7 days per week.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	83.0	Novartis Pharmaceuticals UK Ltd	Full Versi on	General comme nt		The draft guideline is fundamentally flawed with respect to the recommendations relating to the use of bisphosphonates and in particular zoledronic acid for the prevention of metastatic spinal cord compression (MSCC) and pain. Our main concerns are as follows: - level one evidence relating to zoledronic acid for the prevention of MSCC has not been taken into account in the recommendations for prostate cancer, non small cell lung cancer (NSCLC), renal cell cancer (RCC) and other solid tumours; - inappropriate and over-reliance has been placed on the Yuen et al 2006 meta-analysis to formulate the recommendations for prostate cancer. This meta-analysis assumes a class effect where only one therapy in the class has demonstrated a benefit and is licensed for this indication; - the draft recommendations do not take into account the clinically important preventative role of zoledronic acid in these patients; - there has been an inconsistent approach to the development of these guidelines with respect to the bisphosphonate recommendations. For example all bisphosphonates have been recommended for the prevention of MSCC in breast cancer and multiple myeloma despite the fact that not all bisphosphonates have shown level one efficacy in these indications. However for prostate cancer level one evidence for zoledronic acid is ignored. These concerns are discussed in more detail below in relation to the relevant sections of the draft guideline. In general, the draft guideline does not recommend the use of bisphosphonates for the prevention of MSCC. However, zoledronic acid has been shown	We are grateful for all the comments and have modified the summary of evidence as a result. As stated before: - There is no "level one" evidence that zoledronic acid prevents MSCC in any tumour type. - The GDG was not convinced that there was sufficient evidence to say that any bisphosphonate has a specific rather than class effect on the relevant outcomes.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						across a wide range of malignancies including breast cancer, multiple myeloma, prostate cancer, NSCLC, RCC and other solid tumours to reduce the incidence of all of the individual components of the primary end point skeletal related events (SREs), which includes spinal cord compression. This is reflected in its licensed indications ie the prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumour-induced hypercalcaemia) in patients with advanced malignancies involving bone. This large body of evidence from RCTs has resulted in zoledronic acid having the broadest licence of all the bisphosphonates. The table below illustrates the differences in the licensed indications across the bisphosphonates. Table 1 – Current licensed indications in metastatic disease for bisphosphonates	

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						 Throughout this response we have highlighted the available level one evidence which was used for the regulatory submissions: 1. Breast Cancer and Multiple Myeloma (Core phase) Rosen et al, Cancer J, 20011 2. Breast Cancer and Multiple Myeloma (Extended Phase) Rosen et al, JCO, 20032 3. Prostate Cancer (Core Phase) Saad et al, JNCI, 20023 4. Prostate Cancer (Extended Phase) Saad et al, JNCI, 20044 5. Lung, Renal and other solid tumours: Rosen et al, Cancer 20045	

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						There is also emerging new data which suggests a direct anti-tumour effect.	
SH	83.1	Novartis Pharmaceuticals UK Ltd	Full Version	Chapter 6.2	p.78 Lines 41-42 Page 79 Lines 24-38 Page 79 Line 29-35	The draft guideline states, "Patients with vertebral involvement from myeloma or breast cancer should be treated with bisphosphonates to reduce pain and the risk of vertebral fracture/collapse." It is unclear why recommendations for bisphosphonate use are restricted to myeloma and breast cancer despite level one evidence demonstrating that zoledronic acid is effective in preventing SREs (including spinal cord compression) for prostate cancer, NSCLC, renal cell carcinoma and other solid tumours.3,4,5 Results from the prostate cancer study3 demonstrated: • zoledronic acid 4mg significantly reduced the number of patients who had at least 1 SRE; • statistically significant fewer patients experienced a fracture; • statistically fewer patients experienced any SRE other than fracture; • a statistically significant difference in time to first occurrence of any SRE; • time to first SRE was not reached for the 4mg zoledronic acid treatment group and was considered to be at least 420 days compared to the 320 days for placebo. Results from the 24 month study extension phase4 showed that during the entire study: • statistically significant fewer patients in the zoledronic acid 4mg arm had at least on	We acknowledge the evidence from the Saad et al study on the apparent reduction in SREs for patients with prostate cancer from zoledronic acid 4mg. However we have two main reservations about the evidence from this relatively small RCT with a high discontinuation rate: 1. There was no evidence of a statistically significant reduction in vertebral collapse and MSCC 2. The results were only significant for the 4mg dose arm and not for 8mg/4mg arm. Rosen et al did not show a significant reduction in SREs for other tumour types at the approved, safe dose (4mg), unless hypercalcaemia was included, an SRE that the GDG did not think relevant to the risk of developing MSCC or vertebral collapse. Becuase of these uncertainties, the GDG did not consider that that it would be appropriate to recommend the routine use of bisphosphonates for the prevention of MSCC and vertebral collapse for patients with these tumour types.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						SRE; • the reduction in annual incidence was statistically significant; • a statistically significant reduction in the median time to first SRE; • fewer patients in the 15-24 month data had at least 1 SRE; • patients who had an SRE before study start also had a higher chance of another SRE during the study; • fewer patients had SREs regardless of the SRE history; • there was a statistically significant 36% reduction in the ongoing risk of SREs. Results from the study in lung cancer, renal cancer and other solid tumours demonstrated5: • proportion of patients with a SRE, 46 % for placebo vs 39% 4 mg zoledronic acid p= 0.127 N.B. when hypercalcaemia is included as a component of SREs, there is a significant reduction in the percentage of patients experiencing a SRE 39% on 4mg zometa vs 48% on placebo p=0.0039; • a significantly delayed median time to first SRE 236 days 4mg zoledronic acid vs 155 days placebo p=0.009; • a significantly reduced the mean annual incidence 1.74 events per year for 4mg zoledronic acid arm vs 2.71 events per year for the placebo arm p=0.012; • zoledronic acid 4mg reduced the risk of experiencing an SRE (using multiple event analysis) by 31% p=0.003.	

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						As acknowledged within the draft guideline, evidence for the efficacy of the bisphosphonates as a class is inconsistent. Therefore recommendations based on a class effect are not supported by the available evidence base. This variation in effect is reflected in the different licensed indications across the class. There is however, level one evidence to support the use of zoledronic acid for the prevention of SREs including spinal cord compression across a wide range of malignancies. In summary, there is level one evidence which demonstrates that zoledronic acid is effective for the treatment of pain and prevention of metastatic spinal cord compression for breast cancer, multiple myeloma, prostate cancer, NSCLC, RCC and other solid tumours. This evidence is highly variable for other bisphosphonates suggesting that a class effect cannot be assumed. We therefore propose that the recommendations are amended to reflect the available evidence base for zoledronic acid and not an assumed class effect.	
SH	83.2	Novartis Pharmaceuticals UK Ltd	Full Version	Chapter 6.2	Page 78 Line 44-46 Page 79 Line 35 Page 79 Line 24-28 Page 79	The draft guideline states, "Patients with vertebral metastases from prostate cancer should be treated with bisphosphonates to reduce pain only when other analgesics have failed." This recommendation fails to take into account level one evidence from RCTs (Saad 2002 and Saad 2004) which demonstrate that zoledronic acid confers a statistically significant reduction in the occurrence of skeletal related events (SREs).3,4 Results of this study are detailed in the previous section of this document.	The GDG was aware of the evidence cited for the reduction in MSCC events in the Saad papers, which was not statistically significant. However they did not feel that this was sufficient to recommend the routine use of zoledronate. They were also aware of the Yuen et al meta-analysis, in which the incidence of SREs was an important, though secondary, endpoint, and were not convinced that there was sufficient evidence to say that zoledronate has a specific rather than class effect.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					Line 33-34	The above recommendation appears to be based on the Yuen et al 2006 meta-analysis and references the NICE "Prostate Cancer Guideline" which states that bisphosphonates do not prevent spinal cord compression. Whilst this is true for bisphosphonates as a class, it should be noted that zoledronic acid reduces spinal cord compression in prostate cancer patients (zoledronic acid 4mg, 9 cases of spinal cord compression vs 14 cases in the placebo group).3 Although, this difference was none significant (p=0.256) there are so few events in the overall study population that statistical significance for each component of a SRE is unlikely as the study was not powered for this endpoint. Meta-analyses of pharmaceutical interventions are only useful where there is a class effect and all the agents considered have activity in the indication studied. Where only one intervention in a class is effective, predictably the outcome of a meta-analysis will be to dilute the overall effect of the effective therapy. Therefore the rationale for conducting a meta-analysis incorporating all bisphosphonates for this indication is unclear and the validity of results from such an analysis are highly questionable. The lack of a demonstrable class effect should not preclude the use of a proven therapy such as zoledronic acid in this indication. The stated objective of the Yuen et al meta-analysis was to determine the effectiveness of bisphosphonates in relieving pain in patients with bone metastases from prostate cancer ie not an assessment of the reduction or prevention of complications of bone metastases. This meta-analysis is fundamentally flawed in this respect as it fails to separate those bisphosphonates that have proven in RCTs to be effective treatment options, from those bisphosphonates that have failed to show efficacy in RCTs.	

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						In addition it should be noted that the recommendations relating to bisphosphonates in the Prostate Cancer Guideline were strongly challenged by patient and professional groups as well as manufacturers. Anthony Mundy and professor Hamdy responded with open letters in the BMJ on behalf of BAUS. (see link http://www.bmj.com/cgi/eletters/336/7644/610) Despite the limitations of the meta-analysis Yuen et al. recommend the use of bisphosphonates for treatment of refractory bone pain and prevention of skeletal events.	Yuen et al did not "recommend the use of bisphosphonates". The 'Implications for clinical practice' section of their review only says that "bisphosphonates may have a role".
SH	83.3	Novartis Pharmaceuticals UK Ltd	Full versio n,	Chapter 6.2,	Page 79 Lines 2-5	The draft guideline states, "Bisphosphonates should not be used to treat pain or with the intention of preventing MSCC in patients with vertebral involvement from tumour types other than myeloma, breast cancer or prostate cancer (when other analgesics have failed), except as part of a randomised controlled trial." This does not take into account RCT evidence (Rosen at al 2004)10 in patients with NSCLC and other solid tumours showing a statistically significant reduction in SREs in all patients on 4mg zoledronic acid compared to placebo when hypercalcaemia was included as an event. A significant delay in the median time to first SRE was also seen of over 2 months, and a statistically significant decrease in the annual incidence of SREs for patients on 4mg zoledronic acid (both of which could be considered more clinically relevant end points). The multiple event analysis accounts for absolute numbers of SREs and the timing between them. This produces a more sensitive analysis of the risk between the 2	The GDG was aware of the evidence from Rosen et al (2004) but did not feel that the evidence from this study alone was sufficient to make a clear recommendation to the NHS on the use of bisphosphonates in this context. The GDG was not convinced that there was sufficient evidence to say that zoledronate has a specific rather than class effect.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						groups and showed a statistically significant reduction in the hazard ratio between 4mg zoledronic acid vs placebo. Zoledronic acid 4mg compared to placebo reduced the risk of experiencing each individual SRE including spinal cord compression. The evidence shows that zoledronic acid does have a preventative role with respect to MSCC that is critical in breast cancer, myeloma, prostate cancer, and other solid tumours. The draft guideline states that bisphosphonates are not uniformly effective in all types of cancer and we fully agree with this statement. This fact highlights the fundamental flaw reflected in this draft guideline. It has been shown that zoledronic acid has produced statistically significantly results, and is clinically effective across multiple indications looking at the same primary and secondary end points in every indication. This is not the case with any other bisphosphonate, for example other bisphosphonates including clodronate and pamidronate have been trialled in prostate cancer and failed to show conclusive significant results. Although these bisphosphonates have a licence in breast cancer it shows the fallibility of considering these compounds as a class. Although we acknowledge the need to treat spinal cord compression, reducing the risk of spinal fracture/collapse should be a priority. This is not reflected in the draft guideline. A preventative approach to therapy is important to maintain spinal integrity and prevent cord compression. The statement, "…when other analgesics have failed..", implies that	Thank you. The statement has been corrected to

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						bisphosphonates are analgesics. However, based on the available evidence this is clearly not the case as analgesia is only one of the beneficial properties conferred by bisphosphonates and in particular zoledronic acid.	"…when conventional analgesics have failed….".
SH	83.4	Novartis Pharmaceuticals UK Ltd			Page 78 Line 32	The draft guideline states, "They do not prevent skeletal metastases… or prevent MSCC, but they are widely used in cancer patients to treat hypercalcaemia and to reduce skeletal-related events (SREs)." Although none of the bisphosphonates have a licence to prevent skeletal metastases, there is a growing body of evidence that supports pre-clinical work showing that zoledronic acid does have a direct and indirect anti-tumour effect. Initial clinical work has been contradictory with oral clodronate showing an efficacy in one trial but failing to show any efficacy in a similar designed trial. However the most potent of all the bisphosphonates, zoledronic acid has recently shown direct anti-tumour activity in a trial run by the Austrian Breast and Colorectal Cancer Study Group - 12 (ABCSG-12) Gnant et al 2008.9 Results from this study demonstrated a 36% reduction in disease free survival (DFS) and a 35% reduction in recurrence free survival (RFS), but it also showed a reduction in all types of recurrence including distant metastases in bone and soft tissue. Supporting evidence is also provided by a recent combined analysis of the 12 month Z(O)fast data which showed a reduction in DFS between the up-front and delayed zoledronic arms. Although this was a secondary end point in	Thank you for the information on Gnant et al and Z(O)fast trials. It is not possible for us to include evidence from ongoing trials, partial data from which have been only presented in abstract. We will of course be very interested in the final results.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						both studies which are ongoing, it still suggests that this efficacy is clinically relevant. This may be the first robust clinically significant data that shows a direct anti-tumour effect and would mean a potential treatment paradigm change where treatments act directly on the tumour as well as preventing distant recurrence from the primary tumour. As noted by Paiget as early as the 1890's the "soil and seed hypothesis" becomes relevant. There is an effective treatment for both in the form of zoledronic acid. It is likely that at least some of the anti-tumour activity exerted by zoledronic acid acts against the primary tumour "seed" as well as exerting an effect on common metastatic sites "the soil" by making them a less favourable environment for the dissemination of tumour cells. This new and unique stance is an exciting prospect for many clinicians and results of confirmatory studies such as AZURE in breast cancer, ZEUS and STAMPEDE in prostate cancer, and 2419 in lung cancer are awaited. Results from the breast cancer study, AZURE will be available later this year. In addition, the premise that bisphosphonates are used to reduce SREs but do not prevent MSCC, is a contradiction in terms. Spinal cord compression is one of the components of SREs and as discussed previously zoledronic acid has level one evidence demonstrating that zoledronic acid is effective in preventing SREs (which includes spinal cord compression) for prostate cancer, NSCLC, renal cell carcinoma and other solid tumours.3,4,5	We do not see the contradiction. It is quite possible for there to be evidence for a reduction in SREs overall without a significant effect on MSCC specifically.
SH	83.5	Novartis Pharmaceuticals			Page	The draft guideline states,	

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		UK Ltd			79 Line 7-9	"These recommendations are based on evidence from high quality meta-analysis, systematic reviews of RCTs and RCTs with a low risk of bias." Whilst we fully agree that recommendations should be based on the types of evidence listed above, for the reasons we have stated previously we do not believe this statement to be true. The evidence clearly demonstrates that bisphosphonates differ with respect to their therapeutic profiles and therefore a class effect cannot be assumed. In addition, this is a difficult area for performing meta-analyses because of the multitude of different primary and exploratory end points used (including pain, bone outcomes, and QoL). Also due to the variability in efficacy demonstrated across the bisphosphonates, the lack of common end points amongst trials, and the lack of head-to-head comparisons between the bisphosphonates (excluding zoledronic acid where head to head trials have been conducted against pamidronate in breast cancer and have shown superior benefits), meta-analyses will result in a dilution of effect for statistically significant trial end points. As MSCC is such a critical event we ask the GDG to consider high quality RCTs that show efficacy in the preventing these events. It is important to note that not only do all of the trials with zoledronic acid show statistically significant reductions in SREs, but also in the time to first SRE, the SMR (number of events per year -counting events in 21 day windows to avoid the possible double counting of related events), and the statistically robust multiple event Anderson-Gill analysis which quantifies the overall relative risk (RR) whilst on study	As stated previously, the GDG did not feel that the evidence was strong enough to conclude that zoledronate has a specific rather then class effect.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						by treatment. These end points are considered by some to be more clinically relevant and therefore we request that the GDG should consider this as well as the SRE end point. In summary, the recommendations regarding bisphosphonates should be amended to reflect the available evidence for zoledronic acid which demonstrates statistically significant results for the prevention of spinal cord compression and pain in breast cancer, multiple myeloma, prostate cancer, NSCLC, RCC and other solid tumours. This is not the case for any other bisphosphonate. References:	There is no evidence for a statistically significant effect on reducing the risk of MSCC in any tumour type.
SH	83.6	Novartis Pharmaceuticals UK Ltd				1. Lee S. Rosen, M.D., et al. Zoledronic acid versus pamidronate in the treatment of skeletal metastases in patients with breast cancer or osteolytic lesions of multiple myeloma. The Cancer Journal 2001, Vol 7, Pages 377-387. 2. Lee S. Rosen, M.D., et al. Long-term efficacy and safety of zoledronic acid compared with pamidronate disodium in the treatment of skeletal complications in patients with advanced multiple myeloma or breast carcinoma. Cancer 2003 98, 8, Pages 1735 – 1744. 3. Saad F, Gleason DM, Murray R et al. A randomized, placebo- controlled trial of zoledronic acid in patients with hormone-refractory metastatic prostate cancer. Journal of National Cancer Institute 2002;94:1458-1468. 4. Saad F, Gleason DM, Murray R et al. Long-term efficacy of zoledronic acid for the prevention of skeletal complications in patients	Thank you.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						with metastatic hormone-refractory prostate cancer. Journal of National Cancer Institute 2004;96:879-882. 5. Rosen et al. Long-term efficacy and safety of zoledronic acid for the treatment of skeletal metastases in patients with Nonsmall cell Lung carcinoma and other solid tumours. American Cancer Society; 2004 p.2613-2621. 6. Yeun et al. Bisphosphonates for advanced prostate cancer (review). The Cochrane Library 2006. Issue 4. 7. Eastham et al. Effect of zoledronic acid on bone pain and skeletal morbidity in patients with advanced prostate cancer; analysis by baseline pain. JCO 2005 23 (165 I of II) 3935 Ab 4561. 8. Saad et al. Poster presented at ASCO prostate cancer symposium 2007. Benefit of zoledronic acid in patients with bone metastases from prostate cancer who have early bone disease. Abstract 94. 9. Gnant et al. ABCSG-12 Trial results presented at ASCO 2008, Abstract #LBA4 10. Rosen et al. Zoledronic acid versus placebo in the treatment of skeletal metastases in patients with lung cancer and other solid tumours. JCO; 2003. Vol 21 No 16 p.3150-3157.	
SH	84	PERIGON Healthcare Ltd				This organisation was approached but did not respond	
SH	85.0	Prostate Cancer Charity, The	Full	4	8-12	The Prostate Cancer Charity is very supportive of this recommendation about giving patients with diagnosed bone metastases or at high risk of developing bone metastases an information leaflet	Thank you.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						that explains the early symptoms of MSCC and advises them what to do if they develop symptoms. We believe it is essential that this group of patients are given this information so that they are aware that they need to seek medical advice promptly if they develop new symptoms. Our experience from calls received to our helpline at The Prostate Cancer Charity is that people are not being given information about the signs and symptoms of MSCC. We have received calls from people with symptoms that could indicate MSCC, they have been unaware of MSCC and its related symptoms and did not know that they should be seeking urgent advice from a healthcare professional. We are therefore very pleased to see this recommendation listed as a key priority.	
SH	85.1	Prostate Cancer Charity, The	Full	48	5-6	The Prostate Cancer Charity supports the appointment of a network lead for MSCC as we believe this will greatly improve the co-ordination and standard of care for patients with MSCC. We would like to see the appointment of this role listed as one of the key priorities in the guidance to ensure implementation.	Thank you. All recommendations in the guideline are supposed to be implemented, not just those highlighted as key priorities.
SH	85.2	Prostate Cancer Charity, The	Full	48	5-6	We feel it would be appropriate for the Network lead for MSCC to have a role in ensuring that appropriate information leaflets on the symptoms of MSCC and what to do if symptoms develop are available within the network and are given to patients. We would like to see this added to the list of key responsibilities for this role. We also believe it would be appropriate for the Network lead to conduct audits to ensure patients	We agree and feel that this is implicit within the recommendation on p66. The network lead is responsible for implementation and audit of this guideline, of which emotional and

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						with MSCC are having their psychological, spiritual and rehabilitation needs appropriately assessed. Where these needs are not being appropriately met, the Network lead should take action to address this. We would like to see this added to the list of key responsibilities for the role.	family support (p9) is a part.
SH	85.3	Prostate Cancer Charity, The	Full	60	30-31	We feel this line should read 'Written and verbal information….' It is important that patients receive written as well as verbal information about how to access psychological support services so that they can keep a copy of this information for future reference.	Changes have been made to this recommendation.
SH	85.4	Prostate Cancer Charity, The	Full	66	32-36	The Prostate Cancer Charity fully supports the recommendation that patients diagnosed with bone metastases or at high risk of developing them should be given an information leaflet on the symptoms of MSCC and who to contact. Our experience from calls to our helpline supports the anecdotal evidence contained within the guidance that patients are not currently receiving this type of information. However, we feel this recommendation should also state that patients should have a chance to discuss the contents of the leaflet with a health professional. Some people may find the content of the leaflet very worrying and they should have the opportunity to raise questions or concerns with a health professional and clarify the information on symptoms and what to do if symptoms develop.	Thank you – we agree. We have amended the recommendation to include verbal and written information.
SH	85.5	Prostate Cancer Charity, The	Full	66	32-43	We support these recommendations, however, we feel that it is very important that the carer(s) of patients with bone metastases or at high risk of developing them should also receive information	Thank you. We agree this information should be widely available. We have revised the recommendation.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						about the symptoms of MSCC and who to contact if they suspect that the patient they are caring for is demonstrating symptoms of MSCC. Patients at risk of MSCC might have difficulty distinguishing between existing symptoms of the disease and those related to MSCC. A carer may be able to be more objective and could play are key role in ensuring that the patient receives immediate medical attention. This guidance should also recommend that information about the early symptoms of MSCC should also be made available in leaflet form for the carers of men at risk of MSCC so that they can refer back to it for guidance.	
SH	85.6	Prostate Cancer Charity, The	Full	66	37-39	We support the recommendations that patients with cancer who present with spinal pain should be made aware of the symptoms of MSCC and who to contact if symptoms develop. However, we feel that this recommendation should state that an information leaflet should be given as per the previous recommendation. It is helpful for patients to have a leaflet to refer to and remind them about the information they were given regarding MSCC (lines 27-31).	We have combined this recommendation with the previous one so that patients with cancer who present with spinal pain are also given an information leaflet.
SH	85.7	Prostate Cancer Charity, The	Full	68	41	We feel the recommendation that patients should be reviewed frequently for persistence or progression of pain is a little vague. It would be helpful if the recommendation could be more specific about frequency of review.	The GDG feel that it is not possible to dictate frequency as this will depend on individual clinical circumstances.
SH	85.8	Prostate Cancer Charity, The	Full	122	26-28	We support this recommendation; however we believe it is essential that all patients admitted to hospital with MSCC are assessed by physiotherapy and occupational therapy to ensure they receive	Thank you. We have amended the recommendation.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						appropriate rehabilitation support. We therefore feel that the recommendation wording should be stronger e.g. change to 'All patients admitted to hospital with MSCC should be assessed by physiotherapy and occupational therapy….'	
SH	85.9	Prostate Cancer Charity, The	Full	122	34-36	This recommendation should clarify which health care professionals should have responsibility for assessing whether patients should be offered admission to a specialist rehabilitation unit. We believe this should be the specialist in charge of their care as this will be a complex judgement to make.	It is not possibe or appropriate for the recommendation to allocate specific responsibility. This might vary according to local circumstances. However, ultimately, it would always be the responsibility of the consultant under whose care the patient currently is.
SH	85.10	Prostate Cancer Charity, The	Full	123	16-18	This recommendation should clarify who is responsible for ensuring that patients with MSCC discharged home receive the equipment they need in a timely fashion.	This would be dependant on where the patient is. In hospital it should be the named clinical lead. In the community it is likely to be the patients key worker.
SH	85.11	Prostate Cancer Charity, The	Full	123	16.18	We strongly support the recommendation that the carer(s) of patients with MSCC who are being discharged home should be offered support and training before discharge. However, we feel the recommendations should clarify who, within the patient's multi-disciplinary team, is responsible for arranging and providing this support and training.	This should be the named individual within the clinical team responsible for coordinating the patients discharge planning. They should be responsible for the coordination but not necessarily delivering the training.
SH	85.12	Prostate Cancer Charity,	Full	143	All	As stated in previous comments The Prostate Cancer information leaflet on the symptoms of MSCC and However, we feel that patients may find it difficult to the ordinary based on the information provided in this be able to use the leaflet effectively to judge when to patient should have the opportunity to discuss the essional when they are given it to enable them to d also be helpful if the leaflet could advise patients to ny questions about the information they have read and ofessionals contact numbers to be added.	Thank you for your comments. This information adapted or developed by local service providers.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	85.13	Prostate Cancer Charity,	Full	143	All	The advice regarding speaking to a doctor, nurse or ıld be made clearer. If it is the weekend some patients ;oon as is practically possibly means waiting until after if their GP is unavailable they should contact a	Thank you for your comments. This information ıdapted or developed by local service providers.
SH	85.14	Prostate Cancer Charity,	Full	143	All	The advice regarding bending the back as little as could be made clearer e.g. is it safe for them to travel the GP to visit them at home? Or call a paramedic?	Thank you for your comments. This information ıdapted or developed by local service providers.
SH	85.15	Prostate Cancer Charity, The	Full	143	All	There is no mention of losing bladder or bowel function these are important symptoms for patients to be aware of if they have not reported other earlier symptoms such as back pain. This is particularly important because at this stage they would need to seek urgent medical attention.	Thank you for your comments. This information leaflet is only an example and can be adapted or developed by local service providers.
SH	85.16	Prostate Cancer Charity, The	Full	53-60		The Prostate Cancer Charity is very pleased to see that the GDG conducted an exploration of the patient experience of MSCC care in England and Wales and received views from patients with MSCC and their families and carers. We welcome the incorporation of extracts from patient narratives into the guidance; these extracts clearly highlight the issues faced by patients and some of the key aspects of care that they would like to see improved.	Thank you.
SH	121.0	Queen Elizabeth Hospital (Norfolk)	Full	79	2	Re Bisphosphonates for pain control. I would not agree that they are not indicated. Cochrane review (referenced below) indicate that Bisphosphonates should be considered where analgesics and/or radiotherapy are inadequate for the management of painful bone metastases	We have recommended the use of bisphosphonates for the relief of pain in breast, myeloma and prostate where the evidence supports this. There is insufficient evidence in other cancers to recommend their use and we have recommended research is conducted in this area.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						Wong R, Wiffen PJ. Bisphosphonates for the relief of pain secondary to bone metastases. *Cochrane Database of Systematic Reviews* 2002, Issue 2. Art. No.: CD002068. DOI: 10.1002/14651858.CD002068	
SH	121.1	Queen Elizabeth Hospital (Norfolk)	Full	General		Generally excellent guideline	Thank you.
SH	86	Robert Jones & Agnes Hunt Orthopaedic & District Hospital NHS Trust				This organisation was approached but did not respond	
SH	87	Royal College of General Practitioners				This organisation was approached but did not respond	
SH	88	Royal College of Midwives				This organisation was approached but did not respond	
SH	89.0	Royal College of Nursing	Full	48	1	In full support of NSSG	Thank you.
SH	89.1	Royal College of Nursing	Full	48	5	In full support of Network lead	Thank you
SH	89.2	Royal College of Nursing	Full	60	21	Not all Cancer centres have access to specialist psychological support services	The guideline is intended to improve service provision.
SH	89.3	Royal College of Nursing	Full	61	20-22	This may put increased pressure on Cancer centres as not all Cancer units or DGH have out of hours MRI cover	The guideline is intended to improve service provision
SH	89.4	Royal College of Nursing	Full	122	5	Only 1 specialist rehabilitation unit exists in Wales?	We are not sure what is being referred to.
SH	89.5	Royal College of Nursing	Full	32-36		Simple algorithms - useful	Thank you.
SH	89.6	Royal College of Nursing	Full	54-60		Whole section – powerful, useful patient stories	Thank you.
SH	89.7	Royal College of Nursing	Full	144	1-36	Appendix 2 – Patient information leaflet (example) – very useful	Thank you.
SH	90	Royal College of Paediatrics and Child Health				This organisation was approached but did not respond	
SH	91.0	Royal College of Pathologists	Full	General		This draft for consultation largely relates to solid tumours as the word "metastatic" in the title implies. With regards to solid tumours, I am aware that there is still controversy about the relative merits of early surgery and radiotherapy, and I am sure members of the Clinical Oncology community may want to have input on this, as the solidity of the available trial data	Thank you.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						has been questioned. This is, however, not my area of expertise, and I will not comment further.	
SH	91.1	Royal College of Pathologists	Full	General		With regard to the highly chemosensitive haematological malignancies, I believe this guideline is inappropriate and yet reference is made in places to myeloma and lymphoma. E.g. reference to use of bisphosphonates in myeloma on page 78 lines 40 – 42. Some specific comments follow:	The scope covers metastatic spinal cord compression and concentrates largely on solid tumours including plasmacytoma and lymphoma when there may be a need for surgical decompression. We recognise that chemotherapy is occasionally appropriate as part of the general treatment for chemosensitive disease. We have added text to section 6.1 and 6.2 to specifically address the differences and additional needs of patients with haematological malignancies.
SH	91.2	Royal College of Pathologists	Full	195		I note from, that of the 17 members of the CDG there is only one Clinical Oncologist, no Medical Oncologist and no Haematologist. This I suspect accounts for the skewing of the report.	There were two clinical oncology members on the GDG with additional oncological support provided the NCC-C Director and needs assessment team. The Chair and Clinical Lead did not feel that a haematologist should be a core member of the GDG.
SH	91.3	Royal College of Pathologists	Full	8	18–22	Re Senior Professional Advice: Whenever leukaemia, lymphoma or myeloma have been diagnosed or suspected, an expert in these diseases should be central to the decision making process. This could be a Clinical Oncologist, but often will not be.	This is implicit in the requirement for appropriate senior advice as part of any treatment planning but we have changed the text to read "…with advice from primary site clinicians or other experts as required."
SH	91.4	Royal College of Pathologists	Full	76		This chapter makes no specific mention of chemotherapy which is an integral part of the management of cord compression due to highly chemosensitive tumours. In leukaemias, lymphomas and even myelomas, particularly in treatment naive patients, the tumour will frequently respond rapidly to the high dose steroids and even more rapidly to specific chemotherapy, such that there is no advantage to giving radiotherapy, and in the absence of mechanical instability (rarely a feature of cord	The background information has been altered to include haematological malignancies. The importance of involving primary site clinicians, including haematologists, at initial planning of treatment has been added to the recommendations on combination therapy. We did not find direct evidence about chemotherapy treating the MSCC (or spinal disease); any evidence about chemotherapy for

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						compression in leukaemia and lymphoma) surgery may be contra-indicated. Complex surgery which delays potentially curative chemotherapy can be disastrous. In fact, in some instances, even where there is mechanical instability, it may be preferable to immobilise with external support so as to start chemotherapy immediately, with any surgery being reserved for a later date. I recognise that in newly presenting patients there is a need for a surgical biopsy but in the haematological malignancies there are frequently more accessible sites. It is stated on page 16 lines 14 and 15 that "all patients should receive consolidation radiotherapy after successful surgery and there is a major issue as to whether this also applies after successful chemotherapy. The evidence base for this is very limited but needs consideration.	these primary cancers reports different outcomes such as survival and recurrence times. This is treating the primary disease not about MSCC.
SH	91.5	Royal College of Pathologists	Full	37 and 41	8 – 12	Epidemiology section: I suspect that the haematological malignancies are a relatively common cause of cord compression, although my impression is likely to be biased by own clinical practice. Epidemiological studies relying on surgical series will not be reliable, of course, as many cases will not be referred to a surgical centre.	Thank you. Myeloma is increasingly seen and prior to vertebral collapse may respond well to vertebroplasty, avoiding open surgery whilst allowing definitive care of the spinal column and cord during haematological treatment. But if neural compression is of bony origin may require conventional surgical decompression.
SH	91.6	Royal College of Pathologists	Full	10	22-26	This section refers to the need for "frequent review". I think a guideline should be more specific than "frequent".	The GDG feel that it is not possible to dictate frequency as this will depend on individual clinical circumstances.
SH	91.7	Royal College of Pathologists	Full	General		Dealing with cord compression in the haematological malignancies is a very complex problem requiring disease-specific expertise. There are many areas of uncertainty and guidelines would be helpful. These guidelines are not they, however, and either the haematological malignancies should be explicitly removed from the advice or a great deal more work needs to be done.	We agree that haematological malignancies are a huge group in their own right and perhaps need a guideline. We will pass this suggestion on to the topic selection committee at NICE.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	92	Royal College of Physicians of London	Full Version	general		We feel that this comprehensive document assumes that patients with this problem will have recognised cancer and be in a cancer network unit. This is not always the case. We would recommend that the vital information contained in the guideline should also be made available to clinicians other than oncologists. It would be necessary to make this as concise as possible, perhaps 10 key points could emphasised in some way?	The guideline recognises that 23% of patients do not have a primary cancer diagnosis (p 38, line 33; p 67, line 17 and p73, line 16). The final version of this document will be published on the NICE website and so will be freely available to everyone. A list of 10 key priorities for implementation will also be included (this list is currently on p4-5 of the consultation document).
SH	93	Royal College of Psychiatrists				This organisation was approached but did not respond	
SH	94.0	Royal College of Radiologists	Full version	general		Firstly we would like to congratulate the authors on making a substantial first step in improving the care of patients with MSCC. This is an impressive document which proposes a wide-ranging reorganisation of services and should see treatment improve and become more timely for these patients. However, rather than an evidence-based guideline, the vast majority of recommendations appear to be consensus statements or, at best, based on observational studies. The reasons for this are understandable as clearly there are no good data available to base recommendations on. This is therefore essentially a consensus document and this should be made clear.	Thank you. This guideline was developed in accordance with the systematic approach of evidence-based medicine. Where relevant evidence was available, this evidence has been appraised and recommendations have been written based on this. Where no evidence existed, recommendations have been drafted based on consensus of the GDG. Therefore we do not feel it would be appropriate to refer to this guideline as "essentially consensus based".
SH	94.1	Royal College of Radiologists	Full version	47		The service changes needed to achieve successful implementation of the recommendations cannot be underestimated. In particular, there are implications for MRI, spinal surgery and radiotherapy services. The 'advertising' of an improved service will inevitably create significant amounts of additional activity and the diagnosis of suspected MSCC will trigger a substantial number of additional MRI requests and other activity.	We agree. The implementation team at NICE will be looking at ways to implement key recommendations of the guideline.
SH	94.2	Royal College of	Full	49		The MSCC co-ordinator would need to be available	We have amended the background information to

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		Radiologists	version			24 hours a day and there are clear resource implications for this to occur. It would be inappropriate to assume that this additional work (which would be significant) could be simply added on to the responsibilities of other medical or nursing on-call staff in spinal surgery or radiotherapy units.	clarify that this a 24 hour role. This role is already filled on ad-hoc basis (usually registrar on call). The guideline formally establishes this role (see p49, lines 44-47).
SH	94.3	Royal College of Radiologists	Full version	47		Availability of rapid hospital transfer to achieve the delivery of treatment within 24 hours requires a system for prioritization and improved flexibility. Ambulance transport is usually the 'rate-limiting' step for rapid treatment and, although this will depend on the geography of the cancer network, the deficiencies and waiting that occur even for 'urgent' ambulance transfer will prevent the successful implementation of this guidance unless improved services can be obtained for this category of patients.	We agree. The implementation team at NICE may look into this. This is for local determination at cancer network level.
SH	94.4	Royal College of Radiologists	Full version	61	32	A weakness is the fact that there is reference to timeliness with the statement 'ideally within 24 hours of first presentation' but it does not make explicitly clear to whom this first presentation is. Is it to the GP, secondary care, or to an oncologist? It should be made clear that this refers to the first clinical presentation whether it be to primary or secondary care.	We have amended the recommendation.
SH	94.5	Royal College of Radiologists	Full version	general		The need to establish a diagnosis is not specified anywhere in this document. It identifies that 23% of patients have no pre-existing malignant diagnosis and clearly in them there will be a need for a biopsy to establish their management at some point, and indeed this may be an indication for surgical intervention.	We feel this issue is addressed by the recommendation on p93, lines 13-14, which has been amended to explicitly include vertebral biopsy.
SH	94.6	Royal College of Radiologists	Full version	4 and 61	6 and 32	The possibility that a patient with MSCC is actually presenting with a curable lymphoma is not considered in this document. This is a dangerous omission, following on from the failure to emphasise the need for a histological diagnosis. The difficulty is	This occasional circumstance is acknowledged but the frequency with which this occurs is insufficient to justify specific recommendations within the guideline.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						compounded by the advice to administer steroids without considering the histological diagnosis. Steroids can make histology uninterpretable if the patient has a lymphoma.	
SH	94.7	Royal College of Radiologists	Full version	4 and 61	7 and 32	Define within 24 hours of first presentation to any clinical care whether in the primary or secondary sector (medical, nursing or other).	We have amended the recommendation.
SH	94.8	Royal College of Radiologists	Full version	4 and 66	8 and 32	'At high risk of developing bone metastases' need clearer definition eg does this mean all women with breast cancer? Information for patients at risk seems a good idea however.	The definition of patients "at high risk" is included in the background information (chapter 1, p37) and includes women with breast cancer and men with prostate cancer.
SH	94.9	Royal College of Radiologists	Full version	4 and 68	13 and 16	The MSCC co-ordinator would be very busy with the definitions of symptoms of worry as defined.	Thank you, we agree.
SH	94.10	Royal College of Radiologists	Full version	4 and 71	30 and 25	Treatment should be undertaken within 24 hours not merely planned.	Currently the management of patients with MSCC takes between 6 weeks and 9 months. The guideline is attempting to limit the time this process takes by advising optimal timescales, all of which should be completed prior to neurological deterioration.
SH	94.11	Royal College of Radiologists	Full version	5 and 98	7 and 10	It is unclear what this reference to 'daytime out of hours facility' means.	We have changed this to "…daytime, 7 days a week…"
SH	94.12	Royal College of Radiologists	Full version	6 and 99	15 and 3	We are not convinced that IMRT will have much of a role in radiotherapy for MSCC.	We feel that it is important to research the clinical and cost effectiveness of new radiotherapy techniques in order to determine their roles.
SH	94.13	Royal College of Radiologists	Full version		General	Consider adding investigation of the role of bisphosphonates in the prevention of MSCC?	This is already covered in the recommendation on p79, line 13-16.
SH	94.14	Royal College of Radiologists	Full version	7 and 48	13 and 1	Establishing a network group purely for MSCC will be challenging to implement. Such a network would cut across the site specific networks which need to be involved with the treatment of these patients.	We are aware of this which is why a formal MDT is not proposed for the care of individual patients but a twice annual meeting is thought reasonable to monitor the care pathway (p47 25-29).
SH	94.15	Royal College of Radiologists	Full versio	8 and 51	23 and 4	Discussion with an oncologist is recommended frequently. Discussion with the oncologist who know	This is implicit in the requirement for appropriate senior advice as part of any treatment planning but

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
			n			the patient is even more beneficial.	we have changed the text to read "…with advice from primary site clinicians or other experts as required."
SH	94.16	Royal College of Radiologists	Full version	4 and 71	30 and 25	Treatment should be undertaken within 24 hours not merely planned.	Currently the management of patients with MSCC takes between 6 weeks and 9 months. The guideline is attempting to limit the time this process takes by advising optimal timescales, all of which should be completed prior to neurological deterioration.
SH	94.17	Royal College of Radiologists	Full version	9 and 61	17 and 24	We fully support displacement of routine patients to allow MRI of the patients with MSCC. The document suggests displacing them to later in the day and making everyone else wait longer. The alternative would be to cancel one or two non urgent patients (as it is common for surgery) .	This was not considered in the economic evaluation of extending MRI sessions but probably would be cost effective if inconvenient for other patients. We have changed to include alternative sessions.
SH	94.18	Royal College of Radiologists	Full version	9 and 61	24 and 32	Within 24 hours of first presentation to any clinical care whether in the primary or secondary sector (medical, nursing or other).	Currently the management of patients with MSCC takes between 6 weeks and 9 months. The guideline is attempting to limit the time this process takes by advising optimal timescales, all of which should be completed prior to neurological deterioration.
SH	94.19	Royal College of Radiologists	Full version	10 and 68	22 and 38	Assessment of all patients with a history of cancer who develop back pain potentially would swamp clinics and MRI facilities. Only those with more specific criteria should be reviewed (as we would expect to happen now).	Only patients with persistent or progressive pain or developing neurology are recommended for MRI.
SH	94.20	Royal College of Radiologists	Full version	10 and 71	35 and 25	Change the wording to 'within 24 hours of presentation to any clinician'. Introducing a new term suspected diagnosis will create muddle.	Currently the management of patients with MSCC takes between 6 weeks and 9 months. The guideline is attempting to limit the time this process takes by advising optimal timescales, all of which should be completed prior to neurological deterioration.
SH	94.21	Royal College of Radiologists	Full version	11 and 76	22 and 2	There is a whole chapter missing here on establishing a diagnosis. Patients with pre-existing malignancy are usually considered to have metastatic	We have made the requirement for diagnostic biopsy more apparent in the recommendations.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						disease but even here if there is a very long interval from the primary diagnosis it will be prudent to insist on re-biopsy. Our main concern is with the 23% of patients identified in this report as not having pre-existing malignancy. It is indeed possible that they do not have malignancy at all. They might rarely have another diagnosis, for example tuberculosis. A new section should include the need to determine what the histological diagnosis is if it is not known previously. If a patient has metastatic disease in other sites then one of these can be biopsied after treatment of the spinal cord compression. It is particularly important to consider lymphoma here as spinal cord compression can be part of the curable presentation in these diseases. Similarly it is essential to ensure that steroids are not given before biopsy as they can make the material un-interpretable. We recommend a new chapter on this issue.	
SH	94.22	Royal College of Radiologists	Full version	12 and 78	1 and 44	The recommendation about bisphosphonates is unclear and would appear to read that patients with prostate cancer should be considered for use to prevent cord compression. This would mean all patients were treated. We suspect this is just unclear wording.	The GDG do not feel that the recommendation is unclear. It states that bisphosphonates are to be used for pain control only if analgesia fails. It does not recommend the use of bisphosphonates in prosate cancer to prevent skeletal related events.
SH	94.23	Royal College of Radiologists	Full version	13 and 86	29 and 40	As soon as possible after assessment, once due consideration has been given to the nature of the histological diagnosis and the possible need for biopsy.	The issue of timing is contentious for the rare case of epidural lymphoma. We have added text to cover this. We have also included the need for biopsy in recommendation p93, lines 13-14.
SH	94.24	Royal College of Radiologists	Full version	16 and 96	2 and 6	Assessment of prognosis (<3/12, <12/12, >12/12) is suggested to be required for triage and decision making but is notoriously unreliable, and indicators are not provided.	The GDG recognises the limitations of this scoring system but feel it is a useful adjunct to determining prognosis, supported by health economic evaluation.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	94.25	Royal College of Radiologists	Full version	16 and 98	12 and 10	What does 'including daytimes out of hours facilities' mean?	We have changed this to "…daytime, 7 days a week…"
SH	94.26	Royal College of Radiologists	Full version	16 and 103	32 and 22	The statement 'biologically equivalent dose of 100Gy' is incorrect. The key reference has been quoted in your document (Rades et al, IJROBP, 2006). The correct dose is $100Gy_2$ (with subscript 2) which means equivalent dose in 2Gy fractions.	Thank you for noting this we will correct the text to read "$100Gy_2$".
SH	94.27	Royal College of Radiologists	Full version	116		The guidance on nursing is didactic and not supported by any evidence.	In the absence of evidence recommendations are based on GDG consensus, unsure what specifically the comment is referring to.
SH	94.28	Royal College of Radiologists	Full version	67	17	The fact that 23% of patients with MSCC have no prior cancer diagnosis is not adequately dealt with in this guideline. There needs to be a new section on how to establish the diagnosis in these patients and the essential role of biopsy in their management.	The absence of primary malignant diagnosis is referenced 3 times within the guideline (p 38, line 33; p 67, line 17 and p73, line 16). We acknowledge the increased difficulty in making this diagnosis in the 1 in 4 patients who present without a prior cancer diagnosis. The recommendation on p93, lines 13-14, has been amended to explicitly include vertebral biopsy.
SH	94.30	Royal College of Radiologists	Full version	76	37	The first essential element of treatment planning is to establish a histological diagnosis by biopsy if necessary.	Thank you for your comment. we have changed the recommendation.
SH	94.31	Royal College of Radiologists	Full version	84	30-41	This section is muddled. It refers to radio-resistant tumours but does not define which they are other than to say that surgery is the treatment of choice for them. As discussed elsewhere there is moderately good evidence that outcomes are improved by having surgery before radiotherapy in suitable cases. This is the evidence base and it should be stated at this point. Rather than referring to radio-resistant tumours it would be more helpful to refer specifically to identified radio-sensitive tumours such as myeloma, and lymphoma (not mentioned at all) which	The term "radio-resistant tumours" has been deleted. The backgrounds for sections 6.1 and 6.2 have been amended to include haematological malignancies.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						are probably best managed by radiotherapy unless there is spinal instability. Breast and prostate cancer should be at least considered for surgery. Lung cancer also needs to be mentioned in the review as does bowel cancer. It is also possible to manage lymphoma with initial chemotherapy. This has been completely omitted. These two paragraphs need completely redrafting.	
SH	94.32	Royal College of Radiologists	Full versio n	86	26	Corticosteroids have an important role but should not be given if a histological diagnosis has not been established either in the past or at this presentation. Lymphoma is a curable condition and needs to be histologically diagnosed before steroids are given. This should be emphasised at this point.	Benefits of steroids for the majority of patients with spinal cord compression by solid tumour, outweighs the potential detriment for the small group with cord compression associated with lymphoma. The recommendations have been changed to include histology. Timelines for steroid treatment will be considered.
SH	94.33	Royal College of Radiologists	Full versio n	86	39	Suggest adding a new bullet point 'before steroids are given a histological diagnosis must have been established by biopsy either at this presentation or previously'.	Benefits of steroids for the majority of patients with spinal cord compression by solid tumour, outweighs the potential detriment for the small group with cord compression associated with lymphoma. The recommendations have been changed to include histology. Timelines for steroid treatment will be considered
SH	94.34	Royal College of Radiologists	Full versio n	103	23	The statement 'biologically equivalent dose of 100Gy' is incorrect. The key reference has been quoted in your document (Rades et al, IJROBP, 2006). The correct dose is $100Gy_2$ (with subscript 2) which means equivalent dose in 2Gy fractions. In addition, that paper made no assumptions about recovery after the previous course and included patients treated at an interval of 2-40 months.	We will correct this.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	94.35	Royal College of Radiologists	Full version	141	20	It is unclear why non-urgent patients cannot simply be cancelled. The suggestion seems to be to make the whole list run late whereas cancelling a couple of patients might be a simpler solution. Cancellation at the last minute is not uncommon in surgery. Patients should be warned of the possibility.	The recommendation has been altered to reflect this point .
SH	94.36	Royal College of Radiologists	Full version	143	Appendix 2	This patient information sheet is offered as an example but we consider it to be inadequate. Attached for information is a document used within the West Anglia cancer network for five years. It was intended for patients with known bone metastases.	Thank you for submitting the document used within the West Anglia network. The GDG were happy with the example in the guideline, which can be adapted or developed by local service providers.
SH	94.37	Royal College of Radiologists	Full version	143	16	Pain can also radiate round the abdomen and down the arms and down the legs.	This s only an example and can be adopted by local service providers.
SH	94.38	Royal College of Radiologists	Full version	143	20	This advice is disingenuous. It is not useful to advise patients to speak to a clinician as soon as practical (certainly within 24 hours). We want them to act more rapidly. The consequences of not doing so should be more clearly spelt out – see attached WACN information sheet.	This s only an example and can be adopted by local service providers.
SH	95	Royal College of Surgeons of England				This organisation was approached but did not respond	
SH	96.0	Royal Society of Medicine	Full	General		Reading the draft guideline it strikes me that the short prognosis that for example our audit confirmed (median 30 days survival) and thus the need for end of life/palliative care for patients with MSCC has little attention. I think the guideline should highlight more that the overall performance status of patients with suspected MSCC needs to be taken into account when deciding on treatment. There are patients as we all know who should only receive symptom control because they are too unwell to consider anything else.	Thank you for your comment. The GDG attempts in its selection for treatment section (chapter 6) to distinguish patients who are too ill, too frail or otherwise inappropriate for active treatment of MSCC (such as those who present late). We do not feel that adding recommendations on this topic would be appropriate but will add background Information about the importance of palliative care and recommendations for palliative care are in chapter 7.
SH	96.1	Royal Society of Medicine	Full	General		The guideline does not highlight enough that patients without a previous cancer diagnosis with back pain	The absence of primary malignant diagnosis is referenced 3 times within the guideline (p 38, line

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						are often missed or the diagnosis of MSCC is delayed. It mentions those patients, but only with one sentence and not at the beginning. In our audit again these patients experienced the longest delay in diagnosis.	33; p 67, line 17 and p73, line 16). We acknowledge the increased difficulty in making this diagnosis in the 1 in 4 patients who present without a prior cancer diagnosis.
SH	97	Royal United Hospital Bath NHS Trust				This organisation was approached but did not respond	
SH	98	SACAR				This organisation was approached but did not respond	
SH	99	Sandwell PCT				This organisation was approached but did not respond	
SH	100	Scottish Intercollegiate Guidelines Network (SIGN)				This organisation was approached but did not respond	
SH	101	Sheffield PCT				This organisation was approached but did not respond	
SH	102	Sheffield Teaching Hospitals NHS Foundation Trust				This organisation was approached but did not respond	
SH	103	Social Care Institute for Excellence (SCIE)				This organisation was approached but did not respond	
SH	104.0	Society and College of Radiographers	Full Version	General		The SCoR welcomes this guideline and considers that a logical and smooth pathway for managing these patients, many who have been poorly served in the past will raise standards and improved outcomes and quality of life for those suffering from metastatic cord compression, and also for relatives and carers.	Thank you.
SH	104.1	Society and College of Radiographers	Full Version	General		We note that the evidence for the guideline often is more anecdotal, or limited to the practice and audits at one or two centres. Whilst this may be the only information to inform the group, it may have weaknesses	This guideline was developed in accordance with the systematic approach of evidence-based medicine. Where relevant evidence was available, this evidence has been appraised and recommendations have been written based on this. Where no evidence existed, recommendations have been drafted based on consensus of the GDG.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	104.2	Society and College of Radiographers	Full Version	General		We consider that the challenges for implementation will be large, and that there is likely to be a large unmet need which will increase pressure on MR and Radiotherapy departments, many of which are already under considerable pressure.	We agree. These issues will be passed onto the Implementation team at NICE.
SH	104.3	Society and College of Radiographers	Full Version	4	7	SCoR would suggest use of 'further' neurological deterioration. When does the clock start for first presentation?	We do not think that using the term "further" is appropriate because this implies potential acceptance of significant neurological compromise which would require earlier intervention. We have amended the text regarding "first presentation".
SH	104.4	Society and College of Radiographers	Full Version	4	37	SCoR would encourage recommendation of specific method of assessments	Specific methods are not available. The GDG acknowledges the difficulties confirming spinal stability and has attempted a pragmatic description of current practice being a combination of clinical and radiological features, and careful observation in a multidisciplinary setting (see mobilisation section on p 84 - 86). The guidance is only permitted 10 key recommendations for implementation and for necessity these are wide ranging.
SH	104.5	Society and College of Radiographers	Full Version	6	15	SCoR are not convinced that IMRT will have much of a role for radiotherapy in patients with MSCC	We feel that it is important to research the clinical and cost effectiveness of new radiotherapy techniques in order to determine their roles.
SH	104.6	Society and College of Radiographers	Full Version	47	41-43	The impact on the workforce requires assessment	The economic evaluation undertaken showed that it was cost effective to extend access to MRI outside normal working hours. This is for local implementation.
SH	104.7	Society and College of Radiographers	Full Version	48	19-31	SCoR welcomes the professional inclusivity and that the lead healthcare professional post could easily be filled by a consultant radiographer	Thank you
SH	104.8	Society and College of Radiographers	Full Version	50	15-16	This may also be suitable for a consultant radiographer, however, someone will need to fulfil this role 24/7 and consideration needs to how this post will be staffed	This will be for local agreement and cannot be specified by the guideline.
SH	104.9	Society and College of	Full	50-51	44 - 2	The post of SPA could also include appropriately	We disagree - this is a role for a senior medical

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		Radiographers	Version			trained and accredited non medical consultant practitioner specialising in the diagnosis and treatment of MSCC, for example a Consultant Therapeutic or Diagnostic Radiographer. Radiographers working at consultant level are now managing pathways of care and could effectively and efficiently undertake/contribute to this treatment pathway and this could offer a more cost effective way for the service to be delivered (those with appropriate post registration related to MSCC could effectively diagnose and deliver treatment for certain categories of MSCC patients)	consultant.
SH	104.10	Society and College of Radiographers	Full Version	51	4-7	Radiographers also have image interpretation skills – Radiographers working at consultant level are now reporting, advising and or managing pathways of care and could effectively undertake/contribute to this pathway	Whilst interpretation of imaging is recognised as being within the remit of appropriately trained radiographers, the GDG feel that responsibility for complex decision making and choice of treatment modality and its delivery, should remain the responsibility of senior medical professionals.
SH	104.11	Society and College of Radiographers	Full Version	61	4	Effects of delayed diagnosis and treatment This sub title does not seem to reflect subsequent statements which do not talk about delayed diagnosis but how to manage urgent patients	We have moved all these sections to improve the flow of the document.
SH	104.12	Society and College of Radiographers	Full Version	66	32-39	SCoR welcomes this guidance and is especially please to note the recommendations around raising the awareness and symptoms of potential MSCC with patients themselves	Thank you.
SH	104.13	Society and College of Radiographers	Full Version	61	24-26	Configuring lists to allow patients to be accommodated at short notice is welcomed. However displacing routine patients, and asking them to wait perhaps considerable length of time may lead to a great many unhappy 'routine' patients and increase in complaints from them. It would perhaps be better to postpone an in patient slot until the end of a list.	This recommendation has been altered to say displaced to ad hoc overtime or alternative sessions.
SH	104.14	Society and College of Radiographers	Full Version	66	41-43	SCoR welcome the recommendation	Thank you.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	104.15	Society and College of Radiographers	Full Version	71	25-28	SCoR would recommend use of skin marker in imaging to reduce risk of incorrect level being treated. This is pertinent where FOV is limited and facility to stitch images not readily available or patient needs to be moved	The guideline recommends imaging of the whole spine (p71, line 25). Skin marking is not required at the point of diagnosis.
SH	104.16	Society and College of Radiographers	Full Version	74	17-24	SCoR would welcome the addition of 'or specialist reporting radiographer ' after radiologist on this line	MRI of metastatic cord compression is a complex image interpretation of a single disease entity and therefore not suitable for Specialist radiographer interpretation. Symptoms of MSCC can be mimicked by many other disease entities i.e. patients with cancer may get acute degenerative disc protrusions or due to their treatment might get an infection or haemorrhage. The might suffer from a para-neoplastic phenomena, reaction to drugs or due to hyper-viscosity syndromes may infarct the cord. Their scans therefore require expert interpretation and a good understanding of the clinical possibilities. This is particularly important as patients may go on to receive radiotherapy, based on the report, which in some situations would be detrimental if the wrong diagnosis was made.
SH	104.17	Society and College of Radiographers	Full Version	74	17-40	– Suitable analgesia may be required prior to imaging	This is a fundamental part of good practice and we do not feel that it needs to be explicitly stated.
SH	104.18	Society and College of Radiographers	Full version	90 96 98	43-46 6-10 16-18 10-12	Need to consider workload issues	This is for local disseminating at cancer network level.
SH	104.19	Society and College of Radiographers	Full Version	122 - 123	26 onwards	This may be a challenge for social care and community teams	Possibly, but not sure which recommendation is being specifically referred to by this comment.
SH	104.20	Society and College of Radiographers	Full Versi	32		SCoR would consider that a positive MRI would not lead directly to 'supportive care' without some	We have changed the box to read "Supportive/palliative care".

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
			on			palliative treatment	
SH	104.21	Society and College of Radiographers	Full Version	34-35		Box 3 – would a timescale for imaging be helpful. Also should there be a mention of bony imaging or biopsy in one of the boxes	We will discuss this with the GDG and change where appropriate.
SH	104.22	Society and College of Radiographers	Full Version	40	28 - 34	Were questionnaires sent to radiology departments too? This may have given a different perspective.	The questionnaire was sent to DGHs but only a limited response was given.
SH	104.23	Society and College of Radiographers	Full Version	41	24	Some of these finding seem quite positive. It would be interesting to know if those filling in questionnaires had true or perceived picture of provision.	We agree it would be interesting to know.
SH	104.24	Society and College of Radiographers	Full Version	42	39 - 46	In view of calls for rapid access, which previous research seem to indicate is there, 72 hours seems quite a long time to wait for surgery	This is a survey of current practice prior to development of this guideline and a baseline for future audit.
SH	104.25	Society and College of Radiographers	Full Version	44 -45	17 onwards	There seems to be evidence here of serious weakness in rehabilitation facilities. A service is only as good as its weakest link	This is a survey of current practice prior to development of this guideline and a baseline for future audit.
SH	104.26	Society and College of Radiographers	Full Version	47	33 - 43	Limited 24 hour availability is not necessarily supported by previous evidence in this paper. 24 hour availability is not available in some centres, but there appears to be better coverage than might be expected. 24 hour access needs to be driven by true service requirements. However if there is to be an increase of 24 hour MR accessibility the increase in staffing and workforce issues needs to be addressed	We agree.
SH	104.27	Society and College of Radiographers	Full Version	50	42 - 46	Radiologists - add 'or specialist reporting radiographers'	The GDG do not feel that this would be appropriate.
SH	104.28	Society and College of Radiographers	Full Version	53 - 59		There seems to be a requirement to engage with alternative health providers and independent practitioners. Many people with backache see chiropractors and osteopaths. Also the fault, as demonstrated in evidence, is not confined to 'primary care' Patients have been appropriately referred into secondary care and then inappropriately managed.	We think that the guideline is one of the tools to increase general awareness.
SH	104.29	Society and College of Radiographers	Full Versi	62	26 - 38	This is a huge assumption. Although this may be true there is no evidence in the referenced papers to	Agreed. But this assumption was used to explore worse case scenario and even this did not justify

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
			on			support this. Would a neurologically stable patient be damaged by waiting? Would their outcome be different to that of someone 'going off their legs' SCoR are concerned that an assumption like this can be turned into a statement of fact very easily with absolutely no supporting or objective evidence and radiology departments forced to supply a service which is not required. There is good evidence that delay in diagnosis of spinal cord problems leads to poorer outcomes, but once identified imaging does not necessarily cause a problem. The subsequent statement that Thus the benefit of longer and more frequent opening hours leads to faster access to diagnosis and treatment with better health outcomes is not accurate or supported by any evidence	24 h service in DGHs. Delays do occur and the guideline seeks a pragmatic solution with health economics backing supporting urgent scans in normal working hrs displacing booked elective patients if necessary.
SH	104.30	Society and College of Radiographers	Full Version	64	2a	Although this makes sense, there is often great resistance from patients forced to wait. They may wish to rebook and not wait. Would this 'stop the clock' on the 18/52 wait or might is risk breach?	We have amended this recommendation. They would need inclusion in the 18 week target and ad hoc overtime as suggested.
SH	104.31	Society and College of Radiographers	Full Version	67	16-19	SCoR support this statement	Thank you.
SH	104.32	Society and College of Radiographers	Full Version	69	41 - 45	SCoR support this statement	Thank you.
SH	104.33	Society and College of Radiographers	Full Version	70	11 - 13	SCoR would support this research project	Thank you.
SH	104.34	Society and College of Radiographers	Full Version	71	11 - 21	This statement may be true, but there may well be pressure from patients in this category and/or their relatives and friends for imaging	Possibly, but there is no clinical benefit or justification for screening asymptomatic patients.
SH	104.35	Society and College of Radiographers	Full Version	74	18	Or specialist reporting radiographer	MRI of metastatic cord compression is a complex image interpretation of a single disease entity and therefore not suitable for Specialist radiographer interpretation. Symptoms of MSCC can be mimicked by many other disease entities i.e.

Type	Order No	Stakeholder	Docu ment	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
							patients with cancer may get acute degenerative disc protrusions or due to their treatment might get an infection or haemorrhage. The might suffer from a para-neoplastic phenomena, reaction to drugs or due to hyper-viscosity syndromes may infarct the cord. Their scans therefore require expert interpretation and a good understanding of the clinical possibilities. This is particularly important as patients may go on to receive radiotherapy, based on the report, which in some situations would be detrimental if the wrong diagnosis was made.
SH	104.36	Society and College of Radiographers	Full Version	"	21	And appropriate marking of level	Sorry but we are not clear to what part of the guideline you are referring.
SH	104.37	Society and College of Radiographers	Full Version	103	22 - 25	We would suggest this dose may be incorrect/typo error	We will correct this.
SH	104.38	Society and College of Radiographers	Full Version	127	19 - 21	There will inevitably be workforce issues including training, recruitment and retention where the out of hours service is to be extended. Also, as previously stated in the draft document there is likely to be an increase in referrals.	This is for local commissioning.
SH	104.39	Society and College of Radiographers	Full Version	130	12 - 26	This is a huge assumption, as previously stated, it may be true, but there is no evidence to support this.	It is agreed that this is an important assumption - and in many respects it drives the results. The assumption was made because without it, the model would not work - that is if it was not accepted / built into the model that faster access to scanning and treatment would lead to improvements in health, there would be no health benefit of faster access and thus it could never be effective or cost-effective. There is some evidence to suggest that faster access would lead to improved outcomes, however, it is acknowledged in the text that the quality of this evidence is poor.
SH	104.4	Society and College of	Full	135 -	33	Costs can be dependent on set up and location of	It is agreed that costs can be, and often are,

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	0	Radiographers	Version	136	onwards	MR units. Radiographic staff cannot be 'alone' without another 'MR authorised' (see MHRA Guidelines 2007) person in case of emergency. Radiologist will need to be MR authorised if present, if not present there will need to be another 'MR authorised' person in vicinity. This may need to be costed into the equation.	dependent on location of MRI facilities - other than conducting sensitivity analysis (which has been done) around the costs of MRI, it is difficult to know how else to deal with this issue since the guideline is for a national, rather than location specific, audience. It should be noted that sensitivity analysis always revealed option 2b to be the most cost-effective (within reasonable bounds). It should also be noted that implicit within the calculation is that the radiologist is MR authorised.
SH	104.41	Society and College of Radiographers	Full Version	135 - 136	33 onwards	If on call, does this include travel and stand by costs? Also costs as above.	The additional costs of neuroradiologists were not included (at all) because they were already assumed to be on call.
SH	104.42	Society and College of Radiographers	Full Version	140	30 - 32	SCoR consider this to be an ideal opportunity for research and would support this being commissioned	Thank you.
SH	104.43	Society and College of Radiographers	Full Version	141	20 - 21	As previously stated, forcing patients into a busy MR list and thus making the rest of the days list run perhaps very late (cord compression patients may not need very much 'imaging' time but can be time consuming in all other respects – comfort/patient movement/moving and handling etc) could cause major in terms of routine patient discontent, inconvenience to patients (they have their own pressures of work and childcare etc) staff pressures and stress. It may be best to actually cancel another patient.	The recommendation has been altered to reflect this point.
SH	104.44	Society and College of Radiographers	Full Version	143	20	Suggest speak to Dr. Nurse paramedic ASAP	This s only an example and can be adopted by local service providers.
SH	104.45	Society and College of Radiographers	Full Version	150	42 - 44	This cost seems very low!	These costs were largely estimated on the basis of expert opinion as the necessary direct evidence was not available. Thus, it is difficult to know whether or not these costs are in actual fact, low.
SH	104.46	Society and College of Radiographers	Full Versi	184	44 - 46	We would suggest separating Diagnostic and Therapeutic Radiographers	We have not distinguished between diagnostic and therapeutic radiographers therefore we cannot

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
			on			Diagnostic Radiographer – A registered Healthcare professional who is qualified to undertake and interpret radiographic images which may include X-rays, CT, MR, U/S and Nuclear Medicine Therapeutic Radiographer – a registered healthcare professional who is qualified to deliver ionising radiation to patients who require radiotherapy treatment. They manage the pathway of care, support and information along the individual radiotherapy patient pathway	include a definition in the glossary.
SH	105	Society of British Neurological Surgeons				This organisation was approached but did not respond	
SH	106	South Birmingham Primary Care Trust				This organisation was approached but did not respond	
SH	107	South East Wales Cancer Network				This organisation was approached but did not respond	
SH	108	Staffordshire Moorlands PCT				This organisation was approached but did not respond	
SH	109	Stockport PCT				This organisation was approached but did not respond	
SH	110.0	Sussex Cancer Network	Full version	50	44-46	What is the impact of the CNS IOG on the requirement to have spinal surgeons available at all times? If a cancer network does not have a designated spinal cord MDT within their boundaries, does this mean that there will be suitable spinal surgeons available to fulfil the MSCC guideline?	The CNS IOG does not address MSCC. The network needs to identify who they are and how they are contacted. See key priority 1.
SH	110.1	Sussex Cancer Network	Full version	96	16-17	Concern around the statement that "surgical treatment should not be considered for patients with MSCC whose prognosis is assessed as being less than 3 months". Sussex Cancer Network Central Nervous System NSSG felt this to be an inappropriate statement.	Thank you for comment. The scoring systems and prognostic factors indicate that patients in the final 3 months of life have poor outcomes and do not benefit from complex, major spinal surgery.
SH	110.2	Sussex Cancer Network	Full version	48	15-17	The wording makes this sound like it is an MDT. Perhaps it should be amended to read that it is about reviewing pathways and outcomes, rather than arrangements for care of these patients	We have changed the text to clarify.

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	110.3	Sussex Cancer Network	Full version	66	32-36	Perhaps this needs to also say that GPs and District Nurses should be given the information leaflet too as they need to be educated about the signs and symptoms of MSCC.	We agree. The purpose of this guideline is to inform people more widely about MSCC.
SH	110.4	Sussex Cancer Network	Full version	122	41-44	Should read "including primary and specialist palliative care"	We have changed the recommendation.
SH	111	Tayside NHS Trust				This organisation was approached but did not respond	
SH	112	Thames Valley Cancer Network				This organisation was approached but did not respond	
SH	113	University Hospital Aintree				This organisation was approached but did not respond	
SH	124.0	University Hospital Coventry	Full	50	11	Please not another bureaucratic non-post! The MSCC Coordinator exists already in Cancer Centres and is called the Consultant Clinical Oncologist or Spinal Surgeon on call! People know who we are and how to contact us and we often know or can find out about the patient and can assess the appropriateness of transfer. At Units many of these patients will come in under the on call Physician and I'm sure that reinforcing /reminding and formalising Dr to Dr links will achieve this and prevent fruitless transfer of inappropriate or dying patients.	We agree. It's perfectly reasonable that this role does already exist in a variety of forms and is perfectly reasonable for you to continue with current arrangements with senior clinicians nominated MSCC coordinators. Simultaneously providing senior professional advice.
SH	124.1	University Hospital Coventry	Full	4 and 61	6 and 32	"treatment should *always* start before *any* neurological deterioration" Is this possible? Do you mean should start before further neurological deterioration whenever possible? Most patients with MSCC are diagnosed because of neurological deterioration and sometimes this may progress relentlessly despite treatment.	We have removed the word "any".
SH	124.2	University Hospital Coventry	Full	General		I'm a stakeholder as I have had an interest in MSCC for some time and will be one of the people who actually puts them into practice!	Thank you. Implementation tools will be developed to accompany this guideline.
SH	114.1	Walton Centre for Neurology	Full	General		DGHs that have MRI scanning ability should do the	We recommend that MRI scans should be

Type	Order No	Stakeholder	Document	Section No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		and Neurosurgery NHS Trust	Version			screening MRI 24/7 not just the receiving tertiary centres that also have pressures for other conditions e.g. cauda equine syndrome and other neurological emergencies such as stroke. It also seems contradictory to keep a patient on bed rest but to be prepared to transfer them often long distances just for imaging.	performed within a 24 hour time period (p 71). We require acute hospitals to reconfigure their MRI lists (p 61). We recognise that 24 hour provision at every hospital is not appropriate for MSCC alone and if necessary in these circumstances, patients should be transferred to the major treating centre.
SH	114.2	Walton Centre for Neurology and Neurosurgery NHS Trust	Full version	85	23	Inappropriate to convert an ambulant patient into "bed rest only" if imaging / treatment can not be undertaken in a 24 hour period.	We will define timelines in the final version of the guideline.
SH	114.3	Walton Centre for Neurology and Neurosurgery NHS Trust	Full version	General		The Tokuhashi score will identify poor prognosis patients with survival less than 6 months but more than 3 months. Hence it should be used cautiously and as part of a discussion in an MDT otherwise patients could be denied appropriate palliation.	The health economic evaluation supports surgery for patients with a prognosis of more than 3 months, provided senior professional advice and an MDT think it worthwhile.
SH	115	Welsh Assembly Government				This organisation was approached but did not respond	
SH	116	Welsh Scientific Advisory Committee (WSAC)				This organisation was approached but did not respond	
SH	117	Wessex Neurological Centre				This organisation was approached but did not respond	
SH	118	Western Cheshire PCT				This organisation was approached but did not respond	
SH	119	Western Health and Social Care Trust				This organisation was approached but did not respond	
SH	120	York NHS Foundation Trust				This organisation was approached but did not respond	