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Guidelines for the assessment of oral mucositis in adult chemotherapy, radiotherapy and haematopoietic stem cell transplant patients

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ABSTRACT

Oral mucositis (OM) is a serious consequence of some chemotherapy and radiotherapy regimens. A number of reliable instruments are available to assess OM, but none are universally accepted. A unique collaboration of multi-disciplinary experts from Europe was formed to make recommendations on OM assessment, based on a systematic literature review and the experts' experience. The main recommendations are listed. There should be a comprehensive baseline assessment. OM should be frequently assessed using a standardised instrument, or a combination of instruments. Physical, functional and subjective changes should be measured. Subjective measures should be assessed prior to any physical examination. The use of pain scoring, in particular patient self-reporting, should form part of any OM assessment. Any assessment instrument should be validated, easy to use and comfortable for the patient. Training of, and monitoring in, the use of the instrument is vital to successful monitoring of OM.

1. Introduction

Oral mucositis (OM) is a frequently distressing, and sometimes serious, consequence of treatment with certain types of cancer therapies, with an incidence ranging from 15% to 90%.[1–3] OM is a multistage biological process that can cause erythema, swelling, bleeding and painful ulceration of the mucosal tissue.[4]

The impact of OM is generally under-rated, although patients often cite OM as one of the worst side effects of their

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treatment.[5,6] Recent studies also show that severe OM is associated with inferior overall survival following haematopoietic stem cell transplantation (HSCT).[7] OM impacts on healthcare costs, due to increased length of in-patient stays and demands on resources.[8,9] The prevention and palliation of OM is a priority for those involved in the management of these patients. The Multinational Association of Supportive Care in Cancer (MASCC)/International Society of Oral Oncology (ISOO) guidelines provide clinicians with a comprehensive assessment of OM prevention and treatment protocols and make recommendations for best clinical practice.[10,11] Diagnosing and grading the severity of OM forms the basis of management and, accordingly, a number of validated and reliable instruments are available for this purpose.[12]

Their individual limitations, however, often lead investigators and clinicians to adapt existing scales or develop new ones. Unfortunately, there is a lack of consistency amongst these scales, and consequently, none are universally accepted.[1] It is the absence of a universally accepted assessment scale, the lack of guidelines on best practice in OM assessment and the use of inconsistent and incompatible OM assessment instruments that continues to hinder progress in the measurement and management of this condition.

Nursing, medical and dental experts from the European Group for Blood and Marrow Transplantation (EBMT) and the European Oncology Nursing Society (EONS) convened to form the Oral Mucositis Assessment Guidelines (OMAG) taskforce to generate guidelines for the use of tools in assessing OM in the adult patient with a malignancy. The aim of the taskforce was not to develop another tool, but to thoroughly analyse the assessment instruments currently available, their implementation and to formulate recommendations with which to address inconsistencies in the assessment of OM.

2. Methodology

2.1. Literature search

The methodology is similar to the one used in the recent guidelines from the United Kingdom Children's Cancer Study Group (UKCCSG) and the Paediatric Oncology Nurses Forum (PONF) Mouth Care Group (UKCCS-PONF guidelines).[13]

Questions considered pertinent to OM assessment were defined by the EMBT/EONS OMAG taskforce (Appendix 1). Search terms were defined and MEDLINE, EMBASE and the Cochrane Library were searched electronically (Appendix 2). To be considered relevant, the studies had to be phase II or III original clinical studies published in English between 1st January 1990 and 31st January 2006, and involve patients ⩾18 years of age. Studies were included if OM was a primary endpoint or if they compared OM assessment tools. Additional papers not identified in these electronic searches were suggested by members of the taskforce.

Relevant articles in press were identified by searching for abstracts on conference websites (Appendix 2). Abstracts that met the inclusion criteria were compared against papers already identified in the electronic literature search and papers recently published through PUBMED. If data from the abstracts had not been published, the first author was contacted to see if the paper was in press and could be included in this analysis.

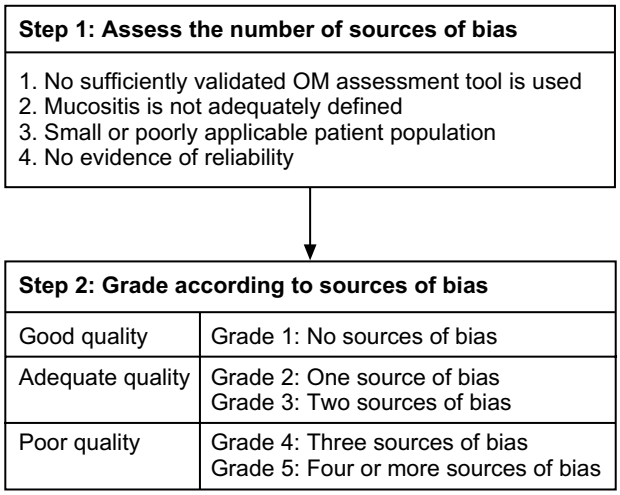

Fig. 1 – Studies were assessed for bias and graded accordingly.

2.2. Evidence assessment

A system for grading the quality of individual studies was adapted from frameworks of diagnostic test accuracy tools.[14–19] Each study was graded according to the number of predefined sources of bias in the study design (Fig. 1). The quality of each study was then rated as good (Grade 1), adequate (Grades 2 and 3) or poor (Grades 4 and 5).

The papers were then reviewed for evidence to support or counter each of the taskforce's questions and the overall evidence that answered each question was then rated, according to the following criteria:[15,16,18,20] quantity – rated as a high (>10), moderate (3–10) or low (⩽2) number of studies; consistency – the extent to which similar findings were reported, rated as good or poor; generalisability – how reasonable it is to apply the results of these studies to the target population, rated as good or poor; and clinical applicability – the potential clinical impact of the findings, rated as good or poor. Finally, the strength of the body of evidence behind each recommendation was deduced as shown in Table 1, and the recommendation was graded.

2.3. Definition of therapy

For the purposes of these guidelines, the term 'therapy' meant the administration of a cycle of radiotherapy (RT), chemotherapy (CT) or the period of conditioning treatment prior to stem cell transplantation.

3. Results and discussion

3.1. Literature search

A total of 57 papers, most of which were research studies, met the inclusion criteria and addressed at least one of the questions (Appendix 1).[7,12,21–75] The findings from the collation of

Table 1 – Grading of evidence for recommendations

Quality and quantity of studies in body of evidence	Consistency, generalisability and clinical applicability of evidence	Strength of evidence	Strength of recommendation
High/moderate number of good-quality studies *or* High number of adequate-quality studies	→ All good	→ Strong	→ Strongly recommended
High/moderate number of good-quality studies *or* High number of adequate-quality studies	→ One or more are poor	→ Sufficient	→ Recommended
Moderate number of adequate-quality studies *or* Low number of good-quality studies	→ All good	→ Sufficient	→ Recommended based on expert opinion
None of the above criteria met	→	Insufficient	→ Available studies do not provide sufficient evidence to formulate a guideline

The evidence for each recommendation is grouped, and the overall strength of the recommendation is graded according to the quality and quantity of studies providing evidence and the consistency, generalisability and clinical applicability of the body of evidence.

evidence and the corresponding strength of evidence are covered for each recommendation below.

3.2. *Recommendation 1: use of a standardised procedure for assessment*

OM should be assessed using a standardised protocol.

Evidence: strong/sufficient, therefore (strongly) recommended.

3.2.1. *Commentary on recommendation 1: use of a standardised procedure*

Standardised procedures are defined here as OM assessment protocols that followed validated assessment tools (i.e. the tools and their validation studies were referenced in the paper), explicitly described the assessment procedure, or at the very least, outlined the frequency of assessment and defined the healthcare professionals involved.

A total of 22 different assessment tools were used in the papers that provided evidence for this recommendation. Only two[47,74] out of 57 eligible studies did not describe the OM assessment protocol in sufficient detail. Eleven studies[12,23,25–27,29,40,43,55,64,73] used well-described self-developed or modified instruments. Table 2[76] lists all the tools (excluding self-developed scales except where the studies were for the express purpose of developing a scale), and the elements used in assessing OM. Pain, erythema and ulceration are the most commonly used measures across the tools.

The World Health Organisation (WHO) scale was the most frequently used in the included studies (12 studies).[21,24,29,39,48,49,52,56,60,65,69,72] Of these studies, 10 were graded Grade 1 or 2,[21,24,29,39,48,49,52,60,65,69] showing that despite its simplicity, this scale does not limit study quality.

The Oral Assessment Guide (OAG) scale was the second most frequently used. Although the Oral Mucositis Assessment Scale (OMAS) or Oral Mucositis Index (OMI)-based scales were specifically developed for OM staging, few studies in this analysis employed these tools, probably due to their complexity in clinical practice.

Four studies compared two scales in parallel, particularly for validation purposes. Good correlations were found between OMAS and National Cancer Institute Common Toxicity Criteria (NCI-CTC) scores,[41] and the Western Consortium for Cancer Nursing Research (WCCNR) and MacDibbs Mouth Assessment scales.[54] Donnelly and colleagues[39] showed that a Daily Mucositis Score (DMS) achieved by adding scores for various elements of OM, was more successful than the WHO tool in monitoring OM through all its stages of development. Dodd and colleagues used several scales, and concluded that the tool must be chosen with the purpose of assessment in mind.[35] The taskforce recommends that this principle should be used when choosing the OM assessment tool.

3.3. *Recommendation 2: routine assessment of OM*

For a patient's OM to be managed, routine assessments should take place. Patient self-reporting should form an integrated part of the assessment.

Evidence: sufficient strength, therefore recommended.

3.3.1. *Commentary on recommendation 2: routine assessment of OM*

A total of 13 studies (two high-quality[52,64] and nine adequate-quality[32,34,37,39,48,50,51,71,75]) provided evidence that frequent OM grading directed the active management of OM. In general, once OM scores passed certain thresholds, new, predetermined management strategies were implemented.[9,37,60,71] Interventions were usually initiated when OM was scored as moderate to severe. These studies used a total of nine assessment instruments, indicating that no single scale is particularly geared towards enabling clinical interventions.

Table 2 – Assessment tools and elements used

Instrument – original or modified (number of studies)	WHO (12)	OAG (8)	NCI-CTC (7)	OMI (4)	MacDibbs (3)	OMAS (3)	Nebraska (3)	RTOG (2)	WCCNR (2)	CALGB (1)	DMS (1)	Kolibinson (1)	NCCTG (1)	Seto[76] (1)	Walsh[71]
Physical changes															
Erythema	√	√	√	√	√	√	√	√	√	√	√	√		√	√
Ulceration	√	√	√	√	√	√	√	√	√	√	√	√		√	√
Oedema		√	√	√	√		√		√	√	√				√
Salivary changes		√	√		√		√		√	√					√
Swallowing	√	√			√		√		√		√				√
Functional changes															
Voice		√			√		√								√
Eating solid food	√		√		√					√			√		
Pain	√	√	√		√	√	√	√	√	√	√		√	√	√
Lips		√					√								√
Tongue		√					√								√
Sites															
Mucous membranes		√					√		√			√[a]			√
Gingiva		√					√								√
Teeth		√					√								
Other elements															
Atrophy				√											
Pseudomembranes				√											
Lichenoid				√											
Hyperkeratosis				√	√										
VAS				√											
Dryness					√										
Taste					√										
Hyperkeratosis															
Sputum smear for fungus					√										
Herpes simplex															
Culture					√										
Bleeding								√	√						√

Some scales, such as those that quantify oral changes, e.g. OMI and OMAS, are developed for research purposes rather than for patient care; the total number of studies is greater than 57 as some studies used more than one instrument.

Abbreviations: WHO, World Health Organisation; OAG, Oral Assessment Guide; NCI-CTC, National Cancer Institute Common Toxicity Criteria; OMI, Oral Mucositis Index; VAS, Visual Analogue Scale; OMAS, Oral Mucositis Assessment Scale; Nebraska, Nebraska Oral Assessment Score; RTOG, Radiation Therapy Oncology Group Acute Toxicity Scoring; WCCNR, Western Consortium for Cancer Nursing Research; CALGB, Cancer and Leukaemia Group B; DMS, Daily Mucositis Score; NCCTG, North Central Cancer Treatment Group, NNMSS, Nijmegen Nursing Mucositis Scoring System.

a Nine oral sites in total.

Eiler's OAG was used in five of the 13 studies (Grades 2–4).[34,36,51,70,75] This instrument scores OM when changes to the mucosa are first observed, thus allowing early preventative or analgesic interventions. It is essential that risk factors of OM, or OM itself, are recognised at an early stage so that adequate measures can be implemented.[12] Authors using OAG note that the tool enables clinicians to document daily changes in oral status, plan appropriate interventions and follow trends.[75] The tool was found to be understandable, required only 3–4 min to complete and was clinically applicable for oncology nurses.[44]

Several studies by Dodd and colleagues[34,36,37] used an extension of the OAG, a thorough patient self-assessment programme (PRO-SELF Mouth Aware [PSMA] programme). The PSMA programme aims to support cancer patients with information on oral complications, self-care techniques and contact with nurses experienced in OM. Through this programme, patients learn the principles of good oral hygiene and how to thoroughly examine their mouth using assessment criteria based on the OAG.[77]

It is the opinion of the taskforce that routine assessment of the oral cavity (both by patient and clinician) and information or educational programmes should ensure that the patient and healthcare professional are more aware of changes to the oral mucosa, the risks of OM and that patients are supported in improving their oral care practices.[34,36,37,77]

3.4. *Recommendation 3: baseline oral assessments*

A comprehensive baseline oral assessment should be made prior to treatment, where OM is expected.

A further baseline assessment of OM should be taken as close to the administration of the first treatment dose as possible.

Evidence: sufficient/insufficient, supplemented by expert opinion, therefore recommended based on expert opinion.

3.4.1. *Commentary on recommendation 3: baseline oral assessments*

There is sufficient evidence that baseline assessments of the oral cavity should be made prior to any potentially damaging therapy. Only 17 papers[7,12,22,25,30–32,46,53,58,62,68,70–73,75] did not specify baseline readings, in some cases because patients had already received CT or RT prior to study entry.

The taskforce suggests two types of baseline assessment: one in preparation for the proposed treatment and the second immediately before treatment administration. The first should be a comprehensive examination by dentists to identify, and if possible address, pre-existing conditions and OM risk factors (e.g. dental or oral infection, broken teeth, periodontal disease or poor oral hygiene). The examination and treatment of pre-existing problems should take place as early as possible prior to initiation of therapy.[78]

The second baseline assessment, conducted immediately prior to treatment, establishes a basis from which changes in the oral mucosa can be determined. In nine studies,[22,23,31,32,39,58,59,69,74] oral assessments only began on the day of stem cell administration, despite conclusive evidence that the onset of OM can occur during the conditioning phase of treatment.[1,7,39,72,79] Similarly, the onset of OM following RT can be rapid: for some head and neck patients, symptoms can be observed as early as the first day of RT.[80–82] It is therefore essential that baseline assessments are made before the onset of treatment.

3.5. *Recommendation 4: frequency of assessment*

4A – Frequent assessment of OM is recommended throughout the course of therapy, and especially for patients most at risk of developing OM. For outpatients, this will require some degree of self-assessment, although self-assessment for in-patients may also be beneficial.

Evidence: sufficient, therefore recommended.

4B – Assessment, whether by clinicians or patients, should take place on a daily basis during the period when OM is likely to first occur or be at its peak. Depending on the severity of baseline OM assessments and risk factors, assessments will need to continue at regular intervals (daily, every 2–3 days, weekly) as OM resolves.

Evidence: insufficient, supplemented by expert opinion, therefore recommended based on expert opinion.

3.5.1. *Commentary on recommendation 4: frequency of assessment*

One of the unresolved issues of OM is the frequency of its assessment. In this analysis, the frequency of examinations during treatment varied from a four-times-daily patient self-assessment[34] to weekly, but none of the studies looked specifically at the timing of assessments. Five good-quality studies[35,52,59,61,64] and 21 adequate-quality studies[7,21,23–25,28–30,33,37,41–44,49,55,56,58,60,68,73] support a frequency of a less than once-daily assessment compared with two good-quality[65,66] and 17 adequate-quality studies[7,12,22,31,32,39,42,46,50,51,53,57,62,68,69,72,74] favouring a daily assessment.

The severity of OM can alter dramatically in 24–48 h and symptoms can change depending on pain relief and other treatments; it seems prudent to conduct examinations every one or two days, particularly at times when it is likely to arise or when it is particularly severe or painful. The taskforce believes that, where patients are unable to maintain their oral health or require pain relief, daily assessment, including pain assessment, is essential.

In practice, it may be difficult to have such frequent assessments, especially in the outpatient setting where patients between treatment cycles may not be seen for several weeks. It is the opinion of the taskforce that all patients should be trained in self-assessment and report typical signs/symptoms to the healthcare team. The PSMA programme[34] is a good example of a self-assessment scheme that can be adapted for in- and outpatient use.

3.6. *Recommendation 5: post-treatment assessment*

OM assessments should continue until OM is fully resolved or the trend to resolution is established. If OM has not resolved on discharge, follow-up of the patient is recommended. In the in-patient setting, assessment should continue until OM is resolved, which in most cases is approximately 2–4 weeks after treatment.

Evidence: sufficient to strong, therefore strongly recommended.

3.6.1. *Commentary on recommendation 5: post-treatment assessment*

Once treatment is stopped, OM may continue to increase in severity before resolving.[1,3,72,76] Only 13 studies (one good-quality study,[35] nine adequate-quality[29,33,34,46,48,53,62,68,73] and three poor-quality[36,38,70]) covered post-treatment assessment in outpatients. Overall, the evidence favoured follow-up in outpatients post-RT and CT using self-assessment systems.

For HSCT patients, the evidence also favours follow-up; three good-[59,65,66] and seven adequate-quality studies[7,23,31,39,50,58,74] continued OM assessment for between 18–28 days following transplantation. A further 12 studies, all of good or adequate-quality,[12,22,25,30–32,42,43,57,69,72,75] specified follow-up OM assessments of between 14 and 31 days.

Few papers mentioned any follow-up after 28 days for inpatients, so it is unclear how patients who continued to show signs of OM were monitored. Studies are required to assess the risks of discharging patients with OM, the effect OM has on the patient's quality of life (QoL) and what level of follow-up is appropriate. These questions must be addressed before the importance of long-term monitoring of OM can be determined.

3.7. *Recommendation 6: inclusion of patient-reported outcomes*

6A – Patient-reported outcomes, for pain at the very least, should be included in all OM assessments.

Evidence: sufficient/strong, therefore strongly recommended.

6B – Assessment of subjective measures should happen prior to any physical examination (including self-examination) of the mouth.

Evidence: insufficient, supplemented by expert opinion, therefore recommended based on expert opinion.

3.7.1. *Commentary on recommendation 6: inclusion of patient-reported outcomes*

Thirty-three[12,23,24,26–29,31–35,37–40,43,46,49–53,58,60,61,63–65,67,69,71,73] out of 57 papers supported the use of patient-reported outcomes for each OM assessment, whereas 11 papers[21,22,25,34,36,48,54,57,70,74,75] provided evidence that they were unnecessary.

The degree of patient involvement varied considerably. In the studies using the NCI-CTC and WHO scales ($n = 22$), minimal self-assessment requires patients to indicate presence or absence of pain only, but the majority of these studies were supplemented with a more comprehensive self-assessment. Nine studies out of the 33 used a visual analogue scale (VAS)[12,23,24,29,32,40,61,64,69] and four studies[28,50–52] used longer patient questionnaires.

Changes in subjective measures of OM, e.g. pain, can precede changes in objective examinations.[35] Furthermore, studies by Cella and Sonis and their respective colleagues show that patient-reported measures of OM correlated closely with clinical measures.[28,64] Self-assessment may therefore allow healthcare teams to implement preventative or palliative interventions at an early stage, which may help to reduce the peak severity and/or duration of OM. The taskforce recommends that patient self-reported outcomes should be included with OM assessments. Due to the pain involved in physical examination, the taskforce is of the opinion that self-assessments are best made prior to examination.[64]

3.8. *Recommendation 7: pain scoring*

The use of pain scoring, and VAS tools in particular, should be used at each routine assessment.

Evidence: insufficient, supplemented by expert opinion, therefore recommended based on expert opinion.

3.8.1. *Commentary on recommendation 7: pain scoring*

Subjective assessments of pain are included in the majority of scales, but are often limited to the question 'Do you have pain?' without any indication of severity. For this analysis, pain scoring is taken to be pain assessments that use either a VAS or scales that grade different intensities of pain according to specific descriptors, such as the Brief Pain Inventory.

Pain scoring was reported in six good-quality[40,52,61,64–66] and 18 adequate-quality studies.[12,23,24,28,29,31–33,37,39,46,50,51,53,60,69,71,73] In four studies, pain scoring was added to instruments that did not include pain assessments.[23,50,51,61] Nine studies using the WHO or NCI-CTC scales[24,28,29,32,39,43,52,60] added scoring, even though a yes/no measure of pain is integral to these scales.

There is now sufficient evidence that patient-reported outcomes for pain should be included in assessments (see Recommendation 6). It is the opinion of the taskforce that pain scores relate to changes in the oral mucosa and provide an indication of the course of OM and the effectiveness of interventions over time. In particular, a VAS is simple to use by patients and also easy to analyse by healthcare teams.[40]

3.9. *Recommendation 8: objective, subjective and functional measures of OM*

8A – OM assessments should use instruments or a combination of suitable scales containing elements covering physical changes in the oral mucosa, functional changes and subjective changes.

Evidence: strong, therefore strongly recommended.

8B – Where a selected instrument lacks one or more of these categories, a combination of scales should be adopted. The taskforce favours the combination of physical and functional grading and a VAS for patient pain and other subjective factors.

Evidence: insufficient, supplemented by expert opinion, therefore recommended based on expert opinion.

3.9.1. *Commentary on recommendation 8: objective, subjective and functional measures of OM*

There is strong evidence (eight good-quality studies)[35,40,52,54,61,64–66] and 39 adequate-quality studies[7,12,21–26,28–34,37,39,41–44,46,48–51,55–58,60,62,68,69,71–75] that the oral cavity should be examined to assess physical (objective) changes, using a good light source. Only one study graded OM purely on patient-reported pain, with no physical assessment.[53]

In terms of functional changes (swallowing, voice and chewing), 41 studies supported their use in assessment.[21–24,26–29,31–41,43–46,49,51–53,55,57,60,62,64–72,75] There was also strong evidence to support the assessment of subjective measures of OM (pain, dryness and sensitivity); only eight studies did not include any subjective measure at all.[7,25,41,42,48,54,59,74]

The evidence for combining tools was mixed, with 22 supporting[23,24,28,29,31–33,35,38,39,43,50,52,53,55,51,60,61,65,69,71,73] and 35 not supporting[7,12,21,22,25–27,30,34,36,37,40–42,44–49,54,56–59,62–64,66–68,70,72,74,75] a combination. In the studies that support a combination of assessment tools, most of them added a patient self-assessment element, often a VAS. It is the opinion of the taskforce that where OM assessments lack functional and/or subjective measures, patient-reported assessments should be added to the routine assessment procedure. The MASCC guidelines highlight that objective, subjective and functional measures should be clearly differentiated in scales.[10,83]

3.10. *Recommendation 9: validity and reliability of tools*

Validated assessment instruments should be used. If tools are modified, or new scales are employed, they should be fully validated. Inter-rater reliability should be tested regularly.

Evidence: insufficient, supplemented by expert opinion, therefore recommended based on expert opinion.

3.10.1. *Commentary on recommendation 9: validity and reliability of tools*

The evidence for using validated tools was taken from studies that included a discussion of these issues, tested the tool's validity or referenced an original paper that validated the tool in question. A high proportion of papers ($n = 38$) did not mention validity in any of these ways, including four studies that used their own assessment scales.[27,29,43,74] It is worth noting that the widely-used WHO scale has never undergone rigorous validation tests; its use is based upon the opinion of experts and nearly 30 years of accumulated experience.

Several studies used scales developed for different settings or contexts, for example, the use of OMI to assess OM in leukaemia rather than HSCT patients.[51] These findings raise the question of whether investigators consider the appropriateness and limitations of particular instruments, or whether they choose a scale based on their own experience and expertise. In practice, it is likely that clinicians favour familiar instruments or scales that staff find easy to learn.

Five good-quality studies[52,54,61,64,65] and 12 adequate-quality studies[12,23,31,34,37,44,50,51,55,58,62,71] referred to the reliability of the tool, however, 39 studies did not consider reliability at all. In these cases, reliability may have been presumed by the authors, especially for the widely accepted tools.

In clinical practice, the taskforce recommends that reliability should be regularly monitored. Whilst this testing may not be strictly necessary for tools of proven reliability, it ensures that OM monitoring remains consistent between personnel and highlights when training courses on OM assessment are required.

3.11. *Recommendation 10: ease of use and patient comfort*

Assessments should be easy to use by the clinician and be comfortable for the patient. Any physical examination of the oral cavity should take the minimum amount of time and be a minimally invasive procedure.

Evidence: insufficient, supplemented by expert opinion, therefore recommended based on expert opinion.

3.11.1. *Commentary on recommendation 10: ease of use and patient comfort*

Assessment of the oral cavity can be an uncomfortable experience for the patient; it is intrusive and many patients feel self-conscious about having their mouths examined. The examination itself may be painful and there is a risk of bleeding.

A total of eight studies (two good-quality,[54,64] six adequate-quality[12,30,39,49,50,71]) included discussions on ease of use and duration of assessment, but no studies specifically addressed these issues. There was also a lack of focus on patient comfort during assessment, which may reflect the investigative nature of the papers.

The WCCNR tool and the Nijmegen Nursing Mucositis Scoring System (NNMSS) system were found to be ideal for use in busy clinical practice, as they were quick and easy to use.[12,54] Similar observations were made regarding the OMAS tool.[1]

Excessive touching of the sensitive oral mucosa could induce greater damage and worsen its condition. For this reason, the taskforce is of the opinion that physical exams should take the least amount of time, be minimally invasive but precise. The taskforce recommends that scales with extensive oral examination by trained personnel, such as the MacDibbs and OMI scales should only be used after careful consideration and elimination of all other alternatives.

3.12. *Recommendation 11: training*

Clinicians assessing patients should be specifically trained in the application of the scale. Periodic inter-rater reliability should be used to monitor the need for staff training.

Evidence: insufficient, supplemented by expert opinion, therefore recommended based on expert opinion.

3.12.1. *Commentary on recommendation 11: training*

For the purposes of these guidelines, where the investigators were described as experienced, or calibration procedures or inter-rater reliability tests were used, the studies were considered to have included training. A total of 22 studies mentioned formal training of assessors.[12,23,31,33–38,43,50–54,58,64,65,69,71,74,75] The taskforce recommends that examiners should be familiar and proficient in using the assessment tool in question. Several papers describe structured training such as the use of photographs to help maintain assessment standards.[23,31,61,71] The consistency and reliability of the tester and method should be monitored at regular intervals to determine the need for training and retraining amongst staff.[84] The

Table 3 – Summary of recommendations

Recommendation	No.
Strongly recommended	
OM should be assessed using a standardised protocol	1
OM assessments should continue after the end treatment until OM is fully resolved or the trend to resolution is established	5
Patient-reported outcomes should be included in all OM assessments	6A
OM assessments should use instruments or a combination of suitable scales containing elements covering physical changes in the oral mucosa, functional changes and subjective changes	8A
Recommended	
Routine assessments should take place	2
Patient self-reporting should form an integrated part of the assessment	
Frequent assessment of OM is recommended throughout the course of any therapy, especially for patients who are most at risk of developing OM	4A
Recommended based on expert opinion	
A comprehensive baseline oral assessment should be made prior to treatment, where OM is expected	3
A further baseline assessment of OM should be taken as close to the administration of the first treatment dose as possible	4B
Assessment for all patients should take place on a daily basis during the period when OM is likely to first occur, or be at its peak	
Depending on the severity of baseline OM assessments and risk factors,assessments will need to continue at regular intervals (daily, every 2–3 days, weekly) as OM resolves	
Assessment of subjective measures should happen prior to any physical examination (including self-examination) of the mouth	6B
The use of pain scoring, in relation to changes in the oral cavity,should form part of OM assessment	7
Where a selected instrument lacks one or more of these categories a combination of scales should be adopted	8B
Either validated assessment instruments should be used, or if tools are modified or new scales are to be employed they should be fully validated	9
Inter-rater reliability should be tested on a regular basis	
Assessments should be easy to use by the clinician and to be comfortable for the patient. Any physical examination should take the minimum amount of time and be a minimally invasive procedure	10
Clinicians assessing patients should be specifically trained in the application of the scale. Periodic inter-rater reliability should be used to monitor the need for staff training	11

Abbreviation: OM, oral mucositis.

PSMA programme,[34,36,37] effectively trains patients as well as staff. It is the opinion of the taskforce thorough training, as outlined in these studies, should be more widely adopted.

4. Summary

Table 3 shows a summary of the recommendations. The taskforce believes that this analysis points to some general principles for selecting OM assessment instruments. In the out-patient setting emphasis should be placed on patient self-evaluation. The PSMA programme demonstrates that patients are capable of clinically-relevant assessments which can be verified by a healthcare professional during patients' visits to clinic. In the in-patient setting where the burden of assessment falls on nursing staff, instruments should be quick and easy to implement while clinically effective. This analysis points to simple-to-use scales such as the WHO scale or the OAG, coupled with a VAS for pain. However, several instruments have been developed more recently and the taskforce calls for more studies into their clinical application (preferably head-to-head with the WHO and OAG).

The choice of instrument for the assessment of OM in the research setting requires careful consideration; investigators must ensure that the instrument covers all elements of OM relevant to the study.

The recommendations represent a consensus based on an interpretation of the recent literature identified in an extensive literature review, and the expert experience of the OMAG taskforce. Any clinician using these guidelines is expected to use their own experience to determine appropriate care for their patients.

EBMT and EONS make no guarantees of any kind in the use or application of these guidelines and disclaims any liability for their application in any way.

Conflict of interest statement

Barry Quinn and Rebecca Stone received honoraria and financial payments for consultancy work from Amgen. Carin M.J. Potting received an honorarium from Amgen (Europe) GmbH for attendance at an advisory board meeting. Nicole M.A. Blijlevens has received honoraria and research funding from Amgen. Monica Fliedner, Anita Margulies and Lena Sharp have no conflict of interest in this work.

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Appendix 1

Questions considered pertinent to OM assessment, defined prospectively by the taskforce

Question no.	Question text
Question 1.1	Is a standardised procedure used?
Question 1.2	What elements are included in the procedure?
Question 2	Is there evidence to suggest that routine assessment can affect: a. the management of OM? b. healthcare team reported outcomes? c. patient reported outcomes?
Question 3.1	In an inpatient setting, is there evidence to support an OM assessment: a. prior to initiating treatment? b. during treatment? c. post-treatment?
Question 3.2	Was the OM assessment sufficient to meet study goals?
Question 4.1	In an outpatient setting, is there evidence to support an OM assessment: a. prior to initiating treatment? b. during treatment? c. post-treatment?
Question 4.2	Was the OM assessment sufficient to meet study goals?
Question 5.1	How often was an OM assessment carried out? a. less than one daily? b. once daily? c. more than once daily?
Question 5.2	Is there evidence that this frequency was sufficient to meet study goals?
Question 6	Is there evidence to support patient reported outcomes (subjective assessment) in the assessment procedure? a. before oral cavity examination? b. with each assessment? c. not at all?
Question 7	Is there evidence to suggest that the patient's oral intake was taken into account during assessment?
Question 8.1	Is there evidence to suggest that the patient's pain score was taken into account during assessment?
Question 8.2	Was the pain score self reported,or reported by a healthcare professional?
Question 9	Is there support for examination of the oral cavity for the following: a. objective changes (e.g. erythema, lesions, oedema)? b. subjective changes (e.g. pain, sensitivity, dryness)? c. functional changes (e.g. voice, swallowing, chewing)?
Question 10.1	Is there evidence to support one assessment scale over another?
Question 10.2	Is there evidence to support a combination of assessment tools?
Question 11	When deciding which tool to use, does the paper refer to the following factors: a. validity? b. reliability? c. ease of use for the healthcare clinician? d. time taken to use the tool? e. comfort for the patient?
Question 12	Was training given to the assessors prior to use of an assessment tool in OM?

Abbreviation: OM, oral mucositis.

Appendix 2. Literature search terms

Published papers

An electronic search of the Cochrane library and Medline and Embase databases used the following search terms:

'Oral mucositis' OR oromucositis OR ('mucosal cells' AND (mouth OR oral)) OR 'Stomatitis' [MeSH] OR stomatitis

AND

(('Radiotherapy' [MeSH] OR 'CT, Adjuvant' [MeSH]) OR radiotherapy OR chemotherapy OR 'Bone Marrow Transplation' [MeSH] OR 'Bone Marrow Transplantation' OR 'Bone Marrow Transpl' OR 'Bone Marrow Transplants' OR 'Stem Cell Transplantation' [MeSH] OR 'Stem Cell Transplantation' OR 'Stem Cell Transplant' OR 'Stem Cell Transplants')

AND

(assessment OR examination)

Limits: All Adult: 19+ years, Publication Date from 1989/12/31, English, Humans. All the MeSH terms were exploded to capture anything that appealed below the term in the hierarchy and free text terms were used to ensure that all the relevant information was found.

Abstracts

Where available online at time of searching, abstracts from the following conferences were searched from 2003 to 2005: ASH (2005 only available), ESMO (2004), ECCO (2005 only available), ASCO (2003–2005) and EBMT (2003–2005). Conference websites were searched with specific combinations of the following keywords:

- Oral mucositis AND assessment OR examination OR stomatitis OR radiotherapy OR chemotherapy OR bone marrow transplantation OR bone marrow transplant OR bone marrow transplants OR stem cell transplantation OR stem cell transplant OR stem cell transplants.
- Stomatitis AND assessment OR examination OR stomatitis OR radiotherapy OR chemotherapy OR bone marrow transplantation OR bone marrow transplant OR bone marrow transplants OR stem cell transplantation OR stem cell transplant OR stem cell transplants.
- Mucosal AND assessment OR examination OR stomatitis OR radiotherapy OR chemotherapy OR bone marrow transplantation OR bone marrow transplant OR bone marrow transplants OR stem cell transplantation OR stem cell transplant OR stem cell transplants.

Identified abstracts were examined and those where OM was not a primary endpoint were discarded. For abstracts in which OM was a primary endpoint, the abstract was compared against papers already identified in the electronic literature search and against papers recently published through PubMed using the following combination of keywords: Author initial AND (Mucositis OR stomatitis). If the data were not published, the first author of the abstract will be contacted to see if the paper is 'in press'.

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