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Establishing content validity of the oral assessment guide in children and young people

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ARTICLE INFO

Article history:
Received 11 August 2005
Received in revised form
10 February 2006
Accepted 27 February 2006
Available online 26 July 2006

Keywords:
Oral assessment guide
Children
Cancer
Instrument development
Content validity

ABSTRACT

There is a need for accurate and consistent oral assessment to measure mucosal changes and oral complications associated with cancer therapies. Mucositis is an important and common side effect of cancer therapies that merits the identification of improved health-care interventions. Developing appropriate and reliable oral assessment instruments for use with children is relevant to the evaluation of these interventions. The purpose of this study was to determine the content validity of the oral assessment guide (OAG) in children: an instrument that was designed to objectively assess the physiological changes of the oral cavity following administration of chemotherapy and radiotherapy to adults. This process is considered to be most effective when undertaken systematically. A judgement quantification process was used with health care professionals in paediatric oncology to establish content validity of items ($n = 9$) and instrument ($n = 10$). A revised OAG more pertinent to children and young people was produced in the light of this process.

1. Introduction

Paediatric oncology nurses perform an essential role in evaluating and promoting oral hygiene, and minimising the potentially debilitating effects of oral mucositis (OM). It is nurses who most commonly make decisions regarding oral care. For appropriate care to be prescribed a thorough oral assessment is required and represents the vital 'first step' in planning effective care. The oral assessment guide (OAG)[1] is a validated instrument, which has been used extensively with adults who have cancer. It is also used in a number of paediatric oncology centres in the United Kingdom (UK) even though it has not specifically been evaluated for use in children.

Valid and reliable oral assessment is essential to ensure accurate appraisal of children's oral status. The use of the

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doi:10.1016/j.ejca.2006.02.018

most effective methods for prevention and treatment of oral mucositis is made possible through practice that encompasses oral assessment. Use of an unreliable or invalid instrument may invalidate the testing of research hypotheses and, in clinical care, may adversely influence nursing diagnosis and the care prescribed. Whether or not the OAG is a reliable and valid measure for assessing oral status in children with cancer following chemotherapy and/or radiotherapy has yet to be determined. This study sought to establish content validity of the OAG in children and young people using a judgement quantification process.

2. Background

2.1. Oral complications

Treatment of childhood cancer is becoming increasingly successful, with survival rates reported as 70–75% in parts of Europe and North America.[2] This success has come at a cost with an increase in patient morbidity,[3] including side effects, such as oral mucositis (OM).[4]

Oral mucositis refers to the inflammatory reaction and sequelae that occur in the mouth and oropharynx due to effects of radiation and chemotherapeutic agents.[5] This is a common, debilitating complication of cancer chemotherapy and radiotherapy with frequency ranging from 40% to 76% for adult patients treated with standard dose[6,7] and in the majority of patients undergoing high-dose chemotherapy, such as that used for bone marrow transplantation conditioning.[8] Children are at particularly high risk of developing OM, with estimates ranging from 52% to 80%.[9,10] This frequency has been reported as three times that of adults.[11]

With the availability of cytokine therapy to reduce the duration and severity of haematological toxicities associated with chemotherapy, the awareness of OM as a significant side effect has reported to have increased.[12] Three major reasons have been identified for this increase.[12] Firstly, bone-marrow-stimulating cytokine therapy has had a major effect on reducing duration of chemotherapy-induced granulocytopaenia. Similarly, interleukin-11 reduces duration of chemotherapy-induced thrombocytopaenia.[13] The result of which has been to increase the significance of mucositis as toxicity. Secondly, because of increased understanding of the biology of mucositis,[14] investigators have identified several therapeutic opportunities to which biotechnology and pharmaceutical companies are responding with the application of novel agents that are of potential therapeutic benefit.[15] Finally, the pursuit of new agents, combination therapies, and dose escalations are restrained because of the development of mucositis.[16,17] The need to provide a means of evaluating the relationship between dosage, delivery methods and complications is therefore essential.[18] A significant obstacle to interventional and epidemiological mucositis studies has been the lack of an accepted, validated, and objective scoring system for mucositis.[13,18]

2.2. Oral assessment

The lack of well tested and validated instruments also has implications for clinical care. Oral assessment has the potential to provide baseline data; predict, and thus, prevent or minimise oral complications; and evaluate nursing interventions.[19] Pre-intervention assessment has been found to reduce both incidence and severity of oral complications.[4] Better defining oral assessment can also help clarify terminology and provide accurate descriptions of a child's oral status. In addition, it has been suggested that a numerical assessment tool would ensure consistency of assessment between assessors.[20] Structured symptom assessment results in health professionals having a greater awareness of patients' experience of symptoms.[21] Overall, assessment enables a more informed and accurate identification of signs and symptoms; targeted symptom control may then help to improve patient quality of life. In current practice, structured assessment rarely underpins decisions about clinical care.

A 'gold standard' instrument to assess OM in children continues to elude the professions[22] yet a validated and reliable scale is paramount in the provision of best practice nursing care, and essential for evaluation in clinical trials. Several oral assessment scales are documented, many of which have been reviewed by Parulekar et al.,[18] all of which have been developed for use in the adult population. A more recent search of the literature revealed reports on 42 individual assessment instruments. It is somewhat surprising that in adult cancer care no instrument is universally accepted in clinical practice or in research.[18]

2.3. Current use of OAG

A mouth care working party was established in our centre in the late 1980s. Initial activities concerned the absence of a structured oral assessment tool. It was felt that nurses had no common language in which to communicate the status of oral health and therefore it was not uncommon to hear subjective phrases such as 'it looks a bit sore', or 'it's a little red', when describing the condition of a child's oral mucosa. The utilisation of an objective oral assessment tool was sought in order to clarify terminology, provide accurate descriptions of the oral status and ensure consistency of assessment to; provide baseline data; plan effective care; predict, prevent or minimise oral complications; and evaluate nursing interventions.[19] A critique of the literature highlighted three assessment instruments with reported validity and reliability. A clinical team using the following criteria reviewed these instruments: it needed to be concise, user-friendly, systematic and suitable for use in clinical practice.[23] The OAG developed by Eilers et al.[1] was selected (Fig. 1). Excellent inter-rater agreement between clinical nurses has been shown[1,24] and it is preferred over other instruments.[24] The OAG has been found to be clinically useful to assess, record and communicate oral changes for adults following bone marrow transplantation (BMT).[1] Similarly, the OAG is noted to be effective in detecting changes in oral status and in guiding nursing interventions in adults undergoing BMT who had received high-dose chemotherapy and radiotherapy.[25] However, the OAG has been criticised for failing to assess functional parameters, such as eating, drinking, talking, swallowing or pain.[24] Face validity, that is judgment of what the instrument appears to measure to

Category	Method of administration	1	2	3
Voice	Converse with patient. Listen to crying.	Normal	Deeper or raspy	Difficulty talking, crying or painful.
Swallow	Ask patient to swallow.	Normal swallow	Some pain on swallowing.	Unable to swallow.
Lips and corner of the mouth	Observe and feel tissue.	Smooth and pink and moist.	Dry or cracked.	Ulcerated or bleeding.
Tongue	Observe appearance of tissue.	Pink and moist and papillae present.	Coated or loss of papillae with a shiny appearance with or without redness Fungal infection	Blistered or cracked.
Saliva	Observe consistency and quality of saliva or insert depressor into mouth, touching centre of the tongue and the floor of the mouth.	Watery Excess salivation due to teething	Thick or ropy	Absent
Mucous Membrane	Observe the appearance of the tissue	Pink and moist	Reddened or coated without ulceration. Fungal infection	Ulceration with or without bleeding.
Gingivae	Gently press tissue with a gloved finger	Pink and firm Oedema due to teething	Oedematous with or without redness, smooth.	Spontaneous bleeding or bleeding with pressure
Teeth (If no teeth score as 1)	Visual Observe appearance of teeth	Clean and no debris	Plaque or debris in localised areas (between teeth if present)	Plaque or debris generalised along gum line

Oral Assessment Guide Adapted and reprinted from Eilers, J. Berger, A. and Petersen, M. (1988).

Fig. 1 – Oral assessment guide.

the untrained eye, has been presumed as the instrument has been found to be reliable and clinically useful for assessing oral cavity status, determining changes and guiding nursing interventions in adult and paediatric cancer care.[25–28] Terminology was adapted slightly for a paediatric population, permission was sought and granted, and the OAG implemented. The instrument has since been central to an oral care protocol. A number of cycles of action research and clinical audit have identified further problems in the delivery of oral care, resulting in a refining process of an oral care protocol and algorithm.[26] Further minor changes have been made to the OAG, responding to feedback from clinical staff to make it clearer and pertinent to the paediatric population.[26]

Making further changes to a validated instrument reawakened previous concerns regarding the relevance of an instrument developed for use in adults and used with children. There are inherent problems with scales being used in children, which have been developed for a different population as the scale items may not be sufficiently sensitive to discriminate important differences between groups or detect changes over time.[29] Toxicity scales are often underpinned by subjective interpretation and evaluation[30–33] and may neglect anatomical characteristics specific to children which may cause greater intra- and inter-observer variability.[22] The purpose of this study was to identify whether the OAG is a reliable and valid measure for assessing oral status in children following chemotherapy and/or radiotherapy.

3. Research design

This study was designed to establish content validity of the OAG using a rigorous judgement quantification process outlined by Lynn.[34] Data collection occurred during a 4-month period in 2003.

4. Ethical approval

The study was approved by the local Research Ethics Committee.

5. Methodology

Content validity is the determination of the content representative ness or relevance of the elements/items of an instrument. This requires a two-stage (development or judgement) process.[34] Judgement quantification entails asking a specific number of experts to evaluate the validity of items individually and as a set.[35] Content validity is based on consensual judgements by subject matter experts working independently.[36] An index of content validity showing the proportion of agreement among judges is calculated. In nursing, the assessment of content validity has often been rather cursory and has historically been reported with a simple statement that a panel of judges agreed that the items possessed content validity.[37] The characteristics and qualifications of these panel experts and the process they are asked to use to assess validity often is not reported.[35] The rigour of the validation process can be greatly influenced by how experts are chosen and utilised for instrument development. Increasingly, therefore content validity has been undertaken using more systematic and elaborate approaches as an initial phase in instrument development.[38–40] The importance of content validity during the entire process of instrument development cannot be underestimated as an instrument can be reliable without being valid, but an unreliable instrument cannot be valid.[41]

5.1. *Instrument*

The OAG[1] consists of eight categories that reflect oral health (Fig. 1). Each category descriptor is assessed on a numerical

scale from 1 to 3 giving a rating of 1 normal, 2 mild alterations without severe compromise of either epithelial integrity or systemic functioning, and 3 definite compromises. The eight subscale scores are summed to obtain an overall assessment (minimum 8, maximum 24).

5.2. *Establishing content validity*

Determination of validity was undertaken following steps outlined by Lynn,[34] which involved establishment of the content relevance of the items of the OAG. The first step involved the assertion by experts that items were valid. This was followed by a further step involving a different group of experts to ensure that the entire instrument was valid. In each step an index of content validity (CVI) (using a 4-point ordinal rating scale where 1 connotes an irrelevant item and 4 an extremely relevant item) was calculated, showing the proportion of agreement among the experts for each item. The total CVI was the proportion of items that received a rating of 3 or 4. If the experts identified any missing items, the process of CVI for additional items would be repeated. The CVI score for the entire instrument was the proportion of total items judged content valid. The formula for the proportion of experts whose endorsement is required to establish content validity beyond the 0.05 level of significance was used; a CVI score of 0.80 or superior is generally considered to have excellent content validity.[34]

5.3. *Sample and procedure*

5.3.1. *Items content valid*

Experts were identified by members of the research team and recruited from the UK. They included a cross section of health care professionals who had at least 5 years experience in paediatric oncology and had used an oral assessment scale, or more than 5 years experience as a dentist caring for children with cancer. The maximum number of experts suggested to achieve content validity has not been established, but it is unlikely ever to exceed 10.[34] Using Lynn's formula[34] three oncology nurse experts, three dentists and three paediatric oncologists were approached to review the relevance of each item of the OAG. Communication throughout the process was undertaken through email.

The experts were provided with detailed information regarding the process and their role, as recommended by Lynn.[34] In the first instance they were requested to examine the OAG, and respond to a questionnaire, indicating their expert opinion on the inclusion and exclusion of each category of oral health, and to suggest revision (Table 1). The research team were particularly interested in whether the indicators of the OAG sampled the entire domain or missed any important aspects of OM. All respondents' comments were received within 1 month of initial correspondence. The local project team convened to discuss findings, calculate the CVI for each item and combine and categorise comments providing appropriate strength of evidence to refine and alter the instrument.

5.3.2. *Instrument content valid*

Identification of sample was undertaken using the same process as with the earlier step of item validity. Four oncology nurses, four dentists and four paediatric oncologists were approached from the UK and elsewhere and agreed to participate.

The experts examined the revised OAG, and responded to a questionnaire (Table 1), indicating their opinion on the inclusion and exclusion of each category of oral health, and suggested revisions. Ten of the twelve respondents' com-

Table 1 – Example of questionnaire: please circle the number you feel applies to each item and make any comment you feel is necessary to improve the assessment scale

Category	Score	Scale	Score
Voice	1 2 3 4	1 = Normal	1 2 3 4
		2 = Deeper or raspy	1 2 3 4
		3 = Difficulty talking, crying or painful	1 2 3 4
Swallow	1 2 3 4	1 = Normal swallow	1 2 3 4
		2 = Some pain on swallowing	1 2 3 4
		3 = Unable to swallow. Pooling of secretions	1 2 3 4
Lips and corners of the mouth	1 2 3 4	1 = Smooth, pink and moist	1 2 3 4
		2 = Dry or cracked	1 2 3 4
		3 = Ulcerated or bleeding	1 2 3 4
Tongue	1 2 3 4	1 = Pink, moist, papillae present	1 2 3 4
		2 = Coated/loss of papillae, shiny appearance with or without redness and/or oral candida	1 2 3 4
		3 = Blistered or cracked	1 2 3 4
Saliva	1 2 3 4	1 = Watery, excessive salivation due to teething	1 2 3 4
		2 = Thick or ropy	1 2 3 4
		3 = Absent	1 2 3 4
Mucous membranes	1 2 3 4	1 = Pink and moist	1 2 3 4
		2 = Reddened or coated without ulceration and/or oral candida	1 2 3 4
		3 = Ulceration with or without bleeding	1 2 3 4
Gingivae	1 2 3 4	1 = Pink or coral with a stippled (dotted) surface. Gum margins tight and well defined, no swelling. Oedema due to teething	1 2 3 4
		2 = Oedematous with or without redness, smooth	1 2 3 4
		3 = Spontaneous bleeding	1 2 3 4
Teeth (if no teeth score 1)	1 2 3 4	1 = Clean, no debris	1 2 3 4
		2 = Plaque/debris in localised areas	1 2 3 4
		3 = Plaque or debris generalised along gum margin	1 2 3 4

Comments on each category were requested.
1 = Not relevant; 2 = unable to assess relevance without revision; 3 = relevant but needs minor alterations; 4 = very relevant and succinct.

ments were received within 2 weeks. A group of local specialists involving a clinical physician, clinical nurse specialists in pain management and senior ward nurses, was convened to discuss the CVI results and all comments. As before, a CVI was calculated for each item and grading, all comments were combined and categorised. Once the entire project team had discussed and agreed on a further revision of the OAG, this was sent to all responding experts asking them to repeat the process.

6. Results of judgment quantification stage

For both item and instrument validity comments received from experts were categorised into three distinct headings: relevance, terminology, general comments.

6.1. *Items content valid*

Responses were received from all nine experts (100%).

6.1.1. *Relevance*

All eight categories of oral health revealed excellent CVI and established content validity for each category beyond the 0.05 level of significance (Table 2).

6.1.2. *Terminology*

Experts felt that the term patient should be changed to child. The inclusion of more detail, particularly the description of grading for gingivae, would clarify the process for those assessing. Three of the experts felt that the assessment needed to clarify what type of fungal infection that was most likely to be present; hence *Candidia* replaced the term fungal infection.

6.1.3. *General comments*

All experts were selected due to their clinical expertise in paediatric oncology. This was reflected in their general comments. There was consensus that the compliance of young children would affect the method of assessment. Observing the child would improve responses, as children are not always able to follow instructions, particularly the very young e.g. swallowing on demand. Ensuring all assessors were using the same administration technique is a prerequisite for assessment, and was commented on by respondents. It was decided that the use of a pen torch was essential. This would ensure a standard assessment method and provide consistency to the process of validation.

Table 2 – Respondent CVI score for content validity item review – nine experts

Category	Number of ratings of 3 or 4	Actual CVI
Voice	8	0.89
Swallow	8	0.89
Lips and edge of the mouth	7	0.78
Tongue	9	1.00
Saliva	8	0.89
Mucous membranes	9	1.00
Gingivae	7	0.78
Teeth	7	0.78

6.2. *Instrument content valid*

Ten of the 12 (83%) experts responded.

6.2.1. *Relevance*

Table 3 shows the CVI for each category and grading, establishing content validity in all areas beyond the 0.05 level of significance, and provides a CVI for the entire instrument of 1.00. Swallow, lips and corners of the mouth, tongue, mucous membranes and gingivae all ranked highly with no additional comments included. In contrast, voice, saliva and teeth prompted experts to discuss their relevance. Two experts expressed that assessment of the voice was the least valuable indicator for OM as the quality of speech is dependant on other factors, such as the emotional state of the child and vincristine-induced hoarseness. Four experts did not agree with the inclusion of teething (not assessed in the original OAG) in both the saliva and gingivae categories as it was not viewed as a direct result of chemotherapy, but rather a normal process depending on the age of the baby. As with item validity, there was disagreement on the inclusion of teeth in the instrument. Even though it had achieved excellent CVI, four experts struggled with the inclusion of this category as they felt if did not relate directly to the degree of OM.

6.2.2. *Terminology*

The main concern with terminology was that it tended to be very subjective. All experts believed the OAG for children must be objective. By reducing subjectivity of the assessment, such as the inclusion or exclusion of assessing pain, all experts believed the assessment could be improved. As with item validity, more description of the grading for each category, giving explicit information to the assessor, was felt to improve the instrument. This was particularly in relation to the categories tongue, saliva, mucous membranes and gingivae.

6.2.3. *General comments*

There were two general concerns voiced by experts; firstly in relation to the inclusion or exclusion of pain assessment, and secondly, the absence of a weighting system in respect of individual categories. It was felt that some categories could be viewed as more important than others. The project team discussed this but felt that although this may be the case, no one category can stand in isolation. All have value in some respect and all categories are interdependent as a measure of oral status. Pain is by far the most subjective element of oral assessment; however five of the panel believed that it was the best guide to the severity of OM and the requirement for analgesia. The difficulties surrounding accurate assessment of pain in children was voiced by all experts. Additionally it was stated that the ability to assess would be hampered as the degree of pain increases. Three experts requested that questioning the child about their pain, although difficult, is valuable and its importance in the role of overall assessment must be considered.

Table 3 – Respondent CVI score for content validity entire instrument

Category	Number of ratings of 3 or 4	Actual CVI
Voice	8	0.8
Swallow	10	1.0
Lips and edge of the mouth	10	1.0
Tongue	10	1.0
Saliva	10	1.0
Mucous membranes	10	1.0
Gingivae	10	1.0
Teeth	8	0.8
Voice		
Normal	10	1.0
Deeper or raspy	8	0.8
Difficulty talking, crying or painful	9	0.9
Swallow		
Normal swallow	10	1.0
Some pain on swallowing	10	1.0
Unable to swallow, pooling of secretions	10	1.0
Lips and corner of the mouth		
Smooth, pink and moist	10	1.0
Dry or cracked	9	0.9
Ulcerated or bleeding	10	1.0
Tongue		
Pink, moist, papillae present	10	1.0
Coated/loss of papillae. Shiny appearance with or without redness and/or oral candida	9	0.9
Blistered or cracked	10	1.0
Saliva		
Watery, excess saliva due to teething	8	0.8
Thick or ropy	10	1.0
Absent	9	0.9
Mucous membranes		
Pink and moist	9	0.9
Reddened or coated without ulceration and/or oral candida	10	1.0
Ulceration with or without bleeding	10	1.0
Gingivae		
Pink or coral with a stippled surface. Gum margins tight and well defined, no swelling. Oedema due to teething	10	1.0
Oedematous with or without redness	10	1.0
Spontaneous bleeding	9	0.9
Teeth		
Clean, no debris	9	0.9
Plaque/debris in localised area	9	0.9
Plaque or debris generalised along gum margin	9	0.9

Following changes the revised OAG was distributed to experts undertaking content validity of the instrument. All 10 (100%) experts responded. The CVI for the entire instrument was calculated as 1.00 with all but one category providing full validity agreement from all experts with no amendments to terminology or phrasing. The process of content validity for the oral assessment guide in children and young people (Fig. 2) was completed 4 months from initial contact with experts.

7. Discussion

Validity is a crucial factor in the selection or application of an instrument. It involves the agreement by a specific number of experts that the items and entire instrument are valid. During each stage, defined experts rate the content relevance of the items on an instrument, and CVI calculations are applied to both items and the entire instrument. The experts identify areas of omission and suggest areas of improvement or modification. This study has determined expert judgement on modifications required to ensure the OAG reflects sensitivities of a paediatric population.

Content specialists agreed that the eight parameters of the OAG, swallow, lips and corner of mouth, tongue, saliva, mucous membranes, gingival, teeth, and voice were valid domains for scoring oral problems. Although there was mention of the relevance of some domains, such as teeth and voice, the CVI remained high for these domains and so they remain. The inclusion of the category of teeth created the most discussion. Overall, this category was considered to represent a general level of good oral health, a condition that influences the progression and severity of oral problems, as such experts agreed it should remain. The only change made to the domains of the instrument was the order in which they appear. This appeared to be a most sensible suggestion, as assessing the voice last would give the assessor time to observe the child and either hear them cry or speak in order to make a true assessment that mirrors how assessments are carried out in practice.

Method of administration was the focus of many of the comments made by experts. It is evident from suggested modifications that experts were reflecting on real time assessment techniques and terminology pertinent when caring for children and young people. The inclusion of observation and/or a response to make an active movement e.g. speak or swallow, is more acceptable to children, and those caring for them, whereas pressing the tissues (albeit gently) will almost certainly be painful and may cause damage. The latter more invasive approach to assessing gingivae is more likely to result in the child refusing future assessments, and may jeopardise oral care. The addition of functional parameters, such as swallowing and talking were important child focused methods of assessment, without which alteration of a child's functional status would fail to be reported.[39] Assessment of functional parameters is enhanced in the modified instrument by including parents/carers in the assessment process. This change reflects the philosophy when caring for children, where working together helps to establish a supportive environment when undertaking procedures with children.[42]

Descriptive statements that divided the domains into gradations for scoring purposes were developed and expanded to be more easily recognisable descriptions. These were refined by the project team and 'tested' on clinicians. Accurate and

Category	Method of assessment	1	2	3
Swallow	Ask the child to swallow or observe the swallowing process. Ask the parent if there are any notable changes.	Normal. Without difficulty	Difficulty in swallowing	Unable to swallow at all. Pooling, dribbling of secretions
Lips and corner of mouth	Observe appearance of tissue	Normal. Smooth, pink and moist	Dry, cracked or swollen	Ulcerated or bleeding
Tongue	Observe the appearance of the tongue using a pen-torch to illuminate the oral cavity	Normal. Firm without fissures (cracking or splitting) or prominent papilla. Pink and moist	Coated or loss of papillae with a shiny appearance with or without redness and/or oral *Candida*	Ulcerated, sloughing or cracked
Saliva	Observe consistency and quality of saliva	Normal. Thin and watery	Excess amount of saliva, drooling	**Thick, ropy** or absent
Mucous membrane	Observe the appearance of tissue using a pen-torch to illuminate the oral cavity	Normal. Pink and moist	Reddened or coated without ulceration and/or oral *Candida*	Ulceration and sloughing, with or without bleeding
Gingivae	Observe the appearance of tissue using a pen-torch to illuminate the oral cavity	Normal. Pink or coral with a stippled (dotted) surface. Gum margins tight and well defined, no swelling.	Oedematous with or without redness, smooth	Spontaneous bleeding
Teeth (If no teeth score 1)	Observe the appearance of teeth using a pen-torch to illuminate the oral cavity	Normal. Clean and no debris	Plaque or debris in localised areas	Plaque or debris generalised along gum line
Voice	Talk and listen to the child. Ask the parent if there are any notable changes	Normal tone and quality when talking or crying	Deeper or raspy	Difficult to talk, cry or not talking at all

NB if score >8 introduce pain assessment instrument

Oral assessment guide-Adapted from Eilers et al. (1988) by the mouth care working party at Great Ormond Street Hospital for Children NHS Trust (2005).

Fig. 2 – Oral assessment guide for children and young people.

unambiguous terminology that is meaningful and understood by clinicians was considered fundamental to precision of the instrument. Likewise, providing full descriptions would leave no room for error when allocating a score. Similarly, examples from practice such as pooling, dribbling of secretions were considered to express the reality of the symptom for children. The requirement for detail was highlighted, as was the need to be clear and appropriate in how oral pain was assessed.

Variation in descriptions of pain included in assessment scales has been noted previously.[18] Mucositis and ulceration can cause pain and misery disproportionate to the size of the area affected.[43] Children may not complain of oral pain until it is already well established. The project team considered comments from experts, local pain team clinicians and their own expert knowledge and decided to remove all mention of pain from the OAG: thus responding to controversy over a scoring instrument that tries to measure both objective and subjective parameters. The modified OAG instructs clinicians to introduce a separate pain assessment instrument on a score >8. The inclusion of a second assessment instrument may appear burdensome, to the child and clinicians. However, clinician awareness and control of pain is necessary for optimal functioning and quality of life. Pain assessment instruments allow for more detailed self-reporting of pain, added to observation of parents and clinicians that will provide a more complete picture of the symptom.

Lack of agreement has been noted regarding the score attached to a specific sign or symptom complex in different instruments.[18] The use of a scoring system was also a concern shared by some of the experts. This related to the inclusion of a composite score, not the scoring of individual items. The assumption is that all items are equally important in contributing to the total score. Weighting traits for greater sophistication results in increased computation.[44] Such increased complexity of use raised concerns about clinical application and ease of use. The project team therefore decided to leave the scoring system unchanged.

8. Conclusion

Nineteen specialists, all experts in the field of paediatric oncology, have provided fundamental analysis of content validity for the OAG for children and young people. The use of a judgement quantification process to content analysis of an established instrument was found to offer structure, rigour and clear guidance. High CVI scores were consistently recorded which, without the comments and suggestions for modifications may have been misleading and failed to direct the project team to revise descriptors and ensure the instrument is fit for purpose. The re-organisation of the categories and removal of pain descriptors has resulted in a systematic and objective instrument that can be used in the clinical setting. Clinicians can now be assured of the content validity of the OAG for use with children and young people. The revised instrument, the GOSH OAG (Fig. 2), is available from the lead author. Future plans include further development and validation of the GOSH OAG to reveal meaning and uses of scores in the clinical setting.

Conflict of interest statement

All authors state that there were no financial or personal relationships with other people or organizations that could inappropriately influence (bias) our work. There is no conflict of interest to declare.

Acknowledgements

This work was supported by a General Nursing Council Grant.

Thank you to all the experts who participated in our study: Liz Auld Manchester, Dr. Angus Cameron Australia, Karis Cheng Kwong Hong Kong, Suzanne Coulson Leeds, Dr. Goran Dahloff Sweden, Dr. Steve Daw London, Gill Dixon Leeds, Professor Tim Eden Manchester, Dr. Helen Estyn-Jones London, Alison Hall Glasgow, Dr. Lindsay Hunter Cardiff, Dr. Meriel Jenney Cardiff, Sarah Kirk Birmingham, Dr. Donna Lancaster London, Dr. Carol Mason London, Shane Morris-Coutes New Zealand, Dr. Barry Pizer Liverpool, Dr. Jon Pritchard Edinburgh, Professor Graham Roberts London, Karen Selwood Liverpool, Dr. Yvla-Britt Wahlen Sweden, Professor Richard Widmer Australia.

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