Overview

The Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD; Dworkin and LeResche, 1992) is one of the most successful approaches to pain diagnosis in terms of clearly operationalized data collection procedures, specific diagnostic criteria, and incorporation of a dual assessment for both somatic diagnosis and evaluation of the functional status of the individual. It is not surprising that the RDC/TMD protocol has been translated into over 20 languages and has an overwhelming number of citations in the literature, and applied research using the RDC/TMD has been supplemented by an increasing amount of methods research on the RDC/TMD itself. In 2001, the National Institute for Dental and Craniofacial Research (NIDCR/NIH) funded a prospective project, Research Diagnostic Criteria: Reliability and Validity (Validity Study; E. Schiffman, PI), which was the largest study of the components of the RDC/TMD to date, supplementing an extensive range of studies conducted by other researchers. The primary findings from the Validity Study were presented by the investigators in a one-day symposium at the July 2008 meeting of the International Association for Dental Research, Toronto, Canada, organized by the International RDC/TMD Consortium Network (TMD Consortium). At that symposium, researchers not associated with the study were invited to provide critical commentary. Immediately following that symposium, the need for a closed workshop involving a variety of TMD researchers as well as external experts and consultants was identified with the explicit goal of finalizing the revision of the RDC/TMD into a set of valid diagnostic criteria for use in both clinical and research applications.

Subsequently, at the August 2008 annual meeting of the International Association for the Study of Pain (IASP) in Glasgow, Scotland, the Orofacial Pain Special Interest Group (Orofacial Pain SIG) formed a working committee in order to foster the development of a formal Research Diagnostic Criteria for Orofacial Pain Disorders. This taxonomy was intended to initially focus on the orofacial pain conditions other than TMD.

The Orofacial Pain SIG has worked with the TMD Consortium to create this workshop that includes participants from TMD, orofacial pain, neurology, rheumatology, radiology, psychology, bioinformatics, patient advocacy, and the NIH; additionally, representation from other organizations with closely related taxonomic structures includes the American Academy of Orofacial Pain (AAOP), European Academy of Craniofacial Disorders (EACD), and the International Headache Society (IHS). The breadth of this undertaking required multi-specialty and international representation.

This workshop is intended to be the first of many meetings that the International RDC/TMD Consortium Network and the Orofacial Pain SIG will separately or jointly organize. Consequently, the overall purposes of the present workshop are to:

1. **Finalize the revision of the RDC/TMD,** and
2. **Provide a broad foundation for the further development of suitable diagnostic systems for TMD and orofacial pain.**
The IASP in Montreal, Canada (August 2010), will be the venue for the next meeting which will be a 1-day satellite symposium, jointly organized by the Orofacial Pain SIG and the NeuroSIG. After this workshop, a planning committee will form and begin the development of the next workshop, tentatively scheduled to be held in conjunction with the IADR in San Diego (March 2011). The particular form of that workshop will be shaped by the recommendations from the present workshop as well as by workgroup progress in the period immediately following this workshop. The 2011 workshop, like the present one, will address the goal of inclusiveness of the many individuals who work in these areas. We plan to overlap with participants from this workshop in order to maintain both sufficient representation as well as continuity of development.

**Workshop Goals**

1. Create Diagnostic Criteria for TMD (DC/TMD, v1.0), founded on evidence-based revisions to the RDC/TMD, for immediate implementation in clinical settings and prospective research.

2. Identify new diagnostic areas of TMD and associated research diagnostic criteria for TMDs as well as other Axis II measures for new investigation (RDC/TMD, v2.0).

3. Create an initial draft of Research Diagnostic Criteria for selected other orofacial pain conditions (RDC/OFP v1.0) where existing data are sufficient.

4. Initiate a working Orofacial Pain Taxonomy Consensus Group to continue the development of a single integrated taxonomic structure for temporomandibular disorders, orofacial pain disorders, regional neuropathic pains, odontogenic and soft tissue pains, and related headache based on classification principles currently implemented in medical ontology and bioinformatics; this goal includes consideration of nomenclature.

5. Identify research directions.

6. Disseminate the results in appropriate journals.

**Mechanism**

This meeting is a 2.5 day closed workshop with the specific purpose of developing consensus guidelines as identified by the Goals. The workshop is closed in order to have the necessary setting by which sufficient discussion and consensus can be achieved. The participants selected for invitation to this workshop was a consensus product of the Planning Committee. The Committee is extremely grateful to all of the participants for the extraordinary level of acceptance to our invitations.

Some funding has been obtained from the TMD Consortium, Orofacial Pain SIG, Medotech, and Canadian Institute for Health Research. The TMD Consortium is a Network within the IADR, and the IADR is also a significant sponsor for this meeting. The Planning Committee is grateful for the generosity of the participants in largely funding themselves. With limited funding, our priority for travel funds was external consultants and emeritus individuals who no longer have access to institutional funds, and to provide needed coffee breaks; one lunch is catered.

The planning committee consists of Jean-Paul Goulet (Canada), Thomas List (Sweden), Richard Ohrbach (US), and Peter Svensson (Denmark); these individuals will share the chair responsibilities of the general sessions. Working-group chairs and pre-workshop coordinators were selected by the Planning Committee.
Description of the Workshop

This workshop is comprised of the following elements:

- General sessions for discussion and consensus
- Workgroup sessions for finalizing recommendations based on workgroup goals
- Formal presentations to serve as foundations for future goals
  - Patient advocacy
  - Systematic review guidelines
  - Biomedical ontology
- Planning for the next meetings

The Membership Assignments indicate the roles requested of each participant. Individuals without specific assignment will rotate among groups in order to facilitate progress toward the goals.

The general sessions will be comprised of formal presentations at the beginning of the meeting. These presentations will include summaries by each workgroup chair, followed by general discussion. The initial presentation by each workgroup chair should be limited to 15 minutes and summarize the current status of the respective domain, identify the major workgroup challenges associated with the goals of the workgroup and workshop, and provide an initial description of the planned activity of the workgroup. We expect that workgroup chairs will consult with the workgroup members in order to finalize these initial summaries. More detail to the workgroup chairs will follow regarding this part of the pre-workshop activity.

The patients’ perspective of evaluation and diagnosis will be presented, in order for us to better consider long-term development goals in that light, and the morning will conclude with a review of guidelines for a systematic review of the diagnostic literature that will be within the scope of post-workshop activity for at least two workgroups and which serves as a common methods reference as measures and diagnoses are reviewed. See Appendix 1 for summary of pre-workshop activities related to this workshop activity.

On the second day, the longer-term goals as identified by Workshop Goal 4 will be addressed. The general session will begin with a presentation regarding the generic task associated with developing the single integrated taxonomic structure referred to in Goal 4, a description of the pitfalls generally associated with developing such structures, the dangers of not considering sound principles of logical relations inherent in such endeavors, the advantages to our field that will emerge with developing a good integrated taxonomic structure for all aspects of orofacial pain, and examples of how application of these methodologies for integration have been implemented in other fields. This presentation will be followed by an active workshop of the application of medical ontology to Workshop Goal 4 conducted by the ontology consultants in order to provide our field with additional tools for developing disease classifications. See Appendix 2 for more information regarding medical ontology.

Subsequent general sessions will be comprised of further workgroup presentations, critique, and synthesis.

Workgroup sessions are minimally structured in order to provide the participants the necessary space for addressing the stated goals. It is recognized that the Workgroups will begin their efforts from different vantage points. Workgroups dealing with Axis I TMD goals (Muscle Disorders and Headache; TMJ Disorders) will consider revisions to already defined diagnostic TMD categories and potential expansion to related clinical subtypes for which diagnostic tests and clinical measures have varying degrees of established reliability and validity. The Biobehavioral Domain Workgroup, while also engaging in revisions and expansion, will typically not deal with diagnostic tests per se or criteria but focus on assessment domains and measures which already have very-
well established psychometric data to support their reliability and validity. In contrast, the Orofacial Pain Workgroup is, in effect, creating a new diagnostic schema and will be faced with challenges similar to those facing the original creation of the RDC/TMD, including operationally defining relevant pain conditions as well as identifying the status of potential diagnostic tests and clinical measures with regard to reliability, validity and clinical utility.

Because the most critical need for assessment, diagnosis, and clinical classification is to allow for differential management of these diverse pain conditions, it is anticipated that each of the Workgroups will grapple at some level with the rationale and methods for integrating the physical diagnosis domain and the biobehavioral assessment domain in order to foster more evidence-based guidelines leading to better treatment decisions and evolve criteria for outcomes related to not only treatment efficacy but also to those factors that may constitute risk affecting prognosis and treatment response. Such factors include the biobehavioral domain, genetics, proteomics, and neuroscience, and the anticipated role of current classification methodologies is to help us ultimately construct a classification system that will better permit organizing the diverse information ranging from genetics to behavior so that that information has greater utility in the clinical setting.

Workshop documents will be placed on the website for easy access and download by participants; please print the documents if you wish to have a paper copy. The TMD Consortium website is www.rdc-tmdinternational.org. A password-protected section of the website has been set up for this meeting, and further instructions for document access will be separately sent to the participants. Participants can request specific materials to be placed on the website in order to make them accessible to the workshop participants; please send them in their posting-format to ohrbach@buffalo.edu. Paper copies of the final Program document as well as any specific handout requested by participants will be provided at the meeting.

**Dress**

This is a workshop, so please dress comfortably (casual). Typical weather in Miami Beach for late March: 77°F max, 73°F average, and 68°F min, and rain is minimal.

**Workshop Facilities**

The Loews Miami Beach Hotel
- 1601 Collins Avenue, Miami, Florida 33139
- Voice (305) 604-1601
- FAX (305) 604-3999

The meeting rooms in the Loews Hotel for this workshop are on the third level. The general sessions will occur with all participants meeting together. A laptop and projector will be available for presentations; please bring thumbdrives for transfer of any files as we wish to use a single laptop with the projector for the general discussions. For the Wednesday discussion meeting, we plan to also have “clickers” (remote response units) in order to facilitate voting toward consensus, as needed; one of the participants will manage that aspect of the meeting. Coffee breaks will occur in the main meeting room.

Small meeting rooms have been reserved for the workgroups’ use on Monday and Tuesday, and paper presentation boards will be available. We ask that participants bring as paper copies any materials that they wish to share or discuss within their workgroups, and that the workgroup time be devoted to discussion and to not use computer-based presentations during those sessions.
The meeting budget is sufficient to provide a catered lunch on Tuesday. For Monday, the schedule is designed to allow participants as organized by the workgroups to take lunch as appropriate to their own schedule. The hotel has several restaurants:

- Emeril’s Miami Beach, lunch 11:30a – 2:30p; reservations call extension 4550
- Preston’s Brasserie, lunch noon – 2p; reservations call extension 3433
- Nautilus (poolside), lunch 11a – 5p; no reservations required
March 29 – Sunday
Arrive in Miami
Contact another participant and meet for dinner!

March 30 – Monday

Cowrie I  Session I: Developing New Taxonomies
8:00 Chairs: J-P Goulet and R Ohrbach
Introduction
  Welcome J-P Goulet
  Overview of scope and goals R Ohrbach
8:30 Workgroup Summaries Workgroup Chairs
9:30 Discussion
10:00 Refreshment Break
10:30 What Do Patients Want from a Diagnosis? T Cowley
10:50 Criteria for Systematic Review M Drangsholt
11:20 Discussion

11:45 Session II: Individual Workgroups
  Periwinkle: Muscle Disorders
  Lucina: Orofacial Pain Disorders
  Crown: TMJ Disorders
  Venus: Biobehavioral Domain

TBD Lunch (on your own – with your group)
TBD Workgroups continue
3:00 Afternoon break: refreshments
3:30 Workgroups continue
TBD Dinner (on your own)

TBD  Workgroups continue after dinner

TBD = to be determined by the workgroup members

Loews Hotel – Third Level Meeting Rooms
March 31 – Tuesday

Cowrie I  Session III: Biomedical Ontology
8:00  Chairs: T List, P Svensson, R Ohrbach
8:05  Ontology: Background and Rationale  B Smith
9:45  Refreshment Break
10:05  Ontology Workshop for Orofacial Pain  B Smith
       W Ceusters
       L Goldberg

11:30  Session IV: Workgroups continue
       Triton: Muscle Disorders  Lucina: Orofacial Pain Disorders
       Moon: TMJ Disorders  Sundial: Biobehavioral Domain

12:30  Lunch buffet sponsored by Medotech (Cowrie I)
1:30  Workgroups continue
3:30  Refreshment break

Cowrie I  Session V: Interim Workgroup Recommendations and Discussion
4:00  (Chairs: T List, P Svensson, J-P Goulet)
Workgroup Summaries and Discussion  Workgroup Chairs

6:00  Bar and dinner (on own)
8:00  Workgroups resume as needed

April 1 – Wednesday

Cowrie I  Session VI: DC/TMD Consensus And Future Recommendations
8:00  (Chairs: J-P Goulet, T List, R Ohrbach, P Svensson)
      Final Recommendations and Discussion  Workgroup Chairs
10:00  Refreshment break
10:20  Continue Consensus Discussion
11:30  Session VII: Next Steps
      (Chairs: J-P Goulet, T List, R Ohrbach, P Svensson)
12:15  Adjourn
Goals and Guidelines for the Workgroups

Workgroup 1. Muscle Disorders and Headache

Workgroup Goals

1. Propose diagnostic criteria for the most common Axis-I muscle disorders which are sufficiently evidence-based for incorporation into the DC/TMD.

2. Evaluate scientific evidence for the diagnostic accuracy of various methods for determining diagnoses of Axis-I muscle disorders, and define the assessment methods and measures to be used for the most common Axis-I muscle disorders in the DC/TMD.

3. Discuss the relevance of developing guidelines for the assessment of headache in TMD patients for inclusion into the DC/TMD, and if so, determine operationalized tests and diagnostic criteria pending sufficient existing data or make other recommendations.

4. Identify other less common muscle disorders that have sufficient information to now create potential diagnostic criteria and the associated assessment methods and measures to be used in RDC/TMD v2.0 which forms an addendum to the DC/TMD.

5. Address nomenclature for tests, disorders, and aggregates of disorders.

6. Determine which areas should be relegated to further discussion in the next cycle of such workshops.

7. Identify important research questions regarding the assessment methods and diagnosis of muscle disorders and any headache diagnoses in individuals with TMD, including integration of Axis I with Axis II, genetics, proteomics, and behavioural-brain science.

8. Determine the scope, methods, and authorship of a systematic review regarding diagnosis of muscle disorders and headache pertinent to TMD, to be undertaken after the workshop.

The Validation Study Group’s initial manuscripts (currently under final review) and papers recommended by Frank Lobbezoo serve as the primary literature for review by the workgroup. A secondary literature was created through a comprehensive literature search conducted by University librarians at Malmö University; see Appendix 1. The pre-workshop coordinators (Yoly Gonzalez, Ambra Michelotti) reviewed the abstracts and selected the most relevant publications, and of these the first-recommended set of publications will be posted as PDF files on the Consortium web site for download.

The first task for the workgroup chair is to facilitate a group decision regarding how consensus recommendations for each of the 8 goals will be attained. Options include open discussions, use of the Delphi method (see Appendix 3), or some mixture. The initial recommendations relevant to the goals are to be presented for discussion at the session on Tuesday afternoon, while final recommendations will be presented at the plenary session on Wednesday.

The second task of the workgroup is to propose disorders and diagnostic criteria that meet evidence-based guidelines (based on the QUODAS standard) and which will be incorporated into the DC/TMD as Group I disorders. Workgroup participants should review the primary files in preparation for the meeting. Disorders and criteria appropriate for a potential RDC/TMD v2.0, as an addendum to the DC/TMD, as well as matters best
deferred to a future meeting are the remaining aspects of this task. Nomenclature concerns are part of this task. On Wednesday, all four groups will reach a consensus on the diagnostic criteria for myofascial pain and headaches pertinent to TMD based on the recommendations from Group I.

With respect to the second task, a set of recommendations for myofascial pain are primary, which is recognized as the most common muscle disorder according to the literature, the RDC/TMD, and American Academy of Orofacial Pain guidelines. Thereafter, it is up to the workgroup members to decide from the current data available if there are other less common muscle disorders for which it is possible to define diagnostic criteria and make the appropriate recommendations.

The third task of the workgroup is to identify research directions. NIDCR program officers will rotate among the workgroups in order to help facilitate this part of our workshop. The emphasis in identifying research directions is to focus not only on research questions specific to this domain of muscle pain disorders and headache, but to also consider how these disorders interact with the domains of genetics, proteomics, and brain-behavior.

The fourth task of the workgroup is to plan the systematic review of diagnostic accuracy of myofascial pain related to TMD. During the workshop, participants will be calibrated in systematic review methods. In preparation for this aspect of the workshop, the secondary literature should also be scanned if possible.

In terms of other contributions to the general sessions, the Workgroup is asked to provide input with regard to possible approaches to integrating Axis I and Axis II, considering as well the expected influence from ongoing end emerging efforts in genetics and central and peripheral neurophysiology,
Goals and Guidelines for the Workgroups

Workgroup 2. TMJ Disorders

Workgroup Goals

1. Propose diagnostic criteria for the most common Axis-I Group II disorders (internal derangements) and Group III disorders (joint pain, arthritic conditions) associated with the TMJ, which are sufficiently evidence-based for incorporation into the DC/TMD.

2. Evaluate scientific evidence for the diagnostic accuracy of various methods for determining diagnoses of internal derangements and TMJ arthritides, and define the assessment methods and measures to be used in the joint disorders to be incorporated into the DC/TMD.

3. Identify other less common joint disorders that have sufficient information to now create potential diagnostic criteria along with the assessment methods and measures to be used in RDC/TMD v2.0 which forms an addendum to the DC/TMD.

4. Address nomenclature for tests, disorders, and aggregates of disorders.

5. Identify important research questions regarding the assessment methods and diagnosis of TMJ disorders, including integration of Axis I with Axis II, genetics, proteomics, and behavioural-brain science.

6. Determine which areas should be relegated to further discussion in the next cycle of such workshops.

7. Determine the scope, methods, and authorship of a systematic review regarding diagnosis of TMJ disorders, to be undertaken after the workshop.

The Validation Study Group’s initial manuscripts (currently under final review) and papers recommended by Arne Petersson serve as the primary literature for review by the workgroup. A secondary literature was created though a comprehensive literature search conducted by University librarians at Malmö University; see Appendix 1. The pre-workshop coordinators (Frank Lobbezoo, Arne Petersson) reviewed the abstracts and selected the most relevant publications, and of these the consensus recommendation regarding the initial 50 publications are posted as PDF files on the Consortium web site for download.

The first task for the workgroup chair is to facilitate a group decision regarding how consensus recommendations for each of the 7 goals will be attained. Options include open discussions, use of the Delphi method (see Appendix 3), or some mixture. The initial recommendations relevant to the goals are to be presented for discussion at the session on Tuesday afternoon, while final recommendations will be presented at the plenary session on Wednesday.

The second task of the group is to discuss the proposed RDC/TMD criteria and create clinical diagnostic criteria for Groups II and III disorders based on relevant literature. Workgroup participants should review the primary files in preparation for the meeting. On Wednesday, all four groups will reach a consensus on the diagnostic criteria for internal derangements and arthritic disorders based on the recommendations from Group I. Nomenclature concerns are part of this task.

The third task of the workgroup is to identify research directions. NIDCR program officers will rotate among the workgroups in order to help facilitate this part of our workshop. The emphasis in identifying research directions is to focus not only on research questions
specific to this domain of TMJ disorders, but to also consider how these disorders interact with the domains of genetics, proteomics, and brain-behavior.

The fourth task of the workgroup is to plan the systematic review of diagnostic accuracy of Group II and Group III disorders. During the workshop, participants will be calibrated in systematic review methods. In preparation for this aspect of the workshop, the secondary literature should also be scanned if possible.

The primary expectation regarding task 2 is a set of recommendations for the Axis-I temporomandibular joint disorders included in the RDC/TMD taxonomy unless the workgroup members decide otherwise. These disorders include disc displacement with reduction; disc displacement without reduction with limited opening (acute form); disc displacement without reduction without limited opening (chronic form); arthralgia; osteoarthritis of the TMJ; and osteoarthrosis of the TMJ. Thereafter, it is up to the workgroup members to decide from the current data available if there are other less common joint disorders for which it is possible to define diagnostic criteria and make the appropriate recommendations.

In terms of other contributions to the general sessions, the Workgroup is asked to provide input with regard to possible approaches to integrating Axis I and Axis II, considering as well the expected influence from ongoing end emerging efforts in genetics and central and peripheral neurophysiology,
Goals and Guidelines for the Workgroups

Workgroup 3. Orofacial Pain Disorders

Workgroup Goals
1. Decide how the workgroup will initiate the development of a classification system for orofacial pain.
2. The proposed matrix model for multidimensional pain diagnosis of orofacial pain conditions (see Appendix) provides one approach towards development of an orofacial pain classification; if acceptable, create recommendations for the history questions and examination tests as depicted in that approach.
3. Address nomenclature for tests, disorders, and aggregates of disorders.
4. Initiate a taxonomy consensus on selected orofacial pain conditions in order to create the first draft of the RDC/OFP.
5. Propose a platform for how any preliminary data (such as based upon the multidimensional matrix model) can be collected for the next meeting in Montreal.
6. Identify important research questions regarding the assessment methods and diagnosis of orofacial pain disorders, including integration of Axis I with Axis II, genetics, proteomics, and behavioural-brain science.
7. Decide at what stage a collaborative effort with biomedical ontology would be best.
8. Determine which areas should be relegated to further discussion in the next cycle of such workshops.

Dominik Ettlin, Don Nixdorf, and Joanna Zakrzewska reviewed the literature search (see Appendix 1) on diagnostic accuracy of orofacial pain conditions. Aside from trigeminal neuralgia, no other published studies on diagnostic accuracy were found and consequently the aims of the orofacial pain group were modified. Dominic Ettlin proposed a roadmap for RDC–Orofacial pain disorders (see Appendix 4). To prepare for the meeting, the Consortium website contains relevant literature.

The first task of the workgroup chair is to facilitate a group decision regarding how consensus recommendations for each of the 8 goals will be attained. Options include open discussions, use of the Delphi method (see Appendix 3), or some mixture. The initial recommendations relevant to the goals are to be presented for discussion at the session on Tuesday afternoon, while final recommendations will be presented at the plenary session on Wednesday.

The second task of the workgroup is to address prospective data collection whereby more evidence can be obtained. A recommended approach is to review the history questions and diagnostic tests in the proposed matrix model for multidimensional pain diagnosis (see Appendix II). If the workgroup proceeds in this direction, the members will draft recommendations for (i) which constructs should be incorporated (e.g., origin, time pattern, quality) and (ii) how they should be operationally defined (e.g., sensory-discriminative or affective-motivational pain qualities might be measured with some version of the McGill Pain Questionnaire). Proposals will be developed for how the prospective information in the matrix would be used for a disorder diagnosis in the orofacial pain domain. At this stage of development, reliability and proposed cut-points should be considered in terms of priorities for which constructs to assess first and how to operationalize them. The workgroup should propose a plan that describes how preliminary data, based on the
multidimensional matrix model suggested by the group, might be collected. The collection of any such data should be considered for presentation at the next consensus workshop (tentatively planned for March 2011). The group will present interim recommendations on Tuesday followed by final recommendations for consensus on Wednesday.

The third task of the workgroup will be to initiate taxonomy discussions on selected orofacial pain conditions such as atypical odontalgia, atypical facial pain, and burning mouth syndrome in order to draft an initial RDC/OFP. The workgroup will propose diagnostic criteria for the selected orofacial pain conditions for the consensus discussion on Wednesday. Nomenclature concerns are included in this task. In conjunction with the 4th workshop goal (development of a formal ontology for orofacial pain disorders broadly), statistical models for taxonomic classification (e.g., cluster analysis, ontology-based cluster analysis, CART, etc) should also be considered at this stage. The first draft may well be based on principles such as guided the development of the first draft of the RDC/TMD. Diagnostic grouping will be attempted where feasible in order to converge on a first draft of an orofacial pain taxonomy.

The fourth task is to determine whether any research recommendations can be made relative to the current status of classification of the orofacial pain disorders (excluding TMD).

The fifth task pertains to planning for post-workshop activities that are expected to be particularly complex and challenging for this workgroup. These activities include seeking consensus from a larger group of orofacial pain professionals regarding key issues (such as via the Delphi method), whether and when to engage in a collaboration towards a more formal ontology, and insuring linkage of group activity with adjacent organizations (e.g., IHS, AAOP) in terms of classification efforts.

In terms of other contributions to the general sessions, the Workgroup is asked to provide input with regard to possible approaches to integrating Axis I and Axis II, considering as well the expected influence from ongoing end emerging efforts in genetics and central and peripheral neurophysiology,
Goals and Guidelines for the Workgroups

Workgroup 4. Biobehavioral Domain

Workgroup Goals
1. Create recommendations for Axis II of the DC/TMD.
2. Evaluate scientific evidence for the clinical utility of various constructs and measures used for determining the status of individuals with persistent pain.
3. Present a model and guidelines for integration of Axis I and Axis II to compel comprehensive evidence-based decisions about treatment recommendations.
4. Create a model for incorporation of additional domains and measures (e.g., genetics, neuroscience data) into the overall person assessment for inclusion into the RDC/TMD v2.0 as an addendum to the DC/TMD.
5. Address nomenclature for tests, disorders, and aggregates of disorders.
6. Identify important research questions regarding the assessment and therapeutic implications of Axis II, including integration of Axis II with Axis I, genetics, proteomics, and behavioural-brain science.
7. Determine which areas should be relegated to further discussion in the next cycle of such workshops.

The Validation Study Group’s initial manuscripts (currently under final review or accepted for publication) and as-yet unpublished analyses to be presented at the workgroup meeting, as well as additional papers to be recommended by the workgroup members prior to the workgroup meeting, serve as the primary literature for review by the workgroup. A secondary literature bibliography was created though a comprehensive literature search conducted by University librarians at the University at Buffalo; see Appendix 1. The pre-workshop coordinators (Sam Dworkin, Mike John) reviewed the abstracts emerging from this literature review and it became clear that the scope and goals of a systematic review would need further discussion by the members of the workgroup. Further discussion between Sam Dworkin and Richard Ohrbach resulted in a plan for abstract selection and preliminary review that may be conducted before the workshop begins; more detail will be sent to the workgroup members. The goal of a systematic review of psychological constructs and measures used in TMD and orofacial pain will be discussed at the workshop.

The first task of the workgroup chair is to facilitate a group decision regarding how consensus recommendations for each of the 7 goals will be attained. Options include open discussions, use of the Delphi method (see Appendix 3), or some mixture. The initial recommendations relevant to the goals are to be presented for discussion at the session on Tuesday afternoon, while final recommendations will be presented at the plenary session on Wednesday.

The second task of the workgroup is to review constructs and measures for Axis II based on relevant literature, and make recommendations for the DC/TMD. Workgroup participants should review the primary files in preparation for the meeting. If Axis II expands, as expected with respect to the number of constructs that should be assessed in order to provide a sufficiently comprehensive assessment of the individual, pragmatic aspects of how Axis II should be used (e.g., clinical settings vs research settings) should be addressed in terms of balancing comprehensiveness.
without overburdening the patient or research subject. An additional aspect within this task is to consider how the information from these instruments is interpreted both in the clinical setting by the health care provider and in the research setting based on group statistics. On Wednesday, all four groups will reach a consensus on the measures based on the recommendations from workgroup 4.

The third task of the workgroup is to identify research directions. NIDCR program officers will rotate among the workgroups in order to help facilitate this part of our workshop. The emphasis in identifying research directions is to focus not only on research questions specific to this domain of biobehavioral assessment, but to also consider how this domain interacts with the physical diagnosis domain and the domains of genetics, proteomics, and the brain.

The fourth task of the workgroup is to plan the systematic review of behavioral measures related to TMD and to orofacial pain. During the workshop, participants will be calibrated in systematic review methods. The primary aims of reviewing this literature are to address determination of clinical thresholds, implications of the relationship between Axis I and Axis II, and extension of Axis II into a larger multi-axial space. These developments are expected to require collaboration with biomedical ontology.

In terms of other contributions to the general sessions, the Workgroup is asked to provide input with regard to possible approaches to integrating Axis I and Axis II, considering as well the expected influence from ongoing end emerging efforts in genetics and central and peripheral neurophysiology,
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International Consensus Workshop:
Convergence on an Orofacial Pain Taxonomy

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Appendix 1

Systematic Review Guidelines

Review process

Pre-workshop

- The planning committee with the assistance of university librarians did a literature search.
- Two members from each of the four working groups screened the reference list and selected, based on content validity, publications for further review.
- PDF files of the publications were retrieved by planning committee members and group coordinators; the PDF files are posted on the RDC/TMD Consortium website for access by workshop members only.

Workshop

- All participants will be calibrated in the review process.
- Groups will discuss and reach a consensus on the evidence of diagnostic accuracy.
- Each group will craft a manuscript that summarizes the group’s review and recommendations.

Procedure

University librarians conducted literature searches for:

- Clinical diagnosis (Axis I) at Malmö University.
- Psychosocial domain (Axis II) at the University at Buffalo.

The reference lists were sent to the pre-meeting coordinators. One pre-meeting coordinator was assigned to each of the four working groups (muscle disorders, temporomandibular joint disorders, orofacial pain disorders, and psychological domain relevant to pain disorders). Each pre-meeting coordinator and one other person from the working group screened, based on content validity as determined by the title and abstract, the reference lists and select publications that are relevant to the group. From this list, 50 of the most relevant articles were selected and posted as PDF files on the International RDC/TMD Consortium Network website ([www.rdc-tmdinternational.org](http://www.rdc-tmdinternational.org)) for access by working group members.

Each working group has been assigned a chairperson who, together with the pre-workshop coordinator, will lead a consensus discussion based on the pre-workshop review and grading of the publications. The goal of the discussion is to reach a consensus regarding evidence-based diagnostic accuracy and utility of the publications relating to the working group’s assigned disorder. The consensus will focus on how to best diagnose the disorder in both clinical and research settings.

Search strategies

In a first step, the Cochrane Library and PubMed databases were searched for all relevant literature from 1948 to the present. For each diagnosis, articles on diagnostic accuracy, including diagnostic reliability and validity, were searched.
For the Axis I and orofacial pain disorders publications, the search strategy used these MeSH terms and search words in free text:

*Sensitivity and specificity, reproducibility of results, diagnostic accuracy, craniomandibular disorders/diagnosis, Temporomandibular disorders, facial pain/classification, facial pain diagnosis, atypical odontalgia, burning mouth syndrome, headache, and rheumatoid arthritis of TMJ.*

For the Axis II publications, the search strategy used the following for the first search (restricted to English, and published since 1985):

*The standard terms for TMD or facial pain or headache; AND publications containing any of the keywords or free text words of: depression, anxiety, somatoform disorders, fear, anger, catastrophizing, pain beliefs, live events, psychological stress, ANS arousal, substance abuse, health services utilization.*

A second Axis II search was conducted, using “chronic pain” as the disorder term combined using Boolean ‘AND’ with the psychology search terms (as above), again restricted to English and published since 1985.

The resulting reference lists and abstracts will be assessed by at least two group members as described above. All publications that are considered relevant by at least one of the two examiners will be ordered in full text.

The reference lists will be supplemented with (i) additional relevant publications identified from the bibliographies listed in the selected publications from the original lists, (ii) workshop documentation, (iii) relevant publications known to working group member experts, and (iv) relevant publications that are accepted by a journal but not yet published. If any relevant literature is missing from the lists, the searches will be redone with adjusted strategies.

**Selection of studies**

Inclusion criteria for publications include (i) investigation of diagnostic accuracy of laboratory findings, imaging exams, clinical exams, or questionnaires for diagnosing TMD/orofacial pain and (ii) assessment of the diagnostic accuracy of core outcome measures of the psychosocial domain relevant to musculoskeletal disorders and pain in general as well as to TMD or orofacial pain in particular. Only studies whose aim agrees with at least one of this project’s goals will be included. In other words, the studies must try to answer questions on the diagnostic accuracy of identifying patients with TMD/orofacial pain.

The following screening items were the basis for inclusion of articles (Axis I).

- Organism: Research on humans?
- Publication type: Systematic reviews or primary research?
- Outcome: TMJ structure function/ Orofacial Pain? (includes: TMD, Pulpitis, burning mouth, atypical facial pain, atypical odontalgia, trigeminal neuralgia, headache vs. TMD, and other)
- Procedure: Diagnostic tests? (Any, questionnaire, imagining, clinical examination, others)
- Results: expressed as diagnostic accuracy (e.g. observer performance, sensitivity, specificity, or ROC curve)

For headache only diagnostic studies assessing headache attributed to facial pain/TMD were included.

Exclusion criteria are experimental studies, letters, editorials, short communications, abstracts, and articles in languages other than English.
Review of articles

All articles that fulfill the inclusion criteria will be graded by two independent examiners using a protocol based on QUADAS, an evidence-based tool for the quality assessment of studies of diagnostic accuracy. The QUADAS criteria assess the methodological quality of a diagnostic study in generic terms (relevant to all diagnostic studies), and they can therefore be utilized in a project where different methods are used to derive a diagnosis. The QUADAS criteria consist of 14 items phrased as questions, each of which should be scored as yes, no, or unclear. The tool does not incorporate a quality score.

The protocol will be used to compile data on design and results and to grade the evidence. Each study’s evidence grade must be assessed so that a conclusion based on the total scientific evidence for the method can be made. In this way, studies with contradictory results can be compared with each other.

References


Appendix 2

What is an ontology and why is it important

Barry Smith

Background

Increasingly, the NIH is mandating that data emanating from NIH-funded projects should be made available in forms that make these data more broadly usable. To achieve this end a variety of standards are being developed for the representation of the biomedical data resulting from research. One kind of standard takes the form of what are called “common data elements” (CDEs), which are lists of terms devised for use by researchers working in a given domain, whose meanings are specified by means of natural language definitions. A second kind of standard is an ontology, which provides controlled representations of the phenomena in a given domain by means of terms (nouns and noun-phrases) together with logically structured definitions and relations. When the terms in question are used to annotate (tag, describe) data created by multiple heterogeneous research groups, this brings important advantages in retrievability and in integration of data. As is shown by the case of the Gene Ontology, this allows new kinds of information-based scientific and clinical research.

Ontologies vs. Common Data Elements (CDEs)

Ontologies bring a number of advantages as contrasted with an approach based on CDEs. They are more easily extendible and modifiable in light of scientific advance. They are also more easily factorable, which means that new ontologies can take advantage in new work of ontologies created earlier for other purposes. Ontology technology has been more thoroughly tested – above all in molecular biology domains, and in model organism research – and is able to draw on a variety of sophisticated software tools.

In contrast to existing CDE-based approaches, new ontologies are being deliberately built in such a way as to work well with existing ontologies (for example, within the OBO Foundry, an initiative to create a complete set of ontologies covering the basic biological sciences and extending from there to clinical medicine).1 Thus if an ontology is once developed for a domain such as orofacial pain, then the same ontology can be reconfigured to serve other pain domains, and lessons learned from its use in one domain can be easily communicated to those using the reconfigured ontologies in the other domains. Ontologies are structured in such a way as to allow enhanced retrieval of and automated reasoning over information not only by insiders (who tend to be the ones familiar with CDEs) but also by outsiders (including those working in other disciplines).

Ontologies developed within the framework of the OBO Foundry are distinguished from CDEs further in that they are determined not by how the information about a given domain is organized, but rather by the biology of the domain. The strategy rests on the idea that, because the biology is common to all the various data artifacts produced by different groups, the biology can serve to ground a common representation – the ontology – which can integrate these various different data artifacts together.

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Difference between ontology and taxonomy

Ontologies are ways of annotating (tagging) data. The resultant annotations make the data searchable not only through the use of ontology terms, but also through use of logically related terms; thus the ontology can be used to retrieve data associated with terms referring to parts of specific anatomical entities, to anatomical entities immediately connected to specific anatomical entities, or to biological processes in which specific anatomical entities participate. Considered in graph-theoretic terms, the terms in the ontology are nodes, connected together by means of edges representing relations such as `subtype`, `part_of`, `connected_to`, and so on. A taxonomy, conceived in this light, is one very simple kind of ontology, in that only the one relation of `subtype` is recognized. A taxonomy is, in other words, just the first step towards an ontology – which adds logical relations, definitions, and a structure that is designed to allow easy integration with other ontologies and thus with other taxonomies. Moreover, the additional relations provided by an ontology, as contrasted with a simple taxonomy, provide the necessary linkages across data sets, the basis for additional analytic approaches, and enriched theoretical modeling. See for instance the relations `has_part`, etc. indicated in the right-hand column here (from the Protein Ontology):

### How will an ontology yield a description of disease that works clinically?

One illustration of how ontology development can help in clinical research and in diagnosis and treatment is provided by the Infectious Disease Ontology (IDO), a joint initiative of the University at Buffalo and Duke University Medical Center, together with infectious disease researchers throughout the world. The Infectious Disease Ontology is designed to allow geneticists, scientists, clinicians and public health agencies to more easily share and compare many different types of data concerning pathogens, patients and disease processes. Diseases being studied by the IDO Consortium include malaria and other vector-borne diseases, tuberculosis, infective endocarditis, MRSA, influenza and dengue fever.
One goal of the IDO initiative is to apply the ontology to the task of predicting disease genes and testing these predictions against the large collection of patient data that is being collected by the Duke Staphylococcus aureus Bacteremia Group. While much relevant research has been done on individual genes connected with Staph. aureus infection, and much clinical work has been done on whole organisms, both human and non-human, these data have been developed thus far in separate information silos. By drawing together multiple research consortia and training them in the use of a common IDO, this will enable exploitation in a single resource of information at the level of individual molecules, cells, organs, organisms and populations, and ultimately provide way to speed diagnosis and treatment. An example of such use would arise where a new infectious outbreak is detected but the responsible pathogen has not been identified. By bringing together all infectious disease information within a single framework, IDO would provide a resource for pathogen identification of much greater completeness and effectiveness than anything currently existing.

**How will we approach TMD and orofacial pain using ontological principles?**

The TMD taxonomy is nearing its second edition after some 20 years of further research; yet, the rising interest in comorbid disorders, the desire to increase our understanding of TMD based on factors ranging from genetic to behavioral, and beginning the development of an organized system of measures and criteria for orofacial pain disorders are all areas in which ontological principles can facilitate research. Our goal at this workshop is to provide background into ontology and into some of the ways it is being successfully applied to support clinical research and to provide content-relevant consultation in order to demonstrate the utility of applying ontological principles in the specific domain of orofacial pain disorders.
Appendix 3

Example of a Delphi Technique Format

For guidance, hereafter is an outline that could serve as a template to help workgroup members work through the steps leading to consensual recommendations. Although more laborious and time consuming, a Delphi technique permits more information to enter into the level of agreement achieved among the workgroup members.

Regarding goals 1 and 2 for the muscle and temporomandibular joint groups, the questions to be answered are:

“What are the best criteria to “rule in” a diagnosis of .............. ?”
“What assessment methods and measures should one rely on?”

1- The workgroup chair asks each member to submit his/her list of criteria to rule in “a specified diagnosis” and to indicate the data collection methods and measures being recommended.

2- The workgroup chair makes a list of all the criteria with the corresponding data collection methods and measures suggested by the workgroup members.

3- The workgroup chair presents the list to the workgroup members who have to decide which criteria and their corresponding data collection methods and measures for which there is a general consensus. To that end, members rate separately each criterion on a 7 points Likert scale by saying if they strongly disagree (1) or strongly agree (7) about its inclusion.

All criteria with an average score of at least 4 out of 7 are retained while the remaining criteria go a second round of evaluation after discarding those with an average score below 2. (The threshold scores of 4 and of 2 are determined by the workgroup members.)

4- Before making a new list with the remaining criteria (those not discarded but below the threshold score), the workgroup chair asks the workgroup members if they have any new criterion with the corresponding data collection methods and measures to add to the list which is then finalized for a second round of evaluation.

5- The workgroup chair presents this second list and repeats STEP 3.

Criteria with an average score below (4 / 7) are discarded while the remaining are added to the criteria that were selected on the first round.

6- The definitive “consensual list” of diagnostic criteria with their corresponding data collection methods and measures is created with all the criteria that had an average score above the pre-determined threshold during evaluation round 1 and 2. The selected diagnostic criteria have to be mutually exclusive.

Lastly, workgroup members are asked how confident they are about ruling in “a specified diagnosis” using the consensual list of criteria. The level of confidence is assessed with a 5 levels graded scale (None - Poor – Fair – Good – Excellent).

An overall high level of confidence regarding the criteria that are recommended may suggest a “Definite” diagnosis as opposed to a “Probable” diagnosis.
Appendix 4

Roadmap Proposal for Establishing RDC-OFP
Dominik A. Ettlin, pre-workshop coordinator orofacial pain disorders

Original workshop goals for all groups

The committee organizing the workshop “Convergence on an Orofacial Pain Taxonomy” charged pre-workshop coordinators of the four groups (muscle disorders, temporomandibular joint disorders, orofacial pain disorders, and psychological domain relevant to pain disorders) with evaluating scientific evidence for the diagnostic accuracy of various methods for determining the different diagnoses.

In muscle and temporomandibular disorders, pain presents as a *symptom* related to (at least presumed) specific pathology, and adequate management of the underlying muscle or joint disorder is expected to eliminate the secondary pain. Conversely, current criteria proposed for orofacial pain disorders such as primary trigeminal neuralgia, persistent idiopathic orofacial pain, atypical odontalgia, trigeminal post-traumatic or post-interventional neuropathies, and burning mouth syndrome do not identify specific pathophysiological mechanisms. In these disorders, pain is less considered a *symptom*, but rather a *primary disease* of unknown origin, comparable to primary headaches. Since non-specific primary pain by definition is a subjective experience, it is inaccessible to any objective measures, and thus no diagnostic gold standard (a prerequisite for assessing diagnostic accuracy) can ever exist (Mileman and van den Hout, 2009). Hence, it is feasible to systematically review the scientific literature for the diagnostic accuracy of various methods for determining muscle and temporomandibular joint disorders, whereas a systematic review on methods accurately diagnosing non-specific orofacial pain disorders is unfeasible.

Proposal for modified workshop goals for the “orofacial pain disorders” group

Although various societies such as the American academy of orofacial pain (AAOP), the International headache society (IHS) as well as the International association for the study of pain (IASP) each have put forward their own diagnostic criteria for the above mentioned non-specific orofacial pain disorders, it is widely acknowledged that there is a lack of consistent classification, thus severely limiting attempts to clinically assess and scientifically investigate them (Sharav and Benoliel, 2008). By taking into account existing taxonomies from IHS, IASP, RDC-TMD, AAOP and ICD-10, I compiled the classification overview for orofacial pain disorders as shown in Figure 1.

Pain, be it symptom or primary disease, is considered a multidimensional human experience (Merskey and Bogduk, 1994). Consequently follows a need to define pain disorders multidimensionally. This may be accomplished by establishing a matrix of pain dimensions as proposed in Figure 2.

Based on this proposed matrix model, multidimensional diagnostic pain data may be collected for clinical and research purposes related to orofacial pain disorders of primary (and possibly secondary) origin.
Step 1: As a first step, the tasks for the “orofacial pain disorders” panel in Miami include:

A. Consent on which pain dimensions (e.g. origin, time pattern, quality, etc.) are pertinent for pain diagnosis or taxonomy.

B. Then identify which sub-dimensions (e.g. sensory-discriminative / affective-motivational pain qualities) are meaningful for characterizing each pain dimension.

C. Finally, in collaboration with the “psychological domain” panel, prepare a universally acceptable core questionnaire composed of a minimum set of existing questionnaires, supplemented by additional items for standardized worldwide OFP data collection. (Note: this core questionnaire does not preclude researchers from collecting additional data of personal interest.)

Step 2: During a second step (Meeting in Montreal), preliminary data collected by the multidimensional diagnostic matrix model may be presented for cluster analysis and for refinement of the initial core questionnaire. Diagnostic grouping may be attempted where feasible and converging orofacial pain taxonomy may thus become established.

I acknowledge that my proposal is an unconventional and ambitious roadmap, but I am confident that the combined resources of the participating scientists and clinical experts will bring us a critical step closer to our common goal, namely to a convergence on a universally accepted orofacial pain taxonomy! I am also confident that a high impact publication can result from the panel’s work and I hope you are equally convinced…☺️. I look forward to your critical feedback!

References


Figure 1

1° HA / 1° NEURALGIA
- Unassociated with specific pathology
- Diagnostic features defined by IHS panel

1° OFP
- Unassociated with 1° HA nor specific pathology
- Diag. features to be defined by RDC/OFP panel

1° PAIN DISORDER
- Somatoform pain disorder
- Pain d/o with somatic and psychological factors

1° HA with OF pain location

1° Pain disorder with OF pain location

Neuropathic OFP
- Activity generated within the nociceptive system
  without adequate stimulation of its peripheral sensory endings.
- Diagn. features / Grading syst. defined by IASP
  (Treede, RD. Neurology 2008;70:1630-1635)

2° HA / 2° NEURALGIA
- Associated with specific pathology
- Diagnostic features based on associated pathol.
  (ICHD-II)

2° OFP
- Associated with specific pathology
- Diagnostic features based on associated pathol.
  (AAOP / RDC-TMD / ICHD-II / IASP)

PSYCHOLOGICAL COMORBIDITIES
Matrix Model for Multidimensional Pain Diagnosis

<table>
<thead>
<tr>
<th>Onset/Origin</th>
<th>Time Pattern</th>
<th>Quality</th>
<th>Distib.</th>
<th>Location</th>
<th>Duration</th>
<th>Present for...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td>episodic</td>
<td>sensory</td>
<td>localized</td>
<td>dental</td>
<td></td>
<td>months</td>
</tr>
<tr>
<td>Post-interv.</td>
<td>persistent</td>
<td>affective</td>
<td>diffuse</td>
<td>oral mucosal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-traumatic</td>
<td>persistent w/ episodic</td>
<td>diffuse</td>
<td>facial</td>
<td>orofacial</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Paraphenomena
- Sensory paraphenomena
- Motor paraphenomena

Modifiers
- Somatic factors
- Emotional factors
- Specific medication

Confounders
- Other chronic pains
- Other chronic medical disorders
- Pending medico-legal issues

Impact
- GCPS

Abnormal Findings
- <3 muscles tender to palpation not reproducing OFP complaint
- Abnormal (quantitative) sensory tests / other abnormal findings

Psychological Comorbidities
- Anxiety disorder
- Depression
- Dysfunctional coping
- Dysfunctional illness perception
- Reduced QOL

Superscripts indicate need for specification of items (to be defined/selected by expert panel):
- tfx-: prefix indicating pain dynamics, i.e., transformation over time, e.g., tfx-diffuse
- 1: non-specific (unknown etiology/pathophysiology)
- 2: exchange of restoration, periodontal scaling, crown placement, root canal treatment, etc.
- (note: does not preclude classification under "neuropathic pain")
- 3: type of trauma, circumstances, loss of conscious, hospitalization, etc.
- (note: does not preclude classification under "neuropathic pain")
- 4: duration of pain and of pain-free intervals; daytime preference
- 5: no pain-free intervals except for sleep
- 6: persistent with episodic exacerbations, specify daytime preference of exacerbations
- 7: results from multidimensional pain questionnaire (to be selected by expert panel)
- 8: limited to receptive field of one single branch of the trigeminal nerve
- 9: beyond receptive field of one single branch of the trigeminal nerve
- 10: specify radiating pain pattern
- 11: positive and negative signs & sy: e.g., paresthesia, sensation of numbness, sensation of swelling, allodynia, tinnitus, ear fullness, facial flushing, sweating, tearing, nasal congestion, taste disturbance, xerostomia, nausea/vomiting, visual disturbances, etc.
- 12: muscle twitching, muscle spasms
- 13: cold, hot, touch, pressure, jaw function, bodily activity, flu-like symptoms
- 14: stress, relaxation, distraction
- 15: known medication offering pain relief (quantify in %), known medication offering no pain relief
- 16: Headache (various types), neck-/shoulder pain, low back pain, widespread pain, polyarthritis, fibromyalgia
- 17: sleep disorder, metabolic disorders/deficiencies, substance abuse, etc. (require expert diagnosis)
- 18: pertinent items to be defined by expert panel
- 19: value of chronic graded pain scale (note: includes pain intensity)
- 20: if more than 3 muscles: co-morbid myogenous pain (see RDC-TMD criteria)
- 21: pertinent tests to be selected by expert panel
- 22: battery of screening questionnaires to be selected by expert panel

Prepared by Dominik Ettlin
Pre-workshop coordinator
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