Division of Workers' Compensation Medical Treatment Guidelines-Methodology

This document provides a description of how the Division of Workers' Compensation guidelines revision processes fulfill guideline criteria as directed by multiple national and international standards on guidelines development, recommendations, and quality of medical evidence. The organizations cited are:

1. Appraisal of Guidelines for Research and Evaluation II (AGREE II)
2. The Cochrane Collaboration
3. Grades of Recommendation Assessment, Development, and Education (GRADE)
4. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)
5. Consolidated Standards of Reporting Trials (CONSORT)

Source criteria for evidence	DOWC criteria for evidence	Additional Information
"AGREE II Guideline Criteria"		
AGREE #1: The overall objective(s) of the guideline is (are) specifically described.	Required by statute. Intended to improve the medical care for injured workers.	
AGREE #2: The clinical question(s) covered by the guideline is (are) specifically described.	We are required to address diagnoses and treatment for the most frequent and costly cases. Those we have guidelines for: Low Back Pain (LBP) Thoracic Outlet Syndrome (TOS) Shoulder Injury (SHO) Cumulative Trauma Conditions (CTC) Lower Extremity (LXT) Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy (CRPS/RSD) Cervical Spine Injury (CSI) Chronic Pain Disorder (CPD) Traumatic Brain Injury (TBI)	
AGREE #3: The patients to whom the guideline is meant to apply are specifically described.	Injured workers (generally age group of 16-80).	
AGREE #4: The guideline development group includes	Our Task Force for internal development of guidelines	

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individuals from all the relevant professional groups.	from evidence statements includes all of the specialists listed depending on body part. This includes surgeons, case managers, OT, PT, Chiropractic, DO, Physiatrist, Occupational medicine doctors, neurologist, psychiatrist, psychologists, and pharmacists.	
AGREE #5: The patients' views and preferences have been sought.	A claimant's attorney represents patients on the task force.	
AGREE #6: The target users of the guidelines are clearly defined.	Insurers, health care providers, independent medical examiners, case managers. Patients may use however not the primary audience.	
AGREE #7: Systematic methods to search for evidence	Documented with search terms and dates of search, with MEDLINE, British Clinical Evidence related Specialty Society guidelines and Cochrane Library as dominant databases. Current review of relevant journals/hand searches.	Some use is made of Web of Science to find where selected studies have been referenced. Other articles are obtained through references in reviewed articles and related searches.
AGREE #8: The criteria for selecting evidence clearly described	Evidence statements done with selection for randomized trials in English, weighted toward studies published since most recent guideline	Applies to explicit evidence statements in the guideline, with other study designs acceptable as information but not as evidence Criteria for evidence are drawn principally from the Cochrane Risk of Bias tool for individual randomized trials and from the PRISMA statement for systematic reviews Nonrandomized trials may sometimes be upgraded to evidence statements when all

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		GRADE criteria are met (see below)
AGREE #9: The strength and limitations of the body of evidence are clearly identified	DOWC Assessment Criteria on Systematic Reviews and Meta-analyses list assessment criteria for strengths and limitations of selected bodies of literature. Also, areas that do not have evidence and thus are consensus-based are delineated in the guidelines.	
AGREE #10: The methods used for formatting the recommendations are clearly described.	1) Evidence statements formatted; 2) General clinical reviews collected & used to make suggested recommendations for consensus consideration using; and 3) Task force reaching consensus by vote unanimous decision in most cases.	
AGREE #11: The health benefits, side effects and risks have been considered in formulating the recommendations.	Fully described for groups and considered by Task force – See contraindication & complication sections for all users.	
AGREE #12: There is an explicit link between recommendations and supporting evidence	Not done in the official rule due to State regulations, but presented in the referenced version of the guideline on the DOWC website, wherein each evidence statement is accompanied by author and year of the bibliography/critiqued article. DOWC evidence statements generally adhere narrowly to the patient type and specific intervention described in the source for the study.	In addition to evidence statements, many informational statements are accompanied by author and year references in the online referenced guideline For example, “there is some evidence that the addition of steroids to a transformational bupivacaine injection may reduce the frequency of surgery in the first year after treatment in patients with neurologic compression and corresponding imaging findings, who are strong candidates for surgery and have completed 6 weeks of therapy without adequate benefit (Riew, 2000)”

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AGREE #13: The guideline has been externally reviewed by experts prior to publication.	After the internal panel/task force draft is complete it goes to an extensive external expert panel for review & response.	
AGREE #14: A procedure for updating the guideline is provided.	It is updated through complete repeat of process every 5-6 years. Researchers continually track literature & if major changes need to be made earlier that can be done annually.	
AGREE #15: The recommendations are specific and unambiguous.	We strive for this result.	
AGREE #16: The different options for management of the condition are clearly presented.	Several of the guidelines have specific treatment plans for specific diagnoses. Others have overview of care sections.	
AGREE #17: Key recommendations are easily identifiable.	See General Principals and indications & frequency sections.	
AGREE #18: The guideline is supported with tools for application.	On line version available.	
AGREE #19: The potential organizational barriers in applying the recommendations have been discussed.	These are discussed by the task force as well as addressed at public hearings prior to full adoption.	
AGREE #20: The potential cost implications of applying the recommendations have been considered.	Cost considered key for task force consensus decision making although only when there are competing equally effective treatments. The public comments on cost at rule hearing. However, this does not change recommendations unless there are other less costly equally effective treatments.	
AGREE #21: The guideline presents key review criteria for monitoring and/or audit purposes.	Indications for procedures, timing & frequency can all be audited.	
AGREE #22: The guideline is	This is a government	

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editorially independent from the funding body.	guideline.	
AGREE #23: Conflicts of interest of guidelines development members have been recorded.	Yes.	
Cochrane Risk of Bias Tool for Randomized Clinical Trials		
Cochrane Risk of Bias Tool uses multiple criteria for Randomized Clinical Trials: randomization sequence generation; concealment of allocation; blinding of providers, assessors of outcome, and participants; incomplete outcome data (attrition), selective outcome reporting; and other sources of bias (baseline imbalance, deviations from study protocol, imbalance in co-interventions between groups), similar timing of assessment, and inappropriate analysis of results (e.g., omission of intention-to-treat analysis in studies with incomplete adherence to study protocol)	The DOWC has a publically available "Randomized clinical trials tabular form" document with 27 criteria with designations of "green, yellow, and red" for satisfactory, unclear, and unsatisfactory adherence of studies to the criteria; each of the Cochrane Risk of Bias criteria are included in the document	Not all 27 criteria are applicable to any specific study or clinical question. For example, there are interventions (such as active therapy) which the Division supports but for which patient blinding is impossible and it is not reasonable to require it. DOWC adds some considerations in addition to the Risk of Bias tool: a preference for functional outcomes in addition to pain intensity alone, and (when feasible) a statement about biological mechanisms involved in the treatment
The GRADE initiative provides three criteria whereby a non-randomized clinical study may be upgraded, and are especially appropriate when randomization is not practical; these criteria are (1) a large treatment outcome difference between groups, (2) a clear dose-response effect, and (3) direction of confounding does not favor the effect of the treatment of interest (i.e., the sicker patients received the	The GRADE criteria are included in the "Randomized clinical trials tabular form" with three items which are required for a non-randomized trial to be upgraded to the level of evidence	The non-randomized studies MUST have a well-described control group which received a well-described different treatment; case series (wherein all patients received the treatment and success rates were high) do NOT qualify for the GRADE criteria, since no outcome differences can be estimated if there were not at least two treatment groups in the study. Historical controls (how well patients did in past years with different

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treatment and nevertheless fared better on the outcome		treatments) are not acceptable under GRADE or under the DOWC
The CONSORT 2010 Statement is a checklist of items to include in the reporting of a randomized trial. Many of its criteria are included in the Cochrane Risk of Bias Tool but some are separate: details about eligibility criteria for patients, clearly designated primary and secondary outcomes, enough details about the treatments to enable clinicians to reproduce them, the flow of participants through different phases of the study, statistical methods used, results presented with estimates of precision (such as a 95% confidence interval), and descriptions of harms and adverse effects for each treatment group.	These CONSORT items not included in the Cochrane Risk of Bias Tool are listed in the DOWC "Randomized clinical trials tabular form" document, together with the green, yellow, and red designations for how well they were reported	The CONSORT items not related to Risk of Bias are crucial for interpretation of the study, and a study which adequately controls bias may fail to meet evidence criteria if too many details about the study population and the treatments administered are lacking
Meta-analysis & Synthesis		
The PRISMA statement is a recognized set of criteria for transparent reporting of systematic reviews and meta-analyses. Important criteria are study objectives, information sources (databases used), search information, study selection criteria, data collection and synthesis, and several criteria related to risk of bias: risk of bias in individual studies in methods, risk of bias across studies in methods, risk of bias in individual studies in results, and risk of bias across studies	The DOWC has a publically available "Systematic reviews and meta-analysis tabular form" document with green, yellow, and red designations for nine items (some incorporating multiple criteria), drawn from the PRISMA model. Study objectives, search criteria, descriptions of study selection, information sources with dates of most recent studies, and methods of synthesis run parallel to the PRISMA criteria	Some PRISMA items (protocol and registration, sources of funding for the review) are considered to be guidelines for journal editors when reviewing the reporting of systematic reviews. Risk of bias is considered essential in the PRISMA statement, and is required by the DOWC document as well; reviews which do not discuss issues of bias are considered to be narrative reviews and their conclusions do not qualify as evidence.

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in results		Risk of bias across studies (publication bias) is a PRISMA criterion, and, while desirable when possible, is not a DOWC criterion due to the fact that there are rarely the number of trials needed to accurately assess publication bias "Implications for practice," listed in the PRISMA statement, is not explicitly listed in the DOWC document but is considered as the "bottom line" for applying the results of the systematic review to the guideline.
GRADE is an approach to the synthesis of evidence of healthcare interventions with the goal of rating its overall quality. There are five basic considerations for GRADE: study limitations, consistency, directness, precision, and publication bias	See below	
GRADE study limitations: GRADE can downgrade a randomized clinical trial for having serious limitations; these are essentially the same as those for risk of bias above: lack of allocation concealment, lack of blinding, incomplete accounting of patients, lack of an intention-to-treat analysis of results, reporting bias, un-validated outcome measures, stopping early for benefit, and carryover effects in crossover	These criteria are included in the Risk of Bias assessment above	

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trials		
GRADE consistency: GRADE considers the degree to which different studies of the same treatment for the same condition agree with one another. Evidence may be downgraded if treatment effects are widely different between studies which enroll similar patients and treat them in similar ways	The DOWC "Systematic reviews and meta-analysis tabular form" document includes criteria similar to those in GRADE: estimates of homogeneity between studies, and exploration of sources of heterogeneity when the treatment effects differ substantially between trials	Many times, heterogeneity does not mean that studies conflict with one another; sometimes they enroll different kinds of patients, apply different doses of a treatment, or select different follow-up times for reporting results
GRADE directness GRADE may decrease the quality of evidence when there are substantial differences between the population, intervention, and outcomes in the available literature and those of the population for which evidence is being evaluated GRADE may also decrease the quality of evidence if the outcome measured is only indirectly associated with the outcomes which are important to patients, as when raising HDL cholesterol levels does not reduce the risk of a heart attack	DOWC generally defers these judgments to the panels of clinicians with subject matter expertise, especially when these experts treat a variety of patients outside Workers' Compensation. These judgments are generically known as "external validity," or applicability of one study result to a population differing from that in which the study was conducted DOWC does not generally regard measures from clinical examinations (for example, joint range of motion) as of direct interest unless there are differences in function such as ability to perform daily activities	Many studies of chronic pain are done in patients with cancer, who differ greatly from injured workers who may return to work. Many musculoskeletal treatments are reported in the Sports Medicine literature, and must be applied with caution, if at all, to a population of injured workers. There is a considerable difference between return to play and return to work.
GRADE precision GRADE suggests that treatment effects be reported with 95% confidence intervals in order to address imprecision. If the lower end of the confidence interval were true and led to one kind of clinical decision, while a	The DOWC "Randomized clinical trials tabular form" document includes reporting of a 95% confidence interval as an important criterion of quality of evidence	Many studies, through no fault of any author, are able to enroll only a small number of patients in their trial. Even a randomized trial which is excellent in all other criteria may result in an imprecise estimate of the treatment effect

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different decision would be made if truth were at the other end of the same confidence interval, the quality of evidence is downgraded considerably		
GRADE publication bias GRADE recognizes that the medical literature in general suffers from biases which are not seen when examining individual studies. Not all studies of comparable quality are equally likely to be published in major journals; studies which report positive effects are often more likely to be published than those reporting no effects of a treatment; in addition, they are likely to be published earlier, and several years may elapse before "negative" studies are published. When industry-sponsored studies are published, the problem of publication bias is increased. There is also a "file drawer" problem, when authors of inconclusive or negative studies do not submit them for publication but file them away where they cannot be read.	The DOWC "Randomized clinical trials tabular form" document has an item dealing with reporting of study sponsorship. GRADE does mention some approaches to estimating publication bias, but GRADE also recognizes that these methods suffer from limitations, and GRADE is uncertain when to rate down for suspected publication bias. DOWC similarly recognizes that publication bias is a real phenomenon, but rarely has sufficient evidence to judge its presence, and follows GRADE in being cautious about applying it to levels of evidence	

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