Appendix B

Methodology Description AGREE II

www.mcg.com/odg

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Background

AGREE stands for "Appraisal of Guidelines for Research and Evaluation." It originates from an international collaboration of researchers and policy makers who work together to improve the quality and effectiveness of clinical practice guidelines by establishing a shared framework for their development, reporting and assessment.

Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. In addition, guidelines can play an important role in health policy formation and have evolved to cover topics across the health care continuum (e.g., health promotion, screening, diagnosis). The potential benefits of guidelines are only as good as the quality of the guidelines themselves.

Appropriate methodologies and rigorous strategies in the guideline development process are important for the successful implementation of the resulting recommendations. The quality of guidelines can be extremely variable and some often fall short of basic standards. The AGREE Instrument was developed to address the issue of variability in guideline quality. To that end, the AGREE Instrument is a tool that assesses the methodological rigor and transparency in which a guideline is developed. The original AGREE instrument has been refined, which has resulted in the new AGREE II. The purpose of the AGREE II, is to provide a framework to: 1) Assess the quality of guidelines; 2) Provide a methodological strategy for the development of guidelines; and 3) Inform what information and how information ought to be reported in guidelines. The AGREE II replaces the original instrument as the preferred tool and can be used as part of an overall quality mandate aimed to improve health care. www.agreetrust.org.

Independent Analysis

In total to date, four independent, objective evaluations of ODG have been conducted using the AGREE Instrument. All have scored ODG good to outstanding.

Evaluating Medical Treatment Guideline Sets for California

In mid-2004, the RAND Corporation used the AGREE Instrument to compete the study, "Evaluating Medical Treatment Guideline Sets for Injured Workers in California." This study was prepared for the Commission on Health and Safety and Workers' Compensation and the Division of Workers' Compensation, California Department of Industrial Relations. It was first published in November, 2004. After identifying 73 relevant guidelines, Rand narrowed the list to five guidelines meeting all the screening criteria, and they performed a detailed Technical Quality Evaluation using AGREE. The results

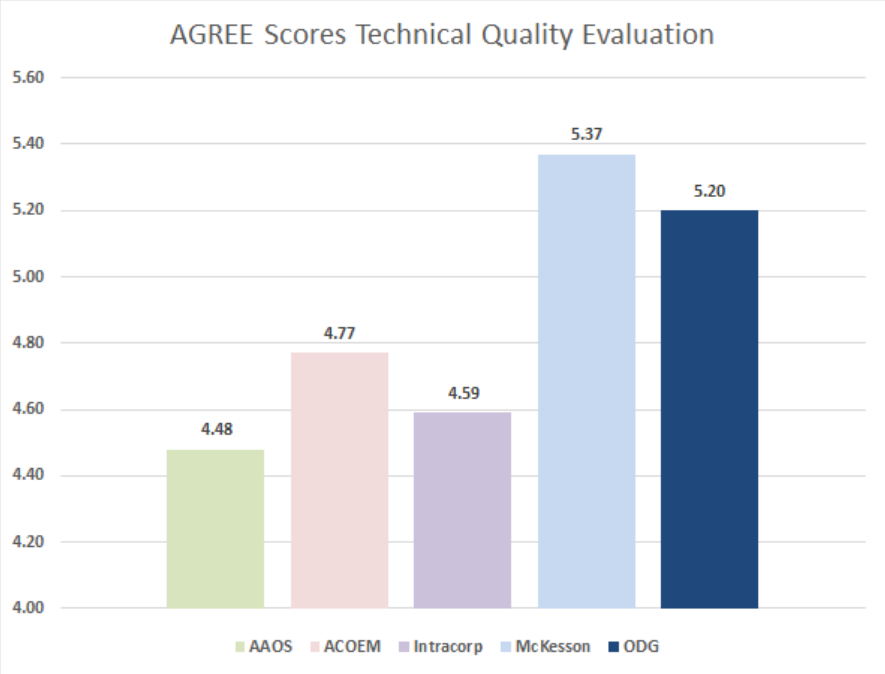
of this AGREE evaluation are reported on page 32 of the study as Table 5.2 and page 12 of the Executive Summary as Table S.2[1] as shown here.

Evaluating Medical Treatment Guideline Sets for Injured Workers in California

Table S.2
Technical Quality Evaluation—AGREE Instrument Results (Standardized Domain Scores)

Domain	AAOS	ACOEM	Intracorp	McKesson	ODG
Scope and purpose	1.00	0.89	0.89	1.00	1.00
Stakeholder involvement	0.54	0.79	0.79	0.88	0.79
Rigor of development	0.81	0.88	0.83	0.88	0.81
Clarity and presentation	0.96	0.88	1.00	1.00	0.96
Applicability	0.17	0.33	0.33	0.61	0.72
Editorial independence	1.00	1.00	0.75	1.00	0.92

Summing the total score for each guideline, McKesson is first at 5.37, ODG is second at 5.20, ACOEM is third at 4.77, Intracorp is fourth at 4.59, and AAOS is fifth at 4.48.



[1] Nuckols TK et al. Evaluating Medical Treatment Guideline Sets for Injured Workers in California. Published 2005 by the RAND Corporation, 1776 Main Street, P.O. Box 2138, Santa Monica, CA 90407-2138. Table 5.2, page 32. http://www.rand.org/pubs/monographs/2005/RAND_MG400.sum.pdf

Note: The McKesson workers' comp guideline has been discontinued by McKesson, and the Intracorp Guidelines are no longer available commercially post-acquisition of Intracorp by GENEX Services, which uses ODG.

Systematic Review of Clinical Practice Guidelines, Low Back

Systematic Review of Clinical Practice Guidelines on the Management of Acute/Subacute Soft Tissue Injuries to the Low Back[2] is a comprehensive, high-quality review of existing guidelines published in 2008 by the Adelaide Health Technology Assessment (AHTA). AHTA, Discipline of Public Health, School of Population Health & Clinical Practice, University of Adelaide, on behalf of WorkCover SA, the South Australia workplace injury authority.

AHTA searched and reviewed guidelines worldwide, then narrowed the field using the AGREE Instrument. Of the 27 remaining guidelines, a threshold of 80% in the Rigor Scores was used to identify the higher quality guidelines and narrow even further. The nine remaining guidelines were then evaluated using evaluation protocol from the ADAPTE Collaboration (an international collaboration of researchers, guideline developers, and guideline implementers who aim to promote the development and use of clinical practice guidelines). The evaluation protocol included search and selection of evidence, consistency between recommendations and underlying evidence, plus acceptability and applicability. ODG scored 2nd place worldwide. Only the *Canadian Diagnostic Imaging Guideline* scored higher. However, as noted by the study, the Canadian guideline "*covers only on a narrow area of diagnostic imaging."* ODG is identified as "*the most comprehensive and up-to-date guideline and focuses on acute and chronic lumbar and thoracic problems targeted at all medical specialist groups, as well as the worker's compensation setting. It was developed (and is being updated annually) by a multidisciplinary professional group, with a literature search being conducted at least every six months. The guideline covers multiple conditions and the overall search strategy appears to be comprehensive*." (page 22)

The study concludes by recommending ODG and two other guidelines:

"This review has identified the most appropriate clinical practice guidelines for application in the South Australian Workers Compensation setting – these are the guidelines developed by the National Health and Medical Research Council and ODG. Either of these two guidelines would be suitable, although the ODG guideline is considerably more comprehensive and current, is not limited to only high level evidence and is also aimed at the worker's comp setting. In addition, the Canadian diagnostic imaging guideline would be suitable as a basis for those recommendations regarding imaging." (page 25)

Below are the AGREE and ADAPTE Scores for ODG from the study (page 63):

[2] Ju H, Liufu Z, Newton S, Merlin T (2008). Systematic review of clinical practice guidelines on the management of acute/subacute soft tissue injuries to the low back. tracSA, Adelaide, SA.

GUIDELINE DETAILS	
STAGE 1	
Reference No. 21	**Citation** (Work Loss Data Institute 2007)
Country USA	**Organisation** **Work Loss Data Institute**
Patient population Working age adults with low back pain (LBP)	**Search period** Since 1993, then updated annually
Health care setting Primary and secondary care settings, Workers' compensation setting	**Scope of guidelines[1]** All possible management for acute / chronic lumbar & thoracic problem
Target audience[2] Independent treating physicians, allied healthcare providers, insurance claims professionals, nurse case managers, state and federal workers' compensation authorities, employer representatives	**Grades of evidence included[3]** Yes (rating from 1a—11c) 1. Systematic review / meta-analysis 2. Controlled trial – randomised or controlled 3. Cohort study – prospective or retrospective 4. Case control series 5. Unstructured review 6. Nationally recognized treatment guidelines (from guidelines.gov) 7. State treatment guidelines 8. Other treatment guidelines 9. Textbook 10. Conference Proceedings / presentation slides 11. Case reports and descriptions a. High quality b. Medium quality c. Low quality
Sources of evidence[4] MEDLINE, Cochrane Library, NGC, MD Consult, eMedicine, CINAHL, conference proceedings in occupational health and disability evaluation	

QUALITY ASSESSMENT (AGREE)[5]					
Scope and purpose	**Stakeholder involvement**	**Rigour of development**	**Clarity and presentation**	**Applicability**	**Editorial independence**
83%	88%	83%	92%	83%	92%

STAGE 2 (If meet criteria)				
QUALITY EVALUATION (ADAPTE)[6]				
		Yes	**Unsure**	**No**
Search and selection of evidence	The search for evidence comprehensive?		√	
	Bias in the selection of articles avoided?		√	
Scientific validity	The evidence was valid?	√		
	Coherence between the evidence and recommendations?	√		
	The scientific quality of the recommendations does not present risks of bias?	√		
Acceptability / applicability	The recommendations are acceptable?[7]	√		
	The recommendations are applicable?[8]	√		

AGREE Domain	ODG Score
Scope and Purpose	83%
Stakeholder Involvement	88%
Rigor of Development	83%
Clarity of Presentation	92%
Applicability	83%
Editorial Independence	92%
Average Score Across AGREE Domains	**87%**
Recommended for Use (yes or no):	Yes

State of Montana Utilization & Treatment Guideline Project

In February 2010, the Montana Department of Labor and Industry posted findings from the Technical Review of Guidelines by the State's Medical Provider Group (MPG) under the Utilization and Treatment Guidelines Project. The Technical Review rated the four best available workers' comp guidelines (according to the committee, these were ODG, ACOEM, and the Washington and Colorado Guidelines) covering items 8-21 of the AGREE Instrument.

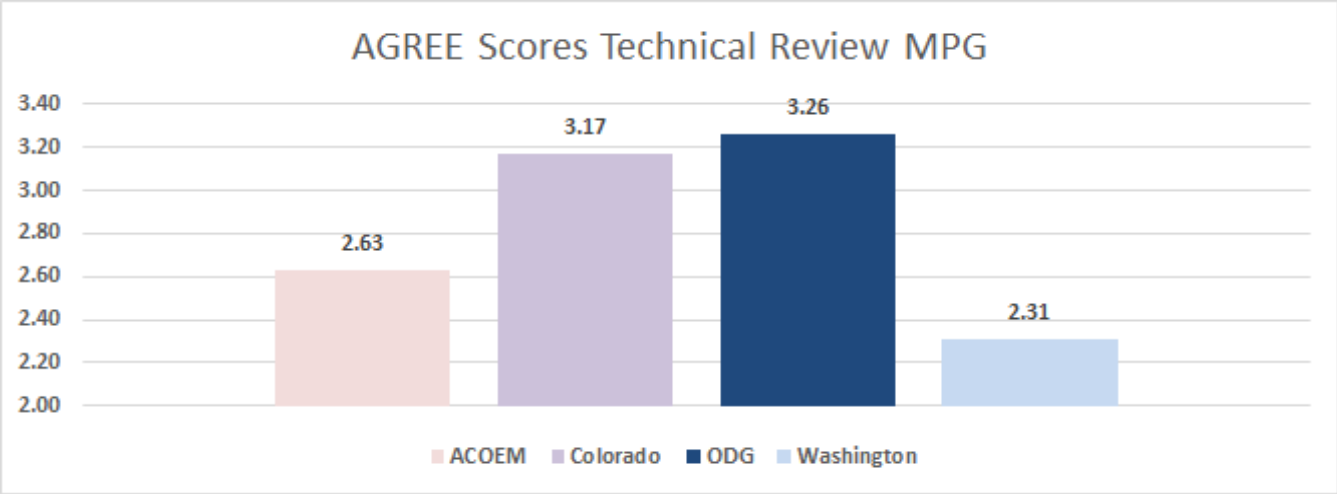
Specifically, the following measures were rated on a scale of 1 (low quality) to 4 (high quality):

Rigor of development (items 8-14)
8. Systematic methods were used to search for evidence.
9. The criteria for selecting the evidence are clearly described.
10. The methods used for formulating the recommendations are clearly described.
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.
12. There is an explicit link between the recommendations and the supporting evidence.
13. The guideline has been externally reviewed by experts prior to its publication.
14. A procedure for updating the guideline is provided.

Clarity and presentation (items 15-18)
15. The recommendations are specific and unambiguous.
16. The different options for management of conditions are clearly presented.
17. Key recommendations are easily identifiable.
18. The guideline is supported with tools for application.

Applicability (items 19-21)
19. The potential organizational barriers to applying the recommendations have been discussed.
20. The potential cost implications of applying the recommendations have been considered.
21. Key review criteria are included for monitoring and review purposes.

ODG ranked first with an average score of 3.26, followed by Colorado at 3.17, ACOEM at 2.63, and Washington at 2.31. Below are the average scores across all measures-



Below are the complete scores for ODG in each category, across all reviewers-

ODG

	1	2	3	4	5	6	7	8	9	10	11	12	13	
1. Systematic methods were used to search for evidence	3	4	4	4	4	4	4				3	2	4	3.6
2. The criteria for selecting the evidence are clearly described	2	4	4	3	4	4	4				4	3	3	3.5
3. The methods used for formulating the recommendations are clearly described	2	4	4	4	4	4	4				4	3	3	3.6
4. The health benefits, side effects and risks have been considered in formulating the recommendations	2	4	4	3	4	4	4				3	3	2	3.3
5. There is an explicit link between the recommendations and the supporting evidence	2	4	3	4	4	3	4				3	2	3	3.2
6. The guideline has been externally reviewed by experts prior to its publication	3	4	4	4	4	3	4				4	2	3	3.5
7. A procedure for updating the guideline is provided	3		4	4	4	4	4				3	3	4	3.7
8. The recommendations are specific and unambiguous	3		2	3	3	3	4				3	2	4	3.0
9. The different options for management of the condition are clearly presented	3		2	4	3	4	4				3	3	3	3.2
10. Key recommendations are easily identifiable	2		2	3	3	3	4				4	3	3	3.0
11. The guideline is supported with tools for application	2		3	4	4	4	4				3	2	3	3.2
12. The potential organizational barriers in applying the recommendations have been discussed	2		3	2	2	3	4				3	3	3	2.8
13. The potential cost implications of applying the recommendations have been considered	2		4	1	2	2	4				2	3	3	2.6
14. The guideline presents key review criteria for monitoring and/or audit purposes	2		4	2	3	3	4				2	3	2	2.8
	2.4	4	3.4	3.2	3.4	3.4	4				3.14	2.64	3.1	3.26

Utilization & Treatment Guideline Project
Medical Provider Group
Technical Review of Guidelines
FINAL: February 24, 2010

MPG Technical Ratings-Final
20100224

Note: Some reviewers are absent for various items. All scores are numeric, 1, 2, 3 or 4.

Technical Quality and Clinical Acceptability of a Utilization Review Guideline for Occupational Conditions: ODG® Treatment Guidelines by the Work Loss Data Institute

Conducted on behalf of one of the largest international workers' comp insurance companies in the world, a monopoly state fund, Rand Corporation evaluated ODG for Clinical Acceptability and Technical Quality. The results in all categories were positive, and Rand recommended use of ODG. ODG's noted strengths include "an expansive scope, clearly written recommendations, frequent updating, regular and extensive input from clinicians, and a well-designed tool for applying recommendations". The insurance company has proceeded with enterprise-wide implementation and automation of the ODG guidelines.

Clinical Acceptability

Expert panelists in diverse clinical specialties found the ODG guidelines reflected a relatively high degree of confidence in the clinical acceptability of the guideline, validating clinical validity in 41 of the 47 topics reviewed (with the others uncertain). At 87%, this score is extremely high by historical standards.

Technical Quality

ODG scored well in both the AGREE and AMSTAR Instruments and was recommended for use by Rand.

AMSTAR scores-

Systematic Reviews: Modified AMSTAR Instrument

Table 2.3 presents results for the modified AMSTAR appraisal. Appraisers agreed that the overall quality of ODG literature reviews was fair to good, based on the documentation available in the ODG guideline, as well as interviews with ODG developers.

Table 2.3. Modified AMSTAR Appraisal

Domains and Questions	Group Rating*
1. Was an *a priori* design provided?	Good
2. Was there duplicate study selection and data extraction?	Fair
3. Was a comprehensive literature search performed?	Fair
4. Was the status of publication (i.e., grey literature) used as an inclusion criterion?	Outstanding
5. Was a list of studies (included and excluded) provided?	Good
6. Were the characteristics of the included studies provided?	Fair
7. Was the scientific quality of the included studies assessed and documented?	Good
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?	Fair
9. Were the methods used to combine the findings of studies appropriate?	Good
10. Was the likelihood of publication bias assessed?	Fair
11. Were any conflicts of interest stated?	Fair
Overall Rating	Fair to Good

The appraisers noted that the ODG literature reviews have an expansive scope and are updated very frequently. In addition, WLDI appears to use some standard methods for systematic reviews, including conducting broad searches of the medical literature, including grey literature; having at least two reviewers assess the eligibility of the articles identified; assessing the scientific quality of the eligible articles; and summarising findings of at least some studies.

AGREE scores-

AGREE Domain	Score
Scope and Purpose	64%
Stakeholder Involvement	67%
Rigor of Development	55%
Clarity of Presentation	75%
Applicability	74%
Editorial Independence	69%
Average Score Across AGREE Domains	**67%**
Recommended for Use (yes or no):	Yes

AGREE II

The following methodology description aims to provide editorial and scientific clarity on the development of ODG by the publisher, MCG, using the AGREE II format. ODG includes about a dozen different claims management and decision support tools, but the sections relevant to AGREE are the evidence-based Procedure Summaries. These are the most important piece in the treatment guidelines. There are about 3,200 of them, organized primarily by Body System.

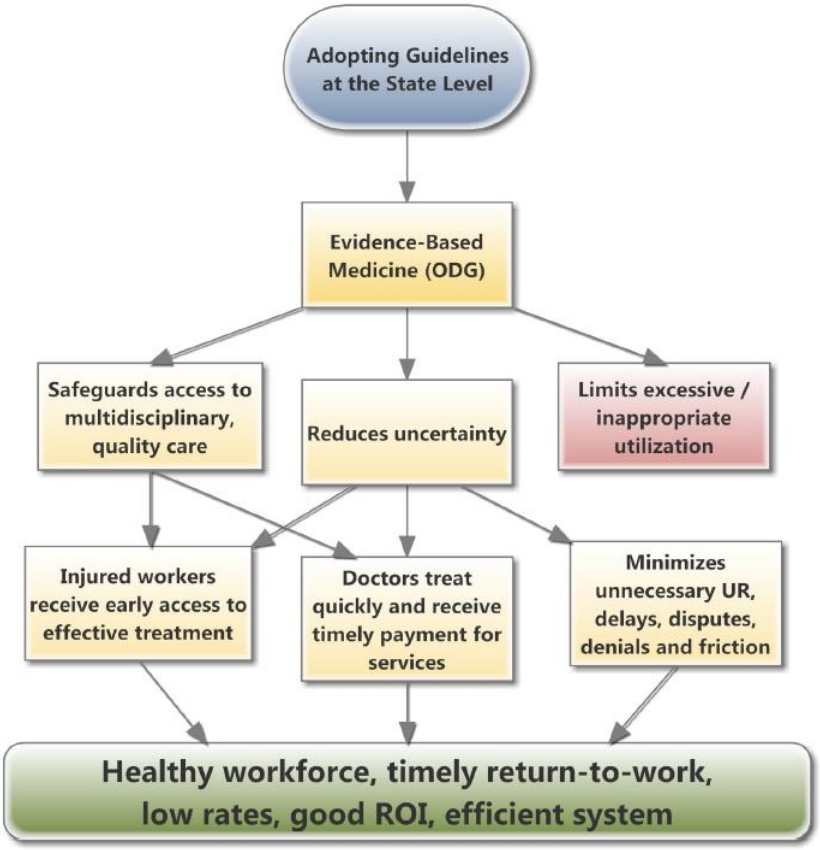
Domain 1. Scope and Purpose

1. The overall objective(s) of the guideline is (are) specifically described.

The ODG mission statement is to *apply evidence-based medicine to improve healthcare outcomes*. ODG is based on a systematic review of the medical literature. The scope of ODG is primarily workplace health and injury claims, and the purpose is to is to optimize health, functional and return-to-work outcomes by critically appraising the medical evidence on therapies and interventions that may be considered, providing evidence-based recommendations, clinical practice guidance, and criteria for use.

Workers' compensation is unique in that payers (insurers companies and self-insured employers) cannot set their own health policy, as is done by insurance plans in group and general healthcare. This creates tremendous uncertainty on the part of healthcare providers and managed care organizations on the questions of medical necessity and appropriateness of care. Delays in treating patients can result, because providers do not have confidence about reimbursement. Also unique is the lack of coinsurance (copays and deductibles), which when combined with the fee-for-service medical model, have resulted in excessive utilization of medical services by many providers. This, in turn, causes payers to spend heavily on Utilization Review services. The result is tremendous friction and waste, with the uncertainty causing unnecessary delays, disputes and denials, in many cases preventing patients from receiving quality care, and in others subjecting them to inappropriate and often dangerous interventions.

ODG is filling this void, providing evidence-based care guidelines independently and objectively. ODG is designed to serve a dual mandate, to (1) safeguard access and expedite approval for quality care, while (2) limiting excessive or inappropriate utilization of medical services.



Important to achieving these objectives is comprehensiveness. If conditions are missing from a workplace treatment guideline, or treatments are not covered for any condition, there will be uncertainty, and the guideline cannot accomplish its purpose. ODG is designed to cover virtually any condition seen in workers' compensation, as well as all possible treatments for those conditions. This means covering new technologies as they are introduced, requiring frequent updating, and validating the ODG guidelines against claims data.

2. The health question(s) covered by the guideline is (are) specifically described.

For each intervention used in workers' compensation populations, ODG provides a Procedure Summary, named for the topics they cover, categorized by body system, and each is an evidence-based guideline by itself, designed specifically to answer the following questions:

What does the overall body of medical evidence communicate with respect to safety and efficacy of the intervention in restoring lost function, health, pain relief, and quality of life? What is the appropriate, evidence-based patient selection criteria, if any, for this intervention?

Each Procedure Summary includes a summary of the body of evidence, highlights from individual studies with citations into abstracts in PubMed.gov (US National Library of Medicine), clinical practice guidelines with recommendations for use, discussion on risk versus benefit, number of visits, and patient selection criteria, where appropriate.

3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

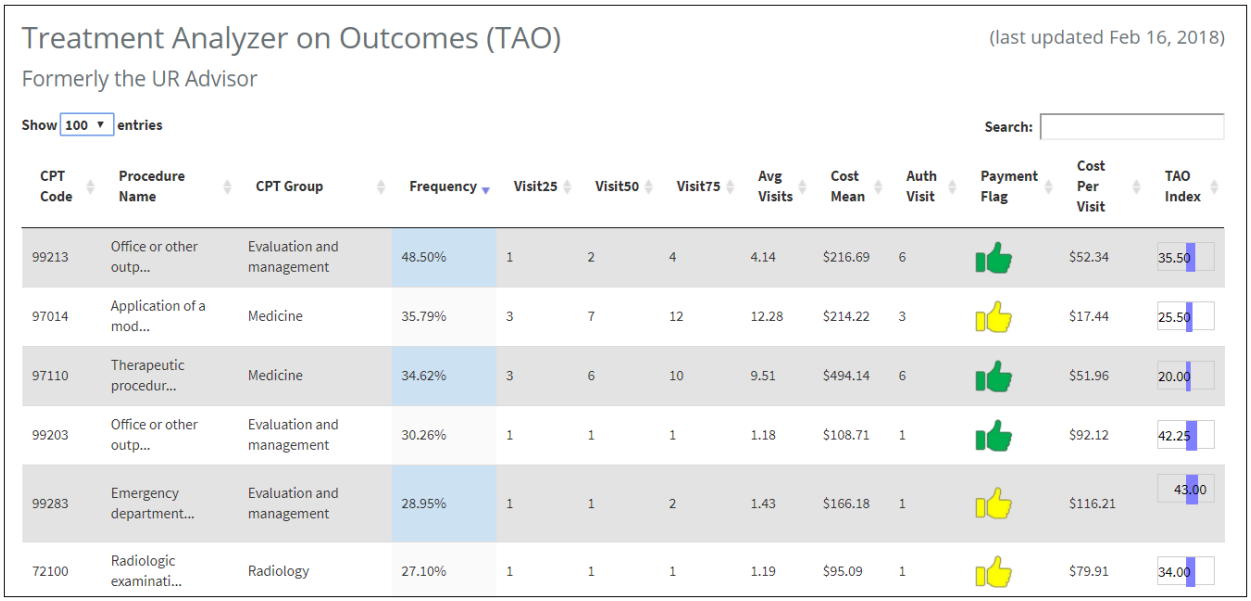
ODG is a workplace health and injury guideline, designed to apply to working adults (generally between the ages of 18 to 80). There are about 3,200 Procedure Summaries in ODG evaluating the medical evidence and efficacy of interventions categorized in the following chapters-

ODG Treatment Chapter
Ankle and Foot
Burns
Carpal Tunnel Syndrome
Diabetes
Elbow
Eye
Fitness for Duty
Forearm, Wrist, and Hand
Head
Hernia
Hip and Pelvis
Infectious Diseases
Knee and Leg
Low Back
Mental Illness and Stress
Neck and Upper Back
Pain
Pulmonary
Shoulder

Treatment guidelines by category code include more than 200 CAM therapies, 400 diagnostic tests, 500 physical medicine options, 500 surgeries, 800 medication listings with over 45,000 unique National Drug Codes, and more than three million CPT-ICD combinations.

Code	Treatment Category	Count
1	Complementary/Alternative Medicine	204
2	Diagnostic Testing	415
3	Electrical / Stimulators	273
4	Imaging	176
5	Implants	150
6	Injections	220
7	Medications	852
8	Physical Medicine	556
9	Orthotics	155
10	Psychological	192
11	Surgery	562
12	Other	829

For every ICD code, ODG provides guidance on every procedure code that may be considered, over three million unique combinations:



Treatment Analyzer on Outcomes (TAO) (last updated Feb 16, 2018)

Formerly the UR Advisor

Show 100 entries Search:

CPT Code	Procedure Name	CPT Group	Frequency	Visit25	Visit50	Visit75	Avg Visits	Cost Mean	Auth Visit	Payment Flag	Cost Per Visit	TAO Index
99213	Office or other outp...	Evaluation and management	48.50%	1	2	4	4.14	$216.69	6		$52.34	35.50
97014	Application of a mod...	Medicine	35.79%	3	7	12	12.28	$214.22	3		$17.44	25.50
97110	Therapeutic procedur...	Medicine	34.62%	3	6	10	9.51	$494.14	6		$51.96	20.00
99203	Office or other outp...	Evaluation and management	30.26%	1	1	1	1.18	$108.71	1		$92.12	42.25
99283	Emergency department...	Evaluation and management	28.95%	1	1	2	1.43	$166.18	1		$116.21	43.00
72100	Radiologic examinati...	Radiology	27.10%	1	1	1	1.19	$95.09	1		$79.91	34.00

Domain 2. Stakeholder involvement

4. The guideline development group includes individuals from all the relevant professional groups.

The MCG in-house team includes more than 20 physicians, 60 nurses, and several PhD-level methodologists. In addition, an external ODG Advisory Board is maintained.

The ODG Advisory Board includes individuals from all the relevant professional groups active in workplace health and injury cases, including primary care, occupational health specialists, orthopedic surgeons, neurologists, neurosurgeons, physical medicine specialists, physical therapists, chiropractors, radiologists, anesthesiologists, doctors of osteopathy, occupational health nurses, certified clinical case managers, and others. ODG is independent of any one medical specialty group and multidisciplinary in scope, striving to represent all medical specialties active in workplace health and injury cases.

The ODG Board includes about 100 physicians, representing dozens of stakeholder groups, professional societies, and associations, and can be found online.

The ODG Board is piloted by Editor-in-Chief Dr. Stephen Norwood and Senior Medical Editor Dr. Charles W. Kennedy, both of whom are orthopedic surgeons. Dr. Kennedy is a founding member of the Evidence-Analysis Committee for the American Association of Orthopaedic Surgeons (AAOS).

ODG Chapter Leads include Dr. Suzanne Novak, Dr. Bill Waters, Dr. J. Mark Melhorn, Dr. Mark Ashley, Dr. Stephen Norwood MD, and Dr. Steve Demeter. Senior Chiropractic Editor is Dr. Preston Fitzgerald, DC, and Senior Physical Therapy Editor is Stuart H. Platt, MSPT, PT.

5. The views and preferences of the target population (patients, public, etc.) have been sought.

ODG has a standing request for suggestions from the public to improve guideline content and clarity. Because of the ongoing update process used at ODG, encouragement of stakeholder suggestions, and its widespread use by more than 75,000 users worldwide, primarily in the USA, Canada, Europe, and Australia, including adoption by more than a dozen jurisdictions in North America, ODG receives many editorial suggestions from patient advocacy groups and associations, and these suggestions may prompt additional research into the scientific evidence, and in some cases, updates to the guidelines.

Below is the open call for suggestions as posted on the ODG site:

Process for suggesting ODG updates: The ODG process for incorporating suggestions from the public is both inclusive and transparent. The public updating suggestion process is document-based, i.e., driven by high-quality published studies as described above in the Explanation of Medical Literature Ratings. In-person meetings, telephone conferences, or other verbal presentations are not accepted.

Suggestion submission process outline:

- Outside parties with suggestions for change are asked to copy the current procedure summary entry in ODG. ODG requests that the submitting party use Track Changes to highlight their suggestions.
- Submit any high-quality scientific studies supporting their suggestion:
    - The submitter should determine that a submitted study is not already referenced in ODG either as a stand-alone reference or as part of the references included in a Systematic Review or Meta-Analysis.

    - If a study is not found in ODG and meets ODG's criteria for inclusion, i.e., the study has been accepted for publication in a peer-reviewed journal, and that journal is one of the journals accepted for inclusion in MEDLINE® by the National Library of Medicine, then WLDI will review and rank the study or studies and circulate them, together with the suggested revision, to topic-specific subject matter experts before considering any updates. (For complete Journal Selection Criteria, see www.nlm.nih.gov/pubs/factsheets/jsel.html.)
- Send suggestions for change(s) and any high-quality scientific studies supporting their suggestion:
    - Via email to the ODG Helpdesk at odg@worklossdata.com
    - Via US Mail to: Managing Editor, Work Loss Data Institute, 3006 Bee Caves Road, Suite A250, Austin, TX 78746.
- All suggestions will be acknowledged upon receipt via email or US Mail in accordance with the method used for the suggestion submission.
    - Minor wording improvements for usability and clarification, or adding a new reference which further supports the existing ODG conclusion, can take as little as a week or two, whereas a change in overall recommendation for a major treatment could take up to a year, depending on the evidence available.
    - Submitters interested in obtaining information on the status of their submission should contact the ODG Helpdesk at ODG@worklossdata.com or 800-488-5548. Inquiries may be given a status of: a) in queue for review; b) in internal ranking & review process; c) in circulation among subject matter experts d) in final update/review process.
    - When updates are made to ODG, they are noted in an update log file posted online and freely available to the public, and ODG will also notify any individuals or association that requested updates or alerts on the topic.
    - This public suggestion process is a very powerful mechanism in keeping ODG current, clear and comprehensive. Since ODG gets millions of hits per year, the sheer volume of ODG users has resulted in a potent force for suggestions to improve the product when clarification is needed or topics are missing.

This open process is one reason stakeholders describe ODG as fair and well-balanced, especially compared with guidelines developed in isolation by state boards, specialty societies, or insurance plans.

6. The target users of the guideline are clearly defined.

ODG is designed for use by independent treating physicians, allied healthcare providers, medical review organizations, insurance claims professionals, nurse case managers, managed care organizations, and regulatory authorities. Without any specific affiliation, ODG is unique in its ability to bridge the interests of the many professional groups involved in diagnosing, treating and reviewing the various conditions associated with workers' compensation.

Domain 3. Rigor of Development

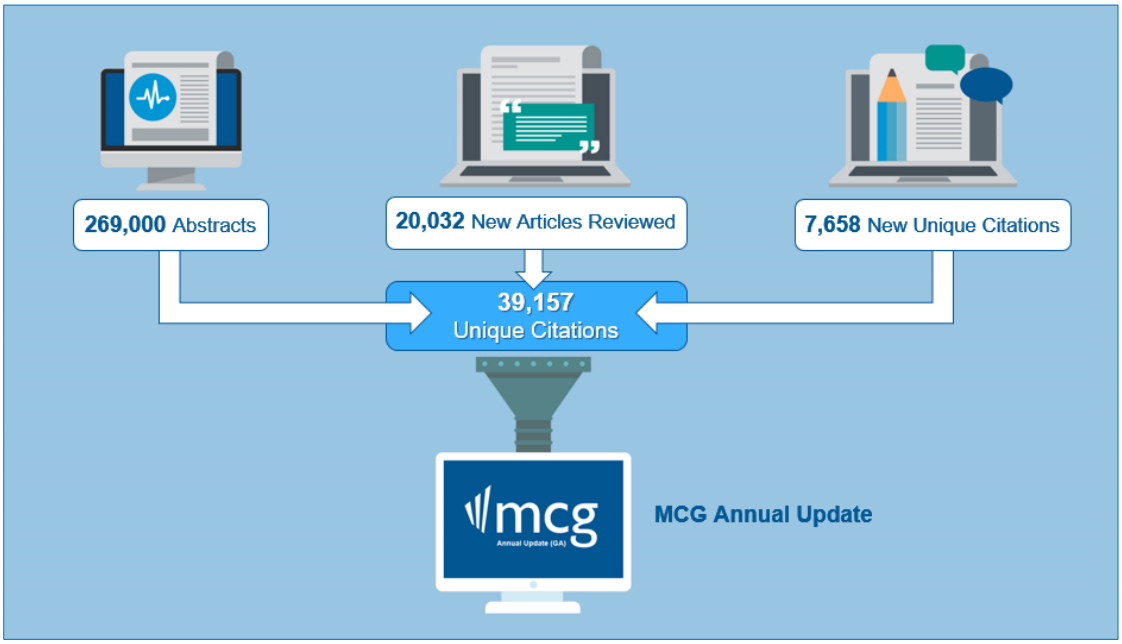
7. Systematic methods were used to search for evidence.

For each MCG guideline, the published professional literature (the National Library of Medicine database via the PubMed search engine) is systematically queried at least annually using specially developed, customized, tested, proprietary search strings. Search strategies are developed to allow efficient yet comprehensive analysis of relevant publications for a given topic and to maximize retrieval of articles with certain desired characteristics pertinent to a guideline. Guideline searches preferentially seek randomized controlled trials and systematic reviews where available, as well as published clinical guidelines, and publications related to potential appropriateness of care.

For each guideline, all retrieved publications are individually reviewed by an MCG clinical editor and assessed in terms of quality, utility, and relevance. Preference is given to publications that

1. Are designed with rigorous scientific methodology.
2. Are published in higher-quality journals (journals read and cited most often within their field).
3. Address an aspect of specific importance to the guideline in question.
4. Represent an update or contain new data or information not reflected in the current guideline.

Each year, more than 250,000 abstracts are reviewed by MCG staff, with 20,000 full articles obtained and analyzed, incorporating about 8,000 new citations into various MCG guideline products.



ODG in-house PhD-level methodologists grade each article using the alpha-numeric quality ranking in the ODG Medical Literature Ratings, then report the scores in a combined summary document. Articles that do not meet the inclusion criteria as adequate evidence are listed separately. Search terms and questions for ODG are diagnosis, treatment, symptom, sign, and/or body-part driven, generated based on new or previously indexed existing evidence, treatment parameters, treatment and review requests by users, and experience.

See Exhibit A for a sampling of search terms used for the Low Back chapter of ODG. See Exhibit G for sample evidence tables from ODG, which can be generated using MCG proprietary literature tools.

In searching and reviewing the medical literature, answers to the following questions are sought: (1) If the diagnostic criteria for a given condition have changed, what are the new diagnostic criteria? (2) What occupational exposures or activities are associated causally with the condition? (3) What are the most effective methods and approaches for the early identification and diagnosis of the condition? (4) What historical information, clinical examination findings or ancillary test results (such as laboratory or x-ray studies) are of value in determining whether a condition was caused by the patient's employment? (5) What are the most effective methods and approaches for treating the condition? (6) What are the specific indications, if any, for surgery as a means of treating the condition? (7) What are the relative benefits and harms of the various surgical and non-surgical interventions that may be used to treat the condition? (8) What is the relationship, if any, between a patient's age, gender, socioeconomic status and/or racial or ethnic grouping and specific treatment outcomes for the condition? (9) What instruments or techniques, if any, accurately assess functional limitations in an individual with the condition? (10) What is the natural history of the disorder? (11) Prior to treatment, what are typical functional limitations for an individual with the condition? (12) Following treatment, what are the typical functional limitations for an individual with the condition? (13) Following treatment, what are the most cost-effective methods for preventing the recurrence of signs or symptoms of the condition, and how does this vary depending upon patient-specific matters such as underlying health problems? (14) What does the overall body of medical evidence communicate with respect to safety and efficacy of the intervention in restoring lost function, health, pain relief, and quality of life? (15) What is the appropriate, evidence-based patient selection criteria, if any, for this intervention?

Reference lists with evidence grading are found within each chapter in ODG. The studies are also sourced directly into the clinical guidelines, and users can pull up the abstracts to confirm the guidelines are consistent with the published evidence. No other workers' comp guideline offers this advantage.

8. The criteria for selecting the evidence are clearly described.

As indicated in Exhibit C, ODG Medical Literature Ratings, preference is given to evidence that meets the following criteria: The article is written in the English language, and the article had any of the following attributes: (1) It is a systematic review of the relevant medical literature, or (2) The article reports a randomized controlled trial, or (3) The article reports a cohort study, whether prospective or retrospective, or (4) The article reports a case control series involving at least 25 subjects, in which the assessment of outcome is determined by a person or entity independent from the persons or institution that performs the intervention the outcome of which is being assessed.

Especially when articles on a specific topic that meet the above criteria are limited in number and quality, ODG also reviews lower quality evidence, but all evidence is ranked alphanumerically using the methodology in Exhibit C (and found in second chapter of ODG) so that the quality is clearly and consistently weighted. The ranking used is alphanumeric ranging from 1a to 10c-

Ranking by Type of Evidence:

STUDIES

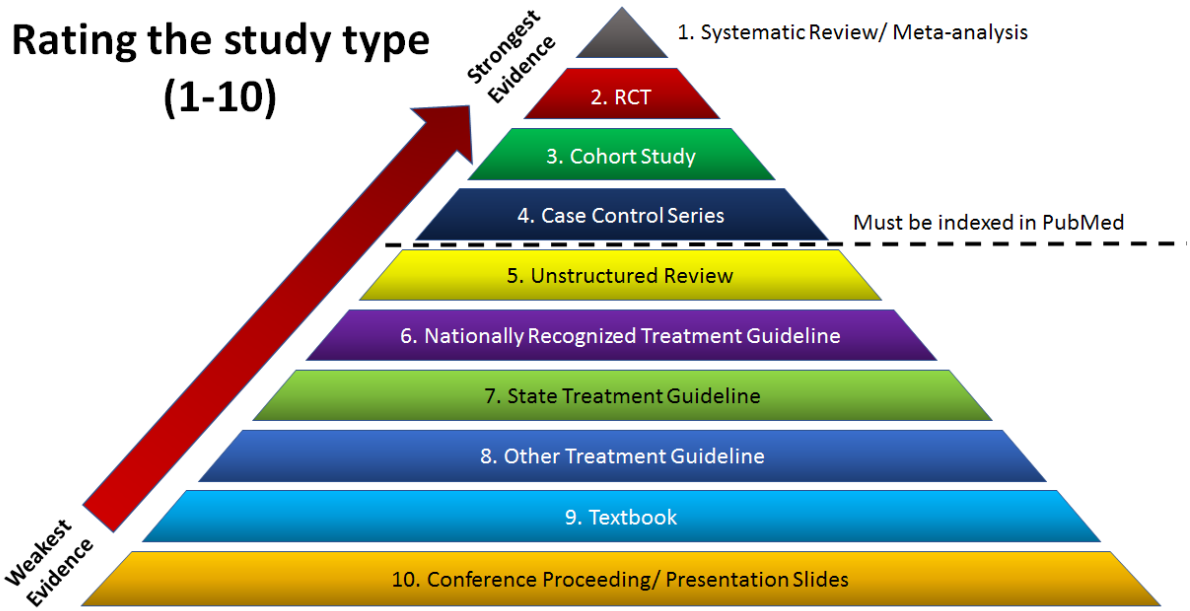
1. Systematic Review/Meta-Analysis
2. Controlled Trial – Randomized (RCT) or Controlled
3. Cohort Study - Prospective or Retrospective
4. Case Series
5. Unstructured Review

OTHER:

6. Nationally Recognized Treatment Guideline (from guidelines.gov)
7. State Treatment Guideline
8. Other Treatment Guideline
9. Textbook
10. Conference Proceedings/Presentation Slides
11. Case Reports and Descriptions

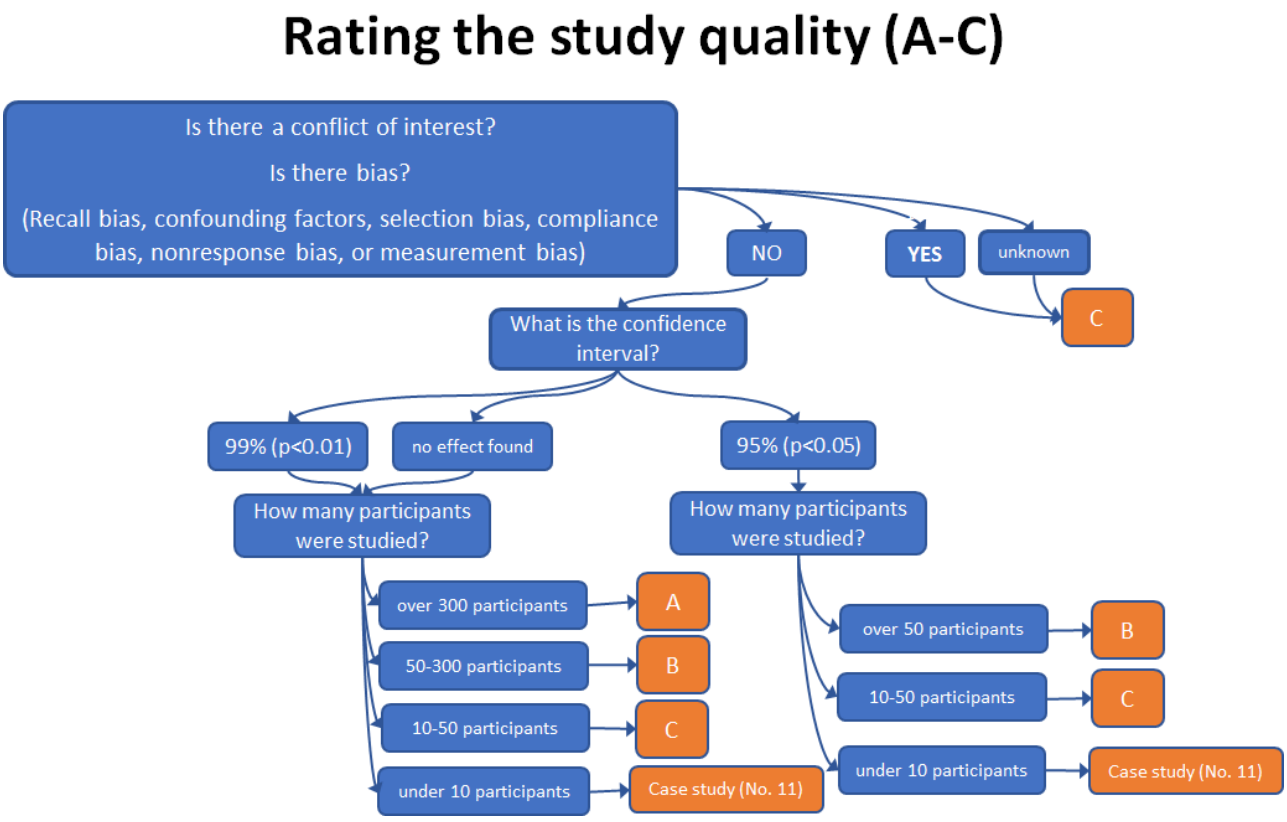
Ranking by Quality within Type of Evidence:

a. High Quality
b. Medium Quality
c. Low Quality



Proceeding beyond the randomized controlled clinical trials (RCTs) is critical, because the biggest problem with evidence-based medicine is that there is not enough of it. For many treatments, academic evidence is low in quantity, quality, or both. RCTs (and meta-analyses of those trials) are the gold standard for publishers, but these studies do not exist for many routine, low-cost interventions, or invasive treatments where rounding out an experimental and control group for sham surgery is not easy or ethical. Guidelines that opt to use only RCTs find a dearth of qualifying evidence, and the inevitable result is that most of their recommendations default to a designation labeled I, for "Insufficient Evidence."

Once categorized as Insufficient Evidence, treatment recommendations become a consensus of authors, who naturally recommend procedures they are most comfortable with from their personal experience and specialty training. This problem is known as "confirmation bias," which is the tendency to interpret, favor, and recall information in a way that confirms one's preexisting beliefs, trade, schooling or hypotheses, while giving less consideration to alternatives. It may have served our species well from an evolutionary standpoint, when we had to process information quickly or risk being eaten by predators, but is generally not compatible with evidence-based medicine or the scientific method.



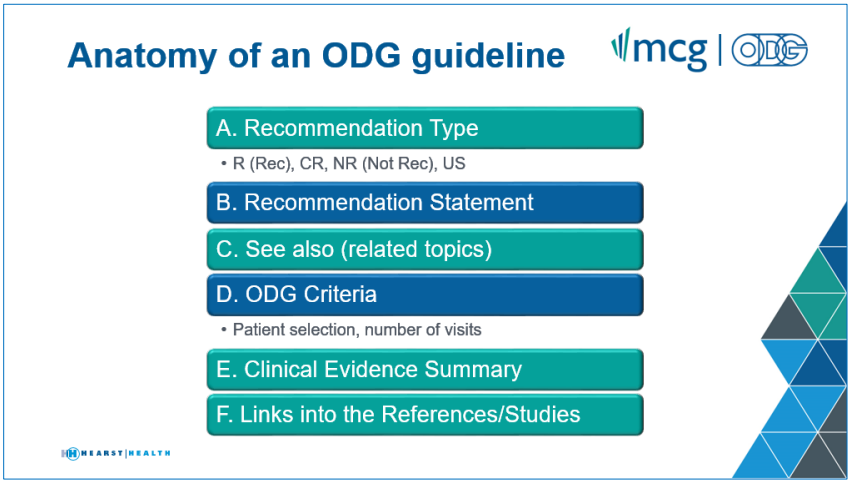
To account for evidence limitations, the leading commercial guidelines like MCG take a pragmatic, multidisciplinary approach, allocating the most weight to RCTs and meta-analyses, but in their absence

using progressively lower levels of evidence, including cohort studies, case-control series, and unstructured reviews. In a world of imperfect knowledge, this type of evidence hierarchy allows the best *available* evidence to trump lower levels and drive guideline recommendations. It has worked well in ODG state adoptions and national implementations.

Treatments *should* be approved on a trial basis with lower levels of evidence if they are conservative (non-invasive, low risk, and low cost). They facilitate recovery, allowing the human body to do what it does: heal with time. A good medical system is not one where providers must fight for the first dollar spent on physical therapy (PT), chiropractic care, or alternative medicine.

9. The strengths and limitations of the body of evidence are clearly described.

Each guideline is broken into the following sections-



Four categories of recommendations are available: R for Recommended, CR for Conditionally Recommended (for carefully selected patients only), NR for Not Recommended, and US for Under Study.

In Section E, the Clinical Evidence Summary, the strengths and limitations of the body of evidence are clearly described. Because ODG has been adopted for medical necessity determinations to set health policy statewide in many states and jurisdictions, it is important that ODG take a definitive position and provide clarity. The strength and limitations of the body of evidence are considered, and the ways in which caution is needed are discussed, especially when the evidence is conflicting.

Summarizing the body of evidence in this fashion allows ODG to take into consideration other factors in addition to study quality, such as (1) the trade-offs between risks versus benefits; (2) the magnitude of effect of an intervention; (3) the availability of dependable sources of the treatment; (4) the education and experience of providers; (5) the consistency of study outcomes; and (6) variability of the treatment parameters being studied.

To give additional insight into the reasoning underlying certain recommendations and the strength of recommendation, a system of Recommendation Grades has been introduced. For all MCG Ambulatory

Care guidelines, each Criteria annotation and Inconclusive or Non-Supportive Evidence annotation has been assigned a Recommendation Grade that summarizes the reasoning behind this conclusion in terms of the evidence base. One of 2 different Recommendation Grades may be assigned to a Criteria annotation, and one of 3 different Recommendation Grades may be assigned to an Inconclusive or Non-Supportive Evidence annotation. Recommendation Grades are as follows:

- RG A1: Evidence demonstrates at least moderate certainty of at least moderate net benefit.
- RG A2: Evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care.
- RG B: Evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended.
- RG C1: Evidence demonstrates a lack of net benefit; additional research is recommended.
- RG C2: Evidence demonstrates potential harm that outweighs benefit; additional research is recommended.

10. The methods for formulating the recommendations are clearly described.

MCG clinical editors evaluate all new evidence and update the guidelines as needed to ensure their continued clinical validity. MCG medical librarians and clinical editors track newly released or updated guidelines from outside sources (e.g., medical specialty societies, Cochrane Reviews), as well as new editions of textbooks. Relevant new content is incorporated into all guidelines as appropriate.

Each updated guideline is then reviewed by a supervising clinical editor or ODG Chapter Lead to verify accuracy and appropriateness of all changes before approval by the ODG Editor-in-Chief.

Certain content (e.g., length of disability, time away from work, goal length of stay, and auto-authorization) is supported by and validated through utilization analysis using various claims-based databases. These include nationally representative samples of general and workers' comp claims. Databases utilized include those developed outside of MCG as well as those that are proprietary to MCG. In terms of guideline development, the purpose of database analysis is to confirm the reasonability and clinical appropriateness of care guidelines' utilization goals and objectives.

After the release of an updated edition of the guidelines, if an error in content is detected that, in the judgment of the editorial staff, is significant enough to potentially adversely affect patient care, all clients are notified and a corrected version of the care guidelines is released.

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

Health benefits (long- and short-term), functional restoration, side effects, pain relief, quality of life, and risks are examined and drive the ODG guideline recommendations. They are also summarized within the Clinical Evidence Summary. A risk versus benefit section is highlighted primarily for surgical interventions, which discusses risks and quantifies the number needed to treat (NNT) or harm (NNH).

For example, for cases with intervertebral disc disorders, epidural steroid injections are shown to provide short-term improvement in leg pain and sensory deficits. However, these injections offer no significant long-term functional benefit. Therefore, the number of injections should be limited to two, which are used to reduce pain and inflammation, restore range of motion and thereby facilitate progress in more active treatment programs (with long-term functional benefit).

Restoration of function is a driving force for many recommendations because it is associated with pain relief, health benefits, quality of life, patient satisfaction and limited risk. When formulating treatment recommendations, side effects and risks are balanced against the potential benefits and the strength of evidence supporting those benefits. An intervention that is invasive and carries high risks would require stronger evidence for a recommendation than one without those features.

12. There is an explicit link between the recommendations and the supporting evidence.

Within the ODG guidelines, each summary of the medical evidence and subsequent recommendation includes a list of references that are hyperlinked to the supporting studies, with authors and publication date, along with the ODG evidence ranking. Also provided is a link associated with the PMID number, which opens the abstract in PubMed.gov, where they can be reviewed, and full-text copies can be ordered where available from the publisher. Users can click right from the guideline into the studies.

13. The guideline has been externally reviewed by experts prior to its publication.

On an annual basis, each guideline undergoes external review by clinically active experts (e.g., board-certified specialist physicians without stated financial conflicts of interest) to confirm the clinical appropriateness, accuracy, validity, and applicability of each guideline. A supervising clinical editor evaluates all comments from these external reviewers and makes necessary changes to the guideline. When circulating new content to ODG contributors, citations are included, including ODG's proprietary ranking system for those studies. ODG uses a modified Delphi process, which means that the positions taken by individual contributors are not made publicly available. This policy is also important to protect individual ODG contributors from personal repercussions, including legal liability, undesired solicitations, and personal attacks. The final ODG Board determination is then published.

When ODG subject matter experts reach a consensus that the content best reflects the evidence rankings, that content will be published in ODG. If there is disagreement among these subject matter experts, then changes or new content will need to be reviewed by the entire board, and publication will require support from at least 80% of the members.

Content is reviewed before publication by the ODG Advisory Board, which is primarily composed of external reviewers, in addition to the Chapter Leads, who work on a compensated basis for ODG.

Feedback from medical specialty societies is also sought. Complimentary review access is made available to all major medical specialty groups as well as other stakeholders, like state and provincial workers' compensation boards, and the International Association of Industrial Accident Boards and Commissions.

Among those groups providing feedback are the American Academy of Disability Evaluating Physicians, American Academy of Neurology, American Association of Occupational Health Nurses, American Academy of Orthopaedic Surgeons, American Academy of Pain Medicine, American Academy of Physical Medicine and Rehabilitation, American Association of Neurological Surgeons, American Board of Independent Medical Examiners, American Chiropractic Association, American College of Radiology, American Federation of Labor and Congress of Industrial Organizations, American Pain Society, American Physical Therapy Association, American Society of Anesthesiologists, American Society of Interventional Pain Physicians, California Medical Evidence Evaluation Advisory Committee, California Society of Industrial Medicine and Surgery, California Workers' Compensation Institute, Canadian Chiropractic Association, Congress of Neurological Surgeons, Council of Acupuncture and Oriental Medicine Associations, Council on Chiropractic Guidelines and Practice Parameters, Department of Defense, Insurance Council of Texas, Kaiser Permanente, North American Neuromodulation Society, North American Spine Society, Reflex Sympathetic Dystrophy Syndrome Association, Texas Medical Association, the Texas Orthopedic Association, and the Workers' Compensation Research Institute.

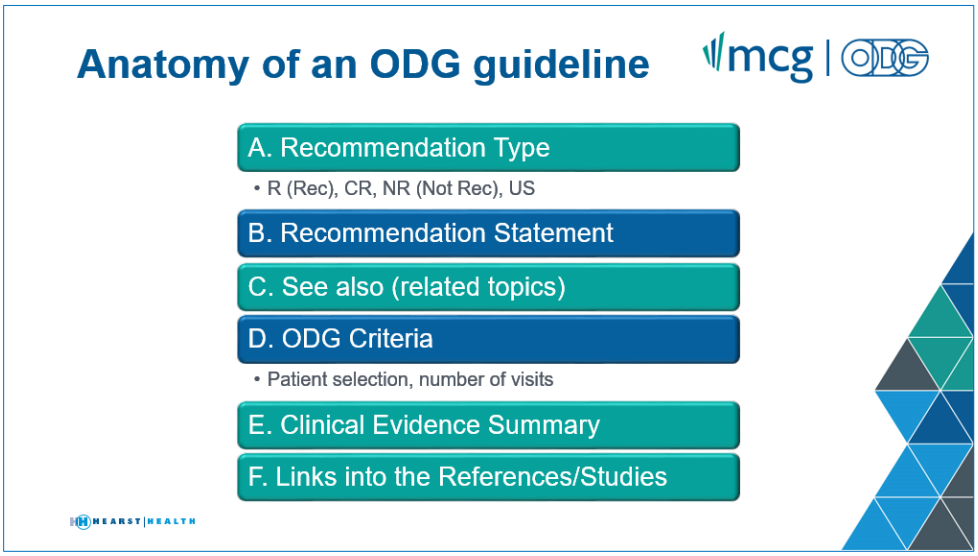
14. A procedure for updating the guideline is provided.

The update process for ODG is in continuous operation with literature searches conducted for each topic on average every three months, but at least once per year. In addition to manual searches of MEDLINE and other literature databases, ODG uses machine-based computer algorithms to generate Search terms and monitor publications. The CPT and ICD databases are also used to generate Searches using text-readers. As new technologies are unveiled in publications, evidence reviews are also initiated. These processes also occur when users contact the ODG Helpdesk because they cannot find something. Over 75,000 users on the frontline of medical management and clinical practice represent a powerful force for suggesting updates. New literature is reviewed, ranked, and weighted by the ODG methodologists, who determine if new or updated ODG content is warranted. When it is, that content is drafted by the Chapter Lead and distributed to the Board using the Delphi process described above.

Domain 4. Clarity of Presentation

15. The recommendations are specific and unambiguous.

Ease-of-use and clarity are the hallmarks of ODG, and they reduce uncertainty and facilitate early access to treatment for the injured worker. ODG is not written like a medical textbook or clinical trial, which may be vague in its recommendations, and may also suffer from conflicting recommendations in different sections written by different authors. The anatomy of an ODG guideline is as follows-



Just four categories of recommendations are available:

Recommended
Conditionally Recommended (for carefully selected patients only)
Not Recommended
Under Study

Each guideline has a *Recommendation Statement*, indicating if the intervention will be recommended or not, beginning with the words "Recommended," "Not recommended," or "Under study." Thereafter, the ODG Criteria are provided, if applicable, including the appropriate patient selection criteria, or number of visits, to optimize success of the intervention. Lastly, ODG provides a clinical summary of the medical evidence, drawing attention to key issues, like Risk vs. Benefit, and linking into the supporting medical studies, including the ranking of each study, and the full abstract.

16. The different options for management of the condition or health issue are clearly presented.

ODG changed the paradigm for evidence-based treatment guidelines with release of the ODG Procedure Summaries in 2003. Prior to that, treatment guidelines took an algorithmic or step-by-step approach to care based on a diagnosis (if this, then that…). This approach inspired the term "cookbook medicine."

However, the ODG approach is superior: for each condition or body system, ODG provides a Procedure Summary database, listing all possible approaches to care, evaluating each one on their merit, and providing criteria for use for each topic as an individual treatment guideline by itself. In this way, a comprehensive list of options for management is clearly presented, and doctors and patients are treated as individuals, free to choose among many evidence-based alternatives.

There may be over 400 entries in each chapter. Many of the procedures are recommended and many are not, but there is not any one approach that is right for every patient. Providers and patients can

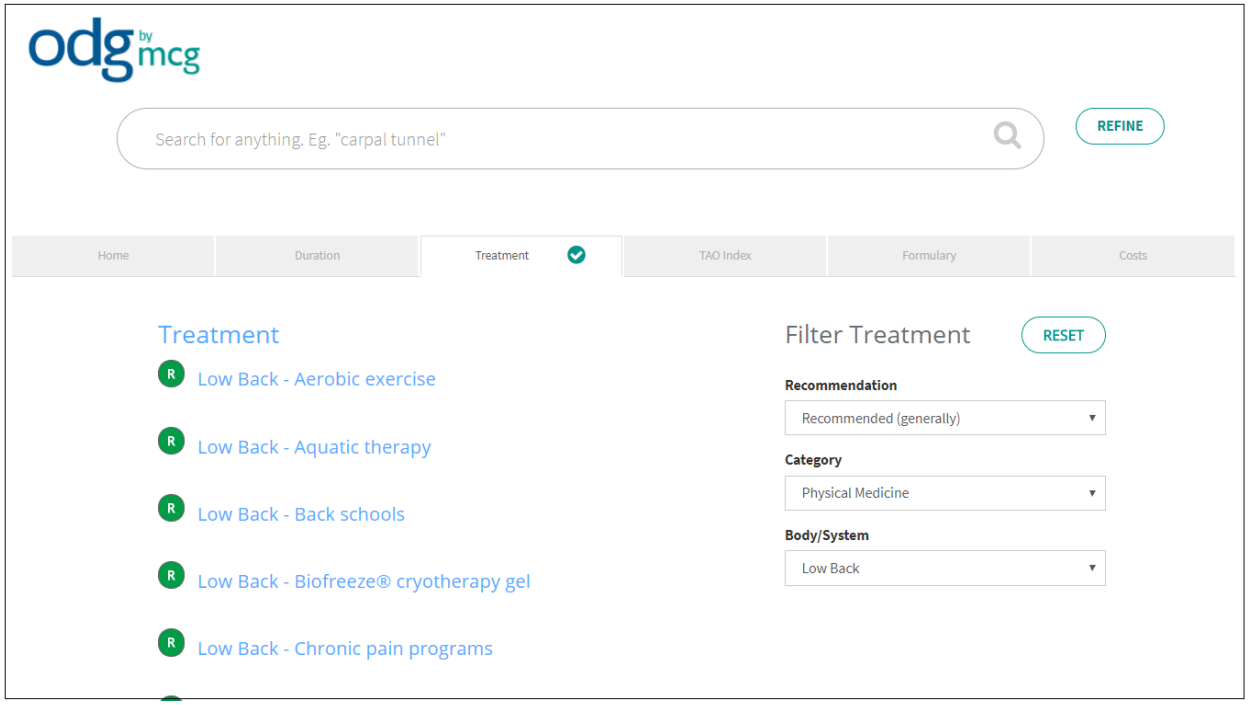
select from a comprehensive list of treatments depending on provider experience and patient preferences.

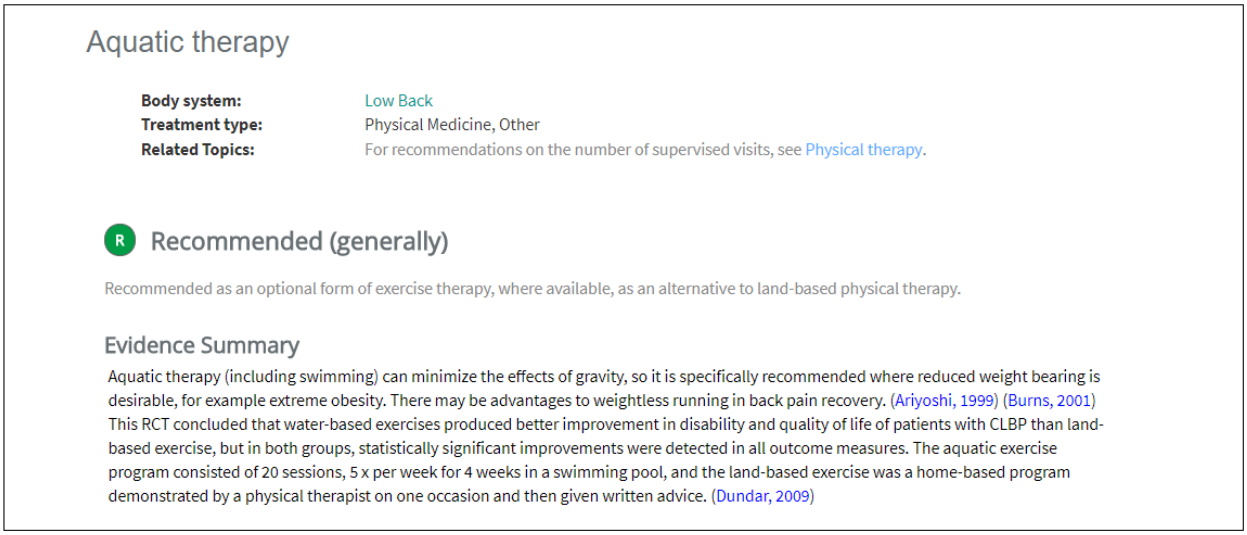
The Procedure Summaries include all different types of interventions, including thousands of topics among Complementary and Alternative Medicine, Diagnostic Testing, Electrical / Stimulators, Imaging, Implants, Injections, Medications, Physical Medicine, Orthotics, Psychological, Surgery, and more.

A Drug Formulary and UR Advisor database are also included, listing approaches by ICD-CPT and National Drug Code, over three million records.

17. Key recommendations are easily identifiable.

Every therapy is listed alphabetically in chapters categorized by Body System, with cross references for alternative descriptions. A robust Search option is also included. Entries in the Procedure Summaries always start with the words, “Recommended,” “Not recommended,” or “Under study.” Patient selection criteria are highlighted in blue, followed by a summary of the supporting medical evidence, with links from the citations to the abstracts in PubMed.





Aquatic therapy

Body system: Low Back
Treatment type: Physical Medicine, Other
Related Topics: For recommendations on the number of supervised visits, see Physical therapy.

R Recommended (generally)

Recommended as an optional form of exercise therapy, where available, as an alternative to land-based physical therapy.

Evidence Summary

Aquatic therapy (including swimming) can minimize the effects of gravity, so it is specifically recommended where reduced weight bearing is desirable, for example extreme obesity. There may be advantages to weightless running in back pain recovery. (Ariyoshi, 1999) (Burns, 2001) This RCT concluded that water-based exercises produced better improvement in disability and quality of life of patients with CLBP than land-based exercise, but in both groups, statistically significant improvements were detected in all outcome measures. The aquatic exercise program consisted of 20 sessions, 5 x per week for 4 weeks in a swimming pool, and the land-based exercise was a home-based program demonstrated by a physical therapist on one occasion and then given written advice. (Dundar, 2009)

Domain 5. Applicability

18. The guideline describes facilitators and barriers to its application.

Application of ODG requires (a) purchase and (b) training/education. The cost depends on the quantity of users (or other metrics that drive organizational size, like annual insurance premium). This subscription fee across all customers supports the comprehensive and ongoing review and update process.

Training options are numerous, including complimentary live Webinars (1:1 or in groups). These Webinars are hosted monthly and are open to the public, or they can be scheduled individually. An automated training program called *ODG: Good to Go!* is also available, which includes the option to become ODG Certified by passing an exam based on the training course.

Another facilitator to the application of ODG is workflow integration into electronic medical record and/or case/claims management software applications with the ODG Application Programming Interface (API). The API delivers ODG content through an automated feed into other applications by medical code (ICD, CPT, NDC, and HCPCS) or by keyword. This ensures the ODG guidelines can be seamlessly integrated into healthcare delivery and review systems. The average response time from the ODG API is 0.33 seconds (it takes external systems just one third of a second to retrieve and display ODG content by medical code).

The API receives more than 2 million queries per month on average. API specifications are available upon request to the ODG Helpdesk (ODG@worklossdata.com).

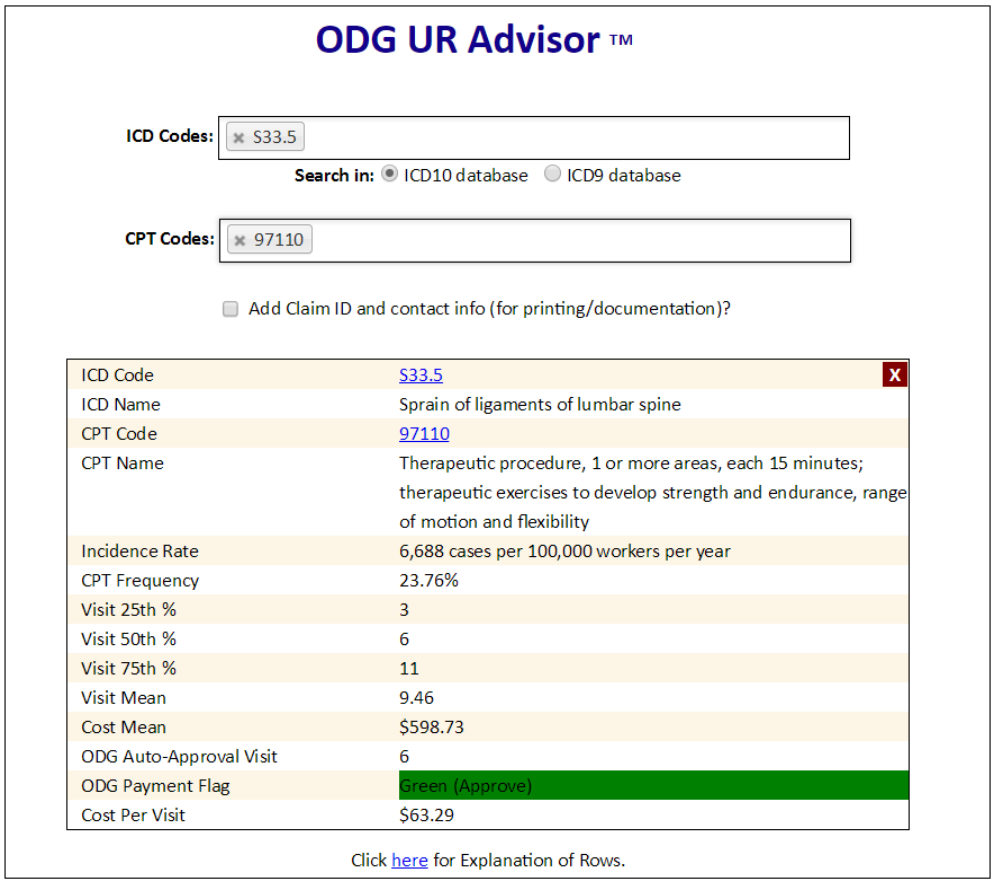
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

Included with ODG is a Users' Guide, which provides advice and guidance on how the ODG recommendations can be put into practice. An automated training tool is also available, *ODG: Good to*

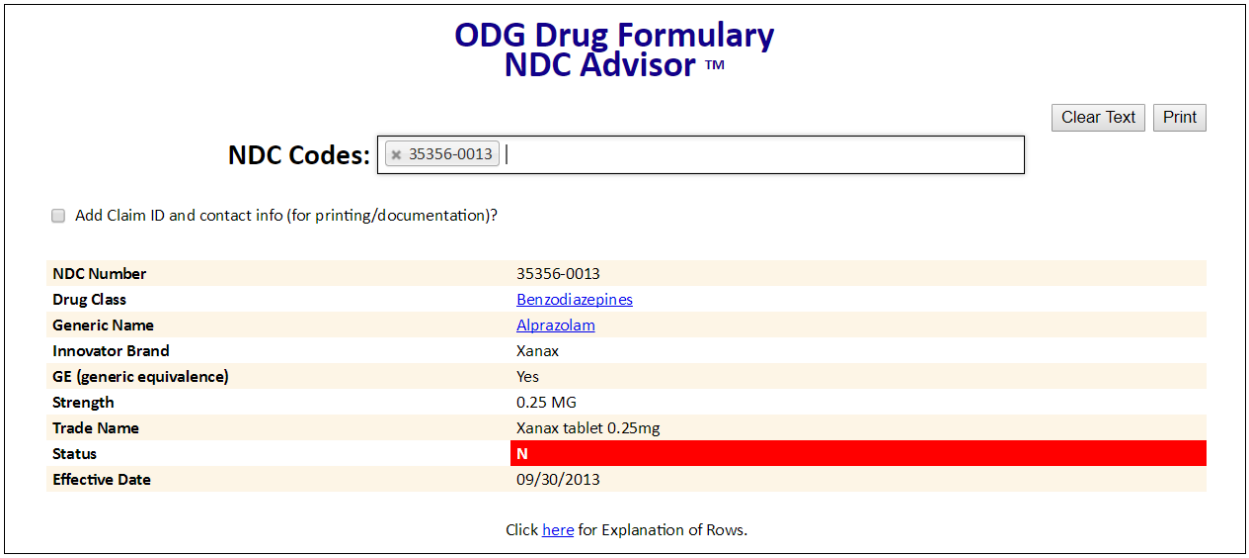
Go! Complimentary live Webinars are hosted monthly and open to the public, or they can be scheduled individually. Lastly, the ODG Helpdesk is available for Q&A and live support.

Also included are application tools such as the ODG UR Advisor™, Drug Formulary, NDC Advisor™, Opioid MED Calculator™, Comorbidity Calculator™, and RTW Prescription™.

The TAO / UR Advisor is designed to auto-approve care consistent with ODG, mapping utilization data and ODG recommendations to CPT-ICD codes with Approval Flags to implement the guidelines easily and consistently, and for monitoring performance, auditing, and reporting.



The Drug Formulary assigns a Status (Y or N) for each medication (by generic name, brand name, or National Drug Code), indicating if that drug is a first-line treatment option, with links to the ODG Procedure Summary for complete guidance on patient selection (i.e., diagnosis, duration and dose).



ODG Drug Formulary
NDC Advisor ™

Clear Text | Print

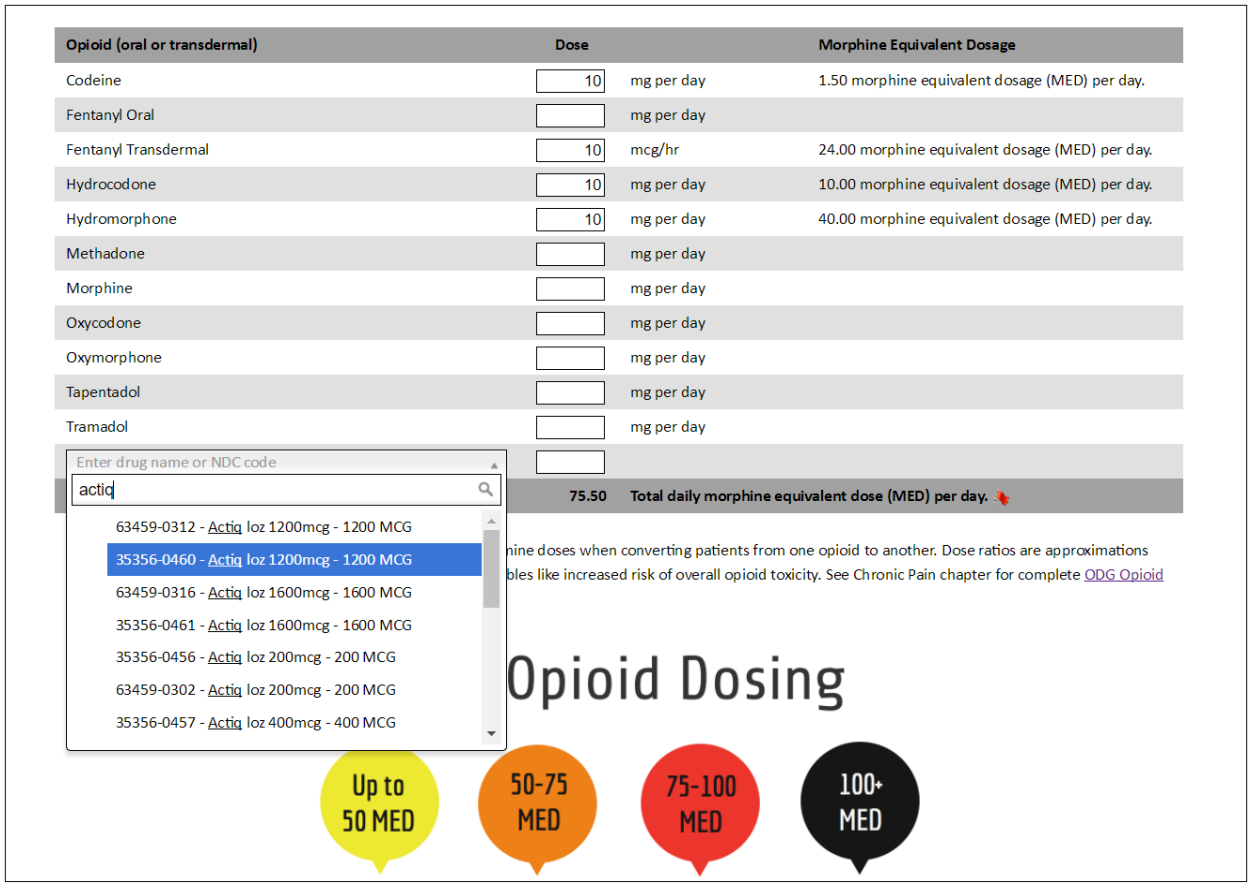
NDC Codes: × 35356-0013

Add Claim ID and contact info (for printing/documentation)?

NDC Number	35356-0013
Drug Class	Benzodiazepines
Generic Name	Alprazolam
Innovator Brand	Xanax
GE (generic equivalence)	Yes
Strength	0.25 MG
Trade Name	Xanax tablet 0.25mg
Status	N
Effective Date	09/30/2013

Click here for Explanation of Rows.

The MED Calculator from ODG tracks total opioid dosage in morphine equivalents, especially valuable for patients receiving multiple opioids. Flags trigger as the dosage approaches, reaches, and then exceed ODG guideline recommendations. All ODG content output can be exported and shared.



Opioid (oral or transdermal)	Dose		Morphine Equivalent Dosage
Codeine	10	mg per day	1.50 morphine equivalent dosage (MED) per day.
Fentanyl Oral		mg per day	
Fentanyl Transdermal	10	mcg/hr	24.00 morphine equivalent dosage (MED) per day.
Hydrocodone	10	mg per day	10.00 morphine equivalent dosage (MED) per day.
Hydromorphone	10	mg per day	40.00 morphine equivalent dosage (MED) per day.
Methadone		mg per day	
Morphine		mg per day	
Oxycodone		mg per day	
Oxymorphone		mg per day	
Tapentadol		mg per day	
Tramadol		mg per day	
Enter drug name or NDC code			
actiq	75.50	Total daily morphine equivalent dose (MED) per day.	

63459-0312 - Actiq lozenge 1200mcg - 1200 MCG
35356-0460 - Actiq lozenge 1200mcg - 1200 MCG
63459-0316 - Actiq lozenge 1600mcg - 1600 MCG
35356-0461 - Actiq lozenge 1600mcg - 1600 MCG
35356-0456 - Actiq lozenge 200mcg - 200 MCG
63459-0302 - Actiq lozenge 200mcg - 200 MCG
35356-0457 - Actiq lozenge 400mcg - 400 MCG

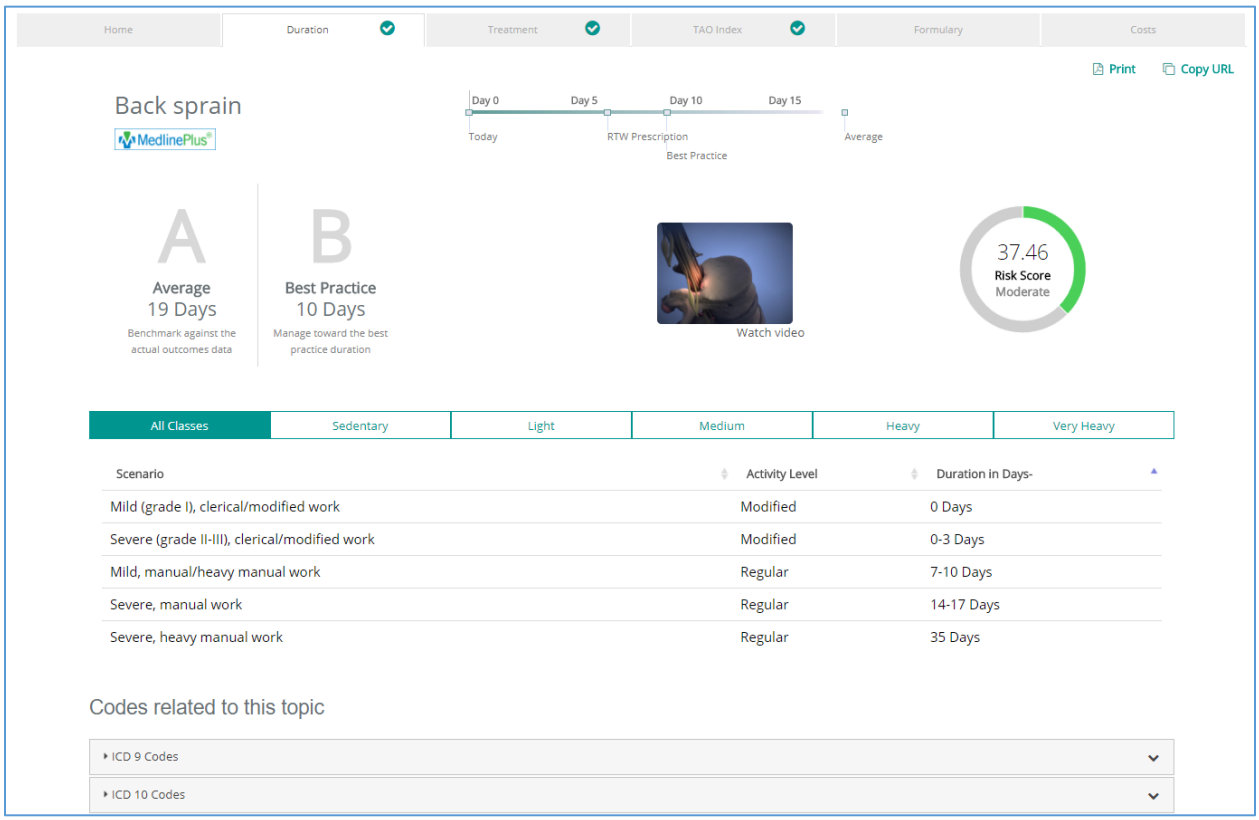
...nine doses when converting patients from one opioid to another. Dose ratios are approximations
...bles like increased risk of overall opioid toxicity. See Chronic Pain chapter for complete ODG Opioid

Opioid Dosing

Up to 50 MED | 50-75 MED | 75-100 MED | 100+ MED

The Comorbidity Calculator and RTW Prescription offer target return-to-work (RTW) date and recommendations for transitional duty (e.g., activity modifications) at the diagnosis or procedure level as well as at the claim level considering all co-morbids and demographics.

These tools are used to facilitate timely RTW as part of the treatment plan.

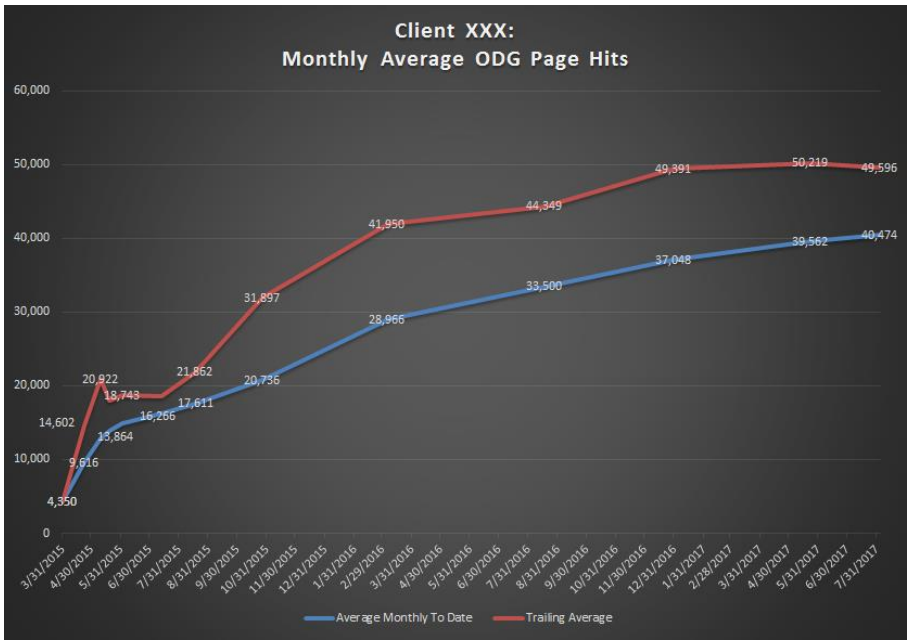


20. The potential cost implications of applying the recommendations have been considered.

The subscription fee depends on organizational size (based on the quantity of users or other metrics, like premium under management). Current pricing information can be found at www.worklossdata.com.

21. The guideline presents monitoring and/or auditing criteria.

Usage statistics (page views) are available monthly.



The API can also be used to monitor performance of healthcare providers, to see what percentage of their treatments are consistent with ODG and how that percentage compares to their peers.

Domain 6. Editorial Independence

22. The views of the funding body have not influenced the content of the guideline.

The subscription fees support the guideline development and update process, and these are borne across thousands of individual users worldwide. They have no say or influence in the guideline content, although they are encouraged to alert the publisher if there are new topics they would like guideline content on, or if the guideline content lacks clarity. ODG is without any specific affiliation and therefore unique in being able to bridge the interests of the many professional groups involved in diagnosing and treating workers' compensation conditions.

23. Competing interests of guideline development group members have been recorded and addressed.

MCG requests and records conflicts of interest for the guideline development group, while attempting to balance any competing interest by seeking multidisciplinary members from various specialties.

MCG Definition of Potential Conflicts of Interest

A potential conflict of interest (COI) is defined as the possibility that a person's actions or decisions may be affected, or have the appearance of being affected, because of an actual or potential divergence between MCG's mission to produce independent, evidence-based guidelines and that person's other interests, including personal or professional financial or intellectual motivations.

- Financial – A person has a potential financial COI if the person or a 1st-degree relative of the person (including parents, siblings, spouse, companion, or children) engages in any of the following within the past 24 months:
  - A compensatory arrangement, ownership, or investment interest in any entity with which MCG has a transaction or arrangement
  - A compensatory arrangement, ownership, or investment interest in any entity that produces a device, test, or medication that is discussed in a guideline, or any facility whose business practices could be affected by the content of a guideline
  - NOTE: compensatory arrangements may include, but are not limited to, research grants (from universities, non-profit organization, universities, etc.), royalties, in-kind benefits, stock options, consultant/speaking fees, and salaries

- Intellectual – A person has a potential intellectual COI if the person has strong personal beliefs, from personal and/or professional experiences, that will not allow objective review of scientific evidence or that may dictate development of guideline content, updates, or incorporation of external review feedback; examples may include, but are not limited to, the following:
  - Authorship of a research article and inability to consider alternative viewpoints or conclusions in that subject matter area
  - Appointed or elected position with, or membership in, a specialty society that holds a specific opinion that cannot or will not change, and all members must endorse
  - Brother/sister is a survivor of a specific disease and serves as a volunteer spokesperson for a non-profit advocacy organization

- Institutional – A person has a potential institutional COI if the work the person performs for MCG is used for the benefit of another employer or used in the capacity of that person's other professional work; all work performed for MCG is proprietary and confidential and may not be used for any other purpose unless otherwise explicitly approved by an appropriate representative of MCG

Potential Conflicts of Interest Form

- Please list all potential conflicts of interest in the appropriate table below

Description of potential **Financial** COIs within the last 24 months for yourself (name of company or organization and your role)	Estimate of amount of potential Financial COI	What steps will you take to mitigate this potential COI and to ensure that it will not interfere with your work at MCG?

Description of potential **Financial** COIs within the last 24 months for your family members (name of company or organization and your family member's role)	Estimate of amount of potential Financial COI	What steps will you take to mitigate this potential COI and to ensure that it will not interfere with your work at MCG?

Description of potential **Intellectual** COIs for yourself (name of company or organization and your role, if appropriate)	What steps will you take to mitigate this potential COI and to ensure that it will not interfere with your work at MCG?

Description of potential Institutional COIs for yourself (name of company or organization and your role, if appropriate)	What steps will you take to mitigate this potential COI and to ensure that it will not interfere with your work at MCG?

I HAVE NO POTENTIAL CONFLICTS OF INTEREST TO REPORT AT THIS TIME: ☐

SIGNATURE: _____ DATE: _____

PRINTED NAME: _____

Exhibit 1: Return-to-Work Guidelines

ODG links together various databases of lost-time and cost data to provide length-of-disability experience and cost projections that can be used to manage and benchmark time away from work. Over the last 20+ years, ODG has incorporated over 20 million claims into the ODG products. Actively today, ODG uses about a third of this total, which can vary depending on the tool. From the beginning in 1996, ODG was based on actual experience, not merely "expert" opinion. This made ODG fair to employees and defensible by employers. With changes to the Federal Rules of Evidence, the ODG guidelines also became the most likely to stand up in court. As a result of U.S. Supreme Court decisions, the Federal Rules of Evidence were recently amended in December 2000 to state that statistical studies will be admissible under the Federal Rules of Evidence, and that such methods generally satisfy important aspects of the "scientific knowledge" requirement articulated in the Daubert Decision.[1] Furthermore, it states that "courts have described surveys as the most direct form of evidence that can be offered, and several courts have drawn negative inferences from the absence of a survey."[2]

RETURN-TO-WORK Best Practice GUIDELINES

The next step in the evolution of ODG was the identification of pathways for each condition, based primarily on drilling down into the raw data, which has a wealth of detail on type of therapy, type of job, demographics, comorbidities and severity. These pathways provided the different treatment options with their resultant time out of work, including considerations for severity and type of job. When different types of jobs made a difference in disability duration, job considerations specific to that diagnosis are identified. With different return-to-work pathways for each type of job, modified duty opportunities can be identified, and the appropriate time frames determined. The term Best Practice describes the use of these pathways and timeframes to manage disability consistent with physiological recovery time.

The Best Practice guidelines were first launched in the 1997 edition of ODG, but they have been expanded in each subsequent annual edition. Currently, ODG has Best Practice guidelines for more than 90% of ICD codes in the form of scenarios or a target date from the RTW modeling tool. The Best Practice disability duration data is contained as the B value (as opposed to the A value, which is actual or average durations from the Claims Dataset) and expanded on in the RTW scenarios where available. These durations are what can be achieved through management of the disability case, based on analyzing the raw data and comparing findings with the experience of the ODG Advisory Board.

The five job classifications in the Department of Labor's *Dictionary of Occupational Titles* are noted and where they apply, "sedentary" corresponds to class 1 (sitting, up to 10 pounds of force), "light" is class 2 (up to 20 pounds), "medium" is class 3 (up to 50 pounds), and "heavy" is class 4 (up to 100 pounds) and "very heavy" is class 5 (over 100 pounds). Other factors may also be noted in the scenarios, like clerical work versus manual work, but it may also be other factors such as sedentary versus standing, or use of a body part such as non-dominant versus dominant arm.

The A (or average) values are from the claims dataset, representing actual data, and can be configured to show Average RTW or Average MMI (maximum medical improvement), which can be set to workers' comp, non-occupational, or any/all data. Throughout the ODG guidelines there is consistency in the definition of days. Return-to-work durations are always in calendar days away from work from the date of injury, except in the case of surgery, and then they count from surgery date. Length of disability of seven days is equal to one week. A partial day missed is treated as one day if the employee would be expected to be out for most of the day (e.g., for a colonoscopy). Time off for an hour or two, say for

routine diagnostic examination, physical therapy, or limited chemotherapy, would be treated as zero days. If type of job is selected or noted (i.e. sedentary), than the duration reflects time away from work until that level of activity. If no job type is selected, the duration is RTW at any level (full or modified).

These guidelines are meant to be used to identify target durations for prospective management and benchmarking, or noting cases that are out of the norm, where questions may be asked, such as what makes them different. The final opinion regarding any medical condition and the ability of a patient to return to work should rest with the physician treating that patient. Where the Best Practice disability duration guidelines indicate "by report", variances in the data made it impossible to select a benchmark number of days, and the report by the evaluating physician should guide the amount of time off work.

It should also be noted that achieving the best practice guidelines disability durations typically requires appropriate job descriptions and availability of altered work. Depending on the type of work, some injuries will have a residual chronic pain syndrome that will require accommodation. It is recommended that these guidelines be achieved in a setting that includes modified duty work as well as case management. Some employers have found that with aggressive Return-To-Work modified duty programs, disability schedules can be considerably shortened compared to the Best Practice guidelines. On the other hand, modified duty policies are quite variable among employers, and the clinician needs to acknowledge that the level of function they approve may not be accommodated.

Some physicians consider the return-to-work dates in the Best Practice guidelines to be aggressive, and there may be some cases that do not meet these guidelines. Some patients can return to work earlier than the best practices suggest, and others later than suggested. When patients fall outside these values, most notably if the projected disability duration exceeds Best Practice estimates, the case manager should consult the treating physician as to why the case might not fit the guidelines.

One of the challenges in disability management is what to do when a person has recurrent problems. For instance, when someone has headaches, rheumatoid arthritis, osteoarthritis, or cancer that has recurrent symptoms, it is very difficult to determine a Best Practice disability duration.

For assistance in using this publication, or information on other services, please call 1-800-488-5548.

Exhibit A: Sample Search Terms Used

For the Low Back chapter, the following is a list of treatment methods covered in the Procedure Summary. There are about 375 entries; many procedures are recommended and many are not, but there is not any one approach that is right for every patient. Providers and patients can select from a list of recommended treatments depending on provider experience and patient preferences.

Each topic is listed with a summary of existing medical evidence and recommendations for use. The evidence summaries and subsequent recommendations are linked to the supporting studies, in abstract form. As new technologies are introduced, evidence reviews are initiated and new summaries are added to the Procedure Summaries. This is also a partial list of search terms, used along with the words back or lumbar or pain, plus the diagnosis and procedure codes pertinent to the lower back (approximately 1,000 different codes), in researching evidence for the Low Back chapter of ODG.

Abobotulinum toxinA (Dysport)
AccuraScope procedure (North American Spine)
Acetaminophen
Activity restrictions
Acupuncture
Acupressure
Adalimumab (Humira®)
Adhesiolysis
Adhesiolysis, percutaneous
Adhesiolysis, spinal endoscopic
Adjacent segment disease/degeneration (fusion)
Aerobic exercise
Age adjustment factors
Alexander technique
Alignmed posture garments
Allograft transplantation
Amniotic membrane allograft (AmnioFix)
Annuloplasty (IDET)
Antibiotics (for back pain)
Antidepressants
Anti-inflammatory medications
AposTherapy shoe
AquaMED
Aquatic therapy
Arthrodesis
Arthroplasty
Artificial disk
Autologous stem cells
Back brace
Back brace, post operative (fusion)
Back schools
Bed rest
Behavioral treatment
Biacuplasty
Biofeedback
Biofreeze® cryotherapy gel
Bone growth stimulators (BGS)
Bone-morphogenetic protein (BMP)
Bone scan
Botulinum toxin (Botox®)
Bupivacaine (Marcaine®)
Bupropion (Wellbutrin®)
C-arm fluoroscopy
Catastrophizing
Causation
Centralization phenomenon (McKenzie)
Charite
Chemonucleolysis (chymopapain)
Chiropractic
Chronic pain programs
Coblation nucleoplasty
Coccygectomy
Cognitive intervention
Colchicine
Cold/heat packs
Comprehensive muscular activity profiler (CMAPPro™)
Computed tomography (CT)
Computerized range of motion (ROM)
Conservative care
Core stability exercise
Corsets
Corticosteroids (oral/parenteral/IM for low back pain)
Cryotherapy
CT (computed tomography)
CT myelography
Current perception threshold (CPT) testing
Cybex® exercise machine
Dascor™ Disc Arthroplasty Nucleus
Decompression
Dehydroepi-androsterone (DHEA)
Delayed treatment
Dermatosensory evoked potentials (DSEPs)
Diagnostic imaging
DIAM (device for intervertebral assisted motion)
Diathermy
Digital motion X-ray (DMX)

Directional preference (DP) therapy
Differential Diagnosis
Disc prosthesis
Disc regeneration therapy
Disc replacement
Disc transplantation
Discectomy/ laminectomy
Discoblocks
Discography
Drug therapy
DRX® (traction)
Dry hydrotherapy (hydromassage, aquamassage, water massage)
Dynamic neutralization system (Dynesys®)
Dynamic spinal visualization
Dynesys®
Early access to treatment
Education
Electrical stimulators (E-stim)
Electrodiagnostic functional assessment (EFA)
Electrodiagnostic studies (EDS)
Electromagnetic pulsed therapy
EMGs (electromyography)
Endoscopic fusion
Epidural neurolysis
Epidural neuroplasty
Epidural steroid injections (ESIs), therapeutic
Epidural steroid injections, “series of three”
Epidural steroid injections, diagnostic
Epidurography
Epiduroscopic laser neural decompression
Ergonomics interventions
ESIs (epidural steroid injections)
Etanercept (Enbrel®)
Evoked potential studies
Exercise
Extracorporeal shock wave therapy (ESWT)
Facet injections
Facet joint diagnostic blocks (injections)
Facet joint injections, lumbar
Facet joint injections, multiple series
Facet joint injections, thoracic
Facet joint intra-articular injections (therapeutic blocks)
Facet joint medial branch blocks (therapeutic injections)
Facet joint pain, signs & symptoms
Facet joint chemical rhizotomy
Facet joint radiofrequency neurotomy
Facet joint therapeutic blocks
Facet joint therapeutic steroid injections
Facet rhizotomy (radio frequency medial branch neurotomy)
Fear-avoidance beliefs questionnaire (FABQ)
Feldenkrais
Flexibility
Flexion/extension imaging studies
Fluoroscopy (for ESI's)
Foraminotomy
Fracture treatment
Functional anesthetic discography (FAD)
Functional improvement measures
Functional restoration programs (FRPs)
Fusion (spinal)
Fusion, endoscopic
Fusion for adult idiopathic scoliosis
F-wave tests
Gabapentin (Neurontin®)
Glucosamine
Godelive Denys-Struyf (GDS) method
Gravity boots
Group physical therapy
Gym memberships
Hardware
Hardware implant removal (fixation)
Hardware injection (block)
Heat therapy
Hemilaminectomy
Herbal medicines
Home health services
Home inversion table
Hospitalization
Hospital length of stay (LOS)
H-reflex tests
H-wave stimulation (devices)
Hydrosurgery
Hyperbaric oxygen therapy (HBOT)
Hyperstimulation analgesia
Ice packs
IDD therapy (intervertebral disc decompression)
IDET (intradiscal electrothermal anuloplasty)
Iliac crest donor-site pain treatment
Imaging
Implantable drug-delivery systems (IDDSs)
Implantable spinal cord stimulators
Implants
Infliximab (Remicade®)
Infrared therapy (IR)
Infuse® bone graft
Injections
Insoles
IntelliSkin posture garments
Interdisciplinary rehabilitation programs
Interferential therapy
Interspinous decompression device (X-Stop®)
Interspinous spacer device
Intradiscal electrothermal therapy (IDET)
Intradiscal steroid injection
Intraoperative neurophysiological monitoring (during surgery)
Intrathecal drug administration system
Inversion therapy

iO-Flex System®
Iontophoresis
Keele STarT Back Screening Tool
Kinetic magnetic resonance imaging (kMRI)
Kyphoplasty
Laminectomy/ laminotomy
Laser discectomy
Laser therapy
Ligamentous injections
Localized high-intensity neurostimulation
Lordex® (traction)
Low level laser therapy (LLLT)
LTX 3000
Lumbar extension exercise equipment
Lumbar supports
Lysis of epidural adhesions
Magnet therapy
Magnetic resonance imaging
Manipulation
Manipulation under anesthesia (MUA)
Massage
Mattress selection
McKenzie method
Medial branch blocks (MBBs)
Medications
Medication-assisted spinal manipulation (MSAM)
Meditation
Medrol dose pack
MedX® lumbar extension machine
Methylprednisolone
METRx®
Microcurrent electrical stimulation (MENS devices)
Microdiscectomy
Mild® (minimally invasive lumbar decompression)
Modified duty
Motor control exercise (MCE)
MR neurography
MRIs (magnetic resonance imaging)
Multidisciplinary pain programs
Muscle relaxants
Myelography
MyoVision
Narcotics
NC-stat nerve conduction studies
Nerve conduction studies (NCS)
Nervomatrix
Neurometer®
Neuromodulation devices
Neuromuscular electrical stimulators (NMES)
Neuroplasty
Neuroreflexotherapy
Nonprescription medications
NSAIDs (non-steroidal anti-inflammatory drugs)
Nucleoplasty
Occupational therapy (OT)
Office visits
Onabotulinum toxinA (Botox)
Opioids
Oral corticosteroids
Orthotrac vest
Oxygen-ozone therapy (injection)
Paracetamol
Patient education
Percutaneous decompression
Percutaneous diskectomy (PCD)
Percutaneous electrical nerve stimulation (PENS)
Percutaneous endoscopic laser discectomy (PELD)
Percutaneous epidural neuroplasty
Percutaneous fusion
Percutaneous intradiscal radiofrequency (thermocoagulation)
Percutaneous neuromodulation therapy (PNT)
Percutaneous radiofrequency neurotomy
Percutaneous vertebroplasty (PV)
PGE1
Pharmaceuticals
Phototherapy
Physical therapy (PT)
Pilates
PILD (percutaneous image guided lumbar decompression)
PIRFT
Piriformis injections
Plasma disc decompression
Platelet-rich plasma (PRP)
Posture garments
PostureRay
Powered traction devices
Predictive screening
Prednisone
Preoperative electrocardiogram (ECG)
Preoperative lab testing
Preoperative testing, general
PRICE (pain recovery inventory)
ProDisc
Prolotherapy (sclerotherapy)
Prostaglandin E1 (PGE1)
Psychological screening
Psychological treatment
Pulsed radiofrequency treatment (PRF)
Quadriplegia rehab
Quantitative sensory threshold (QST) testing
Racz neurolysis
Radiofrequency ablation (RFA)
Radiofrequency neurotomy
Radiography (x-rays)
Range of motion (ROM)
Reassurance
Recombinant bone morphogenetic protein
Red flags
Reflexology

Regenerative medicine
Return to work
rhBMP-2
Rhizotomy
Rimabotulinum toxinB (Myobloc)
Roman chairs exercise equipment
Sacroiliac joint fusion
Sacroiliac joint injections (SJI)
Sclerotherapy
Screening questionnaires for disability
Segmental rigidity (diagnosis)
Selective nerve root blocks
Sensory nerve conduction threshold (sNCT) device
Sequestrectomy
Shock wave therapy
Shoe insoles/shoe lifts
Sit-stand workstation
Skilled nursing facility (SNF) care
Soleve™ auto-targeted neurostimulation
SPECT (single photon emission computed tomography)
Spinal augmentation
Spinal cord injury rehabilitation programs
Spinal cord stimulation (SCS)
Spinal stenosis surgery
SpineCATHÒ
SpineJet (HydroCision)
SpineCor brace
Standing MRI
STarT Back Screening Tool (SBST)
Stem cell autologous transplantation
Steroids (for spinal cord injury)
Stimulators, electrical
Straight leg raising test
Stretching
Supports & braces
Surface electromyography (SEMG)
Surgery
Surgical assistant
Sympathetic therapy
Tai Chi
Telehealth
Tempur-Pedic® mattress
Tendon injections
TENS (transcutaneous electrical nerve stimulation)
Teriparatide (Forteo)
Thermal intradiscal procedures (TIPs)
Thermography (infrared stress thermography)
Thiocolchicoside
Thoracolumbar fracture treatment
Three-dimensional (3D) image rendering
Thrombin/ fibrinogen injection
TIPs (Thermal intradiscal procedures)
TNF modifiers
Topiramate (Topamax®)
Traction
Training
Transcutaneous electrical neurostimulation (TENS)
Transforaminal lumbar interbody fusion (TLIF)
Transplantation, intervertebral disc
Trigger point impedance imaging
Trigger point injections (TPIs)
Tubular discectomy
Tumor necrosis factor (TNF) modifiers
Ultrasound, diagnostic (imaging)
Ultrasound, therapeutic
Upright MRI
Vacuum-assisted closure wound-healing
Vertebral axial decompression (VAX-D®)
Vertebroplasty
VibraCussor® (percussion massage device)
Videofluoroscopy (for range of motion)
Walking
Water-based exercises
Waterbeds
Weight-bearing MRI
Work conditioning, work hardening
Work
Wound closure
Wound dressings
XLIF® (eXtreme Lateral Interbody Fusion)
X-rays
X-Stop® Interspinous Process Decompression (IPD®) System
Yoga
Zoledronic acid
Zygapophysial (facet) joint injection

Exhibit B: ODG Advisory Board
(www.worklossdata.com/editorial-advisory-board.html)

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Exhibit C: ODG Medical Literature Ratings

Ratings "1a" through "11c" noted under summary of each study in ODG reference list.

Ranking by Type of Evidence:
(click on links to go to explanation)

STUDIES

OTHER:

Ranking by Quality within Type of Evidence:
(click on links to go to explanation)

Ranking by Type of Evidence

1. Systematic Review/Meta-Analysis

Systematic Reviews: Written by reviewers who use explicit and rigorous methods to identify, critically appraise, and synthesize relevant studies from the published medical research. They use the process of systematically locating, appraising and synthesizing evidence from scientific studies to obtain a reliable overview. The function of a systematic review is: 1) to summarize the literature and 2) to provide new information that may not be clear from individual studies where the effects are small, but become apparent in when the data from many studies are pooled together. Example: Cochrane Database of Systematic Reviews.

Meta-analysis: A type of systematic review that is an overview and uses quantitative methods to summarize the results. A quantitative method of combining the results of independent studies (usually drawn from the published literature) and synthesizing summaries and conclusions which may be used to evaluate therapeutic effectiveness, plan new studies, etc., with application chiefly in the areas of research and medicine. Any study with the Level 1 ranking in ODG must have been accepted for publication in a peer reviewed journal, and that journal must be one of the journals accepted for inclusion in MEDLINE® by the National Library of Medicine. For this Journal Selection Criteria, see

www.nlm.nih.gov/pubs/factsheets/jsel.html. Unpublished studies, or studies in magazines that do not publish original research, would not receive this ranking.

2. Controlled Trial – Randomized (RCT) or Controlled
These are analytical experimental studies, where variables can be better controlled on a prospective basis. In a RCT (Randomized Controlled Clinical Trial), a group of patients is randomized into an experimental group and a control group. These groups are followed up for the variables/outcomes of interest. Advantages: Unbiased distribution of confounders; Blinding more likely; Randomization facilitates statistical analysis. Disadvantages: Expensive: time and money; Volunteer selection bias; Ethically problematic at times. Any study with the Level 2 ranking in ODG must have been accepted for publication in a peer reviewed journal, and that journal must be one of the journals accepted for inclusion in MEDLINE® by the National Library of Medicine. Unpublished studies, or studies in magazines that do not publish original research, would not receive this ranking.

3. Cohort Study - Prospective or Retrospective
Analytical observational studies involving identification of two groups (cohorts) of patients, one which did receive the exposure of interest, and one which did not, and following these cohorts forward for the outcome of interest. Advantages: Ethically safe; Subjects can be matched; Can establish timing and direction of events; Eligibility criteria and outcome assessments can be standardized; Administratively easier and cheaper than RCT. Disadvantages: Controls may be difficult to identify; Exposure may be linked to a hidden confounder; Blinding is difficult; Randomization not present; For rare disease, large sample sizes or long follow-up necessary. Any study with the Level 3 ranking in ODG must have been accepted for publication in a peer reviewed journal, and that journal must be one of the journals accepted for inclusion in MEDLINE® by the National Library of Medicine.

4. Case Series
Analytical observational studies involving identifying groups of patients who have the outcome or treatment of interest (cases) and quantifying the results. Ideally, control patients without the same outcome are also tracked, looking back to see if they had the exposure of interest. (The use of controls would influence the quality rating of a Case Series.) Generally, since the minimum ODG quality rating for studies (“c”) requires at least 10 cases, there must be 10 or more cases for a study to be classified as a Case Series, and otherwise the article would be classified in ODG as Case Reports and Descriptions. Advantages of Case Series: Quick and cheap; Only feasible method for very rare disorders or those with long lag between exposure and outcome; Fewer subjects needed than cross-sectional studies. Disadvantages: Reliance on recall or records to determine exposure status; Confounders; Selection of control groups is difficult; Potential bias: recall, selection. Any study with the Level 4 ranking in ODG must have been accepted for publication in a peer reviewed journal, and that journal must be one of the journals accepted for inclusion in MEDLINE® by the National Library of Medicine.

5. Unstructured Review
Descriptive (versus analytical) and observational (versus experimental) studies, written by reviewers who describe current practice as well as relevant studies from the published medical research, with no attempt to pool the results analytically. Compared to Systematic Reviews, an Unstructured Review makes little attempt to quantify outcomes based on the body of evidence described. Any study with the Level 5 ranking in ODG must have been accepted for publication in a peer reviewed journal, and that

journal must be one of the journals accepted for inclusion in MEDLINE® by the National Library of Medicine.

6. Nationally Recognized Treatment Guideline (from guidelines.gov)
Accepted for inclusion in the National Guideline Clearinghouse by the Federal Agency for Healthcare Research & Quality (AHRQ), which requires that the guideline recommendations be based on a systematic literature search and review of scientific studies published in peer reviewed journals, and revised on a regular basis to maintain currency with new studies.

7. State Treatment Guideline
Treatment guidelines created for use in a specific state in the U.S., or for use in a province in Canada, or for use by another governmental entity, and they have the backing of the respective jurisdictional or governmental authority.

8. Other Treatment Guideline
Other treatment guidelines. These are typically national treatment guidelines not accepted in the National Guideline Clearinghouse, in many cases because the guideline publishers have chosen not to apply for inclusion (for example, commercial guidelines such as UpToDate), or because they are private guidelines created for use under the terms of a specific health insurance policy (for example, Blue Cross, Medicare, Aetna, Cigna, United Healthcare, etc.). Since studies by healthcare insurers are generally given a rating of Level 8, they are not characterized in ODG as among the highest quality references when there are numerous other studies available. However, when there are limited studies available with the high-quality ratings, it may be necessary to identify other studies that could provide guidance on a subject. In fact, many of the healthcare insurance provider structured reviews are very high quality, they represent a thorough analysis and quantitative weighting of all available evidence on a subject, including unpublished studies that the insurer may have conducted, and these healthcare insurance reviews might even rank as Level 1 if they were published in the peer-reviewed literature and available in MEDLINE®. Furthermore, the fact that a treatment is either covered or not covered by healthcare insurance should be relevant to coverage decisions in workers' compensation.

9. Textbook
Medical reference texts, which may represent standards of practice, but which in and of themselves, are not necessarily evidence based versus consensus based or based primarily on the personal experiences of the authors.

10. Conference Proceedings/Presentation Slides
These are studies that have not been published in peer reviewed journals.

11. Case Reports and Descriptions
Descriptive articles published in the peer reviewed journals covering individual cases, and lacking any comparisons to controls. Generally, since the minimum ODG quality rating for studies ("c") requires at least 10 cases, there must be 10 or more cases for a study to be classified as a Case Series, and otherwise the article would be classified in ODG as Case Reports and Descriptions. These articles were not included in the evidence base for any treatment guidelines except for the Council on Chiropractic Guidelines for Practice Parameters (CCGPP) chiropractic practice guidelines.

Ranking by Quality within Type of Evidence:
In evaluating clinical trials ODG has adopted the standards from the "Cochrane Handbook for Systematic Reviews of Interventions," as updated in September 2006. (Higgins, 2006) Specific additional criteria used by ODG include the following:

a. High Quality
Sample size: Generally, over 300, but at least 100, depending on other factors below.
Conflict of interest: Authors and researchers had no financial interest in the product or service being studied.
Study design: Ideally, blinded. No identifiable bias, including recall bias, confounding factors, selection bias, compliance bias, non-response bias, or measurement bias. If a case series, should be a case control series.
Statistical significance: 99% Confidence level that the outcomes likelihood ratio will not cross 1.0 (i.e., the p value is .01).

b. Medium Quality
Sample size: From 20-50 up to 100-300, depending on other factors below.
Conflict of interest: Authors and researchers had no financial interest in the product or service being studied.
Study design: No significant bias, including recall bias, confounding factors, selection bias, compliance bias, non-response bias, or measurement bias. If a case series, should be a case control series.
Statistical significance: 95% Confidence level that the likelihood ratio will not cross 1.0 (i.e., the p value is .05).

c. Low Quality
Sample size: Generally, under 20-50, depending on other factors below, but no less than 10.
Conflict of interest: Authors and researchers may have had some financial interest in the product or service being studied, even if the sample size was large.
Study design: Some obvious bias, including recall bias, confounding factors, selection bias, compliance bias, non-response bias, or measurement bias.
Statistical significance: Does not meet the 95% Confidence level that the likelihood ratio will not cross 1.0 (i.e., the p value is .05).

Higgins JPT, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions 4.2.5. In: The Cochrane Library, Issue 3, 2005. Chichester, UK: John Wiley & Sons, Ltd. September 2006.

6. ASSESSMENT OF STUDY QUALITY
6.0 Quality assessment of studies: Quality assessment of individual studies that are summarized in systematic reviews is necessary to limit bias in conducting the systematic review, gain insight into potential comparisons, and guide interpretation of findings. Factors that warrant assessment are those related to applicability of findings, validity of individual studies, and certain design characteristics that affect interpretation of results. Applicability, which is also called external validity or generalize-ability by some, is related to the definition of the key components of well-formulated questions outlined in section 4. Specifically, whether a review's findings are applicable to a population, intervention strategy

or outcome is dependent upon the studies selected for review, and on how the people, interventions and outcomes of interest were defined by these studies and the authors (reviewers).
6.1 Validity: In the context of a systematic review, the validity of a study is the extent to which its design and conduct are likely to prevent systematic errors, or bias. An important issue not be confused with validity is precision. Precision is a measure of the likelihood of chance effects leading to random errors. It is reflected in the confidence interval around the estimate of effect from each study and the weight given to the results of each study when an overall estimate of effect or weighted average is derived. More precise results are given more weight.
6.2 Sources of bias in trials of healthcare interventions: There are four sources of systematic bias in trials of the effects of healthcare: selection bias, performance bias, attrition bias and detection bias.
6.3 Selection bias: Participants and those who recruit should remain unaware of next assignment in sequence. Empirical research has shown that lack of allocation concealment is associated with bias. For that reason, trials should use approaches such as allocation by a central office unaware of subject characteristics, pre-numbered or coded identical containers which are administered serially to participants, or an on-site computer system combined with allocations kept in an unreadable file that can be accessed only after the characteristics of enrolled participants have been entered.
6.4 Performance bias: This refers to systematic differences in the care provided to the participants in the comparison groups other than the intervention under investigation. To protect against unintended differences in care and placebo effects, those providing and receiving care can be "blinded" so that they did not know the group to which the recipients of care have been allocated.
6.5 Attrition bias: This refers to systematic differences between comparison groups in the loss of participants from the study. The study should consider how losses of participants (withdrawals, dropouts and protocol deviations) are handled.
6.6 Detection bias: This refers to systematic differences between the comparison groups in outcome assessment.

Rating: 1a

Exhibit D: ODG Guiding Principles

To ensure that ODG succeeds in improving outcomes for patients, ODG adheres to nine Guiding Principles, as listed below:

1. Evidence Based. ODG is based on scientific evidence. This evidence drives decisions to recommend for or against each treatment or test. ODG guidelines include recommendations intended to optimize patient care that are informed by systematic reviews of evidence, with a ranking system that gives higher weighting to higher quality evidence. Systematic reviews of high quality randomized controlled trials are given the most weight in ODG.

2. Total Body of Evidence. ODG will consider the entire body of evidence, while giving higher weight to the best quality evidence. However, when high quality evidence is not available for a treatment or test, ODG will consider lower quality evidence to recommend that can help improve patient care. Along the same lines, an absence of high quality evidence is not necessarily by itself evidence that a treatment modality is ineffective.

3. Harms. ODG recommendations are based on an assessment of the benefits and harms of alternative care options. For each recommendation in ODG, there is a clear description of potential benefits and harms, a summary of relevant available evidence (and gaps), description of the quality (including applicability), quantity (including completeness), and consistency of the available evidence. ODG is updated as new evidence is available, to continually optimize patient care by assessing the latest treatments today's science should offer.

4. Clarity. The ODG guidelines can be used to make current patient care decisions. The purpose of ODG is not to recommend that further studies would be helpful, although that is often the case, but to provide current guidance based on what we know, concerning whether a specific procedure is recommended or not recommended, and if recommended, then for whom. ODG describes and summarizes the entire body of medical evidence as support for the overall ODG recommendation on a topic, rather than using a simplistic alphanumeric rating system for the body of evidence. This is important for utilization review and in states that have mandated ODG, where clarity is essential, but providers still have an opportunity to fully understand the complete body of evidence along with the relative quality of supporting studies.

5. Functional Improvement. Treatments recommended in ODG should help patients function in their everyday lives, and not merely address symptoms. The purpose of treating pain is to help patients get on with their lives and their daily activities. Restoration of function should be the primary measure of treatment success. Functional improvement measures should be used over the course of treatment to demonstrate progress in return to functionality, and to justify further use of ongoing treatment methods.

6. Return to Work. ODG has a return-to-work orientation. Prolonged absence from work due to temporary disability has been shown to be detrimental to the physical, psychological and financial health of individuals. The risks of not working are substantial. Returning to work or some type of functional activity is therapeutic, and part of the healing process.

7. Less Invasive. In ODG, more invasive tests or interventions require stronger evidence of efficacy. In non-emergency situations, invasive treatment should be preceded by adequate conservative treatment and may be performed if conservative treatment does not improve the health problem.

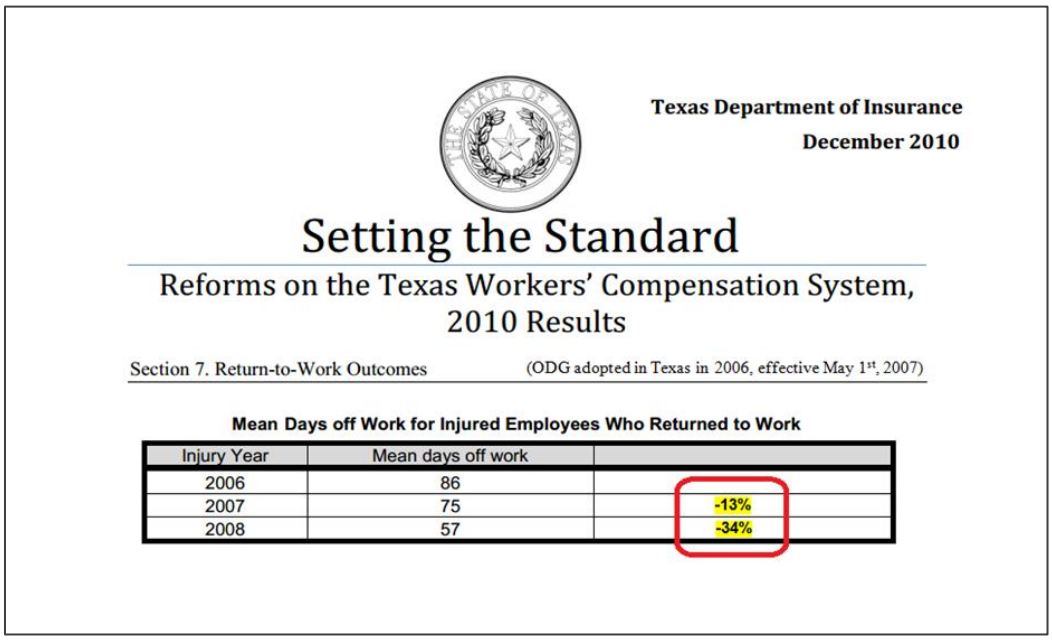
8. Cost. More costly tests or interventions should require stronger evidence of efficacy. If one treatment is no better than another, but costs significantly more, ODG would take that into consideration, and not recommend it as a first-line choice over the other option. While cost is not as important as medical outcomes, it is a consideration if outcomes are no better than equal, and there is a major increase in cost. In those cases, there is no reason to drive up costs if there are no increased patient benefits.

9. Informed Patient. Treatment and testing decisions should be collaborations between the patient and the clinician, with full disclosure of benefits and risks. Shared decision making is an approach to care that seeks to fully inform patients about the risks and benefits of available treatments and engage them as participants in decisions about treatments selected.

Exhibit E: Outcomes from ODG Adoption

Ohio, North Dakota, Texas and Kansas were the first states to adopt ODG in 2003, 2005, 2007 and 2009, respectively. Each are now among the best performing workers' comp systems in the country in industry studies. The National Academy of Social Insurance ranks Texas #1, while the other widely followed study, the Workers' Comp Premium Rate Ranking published by the State of Oregon, puts North Dakota at #1. Texas, like the other big population centers, was one of the worst systems until adopting ODG in May, 2007. It is now one of the best. Below are the results:

- Workers' comp premiums are down 51%
- Average lost-time per claim is down 34%
- Median disability duration is down 30%
- RTW rates are up in all stages, acute, sub-acute AND chronic cases
- Average medical costs are down 30%
- N (non-preferred) pharmacy costs are down 81%
- Total pharmacy costs are down 30%
- High MED (daily morphine equivalent dose) cases have been reduced 97%
- Opioid costs down 18%
- Access to care is up 42%
- Medical denial rates have been cut in half, as providers are encouraged to practice EBM



Texas Department of Insurance
December 2010

Setting the Standard

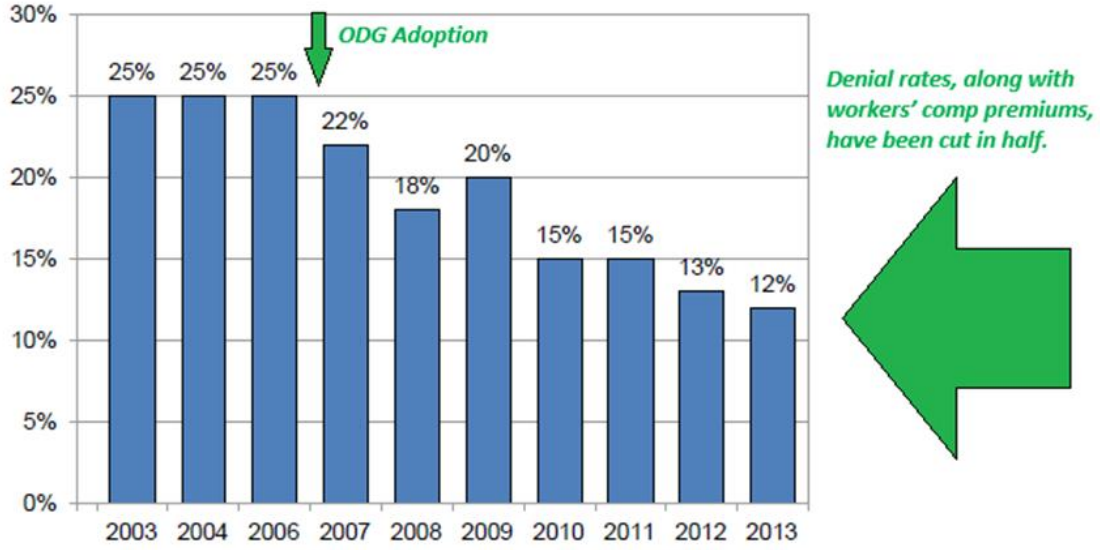
Reforms on the Texas Workers' Compensation System, 2010 Results

Section 7. Return-to-Work Outcomes (ODG adopted in Texas in 2006, effective May 1st, 2007)

Mean Days off Work for Injured Employees Who Returned to Work

Injury Year	Mean days off work	
2006	86	
2007	75	-13%
2008	57	-34%

Figure 5.11: Percentage of Professional Medical Services Denied for the Top 25 Workers' Compensation Insurance Carriers, by Service Year



Note: Denial rates for 2005 were excluded due to missing data. Source: Texas Department of Insurance, Workers' Compensation Research and Evaluation Group, 2014.

North Dakota, unlike Texas, had one of the best performing workers' comp systems in the country when the state adopted ODG in 2005, and workers' comp premiums subsequently dropped another 40%, with $52M in premium returned to North Dakota employers.

Following ODG adoption in Ohio, average medical cost per claim was reduced by 60% and average lost time per claim was reduced 66% (123 days to 42 days). Treatment delay was reduced 77%. ODG approval by healthcare providers in Ohio was measured at 84% (4.18 out of five).

More US states have recently adopted ODG, including Oklahoma, New Mexico, Arizona, and Tennessee, along with several Canadian Provinces and major clients in the Australian states.

Since the ODG guideline and formulary reforms in Oklahoma in 2011, cumulative loss-cost rates have dropped 44%. Following the evidence-based guideline reforms adopting the ODG guidelines and formulary in Tennessee, average claim duration is down 70%, from 177 to 53 days.

Exhibit F: Other Research

Track Record, Not Theory

The ODG guidelines are by far the most widely used in the industry, with more successful adoptions/mandates than any other guideline by several orders of magnitude.

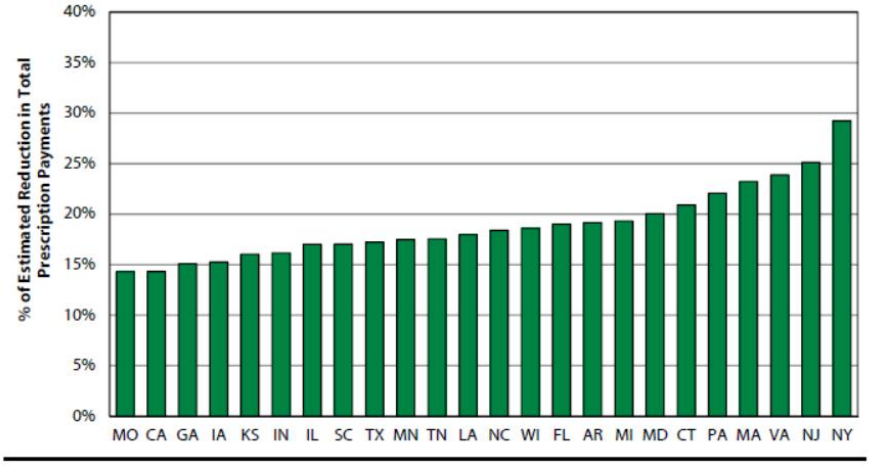
Success stories from ODG implementations are many (http://www.worklossdata.com/odg-in-the-news.html), including access to care up 42%, average and median disability duration down more than 30%, medical and drug costs down 30%, N (non-preferred) drugs down 81%, high-MED claimants reduced 97%, and workers' comp premiums cut in half. Independent studies on ODG by the leading research organizations in workers' comp have supported real-world statistics:

WCRI

The Workers' Compensation Research Institute (WCRI) published a study showing how states can reduce unnecessary pharmacy costs up to 29% with implementation of the ODG Formulary, with the largest benefits expected in states with the most opioid use: (https://www.wcrinet.org/reports/impact-of-a-texas-like-formulary-in-other-states)

Source: WCRI

Figure 4.2 Percentage of Estimated Reduction in Total Prescription Payments under Scenario A, 2011/2012



Notes: The underlying data include prescriptions for claims with more than seven days of lost time that had prescriptions filled over the defined period and paid for by a workers' compensation payor. 2011/2012 refers to claims with injuries occurring from October 1, 2010, to September 30, 2011, and prescriptions filled through March 31, 2012. Texas data are predominantly pre-formulary.

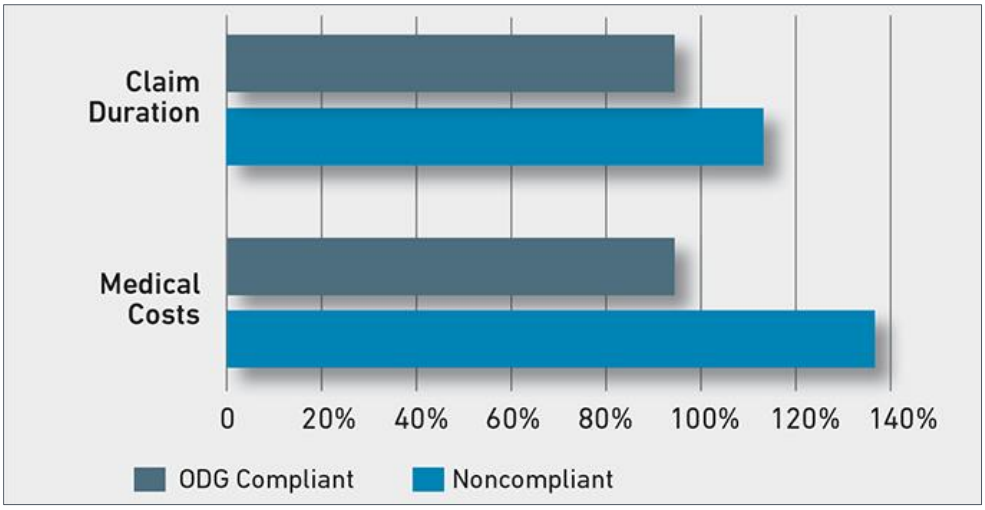
Scenario A: 70 percent reduction in non-formulary drug prescriptions and 0 percent substitution of non-formulary drugs with formulary drugs.

JOEM Study

Johns Hopkins University Medical School in conjunction with Accident Fund Insurance Company conducted a study published in the May 2016 Journal of Occupational and Environmental Medicine

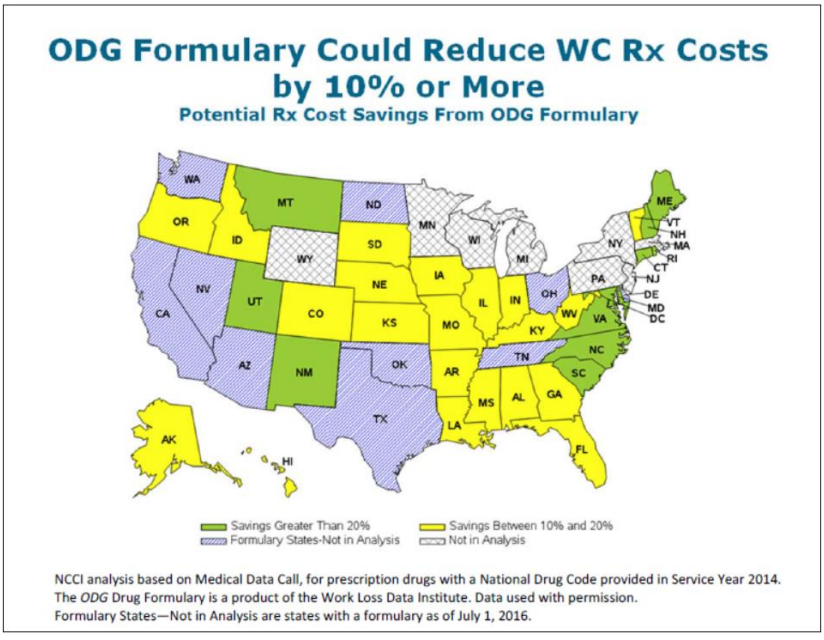
demonstrating that ODG compliance resulted in improved outcomes by 13-18% (shorter claim duration) and 38% lower costs:

(http://riskandinsurance.com/study-supports-benefits-of-evidence-based-medicine/).



NCCI

The National Council on Compensation Insurance (NCCI) published findings showing states can reduce unnecessary pharmacy costs more than 10% with the ODG Formulary: (www.ncci.com/Articles/Documents/II_ResearchBrief_WC_Prescription_Drugs.pdf).



Workers' Comp Research & Evaluation Group

The Workers' Compensation Research and Evaluation Group found that following adoption of the ODG Formulary, the number of N-drug prescriptions in Texas decreased by 80+ percent in all drug groups, while costs fell by 70+ percent in all drug groups. Prescriptions and costs of other drugs decreased by between 5 percent and 25 percent (www.tdi.texas.gov/reports/wcreg/documents/formulary16.pdf).

Average and median disability duration fell by more than 30%, with access to care up.

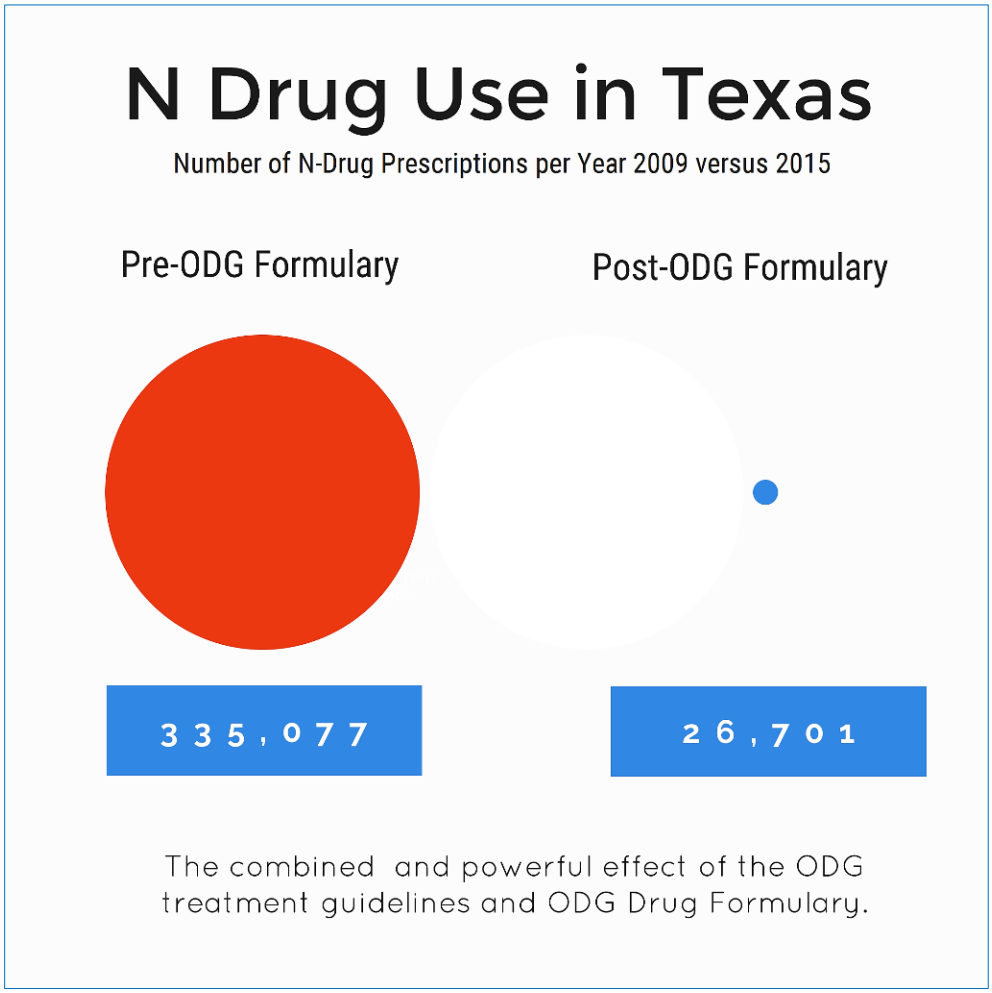
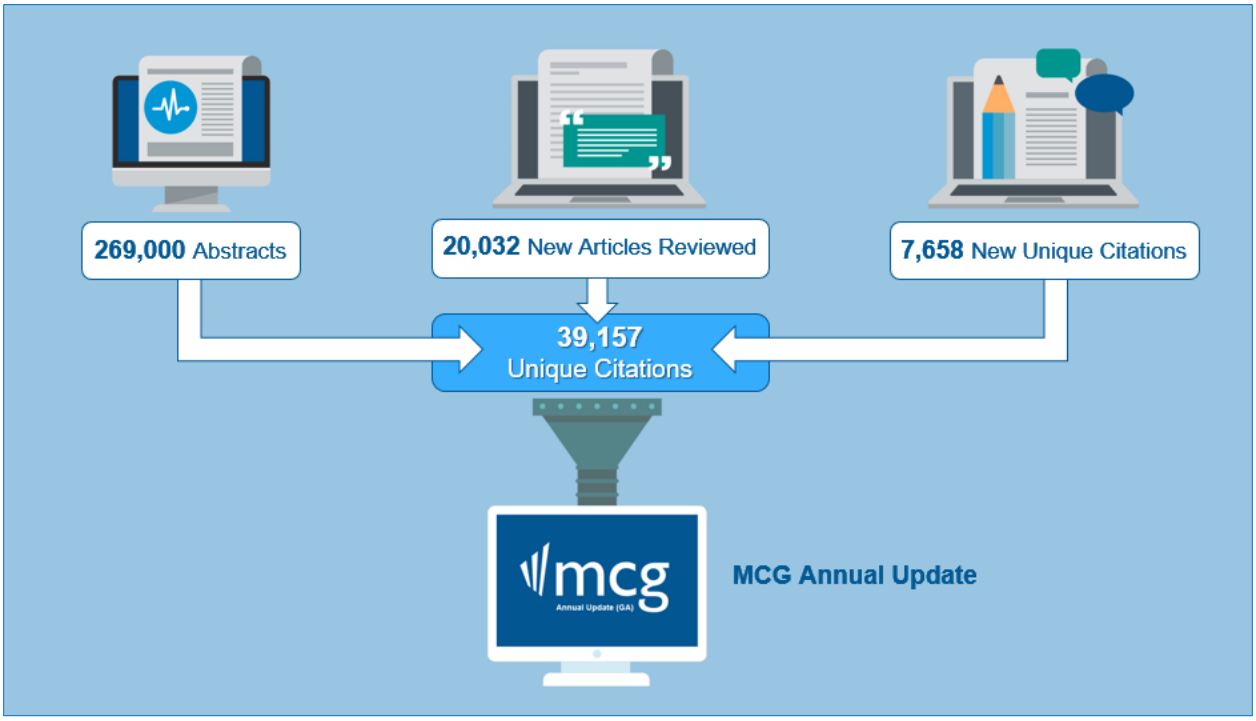


Exhibit G: Evidence Tables

For each MCG guideline, the published professional literature (the National Library of Medicine database via the PubMed search engine) is systematically queried at least annually using specially developed, customized, tested, proprietary search strings. Search strategies are developed to allow efficient yet comprehensive analysis of relevant publications for a given topic and to maximize retrieval of articles with certain desired characteristics pertinent to a guideline. Guideline searches preferentially seek randomized controlled trials and systematic reviews where available, as well as published clinical guidelines, and publications related to potential appropriateness of care.

Each year more than 250,000 abstracts are reviewed by MCG staff, with 20,000 full articles obtained and analyzed, incorporating about 8,000 new citations into the various MCG guideline products.



For articles used in the ODG guidelines, PhD-level methodologists grade each article using the alpha-numeric quality in the ODG Medical Literature Ratings, then report the scores in a combined summary document. Articles that do not meet the inclusion criteria as adequate evidence are listed separately.

Evidence tables can be generated from the proprietary citation management database. Below is an example covering the references used for the ODG Ankle Arthroplasty guideline. This is the evidence table for just one of over 3,000 different ODG Procedure Summary guidelines.

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
Ankle		(Adams, 2014)	A consecutive series of 194 primary Inbone cases followed for a mean 3.7 years showed implant survival of 89%, with 5% talar subsidence reported.	3b	25471913	Patients who underwent total ankle arthroplasty with the INBONE Total Ankle Replacement demonstrated significant improvement in radiographic, functional, and patient-reported outcome scores at a mean of 3.7 years postoperatively. The overall implant survival rate was 89%.	A consecutive series of patients who underwent total ankle arthroplasty with the INBONE Total Ankle Replacement from June 2007 to December 2010 were enrolled in this study. Pain and patient-reported function were assessed with use of a visual analog scale (VAS) for pain, the American Orthopaedic Foot & Ankle Society (AOFAS) ankle-hindfoot score, the Short Musculoskeletal Function Assessment (SMFA), and the Short Form-36 (SF-36) Health Survey. Objective function was measured with	194 primary INBONE total ankle arthroplasties were identified with a mean duration of clinical follow-up of 3.7 years (range, 2.2 to 5.5 years). Patients demonstrated a significant improvement ($p < 0.003$) in VAS pain, AOFAS, SMFA, and SF-36 scores at the time of final follow-up, compared with preoperative values, and in walking speed, STS time, TUG time, and 4SST time at two years postoperatively, compared with preoperatively. The mean coronal tibiotalar angle for varus and valgus ankles significantly improved postoperatively and was maintained until the time of final follow-up. The prevalence of unstable subsidence leading to impending failure was 5%, and the prevalence of revision was 6%.	194

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
							assessment of walking speed, the Timed Up and Go (TUG) test, the Sit-to-Stand (STS) test, and the Four Square Step Test (4SST). Standardized weight-bearing radiographs obtained preoperatively and after total ankle arthroplasty were evaluated. We analyzed clinical, functional, and radiographic measurements with a series of repeated-measures analyses of variance (ANOVAs) with post-hoc testing to assess differences between preoperative, one-year		

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
							postoperative, and most recent follow-up data. On the basis of the number of statistical comparisons, a Bonferroni correction was completed (alpha < 0.003).		
Ankle	Arthroplasty, ankle (TAR)	(Asencio, 2014)	Ankle arthropathy is very frequent in haemophilic patients. Prostheses are valuable alternatives to arthrodesis in non-haemophilic patients. This Study reports the experience of a single centre in France on the use of prostheses in haemophilic patients.	4b	25457668	Ankle arthroplasty is a promising alternative to arthrodesis in haemophilic patients.	Retrospective study of 21 patients with haemarthropathy who underwent ankle arthroplasty (32 ankles), with additional surgery, if needed, from July 2002 to September 2009 (mean follow-up 4.4±1.7 years). The American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hindfoot scale was used to evaluate pain, function, ankle	The overall AOFAS score improved from 40.2±19.4 (pre-surgery) to 85.3±11.4 (post-surgery). The function score increased from 23.6±7.7 to 35.9±6.7 and dorsiflexion from 0.3°±5.0° to 10.3°±4.4°. Two patients underwent further ankle arthrodesis. On X-ray, both tibial and talar components were stable and correctly placed in all ankles. Alignment was good.	21 patients

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
							mobility and alignment.		
Ankle	Arthroplasty, ankle (TAR)	(Bartel, 2015)	Analysis of TAR encompassing all recognized national joint registries, including 5152 primary cases, noted overall 5/10-year implant failure of 13/19%.	1a	26407735	National joint registry datasets should strive for completion of data presentation including revision definitions, modes and time of failure, and patients lost to follow-up or death for complete accuracy of the Kaplan-Meier estimator.	We sought to recreate survival curves among published national joint registry data sets using the Kaplan-Meier estimator.	Overall, 5152 primary and 591 TAR revisions were included over a 2- to 13-year period with prosthesis survival for all national joint registries of 0.94 at 2-years, 0.87 at 5-years and 0.81 at 10-years.	5152
Ankle	Arthroplasty, ankle (TAR)	(Bluth, 2013)	Hemophilia has been associated with significant ankle arthropathy and mid-length retrospective series have demonstrated acceptable outcomes for both AA and TAR.	3b	23490189	Ankle fusion successfully relieves pain and provides a good functional outcome. It is an appropriate treatment for end-stage haemophilic arthropathy of the ankle.	The aim of this study was to evaluate the long-term results of ankle fusion in a large group of haemophilic patients treated at a single institution. The results of 57 ankle fusions performed on 45 patients between 1971 and 2010 were reviewed retrospectively. Data were gathered for	There were no intra-operative or immediate postoperative complications related to fusion of the ankle. The overall non-union rate was 10.4% for tibio-talar fusion and 8.3% for sub-talar fusion. This rate was reduced to 3.7% and 5.6%, respectively, after the introduction of newer surgical techniques in 1995. None of these non-unions required revision surgery. The modified AOFAS scale demonstrated that 75% had no pain in the	45 patients (57 ankle fusions)

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
							type and severity of haemophilia, HIV status, fixation technique, postoperative complications and requirement of additional surgeries. A modified American Orthopaedic Foot & Ankle Society (AOFAS) hindfoot score was calculated for 20 ankles available for follow-up. Patients were followed for a mean of 6.6 years.	operated ankle a mean of 7.2 years following surgery. The remaining 25% scored their average pain as 3 of 10. The functional portion of the score suggested that patients have good alignment, minimal activity limitations or gait abnormalities, and can walk long distances.	
Ankle	Arthroplasty, ankle (TAR)	(Bouchard, 2015)	A small retrospective cohort of 39 obese vs. 48 non-obese TAR patients noted little difference in complications, but mean follow-up was only 3.8 years.	3b	26041851	Although obese patients had increased disability and worse function preoperatively, total ankle replacement significantly and similarly improved pain and disability scores in both obese	This retrospective cohort study compared thirty-nine obese patients (those with a body mass index of ≥30 kg/m(2)) at a mean follow-up	The two cohorts had similar demographic characteristics. Ten (26%) of thirty-nine patients in the obese group were morbidly obese (having a body mass index of >40 kg/m(2)). There were thirty-nine patients in	39

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
						and non-obese patients, with no significant difference in the proportion of complications. We therefore maintain that total ankle replacement is a reliable treatment option for patients with end-stage ankle arthritis, including those who are obese.	time of 3.76 years and forty-eight non-obese patients (those with a body mass index of <30 kg/m(2)) at a mean follow-up time of 3.92 years after total ankle replacement. Outcome measure scores (Ankle Osteoarthritis Scale [AOS] and Short-Form 36 [SF-36]) were collected preoperatively and at least two years postoperatively. Complication and revision data were collected by manual chart audits. Statistical analyses were performed with use of t tests, Wilcoxon signed-rank tests, and Mann-Whitney U	the obese group and forty-eight patients in the non-obese group. The mean body mass index (and standard deviation) was 36.28 ± 5.43 kg/m(2) for the obese group and 25.84 ± 3.00 kg/m(2) for the non-obese group. The obese group had significantly worse preoperative SF-36 Physical Component Summary scores (p = 0.01) than the non-obese group. Preoperatively to postoperatively, both obese and non-obese patients demonstrated significant improvements (p < 0.001) in AOS pain, AOS disability, and SF-36 Physical Component Summary scores, and the changes in these scores were similar for both groups. The SF-36 Mental Component Summary scores did not change significantly (p = 0.30) in either group. There was no significant	

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
							tests. Survival analysis was conducted with use of the Kaplan-Meier method.	difference (p = 0.48) in the proportion of complications or revisions between the groups.	
Ankle	Arthroplasty, ankle (TAR)	(Chambers, 2016)	Advanced radiographic arthritic severity strongly correlated with increased patient satisfaction following TAR. 91% Kellgren-Lawrence grade 4 were satisfied at 2-year follow-up, compared to only 50.0 percent for grades 1-3, and quality of life measures were 94%/47% respectivel	3b	26965495	Although this study does not explain all of the dissatisfaction in TAR, radiologic severity is an important factor that surgeons must consider when planning how best to treat their patients. There may be a different pathophysiology in this patient group that is not well served by arthroplasty.	The Study retrospectively reviewed a single-surgeon, single-implant series of 178 TARs in 170 patients. Of them, 124 patients who took part in the hospital joint registry with a minimum 2-year follow-up were included for this study. The radiographic severity of arthritis was graded using the Kellgren-Lawrence classification. Preoperative weight-bearing radiographs were reviewed	Groups were similar in terms of demographic data (P > .1) and preoperative FAOS scores (P > .89) for pain, function and stiffness. Group D had the biggest improvement in all domains of FAOS. This reached significance in each domain when compared to group C. No significant differences were demonstrated in SF-36 scores. Overall, 91.1% of patients in group D were satisfied at 2 years, compared with 50.0% of patients in groups A, B, and C (P < .001). In addition, 93.9% of patients in group D felt that their quality of life had been improved by the surgery, compared to 47% of patients with groups A, B, and C (P <	170 patients (178 TARS)

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							for severity of arthritis by 2 blinded observers: the first author and an independent colleague from the radiology department. Patients were grouped into 4 subgroups based on degree of severity of radiographic grading for arthritis-A, B, C, and D (for grades 1, 2, 3, and 4 grades, respectively). Data collected included Foot and Ankle Outcome Score (FAOS; pain, function, and stiffness), MOS 36-item Short-Form Health Survey (SF-36) scores, and patient satisfaction scores collected	.001). Further, 77.3% of patients from group D said they would have the operation again, vs only 52.2% of patients with grade III or less (P = .014). Patients who were "very satisfied" or "somewhat satisfied" postoperatively had an average Kellgren-Lawrence (KL) grade of 3.9 preoperatively. In contrast the "very dissatisfied" and "somewhat dissatisfied" patients had an average KL grade of 2.9 (P < .05).	

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
							prospectively and at 1 and 2 years postoperation.		
Ankle	Arthroplasty, ankle (TAR)	(Choi, 2014)	A smaller series noted 5-year clinical failures for diabetics, including delayed wound healing and early-onset osteolysis, increased from 11.6% to 21%.	3b	25452372	These results suggest that diabetes mellitus, especially with poor glycaemic control, negatively affects the short- to mid-term outcome after TAR.	We identified 173 patients who underwent unilateral TAR between 2004 and 2011 with a minimum of two years' follow-up. There were 88 male (50.9%) and 85 female (49.1%) patients with a mean age of 66 years (sd 7.9, 43 to 84). There were 43 diabetic patients, including 25 with controlled diabetes and 18 with uncontrolled diabetes, and 130 non-diabetic patients. The clinical data which were analysed included the	mean AOS and AOFAS scores were significantly better in the non-diabetic group (p = 0.018 and p = 0.038, respectively). In all, nine TARs (21%) in the diabetic group had clinical failure at a mean follow-up of five years (24 to 109), which was significantly higher than the rate of failure of 15 (11.6%) in the non-diabetic group (p = 0.004). The uncontrolled diabetic subgroup had a significantly poorer outcome than the non-diabetic group (p = 0.02), and a higher rate of delayed wound healing. The incidence of early-onset osteolysis was higher in the diabetic group than in the non-diabetic group (p = 0.02).	173

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							Ankle Osteoarthritis Scale (AOS) and the American Orthopaedic Foot and Ankle Society (AOFAS) scores, as well the incidence of peri-operative complications.		
Ankle	Arthroplasty, Ankle (TAR)	(Coetzee, 2016)	A non-randomized single facility comparative study found no significant differences in 2-year outcomes for STAR, Salto Talaris, and Inbone systems.	3b	27595853	This is the first study that compares the results of 3 different total ankle replacement systems done at a single institution over the same period of time. Even though it is not a randomized study, it gives a valuable perspective of the short-term results: no significant differences in 2-year outcomes for STAR, Salto Talaris, and Inbone systems.	The comparative results of 3 different total ankle systems (INBONE, STAR, and Salto Talaris) were evaluated. All the TAA system implants were performed at a single institution from 2007 to 2011. The data were evaluated by authors completely independent from the study institution. The goal was to look at the results in an objective,	At minimum 2-year follow-up there is no statistical difference in outcomes scores or functional tests between the INBONE, STAR, or Salto Talaris, with all 3 TAA systems resulting in statistically significant improvement of all parameters since baseline.	N/A

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							noninstitution perspective.		
Ankle	Arthroplasty, ankle (TAR)	(Daniels, 2014)	A prospective multicenter Canadian Orthopaedic Foot and Ankle Society (COFAS) cohort comparing 388 TAR vs. 107 AA patients with 5-year follow-up noted revision/complication rates of 17/19% for TAR, but only 7/7% for AA.	3a	24430413	Intermediate-term clinical outcomes of total ankle replacement and ankle arthrodesis were comparable in a diverse cohort in which treatment was tailored to patient presentation; rates of reoperation and major complications were higher after ankle replacement.	Patients in the Canadian Orthopaedic Foot and Ankle Society (COFAS) Prospective Ankle Reconstruction Database were treated with total ankle replacement (involving Agility, STAR, Mobility, or HINTEGRA prostheses) or ankle arthrodesis by six subspecialty-trained orthopaedic surgeons at four centers between 2001 and 2007. Data collection included demographics, comorbidities, and the Ankle Osteoarthritis Scale (AOS) and Short Form-36	Of the 388 ankles (281 in the ankle replacement group and 107 in the arthrodesis group), 321 (83%; 232 ankle replacements and eighty-nine arthrodeses) were reviewed at a mean follow-up of 5.5 ± 1.2 years. Patients treated with arthrodesis were younger, more likely to be diabetic, less likely to have inflammatory arthritis, and more likely to be smokers. Seven (7%) of the arthrodeses and forty-eight (17%) of the ankle replacements underwent revision. The major complications rate was 7% for arthrodesis and 19% for ankle replacement. The AOS total, pain, and disability scores and SF-36 physical component summary score improved between the preoperative and final follow-up time points in	388

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							(SF-36) scores. The preoperative and latest follow-up scores for patients with at least four years of follow-up were analyzed. Sensitivity analyses excluded ankles that had undergone revision. A linear mixed-effects regression model compared scores between the groups, adjusting for age, sex, side, smoking status, body mass index, inflammatory arthritis diagnosis, baseline score, and surgeon.	both groups. The mean AOS total score improved from 53.4 points preoperatively to 33.6 points at the time of follow-up in the arthrodesis group and from 51.9 to 26.4 points in the ankle replacement group. Differences in AOS and SF-36 scores between the arthrodesis and ankle replacement groups at follow-up were minimal after adjustment for baseline characteristics and surgeon.	
Ankle	Arthroplasty, Ankle (TAR)	(Daniels, 2015)	This prospective cohort study analyzed intermediate to long-term outcomes of total ankle arthroplasty with	**3a**	26041850	Intermediate patient-reported outcomes were good after ankle arthroplasty with the STAR prosthesis	Consecutive patients who received the STAR prosthesis between 2001	One hundred and eleven ankles underwent arthroplasty with the STAR prosthesis. One-half of the patients were	111 ankles

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			use of the STAR prosthesis at two Canadian centers. The study with 9-year STAR follow-up reported exchange revision of 18% for polyethylene failure in addition to 12% for metal component loosening.			performed by experienced surgeons, and long-term outcomes demonstrated a 12% rate of metal component revision and 18% rate of polyethylene bearing failure. The revision rate was substantially higher among the first twenty ankles than among subsequent ankles, but the early ankles had nearly two years' longer follow-up than subsequent ankles. Additional study to elucidate possible reasons for polyethylene bearing failure is warranted.	and 2005 were enrolled at two large, urban teaching hospitals. Patients were annually evaluated clinically, and the Ankle Osteoarthritis Scale (AOS) and the Short Form (SF)-36 were administered.	male; the mean age was 61.9 ± 11.7 years. Sixty-eight of the ankles underwent a total of 121 additional procedures during ankle arthroplasty, including gastrocnemius release, subtalar arthrodesis, triple arthrodesis, tendoachilles lengthening, and removal of hardware. The mean duration of follow-up for all living patients without revision (seventy-three ankles) was 9.0 ± 1.0 years. Thirteen (12%) of the ankles required metal component revision at a mean of 4.3 ± 3.0 years (range, 0.6 to 10.2 years). Twenty (18%) of the prostheses underwent polyethylene bearing exchange, mostly due to fracture, at a mean of 5.2 ± 2.1 years (range, 1.5 to 9.3 years). Most (97%) of the revisions and exchanges occurred in patients with a diagnosis of primary, secondary,	

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								or posttraumatic osteoarthritis (p = 0.0003). The mean change from baseline to final follow-up was -36.5 ± 23.3 points for AOS pain, -38.6 ± 26.8 points for AOS disability, and 9.6 ± 10.3 points for the SF-36 physical component summary score. The SF-36 mental component summary score was unchanged.	
Ankle	Arthroplasty, Ankle (TAR)	(Day, 2016)	There is rising concern regarding safety and effectiveness because 501(k) implants have proven to be 11-times more likely for recall (not specific to TAR) than the alternative and more rigorous Pre-Market Approval (PMA) process. When orthopaedic surgeons are considering using a new device clinically in their patients, it is important for them to consider how the new device was approved by the FDA. If the device was approved	1b	26984921	Given that 510(k)-cleared devices were 11.5 times more likely to be recalled than PMA-approved devices, it is concerning that most orthopaedic devices are cleared through the 510(k) process with limited clinical trials data.	Using the FDA's public database, the study searched for the following: PMA and 510(k) clearances for orthopaedics and non-orthopaedic specialties, including General & Plastic Surgery, Gastroenterology/Urology, Obstetrics/Gynecology, and Ear Nose & Throat, from 1992 to	From 1992 to 2012, the proportion of non-orthopaedic devices cleared via the 510(k) process decreased from 91% to 53%. However, that of orthopaedic devices decreased only from 94% to 88%. Furthermore, we found that from 2002 to 2012, the percentage of recalled devices was 17.8% for 510(k)-cleared devices and 1.6% for PMA-approved devices. When stratified on the basis of recall class, the odds ratios were 3.5 for class-I devices, 13.2 for	N/A

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			by the 510(k) pathway, then it may have been approved without additional clinical studies confirming efficacy or safety.				2012. Additionally, we searched for all device recall events from 2002 to 2012. For the top-twenty recall companies, we calculated the odds ratio that compares the likelihood of recall for 510(k)-approved devices with that for PMA-approved devices.	class-II devices, and 8.5 for class-III devices.	
Ankle	Arthroplasty, ankle (TAR)	(Demetracopoulos, 2015)	The purpose of this study was to determine the effect of age on the clinical, radiographic, and patient-reported outcomes of patients with end-stage ankle arthritis treated with TAA using modern prostheses.Short-to-medium term TAR outcomes in younger patients were similar to older ones in a	3b	25862101	Outcomes of TAA in younger patients were similar to outcomes in older patients at early follow-up. This study establishes a cohort of patients that will be followed to determine the effect of age on the long-term outcomes of TAA with an emphasis on the need for reoperation and revision.	Patients who underwent primary TAA from June 2007 to July 2011 were prospectively enrolled in the study. Three hundred and ninety-five consecutive patients were reviewed with a mean follow-up	Patients under the age of 55 had a greater improvement in Short-Form 36 (SF-36) Vitality (P = .026) and American Orthopaedic Foot & Ankle Society (AOFAS) Function scores (P < .001) compared with patients over the age of 70 at most recent follow-up. There were no differences in the Visual Analog Scale (VAS) pain score or the	395 patients

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
			prospective cohort study.				of 3.5 years (range, 2-5.4 years). Patients were divided into 3 groups based on age at the time of surgery (<55, 55-70, and >70 years). Patient-reported outcome scores, physical performance scores, and weight-bearing radiographs were used to assess patients preoperatively and at yearly postoperative office visits. Revision was defined as failure of either the tibial or talar components requiring removal of the metallic implants. A repeated-measures analysis of	physical performance outcomes between the age groups. The incidence of wound complications, need for reoperation, and revision were not different between groups.	

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
							variance with post hoc testing and the Pearson chi-square test were used to assess differences between the 3 groups. Statistical significance was set at an alpha level of .05.		
Ankle	Arthroplasty, Ankle (TAR)	(DeVries, 2013	Revision of Agility to Inbone after a mean survival of 6.7 years had unacceptable complications of 31.4% with early failures	4b	23164441	Although the authors present successful conversion of the Agility total ankle replacement to an INBONE total ankle replacement, the difficulty of this procedure is demonstrated by the high complication rate and 2 early failures.	The authors present a series of 14 patients who were converted from the Agility total ankle replacement to an INBONE total ankle replacement. This report is unique in that anterior and posterior approaches are discussed and detailed.	The difficulty of this procedure is demonstrated by the high complication rate and 2 early failures	14

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Ankle	Arthroplasty, ankle (TAR)	(Flavin, 2013)	Comparable and significantly improved gait has been consistently measured with both TAR and AA procedures.	3b	23669163	Patients in both the arthrodesis and arthroplasty groups had significant improvements in various parameters of gait when compared with their own preoperative function. Neither group functioned as well as the normal control subjects. Neither group was superior in every parameter of gait at 1 year postoperatively. However, the data suggest that the major parameters of gait after ankle arthrodesis in deformed ankle arthritis are comparable to gait function after total ankle arthroplasty in nondeformed ankle arthritis.	A prospective study was performed involving 28 patients with posttraumatic and primary ankle osteoarthritis and a control group of 14 normal volunteers. We compared gait in 14 patients who had undergone ankle arthrodesis with the gait of 14 patients who had ankle arthroplasty preoperatively and at 1 year postoperatively. Three-dimensional gait analysis was performed with a 12-camera digital-motion capture system. Temporospatial measurements included stride length and	Baseline parameters showed comparability among the treatment and control groups. Temporospatial analysis, using time as the main effect, showed that compared with ankle arthrodesis, patients with total ankle arthroplasty had higher walking velocity attributable to both increases in stride length and cadence as well as more normalized first and second rockers of the gait cycle. Kinematic analysis, using time and intervention as the main effects, showed that patients who had ankle arthroplasty had better sagittal dorsiflexion (P = .001), whereas those undergoing ankle arthrodesis had better coronal plane eversion (P = .01). Neither ankle arthrodesis nor arthroplasty altered the CoP progression during stance phase. Total ankle arthroplasty produced a more	28 patients & 14 normal volunteers

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							cadence. The kinematic parameters that were measured included the sagittal plane range of motion of the ankle and the coronal plane range of motion of the ankle. Double force plates were used to collect kinetic parameters such as ankle coronal and plantar flexion-dorsiflexion moments and sagittal plane ankle power. Center of pressure (CoP) and its progression in gait cycle were calculated.	symmetrical vertical ground reaction force curve, which was closer to that of the controls than was the curve of the ankle arthrodesis group.	
Ankle	Arthroplasty, ankle (TAR)	(Gross, 2015)	This seemingly contradicts another retrospective series with only 1-year follow-up that reported similar	1b	25561701	A salvage ankle arthrodesis for a failed TAR results in favorable clinical end points and overall	PubMed, Medline, EMBASE, and the Cochrane Central Register	The majority of patients (41%) underwent the index TAR for rheumatoid arthritis. The majority of these	193 Patients (16 Studies)

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			complication rates to non-diabetics.			satisfaction at short-term follow-up if the patients achieve fusion. The bone graft fusion and blade plate group resulted in the highest first-attempt fusion rate, with a low complication rate. Future studies should include prospective, comparative control or surgical groups and use standardized outcome measurements that will make direct comparisons easier.	of Controlled Trials WERE SEARCHEDfor studies that analyzed ankle fusion after failed TAR with a minimum follow-up of 1 year.	revision surgeries were secondary to component loosening, frequently of the talar component (38%). In the cases that were revised to an ankle arthrodesis, 81% fused after their first arthrodesis procedure. The intercalary bone graft group and the blade plate group had the highest rate of fusion after the first attempt at fusion at 100%, whereas the tibiotalocalcaneal fusion with cage group had the lowest fusion rate at 50%. The overall complication rate was 18.2%, whereas the overall nonunion rate was 10.6%.	
Ankle	Arthroplasty, ankle (TAR)	(Gross, 2016)	Another prospective cohort of 455 primary TAR patients, again with less than 4 year follow-up, also noted little difference in complication or early failure rates.	3b	26377200	Total ankle arthroplasty in obese patients was a relatively safe procedure. Although obese patients after TAR had lower functional outcome scores compared to their nonobese	We prospectively identified a consecutive series of 455 primary TARs operated between May 2007 and September 2013	Age, race, and smoking history in the obese group were not significantly higher than the control group; however, sex was significantly related to BMI. There was no difference in complication, infection,	455

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						counterpart, they did experience significant functional and pain improvements at most recent follow-up.	who had a minimum follow-up of 2 years. We identified 266 patients with a body mass index (BMI) <30 (control), 116 with a BMI between 30 and 35 (Obese I), and 73 with a BMI >35 (Obese II). Clinical outcomes including wound issues, infection rate, complications, and failure rates were compared. Functional outcomes including American Orthopaedic Foot & Ankle Society hindfoot score, Short Form-36 (SF-36), Short Musculoskeletal Function Assessment (SMFA), Foot	or failure rates between the groups. Preoperatively, the Obese II group had significantly lower SF-36 scores and higher SMFA function, FADI, and FAOS Symptoms scores. For each of the Obese I, Obese II, and control groups, all functional outcome scores 1 year postoperatively and at most recent follow-up were significantly improved. However, at most recent follow-up, Obese II patients had lower FAOS Pain and SF-36 scores and higher FADI and SMFA Functional scores.	

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							and Ankle Disability Index (FADI), and Foot and Ankle Outcome Score (FAOS) were compared. Average patient follow-up in the Obese I group was 44.7 ± 17.3 months, Obese II was 42.7 ± 16.4 months, and 45.2 ± 17.4 months in the control group.		
Ankle	Arthroplasty, ankle (TAR)	(Henricson, 2011)	The Swedish registry previously reported TAR survival rates of 81% at 5 years, dropping to 69% by 10 years. The early model Scandinavian Total Ankle Replacement (STAR) implant had questionable durability, but with exclusion of those cases, 10-year failure was still 22%.	1a	22066551	The results have slowly improved during the 18-year period investigated. However, we do not believe that the survival rates of ankle replacements in the near future will approach those of hip and knee replacements-even though improved instrumentation and design of the prostheses, together with better patient	Records of uncemented 3-component TARs were retrospectively reviewed, determining risk factors such as age, sex, and diagnosis. Prosthetic survival rates were calculated with exchange or removal of components as endpoint-	Of the 780 prostheses implanted since 1993, 168 (22%) had been revised by June 15, 2010. The overall survival rate fell from 0.81 (95% CI: 0.79-0.83) at 5 years to 0.69 (95% CI: 0.67-0.71) at 10 years. The survival rate was higher, although not statistically significantly so, during the latter part of the period investigated. Excluding the STAR prosthesis, the survival rate for all the	780

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						selection, will presumably give better results.	excluding incidental exchange of the polyethylene meniscus.	remaining designs was 0.78 at 10 years. Women below the age of 60 with osteoarthritis were at a higher risk of revision, but age did not influence the outcome in men or women with rheumatoid arthritis. Revisions due to technical mistakes at the index surgery and instability were undertaken earlier than revisions for other reasons.	
Ankle	Arthroplasty, Ankle (TAR)	(Hofmann, 2016)	A cohort of 81 consecutive Salto Talaris patients reported 97.5% 5-year implant survival, although 17 required additional surgical procedures following the index surgery, and 31% showed radiographic lucencies by 2 years.	3b	28002366	Modern fixed-bearing total ankle arthroplasty had excellent implant survival, improved plantar flexion and total range of motion, and had good-to-excellent functional outcome at a mean follow-up of 5.2 years.	Authors retrospectively reviewed the charts of 78 consecutive patients (81 ankles) who underwent total ankle arthroplasty with a minimum clinical follow-up of 2 years. Sixty-three patients completed standardized questionnaires including the Foot and Ankle	Implant survival was 97.5% at a mean follow-up time of 5.2 years. There was 1 revision of a tibial component and 1 revision of a talar component. Thirty-six patients underwent a concurrent procedure at the time of the index surgery, with the most common being removal of previous hardware. Seventeen patients underwent additional procedures following the index surgery, with the most common being gutter debridement.	81 ankles

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							Disability Index (FADI), the Short Musculoskeletal Function Assessment (SMFA), the Short Form (SF)-36v2, and a visual analog scale (VAS) for pain. In addition, each patient underwent serial range-of-motion examination and radiographic implant evaluation at each follow-up appointment.	Total range of motion averaged 35.5° preoperatively and 39.9° postoperatively (p = 0.02). Fifty-seven ankles (70%) had >2 years of radiographic follow-up, and 25 ankles (31%) displayed evidence of lucency around a metallic component at the final radiographic follow-up. Outcome scores at a mean of 5.2 years revealed promising results for the cohort, with a mean VAS pain score of 17.7 and a mean FADI score of 79.1.	
Ankle	Arthroplasty, ankle (TAR)	(Horne, 2015)	The incidence of venous thrombolic events (VTE) has been shown to be relatively uncommon following TAR, only 0.6% in one series without chemoprophylaxis, suggesting anticoagulation only for patients with other high pre-operative risks.	3b	25712115	Our results suggest that clinically detectable VTE after TAA is uncommon. Patients without identifiable risk factors do not appear to require chemoprophylaxis following TAA. We recommend continuation of antiplatelet or anticoagulation	We conducted a retrospective chart review of 637 patients (664 ankles) who received a TAA between May 2007 and January 2014 and had a minimum follow-up of 3 months. Chemoprophylax is was prescribed	The overall incidence of clinically detected VTE events was 0.60% (4/664), with 0.45% (3 patients) developing a DVT and 0.15% (1 patient) developing a nonfatal pulmonary embolism. Moreover, we identified a subset of 434 patients without identifiable preoperative risk factors who were not taking	637

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						therapy in patients who are taking these medications preoperatively and the initiation of chemoprophylaxis postoperatively in patients with known risk factors for VTE.	only in the setting of a history of VTE or active coagulopathy. Patients were continued on chemoprophylactic agents if they were taking these medications preoperatively. A VTE event was defined when clinical signs and symptoms of deep venous thrombosis (DVT) were confirmed with use of Doppler ultrasonography or pulmonary embolism was confirmed with the use of a computed tomography scan. Routine screening for VTE was not performed.	chemoprophylaxis preoperatively and were not prescribed chemoprophylaxis postoperatively. Two of these patients developed a DVT postoperatively (0.46%). Given the low incidence of clinically detected VTE, no significant correlation could be identified between the occurrence of VTE events and risk factors.	

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Ankle	Arthroplasty, Ankle (TAR)	(Hsu, 2015)	Primary Inbone TAR performed between 2008-2012 had 96.6% 2-year survival, but then revision was required in less than 3 years due to talar subsidence for 8%, and 24% had re-operations related to complications including arthrofibrosis.	3b	25653319	Early results of INBONE intramedullary-fixation total ankle arthroplasty demonstrated improved patient-reported outcomes and increased ankle motion at a minimum follow-up of two years. Arthrofibrosis and talar subsidence were the main postoperative complications that required revision, and these predominantly affected the first-generation INBONE I implants.	Fifty-nine primary total ankle arthroplasties utilizing INBONE I or II implants were performed in fifty-nine patients (thirty-one men and twenty-eight women; mean age, 57.2 years) from 2008 to 2012. The AOFAS (American Orthopaedic Foot & Ankle Society) ankle-hindfoot score and VAS (visual analog scale) pain score were recorded preoperatively and at the time of the latest follow-up. Weight-bearing radiographs were used to determine ankle motion and assess component	All fifty-nine patients were available for follow-up at least two years after surgery; the mean follow-up duration was 35.0 ± 11.9 months. The estimated survival rate at two years was 96.6% in the entire cohort (91.3% in the INBONE I group and 100% in the INBONE II group) when revision of the tibial and/or the talar component was used as the end point. The mean AOFAS ankle-hindfoot score improved from 44.1 to 87.3 at the time of the latest follow-up ($p < 0.01$), and the mean VAS pain score improved from 8.1 to 1.6 ($p < 0.01$). Mean total ankle motion improved from 29.0° to 38.0° ($p < 0.01$). Fourteen patients (24%) required a reoperation because of a postoperative complication. Five of these patients (four with INBONE I implants and one with INBONE II	59

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							alignment and subsidence. Intraoperative and postoperative complications, reoperations, and failures were evaluated.	implants; 8% of the entire cohort) required revision surgery at a mean of 32.4 months (range, fifteen to fifty-eight months) because of symptomatic talar subsidence. Talar revisions utilized an INBONE II implant with a pegged talar sulcus for definitive management. The patients who underwent revision surgery had mean total ankle motion of 41.6°, neutral alignment, and no further reoperations at the time of the latest follow-up.	
Ankle	Arthroplasty, ankle (TAR)	(Jastifer, 2015)	Gait studies comparing TAR and AA have shown improvement walking on uneven surfaces in both groups, but better ability to walk uphill and up and down stairs with TAR.	3b	25201334	Patients with TAA and ankle arthrodesis had improved performance walking on uneven surfaces at 12 months of follow-up compared to preoperatively. TAA patients had higher scores than the ankle arthrodesis patients walking upstairs, downstairs, and uphill.	Between 2010 and 2013, 77 consecutive patients were enrolled in a prospective study and completed 12 months of follow-up. Patients received either a TAA (61 patients) or an ankle arthrodesis	There was no statistically significant difference between the patient groups preoperatively (all P > .05). Both TAA and ankle arthrodesis groups had high patient satisfaction, 3.5 and 3.4 out of 4.0, respectively. Both groups had improvement in Buechel-Pappas scores, VAS pain scores, AOFAS	77 patients

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							(16 patients). Preoperatively, at 6 months and 12 months postoperatively, patients were evaluated clinically and functionally on stairs, an inclined ramp, and an uneven surface. Patients graded their function on these surfaces using a visual analog scale (VAS) in addition to standard clinical grading scales.	Ankle Hindfoot scores, and functional scores (all P values < .05). TAA patients had a significantly better outcome than the arthrodesis patients in the Buechel-Pappas scale (P = .036), AOFAS Ankle Hindfoot score (P = .03), ankle dorsiflexion (P < .001), ankle plantarflexion (P < .001), walking upstairs (P = .013), walking downstairs (P = .012), and walking uphill (P = .016).	
Ankle	Arthroplasty, ankle (TAR)	(Jiang, 2015)	Another large national database comparing 3,002 TAR vs. 12,250 AA cases concluded that there was little difference in early surgical risks between the 2 procedures.	1b	25358807	TAA was independently associated with a lower risk of blood transfusion, non-home discharge, and overall complication when compared to AAD during the index hospitalization period. TAA was also independently	Using the Nationwide Inpatient Sample (NIS) database from 2002 to 2011, 12 250 patients who underwent AAD and 3002 patients who underwent TAA were identified	Multivariate analysis demonstrated that TAA was independently associated with a decreased risk of blood transfusion (relative risk [RR] = 0.53, P < .001), non-home discharge (RR = 0.70, P < .001), and overall complication (RR = 0.79, P = .03). There were similar rates of	12250

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						associated with a higher hospitalization charge, but length of stay was similar between the 2 groups. Until long-term comparative studies are performed, the optimal treatment for end-stage ankle arthritis remains controversial, this study provides greater clarity with regard to hospitalization outcomes after the 2 procedures and shows no significant difference in risk for the majority of medical perioperative complications.	based on International Classification of Diseases, Ninth Revision (ICD-9) codes. The demographics, comorbidities, and perioperative outcomes during the index hospital stay were compared between patients who underwent AAD and TAA. Multivariate analysis was performed to adjust for differences in demographics and comorbidities between the 2 groups.	pneumonia, deep vein thrombosis, pulmonary embolus, cerebrovascular accident, myocardial infarction, and mortality. TAA was independently associated with a significantly higher hospital charge (difference = $24 431, P < .001). There was no significant difference in the adjusted length of stay between the 2 groups (P = .13).	
Ankle	Arthroplasty, ankle (TAR)	(Kamrad, 2015)	Even worse results from the same registry for revision TAR subsequently showed only 55% 10-year survival vs. 74%	1a	25673048	Revision TAR had a 10-year survival of 55%, which is lower than the 10-year survival of 74% for primary TAR reported from the	We analyzed prosthetic survival, self-reported function, and patient	69 patients underwent revision TAR median 22 (0-110) months after the primary procedure. 24 of these failed again after median 26 (1-110)	69

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			(updated) for primary TAR.			same registry. Only half of the patients were satisfied. Future studies should show which, if any, patients benefit from revision TAR and which patients should rather be fused directly.	satisfaction after component exchange. Patients and methods We identified patients in the Swedish Ankle Registry who underwent exchange of a tibial and/or talar component between January 1, 1993 and July 1, 2013 and estimated prosthetic survival by Kaplan-Meier analysis. We evaluated the patient-reported outcome measures (PROMs) SEFAS, EQ-5D, EQ-VAS, SF-36, and patient satisfaction by direct questions.	months. Survival analysis of revision TAR showed a 5-year survival rate of 76% and a 10-year survival of 55%. 29 patients with first revision TAR in situ answered the PROMs at mean 8 (1-17) years after revision and had the following mean scores: SEFAS 22, SF-36 physical 37 and mental 49, EQ-5D index 0.6, and EQ-VAS 64. 15 of the patients were satisfied, 5 were neither satisfied nor dissatisfied, and 9 were dissatisfied.	
Ankle	Arthroplasty, Ankle (TAR)	(Kamrad, 2016)	In cases with total ankle replacement (TAR) failure, a decision	**3a**	26582180	Salvage arthrodesis after failed TAR had a solid arthrodesis rate	Until September 2014, a total of 1110 primary	The first-attempt solid arthrodesis rate of SA was 90%. Overall, 25 of	118

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
			between revision TAR and salvage arthrodesis (SA) must be made. In a previous study, we analyzed revision TAR and found low functional outcome and satisfaction. The aims of the current study were to analyze SA concerning failure rate and patient-related outcome measures (PROMs). Based on this data from the Swedish Registry the authors favored AA for failed TAR.			of 90% at first attempt, but similar to revision TAR, less than 50% of the patients were satisfied and the functional scores were low. Until studies show true benefit of revision TAR over SA, the authors favor SA for failed TAR.	TARs were recorded in the Swedish Ankle Registry. Of the 188 failures, 118 were revised with SA (and 70 with revision TAR). Patient- and implant-specific data for SA cases were analyzed as well as arthrodesis techniques. Failure of SA was defined as repeat arthrodesis or amputation. Generic and region-specific PROMs of 68 patients alive with a solid unilateral SA performed more than 1 year before were analyzed.	53 (47%) patients were very satisfied or satisfied. Mean Self-reported Foot and Ankle Score (SEFAS) was 22 (95% confidence interval 20-24), Euro Qol-5 Dimensions 0.57 (0.49-0.65), Euro Qol-Visual Analogue Scale 59 (53-64), Short Form-36 physical 34 (31-37) and mental 50 (46-54). The scores and satisfaction were similar to those after revision TAR but the reoperation rate was significantly lower in SA ($P < .05$).	
Ankle	Arthroplasty, ankle (TAR)	(Kane, 2015)	Platelet-rich plasma (PRP) has not been shown to improve TAR	3b	26614769	Limited data exist regarding the use of PRP in the augmentation of the	A retrospective review of 133 consecutive Agility TAR	No statistically significant difference existed between patients treated with	133 TAR's

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
			results or specifically incisional healing.			closure of operative incisions. This Study was unable to find a statistically significant reduction in incision-related complications in patients who had their incisions augmented with PRP.	performed by a single surgeon at a single institution was conducted. Platelet-rich plasma was used to augment incisional closure in 78 patients undergoing TAR. Fifty-five patients had incisional closure without PRP application. Incision healing complications were stratified into patients healing without any complications (none), patients requiring prolonged local wound care (minor), and patients requiring a return to the operation theater to address an incisional	PRP incisional augmentation and those without PRP augmentation. Eight patients (10.3%) receiving PRP underwent operative treatment of an incisional complication, whereas 3 patients (5.5%) who had a nonaugmented closure required operative treatment (P = .52). The incidence of minor complications was not statistically significant, with 25 (32.1%) patients receiving PRP and 15 (27.3) patients who had a nonaugmented closure requiring prolonged local treatment (P = .85).	

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							complication (major).		
Ankle	Arthroplasty, ankle (TAR)	(Kennedy, 2015)	The SF-36 Mental Component Summary (MCS) for TAR and AA studies used for years has been shown to not be predictive of functional outcomes following these procedures. (	1b	26491135	The study of patients with end-stage ankle arthritis treated with arthroplasty or arthrodesis, concluded that preoperative mental health status (as measured with the MCS score) did not predict functional outcome (as measured by the change in the AOS score) at the time of intermediate-term postoperative follow-up. AOS scores improved for all patients, regardless of the preoperative MCS score.	Preoperative and postoperative patient scores on the SF-36 MCS and AOS questionnaires were obtained from the Canadian Orthopaedic Foot and Ankle Society (COFAS) End-Stage Ankle Arthritis Database. The relationship between the preoperative MCS score and the change in the total AOS score at the time of final follow-up was summarized with use of a Pearson correlation coefficient (r). Subgroup analyses according to the type of	Of an initial 372 ankles enrolled, 337 (91%, ninety-five arthrodeses and 242 arthroplasties) were reviewed after a mean duration of follow-up of 5.2 ± 1.3 years. Analysis revealed no correlation between the preoperative MCS score and the change in the AOS score, from the preoperative baseline to either a mean 5.2 years postoperatively or two years postoperatively (r < 0.1 in both analyses). There was no difference in the change in the AOS score between patients with a preoperative MCS score of <50 and those with a preoperative MCS score of ≥50.	372 ankles

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							treatment (ankle arthrodesis versus ankle arthroplasty) and preoperative MCS score (<50 versus ≥50) were conducted.		
Ankle	Arthroplasty, ankle (TAR)	(Lee, 2011)	Heterotopic ossification has also been reported to develop following TAR in up to 25%, usually resulting in stiffness and poor clinical outcomes.	3b	21508282	This study demonstrates that the prevalence of heterotopic ossification following primary total ankle arthroplasty is considerable, and that heterotopic ossification is associated with reduced ankle motion and a poor clinical outcome at a mean of two years postoperatively. Care is needed to attempt to reduce the occurrence of heterotopic ossification.	Eighty ankles in eighty patients with a primary total ankle arthroplasty were followed for a mean (and standard deviation) of 31.9 ± 11.3 months (range, twenty-four to sixty-five months). The prevalence and location of heterotopic ossification, predisposing factors, and outcomes were analyzed, and a method of classification was developed.	Twenty (25%) of the eighty ankles demonstrated postoperative heterotopic ossification, with the majority of the cases in the posterior aspect of the ankle. The heterotopic ossification was Class I in four cases (20%); Class II, in five (25%); Class III, in four (20%); and Class IV, in seven (35%). Symptomatic heterotopic ossification was reported in eight patients (10%), and two required surgical resection because of intractable pain. Ankles that developed heterotopic ossification had significantly longer operative times, less postoperative motion,	80

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								and lower American Orthopaedic Foot & Ankle Society ankle-hindfoot scores at the six, twelve, and twenty-four-month follow-up examinations ($p < 0.05$ for all).	
Ankle	Arthroplasty, ankle (TAR)	(Lewis, 2015)	A study comparing 1st and 2nd generation fixed bearing TAR implants reported a decrease in re-operations from 18.5% to 15.9%, only a slight improvement with newer implant designs.	3b	25769492	Patients who underwent TAR with a first- or second-generation fixed-bearing prosthesis with an intramedullary tibial component demonstrated significant improvements in all measures of pain and function with sustained improvements in coronal plane alignment. The second-generation prosthesis demonstrated slightly better improvements at 1 year and was associated with lower reoperation and implant failure rates.	A consecutive series of first- and second-generation primary TARs with modular intramedullary stems were identified. Clinical outcome data were collected prospectively--including visual analog scale for pain, American Orthopaedic Foot & Ankle Society hindfoot-ankle, Short Musculoskeletal Function Assessment, and Short Form-36 scores. Preoperative	Clinical outcome data reflected significant improvements at 1 year postoperatively, and improvements were maintained at 2-year follow-up for each group. Improvement in visual analog scale scores were significantly better in the second-generation group at 1 year postoperatively, but this was not maintained at 2 years. Mean coronal tibiotalar angles for ankles with preoperative varus or valgus deformities were significantly improved. Correction was maintained until final follow-up, with no significant differences in deformity improvement between groups. The	249

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							coronal plane deformity and correction of deformity after TAR were assessed. Complications, subsequent procedures, and failure rates were compared. A total of 193 first- and 56 second-generation patients were identified with a mean follow-up of 3.7 and 2.1 years, respectively.	rate of reoperation at 2 years postoperatively on the affected foot or ankle subsequent to the index ankle replacement for patients in the first-generation group (18.5%) was higher compared to the second-generation group (15.9%), but the time until reoperation was not statistically significant (P = .376). The implant failure rate was higher in the first-generation group (6.0%) compared to the second-generation group (2.6%) at 2 years postoperatively, but the time until failure was not significantly different (P = .295).	
Ankle	Arthroplasty, Ankle (TAR)	(Mann, 2011)	A prospective 9-year follow-up of 84 STAR ankles reported 91% implant retention and 92% patient satisfaction, with 25% reported complications	3b	21733455	The first U.S. prospective long-term survivorship data with the STAR™ Ankle prosthesis found it to be an excellent long-term option for the	Eighty-four total ankle replacements were performed in 80 patients using the STAR™ Ankle prosthesis and followed	Ninety-one percent of prostheses remain implanted at an average follow up of 9.1 years. The probability of implant survival was 96% at 5 years and 90% at 10 years. An average	84 STAR ankles

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						treatment of ankle arthritis.	prospectively. Postoperatively, patients were evaluated with the AOFAS score for pain and function, and serial radiographs were evaluated for stability and alignment of the prosthesis. Implant failure, secondary procedures, and complications were recorded.	39-point improvement in the AOFAS ankle-hindfoot score was noted, from a mean of 43 to a mean of 82 points. We noted a statistically significant increase in both average pain and function sub-scores. Postoperative range of motion averaged 4.5 degrees of dorsiflexion and 35 degrees of plantarflexion. Ninety-two percent of the patients were satisfied with their outcome. Ten patients (13%) developed concerning osteolytic lesions. Change in prosthetic alignment and adjacent joint arthritis were similar to previous reports. We report 21 complications, which included 14 additional surgical procedures.	
Ankle	Arthroplasty, ankle (TAR)	(Matsumoto, 2015)	Use of negative pressure wound therapy decreased incisional healing problems from	3b	25736324	This study demonstrated that there was a decreased incidence of wound healing problems	This is a retrospective cohort study including consecutive	All patients tolerated the incisional NPWT to completion without any dressing failures or skin problems. Both groups	74 Patients

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
			24% to 3% in a retrospective cohort.			following total ankle arthroplasty with incisional NPWT dressings. This is the first study evaluating the efficacy of incisional NPWT as an adjunct treatment for wound healing after total ankle arthroplasty.	patients who underwent total ankle arthroplasty by a single surgeon at a single institution between 2009 and 2013. The incisional negative pressure dressing was applied to all patients who underwent total ankle arthroplasty between 2012 and 2013 with a continuous application of -80 mm Hg negative pressure for 6 days postoperatively. The control group consisted of patients who underwent total ankle arthroplasty between 2009 and 2012 with a	showed similar distributions in demographics and perioperative risk factors for wound healing. There were 9 (24%) wound healing problems in the control group and 1 (3%) in the incisional NPWT group. Incisional NPWT was found to reduce wound healing problems with an odds ratio of 0.10 (95% CI, 0.01-0.50; P = .004).	

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
							conventional nonadherent gauze dressing. Seventy-four patients were involved in this study: 37 in the control group and 37 in the incisional NPWT group.		
Ankle	Arthroplasty, ankle (TAR)	(Mercer, 2016)	Inconsistencies in reporting adverse events related to TAR were observed in a systematic review (SR) of 117 studies, with highly variable complication descriptions, suggesting the need for better standardized reporting tools.	1b	26445992	The reporting of complications and adverse outcomes for total ankle arthroplasty was highly variable. This lack of consistency impedes the accurate reporting and interpretation of data required for the development of cohesive, evidence-based treatment guidelines for end-stage ankle arthritis. Standardized reporting tools are urgently needed. This study presents a prototype worksheet for the standardized assessment and	Studies that met predefined inclusion/exclusion criteria were analyzed to identify terminology used to describe adverse events. All terms were then tabulated and quantified with regard to diversity and frequency of use across all included studies. Terms were also grouped into 10 categories, and the number of reported occurrences of	Of 572 unique terms used to describe adverse outcomes in 117 studies, 55.9% (320/572) were used in only a single study. The category that was most frequently reported was revision surgery, with 86% of papers reporting on this event using 115 different terms. Other categories included "additional non-revision surgeries" (74% of papers, 93 terms), "loosening/osteolysis" (63% of papers, 86 terms), "fractures" (60% of papers, 53 terms), "wound problems" (52% of papers, 27 terms), "infection" (52% of	572

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						reporting of adverse events.	each adverse event was calculated. A reporting tool was then developed.	papers, 27 terms), "implant problems" (50% of papers, 57 terms), "soft tissue injuries" (31% of papers, 30 terms), "heterotopic ossification" (22% of papers, 17 terms), and "pain" (18% of papers, 11 terms).	
Ankle	Arthroplasty, ankle (TAR)	(Nieuwe, 2015)	Most studies on total ankle replacement (TAR) have used a case mix of patients. This study evaluated the outcome of TAR performed for end-stage arthritis either because of fracture or ligamentous injury.	3b	25772269		The Study prospectively followed 88 consecutive patients (50 postfracture ankles and 40 ankles with instability arthritis (2 bilateral)) who underwent TAR between 2001 and 2009. Mean follow-up for both groups was 5 years.	Preoperative varus deformity of 10° or more was present in 23 ankles in the instability group. At 6 years, survival with revision or salvage fusion as an endpoint was 87% (95% CI: 74-99) in the postfracture group and 79% (95% CI: 63-94) in the instability group. Progressive periprosthetic osteolysis was seen in 23 ankles, and required salvage fusion in 6. The number of reoperations was similar in both groups. Clinical outcome, as assessed with 2 ankle scores and 2 questionnaires, showed good results and was	88 patients

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								similar at the latest follow-up	
Ankle	Arthroplasty, ankle (TAR)	(Pedersen, 2014)	Outcomes of TAR for patients with rheumatoid arthritis have proven to be similar to non-inflammatory forms of arthritis.	3b	25378503	Patients with rheumatoid arthritis benefit from total ankle arthroplasty and have similar outcomes to patients with noninflammatory arthritis. The overall pain and disability were worse for patients with rheumatoid arthritis than for those with noninflammatory arthritis preoperatively, but this did not negatively influence their final outcomes. When properly treated, patients with rheumatoid arthritis achieve good results.	Fifty patients with rheumatoid arthritis were compared with fifty patients with noninflammatory arthritis (the control group), matched for age within ten years, prosthesis type, and follow-up time. All patients underwent total ankle arthroplasty. Revisions and major complications were noted. Outcome scores included the Ankle Osteoarthritis Scale (AOS) and Short Form-36 (SF-36) Health Survey.	The groups were similar with respect to body mass index and length of follow-up (mean, 63.8 months for the rheumatoid arthritis group and 65.6 months for noninflammatory arthritis group); the rheumatoid arthritis group was younger (mean, 58.5 years compared with 61.2 years). The mean AOS pain scores were significantly different in the rheumatoid arthritis and noninflammatory arthritis groups preoperatively ($p < 0.01$), but were similar following total ankle arthroplasty (mean and standard deviation, 18.5 ± 17.8 for the rheumatoid arthritis group and 19.7 ± 16.5 for the noninflammatory arthritis group; $p = 0.93$). Both groups showed significant improvement ($p < 0.05$) with regard to	100 patients (50 with RA & 50 with non-inflammatory arthritis)

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								the AOS scores for pain and disability and SF-36 physical component summary scores following surgery. Postoperatively, AOS disability and SF-36 physical component summary scores were better for patients with noninflammatory arthritis. There were seven revisions in the rheumatoid arthritis group and five in noninflammatory arthritis group. There was one major wound complication in the rheumatoid arthritis cohort and none in the control cohort.	
Ankle	Arthroplasty, ankle (TAR)	(Primadi, 2015)	A review of 150 consecutive mobile-bearing TARs indicated a considerable incidence of neurological injuries (15.3%) including posterior tibial, superficial peroneal, deep peroneal, saphenous, and sural nerves--with only half	3b	26435751	The results of this study suggest that the prevalence of neurologic injury after total ankle arthroplasty is considerable, and that neurologic injury is associated with low levels of patient satisfaction and poor clinical outcomes at	We retrospectively analyzed 150 consecutive primary total ankle arthroplasty using the mobile-bearing prosthesis between January 2005 and	There were 23 nerve injuries (15.3 %), including nine in posterior tibial nerves, six superficial peroneal nerves, six deep peroneal nerves, one saphenous nerve, and one sural nerve. Neurologic injury was significantly associated with the development of	150

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			spontaneously and fully recovering.			mean of 3 years, postoperatively. Care is needed to reduce the occurrence of neurologic injuries.	December 2011, in 150 patients with symptomatic ankle end-stage arthritis. All the patients were divided into groups according to whether they had postoperative peripheral neuropathy (23 patients) or not (127 patients). We investigated the prevalence, predisposing factors, and effect on clinical outcomes of neurologic injuries. The mean age was 61.3 years, and the mean follow-up period was 41.8 months.	posttraumatic osteoarthritis, but it was not significantly associated with other predisposing factors, such as age, gender, body mass index, and symptom duration. Of the 23 nerve injuries, 13 (56.5 %) presented a complete, spontaneous recovery, 9 (39.1 %) presented an incomplete recovery, and 1 (4.3 %) presented no recovery. The patients with neurologic injury had significantly lower American Orthopaedic Foot and Ankle Society scores and lower levels of patient satisfaction.	
Ankle	Arthroplasty, ankle (TAR)	(Queen, 2013)	Excessive tibiotalar malalignment in the coronal plane has been considered by some to be a contraindication to	3b	24196462	Total ankle replacement improves clinical and functional outcomes independent of	One hundred and three patients undergoing total ankle	Coronal plane alignment improved following the procedure, with 36.9% of patients having neutral alignment	103 patients

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			total ankle replacement. The purpose of the present study was to compare clinical outcomes and physical performance measures according to preoperative tibiotalar alignment.			preoperative tibiotalar alignment when postoperative alignment is restored to neutral at the time of arthroplasty.	replacement were grouped according to coronal plane tibiotalar alignment. Seventeen patients had an excessive deformity (>15° of varus or valgus), twenty-one had moderate valgus alignment (5° to 15° of valgus), twenty-seven had moderate varus alignment (5° to 15° of varus), and thirty-eight had neutral alignment (<5° of varus or valgus). Outcome measures, including the American Orthopaedic Foot & Ankle Society (AOFAS) hindfoot score, the Foot and	preoperatively as compared with 95% postoperatively. To achieve this alignment, adjunctive procedures, including deltoid ligament release, lateral ligament reconstruction, and posterior soft-tissue releases, were necessary. Significant improvements were seen for the Page: 3 AOFAS pain, function, alignment, and hindfoot scores ($p < 0.001$) and the SF-36 subscales of body pain, physical function, and role physical ($p < 0.001$) following total ankle replacement. Walking speed and the FADI, TUG, and 4SST scores also improved significantly ($p < 0.001$). Subgroup analysis demonstrated no significant differences in clinical outcomes and physical performance measures based on preoperative coronal plane alignment.	

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							Ankle Disability Index (FADI), the Short Form-36 (SF-36), the timed up and go test (TUG), the four square step test (4SST), and walking speed, were assessed preoperatively and at one and two years after total ankle replacement.		
Ankle	Arthroplasty, Ankle (TAR)	(Roukis, 2012)	A systematic review of electronic databases and other relevant sources to identify material relating to the incidence of revision after primary implantation of the Agility™ Total Ankle Replacement System.	1b	22188902	The incidence of revision after primary implantation of the Agility™ Total Ankle Replacement System was less than historically reported and amenable to implant component revision more than 80% of the time. However, methodologically sound cohort studies are needed that include the outcomes after revision surgery, specifically focusing on what implant	Studies were eligible for inclusion only if they involved patients undergoing primary Agility™ Total Ankle Replacement; had evaluated patients at a mean follow-up of 12 months or longer; included details of the revision performed; and included revision etiologies of	No significant effect from the surgeon's learning curve on the incidence of revision or the type of revision surgery performed was identified. However, excluding the inventor increased the incidence of revision twofold, from 6.6% to 12.2%, and skewed the type of revision away from arthrodesis and toward implant component replacement or below-knee amputation	2312 ankles

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
						component replacement techniques are effective in enhancing survivorship of these revised implants and the role of custom-stemmed talar and tibial components have in revision of the Agility™ Total Ankle Replacement System. A direct comparison of the incidence of revision between the various contemporary total ankle replacement systems in common use is also warranted.	aseptic loosening, ballooning osteolysis, cystic changes, malalignment, or instability. A total of 14 studies involving 2312 ankles, with a weighted mean follow-up of 22.8 months, were included. Of the 2312 ankles, 224 (9.7%) underwent revision, of which 182 (81.3%) underwent implant component replacement, 34 (15.2%) underwent arthrodesis, and 8 (3.6%) underwent below-knee amputation.		
Ankle	Arthroplasty, Ankle (TAR)	(Roukis, 2014)	Before market removal, the Agility uncemented	5b	23954094	Geometric metal-reinforced	The authors describe a	The technique preserves the subtalar joint,	**N/A**

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
			TAR was the most commonly used implant in the U.S. from 1998-2007, but intermediate to long-term complications of aseptic osteolysis and talar subsidence or loosening have proven to be problematic, with limited and difficult revision options.			polymethylmethacrylate cement augmentation is a technique that preserves the subtalar joint, provides immediate component stability and restoration of component alignment and height, and is a cost-effective alternative to other available options and still allows for additional revision should late failure occur.	technique for management of extensive talar aseptic osteolysis for revision of Agility™ total ankle replacement systems with use of geometric metal-reinforced polymethylmethacrylate cement augmentation.	provides immediate component stability and restoration of component alignment and height, and is a cost-effective alternative to other available options and still allows for additional revision should late failure occur.	
Ankle	Arthroplasty, Ankle (TAR)	(Roukis, 2015)	An Systematic Review of 212 Salto Talaris TAR implants showed only a 2.4% incidence of revision at less than 3 years, lower than previously reported for other designs.	1b	25907761	The incidence of revision for the Salto(®) mobile version and Salto Talaris™ total ankle prostheses was lower than those reported through systematic review for the Agility™ and Scandinavian Total Ankle Replacement™ systems without obvious selection (inventor) or	Studies were eligible for inclusion only if they had involved primary total ankle replacement with these prostheses and had included the incidence of revision. Eight studies involving 1,209 Salto(®) mobile version prostheses, with	Restricting the data to the inventor, design team, or disclosed consultants, the incidence of revision was 5.2% for the Salto(®) mobile version and 2.6% for the Salto Talaris™ total ankle prostheses. In contrast, data that excluded these individuals had an incidence of revision of 2.8% for the Salto(®) mobile version and 2.0% for the Salto Talaris™	1,209

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						publication (conflict of interest) bias.	a weighted mean follow-up period of 55.2 months, and 5 studies involving 212 Salto Talaris™ total ankle prostheses, with a weighted mean follow-up period of 34.9 months, were included. Forty-eight patients with Salto(®) mobile version prostheses (4%) underwent revision, of whom 24 (70.5%) underwent ankle arthrodesis, 9 (26.5%) metallic component replacement, and 1 (3%) below-the-knee amputation. Five (2.4%) Salto Talaris™ total ankle prostheses underwent revision (3	total ankle prostheses. We could not identify any obvious difference in the etiology responsible for the incidence of revision between these mobile- and fixed-bearing prostheses.	

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							metallic component replacement and 2 ankle arthrodeses).		
Ankle	Arthroplasty, Ankle (TAR)	(Saltzman, 2009)	The goal of the present study was to perform a prospective evaluation of the safety and efficacy of a mobile-bearing prosthesis to treat end stage ankle arthritis. We report the results of three separate cohorts of patients: a group of Scandanavian Total Ankle Replacement (STAR) patients and a control group of ankle fusion patients (the Pivotal Study Groups) and another group of STAR total ankle patients (Continued Access Group) whose surgery was performed following the completion of enrollment in the Pivotal Study.	3b	19589303	By 24 months, ankles treated with STAR ankle replacement (in both the Pivotal and Continued Access Groups) had better function and equivalent pain relief as ankles treated with fusion.	he Pivotal Study design was a non-inferiority study using ankle fusion as the control. A non-randomized multi-centered design with concurrent fusion controls was used. We report the initial perioperative findings up to 24 months following surgery. For an individual patient to be considered an overall success, all of the following criteria needed to be met: a) a 40-point improvement in total Buechel-	Major complications and need for secondary surgical intervention were more common in the Pivotal Study arthroplasty group than the Pivotal Study ankle fusion group. In the Continued Access Group, secondary procedures performed on these arthroplasty patients decreased by half when compared with the Pivotal Arthroplasty Group. When the Pivotal Groups were compared, treatment efficacy was higher for the ankle replacement group due to improvement in functional scores. Pain relief was equivalent between fusion and replacement patients. The hypothesis of non-inferiority of ankle	672 Proced-ures

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
							Pappas ankle score, b) no device failures, revisions, or removals, c) radiographic success, and d) no major complications. In the Pivotal Study (9/00 to 12/01), 158 ankle replacement and 66 arthrodesis procedures were performed; in the Continued Access Study (4/02 to 10/06), 448 ankle replacements were performed, of which 416 were at minimum 24 months post-surgery at time of the database closure.	replacement was met for overall patient success.	
Ankle	Arthroplasty, ankle (TAR)	(Schipper, 2015)	Diabetes is also a proven risk factor. A national database comparison of 12,122 AA vs. 2,973 TAR patients revealed an	1a	25413307	After both AAD and TAA, diabetes mellitus was independently associated with a significantly increased	Using the Nationwide Inpatient Sample database, 12 122 patients who	The overall complication rate in the AAD group was 16.4% in diabetic patients and 7.0% in nondiabetic patients (P <	12122

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			increased complication rate for AA from 7.0 to 16.4% and for TAR from 4.7 to 7.8% for diabetics. Perioperative complications, non-home discharge, and hospital length-of-stay was significantly increased for both procedures.			risk of perioperative complications, nonhome discharge, and length of hospital stay during the index hospitalization.	underwent AAD and 2973 patients who underwent TAA were identified from 2002 to 2011 based on ICD-9 procedure codes. The perioperative complications and hospitalization outcomes were compared between diabetic and nondiabetic patients for each surgery during the index hospital stay.	.001). Multivariate analysis demonstrated that diabetes mellitus was independently associated with an increased risk of myocardial infarction (relative risk [RR] = 3.2, P = .008), urinary tract infection (RR = 4.6, P < .001), blood transfusion (RR = 3.0, P < .001), irrigation and debridement (RR = 1.9, P = .001), and overall complication rate (RR = 2.7, P < .001). Diabetes was also independently associated with a statistically significant increase in length of hospital stay (difference = 0.35 days, P < .001), more frequent nonhome discharge (RR = 1.69, P < .001), and higher hospitalization charges (difference = $1908, P = .04). The overall complication rate in the TAA group was 7.8% in diabetic patients and 4.7% in nondiabetic patients. Multivariate analysis demonstrated	

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								that diabetes was independently associated with increased risk of blood transfusion (RR = 9.8, P = .03) and overall complication rate (RR = 4.1, P = .02). Diabetes was also independently associated with a statistically significant increase in length of stay (difference = 0.41 days, P < .001) and more frequent nonhome discharge (RR = 1.88, P < .001), but there was no significant difference in hospitalization charges (P = .64).	
Ankle	Arthroplasty, ankle (TAR)	(Schipper, 2016)	Conflicting analyses of the effects of obesity on TAR outcomes have been reported, but problems have been seen long-term. BMI >30 significantly decreased 5-year implant survivorship, not seen at early follow-up in a sizable retrospective cohort.	3b	26377201	This study demonstrated an increased long-term risk of implant failure among obese patients that was not seen in the intermediate term. Furthermore, obese patients with primary osteoarthritis were found to have a significantly decreased 5-year implant survivorship after	A chart review was performed for all patients who underwent primary total ankle arthroplasty between 2004 and 2009 with a minimum 5-year follow-up. Patients were separated into a reference group	Based on multivariable logistic regression, obese patients had a significantly greater probability of implant failure by final follow-up (adjusted odds ratio, 2.8 [95% CI, 1.04-7.53]; P = .04). Cox regression analysis of 5-year implant survivorship showed no significant difference between the 2 groups (adjusted	97

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						ankle arthroplasty as compared with obese patients with inflammatory or posttraumatic arthritis and therefore should be counseled appropriately when deciding between arthroplasty and arthrodesis.	with a body mass index less than 30 kg/m2 and an obese group with an index greater than or equal to 30 kg/m2. Minimum 5-year follow-up outcomes were available for 49 patients in the obese group and 48 patients in the nonobese group. Mean follow-up was 8.2 ± 2.0 years (range, 5.1-11.5 years) in the reference group and 7.7 ± 2.0 years (range, 5.0-11.9 years) in the obese group (P = .26).	hazard ratio, 1.89 [95% CI, 0.77-4.65]; P = .17). When compared with obese patients with inflammatory or posttraumatic arthritis, obese patients with osteoarthritis demonstrated a significantly decreased 5-year survivorship (adjusted hazard ratio, 3.73 [95% CI, 1.05-10.43]; P = .04).	
Ankle	Arthroplasty, ankle (TAR)	(Singer, 2013)	Comparable and significantly improved gait has been consistently measured with both TAR and AA procedures.	**3b**	24352777	The gait patterns of patients following three-component, mobile-bearing total ankle arthroplasty more closely resembled normal gait	Gait analyses were performed on patients with isolated ankle arthritis more than one year after undergoing	Patients who had undergone arthroplasty, when compared with patients who had undergone arthrodesis, demonstrated greater postoperative total	44 subjects (17 TAR, 17 AA & 10 Control)

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						when compared with the gait patterns of patients following arthrodesis. Dorsal motion in the sagittal plane was primarily responsible for the differences. Improvement in self-reported clinical outcome scores was similar for both groups. Further investigation is needed to determine why patients who have undergone total ankle arthroplasty do not use the plantar flexion motion in the terminal-stance phase and to explain the limited increase in power generation at toe-off after arthroplasty. Results obtained from this study may be used for future modifications of ankle prostheses and may add to clinicians' ability to inform patients of predicted functional outcomes prior to the	either total ankle arthroplasty or arthrodesis during a ten-year period. Validated outcome questionnaire data were obtained. Seventeen patients undergoing total ankle arthroplasty, seventeen patients undergoing arthrodesis, and ten matched control subjects were included for comparison.	sagittal plane motion (18.1° versus 13.7°; $p < 0.05$), dorsiflexion (11.9° versus 6.8°; $p < 0.05$), and range of tibial tilt (23.1° versus 19.1°; $p < 0.05$). Plantar flexion motion was not equivalent to normal in either group. Ankle moments and power in both treatment groups remained significantly lower compared with the control group ($p < 0.05$ between each treatment group and the control group for both variables). Gait patterns in both treatment groups were not completely normalized. Improvements in patient-reported Ankle Osteoarthritis Scale and Short Form-36 scores were similar for both treatment groups.	

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						treatment of end-stage ankle osteoarthritis.			
Ankle	Arthroplasty, ankle (TAR)	(Singh, 2016)	Despite known high prosthetic failure rates, the utilization of TAR in the U.S. increased over 6-fold from 1998-2010.	1b	24907036	Underlying diagnosis and medical comorbidity changed over time and both can impact outcomes after TAA. Further studies should examine how the outcomes and complications of TAA have evolved over time.	We used the Nationwide Inpatient Sample (NIS) data from 1998 to 2010 to examine time trends in the utilization rates of TAA. We used the Cochran Armitage test for trend to assess time trends across the years and the analysis of variance (ANOVA), Wilcoxon test, or chi-squared test (as appropriate) to compare the first (1998-2000) and the last time periods (2009-2010).	TAA utilization rate increased significant from 1998 to 2010: 0.13 to 0.84 per 100,000 overall, 0.14 to 0.88 per 100,000 in females, and from 0.11 to 0.81 per 100,000 in males ($p < 0.0001$ for each comparison for time trends). Compared to the 1998-2000 period, those undergoing TAA in 2009-2010 were older (41% fewer patients <50 years, $p < 0.0001$), less likely to have rheumatoid arthritis as the underlying diagnosis (55% fewer patients, $p = 0.0001$), more likely to have Deyo-Charlson index of 2 or more (197% more, $p = 0.0010$), and had a shorter length of stay at 2.5 days (17% reduction, $p < 0.0001$). Mortality was rare ranging from 0 to 0.6% and discharge to inpatient facility ranged	10000

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								12.6-14.1%; we noted no significant time trends in either ($p > 0.05$).	
Ankle	Arthroplasty, ankle (TAR)	(Skyttä, 2010)	A Finnish registry also showed only 83% 5-year survivorship, with re-operation primarily for aseptic loosening and instability.	1b	20180720	Based on our findings, we cannot conclude that any prosthesis was superior to any other. A high number of technical errors in primary TARs suggests that this low-volume field of implant arthroplasty should be centralized to fewer units.	573 primary TARs were performed during the period 1982-2006 because of rheumatic, arthritic, or posttraumatic ankle degeneration. We selected contemporary TAR designs that were each used in more than 40 operations, including the S.T.A.R. (n = 217) and AES (n = 298), to assess their respective survival rates. The mean age of the patients was 55 (17-86) years and 63% of operations were performed in women. Kaplan-	The annual incidence of TAR was 1.5 per 10(5) inhabitants. The 5-year overall survivorship for the whole TAR cohort was 83% (95% CI: 81-86), which agrees with earlier reports. The most frequent reasons for revision were aseptic loosening of one or both of the prosthesis components (39%) and instability (39%). We found no difference in survival rate between the S.T.A.R. and AES designs. Furthermore, age, sex, diagnosis, and hospital volume (< 10 and > 100 replacements in each of 17 hospitals) did not affect the TAR survival.	573

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							Meier analysis and the Cox regression model were used for survival analysis. The effects of age, sex, diagnosis, and hospital volume were also studied.		
Ankle	Arthroplasty, Ankle (TAR)	(Tenenbaum, 2014)	This study assessed the hypothesis that arthrodesis of both the ankle and the hindfoot joints produces an objective improvement of function as measured by gait analysis of patients with severe ankle and hindfoot arthritis. One author, noting marked improvement following combined AA and subtalar arthrodesis has suggested that pain is likely more important than stiffness in asymmetric gait.	**3b**	25410503	There was a small loss of sagittal plane motion in the affected limb postoperatively. There were marked increases in gait velocity, ankle moment, and hip motion and power, documenting objective improvements in ambulatory function. The data showed that preoperative ankle motion was greatly diminished. This may suggest that pain is more important than stiffness in asymmetric gait.	Twenty-one patients with severe ankle and hindfoot arthritis who underwent unilateral tibiotalocalcaneal arthrodesis with an intramedullary nail were prospectively studied with three-dimensional (3D) gait analysis at a minimum of one year postoperatively. The mean age at the time of the operation was fifty-nine years,	There was significant improvement in multiple parameters of postoperative gait as compared with the patients' own preoperative function. Temporospatial data showed significant increases in cadence ($p = 0.03$) and walking speed ($p = 0.001$) and decreased total support time ($p = 0.02$). Kinematic results showed that sagittal plane ankle motion had decreased, from 13.2° preoperatively to 10.2° postoperatively, in the operatively treated limb ($p = 0.02$), and increased from 22.2° to 24.1° ($p =$	21 patients

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							and the mean duration of follow-up was seventeen months (range, twelve to thirty-one months). Temporospatial measurements included cadence, step length, walking velocity, and total support time. The kinematic parameters were sagittal plane motion of the ankle, knee, and hip. The kinetic parameters were sagittal plane ankle power and moment and hip power. Symmetry of gait was analyzed by comparing the step lengths on the affected and unaffected sides.	0.01) in the contralateral limb. Hip motion on the affected side increased from 39° to 43° (p = 0.007), and knee motion increased from 56° to 60° (p = 0.054). Kinetic results showed significant increases in ankle moment (p < 0.0001) of the operatively treated limb, ankle power of the contralateral limb (p = 0.009), and hip power on the affected side (p = 0.005) postoperatively. There was a significant improvement in gait symmetry (p = 0.01).	
Ankle	Arthroplasty, ankle (TAR)	(Trajkovski, 2013)	In the past, talar varus deformity has been a	3b	23925742	Satisfactory results can be achieved in	Thirty-six ankles with	The cohorts were similar with respect to age, sex,	72 ankles

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			relative contraindication for TAR. However, cohort studies have shown that similar outcomes can be achieved with newer techniques correcting alignment to neutral.			patients with varus malalignment of ≥10°, which should not be considered a contraindication to total ankle replacement. Complication rates can be reduced by utilizing meticulous surgical technique and taking care to address all causes of the varus deformity, particularly through osteophyte debridement, correction of cavus deformity, and soft-tissue balancing.	preoperative coronal-plane tibiotalar varus deformity of ≥10° ("varus" group) and thirty-six prospectively matched ankles with varus deformity of <10° ("neutral" group) underwent total ankle replacement. Preoperative and postoperative evaluations included AOFAS (American Orthopaedic Foot & Ankle Society) ankle-hindfoot scores, Ankle Osteoarthritis Scale (AOS) scores, Short Form (SF)-36 scores, and radiographic measurements of coronal-plane deformity.	operatively treated side, body mass index, and components used, and the mean duration of clinical follow-up was 34.7 months. Eighteen (50%) of the ankles in the varus group had a preoperative varus deformity of ≥20°. Patients in the varus group underwent more ancillary procedures during the index surgery to achieve a plantigrade foot. The AOFAS score improved by a mean of 57.2 points in the varus group and 51.5 points in the neutral group. The AOS pain and disability component scores decreased significantly in both groups. The improvement in AOS and SF-36 scores did not differ significantly between the groups at the time of the final follow-up. Tibiotalar deformity improved significantly toward a normal weight-bearing axis in the varus group. Thirteen ankles in the	(36 in varus group & 36 in neutral group)

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
								varus group and six in the neutral group underwent additional procedures at a later date.	
Ankle	Arthroplasty, ankle (TAR)	(Werner, 2015)	A national database including 5,361 TAR and 17,668 AA cases also showed significantly higher complication and revision rates for both procedures with >30 BMI. (Werner, 2015)	1b	25767196	Obesity was associated with significantly increased rates of all complications after both TAA and AA. The cause of this association was likely multifactorial, including increased rates of medical comorbidities, intraoperative factors, and larger soft tissue envelopes.	The PearlDiver database was queried for patients undergoing AA and TAA using International Classification of Diseases, 9th Revision (ICD-9) procedure codes. Patients were divided into obese (body mass index ≥30 kg/m(2)) and nonobese (body mass index <30 kg/m(2)) cohorts using ICD-9 codes for body mass index and obesity. Complications within 90 days postoperatively were assessed using ICD-9 and Current	23,029 patients were identified from 2005 to 2011, including 5361 with TAA and 17,668 with AA. Obese TAA patients had a significantly increased risk of 90-day major, minor, local, systemic, venous thromboembolic, infectious, and medical complications compared with nonobese patients. The incidence of revision TAA was also significantly higher in obese patients compared with nonobese patients. Findings were similar for AA, as all types of complications were significantly higher in obese patients compared with nonobese patients.	23029

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
							Procedural Terminology (CPT) codes.		
Ankle	Arthroplasty, Ankle (TAR)	(Williams, 2015)	The purpose of our study was to review a series of failed Agility TAA revised to INBONE II TAA and identify reasons for revision as well as perioperative complications.	4b	25288333	Revision TAA was a viable treatment option for failed TAA. A high risk of perioperative complications remains, and physicians should be aware of the challenges that occur during these procedures in order to plan for them preoperatively.	A retrospective review of 35 cases of failed Agility TAA revised to an INBONE II TAA was performed at 1 institution. Patient demographics, indications for revision, radiographs, and complications were reviewed. The average follow-up was 9.1 months (range, 0-28 months). All revisions were performed by 1 of 2 foot and ankle surgeons familiar with both prostheses.	The Agility TAA lasted a mean of 6.7 years prior to revision to an INBONE II TAA. Revision TAA was indicated due to mechanical loosening, osteolysis, periprosthetic fracture, and a dislocated prosthesis. Adjunctive procedures were performed in 31 of 35 cases. There were 6 intraoperative and 5 acute postoperative complications, leading to an overall 31.4% complication rate. There was 1 patient with continued pain postoperatively who underwent a second revision of the INBONE II 20 months postoperatively.	**35 cases**
Ankle	Arthroplasty, ankle (TAR)	(Zhou, 2016)	A U.S. database of 2340 TAR patients showed in-hospital mortality under 1% and complications 1.4%. Following	1b	26730685	Total ankle arthroplasty in the United States is a relatively safe procedure with low	The University HealthSystems Consortium administrative database was	Average hospital length of stay was 2.2±1.26 days. Average total direct cost for the hospital was	2340

Chapter	Topic	Study	Summary	Rate	PMID	Conclusions	Methods	Results	Sample
			discharge, early complications of 3.2% infection, 2.3% DVT, and 30-day readmission of 2.7% resulted in a conclusion that primary TAR is relatively safe.			overall complication rates. Patients who are male, have a history of community-acquired pneumonia, and have a larger number of preoperative comorbidities had a significant increased risk of developing 1 complication within 30 days of surgery.	searched for patients who underwent TAA in 2007 to 2011. A descriptive analysis of demographics was performed, followed by a similar analysis of clinical benchmarks, including hospital length of stay, hospital direct cost, in-hospital mortality, and 30-day readmission rates. The study included 2340 adult patients with a mean age of 62 years (47% men and 53% women) who underwent TAA. The majority of patients were Caucasian (2073; 88.5%)	$16,212±7000 per case, with 49.7% of patients having private insurance. In-hospital mortality was less than 1%, and overall complications were 1.4%. Complications after discharge included deep venous thrombosis (2.3%), reoperation (0.7%), and infection (3.2%). A readmission rate of 2.7% within the first 30 days from the time of discharge occurred.	

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