

# Guidelines for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis

## *Project Plan*

### **PARTICIPANTS**

#### ***Core Team***

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### **ORGANIZATIONAL LEADERSHIP AND SUPPORT**

This project plan is for the clinical practice guideline on the prevention and treatment of glucocorticoid-induced osteoporosis to be developed by the American College of Rheumatology (ACR) with funding by the ACR.

### **BACKGROUND**

Although glucocorticoid medications are an important part of the management of many inflammatory conditions, their use is associated with significant morbidity and mortality (1). Osteoporosis, with resultant fractures, is one of the most serious complications causing significant pain, disability, and declines in quality of life. A rapid decline in bone mineral density (BMD) begins within the first three months of glucocorticoid use followed by a slower, steady loss with continued use (2). An increased risk of both vertebral and non-vertebral fractures has been reported with dosages of prednisolone or equivalent as low as 2.5–7.5 mg daily (3,4). Risk factors for fracture in glucocorticoid users include baseline bone strength, daily dose and duration of use, gender, and age. The greatest detrimental impact is on trabecular bone leading to a significant increase in vertebral fractures, but with higher dose and long term use femoral fracture risk also increases. More recent data demonstrates that fracture risk declines when glucocorticoid treatment is stopped (3)

Despite increasing information about risk factors for fracture in glucocorticoid users and the availability of new therapies (5, 6, 7, 8, 9, 10), many people receiving glucocorticoids never receive treatment to prevent bone loss or are treated only after bone loss has progressed to fracture (11, 12, 13, 14). The American College of Rheumatology (ACR) identified glucocorticoid-induced osteoporosis as an important public health issue and first published Recommendations for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis in 1996 (15). The ACR updated these guidelines (2001, 2010) as new techniques for assessing fracture risk and new information about risk factors and therapies became available (16,17). The ACR is now using the GRADE approach in guideline development, and this approach will be used in this update of the guidelines. GRADE employs systematic and explicit approach to judgments about the quality of evidence on the harms and benefits of therapies and interventions and to the ratings of the strength of the evidence supporting the recommendations in guidelines (18).

### **OBJECTIVES**

The objective of this project is to develop recommendations for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis (GIOP).

Specifically, we aim to:

1. Develop recommendations for patients who are expected to glucocorticoid medications for 3 months or longer.
2. Compare the benefits and harms of fracture reduction therapies, including lifestyle modification, calcium, vitamin D, bisphosphonates, raloxifene, teriparatide, and denosumab.
3. Clarify differences in treatment recommendations for different populations including women before and after menopause and men younger or older than 50 years of age.

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4. Reassess available information about potential harms and benefits of therapies in special populations (i.e., people with organ transplants, chronic kidney disease, intermittent and repeated high dose GC treatment, significant preexisting dental conditions, non-healing fracture, recent fracture, and children under age 12 who are receiving GC treatment).
5. Develop recommendations for fracture risk assessment and reassessment for glucocorticoid users.

## **METHODS**

### *Identification of studies*

Literature search strategies, based on PICO questions (Population/patients, Intervention, Comparator, and Outcomes; *see Appendix A*) will be developed by the PI (LB), the systematic review leader (TM), and a research librarian (JJ), with input from the Core Leadership Team. The search strategies will be peer reviewed by another medical librarian using Peer Review of Electronic Search Strategies (PRESS) (21). Searches will be performed in OVID Medline (1946 +), Embase (1974 +), the Cochrane Library, and PubMed (mid-1960's +).

The search strategies will be developed using the controlled vocabulary or thesauri language for each database: Medical Subject Headings (MeSH) for OVID Medline, PubMed and Cochrane Library, and Emtree terms for Embase. Text words will also be used in OVID Medline, PubMed, and Embase, and keyword/title/abstract words in the Cochrane Library. For example, in Medline, to retrieve studies on the patient populations of interest, the search will include MeSH terms such as *exp Osteoporosis*; and *exp glucocorticoids*, *exp steroids* and text words *osteoporosis*, *osteoporotic*, *osteopenia*, *etc.* and *glucocorticoids*, *steroids*. Similarly, terms for specified interventions will be used.

### *Search Limits*

Only English language articles will be retrieved. See Appendix B for the draft OVID Medline search strategy.

### *Grey Literature*

The websites of appropriate agencies, such as the Agency for Healthcare Research and Quality (AHRQ), will be searched for peer-reviewed reports not indexed by electronic databases.

### *Literature search update*

Literature searches will be updated just before and again at some point after the Voting Panel meeting but prior to publication of the guideline, to ensure completeness.

### *Inclusion/Exclusion Criteria*

See PICO questions, which outline the defined patient population, interventions, comparators, and outcomes. Only English language studies will be included.

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### *Management of Studies and Data*

References and abstracts will be imported into bibliographic management software (Reference Manager) (19), duplicates removed, and exported to Distiller SR, a web-based systematic review manager (23). Screening and data abstraction forms will be created in Distiller SR. Search results will be divided among reviewers, and two reviewers will screen each title/abstract, with disagreements at the title/abstract screening stage defaulting to inclusion for full manuscript review. Disagreements at the full manuscript screening stage will be discussed and adjudicated by the systematic review leadership (TM or RB), if necessary.

### *Phases*

1. A search for randomized controlled trials and observational studies about prevention and treatment of glucocorticoid-induced osteoporosis, including special populations who have risk factors that make treatment decisions more complicated or who may have contraindications to certain treatment options, will be performed to determine existing studies covering outcomes of interest. Subsequently, identified studies will be assessed using the RevMan (21) and GRADE Pro tools (22).
2. Chosen studies will be quality-assessed using the Cochrane Risk of Bias Tool (27), the Cochrane Effective Practice and Organization of Care Risk of Bias Tool (28) or the Newcastle-Ottawa Scale (29).
3. Additionally, recently published systematic reviews covering outcomes of interest will also be sought and used for reference cross-checking.

### *GRADE methodology*

GRADE methodology will be used in this project to grade available evidence and facilitate development of recommendations. The quality of evidence will be graded as high, moderate, low, or very low. The strength of recommendations will be graded as strong or conditional. A series of articles that describe the GRADE methodology can be found on the GRADE working group's website: the [www.gradeworkinggroup.org](http://www.gradeworkinggroup.org).

### *Analysis and Synthesis*

The systematic review team will analyze and synthesize data from included studies that address the PICO questions. An evidence profile, including a GRADE Summary of Findings table, will be prepared for each PICO question using Review Manager (RevMan) (19) and GRADEprofiler (GRADEpro) software (20). The Summary of Findings table contains the benefits and harms for each outcome across studies, the assumed and corresponding risk for comparators and interventions (95% CI), the absolute risk and relative effect (95% CI), the number of participants/ number of studies and number needed to treat, and the quality of evidence for each critical and important outcome (i.e., high, moderate, low or very low).

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The evidence profile documents the quality of the evidence across studies for each critical and important outcome and summarizes the quality factors (i.e., limitations of study design, inconsistency, indirectness, imprecision, and other considerations).

### *Development of Recommendation Statements*

PICO questions will be reversed into drafted recommendation statements. Using the GRADE Evidence Profiles and Summaries of Findings tables, the voting panel, consisting of adult and pediatric rheumatologists, internists, an endocrinologist, a pulmonary physician, and a patient representative, will consider the drafted recommendation statements in two stages. The first assessment will be done individually, and the results will be anonymous; this vote will only be used to determine where consensus might or might not already exist and develop the voting panel meeting agenda. At the face-to-face voting panel meeting, chaired by the PI (LB), the panel will discuss the evidence in the context of their clinical experience and expertise to arrive at consensus on the final recommendations. The voting panel meeting discussions will be supported by the systematic review leadership (TM and RB), the GRADE expert (GG), and selected members of the systematic review team, who will attend the meeting to provide details about the evidence, as requested.

### **PLANNED APPENDICES (AT MINIMUM)**

- A. Final literature search strategies
- B. GRADE Evidence Profiles and Summary of Findings Tables for each PICO question


### **AUTHORSHIP**

Authorship of the guidelines will include Dr. Lenore Buckley, PI, as the lead author; Dr. Timothy McAlindon, literature review leader; Dr. Howard Fink, core leadership team member; and Dr. Gordon Guyatt, core leadership team member and GRADE consultant. Members of the systematic review team and voting panel will also be authors. The PI will determine final authorship, dependent on the efforts made by individuals throughout the guideline development process, using international authorship standards as guidance.

### **DISCLOSURES / CONFLICTS OF INTEREST**

The ACR's disclosure and COI policies for guideline development will be followed for this project. These can be found in the ACR Guideline Manual on [this page of the ACR web site](#), under Policies & Procedures. *See Appendix C for participant disclosures.*

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### APPENDIX A

#### PICO questions (attached)

### APPENDIX B

#### Literature Search Strategy (draft)

#### Glucocorticoid-induced Osteoporosis - Draft OVID Medline Search

Syntax Guide for OVID Medline	
/ = At the end of a word or phrase means that it is searched as a subject heading	Exp = A command to retrieve all narrower MeSH
Adj = Adjacency; terms are adjacent to each other, in either direction ; adj2 = terms are within 2 words of each other, in either direction	\$ = truncation symbol
Limit = Command to limit results to age groups, years, language, etc.	In process = Records that are electronically submitted and have gone through the second record-level review, i.e. do not contain all indexing, for example.
kw =Author keywords	tw. = textword; in Medline, indexed words from title, abstract
Boolean Operators	
OR = retrieves results that include at least one of the search terms	AND = retrieves results that include all the search terms
NOT = excludes the retrieval of terms from the search	

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>

Search Strategy:

1 exp Glucocorticoids/ (170077)



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- 2 exp Steroids/ (730237)
- 3 (glucocorticoid\$ or steroid\$).tw,kw. (242529)
- 4 or/1-3 (864941)
- 5 exp Osteoporosis/ (47245)
- 6 exp Bone Diseases, Metabolic/ (65851)
- 7 exp Bone Diseases/ci (9044)
- 8 exp Bone Resorption/ (33343)
- 9 bone resorption.tw,kw. (20377)
- 10 (osteop?enia or osteoporo\$).tw,kw. (61429)
- 11 exp Fractures, Bone/ (146838)
- 12 fracture\$.tw,kw. (189665)
- 13 Bone Density/ (43436)
- 14 (bone adj (density or mass or mineral\$ or loss)).tw,kw. (67672)
- 15 BMD.tw,kw. (21977)
- 16 exp Densitometry/ (30083)
- 17 (dexa or dxa).tw,kw. (10939)
- 18 (fracture adj2 (assessment or reassessment or re-assessment)).tw,kw. (1119)
- 19 (FRAX or VFA).tw,kw. (3411)
- 20 "T score".tw,kw. (3157)
- 21 "x-ray absorptiometry".tw,kw. (17363)
- 22 or/5-21 (378316)
- 23 4 and 22 (29389)
- 24 exp Calcium Compounds/ (58851)
- 25 Calcium/ (248645)
- 26 calcium.tw,kw. (314303)

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- 27 or/24-26 (463389)  
28 exp Vitamin D/ (47343)  
29 ("Vitamin D" or Cholecalciferol or Hydroxycholecalciferols or Calcifediol or Dihydroxycholecalciferols or Calcitriol or 24,25-Dihydroxyvitamin D  
30 3).tw,kw. (47547)  
31 (Ergocalciferol\$ or Dihydrotachysterol or Rocaltrol).tw,kw. (1048)  
32 "25-Hydroxyvitamin D 2".tw,kw. (43)  
33 "1,25-dihydroxycholecalciferol".tw,kw. (1170)  
34 "1,25-dihydroxyvitamin D3".tw,kw. (4645)  
35 "25-dihydroxycholecalciferol".tw,kw. (1417)  
36 "25-dihydroxyvitamin D3".kw,tw. (6595)  
37 or/28-35 (66319)  
38 27 and 36 (26611)  
39 exp Diphosphonates/ (22055)  
40 bisphosphonate\$.tw,kw. (12819)  
41 Alendronate/ (3100)  
42 alendronate\$.tw,kw. (3607)  
43 Fosamax.tw. (139)  
44 risedronate\$.tw,kw. (1421)  
45 Actonel.tw,kw. (35)  
46 Ateliva.tw,kw. (0)  
47 ibandronate\$.tw,kw. (856)  
48 Boniva.tw,kw. (8)  
49 zoledronic acid.tw,kw. (2502)  
50 (Reclast or Zometa).tw,kw. (123)  
51 Raloxifene/ (2402)

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- 51 raloxifene.tw,kw. (2869)
- 52 Evista.tw,kw. (62)
- 53 exp Parathyroid Hormone/ (26415)
- 54 parathyroid hormone\$.tw,kw. (27025)
- 55 Teriparatide/ (1502)
- 56 teriparatide.tw,kw. (1029)
- 57 Forteo.tw,kw. (39)
- 58 denosumab.tw,kw. (1224)
- 59 or/38-58 (65873)
- 60 (23 and 37) or (23 and 37 and 59) (8591)
- 61 exp animals/ not humans.sh. (4113127)
- 62 60 not 61 (7433)
- 63 limit 62 to letter (156)
- 64 limit 62 to case reports (599)
- 65 limit 62 to comment (143)
- 66 limit 62 to editorial (79)
- 67 63 or 64 or 65 or 66 (837)
- 68 62 not 67 (6596)
- 69 limit 68 to english language (5483)
- 70 limit 60 to in process (10)
- 71 69 or 70 (5485)

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### APPENDIX C

#### Participants Disclosures

Role	Authors	Primary employer	Sources of personal income	Intellectual Property	Research Grants/Contracts	Medical industry	Organizational Benefit	Activities with other organizations
Principal Investigator /Core Team	Lenore Buckley	Yale University School of Medicine						
Lit Review Lead/Core Team	Timothy McAlindon	Tufts Medical Center	Abbvie; Federal Trade Commission; Flexion; McNeil Consumer HC; Samumed; Sanofi Aventis	Online Clinical Trial Methodology	NIH/NIAMS; AHRQ; Flexion Therapeutics; ACR; OARSI; Abbvie; PCORI; Samumed; Analgesic Solutions			OARSI; ACR
Core Team	Howard Fink	Minneapolis VA Medical Center	University of Minnesota		AHRQ; NIA; VA HSR&D			ASBMR; Minnesota Department of Human Services
GRADE Consultant/ Core Team	Gordon Guyatt	McMaster University						
Expert Panel	Barton Wise	University of California			XOMA; Amgen; Orthotrophix; TEVA			
Expert Panel	Chad Deal	Cleveland Clinic	Amgen; Lilly					
Expert Panel	Jeffrey Curtis	University of Alabama at Birmingham	Amgen		Roche/Genentech; CORRONA; UCB; Janssen; Pfizer; BMS; Crescendo; AbbVie			

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Expert Panel	Jonathan D. Adachi	McMaster University	Amgen; Eli Lilly; Merck		CIHR			International Osteoporosis Foundation; Osteoporosis Canada; Osteoporosis International
Expert Panel	Kenneth Saag	University of Alabama at Birmingham	Abbot; Amgen; Ardea/ AstraZeneca; Bayer; BMS; Crealta; Lilly; Merck; Pfizer; Roche/ Genentech; Takeda		AHRQ; NIAMS; Merck; Takeda, Amgen			American Gout Society; National Osteoporosis Foundation; Neurological, Aging and Musculoskeletal Epidemiol.; Current Opinions in Rheumatology; Medscape Rheumatology
Expert Panel	Mary Bolster	Massachusetts General Hospital			Eli Lilly; Amgen-RRF; Abbvie	Johnson & Johnson		ABIM
Expert Panel	Michael Maricic	Catalina Pointe Rheumatology	Amgen					
Expert Panel	Robert A. Adler	Department of Veterans Affairs	Amgen		Dept. of Defense; Dept. of Veterans Affairs; AHRQ; Genentech			ASBMR; National Bone Health Alliance; J Clin Endocrinol Metab; Endocrine; Current Osteoporosis Reports

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Expert Panel	Roberto Civitelli	Washington University School of Medicine	Amgen; Washington Bone Club		NIH-NIAMS; Amgen	Eli-Lilly; Merck & Co.; Amgen		ASBMR
Voting Panel	Emily Von Scheven	University of California, San Francisco			Lupus Foundation America; Arthritis Foundation; PCORI; UCSF Stanford AF Ctr Excellence	Heartware		CARRA; Arthritis Foundation; Lupus Foundation America
Voting Panel	Jennifer Grossman	UCLA	Lupus Foundation; University of Alabama at Birmingham		UCB; Eli Lilly; Medinimmune; Fernstein Institute for Medical Research; CTC; Pfizer; HGS; NIH			Lupus LA; Lupus Foundation of America
Voting Panel	Joy Rowe	Partner MD						
Voting Panel	Karen E. Hansen	University of Wisconsin			NIH; Takeda Pharmaceuticals			
Voting Panel	Lake D. Morrison	Duke University Medical Center	Intermune; France Foundation		Intermune Pharmaceuticals; Gilead Sciences; Bristol-Myers Squibb; Boehringer Ingelheim			
Voting Panel	Marc L. Miller	Rheumatology Associates	UpToDate; Medical Review Institute of America					
Voting Panel	Marina N Magrey	MetroHealth Medical Center			NIAMS			
Voting Panel	Mary Beth Humphrey	University of Oklahoma Health Sciences Center; VA	UCSF Rheumatology Board Review		NIH	Portola Pharmaceuticals	Presbyterian Health Foundation	

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Voting Panel	Michael R Cannon	Self Employed	Takeda			ABBVIE; Glaxo SmithKline; Johnson & Johnson; Pfizer; Bristol Meyes Squibb		
Voting Panel	Nancy Lane	University of California	Celgene; Lilly					
Voting Panel	Susan Wolver	VCUHS			National Cancer Institute/NIH/DHHS			
Voting Panel	Clifford Rosen	Maine Medical Center	New England Journal of Medicine		NIDDK; NIAMS; NIA			
Voting Panel/Patient Rep	Jane MacKnight	Cincinnati Museum Center						