Developing guidelines in musculoskeletal disorders

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ABSTRACT

Clinical practice guidelines (CPGs) are systematically developed statements to assist practitioners and patients on healthcare decisions. They provide recommendations for the average patient, which should take into account individual clinical judgment and the patient's values and expectations. Quality benchmarks differ from CPGs in that they are best practices that are medically necessary under almost all circumstances, and constitute a standard by which quality of care can be measured.

Scientifically rigorous CPGs should be evidence-based and evolve from multidisciplinary and systematic development processes. To maximize their validity, the available evidence must be graded according to its methodological quality and the strength of the recommendations should be based on these ratings.

We conducted a systematic review of the literature and relevant websites, which identified 276 CPGs for the diagnosis and/or treatment of musculoskeletal disorders. Of these, 61 were retrieved from 3 sources: 1) the American College of Rheumatology (ACR); 2) the European League against Rheumatism (EULAR); and 3) musculoskeletal CPGs retrieved from the National Guideline Clearinghouse. While use of scientific evidence was commonly cited in the discussion, methodological information was often lacking, without specification as to whether the evidence had been systematically reviewed and graded. We also observed substantial overlap between organizations in the development of CPGs for a given disease.

CPGs can improve quality of care by providing evidence-based recommendations. However, it is imperative that they be developed with the utmost transparency, and using a careful and systematic appraisal of the totality of evidence, with recommendations graded according a systematic approach to avoid bias. While many CPGs exist in the rheumatology field, the consensus processes followed in their development is not always explicit, leading to limitations in their interpretations that can hamper broader acceptance and adoption.

Introduction

While understanding the pathophysiology of any given condition helps to enhance our understanding about disease, health improvements are ultimately dependent on the translation of scientific findings into clinical practice, through the testing of effectiveness in clinical trials and outcomes research, and the adequate dissemination of evidence. With ever-increasing new developments in medical knowledge and technology, it is a challenge for individual healthcare providers, administrators and policymakers to keep abreast of the best and most current evidence. Furthermore, the growing number of technologies and interventions has led to large variations in practice, with both the over- and underutilization of effective therapies. Consequently, clinical practice guidelines (CPGs) are being increasingly promoted to guide individual decision-makers in their choices regarding health interventions while ensuring a standard of high-quality evidence-based healthcare. Systematically developed, evidence-based CPGs can provide important guidance to improve best practices and the quality of healthcare (1). In this review we aim to: 1) describe the methods for guideline development and quality assessment; and 2) identify CPGs currently available for the most common rheumatologic diseases.

Clinical practice guidelines (CPGs)

The Institute of Medicine has defined CPGs as "systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances" (2), fostering better relations

between research and practice, and emphasizing quality in healthcare. While an examination of the causes and consequences of practice variation is beyond the scope of our review, it is clear that variations in the diagnosis or treatment of a condition frequently occur, even in common clinical scenarios (3). Guidelines can improve the consistency of care and health outcomes by recommending beneficial therapies, discouraging ineffective ones, and ensuring that patients will be appropriately cared for, in a similar manner, regardless of where or by whom they are treated. The ultimate goal of CPGs is to reduce morbidity and mortality from disease and its treatment, and improve the quality of life and survival, through the most efficient use of healthcare resources (1). In this quest, by using a more user-friendly format, guidelines become a more convenient tool, proposing explicit recommendations that can guide the day-to-day care of most patients with a given disorder. Guidelines are often developed by professional health organizations with the goal of improving health decision-making and quality of care for specific disciplines.

Guidelines can also influence public policy by promoting distributive justice, and advocating better delivery of services (1). In the current climate of health budget cuts, resource allocation needs physician involvement; guidelines that improve the efficiency of healthcare help avoid unnecessary expenses (4).

Physicians have occasionally opposed guidelines by perceiving them as "cookbook medicine." Yet the primary objective of CPGs is to identify all possible decisions, and use evidence to improve decision-making in the context of individual clinical judgment and the patient's values. Clinical guidelines can therefore improve the quality of individual health decision-making while making the best possible use of resources, combining quality-of-care objectives with the financial aims of providers and payers (5).

The first attempt to implement clinical guidelines was made in the 1950s, with the use of "critical pathways," including multidisciplinary recommendations to set the clinical goals that patients should aim for during hospitalization, along with the optimal sequence and timing of interventions by hospital staff to attain those goals (5, 6). In the 1970s, the need to further develop methodical clinical guidance arose, as outcome studies identified extensive differences among practitioner management strategies for patients with the same healthcare problem (5). The development of CPGs assisted in standardizing the management of certain diseases. Traditionally, guidelines originated from panels of experts, where agreements were reached through open discussion without using formal analytical methods (5). Nowadays, guideline development is more structured, including a systematic approach and requiring formal consensus, usually conducted by professional organizations and governmental agencies (7).

As clinical decisions become more complex, often with multiple alternatives, there is a growing need to review the main options and provide guidance to improve health decisions. Many professional societies and corporations have established programs to develop more explicit linkages between recommendations and the supporting evidence (8). Since the 1990s, several methods of guideline development have been described, that involve different aspects of treatments such as the assessment of safety, economic implications, and patients' preferences (9, 10).

In the late 1990s the Emergency Care Research Institute, in collaboration with the US Agency for Healthcare Research and Quality (AHRQ) and the American Medical Association, developed the National Guideline Clearinghouse, a comprehensive database of evidence-based CPGs (11). Since then, similar organizations have been created in other countries to ensure guideline quality (12).

Guidelines, quality improvement and quality indicators

Demands for higher quality have driven healthcare organizations to strive towards achieving benchmarks for best practices. Benchmarking is one form of measuring quality improvement by identifying quality indicators of best practice (13). While CPGs provide recommendations to be applied (sometimes with modifications) to the average patient, benchmarking stipulates the minimum necessary practices required to provide optimal quality of care. Benchmarks can serve as a common tool for healthcare improvement by standardizing the level of performance to be achieved by providers (14).

Pantall and McGeehan define benchmarking as: "the continuous, systematic search for, and implementation of, best practices which lead to superior performance" (15). Benchmarking is a serial process that gathers information for learning purposes, helping to select the best practices. The benchmarking process involves strategies that cover most operational levels such as service delivery, management and professional operations, and must be based on evidence (13).

Benchmarks of care are different from CPGs in that they are used to set concise, achievable goals for improving care, have well defined numerators and denominators, and are easily and reproducibly calculated from existing performance data. CPGs nevertheless retain a key role in quality of care by providing the best available evidence, incorporating expert and patient values, and thereby aiding in the development of quality indicators.

Finally, CPGs have broadened their primary goal of improving quality of care to include issues related to legal defence, accounting and insurance terms (16). They bridge professionalism and regulatory approaches to improve physician accountability and efficiency. While each institution or provider defines its own standard of quality and its own performance measures, CPGs can provide important consensus regarding which "best practices" can be considered as quality indicators.

Methods in the development of clinical practice guidelines

CPGs are being used in many countries in an effort to improve the quality of patient care (5). Yet, there are increasing concerns about the lack of methodological rigor of some guidelines, and the coexistence of guidelines

with conflicting recommendations (3). Different methods have been used in guideline development: a) informal consensus development, where agreements are reached through open discussion (unstructured, subjective group judgment); b) formal consensus development that includes explicit criteria to reach consensus, such as structured expert panel discussions in closed sessions (standardized opinion gathering); c) evidence-based guidelines, where there is a direct linkage of recommendations to the quality of the underlying scientific evidence; and d) explicit guideline development that combines scientific evidence and formal analytic methods with explicit approaches or projections of likely benefits, harms and costs (7).

These methods help to deal with situations requiring decision-making when the evidence is uncertain. For example, expert opinion collaterally with first-hand experience can play a legitimate role in filling gaps where there is no evidence (4). Overall, to achieve their potential as effective tools for improving healthcare, CPGs need to maximize their validity, using a multidisciplinary systematic development process informed by evidence (17). Recommended attributes in evidence-based CPGs are presented in Table I. A "standard classification scheme" has also been proposed to identify and describe the most important characteristics of guidelines in order to facilitate their review (12). Table II shows the classification scheme with relevant examples.

To ensure methodological rigor and quality, guidelines should be developed systematically and fulfil recommended criteria (17). The steps in guideline development include: 1) preparatory decisions (selection of the question and panel members, justification); 2) assessments of appropriateness (review of evidence and expert opinion); 3) appraisal of public policy issues (organizational changes, implications); and 4) document development and evaluation (drafting of the document, peer review, and pre-testing). Figure 1 shows a more detailed recommended approach.

One important point to consider in guideline development is that recommendations can be based on evidence of varying quality, ranging from randomized controlled trials (RCT) to expert opinion. Therefore, a systematic approach that classifies the type of evidence available and grades the strength of the recommendations can minimize bias and facilitate the interpretation of CPGs (18). Since 1979, when the Canadian Task Force issued recommendations whose strength was graded, a growing number of organizations have

Table I. Attributes of Clinical Practice Guidelines (CPGs) (12, 18, 20).

Criteria
- CPGs should contain systematically developed statements that include recommendations, strategies or information that can assist physicians and/or other healthcare practitioners and patients in making decisions about appropriate healthcare for specific clinical circumstances.
- CPGs should be produced under the auspices of medical specialty associations; relevant professional societies, public or private organizations, government agencies at the federal, state, or local level; or healthcare organizations or plans.
- During guideline development, a systematic literature search and/or review of the existing scientific evidence published in peer-reviewed journals should be performed.
- The full text guideline should be available upon request in print or electronic format (for free or for a fee) in the English language.
- Evidence that the guideline was developed, reviewed, or revised and updated should be documented.

Principles
- The recommendations must be evidence-based
- They should be explicitly linked to the type and quality of evidence
- They should be developed by multidisciplinary stakeholder groups

Properties
- The recommendations should define practice questions and explicitly identify all decision options and outcomes
- They should explicitly identify, appraise and summarize – in ways that are most relevant to decision-makers – the best evidence regarding prevention, diagnosis, prognosis, therapy, harm and cost-effectiveness
- They should explicitly identify the decision points at which this valid evidence needs to be integrated with individual clinical experience in deciding on a course of action

Table II. Standard classification scheme for clinical practice guidelines.

	Example
Clinical specialty	Allergy and immunology, rheumatology
Disease/condition	Rheumatoid arthritis
Guideline category	Assessment of therapeutic effectiveness, rehabilitation
Implementation tools	Chart documentation/checklists/forms, quick reference guides/physician guides, slide presentation
Intended users	Advanced practice nurses, managed care organizations
Method of guideline validation	Clinical validation – pilot testing, external peer review
Methods used to analyze the evidence	Decision analysis, meta-analysis, systematic review with evidence tables
Methods used to assess the quality and strength of the evidence	Expert consensus, subjective review, weighting according to a rating scheme
Methods used to collect/select the evidence	Searches by hand of the published literature, searches of electronic databases, searches of unpublished data
Methods used to formulate the recommendations	Informal expert consensus, expert consensus, consensus development conference, balance sheets
Organization type	Federal government agency, independent expert panel, international agency, medical specialty society
Target population	Child, adult; male, female
Treatment/intervention	Steroids, biologics

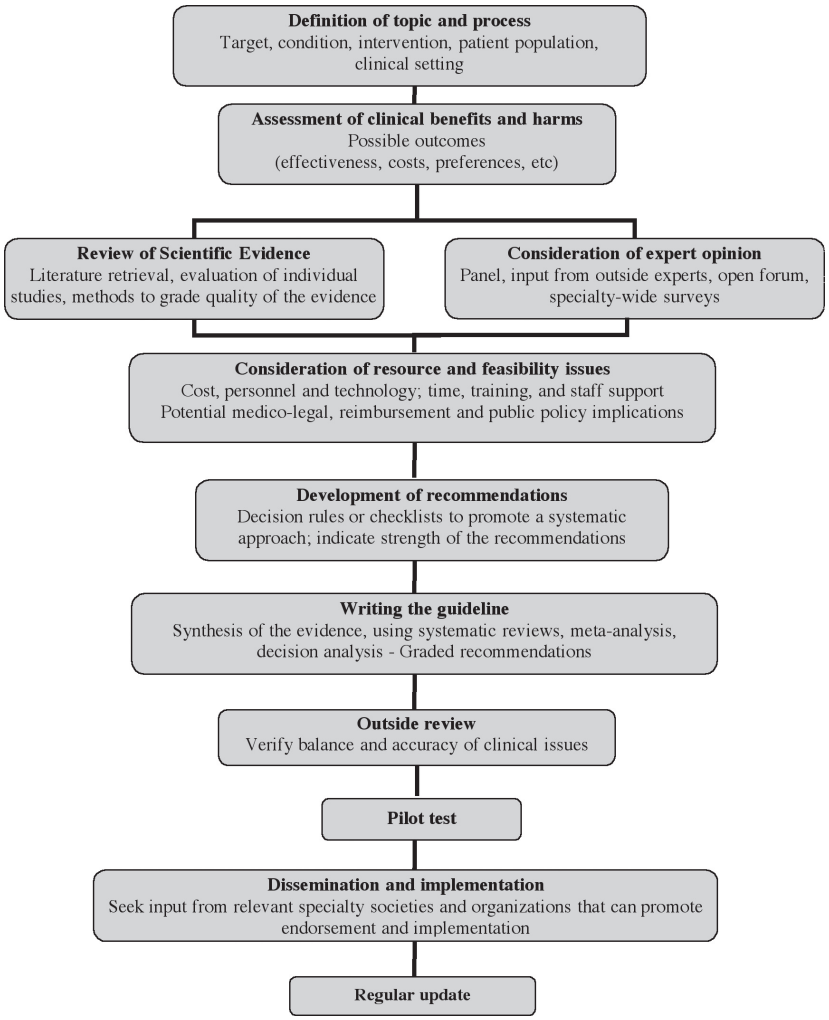

Fig. 1. Steps in CPG development (adapted from ref. 82).

employed various systems to grade the quality of evidence and the strength of recommendations (8).

In an effort to establish standard methods for developing evidence-based practice guidelines, the Appraisal of Guidelines Research and Evaluation (AGREE) project was initiated in 1998 (19). It originated from an international collaboration of researchers and policy makers who worked together to improve the quality of CPGs by creating a shared framework for their development, reporting and assessment (19). The AGREE collaboration has developed a validated, generic instrument that can be used to evaluate CPGs in any disease area (17). It focuses on the methods used for developing guidelines and ensuring the quality of reporting; it does not address the clinical content of the recommendations, nor the quality of the supporting evidence. This instrument consists of 23 items organized into 6 (17). domains; each domain is intended to capture a separate dimension of guideline quality (Table III) The AGREE instrument has been officially recommended by the Council of Europe and by the World Health Organization (WHO) to help both guideline developers and users assess the methodological quality of CPGs (19).

Limitations of guidelines

While CPGs can be an important tool in clinical decision-making, there are also limitations to their development, application and implementation, some of which are briefly discussed below.

Development

In addition to issues related to quality, it is important to recognize that although well-conducted RCTs are the gold standard in clinical research, many relevant management questions cannot be addressed with this study design. Observational studies are often needed to evaluate long-term effectiveness and toxicity, but they are subject to lower ratings in terms of scientific rigor, and therefore recommendations based on observational studies are less definitive than those based on RCTs.

Applicability

Guidelines are recommendations based on the available evidence on how to achieve the best clinical management of "average" patients. Yet, many patients are not "average", and there is a danger of using guidelines as "cookbook" medicine. In addition, guidelines generally rely primarily on the results of clinical trials, which are often conducted in highly selected populations that do not represent the "average" patient for whom the guidelines were presumably drawn up.

Implementation

To be useful, guidelines need to be disseminated, implemented, endorsed and used by clinicians. The development and dissemination of CPGs is a laborious, time-consuming, resource-intensive process. Therefore, implementation is often delayed by months or years and as a consequence the adoption of effective therapies may be delayed. Of even greater concern is the fact that guidelines can become obsolete as new evidence is published. It is therefore imperative to review guidelines periodically. To avoid these potential pitfalls, CPGs must consider all the evidence available, including observational studies, and they need to be explicit about the evidence they are based on, including specification of the populations to which the evidence applies. To be clinically relevant, CPGs must be timely and periodically updated.

Clinical practice guidelines in rheumatology

Many guidelines have been developed for the diagnosis and/or treatment of musculoskeletal conditions including osteoporosis, osteoarthritis, rheumatoid arthritis, vasculitis, systemic lupus erythematosus, gout, and ankylosing spond-

Table III. The AGREE instrument (ref. 19).

Domain	Items
Scope and purpose	Overall aim of the guideline expressed in terms of expected health benefits (*e.g.*, preventing complications in patients with diabetes mellitus) Specific clinical question covered by the guideline Target population
Stakeholder involvement	Professionals involved in guideline development Patients involved in guideline development Target users of the guideline Pre-testing of the guideline
Rigor of development	Search strategy Rules for including or excluding evidence Methods used to formulate recommendations Description of how health benefits, side effects and risks of recommendations were taken into account Explanation of which evidence supports each recommendation Description of external review process Description of the procedure for updating the guideline
Clarity and presentation	Clarity and precision of the recommendations Degree to which the guideline considers all possible alternatives for action Ease of use of the guideline Quality of the strategy for disseminating and fostering implementation of the guideline
Applicability	Potential impact of the guideline on organizational structure and practices Potential impact of the guideline on costs Criteria for measuring adherence to the guideline
Editorial independence	External funding for guideline development Conflicts of interest of development group members

ylitis (3). We searched MEDLINE®, CINAHL and guideline collections (AHRQ, Canadian Medical Association Infobase, National Guideline Clearinghouse, New Zealand Guidelines Group, NICE, Prodigy and the Scottish Intercollegiate Guidelines Network) in order to identify CPGs related to any of the listed conditions. The search criteria had neither language nor publication date restrictions. Our search identified 671 relevant citations: of these 266 were consensus development conferences and were excluded because they did not fulfil the guideline inclusion criteria (12); 114 CPGs were excluded because they were not specifically related to our topic; and 15 additional citations were narrative reviews, comments, letters or editorials, leaving 276 CPGs in the field of rheumatology. This shows the abundance and breadth of guidelines in our field.

In order to provide a broad yet comprehensive perspective, we selected for this review CPGs from three sources: 1) the American College of Rheumatology (ACR); 2) the European League against Rheumatism (EULAR); and 3) musculoskeletal CPGs retrieved from the National Guideline Clearinghouse. We retrieved 61 guidelines pertinent to various rheumatic diseases. In Table IV, guidelines are listed by organization, topic, development type and whether or not a systematic review was conducted by the authors (defined as the inclusion of an explicit statement detailing a comprehensive literature search).

As reported previously by Homik (3), we found that the majority of guidelines published in rheumatology deal with the diagnosis and management of osteoporosis, perhaps because of the various specialties that take care of patients with this disorder, with professional organizations that may feel compelled to provide their own guidelines. The most common approach for developing guidelines in rheumatology was expert opinion. The publication of the guidelines generally provided only the recommendations, with little background on the process by which they were developed. Scientific evidence was often cited in the discussion but, for the most part, the specific methodological information provided was insufficient to assure readers that the evidence was reviewed and graded without bias, and that the recommendations were in fact driven by the evidence.

Conclusions

CPGs in rheumatology have largely relied on expert opinion, rather than systematic evaluation of the published literature, as the basis for their recommendations. This process can undermine the authority of guidelines and potentially result in contrasting or even inappropriate recommendations. With comprehensive systematic reviews of the literature and guidance by multidisciplinary groups, the bias in evidence selection can be minimized; the precision and significance of treatment effect estimates can be best evaluated by considering all the available evidence, with interpretation by various stakeholders. To the lay public the term CPG may represent a high level of scientific authority, yet not all guidelines are created equal. Authors of guidelines have the ultimate responsibility to provide adequate disclosure of the process by which they were developed, including statements of conflict of interest.

We observed a substantial overlap between organizations in the development of guidelines for specific topics. Active cooperation between national and international organizations could yield considerable synergies and improve the overall quality of the recommendations. The development and updating of CPGs require substantial resources. Many guideline programs throughout the world are using similar strategies to achieve similar goals, resulting in multiple guidelines on the same topic. To avoid the unnecessary duplication of efforts, guidelines, systematic reviews and evidence reports could be exchanged by the joint development of methodologies, collaboration in literature searches for the revision of guidelines, and organizing the joint peer review of draft guidelines.

Finally, if clinical guidelines are to improve quality in practice, they must be effectively disseminated and imple-

Table IV. Guidelines in rheumatology published by various international organizations*.

Organization	Year	Topic	Graded evidence and recommendations
General			
American College of Rheumatology	2002 (21)	Immunologic laboratory testing	No
American Pain Society	2002 (22)	Pain in OA, RA, JIA	Yes
Brigham & Women's Hospital	2003 (23)	Lower extremity musculoskeletal disorders	No
Institute for Clinical Systems Improvement	2006 (24)	Low back pain	Yes
Rheumatoid arthritis			
American College of Rheumatology	1994 (25)	Methotrexate liver toxicity	No
American College of Rheumatology	1996 (26)	Management	No
American College of Rheumatology	1996 (27)	Monitoring drug therapy	No
American College of Rheumatology	2002 (28)	Management	No
American College of Rheumatology	2002 (29)	Management (as above)	No
National Institute for Health and Clinical Excellence	2003 (30)	Use of anakinra	No
Ottawa Panel	2004 (31)	Electrotherapy and thermotherapy	Yes
Ottawa Panel	2004 (32)	Therapeutic exercises	Yes
European League against Rheumatism	2007 (33)	Early RA treatment	Yes
Juvenile rheumatoid arthritis			
American Academy of Pediatrics	2006 (34)	Ophthalmological examinations	No
Osteoarthritis			
American College of Rheumatology	2000 (35)	Update on management of hip and knee OA	No
European League against Rheumatism	2000 (36)	Management of knee OA	Yes
American College of Rheumatology	2002 (37)	Update on treatment	No
European League against Rheumatism	2003 (38)	Management of knee OA	Yes
American Academy of Orthopedic Surgeons	2003 (39)	Management of knee OA (phase 1)	Yes
American Academy of Orthopedic Surgeons	2003 (40)	Management of knee OA (phase 2)	Yes
American College of Radiology	2003 (41)	Chronic hip pain	No
Washington State Department of Labor and Industries	2003 (42)	Criteria for knee surgery	No
Institute for Clinical Systems Improvement	2004 (43)	Diagnosis and treatment of knee OA	Yes
National Institutes of Health	2004 (44)	Total knee replacement	No
Ottawa Panel	2005 (45)	Therapeutic exercises	Yes
European League against Rheumatism	2005 (46)	Management of hip OA	Yes
Michigan Quality Improvement Consortium	2005 (47)	Medical management	Yes
University of Michigan Health System	2005 (48)	Knee pain or swelling	Yes
European League against Rheumatism	2007 (49)	Management of hand OA	Yes
Osteoporosis			
American College of Rheumatology	1996 (50)	Prevention and treatment of glucocorticoid-induced OP	No
American College of Rheumatology	1997 (51)	Prevention and treatment of glucocorticoid-induced OP	No
American Association of Clinical Endocrinologists	2001 (52)	Prevention and treatment	Yes
American College of Rheumatology	2001 (53)	Prevention and treatment of glucocorticoid-induced OP	No
American College of Obstetricians and Gynecologists	2002 (54)	Selective estrogen-receptor treatment	Yes
Singapore Ministry of Health	2002 (55)	General management	Yes
American Gastroenterological Association	2003 (56)	Osteoporosis in gastrointestinal disorders	Yes
American Gastroenterological Association	2003 (57)	Osteoporosis in hepatic disorders	Yes
American Medical Directors Association	2003 (58)	General management	No
American Society of Clinical Oncology	2003 (59)	Treatment in breast cancer	No
National Osteoporosis Foundation	2003 (60)	Prevention and treatment	No
National Osteoporosis Foundation	2003 (61)	Rehabilitation	No
Scottish Intercollegiate Guidelines Network	2003 (62)	Management	Yes
U.S. Preventive Services Task Force	2003 (63)	Diagnosis	Yes
International Society for Clinical Densitometry	2004 (64)	Diagnosis	No
National Institute for Health and Clinical Excellence	2005 (65)	Treatment	No
University of Michigan Health System	2005 (66)	Prevention and treatment	Yes
North American Menopause Society	2006 (67)	Management	No
North American Menopause Society	2006 (68)	Prevention and treatment	No
Institute for Clinical Systems Improvement	2006 (69)	Diagnosis and treatment	Yes
Michigan Quality Improvement Consortium	2006 (70)	Management and prevention	Yes

(*Table IV continues*)

Organization	Year	Topic	Graded evidence and recommendations
Ankylosing spondylitis			
European League against Rheumatism	2006 (71)	Management	Yes
Fibromyalgia			
Washington State Department of labor and Industries	2002 (72)	General overview	No
American Pain Society	2004 (73)	Management	Yes
Family Nurse Practitioner Program, University of Texas	2005 (74)	Treatment	Yes
American Pain Society	2005 (75)	Management in adults and children	Yes
Gout			
European League against Rheumatism	2007 (76)	Diagnosis	Yes
European League against Rheumatism	2007 (77)	Management	Yes
Systemic lupus erythematosus			
American College of Rheumatology	1999 (78)	Referral and management	No
American College of Rheumatology	2002 (79)	Immunologic tests for CTD	Yes
Finnish Medical Society	2006 (80)	General overview	Yes
Psoriatic arthritis			
Institute for Health and Clinical Excellence	2006 (81)	Treatment	No

*Selected guidelines included in the National Guideline Clearhouse, American College of Rheumatology and/or European League against Rheumatism. JIA: juvenile idiopathic arthritis; OA: osteoarthritis; RA: rheumatoid arthritis; CTD: connective tissue diseases.

mented. By addressing the limitations of current guidelines, rheumatologists can play a cardinal role in improving the quality, efficiency, and cost-effectiveness of clinical practice related to rheumatic disorders.

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