APPENDIX B
AMERICAN COLLEGE OF RHEUMATOLOGY REPORT ON REASONABLE USE OF MUSCULOSKELETAL ULTRASONOGRAPHY IN RHEUMATOLOGY CLINICAL PRACTICE
TABLE OF CONTENTS

Project Protocol
August 2011

Background

Musculoskeletal ultrasound has been embraced by clinical rheumatologists, researchers in the field of rheumatology, and other subspecialists who treat rheumatology patients in the United States and, to an even greater extent, in Europe. Its widespread adoption has been stimulated by its perceived applicability to the diagnosis and management of rheumatic and musculoskeletal disorders and by claims that it enhances diagnosis and clinical outcomes. Integration of MSUS into standard rheumatology practice raises numerous issues that relate to training, competence, reimbursement and accreditation. All of these are predicated on the premise that the health benefits of the performance of MSUS in a rheumatology clinical setting outweigh any possible negative consequences, i.e., that it is an appropriate procedure in this setting (Fitch et al, 2001; Brook et al., 1986; Park et al., 1986). However, this critical aspect has not been systematically evaluated.

Project Scope

The primary focus of this project will be to evaluate the appropriate use of musculoskeletal ultrasonography in rheumatology practice (rather than in general clinical practice, which might also include radiology, sports medicine, podiatry, etc.). The definition of rheumatology for the purposes of this project is broad and is intended to include the diagnosis and treatment of inflammatory diseases as well as the range of non-inflammatory and soft-tissue disorders encountered in routine rheumatology clinical practice. The ACR anticipates in this quickly developing field that other uses for MSUS will emerge, and acknowledges the need to be able to incorporate such indications into future appropriateness assessments, which will be conducted as frequently as necessary and feasible.

RAND/UCLA Methodology

The widely accepted RAND/UCLA Appropriateness Method for evaluating appropriateness of medical technologies will be used for this project. Using this method, investigators can determine the relative weight of the benefits and harms of an intervention. Initially, a literature review is conducted and the results are reviewed to determine the latest scientific evidence on the procedure to be evaluated in the project. Clinical scenarios are simultaneously developed, to group patients in areas of symptoms, past medical history, relevant test results, etc. A panel of experts then examines the literature review and, using a modified Delphi approach, votes on the appropriate use of the procedure for each clinical scenario, in the context of their experience and expertise. In areas where consensus exists, final recommendations are made; no attempt is made to force consensus. For more information about the RAND/UCLA methodology, visit http://www.rand.org/health/surveys_tools/appropriateness.html.

Clinical Scenarios / Opportunity for Public Comment

A list of clinical scenarios for the use of MSUS in rheumatology practice has been developed. These scenarios will guide the literature review and the discussions about the final recommended criteria. The scenarios cover the broad areas of diagnostic evaluations, procedure guidance, and monitoring disease activity and progression.

Composition of the MSUS Appropriateness Criteria Development Group

The group includes rheumatologists from private practice and academic settings, methodology experts, MSUS experts from Europe, pediatric and radiology specialists, and patient representation. There is a balance between ultrasound users and those who do not routinely use ultrasound in clinical practice. There is also a balance between junior, mid-level and senior clinicians.

Disclosure / Conflict of Interest

Everyone who is intellectually involved in this project will be required to fully disclose their relationships. ACR policy requires that a majority of these participants be unconflicted. In addition, the project leader must be unconflicted and maintain this status until at least one year after publication. Finally, people with major conflicts (e.g., employees of ultrasound equipment manufacturers) must not be included in the project. These ACR COI policies have all been met.

Written disclosures were provided and evaluated before participants were included They will be made again at the project mid-point, and then again at the end. If more frequent updates are necessary due to individual changes, these are made at least verbally, and if possible, in writing. Disclosures have been and will continue to be shared with everyone else in the development group so participants are aware of each other's relationships and any relevant changes to them as the project proceeds. Disclosures will also be provided in the final publication.

Publication and Authorship

Ultimately, a manuscript will be presented for consideration and approval by the ACR Board of Directors and *Arthritis Care & Research*. The review processes will be conducted concurrently but ACR and journal approval decisions will be made independently. It is expected that Core Expert Panel members will be authors on the final manuscript and Task Force Panel members will be acknowledged in the publication; however, there may be exceptions to this based on individual roles and effort. (See RAND/UCLA methodology for more detail on the roles of these two panels.)

Supporting information may also be posted online with the final published criteria (e.g., literature search/review details, feedback from the public comment on this protocol, etc.).

Timeline

It is anticipated that the final criteria will be completed in early 2012, with final votes re: ACR and journal approval taking place by May 2012. Publication would then be in late summer 2012.

ACR Staff Contacts

Amy Miller – amiller@rheumatology.org (project lead; responsible for project, with Dr. McAlindon)
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Clinical scenarios for use of MSUS in rheumatology practice

A Diagnostic Evaluations

A.1 Articular symptoms and/or swelling

1. Patient with articular pain and swelling
    a. *US with Doppler to determine presence or absence of effusion, synovitis, synovial thickening, tenosynovitis, popliteal cysts or osteoarthritis changes*
    b. *US to evaluate damage to fibrocartilaginous structures (e.g., meniscus in knees and wrists, labrum in shoulders and hips)*
    c. *Loose bodies*
    d. *US to detect presence of chondrocalcinosis*
    e. *US to detect double contour sign*
    f. *US of periarticular sites and tendons for tophi*
    g. *Evaluation of deep joints (e.g., hip)*
    h. *Articular evaluations in obese patients*

2. Patient with articular pain and no clinical findings
    a. *As above (1a-d)*

3. Patient with history of acute inflammatory monoarthritis now feeling well
    a. *As above (1a-d)*

4. Patient with oligo-articular pain and synovial swelling without effusion
    a. *As above (1a-d)*

A.2 Periarticular symptoms and/or swelling

5. Patient with periarticular swelling
    a. *US to determine cystic vs. solid swelling, and relation of the swelling to the surrounding tissues (e.g., synovial, tendon, bone) as well as for typical characteristics of tophi or rheumatoid nodules*

6. Patient with noninflammatory joint pain and unknown structural cause of pain
    a. *US with dynamic exam to determine presence of ligamenous tear*
    b. *Tendonopathy*
    c. *Tendon tear*
    d. *Tendon subluxation*
    e. *Impingement*
    f. *Tendon calcification*
    g. *Bursitis*
    h. *Fasciitis (plantar or palmer)*

A.3 Entheseal pain

7. Patient with pain at enthesis site and question of possible underlying inflammatory arthritis

a. *US with Doppler to detect enthesial changes that may be indicative of systemic arthritis as cause of the enthesitis (e.g., erosive changes or chronic hyperemia).*

A.4 Back pain

8. Patient with back pain and question of underlying inflammatory spondyloarthritis
    a. *US with Doppler to detect enthesial changes that may be indicative of spondyloarthritis*

A.5 Regional swelling

9. Patient with regional swelling
    a. *US to determine cystic vs. solid mass and stratify for likelihood of malignancy*
    b. *Evaluation of dermis, subfascial structures, bone*

A.6 Regional musculoskeletal symptoms

10. Patient without preceding trauma and/or without clear localization of symptoms
    a. *US with Doppler to evaluate regional structures as potential causes of pain*
        1) Finger
        2) Wrist
        3) Elbow
        4) Shoulder
        5) Hip
        6) Sacroiliac
        7) Lumbar/cervical facet
        8) Sternal (e.g., sternoclavicular, sternomanubrial, xyphoid)
        9) Knee
        10) Ankle
        11) Foot

11. Patient with localized posttraumatic pain
    a. *US to determine bone, ligament, tendon damage*

12. Patient with regional clicking/snapping +/- pain
    a. *US with dynamic examination to determine cause of clicking/snapping (tendon/muscle/labrum, typically the ITB or iliopsoas tendon in the hip and peroneus tendons in the ankle)*

A.7 Regional neuropathic pain

13. Patient with paresthesia or neuropathic pain where the clinical exam does not give a definitive diagnosis
    a. *US to evaluate for the diagnosis of nerve entrapment*
        1) Median nerve at carpal tunnel
        2) Median nerve at forearm
        3) Radial nerve at forearm
        4) Ulnar nerve at Guyon's canal
        5) Ulnar nerve at Cubital tunnel

6) Peroneal nerve at fibular head
7) Posterior tibial nerve at tarsal tunnel
8) Intradigital nerves – Morton's neuroma

A.8 Fascial disorders

14. Patient with contractures and tightening of the forearms
    a. *US to help differentiate eosinophilic fasciitis from systemic sclerosis*

A.9 Evaluation for giant cell arteritis (GCA)

15. Older patient with new headache but only minimally elevated inflammatory markers
    a. *US to help determine the need for temporal artery biopsy and/or prednisone therapy for giant cell arteritis*

A.8 Evaluation for Sjögren's syndrome

16. Patient with dryness of the mouth and eyes but negative antibodies for Sjögren's
    a. *US to determine whether parotid/submandibular glands have changes typical for Sjögren's*

A.8 Evaluation for muscle weakness

17. Patient with localized weakness
    a. *US to determine tendon tear*

18. Patient with diffuse muscle weakness
    a. *US to determine muscle atrophy and/or edema*

B Procedure Guidance

1. Ultrasound guidance for aspiration of synovial/tenosynovial/bursal fluid collection
2. Ultrasound guidance for aspiration of non-synovial fluid collection (abscess, cyst)
3. Ultrasound guidance for fine needle aspirations of suspected tophaceous mass
4. Ultrasound guidance for needle tenotomy of tendon
5. Ultrasound guidance for barbotage/removal/aspiration of calcium deposit
6. Ultrasound guidance for percutanous needle resection of soft tissue structure – A1 pulley release
7. Ultrasound-guided injection of medications or other therapies into synovial/tenosynovial/bursal structure
8. Ultrasound-guided injection of medications or other therapies into non-synovial structures
    a. *Peritendon*
    b. *Perienthesial*
    c. *Perineural (e.g., carpal tunnel syndrome)*
9. Ultrasound guidance for injection of nerve block/ablation
10. Ultrasound-guided synovial biopsy
11. Ultrasound-guided foreign body removal

C Monitoring Disease Activity and Progression

1. Patient with inflammatory autoimmune arthritis
    a. *US with Doppler to detect active synovitis*
    b. *US with Doppler to measure activity of synovitis*
    c. *US with Doppler to measure extent of erosive change*

2. Patient with osteoarthritis or other structural cause of pain
    a. *US to determine extent of degenerative changes such as*
        1) Osteophyte formation
        2) Cartilage loss
        3) Meniscal extrusion
        4) Synovial thickening
        5) Synovitis (Doppler)
        6) Effusion

APPENDIX B

AMERICAN COLLEGE OF RHEUMATOLOGY REPORT ON REASONABLE USE OF MUSCULOSKELETAL ULTRASONOGRAPHY IN RHEUMATOLOGY CLINICAL PRACTICE

PUBLIC COMMENTS

Alfred Denio, Staff physician Geisinger Medical Center	**Disclosure:** Nothing to disclose.
Protocol comments: The cost issues must be addressed if carriers are going to cover the procedure. When developing appropriateness criteria, consideration for the added cost of the procedure juxtaposed against the data derived expected improvement in outcome would ideally be a good way to determine level of appropriateness. That said, as we know, there is very little in medicine where we can precisely say "for X dollars for this procedure or medication, the patient has X improved chance of having successful outcome" or "will improve X days faster" with this procedure. There should be some statement where data is lacking which perhaps would be a stimulant for more research. Lack of precise data should not keep experts from coming to consensus, as long as it is clear what is expert consensus and what is evidence based.	
Michael Rezaian, Director Rural Outreach Arthritis Centers	**Disclosure:** Nothing to disclose.
Protocol comments: As a rheumatologist who was trained by a radiologist and not a chiropractor and used "Musculoskeletal Ultrasound" for over one year, I can tell you that this is a total waste of time for rheumatologists and above all a total waste of Money as it added very little to my clinical skills or my every day practice of rheumatology. I suspect this whole agenda is being pushed by those who are gaining money from it mainly the companies that are selling the equipment and offering training courses at outrageous prices. This equipment will end up gathering dust next to your "computer transcription System" that you were promised will take care of your dictations.	
Mitchell Lowenstein, Rheumatologist Arthritis Center	**Disclosure:** Nothing to disclose.
Clinical Scenarios comments: I Indications: Evaluation of periarticular soft tissue structures such as the integrity of the rotator cuff, the achilles tendon, the dimension of the median nerve, detection of erosions, etc. Needle localization for injection.	

APPENDIX B

AMERICAN COLLEGE OF RHEUMATOLOGY REPORT ON REASONABLE USE OF MUSCULOSKELETAL ULTRASONOGRAPHY IN RHEUMATOLOGY CLINICAL PRACTICE

PUBLIC COMMENTS

Chris Phillips, Physician Paducah Rheumatology	**Disclosure:** <$10,000 speaking Forest, Abbott, <$10,000 research support (clinical trial) Forest - nothing related to ultrasound.

Protocol comments:
All looks appropriate.

Clinical Scenarios comments:

A.1.1

a - Very appropriate use, I do this daily and it greatly enhances the care I provide
b - Not appropriate to evaluate labrum, meniscus - not sensitive for this
c - Not for loose bodies
d - Maybe helpful for chondrocalcinosis but I think a plain x-ray is better
e -?
f- very useful to eval tendons, tophi, i frequently detect tenosynovitis with u/s
g - limited for hips, depends on probe - i use to inject hip but not to examine it diagnostically
h - use in obese pts for evaluation depends on the joint and the scenario, but often useful esp. at knee for effusion, etc.

A.1.2 Same as above - especially 1a, even more helpful when clinical exam does not reveal pathology, it is worth noting that even when exam does reveal swelling, etc., it is still quite useful to nail down what the exact pathology is

A.1.3 possibly useful with resolved monoarthritis, often would not change management (i.e., none if feeling well), but if suspicion for systemic inflamm arthritis then detection of ongoing subclinical synovitis is useful

A.1.4 yes useful as above

A.2.5 yes very useful to determine nature/etiology of periart swelling, though I'm not so sure about distinguishing tophus from rheumatoid nodule, I've not found it very helpful in looking at these

A.1.6 I have not found good use to look at ligamentous injury; maybe if I had more skill I would, I often go to MRI in this setting. It is quite helpful for eval of tendinopathy, especially "itis" with doppler signal i.e. at achilles, quad tendon, biceps etc., definitely for tendon calcification, bursitis. Regarding plantar fasciitis, I have yet to find it to reliably diagnosis this; it's more clinical and sometimes will show doppler, sometimes wont, I will use to guide injection.

APPENDIX B

AMERICAN COLLEGE OF RHEUMATOLOGY REPORT ON REASONABLE USE OF MUSCULOSKELETAL ULTRASONOGRAPHY IN RHEUMATOLOGY CLINICAL PRACTICE

PUBLIC COMMENTS

Chris Phillips, Clinical Scenarios comments continued:

A.3.7 very helpful here, though I am not so sure how to reliably tell the enthesitis of a spondy from that of a routine tendonitis i.e. Achilles, if the clinical context does not help to distinguish - but clearly this is the study of choice for seeing these changes, better than MRI.

A.4 - I would not examine the back with u/sA59

A.5.9.a definitely for cyst vs. solid, not sure I'd be comfortably stratifying malignancy risk though

A.5.b not seeing a clear role for looking at skin, though I know this is an area of research

A.6.10.a yes on hand, elbow, shoulder, knee, ankle, foot, less so (for me, anyway) for the SI and spine. I will use on chest joints with utility as well.

A.6.11 yes on the tendon, less so the bone of ligament (for me) - I would go to other imaging if I suspect these problems

A.6.12 I understand likely u/s is useful for these purposes, I have not employed it for this, except with trigger finger

A.7 I believe u/s may be very helpful for all these nerve entrapments, I have personally only been comfortable with the carpal tunnel, i.e. measuring the nerve area - it seems (to me at least) there may be more skill/training for further use looking at nerves, I have not been as comfortable using it for this

A.8.14 not sure how to use u/s here, I would not do so

A.9.15 I have yet to see convincing enough data to tell me that if I do or do not see abnormality in the TA on u/s, that I'm confident enough to let this info guide my decision, I will look on occasion but I'd be pretty hesitant to make a decision on this basis alone

A.8.16 I have not found this useful, don't plan on doing so, though I know it has been studied, I would rather biopsy though I usually just make a clinical decision

A.8.17 yes

A.8.18 – No

APPENDIX B

AMERICAN COLLEGE OF RHEUMATOLOGY REPORT ON REASONABLE USE OF MUSCULOSKELETAL ULTRASONOGRAPHY IN RHEUMATOLOGY CLINICAL PRACTICE

PUBLIC COMMENTS

Chris Phillips, Clinical Scenarios comments continued:

B.1-3 Yes, yes, yes, I use u/s for ALL joint injections, in all situations it improves my care, increases fluid aspirated, decreases pain, and I believe improves outcomes, and I think I've seen enough data to believe this is an opinion backed by data, though I know study is ongoing - even for the knee, the number of times I thought it was an easy joint and could not get fluid, or steroid did not inject easily, has really led me to use the image guidance on all procedures - and I believe in the medicolegal environment we are in, this is appropriate - similar to u/s guidance for central lines - why stick a needle in someone blindly if you can guide it? Guidance may be a bit over-reimbursed at present, but that's a different issue...

B.4-5 have not personally performed this procedure

B.6 I would use to inject at pulley, not sure about "resecting"?

B.7 yes, yes, see above

B.8 definitely, even more than joint, here the risk of tendon rupture, nerve injury etc. makes guidance see even more prudent

B.9 I don't do this but I sure wouldn't' want it done to me without guidance

B.10 definitely

B.11 have not done this, unsure of role here?

C.1.a yes, yes, very useful, part of my daily practice, usually in the form of a quick, "limited" MSK exam rather than a complete exam.

C.1.b yes, a bit less so for me than a, but also used

C.1.c I do not do this, I understand it to be a useful tool in this setting and so I think it is appropriate

C.2. for degenerative pain, I would really only rely on the u/s to detect synovitis or effusion - i.e. to aspirate, or with synovitis in a pip/dip, to determine that a DMARD might be warranted for inflammatory OA - I think there is some utility for the other purposes, more as a "quick look" at presence of osteophytes, I think from a billing standpoint this would not be the modality of choice, I would not bill for an exam looking at this.

APPENDIX B

AMERICAN COLLEGE OF RHEUMATOLOGY REPORT ON REASONABLE USE OF MUSCULOSKELETAL ULTRASONOGRAPHY IN RHEUMATOLOGY CLINICAL PRACTICE

PUBLIC COMMENTS

Jay Higgs, Program Director, Rheumatology Fellowship USAF	**Disclosure**: <$10,000 speaking Forest, Abbott, <$10,000 research support (clinical trial) Forest - nothing related to ultrasound.

Protocol comments:
The timeline is OK, but it must be recognized that ultrasonography is a rapidly developing field. Hence, what seems appropriate regarding scope of practice this year may be too narrow next year. Regarding the methodology, the call for comment on clinical scenarios is ambiguous. I am not sure what kind of evaluation you are looking for:
1) a list of what each ultrasonographer MUST be able to do in order to be credentialed?
2) a list of the possible scope of practice for a rheumatologist?
3) a list of what we think is appropriate and billable within the scope of rheumatology?
4) a list of uses for which we think the literature clearly shows benefit?

Clinical Scenarios comments:
Not knowing exactly what kind of comment you want on the clinical scenarios, I will list below only the features you listed in the clinical scenarios for which I do NOT use ultrasound:
A.1.4 not C, since it is not in the differential diagnosis of resolved acute inflammatory arthritis
A.4.8 I do not use ultrasound with Doppler to detect back changes of spondyloarthropathies
A.6.10 Not 6) or 7)
A.7.13.a Not 2)-6)
A.8.14 I do not use ultrasound to differentiate eosinophilic fasciitis from systemic sclerosis.
A.9.15 I do not use ultrasound to determine the need for temporal artery biopsy or prednisone therapy: However I suspect that with further research and refinement of ultrasonography that this may be a use.
A.8.18 I do not use ultrasound to determine muscle atrophy and or edema.
B. Seizure guidelines I do not use ultrasound guidance for A1 pulley release, although I would be interested in learning this procedure if it exists. I also did not use it for numbers 9, 10, 11

Elizabeth Russell, Associate Professor U. of Arkansas	**Disclosure:** Nothing to disclose.

Protocol comments:
The project and its scope seem quite appropriate but certainly expansive.

Clinical Scenarios comments:
The areas of study noted seem reasonable; literature reviews of data in each proposed scenario should include Europe as well as USA.

APPENDIX B

AMERICAN COLLEGE OF RHEUMATOLOGY REPORT ON REASONABLE USE OF MUSCULOSKELETAL ULTRASONOGRAPHY IN RHEUMATOLOGY CLINICAL PRACTICE

PUBLIC COMMENTS

Herbert Baraf, President Arthritis and Rheumatism Associates	**Disclosure:** Nothing to disclose.

Protocol comments:

I am curious if this method has been used by ACR in assessing other areas of diagnosis, evaluation, management, therapy, etc. in our field? Likewise, I wonder whether other specialty societies (e.g. podiatry, pain medicine, neurology, orthopedics) have initiated this approach to evaluate ultrasound for incorporation into their scope of practice. If we are engaging in this exercise for the first time, why have we not done it before? For example when rheumatologists began using joint injection therapy in the 50's or biologic treatments in the 90's. Did we evaluate appropriateness of rheumatologists providing infusion therapy as an added service using this methodology?

Clinical Scenarios comments:

The scenarios are comprehensive. Since we, the College, in essence concede that we have not accepted MSUS as "appropriate" at this time, because it has not yet been through an appropriateness vetting, it would be premature to add a section on reimbursement scenarios. This is unfortunate. As we struggle with whether we are "worthy" to evaluate disease with US and utilize it to assist in needle localization, payers are already limiting its use and restricting its reimbursement. For the 20% or so of rheumatologists using US, the struggle should be with payers, not ourselves. We are running the risk of being "a day late and a dollar short." As an organizer of the ACR's Musculoskeletal US courses (the fourth of which will be held in Chicago in November) I am concerned by where we are on this and by what messages we send to our membership and to the authorities.

Eileen Moynihan, Medical Director, Medicare Highmark Medicare Services	**Disclosure**: I am making these comments as the medical director of a traditional, fee for service Medicare Contractor. (not as a rheumatologist and member of the current BOD)

Clinical Scenarios comments:

Just from experience, you had better choose what definition you are going to use for "obesity". Hopefully some thought about degree of joint deformity may be considered in procedure guidance. I take it from groups outside of ours that ultrasound for back issues are not standard. Medicare data indicates it is done nationally very infrequently for guidance, etc. recently I saw a series of claims for serial musculoskeletal ultrasound for evaluating the inflammation over trigger points and the "success" of treatment for fibromyalgia. (Not a rheumatology practice) but disturbing to see this monthly. Hopefully you will give a thought to inappropriate use while thinking about appropriate use.

APPENDIX B

AMERICAN COLLEGE OF RHEUMATOLOGY REPORT ON REASONABLE USE OF MUSCULOSKELETAL ULTRASONOGRAPHY IN RHEUMATOLOGY CLINICAL PRACTICE

PUBLIC COMMENTS

John Jenkins, Physician AOCMT	**Disclosure:** Nothing to disclose.
Protocol comments: Composition of the development group is too heavily weighted to East and West coast University professors (rather than those who actually know and do efficiently and proficiently MSKUS). As a retired Full Professor of Medicine and current private practitioner, I think the group is not adequately balanced in this respect. This imbalance omits expertise that may not yet be codified in "peer reviewed publications", and therefore limits the breadth of "consensus opinion" that may come from the group. Most of the best MSK ultrasonographers I know are not included in the group.	
Wolfgang Schmidt, Deputy Director Immanuel Krankenhaus Berlin, Medical Center for Rheumatology Berlin Buch	**Disclosure:** Nothing to disclose.
Protocol comments & Clinical Scenarios comments: I agree with the text.	
Jim O'Dell, Larson Professor & Vice Chair University of Nebraska	**Disclosure:** Nothing to disclose.
Protocol comments & Clinical Scenarios comments: I have no additional comments, thanks.	
Midori Nishio, Adjunct Clinical Asst. Prof Medicine Self Employed	**Disclosure**: USSONAR (nonprofit) Board Member
Protocol comments: I am in favor of a Delphi exercise as outlined. There are a lot of UCLA and BU faculty on the development group. It is not clear how many pediatricians are on the panel - Pediatric use criteria should probably be addressed in a separate protocol. **Clinical Scenarios comments:** For the most part I agree with the clinical scenarios described. I think item 1b should not be included. Labral structures are not easily evaluated by US. Hopefully the committee will clarify what they mean in utilizing US in these structures. I think in Procedures, items 4, 5 & 9 are going to turn out to be less data driven and more in the orthopedic realm.	

APPENDIX B

AMERICAN COLLEGE OF RHEUMATOLOGY REPORT ON REASONABLE USE OF MUSCULOSKELETAL ULTRASONOGRAPHY IN RHEUMATOLOGY CLINICAL PRACTICE

PUBLIC COMMENTS

David Bong, Rheumatologist, Sonologist and MSUS Investigator Instituto Poal de Reumatologia	**Disclosure:** Nothing to disclose.

Protocol Comments:

I am somewhat surprised at the timid and cautious introduction which is utilized in the protocol. The use of MSUS is widespread and an integral part of medical, including rheumatologic, practice around the world. Although it suffers from a general lack of good prospective evidence as far as its role in even the simplest and most common problems encountered by all musculoskeletal specialists (common to many other if not most procedures or techniques), MSUS is a valid technique that has great advantages that have been proven to be of benefit to practitioner and patient alike. It has also helped to further our understanding of these processes. Excellent clinical guidelines for the use of MSUS in rheumatology practice have existed for a number of years and build upon the foundation recently detailed by our non-rheumatologist MSUS colleagues and, even now, are undergoing re-evaluation (1,2). Although, these indications may emphasize aspects important to the rheumatologist, the rheumatologist-sonologist still requires the same anatomic and pathologic knowledge base and skill-set required of all MSUS sonologists. Furthermore, I assume that the Clinical Scenarios are the direct result of a review of this literature along with the current experience of a number of the committee members. Therefore I would be very surprised if the committee would submit a finding against the appropriateness of MSUS in these scenarios and find this exercise to be a bit repetitious. In my opinion, this exercise misses the point. We need to be looking at the much more daunting issue, the training of rheumatologists, both in practice and in fellowship, in this challenging technique with its rather steep learning curve. Competent sonologists with the ability to examine and intervene in the entire peripheral musculoskeletal system do not result from a few weekend conferences or remote learning but require mentored, hands-on training by expert sonologists. This requires a commitment of resources by the ACR, rheumatology training programs and other entities responsible for postgraduate education to effective training that leads directly to the education of skillful competent musculoskeletal sonologists if they want to play a role in the future of MSUS (and not just in rheumatology). We sorely need U.S. rheumatologists performing MSUS and applying their admirable investigational natures and skills to this field. Colleagues, the train has left the station and we are a little late!!(1)Musculoskeletal ultrasound a state of the art review in rheumatology. Part 2: Clinical indications for musculoskeletal ultrasound in rheumatology. Rheumatology (2004) 43 (7): 829-838. (2)ACR AIUM Practice Guideline for the Performance of the Musculoskeletal Ultrasound Examination. PRACTICE GUIDELINE. 2007 (Resolution 29)*

Clinical Scenarios Comments:

I hope that the purpose of the scenarios is to raise the so-called bar for the rheumatologist with the foundation being the anatomic and pathologic knowledge base and skills that all MSUS sonologists share.

APPENDIX B

AMERICAN COLLEGE OF RHEUMATOLOGY REPORT ON REASONABLE USE OF MUSCULOSKELETAL ULTRASONOGRAPHY IN RHEUMATOLOGY CLINICAL PRACTICE

PUBLIC COMMENTS

Herbet Lindsley, Professor, Internal Medicine University of Kansas Medical Center	**Disclosure**: Ultrasound user. Equipment: Esaote North America
Protocol Comments: I suggest Wolfgang Schmidt, MD, Berlin, as a core panel member. Methodology appears quite satisfactory. **Clinical Scenarios Comments:** Excellent, comprehensive selections of scenarios. To #10 under A6 I would add TMJ. Value and validity of serial ultrasound measurements needs to be addressed.	
Alina Voinea, Rheumatologist OrthoSurgeons	**Disclosure:** Nothing to disclose.
Protocol Comments: I think the scope and methodology of this project are perfectly appropriate. I am happy the ACR has involved itself in defining the role of MSK US in our daily practice. It is an incredibly useful tool for diagnostic and therapeutic procedures. I was myself trained in using MSK US as a fellow (like everybody else in our program) and am very excited about this project. **Clinical Scenarios Comments**: The list of clinical scenarios seems very adequate. In the Diagnostic Evaluations category, I was wondering why tab 4 was included separately from tab 1.	
William Reed Private practice	**Disclosure:** Nothing to disclose.
Protocol Comments: The protocols and rosters are sound. I appreciate the participants agreeing to do this. **Clinical Scenarios Comments:** The clinical scenarios are inclusive of practical applications for the use of diagnostic ultrasound. I presume, as new applications are identified, they would go through the same steps of review.	

APPENDIX B

AMERICAN COLLEGE OF RHEUMATOLOGY REPORT ON REASONABLE USE OF MUSCULOSKELETAL ULTRASONOGRAPHY IN RHEUMATOLOGY CLINICAL PRACTICE

PUBLIC COMMENTS

Esperanza Naredo, Rheumatologist Hospital Universitario Severo Ochoa	**Disclosure:** Nothing to disclose.
Protocol Comments: This is an exciting project that will be very helpful for the rheumatology community. Comments1.Compoition of the group. I suggest including the criteria for selection of the involved rheumatologists. **Clinical Scenarios Comments:** A.1 Articular symptoms and/or swelling. A.1.1 Patient with articular pain and swelling. I would say and/or again. A.1.f Tendons are periarticular sites. A.4 Patients with oliogo-articular.....scenario difficult to understand. How are you sure that there is no effusion? A.2. Tendon disorders can produce inflammatory pain. I would remove non inflammatory from point 6. A.4. I would include US Doppler to detect sacroileitis C, point 1. I would include US Doppler to detect subclinical synoviis; US Doppler to evaluate remission; US Doppler to evaluate tendon and ligament inflammatory damage	
Alexander Shikhman, CEO ww.ifsmed.com	**Disclosure:** Nothing to disclose.
Clinical Scenarios Comments: Evaluation of the TMJ needs to be added TMJ injections under US Knee meniscal tears Popliteal/baker's cyst evaluation /aspiration.	
Barbara Slusher, Physician Assistant Rheumatology Associates of Houston	**Disclosure:** Speaker for Amgen/Pfizer and UCB. I serve on the Executive Committee for ARHP.
Protocol Comments: Both the project protocol and case scenarios are thoughtful, well written and encompassing. I'm looking forward to the outcomes data and publication. Timeline seems tight but I'm confident the authors/contributors are assured they can meet the deadline. **Clinical Scenario Comments:** As previously stated, the case scenarios are thoughtful, well written and encompassing. Very well thought out! Thank you to the committee for their time and efforts.	

APPENDIX B

AMERICAN COLLEGE OF RHEUMATOLOGY REPORT ON REASONABLE USE OF MUSCULOSKELETAL ULTRASONOGRAPHY IN RHEUMATOLOGY CLINICAL PRACTICE

PUBLIC COMMENTS

Justin Peng, Rheumatologist Arthritis and Rheumatism Associates, PC	**Disclosure:** Nothing to disclose.
Protocol Comments: As a graduating rheumatology fellow this year, and now in private practice, I have found the ultrasound extremely useful, both for joint injections and for diagnostic purposes. For joints like the shoulder, ankle, and hip, I feel that ultrasound is essential. It has also helped me to detect the presence or absence of an effusion or synovitis very quickly. It has also improved the accuracy and safety of carpal tunnel injections. Criteria for appropriate use should take into account the benefits of safety and accuracy, as well as the fact that it takes time to do complete exams. It would be helpful if protocols for doing a complete or limited exam on each joint were standardized.	
Rajat Dhar, Rheumatologist Atlantic Coast Rheumatology	**Disclosure:** Nothing to disclose.
Protocol Comments: All aspects as described in constructing this project are correct in my opinion. It will allow objective assessment of parameters to use the technology appropriately. **Clinical Scenarios Comments:** The clinical scenarios are comprehensively covered. Appropriate use for guidance of injections needs to be specified. Literature that supports the use of guidance for any procedure should be footnoted in any documentation. Thereby no suspicion of appropriate use is raised by third party payers.	
Arnold Ceponis, Assistant Clinical Professor University of California San Diego	**Disclosure:** Nothing to disclose.
Protocol Comments: This is timely and much needed initiative attempting to guide MSKUS application in rheumatology. It is very thorough and well-tuned towards rheumatology practice. I am a daily user of ultrasound in my rheumatology practice. Following comments are based on review of the relevant literature, my personal experience and research. • Background: This is probably the weakest part of this project. As it appears now the justification of ultrasound use by rheumatologists seems to be its low risk of possible negative consequences and only possible clinical benefit. Although relative benefit and cost-effectiveness of some of the ultrasound guided procedures is debatable, there is enough solid data to support MSKUS in diagnosis of crystalline athropathies, early erosive synovitis to name the few. Benefits of bedside MSKUS in rheumatology office and by rheumatologist (often referred to as extension of the physical exam) as opposed to referring to radiology colleagues or rushing to proceed with costly MRI or CT could considered amongst other potential points for discussion in this section.	

APPENDIX B

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PUBLIC COMMENTS

Arnold Ceponis, Protocol comments continued:

- Project scope: Addressing requirements for the equipment suitable for MSKUS maybe considered in some form. In my experience, there is poor reproducibility and quality of power Doppler performance in detecting low flow states between different equipment brands. Inappropriate use of or inadequate equipment / techniques undermines the whole idea of MSKUS use in rheumatology. A very important practical aspect of the MSKUS in rheumatology office is the extent of ultrasound examination. I am not sure where this could fit in, but addressing the scope of complete vs. limited ultrasonographic examination and its implications in the context of clinical scenarios provided may be considered.

Clinical Scenarios Comments:

Proposed clinical scenarios are based on mixture of anatomical / symptomatology and nosological (i.e. disease such as GCA and Sjogren's) criteria and definitions. Such approach attempts to encompass most of the scenarios. It lacks uniformity, but still might be acceptable given its practical applicability. My concerns are as follows:

- Category A.1 definitions are overlapping and sometimes incomplete.
- Category A1: is it implied that symptoms refer to subjective complains and swelling to objective findings? How about category of patients that have joint tenderness and no swelling?
- Category A1.3: omits patients who are currently asymptomatic, but have history of oligo- or polyarthritis. How
- Category A1.1: is different from A1.4, and how effusion and swelling are defined on physical exam in smaller joints? Would it be less confusing and more encompassing to have categories irrespective of number of joints involved and to divide them in to: A1.1 patients with articular symptoms such as pain, and presence of joint swelling and/or tenderness
- A1.2: patients with symptoms such as articular pain w/o presence of objective joint swelling and/or tenderness
- A1.3: patients with historical joint pain and/or swelling now feeling well and having no objective findings. Notably the latter category would allow evaluation of patients who have early arthritis as well as would allow scanning critical sites such as TFC, intrinsic wrist ligaments, femoral /meniscal cartilage and 1st MTP in cases of quiescent crystalline arthropathy. Similar concerns apply to the Category A2Would it be more encompassing to have categories with:A2. Periarticular symptoms and swelling and/or tenderness?
- A2.5: Patients with peri-articular swelling and/or tenderness
- A2.6: Patients with unknown structural cause of pain, but without presence of swelling and/or tenderness, and without history of inflammatory joint disease?
- Category A3: This seems to be very vague and limited to evaluation of enthesal pain in search for active or chronic. Inflammatory enthesopathy. In real clinical setting, most of the enthesopathies (rotator cuff, patellar, Achilles, elbow, plantar fascia, etc.) are mechanical and related to overuse. Ultrasound can be very useful in this setting as well.

APPENDIX B

AMERICAN COLLEGE OF RHEUMATOLOGY REPORT ON REASONABLE USE OF MUSCULOSKELETAL ULTRASONOGRAPHY IN RHEUMATOLOGY CLINICAL PRACTICE

PUBLIC COMMENTS

Arnold Ceponis, Clinical Scenarios comments continued:

- Category A3: should probably address this practical issue. One of the points could be symptoms in multiple sites or in a setting of other clinical presentations such as skin psoriasis or AS or STD as opposed to one symptomatic site in physically active person in looking for active or chronic inflammatory or degenerative enthesopathy.
- Category A6a: This is broad and therefore lacks specificity which is confusing. Listing of the anatomical joint regions implies sonography of both regional structures and joints, but this is not obvious. Introduction of complete and limited examination may be helpful to clarify the extent (in this case complete) of the sonographic examination required in this category.
- Category C: Additional category 3 that would allow monitoring previously established active enthesitis can be considered.
- Categories A8, A9: Use of ultrasonography for evaluation of Temporary arteritis, muscle and facial diseases are operator dependent, require additional training and, at least in USA, are investigational. These categories probably should be listed as investigational and/or limited to experienced operators/centers.
- Numbering of Categories: it is difficult to follow why A9 category is followed by A8?

Thank you for the opportunity to provide the comments.

Susan Richmond, Physician Assistant Rheumatology and Autoimmune Disorders/MCPHS	**Disclosure:** Member, Musculoskeletal Ultrasound Certification Task Force.

Protocol Comments:

The project protocol is quite favorable. I would echo Dr. Flood's comments regarding ensuring the inclusion of other rheumatology providers, such as Physician Assistants and Nurse Practitioners, who also perform MSUS in the course of rheumatology practice.

Clinical Scenarios Comments:

My concerns regarding scenarios are the following:

1. Lumbar/cervical facet joint guided injection certainly are achievable by rheumatologists, but appear to overlap the scope of interventional radiology/pain management. I would not want to limit rheum practices, as there are a few that may do these procedures, however it is unclear if this is pushing the limits of the scope of rheumatology procedures/practice.
2. There are many possible scenarios for stratification of solid lesions, which are suspicious for malignancy, and testing/imaging beyond MSUS are likely needed. While I agree with biopsy of synovium, I think biopsy of solid masses are beyond our scope of practice.

APPENDIX B

AMERICAN COLLEGE OF RHEUMATOLOGY REPORT ON REASONABLE USE OF MUSCULOSKELETAL ULTRASONOGRAPHY IN RHEUMATOLOGY CLINICAL PRACTICE

PUBLIC COMMENTS

John Nitsche, Physician Owner Arthritis and Immunology Associates, LLC	**Disclosure:** Nothing to disclose.

Protocol Comments:

As the "the primary focus of this project will be to evaluate the appropriate use of musculoskeletal ultrasonography in rheumatology practice", it is important that all Rheumatologists who propose to perform these studies be well trained in MSKUS. Proposals for training should be included in the project. There should be a coding specialist in the development group that would present the perspective of Medicare and private health insurance carriers regarding the appropriateness, and likely confidence in re-imbursement, for the physician's efforts in performing the studies.

Clinical Scenarios Comments:

I have personally performed 3,000 MSKUS procedures in my office over the last four years. 50% of the studies have been performed for diagnostic purposes and 50% for therapeutic procedures under ultrasound. I perform all procedures under a combination of the suggested guidelines of AIUM and EULAR. In general, the guidelines for scanning are very comprehensive. If the scans are performed completely as directed, they are very time consuming. Furthermore, there is a steep curve for learning to scan and to recognize normal from abnormal. A machine for the office typically costs $35,00 to $50,000 with probes for MSKUS, and may sit idle in a busy practice if the doctor is not motivated to learn this demanding discipline. My experience has been that the level of re-imbursement for a scan alone (including report and printing of a labeled record), if the physician owns his/her own equipment is equivalent to a level 4 office revisit. If a scan, plus injection is performed, then the re-imbursement is equivalent to a level 3 and level 4 revisit. Thus, either the physician sees fewer patients during the day, schedules his scans in place of a revisit, or runs late if he tries to perform an unscheduled scan on a scheduled revisit. If a physician will perform MSKUS himself/herself in the office, they must enjoy scanning to do the task as ideally visualized. Their reward will be a much greater understanding of anatomy and musculoskeletal disease processes than practice without scanning. The dynamics of practice begin to change. I personally feel that most musculoskeletal procedures, like hospital based and biopsy oriented procedures in the office should be performed under ultrasound. I can attest to the change in my success with joint aspiration and injection under MSKUS, especially visco-supplementation, over the last few years. I have experienced dynamic growth in this area of my practice, especially in repeat procedures. Not surprisingly, the patients are less apprehensive with MSKUS guided therapy. The patients whom I share with my orthopedic colleagues, who perform unguided injections, commonly prefer my practice for injection therapy under MSKUS guidance. I feel comfortable performing injections on patients taking Aspirin, NSAID's and Plavix under MSKUS, without fear of bleeding by using a small caliber needle under careful guidance. Finally, it would be nice if the ACR would sponsor a MSKUS course dedicated to patients with musculoskeletal pathology. We have too many introductory courses that are directed to healthy patients. When the busy physician returns from the third or fourth introductory course, there continues to remain to a void in distinguishing normal from abnormal once the lectures are over. Perhaps the ACR should team with busy clinicians in private practice who have a large spectrum of cases with documented pathology and an interest in MSKUS. I would welcome the opportunity to help in this area.