AMERICAN COLLEGE of RHEUMATOLOGY
Empowering Rheumatology Professionals

American College of Rheumatology
Guideline for Vaccinations in Patients with Rheumatic and Musculoskeletal Diseases

Project Plan – April 2021

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ORGANIZATIONAL LEADERSHIP AND SUPPORT

This clinical practice guideline is being developed by the American College of Rheumatology (ACR) with funding from the ACR.

BACKGROUND

Rheumatic and musculoskeletal diseases (RMDs) affect a large proportion of adults and children in the United States [1]. These conditions are largely incurable and require prolonged use of medications to suppress disease activity, slow damage accrual, improve physical function and maximize health-related quality of life. Many of these RMDs (e.g., autoimmune rheumatic diseases), as well as many of the immunosuppressive or immunomodulatory therapies used to manage them, can place patients at higher risk of developing common or opportunistic infections (including vaccine-preventable infections) and may also affect responses to vaccines.

Vaccines have been long used worldwide to reduce illness from common viral and bacterial pathogens. Recommendations for standardized vaccine schedules for both children and adults have been widely adopted, for healthy people as well as those with chronic medical conditions. [2, 3]

Individuals with RMD and those receiving immunomodulatory therapy may be more susceptible to vaccine-preventable disease, or at higher risk of developing more serious complications of the disease should they become infected, suggesting that vaccination is an important strategy to reduce comorbid illness in affected patients. Therefore, individuals with RMD may benefit from alterations in the standard vaccination schedule or temporary adjust immunomodulatory medication schedules in order to maximize vaccine responsiveness and lower the likelihood and severity of vaccine-preventable illness.

Because vaccines fundamentally work by generating an effective immune response against pathogens, their effectiveness relies upon the function of an individual's immune system to recognize the pathogenic antigen(s) introduced by the vaccine and to generate a neutralizing immune response. Individuals with RMD and those on chronic immunosuppressive therapy may have impaired responses to vaccines that may reduce protection against vaccine-preventable illnesses.

Some of these issues have been addressed in ACR practice guidelines for the management of different diseases (e.g., RA, JIA), but because many issues regarding optimal vaccine use to reduce the burden of vaccine-preventable illness apply across a wide range of RMDs and immunosuppressive medications, the ACR created a dedicated group to review and compile data related to vaccination among all RMDs, particularly autoimmune and inflammatory rheumatic diseases (AIIRD) and the immunosuppressant and immunomodulating therapies used to manage such diseases.

The ultimate goal of this guideline is to provide recommendations regarding vaccinations in RMD populations, including if and when standardized vaccine schedules need to be altered due to underlying disease or its therapies, or conversely, if temporary adjustments to the immunosuppressive medication schedule should be made to optimize the efficacy and safety of a vaccination. Unfortunately, there will be limited high-quality direct evidence to address these issues comprehensively for every situation. Therefore, important questions have been included that consolidate relative issues of vaccine safety and efficacy in different situations facing RMD populations so that patients and providers may use the compiled background data to make informed decisions about individual vaccines and current or planned therapeutic regimens.

OBJECTIVES

The objective of this project is to develop evidence-based recommendations for vaccination in adults and children with RMDs including those on immunosuppressive or immunomodulating medications. In many cases, data are not available comparing different vaccination strategies to guide recommendations; therefore, indirect evidence of safety and efficacy (or immunogenicity as a surrogate) will be compiled to inform individual decision-making.

- The recommendations will cover clinically relevant vaccines that are recommended for use in the U.S. as well as select vaccines recommended for travelers or other sub-populations.
- The recommendations will cover autoimmune and inflammatory RMDs in adults and children that inherently affect the immune system or that often utilize immunosuppressive or immunomodulatory medications for management.
- The recommendations will cover commonly used immunomodulatory medications including glucocorticoids, conventional and targeted synthetic disease modifying antirheumatic drugs (csDMARDs and tsDMARDs), traditional immunosuppressant medications, and biologic therapies that are commercially available in the United States.

Specifically, we aim to:

1. Review the evidence for the risks of vaccine-preventable disease in individuals with RMD compared to the general population.
2. Review the evidence for the immunogenicity and clinical efficacy and safety of vaccines in RMD populations by underlying disease and immunomodulatory therapy.
3. Develop recommendations regarding the use of the high dose quadrivalent annual influenza vaccine in RMD patients on different immunomodulatory therapies.
4. Develop recommendations regarding altering the Center for Disease Control Advisory Committee on Immunization Practices (ACIP) [2] schedule of vaccines for RMD patients on different immunomodulatory therapies, including:
    a. Deferring vaccinations in relation to disease activity and/or immunomodulatory medication use
    b. Use of vaccines at age ranges outside of recommended guidelines in relation to the underlying RMD and/or immunomodulatory therapy
5. Develop recommendations regarding temporary adjustments in immunomodulatory medication dosing to maximize vaccine efficacy and responsiveness including:
    a. Timing vaccinations with respect to intermittently dosed mediations
    b. Holding medications before or after vaccinations

METHODS

Identification of Studies

Literature search strategies, based upon PICO questions (Population/patients, Intervention, Comparator, and Outcomes; *see Appendix A*), will be developed by a medical research librarian in consultation with the Core Team. The search strategies will be peer reviewed by another medical librarian using Peer Review of Electronic Search Strategies (PRESS) [4]. Searches will be performed in OVID Medline (1946 +), Embase (1974 +), the Cochrane Library, and PubMed (mid-1960s +).

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.

Search Limits

Only English language articles will be retrieved.

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 prior to the voting panel meeting to ensure completeness.

Inclusion/Exclusion Criteria

See PICO questions (*see below*), which outline the defined patient population, interventions, comparators, and outcomes. Case reports and case series with fewer than 10 patients will be excluded.

Management of Studies and Data

References and abstracts will be imported into bibliographic management software (Reference Manager) [5], duplicates removed, and exported to Distiller SR, a web-based systematic review manager [6]. Screening 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. Following the same dual review process, disagreements at the full manuscript screening stage will be discussed and adjudicated by the literature review leadership, if necessary.

Phases

1. A search for randomized controlled trials and observational studies about interventions will be performed to identify existing studies assessing the outcomes of interest. Subsequently, we will conduct meta-analyses of identified studies using the RevMan

software [7] and the rating of the certainty of evidence following the GRADE methodology (and using the GRADEPro tool) [8].

2. Chosen studies will be assessed for risk of bias using modified versions of the Cochrane Risk of Bias tool [9] and the Newcastle-Ottawa Scale [10].
3. Additionally, recently published systematic reviews covering outcomes of interest will also be sought and used for reference cross-checking.

GRADE Methodology

GRADE methodology [11] will be used in this project to rate the certainty of the available evidence and facilitate the development of recommendations. The certainty of the evidence (also known as 'quality' of evidence) will be rated as high, moderate, low or very low. This rating is based upon the judgment of the GRADE criteria for downgrading (risk of bias, inconsistency, indirectness, imprecision, and publication bias) or upgrading the certainty of evidence (large magnitude of effect, dose-response gradient, and all plausible confounding that would reduce a demonstrated effect). The strength of recommendations will be graded as strong or conditional. The strength of recommendations will depend upon the balance of benefits and harms, the certainty in the evidence, and patients' preferences and values. A series of articles that describe the GRADE methodology can be found on the GRADE working group's website: www.gradeworkinggroup.org.

Analysis and Synthesis

The literature review team will analyze and synthesize data from included studies that address the PICO questions using Review Manager (RevMan) [7]. A GRADE evidence profile and a Summary of Findings table will be prepared for each PICO question using the GRADEprofiler (GRADEpro) software (8). For each critical or important outcome, the GRADE Summary of Findings table will contain the anticipated absolute effect, the relative effect (95% CI), the number of participants/number of studies, and the certainty in the evidence (i.e., high, moderate, low or very low).

For each critical or important outcome, the GRADE evidence profile will contain the same information as in a Summary of Findings table, in addition to detailed judgments and justifications for the GRADE criteria for downgrading or upgrading the certainty of evidence.

If a meta-analysis is not possible (e.g., data are from non-comparative studies or not in a format amendable to pooling) we will summarize the available evidence (or lack thereof) in a narrative format instead.

Development of Recommendation Statements

PICO questions will be revised into drafted recommendation statements. Using the evidence summaries developed by the literature review team, the voting panel 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. During the voting panel meeting, chaired by the principal investigator, the panelists 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 literature review leader, the GRADE expert, and selected members of the literature review team, who will attend the meeting to provide details about the evidence, as requested. Voting panel discussions and decisions will be informed by a separately convened patient panel (which will meet in the days before the voting panel meeting) to provide unique patient perspectives on the drafted recommendations based upon their experiences and the available literature. Two members of the separate patient panel will participate as full, voting members of the voting panel that determines the final recommendations; their role at the voting panel meeting will be to explicitly represent the patient panel's views to other voting panel members during discussions and decision-making.

PLANNED APPENDICES (AT MINIMUM)

A. Final literature search strategies
B. Evidence summaries for each PICO question, including GRADE evidence profiles and summary of findings tables, when available

AUTHORSHIP

Authorship of the guideline will include principal investigator, Dr. Eliza Chakravarty, as the lead author and voting panel leader; Dr. Joann Fontanarosa, literature review leader; Dr. Elie A. Akl, GRADE expert; Drs. Clifton Bingham, Leonard Calabrese, Laura Cappelli and Kevin Winthrop,

content experts; and any other Core Team members added to the leadership. Members of the literature review team and voting panel will also be authors. The PI will determine final authorship, dependent upon 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 E for participant disclosures.*

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APPENDIX A - PICO Questions (Population, Intervention, Comparator, Outcome)

See appendix B, C, D for lists of diseases, medications, and vaccines.

RISKS OF VACCINE-PREVENTABLE DISEASE (INCLUDING CERVICAL/ANAL CANCER FROM HPV)

Prognosis rather than intervention questions

1. Are patients with RMD disease X at increased risk *to contract* vaccine-preventable diseases compared to the general population?

P - RMD patients
C - General population
O - Contracting vaccine-preventable diseases

2. Are patients with RMD disease X at increased risk *for more severe outcomes from* vaccine-preventable diseases compared to the general population?

P - RMD patients
C - General population
O - Outcomes (mortality/morbidity) from vaccine-preventable diseases (will include all markers of severity, e.g., hospitalization, death)

QUESTIONS REGARDING VACCINE IMMUNOGENICITY/EFFICACY/SAFETY TO INFORM GUIDELINE RECOMMENDATIONS

Prognosis rather than intervention questions

3. In patients with [RMD Disease X], what is the effect of [Drug Y/Drug Class] on immunization responses to [Vaccine Z, Vaccine Type] in comparison with [General population, or Drug Y']?

P - RMD Disease X
I - Vaccine Z
C 1 - Patients receiving drug(s) Y
C 2 - Patients receiving drug(s) Y
C 3 - Healthy controls

O - Immunogenicity (Geometric mean titer (GMT), fold increase in titer, seroconversion, seroprotection, cell mediated immunity)

4. In RMD patients, does the immunogenicity or efficacy of Vaccine Z differ in patients taking high-dose steroids as compared to those using lower doses of steroids or those not using steroids?

P - RMD patients taking high dose steroids I - Vaccine Z
C 1- RMD patients taking low dose steroids
C 2 - RMD patients not taking steroids
O - Rates of infection, immunogenicity

5. In RMD patients on drug Y, do immune responses to neo-antigens (not vaccines) differ from responses seen in the general population?

P - RMD patients receiving drug Y
I - Administration of neo-antigen
C 1 - Administration of neo-antigen to general population
C 2 - Administration of neo-antigen to RMD patients not receiving Drug Y
O – Immunogenicity

6. In patients with [Disease X], is the duration of the immune response to [Vaccine Z] diminished compared to [healthy controls]?

P - Disease X
I - Vaccine Z
C 1 - Patients receiving drug(s)
C 2 - Healthy controls
O - Immunogenicity (see question #2), development of vaccine-preventable disease

7. Do patients with [Disease X] have higher rates of adverse events following [Vaccine Z] compared to [healthy controls]?

P - Disease X
I - Vaccine Z
C 1 - Patients receiving drug(s) Y
C 2 - Healthy controls

O - Reactogenicity (fever, vaccine site reactions, myalgia, arthralgia, headache, rhinitis, sore throat)

8. Do patients with [Disease X] experience flares of their underlying RMD after immunization with [Vaccine Z]?
P - RMD Disease X
I - Administer Vaccine Z
C - Do not administer vaccine Z
O - Increase in disease activity

QUESTIONS ABOUT ANNUAL INFLUENZA VACCINE

9. In RMD patients age 65 and older, is high dose (Fluzone high dose) influenza vaccine more effective than seasonal regular dose influenza vaccine?
P - Patients with RMD age 65 and older
I - High dose (Fluzone) influenza vaccine
C - Regular dose influenza vaccine
O - Rates of influenza infection, immunogenicity reactogenicity

10. In RMD patients age 65 and older, is adjuvanted influenza vaccine (FLUAD) more effective than seasonal regular dose influenza vaccine?
P - Patients with RMD age 65 and older
I - FLUAD influenza vaccine
C - Regular dose influenza vaccine
O - Rates of influenza infection, immunogenicity, reactogenicity

11. In RMD patients *under* age 65 years, is high dose (Fluzone high dose) vaccine more effective than seasonal regular dose influenza vaccine?
P - Patients with RMD underage 65
I - Fluzone high dose influenza vaccine
C - Regular dose influenza vaccine
O - Rates of influenza infection, immunogenicity, reactogenicity

12. In RMD patients *under* age 65 years, is adjuvanted influenza vaccine (FLUAD) more effective

than seasonal regular dose influenza vaccine?
P - Patients with RMD under age 65
I - FLUAD adjuvanted influenza vaccine
C - Regular dose influenza vaccine
O - Rates of influenza infection, immunogenicity, reactogenicity

13. In RMD patients, does the immunogenicity or efficacy of influenza vaccine differ in patients who have moderate to severely active underlying disease as compared to those in low-disease activity or remission?
P - Patients with moderate to severely active RMD
I - Influenza vaccination
C - Patients with quiescent/low disease activity RMD
O - Rates of influenza infection, immunogenicity

14. In RMD patients, does the immunogenicity or efficacy of influenza vaccine differ in patients taking high dose steroids as compared to those using lower doses of steroids or those not using steroids?
P - RMD patients taking high dose steroids
I - Influenza vaccination
C 1 - RMD patients taking low dose steroids
C 2 - RMD patients not taking steroids
O - Rates of influenza infection, immunogenicity

15. In RMD patients, does the immunogenicity or efficacy of influenza vaccine differ in patients taking Drug Y as compared to those not using drug Y at the time of vaccination?
P - RMD patients taking Drug Y
I - Influenza vaccination
C - RMD patients not taking drug Y
O - Rates of influenza infection, immunogenicity

QUESTIONS ABOUT TIMING OF VACCINE WITH RESPECT TO IMMUNOSUPPRESSIVE MEDICATIONS OR DISEASE ACTIVITY

16. Should patients with RMD taking drug Y hold their drug for a period of time prior to or after

receiving (not live-attenuated) vaccines?
P - Patients with RMD on drug Y
I 1 - Hold drug Y prior to vaccine
I 2 - Hold drug Y after vaccine
C - Usual dosing of drug Y
O - Reactogenicity, disease flare, immunogenicity

17. Should patients with RMD who are taking biologic medications with usual dosing schedules of monthly or longer* schedule (not live-attenuated) vaccine administration relative to next dose of medication?
P - Patients with RMD on intermittent-dosing biologic medications
I 1 - Vaccination 1 month before next biologic medication dose
I 2 - Vaccination > 1 month before next biologic medication dose
C - No schedule adjustment of vaccine relative to medication dose
O - Reactogenicity, disease flare, immunogenicity

*Rituximab, ocrelizumab, belimumab, ustekinumab, tocilizumab (IV), TNF inhibitors (infliximab, golimumab, certolizumab), IVIg, abatacept (IV), secukinumab, ixekizumab, guselkumab, canakinumab, tildrakizumab, risankizumab

18. Should moderately to severely ill RMD patients with disease X defer vaccination (for NOT live-attenuated) until disease is better controlled?
P - RMD patients with moderate to severe active disease
I - Delay vaccine until low disease activity or remission
C - Proceed with vaccinations without change in schedule
O - Reactogenicity, immunogenicity

QUESTIONS RELATED TO VACCINATION OUTSIDE OF STANDARDIZED AGE RANGES

19. Should RMD patients be vaccinated against HPV at ages older than age 26?
P - RMD patients older than 26 without complete HPV vaccination
I - Vaccinate for HPV
C - Do not vaccinate for HPV
O - Rates of HPV infection, incidence of HPV-related cancer (cervical, anal, head and neck cancer)

20. Should RMD patients with RMD receive vaccination against pneumococcus at ages less than 65 years?

P - RMD patients under age 65 with RMD who have not received pneumococcal vaccine
I - Vaccinate against pneumococcus
C - No pneumococcal vaccination
O - Rates of pneumonia and associated complications, reactogenicity, immunogenicity

21. Should RMD patients receive Shingrix vaccine (against varicella zoster virus [VZV]) at ages younger than 50 years?

P - RMD patients under 50 years who have not received Shingrix
I - Administer Shingrix vaccine
C - Do not administer Shingrix vaccine
O - Rates of herpes zoster (shingles) and shingles-related complications (post herpetic neuralgia, disseminated herpes zoster infection), reactogenicity, immunogenicity

22. Should RMD patients receive standardized regimens of vaccine combinations?

P - RMD patients
I - Administer vaccines individually rather than in standardized combinations
C - Administer combination vaccines according to ACIP guidelines
O - Change in RMD disease activity

QUESTIONS REGARDING USE OF LIVE-ATTENUATED VACCINES

23. Should RMD patients taking drug Y receive live-attenuated vaccines?

P - RMD Patients taking drug Y
I - Receive live-attenuated vaccine
C - Do not receive live-attenuated vaccine
O - Development of vaccine-preventable infection

24. Should RMD patients taking drug Y hold the drug for a period of time prior to or after receiving live-attenuated vaccines?

P - RMD patients taking drug Y

I 1 - Hold drug Y prior to vaccination
I 2 - Hold drug Y after vaccination
C - No alterations in drug dosing
O - Development of vaccine-preventable infection

25. Should neonates/infants with second and third trimester antenatal exposure to TNF inhibitors or Rituximab receive live-attenuated rotavirus vaccine in their first 6 months of life?

P - neonates/infants with 2nd or 3rd trimester exposure to TNF inhibitors or Rituximab
I - Administer rotavirus vaccine in first 6 months of life
C 1 - Do not administer rotavirus vaccine
C 2 - Delay live-attenuated rotavirus vaccine until after first 6 months of life
O - Rates of rotavirus infection

26. Should family members of RMD patients receive live-attenuated vaccines?

P - Family member of RMD patients
I - Administration of live-attenuated vaccines
C - Do not administer live-attenuated vaccines
O - Development of vaccine-preventable infection

Appendix B: Rheumatic and Musculoskeletal Diseases to be addressed (autoimmune and inflammatory diseases) "Disease X"

1. Inflammatory arthropathies
    a. Rheumatoid arthritis
    b. Psoriatic arthritis
    c. Ankylosing spondylitis
    d. Seronegative spondyloarthropathies
    e. Enthesitis-related arthritis
    f. Inflammatory bowel disease-associated arthritis
    g. Juvenile Idiopathic Arthritis
        i. Oligoarticular
        ii. Polyarticular
        iii. Undifferentiated
2. Connective tissue diseases
    a. Systemic lupus erythematosus
    b. Sjogren's syndrome
    c. Systemic sclerosis/Scleroderma
    d. Idiopathic Inflammatory myopathies
    e. Mixed connective tissue disease
    f. Undifferentiated connective tissue disease
    g. Antiphospholipid antibody syndrome
    h. Catastrophic anti-phospholipid syndrome
3. Vasculitides
    a. ANCA-associated vasculitis
        i. Granulomatosus with Polyangiitis (Wegener's Granulomatosus)
        ii. Microscopic polyangiitis
        iii. Eosinophilic Granulomatosus with Polyangiitis (Churg-Strauss Syndrome)
    b. Giant cell arteritis
    c. Polyarteritis nodosa
    d. Takayasu's arteritis
    e. Cryoglobulinemia
    f. Relapsing polychondritis
    g. Behcet's disease

497 h. Kawasaki's disease
498 i. Henoch Schonlein Purpura
499 j. Primary CNS vasculitis
500 k. Anti-GBM/Goodpasture's syndrome
501 l. Cogan's syndrome
502 m. Cutaneous small-vessel vasculitis
503 n. IgA vasculitis
504 o. Rheumatoid vasculitis
505 p. Urticarial vasculitis
506
507 4. Inflammatory disorders
508 a. Sarcoidosis
509 b. Adult-onset Still's disease (systemic onset juvenile idiopathic arthritis)
510 c. Systemic onset juvenile idiopathic arthritis
511 d. Polymyalgia rheumatica
512 e. Gout
513 f. Pseudogout
514 g. IgG4-related disease
515 h. Periodic fever syndromes
516 i. PFAPA (Periodic Fever, Apthous Stomatitis, Pharyngitis, Adenitis)
517 ii. FMF (Familial Mediterranean Fever)
518 iii. HIDS (Hyper-IgD syndrome)
519 iv. TRAPS (Tumor necrosis factor receptor-associated periodic syndrome)
520 i. Autoinflammatory syndromes
521

Appendix C: Immunosuppressive and Immunomodulating medications, "Drug Y"

1. Glucocorticoids: prednisone, prednisolone, methylprednisolone, dexamethasone
2. Immunosuppressive/immunomodulating medications
    a. Mycophenolate mofetil/mycophenolic acid
    b. Azathioprine
    c. Calcineurin inhibitors
        i. Cyclosporine
        ii. Tacrolimus
        iii. Voclosporin
    d. Apremilast
    e. Intravenous immunoglobulin (IVIg)
    f. Cyclophosphamide
    g. Colchicine
    h. NSAIDS
    i. Acetaminophen
3. csDMARDs (conventional synthetic disease-modifying anti-rheumatic drugs)
    a. Methotrexate
    b. Leflunomide
    c. Sulfasalazine
    d. Hydroxychloroquine
4. bDMARDS (biologic DMARDs) including biosimilars
    a. Tumor necrosis factor inhibitors (TNFi)
        i. Etanercept
        ii. Infliximab
        iii. Adalimumab
        iv. Golimumab
        v. Certolizumab pegol
    b. B-cell depleting agents
        i. Rituximab
        ii. Ocrelizumab
        iii. Obinutuzumab
    c. T-cell co-stimulation blockers
        i. Abatacept

555 d. IL-I inhibitors
556 i. Anakinra
557 ii. Canakinumab
558 iii. Rilonacept
559 e. IL-6 inhibitors
560 i. Tocilizumab
561 ii. Sarilumab
562 f. IL-17 inhibitors
563 i. Secukinumab
564 ii. Ixekizumab
565 g. IL-12/IL-23 inhibitors
566 i. Ustekinumab
567 h. IL-23 inhibitors
568 i. Guselkumab
569 ii. Tildrakizumab
570 iii. Risankizumab
571 i. BLyS/Baff inhibitors
572 i. Belimumab
573 ii. Tabalumab
574 j. Interferon alpha blockers
575 i. Anifrolumab
576 k. RANKL inhibitors
577 i. Denosumab
578 5. tsDMARDs (targeted synthetic DMARDs)
579 a. JAK inhibitors
580 i. Tofacitinib
581 ii. Baricitinib
582 iii. Upadacitinib
583 iv. Filgotinib
584 v. Ruxolitinib
585

Appendix D: Vaccines of clinical interest (by mechanism of action) "Vaccine Z"

1. Protein/Subunit/Recombinant/Inactivated organism
    a. Seasonal influenza (inactivated or recombinant, injectable)
        i. Standard dose
        ii. High dose
        iii. Adjuvanted
    b. Tetanus toxoid/Td/Tdap
    c. Hepatitis B
    d. Human Papilloma Virus (HPV)
    e. Hepatitis A
    f. Herpes zoster (recombinant Shingrix)
    g. Meningococcus B (recombinant MenB--Bexsero, Trumenba)
    h. Inactivated polio (IPV)
    i. COVID (when data available)
2. Polysaccharide
    a. Pneumococcus (PPSV23, Pneumovax)
    b. Typhoid (Vi-PS, injectable)
3. Conjugate
    a. Pneumococcus (PCV13, Prevnar)
    b. Meningococcus ACWY (conjugate—MenACWY, Menactra, Menveo)
    c. H. influenza b (Hib)
4. mRNA and others
    a. SARS-COV 2(when peer reviewed published data are available) (Pfizer, Moderna, Johnson & Johnson, and others, as they are available in the U.S.)
5. Live attenuated vaccines
    a. MMR
    b. Yellow fever
    c. Zoster (live attenuated, Zostavax)
    d. Rotavirus
    e. Varicella
    f. Influenza (live attenuated, nasal spray)
    g. Typhoid (live attenuated, oral Ty21a)

6. T-cell dependent Neo-antigens
    a. Bacteriophage ϕX174
    b. Keyhole limpet haemocynan (KLH)

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Project Plan – April 2021

APPENDIX E – Participant Disclosures - 2022 Vaccinations Guideline
In order for the College to most effectively further its mission and to otherwise maintain its excellent reputation in the medical community and with the public, it is important that confidence in the College's integrity be maintained. The cornerstone of the ACR's Disclosure Policy is disclosure of actual and potential conflicts so that they can be evaluated by the College in order to avoid undue influence of potential conflicts. The purpose of the ACR's Disclosure Policy is identification of relationships which may pose actual or potential conflicts. These actual or potential conflicts can then be evaluated by the College so that adjustments can be made that will avoid any undue influence. This policy is based on the principle that, in many cases, full disclosure of the actual or potentially conflicting relationship will of itself suffice to protect the integrity of the College and its interests.

Participants	Role	Primary Employment	Sources of Personal Income	Intellectual Property	Research Grants/Contracts	Investments to include medical industry and nonmedical industry	Organizational Benefit	Activities with Other Organizations	Family or Other Relations
Eliza Chakravarty	Core Team/Principal Investigator	Oklahoma Medical Research Foundation		N/A	NIH/NIAMS	N/A	N/A	N/A	N/A
Elie Akl	Core Team/GRADE Expert	American University of Beirut	World Health Organization	N/A	N/A	World Health Organization; Robert Koch-Institut	N/A	N/A	N/A
Joann Fontanarosa	Core Team/Lit Review Team Lead	ECRI Institute	N/A	N/A	American Cancer Society; International Society for Thrombosis and Haematosis; Agency for Healthcare Research and Quality (AHRQ); Veteran's Administration/Department of Defense CPG program; Patient-Centered Outcomes Research Institute (PCORI); FDA report on PLGA material and a PCORI Covid19 Horizon Scanning Project	N/A	N/A	N/A	N/A
Clifford (Bing) O. Bingham	Core Team/Content Expert	Johns Hopkins University	Abbvie; Bristol Myers Squibb; Eli Lily; Gilead; Janssen; Pfizer; Regeneron; Sanofi/Genzyme	N/A	Bristol Myers Squibb; NIH	N/A	Abbvie; Janssen; Gilead	OMERACT	N/A
Kevin Winthrop	Core Team/Content Expert	Oregon Health & Science University	Pfizer; AbbVie; Union Chimique Belge (UCB); Eli Lilly; Galapagos; GlaxoSmithKline (GSK); Roche; Gilead	N/A	BMS; Pfizer	N/A	N/A	N/A	N/A

Laura Capelli	Core Team/Content Expert	Johns Hopkins	AbbVie	N/A	Bristol-Myers Squibb; NIAMS	N/A	N/A	N/A	N/A
Len Calabrese	Core Team/Content Expert	Cleveland Clinic	Sanofi Regeneron; GSK; Roche Genentech; AbbVie; Amgen; Myriad; UCB; Gilead; Novartis; Lily; BMS; Horizon	N/A	N/A	N/A	N/A	Healio Rheumatology	Cassie Calabrese, daughter
Alexandra (Alex) Legge	Lit Review Team	Nova Scotia Health Authority	N/A	N/A	N/A	N/A	N/A	Canadian Rheumatology Association; Royal College of Physicians & Surgeons of Canada	N/A
Beth Rutstein	Lit Review Team	University of Pennsylvania	N/A	N/A	The Center for Clinical Effectiveness at CHOP	N/A	N/A	N/A	N/A
Cassie Calabrese	Lit Review Team	Cleveland Clinic	Abbvie; GSK; Sanofi-Regeneron	N/A	N/A	N/A	N/A	National Psoriasis Foundation	Leonard Calabrese, father
Elena Gkrouzman	Lit Review Team	UMass Medical School; UMass Memorial Medical Group	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Herman Tam	Lit Review Team	Provincial Health Services Authority, BC, Canada	American College of Rheumatology	N/A	N/A	N/A	N/A	N/A	N/A
Joanne S. Cunha	Lit Review Team	Brown University; Brown Physicians Inc (primary care + subspecialist group); Providence VA Medical Center	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Kimberly Showalter	Lit Review Team	Hospital for Special Surgery	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Marat Turgunbaev	Lit Review Team	American College of Rheumatology	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Megan Lockwood	Lit Review Team	Massachusetts General Hospital	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Mindy Lo	Lit Review Team	Boston Children's Hospital	AAP PREP Rheumatology Advisory Board	N/A	CARRA; Glaxo-Smith-Kline	N/A	N/A	N/A	Husband consults for 2 healthcare related companies (Oncology)
Miriah C. Gillispie-Taylor	Lit Review Team	Atrium Health	N/A	N/A	Pfizer; CARRA/Arthritis Foundation; PR COIN/AF/CERT; UCB; Bristol Myers Squibb	N/A	N/A	N/A	N/A
Namrata Singh	Lit Review Team	University of Washington	N/A	N/A	Rheumatology Research Foundation; AHA	N/A	N/A	N/A	N/A
Nancy Sullivan	Lit Review Team	ECRI Institute	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Priyanka Iyer	Lit Review Team	UC Irvine Medical Center	N/A	N/A	UC Irvine Department of Medicine	N/A	N/A	N/A	N/A
Rebecca Sadun	Lit Review Team	Duke University	Lupus Foundation of America	N/A	Rheumatology Research Foundation; Arthritis Foundation; Lupus Foundation of America; CRDF Global; Human Vaccine Trial Network	N/A	N/A	N/A	N/A
Benjamin J. Smith	Voting Panel	Florida State University College of Medicine School of Physician Assistant Practice	N/A	N/A	Health Resources and Services Administration	N/A	N/A	ACR/ARP; National Commission on Certification of Physician Assistants; American Academy of Physician Assistants/Johns Hopkins	N/A

Eleanor Anderson Williams	Voting Panel	The Permanente Medical Group	N/A	N/A	The Permanente Medical Group	N/A	N/A	N/A	N/A
Jeffrey Sparks	Voting Panel	Brigham and Women's Hospital	Pfizer; Gilead; Bristol-Myers Squibb; Optum	N/A	NIH/NIAMS; Rheumatology Research Foundation; NIH/NIAID	N/A	N/A	N/A	N/A
Jonathan TL Cheah	Voting Panel	UMass Memorial Medical Group; University of Massachusetts Medical School	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Lindsey Baden	Voting Panel	Brigham and Women's Hospital; New England Journal of Medicine	N/A	N/A	NIH; Wellcome Trust; Gates Foundation, IAVI	N/A	N/A	N/A	N/A
Reuben Arasaratnam	Voting Panel	UT Southwestern Medical Center	University of Kentucky; Methodist Hospital Dallas; Baylor University Medical Center; COVID-19 survey Techspert.io, Cambridge UK.	N/A	Alliance for Academic InterN/Al Medicine	N/A	N/A	N/A	N/A
Tiphanie Vogel	Voting Panel	Baylor College of Medicine	N/A	N/A	ANR Foundation; Thraser Research Fund; RRF; CHEST Foundation; Ligums Family	N/A	N/A	OPA Syndrome Foundation	N/A
Anne Bass	Voting Panel/ACR BOD Liaison	Hospital for Special Surgery	N/A	N/A	HSS complex joint reconstruction center; HSS rheumatology council	N/A	N/A	N/A	N/A
Ida Hakkarinen	Voting Panel/Patient Rep	National Oceanic and Atmospheric Administration	N/A	N/A	N/A	N/A	N/A	N/A	Sibling - William D. Hakkarinen, M.D., AAFP (past President of Maryland Academy of Family Physicians)