Complete Summary

GUIDELINE TITLE

Immunization and multiple sclerosis: a summary of published evidence and recommendations.

BIBLIOGRAPHIC SOURCE(S)

Rutschmann OT, McCrory DC, Matchar DB, Immunization Panel of the Multiple Sclerosis Council for Clinical Practice Guidelines. Immunization and MS: a summary of published evidence and recommendations. Neurology 2002 Dec 24;59(12):1837-43. [29 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

According to the guideline developer, this guideline has been reviewed and is still considered to be current as of December 2006. This review involved new literature searches of electronic databases followed by expert committee review of new evidence that has emerged since the original publication date.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

- Multiple sclerosis (MS) exacerbations after vaccine-preventable infectious episodes
- Multiple sclerosis exacerbations after immunizations

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Prevention
Risk Assessment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Neurology
Preventive Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To provide information on the need to vaccinate patients with multiple sclerosis (MS) by evaluating the risk of multiple sclerosis exacerbation following potentially preventable infections
- To review the available evidence on the safety and efficacy of vaccines in patients with multiple sclerosis
- To provide an overview of the guidelines for vaccinating patients with multiple sclerosis

TARGET POPULATION

Patients with multiple sclerosis (MS)

INTERVENTIONS AND PRACTICES CONSIDERED

Vaccination with the following vaccines:

1. Live attenuated vaccines (bacillus Calmette-Guerin [BCG], measles, Sabin-polio, smallpox, varicella)
2. Inactivated vaccines (hepatitis B, influenza, tetanus, typhoid fever)

MAJOR OUTCOMES CONSIDERED

- Frequency of vaccine-preventable infectious diseases in patients with multiple sclerosis (MS) compared to the frequency of vaccine-preventable infectious diseases in the general population
- Risk of relapses or exacerbation of MS symptoms in patients with MS (1) during a vaccine-preventable infectious disease and (2) after vaccination, and, in particular, between live attenuated and inactivated vaccines

  Effects of attenuated vaccine on MS measured by:

  - Number of exacerbations
  - Mean number of active magnetic resonance imaging (MRI) lesions
  - Clinical changes at 12 months post-vaccination

Effects of inactivated vaccines on MS measured by:

  - Relative risk of relapse
  - Number of exacerbations
  - Number of influenza episodes
  - Number of episodes of clinical deterioration
- Vaccine effectiveness (measured by antibody response) in patients with MS compared to the general population

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Guideline developers reviewed English language MEDLINE (from 1966 to January 2001; U.S. National Library of Medicine, Bethesda, MD), and two other online bibliographic databases, HealthSTAR and CINAHL, and the reference lists of all included articles and review articles. Search strategies included index terms and text words for "MS," transverse myelitis," and index terms for "optic neuritis," "encephalomyelitis," "demyelinating disease," and for general and specific terms relating to vaccination and related infectious diseases.

NUMBER OF SOURCE DOCUMENTS

- 667 citations were obtained.
- 280 full-text articles were screened for inclusion.
- 130 articles were included.
- 53 experimental or observational studies were abstracted in evidence tables, and 77 case reports were summarized in a summary table.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Classification Scheme developed by the American Academy of Neurology (AAN)

Rating of Therapeutic Article

Class I: Prospective, randomized, controlled clinical trial with masked outcome assessment, in a representative population.

The following are required:

- Primary outcome(s) is/are clearly defined.
- Exclusion/inclusion criteria are clearly defined.
- Adequate accounting for dropouts and crossovers with numbers sufficiently low to have minimal potential for bias.
- Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

Class II: Prospective matched group cohort study in a representative population with masked outcome assessment that meets a-d above OR a randomized, controlled clinical trial in a representative population that lacks one criterion a-d.

Class III: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome assessment is independent of patient treatment.

Class IV: Evidence from uncontrolled studies, case series, case reports, or expert opinion.

Rating of Prognostic Article

Class I: Evidence provided by a prospective study of a broad spectrum of persons who may be at risk for developing the outcome (e.g., target disease, work status). The study measures the predictive ability using an independent gold standard for case definition. The predictor is measured in an evaluation that is masked to clinical presentation and the outcome is measured in an evaluation that is masked to the presence of the predictor.

Class II: Evidence provided by a prospective study of a narrow spectrum of persons at risk for having the condition, or by a retrospective study of a broad spectrum of persons with the condition compared to a broad spectrum of controls. The study measures the prognostic accuracy of the risk factor using an acceptable independent gold standard for case definition. The risk factor is measured in an evaluation that is masked to the outcome.

Class III: Evidence provided by a retrospective study where either the persons with the condition or the controls are of a narrow spectrum. The study measures the predictive ability using an acceptable independent gold standard for case definition. The risk factor is measured in an evaluation that is masked to the outcome.

Class IV: Any design where the predictor is not applied in a masked evaluation OR evidence provided by expert opinion or case series without controls.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Each included and abstracted study was evaluated and rated for quality of evidence using the classification scheme developed by the American Academy of Neurology. When feasible, data were pooled and analyzed in meta-analysis using Comprehensive Meta-Analysis software for Windows (version 1.09, Biostat; Englewood, NJ).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Translation of Evidence to Recommendations

Level A rating requires at least one convincing class I study or at least two consistent, convincing class II studies.

Level B rating requires at least one convincing class II study or at least three consistent class III studies.

Level C rating requires at least two convincing and consistent class III studies.

Rating of Recommendation (technology assessment ratings in parentheses)

A = established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population.

B = probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population.

C = possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population.

U = data inadequate or conflicting. Given current knowledge, treatment (test, predictor) is unproven.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Draft guidelines were reviewed for accuracy, quality, and thoroughness by the American Academy of Neurology (AAN) members, topic experts, and pertinent physician organizations.

Final guidelines were approved by the American Academy of Neurology Therapeutics and Technology Assessment Subcommittee on July 17, 2002, the American Academy of Neurology Practice Committee on August 3, 2002, and the American Academy of Neurology Board of Directors on October 19, 2002. They were published in *Neurology* 2002;59:1837-1843.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the ratings of recommendation (A-C, U) and the classification of the evidence (Class I-IV) are provided at the end of the "Major Recommendations" field.

Based on this review, the Immunization Panel of the Multiple Sclerosis (MS) Council for Clinical Practice Guidelines recommends that:

1. Patients with MS should follow Centers for Disease Control indications for immunizations (http://www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm) (Influenza: ***Level A recommendation***; hepatitis B, varicella, tetanus: ***Level C recommendation***; other vaccines: ***Level U recommendation, expert opinion***).
2. Vaccination should be delayed during clinically significant relapses until patients have stabilized or have begun to improve from the relapse, typically 4 to 6 weeks after the start of the relapse. There is, however, no evidence regarding this practice (***Level U recommendation, expert opinion***). For patients who require tetanus vaccination after a wound, the panel recommends not to delay vaccination even if they are in a midst of a relapse, although, again, there is no actual evidence on this point (***Level U recommendation, expert opinion***).
3. There is a divided opinion among experts regarding the potential usefulness of influenza vaccine in patients with MS who do not otherwise meet the Centers for Disease Control indications for vaccination. The panel recommends that potential risks and benefits of vaccination in these circumstances be discussed individually with each patient (***Level U recommendation, expert opinion***).
4. Pneumococcal vaccine should be considered for patients with compromised pulmonary function, such as wheelchair-dependant or bed-bound patients. There is, however, no evidence regarding this practice (***Level U recommendation, expert opinion***).

Definitions:

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

These guidelines may assist physicians in making clinical decisions regarding vaccinating patients with multiple sclerosis (MS). Appropriate vaccinations may minimize the risk of acquiring infectious diseases that may trigger exacerbations.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

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This statement is provided as an educational service of the American Academy of Neurology (ANA). It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The American Academy of Neurology recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Dec 24 (reviewed 2006 Dec)

GUIDELINE DEVELOPER(S)

American Academy of Neurology - Medical Specialty Society
Multiple Sclerosis Council - Disease Specific Society

SOURCE(S) OF FUNDING

American Academy of Neurology (AAN)

GUIDELINE COMMITTEE

Quality Standards Subcommittee of the American Academy of Neurology Immunization Panel of the Multiple Sclerosis Council for Clinical Practice Guidelines

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: A list of American Academy of Neurology (AAN) guidelines, along with a link to a Portable Document Format (PDF) file for this guideline, is available at the AAN Web site.

Print copies: Available from the AAN Member Services Center, (800) 879-1960, or from AAN, 1080 Montreal Avenue, St. Paul, MN 55116.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- AAN guideline development process [online]. St. Paul (MN): American Academy of Neurology.

Electronic copies: Available from the American Academy of Neurology Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on February 6, 2004.

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