

# General Recommendations Final Five Sections

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# General Recommendations on Immunization Final Five Sections' Review

- ❑ Altered Immunocompetence
- ❑ Special Situations
- ❑ Vaccination Records
- ❑ Vaccination Programs
- ❑ Vaccination Information Sources

# Altered Immunocompetence Revisions: Source Material

- ❑ Cleared ACIP MMWR Vaccine-specific statements
- ❑ Infectious Diseases Society of America's position statement

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- ❑ ACIP Cleared MMWR Vaccine-specific statements
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  - Rubin, LG, Levin MJ, Ljungman P., et. Al. 2013 IDSA Clinical Practice Guidelines for Vaccination of the Immunocompromised Host. Clin. Infect. Dis. 2014; 58: e-44-100.
  - Evidence-based multi-stakeholder set of guidelines
  - November 2011 – CDC reviewed content of document

# General Recommendations – Altered Immunocompetence

- New guidelines from the Infectious Disease Society of America

Clinical Infectious Diseases Advance Access published December 4, 2013

IDSA GUIDELINES

## 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host

Lorry G. Rubin,<sup>1</sup> Myron J. Levin,<sup>2</sup> Per Ljungman,<sup>3,4</sup> E. Graham Davies,<sup>5</sup> Robin Avery,<sup>6</sup> Marcie Tomblyn,<sup>7</sup> Athos Bousvaros,<sup>8</sup> Shireesha Dhanireddy,<sup>9</sup> Lillian Sung,<sup>10</sup> Harry Keyserling,<sup>11</sup> and Insoo Kang<sup>12</sup>

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An international panel of experts prepared an evidenced-based guideline for vaccination of immunocompromised adults and children. These guidelines are intended for use by primary care and subspecialty providers who care for immunocompromised patients. Evidence was often limited. Areas that warrant future investigation are highlighted.

- Areas not addressed by ACIP
- Some differences

# Altered Immunocompetence: Four Major Topic Revisions and Source Material

- Inclusion of new specific conditions/medications classified as “Altered Immunocompetence” - IDSA
- New recommendations for vaccination in the context of those conditions/medications - IDSA
  - Vaccine-type withholding (live, inactivated)
  - Intervals
- Altered immunocompetence as an indication to vaccinate outside of routinely recommended age – CDC Vaccine-specific Statements
- Hematopoietic Cell Transplants (HCT) – IDSA/CDC hybrid

# Altered Immunocompetence: Inclusion of new specific conditions/medications

## □ Conditions

- Interferon gamma/interleukin 12 axis deficiency
- Interferon alpha deficiency
- Interferon gamma deficiency
- Phagocyte function disorders (e.g., Chediak-Higashi syndrome)

## □ Medications

- Induction/consolidation chemotherapy
- Anti-B cell antibodies

## □ Combination medication/conditions

- Patients with major antibody deficiencies receiving immunoglobulins

# Altered Immunocompetence: New Recommendations

- ❑ **Recommendations to withhold live bacterial vaccines only**
  - Interferon gamma/interleukin 12 axis deficiency (Table, Page 13)
- ❑ **Recommendations to withhold both live bacterial and live viral vaccines (P5, L30)**
  - Interferon alpha deficiency
  - Interferon gamma deficiency
  - Some phagocytic deficiency disorders (Table, Page 13)
    - Leukocyte adhesion defect
    - Myeloperoxidase deficiency
    - Chediak-Higashi syndrome



# Altered Immunocompetence: New Recommendations

- **Recommendations to withhold both live and inactivated vaccines**
  - Induction/consolidation chemotherapy (Table Footnote, Page 15)
  - Patients with major antibody deficiencies receiving immunoglobulins (Table Footnote, Page 15)
  - “High-level immunosuppression”
    - Cancer chemotherapy (P5, L6)
    - Radiation therapy (P5, L6)
    - Solid organ transplantation (P11, L13)
    - HIV infection with immunosuppressive parameters (P6, L22)
    - Receiving high-dose immunosuppressive corticosteroid therapy (P10, L33)
    - Biologic immune modulators (P11, L36)

# Altered Immunocompetence: New Recommendations

## □ INTERVALS

### ■ “High-level immunosuppression”

- Medicine to vaccine (3 months) (P5, L10)

Interval of 1 month (for zoster vaccine) ACIP vaccine-specific statement

- Live vaccine to medicine (1 month - IDSA)
- Inactivated vaccine to medicine (2 weeks full recommendation) (P5, L8)
- Exceptions:
  - Anti-B-cell antibodies to vaccine (6 months) (P5, L15)
  - Solid organ transplant rejection therapy to vaccine (2 months) (P11, L32)

### ■ “Low-level immunosuppression”

- Examples (lower dose corticosteroids, alternate day corticosteroids, ACIP zoster-statement defined doses for azathioprine, methotrexate, and 6-mercaptopurine)

# A Note on Inactivated Vaccines and Altered Immunocompetence

- ❑ Aforementioned discussion of withholding vaccines, intervals, integrated into the General Recs with the following General Principles (Beginning P4, L44)
- ❑ **Live Vaccines**
  - Effectiveness concerns and safety concerns (safety concerns primary)
- ❑ **Inactivated Vaccines**
  - Safety concerns and effectiveness concerns (effectiveness primary)
  - Inactivated influenza vaccine is an exception to the withholding rule, but the dose should be repeated if given (Table, P15)

# Altered Immunocompetence as an Indication to Give a Vaccine Outside of Routinely Recommended Ages (P2, L13)

- ❑ Source material – ACIP vaccine-specific statements
- ❑ Apply to Bacterial Vaccines (Hib, meningococcal, pneumococcal)
- ❑ Apply to specific conditions (asplenia, complement component deficiencies)

# Hematopoietic Cell Transplants

- ❑ Not only altered immunocompetence, but immunoablation
- ❑ Requires revaccination with a primary series (number of doses varies by vaccine)
- ❑ 2011 General Recommendations source material: (Tomblyn M, Chiller T, Einsele H, Guidelines for Preventing Infectious Complications among Hematopoietic Cell Transplantation Recipients: A Global Perspective Biol Blood Marrow Transplant 15: 1143-1238 (2009) 2009 American Society for Blood and Marrow Transplantation
- ❑ IDSA now provides same recommendation (significant overlap of expertise)

# Post HCT Revaccination Recommendations

- ❑ Recommended: DTaP, PCV13, PPSV23, Hib, HepA, HepB, meningococcal vaccines, IPV, IIV, HPV, Varicella, MMR
- ❑ Not recommended: BCG, LAIV, Typhoid vaccine, rotavirus vaccine, zoster vaccine
- ❑ (Post-HCT – 1<sup>st</sup> dose ) Interval for inactivated vaccines (3-6 months)
- ❑ (Post-HCT – 1<sup>st</sup> dose) Interval for live vaccines -24 months
- ❑ Post HCT “first-time” vaccination recommendations
  - IDSA doesn't specifically address
  - CDC has vaccine-specific guidance (some unpublished), for zoster vaccine, Tdap vaccine, Hib vaccine

# Altered Immunocompetence: Unchanged from 2011 General Recs

- ❑ **General Principles – the level of immunocompetence should be determined by a physician**
  
- ❑ **Vaccination of Household Contacts of Immunosuppressed Persons**
  - Some clarification language added – rotavirus vaccine virus shedding, and “protected environment” for health-care provider preference for IIV.
  - Otherwise, strong recommendation to vaccinate household contacts of persons with altered immunocompetence
  - Harmonious with IDSA

# General Recommendations on Immunization: Special Situations





## Special Situations: Revisions

- ❑ Vaccination in Breastfeeding Women – Harmonized with Yellow Fever vaccine recommendations (P6, L33)
- ❑ Vaccination in Pregnancy – Harmonized with Tdap ACIP Vaccine-specific recommendations (P7, L29)
- ❑ Vaccination of Persons with Bleeding Disorders (P13, L40)
  - Decision made to leave this as a physician determination to vaccinate by the intramuscular route if the bleeding risk is acceptable

# General Recommendations on Immunization: Vaccination Records



# Vaccination Records: Revisions

- Capabilities of an operational immunization information system (IIS) (P2, L26)
  - *A fully operational IIS also can prevent duplicate vaccinations, forecast when the next dose is due, limit missed appointments, allow recall for those who missed appointments, determine when vaccines need to be repeated (evaluation), reduce vaccine waste, and reduce staff time required to produce or locate vaccination records or certificates.*

# Vaccination Records: Revisions

- **Meaningful Use integration: (P2, L36)**
  - *Electronic health records should maintain interoperability with IIS's as part of an effort to improve the quality of care, reduce health disparities, engage patients and families in their health, improve the security protection for personal health information (REFERENCE [www.cdc.gov/ehrmeaningfuluse/introduction.html](http://www.cdc.gov/ehrmeaningfuluse/introduction.html))*

# General Recommendations on Immunization: Vaccination Programs



# Vaccination Programs: Revisions

## □ Addition of the National Vaccine Adult Standards (P1, L6)

- *All healthcare providers, whether they provide immunizations or not, should incorporate immunization needs assessment into every clinical encounter, strongly recommend needed vaccine(s) and either administer vaccine(s) or refer patients to a provider who can immunize, stay up-to-date on, and educate patients about vaccine recommendations, implement systems to incorporate vaccine assessment into routine clinical care, and understand how to access immunization information systems (i.e. immunization registries)*

# Vaccination Programs: Revisions

- Addition of the following language in the Adult Vaccination section:
  - *Effective for private health insurance plans drafted or updated after September 2010, coverage for ACIP recommended vaccines must be covered without deductibles or co-pays, when delivered by an in-network provider. (P10, L7)*
- Revised language
  - *The Affordable Care Act (ACA) requires insurance companies to cover all immunizations that are included on the immunization schedule with no copay and no deductible. (internal CDC suggested change)*

# Vaccination Information Sources





# List of Sources with Additional Information on Vaccination

- ❑ CDC-INFO Contact Center
- ❑ NCIRD
- ❑ AAP
- ❑ AAFP
- ❑ ACP (new)
- ❑ ACOG (new)
- ❑ IAC
- ❑ VEC
- ❑ IVS
- ❑ GIE-STFM
- ❑ State and Local Health Departments

# List of Sources with Additional Information on Vaccination

- ❑ **Removed “National Network for Immunization Information”**
  - Formerly an affiliate of the Infectious Diseases Society of America, the Pediatric Infectious Diseases Society, AAP, the American Nurses Association, AAFP, the National Association of Pediatric Nurse Practitioners, the American College of Obstetricians and Gynecologists, the University of Texas Medical Branch, the Society for Adolescent Medicine, and the American Medical Association
  - Under new direction, unclear which organization is the parent organization