FIRST GLOBAL LEADERS MEETING

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Do Guidelines Make a Difference

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Why do we have guidelines?

- Influence the practice of medicine
  - Reduce morbidity and mortality
  - Enhance quality of life
  - Cost effective treatment
- Education
  - Physicians
  - Allied health providers

Why do we have guidelines?

- Provide a background upon which to make decisions
  - “legal” standards upon which to judge performance
- Guide insurance companies and third party payers

Positive aspects of developing guidelines

- Provide a framework for managing patients
- Provide further incite into investigations/research
  - Highlight deficiencies in knowledge
- Best practice in the treatment of a disease
  - Evidence-based medicine
- Education
  - Students - medical students, residents, fellows
  - Physicians
  - 3rd party payers

Guidelines (Practice Parameters) for diagnosis and management of primary immune deficiency disorders

- Provide the consultant allergist/immunologist with a practical guide for the recognition, diagnosis and management of PIDD
- Joint Task Force between the AAAAI, ACAAI and the JCAAI – 1995 and 2005
- Process –
  - Review of medical literature
    - Rated by category of evidence (I- IV)
    - Establish strength of recommendations (A-D)
    - Algorithms for major types of PIDD
    - 224 summary statements (63 pages)

Review of evidence for the use of IGIV in human disease[#]

- Review of literature
  - Rated by category of evidence
  - Establish strength of recommendation
- Categories –
  - PIDD
  - Autoimmune diseases (off-label indications)
    - Hematologic
    - Neuromuscular
    - Inflammatory disorders

Orange et al J Allergy Clinical Immunology 117:S525-53, 2006)

IGIV Tool Kit

- Created by the PIDD committee of AAAAI
- Eight guiding principles for the safe, effective and appropriate use of IGIV in PIDD patients
  - Indications
  - Diagnoses
  - Frequency of IGIV treatment
  - Dosages
  - IgG trough levels
  - Site of care
  - Route
  - Product

IGIV Tool Kit

- IgG trough levels
  - Trough levels can be useful in some patients to guide therapy, BUT should not be a consideration (criteria) in access to IGIV therapy
    - Insurance issues
      - Denials
      - Remove PIDD patients from IGIV therapy

Web-based survey of PIDD management in the US[@]

- Survey AAAAI members (response rate 13.5%)
  - 85% AI members <10% time of their practice with PIDD
  - 15% focused AI (>10% of time in care of PIDD)
- Scope of practice
  - 60% of focused AI have experience with rarer forms of immune deficiency vs. <35% of general AI members
    - General AI mostly humoral immune defects

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Web-based survey of PIDD management in the US[@]

- Differences in practice between general AI members and focused AI members
  - General members – average 14 patients vs. 42 patients for focused AI members
  - 44% of general members recommended IVIG for complement deficiencies
  - Dosages-
    - 31% focused AI recommended higher starting doses (>400 mg/kg)

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Web-based survey of PIDD management in the US@

- Trough levels –
  - 75% targeted a level of 500-750 mg/dl
    - More focused AI used trough levels >750 mg/dl
- Pre-medications-
  - Focused AI members more likely to use NSAIDS, anti-histamines, and steroids
- Prophylactic antibiotics
  - 88% of focused vs. 48% of general AI members

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Deficiency of guidelines

- Not specific enough-all inclusive
- Many ways to practice medicine
  - “the art of medicine”
- Guidelines should change –they should never be a static entity
  - “outdated” guidelines
    - FDA does not update package insert in line with new information or guidelines
  - Improper decision making or misinterpretation of guidelines

Deficiency of guidelines

- Consideration of social, economic, cultural conditions
- How do we measure outcomes from having guidelines

Guidelines for Asthma National Asthma Education and Prevention Program (NAEPP)

- First published in 1991
  - Asthma is an inflammatory disease
- Revised 1997 and 2002
- 2007 Expert Panel Report 3 (EPR-3)#

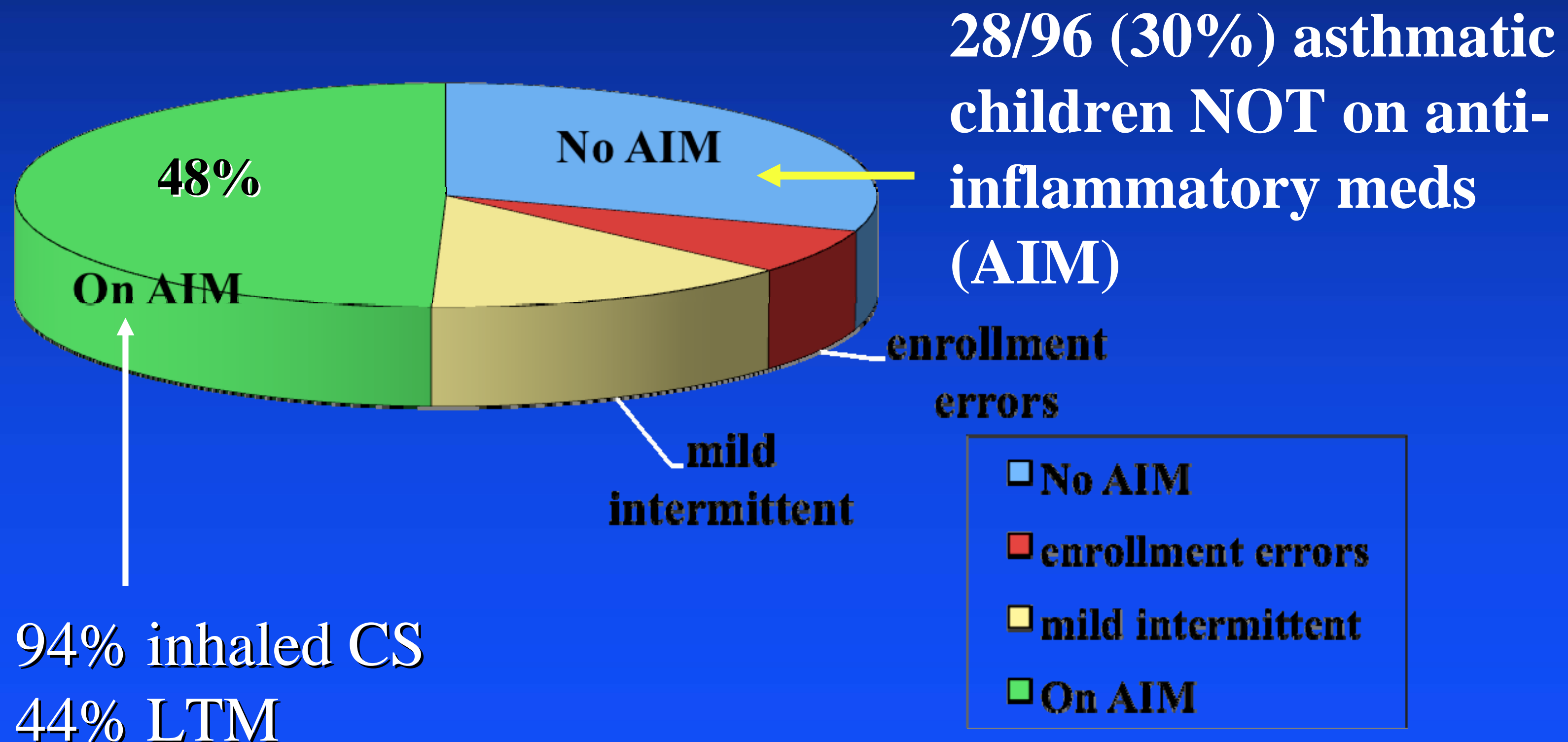
- http://www.nhlbi.nih.gov/guidelines/asthma/index.htm

Survey of Quality of Care for Asthmatic Children in the WCHOB Pediatric ED 1999

- Only 48% of patients with moderate to severe asthma used inhaled steroids

Second ED Asthma Study at WCHOB 2002-2003

Distribution of 96 asthma patients age 2-18



Should we have guidelines?

- Standardize care for best practices
  - Evidence based practices guidelines
  - NOT static but always evolves as new information becomes available
- Education – at all levels
- Guidance for payers
  - Access to good care, e.g. specialist
  - Access to treatments