AAP - Pediatric Information for X-ray Imaging Device Premarket Notifications

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Disclosures

I have no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider of commercial services discussed in this session.
American Academy of Pediatrics (AAP)

- Professional membership organization of 62,000
  - primary care pediatricians,
  - pediatric medical sub-specialists
  - surgical specialists

**AAP Mission:** committed to the attainment of optimal physical, mental and social health and well being for all infants, children, adolescents and young adults.
AAP Commitment to Pediatric Radiation Safety

• 1998 - Committee on Environmental Health Pediatrics “Risk of Ionizing Radiation Exposure to Children” 101;717 Etzel et al

• 2003 - Pediatrics “Children CT Radiation Dose and the ALARA concept” Commentary by Tom Slovis 112;971

• 2004 - Pediatrics “Environmental pediatrics and its impact on government” Goleman et al 113:1146

• 2007 - Pediatrics “Radiation Risk to Children From Computed Tomography” 120:677 Brody, Frush et al
AAP Commitment to Pediatric Radiation Safety

- **2008** - Understanding Radiation Risk from Diagnostic Imaging Safer Health care for Kids. Miller M
- **2008** - CT Scans and Radiation Exposure AAP Grand Rounds 19;28 B Wood
- **2009** - Pediatrics Radiation exposure in extremely low birth weight infants 124:1556 Puch-Kapst et al
- **2010** - Pediatrician education Pamphlet – Section on Radiology link [www.aap.org](http://www.aap.org)
- **2010** - Parent Brochure on Radiation Safety Parenting Corner link [www.aap.org](http://www.aap.org)
- **2010** – AAP Plenary session Image Gently – M Goske
Current Commitment to Pediatric Radiation Safety

- **2012** – AAP members and PediaLink subscribers: *Radiation Exposure*
- **2013** – AAP Surgical Plenary session on radiation safety
- **2013** – Policy statement discussing medical imaging, ionizing radiation, appropriateness, justification and optimization focusing on all modalities
Radiation Risk in Children

1) Children - more radiosensitive than adults
2) Children - longer expected lifetime for effects of radiation exposure to manifest
3) Use of equipment and exposure settings designed for adults can result in excessive radiation exposure for smaller patients
The Problem

- Many pediatric exams performed in facilities lacking specialized expertise in pediatric imaging
- Many general use XR imaging devices don’t address
  - unique issues associated with pediatrics
  - Specific labeling for pediatric use to optimize benefit/risk
- Existing equipment without instructions for pediatric use can be cumbersome and time consuming
Key Components of FDA’s Draft Guidance

- Increased information to support pediatric indications
- Improved training/testing materials for users
- Specifications for pediatric protocols/settings with dose documentation
- Quality assurance tools to track radiation dose
- Educational materials
- Assistance when developing pediatric dose reduction protocol procedures
Issues for FDA to Consider

• Materials need to be user friendly, easily accessible, and understandable on multiple levels (e.g. physicists, physicians, technologists)

• Standardized dose information for pediatric patients – Is it available?

• Display/recording of pt dose or dose index – Variable methods, are they accurate?

• Reporting dose can be problematic – different metrics, proprietary hurdles, level of detail for dose/quality testing need clarification
Labeling Issues for FDA to Consider

• Potential impact of proposed labeling changes on access to care?
• Will manufacturers simply refuse to subspecialize their equipment for children? (costly, small market share)
• Impact on ‘home grown’ pediatric positioning aides developed by end user and not included in 510k application
• Protect against driving increased off-label use
Important to emphasize benefits of X-Ray diagnostic studies for children with regard to risk/benefit

Thank you!