Device Development, Surveillance & Pediatric Cardiovascular Safety: Where are We & Where do We Need to Go?

Cardiac Safety Research Consortium
Pediatric Thinktank
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Today's Talk

- Drug vs. Device Development
- Evolution in CHD therapy
- Pediatric Medical Device Safety & Improvement Act of 2007
- Recent CDRH activities to support pediatric cardiac device development
- Challenges
- Summary

Device vs. Drug Development

Developmental Feature	Device	Drug
Rate of Technology Change	Fast	Slow
Size of Development Enterprise	Smaller	Larger
Ease of in vitro Assessment	High	Low
Reimbursement during Clinical Trials	Frequent	Rare
Influence of MD technique on results	High	Low
Ability to observe performance	High	Low
Definition of “orphan” (# of patients)	4,000	200 k
Full scale studies usually required	1	2
Number of regulatory classes	3	1

Congenital Heart Disease: 50 Years of Therapeutic Innovation

- 1 of every 125 live born infants
- Substantial change in diagnosis & treatment over last 50 years
- Survival to adulthood common→ NEW cohort of adults with congenital heart disease
  - 1999 to 2006— 24.1% overall decline in mortality[1]
- Co-morbidities: neurocognitive impairments; pregnancy complications; limited exercise tolerance; cardiac arrhythmias, endocarditis, other
- Surgical interventions evolved through off-label use of devices

[1]http://circ.ahajournals.org/cgi/content/full/122/22/2254

Pediatric Interventional Cardiology & Off-Label Device Use

- Retrospective review of all procedures
  - One Center (Cincinnati Children's Hospital)
  - July 1, 2005 to June 30, 2008
  - 473 patients with 595 procedures
  - Off-label use 63% of patients & 50% of interventions
  - Most common: Stent implantations (99%)
  - Least common: Septal & ductal occluders

Congenit Heart Dis. 2010 Jan;5(1):2-7

Pediatric Medical Device Safety & Improvement Act of 2007

- Tracking Pediatric Device Approvals
  - Number, Types, & Approval times for PMAs & HDEs
- Extrapolating Adult Effectiveness Data
- Incentivize Pediatric Device Development
  - Allows profit for HDE device for a pediatric need
- Report adverse events for pediatric HDE devices to Office of Pediatric Therapeutics for review by Pediatric Advisory Committee

Pediatric Medical Device Safety & Improvement Act of 2007

- Encourage Innovative Pediatric Medical Device Research
- Establish non-profit consortia to stimulate pediatric device development
- Four Sites Funded:
  - University of Michigan Pediatric Device Consortium
  - UCSF Pediatric Device Consortium
  - Harvard Pediatric Cardiovascular Device Consortium
  - MISTRAL Consortium at Stanford Research Institute

Recent CDRH Activities

- Mar 2010---Assessment of Neurological & Neurocognitive Function in Pediatric Patients
- Jun 2010—Pediatric Heart Valve Workshop
- SCAI Structural Heart Disease Council—Working Groups to Set Performance Goals
- Sept 2010– Clinical Trial Design Workshop for Pediatric Cardiovascular Devices
- Improving Pediatric & Adult Congenital Treatment (IMPACT) Registry—track outcomes of patients undergoing diagnostic catheterizations & catheter-based interventions

Challenges

- Still too-few pediatric devices for treatment of CHD
- Device development process poorly understood
  - Academic centers where studies occur
  - IRBs
- Regulatory & program “toolbox” is still in an early stage of development

Summary

- Dramatic change in treatment for congenital heart disease in the last 50 years
- Too few cardiac devices designed for pediatric patients
- Legal and incentive program to support development is underway

Shout out for CDRH Cardiovascular Device Team!

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