Key Challenges for Post Market Surveillance of Cardiovascular Events Caused by Medical Products

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Passive Surveillance for Cardiovascular Adverse Events in Children

- Guided in part by literature, Advisory Committees, other outside input
- Also look *de novo* at cardiac adverse events in the largest passive surveillance system in the United States: Adverse Event Reporting System (AERS)
- Limitations of AERS: underreporting, biased reporting, lack of complete information in the reports received, lack of denominator, lack of comparison group.
- Nonetheless, especially for rare events with short latency and high quality information, data from AERS can lead to important public health conclusions.

Sudden Cardiac Death Reporting to AERS*: Top Drug Groups in Children by Age

Age Range	Indication of Drug(s)**	Age Range	Indication of Drug(s)**	Age Range	Indication of Drug(s)**
0-1yrs	Treatment for Respiratory Syncytial Virus	2-5yrs	Treatment of mucopolysaccharidosis	6-16yrs	ADHD
	Antimetabolite		Anaesthetic/ paralytic agent		Immunosuppressant

*1960- December 8, 2010
**May include more than one product in each category

Bradycardia Reporting to AERS*: Top Drug Groups in Children by Age

Age Range	Indication of Drug(s)**	Age Range	Indication of Drug(s)**	Age Range	Indication of Drug(s)**
0-1yrs	Treatment for Resp. Syn. Virus	2-5yrs	ADHD	6-16yrs	ADHD
	Supportive care for newborns		Agitation		Anesthesia
	GERD		Anesthesia		Antibiotic
	Pompe Disease therapy		Pompe Disease therapy		Antispastic agent
	Anesthesia				

*1960- December 8, 2010, serious reports
**May include more than one product in each category

Hypertension Reporting to AERS*: Top Drug Groups in Children by Age

Age Range	Indication of Drug(s)**	Age Range	Indication of Drug(s)**	Age Range	Indication of Drug(s)**
0-1yrs	Treatment for Resp. Syn. Virus	2-5yrs	Immunosuppressant	6-16yrs	Immunosuppressant
	Anticoagulant		ADHD		ADHD
	Unknown		Mitotic inhibitor		
	Unknown				

*1960- December 8, 2010, serious reports
** May include more than one product in each category

CONCLUSIONS

- Possible triggers for drug adverse event reporting to passive surveillance system:
  - Adverse event is associated with indication
  - Seriousness of outcome correlated with seriousness of underlying illness
  - Stimulated reporting (media attention)
  - Drug is causally associated with adverse event
- Detective work to differentiate these possibilities
  - Different data streams
  - Improved report quality in AERS
  - Follow-up of key reports