PharmSci 2016

Addressing Methodological and Ethical Issues in Pediatric Medication Safety Research

Agenda

Thursday, May 12th, 2016

6:00-8:00pm **Preconference Reception and Poster Session**
Kerr Lobby

Friday, May 13th, 2016

7:00-8:00am **Registration and Breakfast**

8:00-8:05am **Welcome**
Kerr 1001 *Dean Robert A. Blouin*

8:05-8:10am **Introduction of Keynote Speaker**
Kerr 1001 *George Retsch-Bogart*

8:10-9:00am **Keynote 1**: Children's Medication Safety from the FDA's Perspective
Lisa LaVange (FDA)

At the completion of this knowledge-based activity, the pharmacist/technician will be able to:

1. Describe the Best Pharmaceutical for Children Act (BRCA) and the Pediatric Research Equity Act (PREA) and their impact on pediatric drug development in the US.
2. Discuss novel clinical trial designs that can be used to assess whether a drug is safe and effective for children.

9:05-9:50am **Breakout Sessions**
Kerr 1001 Breakout 1: Engaging Children and Parents on Study Teams
Michael Kappelman, David Wohl, children and parents (UNC)

At the completion of this knowledge-based activity, the pharmacist/technician will be able to:

1. Discuss the rationale for engaging children and parents on study teams.
2. Discuss examples of child/parent engagement in a multicenter clinical trial of pediatric Crohn's disease

9:05-9:50am Breakout 2: Patient-reported Outcomes Assessment in Pediatric Research
Kerr 2001 *Bryce B. Reeve* (UNC)

At the completion of this knowledge-based activity, the pharmacist/technician will be able to:

1. Describe recent initiatives that provide children and adolescents the ability to self-report symptom toxicities, symptoms and functional status impacted by a disease or treatment.
2. Identify issues and challenges to collecting self-reported data from children and adolescents.

9:50-10:00am **Break**

10:00-10:30am **Concurrent Talks on Drug Development/Testing and Communication Issues**
Kerr 1001 Early Phase Studies in Children and Infants: Challenges and Opportunities
Danny Gonzalez (UNC)

At the completion of this knowledge-based activity, the pharmacist/technician will be able to:

1. Review the logistical and ethical challenges to performing early phase studies in children.
2. Outline innovative trials design solutions and strategies to overcome challenges in pediatric drug development.

Kerr 2001 HPV Vaccination and Pharmacists
Noel Brewer (UNC)

At the completion of this knowledge-based activity, the pharmacist/technician will be able to:

1. Discuss how pharmacists can increase HPV vaccination coverage

10:30-11:00am **Concurrent Talks on Drug Development/Testing and Communication Issues**
Kerr 1001 Safety First: Drug development in neonates
Daniel Benjamin, Jr. (Duke)

At the completion of this knowledge-based activity, the pharmacist/technician will be able to:

1. Describe the risks of not evaluating safety of drugs in the nursery
2. Describe Learn to balance risk and benefit in nursery drug development

10:30-11:00am Kerr 2001

Barriers to Pharmacist-Child Communication: Implications for Providing Medication Counseling in Community Pharmacies
Olufunmilola K. Abraham (Pitt)

At the completion of this knowledge-based activity, the pharmacist/technician will be able to:

1. Describe the barriers and facilitators that influence community pharmacy personnel's ability to provide medication counseling to children

11:05-12:00pm

Breakout Sessions

Kerr 1001

Breakout 3: Pediatric Learning Networks: Collaborative Laboratories for Improving Children's Health thru Quality, Safety, and Discovery
Carole Lannon (Cincinnati Children's)

At the completion of this knowledge-based activity, the pharmacist/technician will be able to:

1. Describe key characteristics of successful learning networks for improvement and research
2. Describe strategies for managing variation, collaborating with patients and families as partners, and getting results at scale

Kerr 2001

Breakout 4: International Panel on Pediatric Medication Communication
Oksana Pyzik (University College London), *Julia Gilmartin* (Monash), *Delesha Carpenter* (UNC)

At the completion of this knowledge-based activity, the pharmacist/technician will be able to:

1. Describe barriers to child-pharmacist communication in rural pharmacies (Carpenter)
2. Describe issues related to long-term management of chronic conditions in children (Pyzik)
3. Review methods for conducting research with children in medical settings (Gilmartin)
4. Discuss how we are forming an international collaboration to address pediatric medication communication in Australia, England, and the United States

12:00-1:30pm **Networking Lunch and Best Poster Awards in Kerr Lobby**

1:40-2:30pm
Kerr 1001

Keynote 2: The Comparative Effectiveness Research through Collaborative Electronic Reporting Consortium: Using Pediatric Electronic Health Records for to Address Medication Use, Safety, and Efficacy
Alexander Fiks, MD MSCE

At the completion of this knowledge-based activity, the pharmacist/technician will be able to:

1. Describe the links between how data is collected in practice and its subsequent use for research
2. Describe how to more effectively consider the opportunities and challenges in using electronic health record data in pharmacoepidemiology
3. Discuss opportunities for using the CER^2 database for secondary data and prospective investigation

2:35-3:15pm

Concurrent Talks on Dosing and Medication Errors

Kerr 1001

Adverse Drug Reactions in Children; The Impact on Clinical Care & Prescribing Practices
Jennifer Goldman (Children's Mercy)

At the completion of this knowledge-based activity, the pharmacist/technician will be able to:

1. Review the burden of adverse drug reactions (ADRs) among children
2. Describe the challenges clinicians face once a child has experienced an ADR
3. Identify clinical tools that can prevent/predict ADRs

Kerr 2001

Paradox, Pragmatism, Risk, and Ethics, of Pediatric Medication Safety at the Community Level: The Kids 'n Cures Experience 1999 to 2009
Frank Dundee

At the completion of this knowledge-based activity, the pharmacist/technician will be able to:

1. Increase professional awareness of the ethical role of the community pharmacist as the final overseer for pediatric medication safety at the point of care
2. To help pharmacists develop a skillset to assess risk when presented with difficult therapy decisions in pediatric care

3:20-3:25pm

Introduction of Keynote Speaker
Tim Carey

3:25:4:15pm
Kerr 1001

Keynote 3: Assessing Public and IRB Attitudes about the Ethics of Research on Medical Practices: Relationships, Risk, and Consent
Benjamin Wilfond (Seattle Children's)

At the completion of this knowledge-based activity, the pharmacist/technician will be able to:

1. Describe why the randomized study of oxygen saturation levels in premature infants was described in a New York Times editorial as startling and deplorable
2. Review why the Office of Human Research Protections (OHRP) thinks that research on medical practices using randomization is substantially risky
3. Describe why the public has different views than OHRP about the role of informed consent for research on medical practices

4:15-4:30pm **Closing Remarks and the Future Directions**
Delesha Carpenter (UNC)

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