

**Request for Approval under the “Generic Clearance for the Collection of
Qualitative Feedback on Agency Service Delivery (NICHD)”
(OMB#: 0925-0648 ExpDate: 6/30/2024)**

2021-22 Principles of Pediatric Clinical Pharmacology – Learning Objectives

10/6/2021: Career Development/ Educational Opportunities (Pediatric Trials Network)

Lecture Speaker: Kanecia Zimmerman

Learning Objectives:

- Understand potential career paths in clinical pharmacology
- Identify opportunities for additional training and education

10/13/2021: Leveraging Mentorship for a Productive Fellowship

Lecture Speakers: Kim Brouwer and Sonya Tang Girdwood

Learning Objectives:

- Recognize the need for mentors and a mentoring team
- State the qualities of a good mentor and a good mentee
- Reflect on challenging situations in mentorship through case studies
- Identify strategies to leverage their mentors to maximize productivity in their fellowship

10/20/2021: Influence of Physiologic Changes in The Developing Gastrointestinal Tract on Drug Absorption & Disposition in Children

Lecture Speaker: Valentina Shakhnovich

Learning Objectives:

- Review developmental changes in the maturing pediatric digestive tract
 - o Extrahepatic focus
 - o Influence on peroral drug absorption/disposition
 - o Implications for rectally-administered drugs
- Discuss influences of diet, disease and the microbiome on drug absorption/disposition
- Provide clinical examples and identify gaps in knowledge

10/27/2021: Ontogeny of Drug Biotransformation

Lecture Speaker: Jean Dinh

Learning Objectives:

- Review basic concepts relevant to a discussion of drug biotransformation in a pediatric context
 - o Developmental trajectories
 - o Regulation of endogenous molecules during growth and development
- Discuss specific Phase 1 and Phase 2 pathways
 - o CYP2D6
 - o CYP3A4
 - o CYP2C19
 - o CYP2B6
 - o UGT2B7
- Present a basic strategy for investigating a specific drug or drug-related event in children

11/3/2021: Innovative Clinical Trial Design in Pediatric Drug Studies

Lecture Speaker: Stephen Balevic

Learning Objectives:

- Evaluate barriers to enrollment in pediatric drug studies
- Determine solutions to enrollment in pediatric drug studies

11/10/2021: Pharmacokinetics and Pharmacodynamics of Protein Therapeutics

Lecture Speaker: Bernd Meibohm

Learning Objectives:

- Understand the mechanistic basis for drug disposition of therapeutic proteins and how it differs from traditional small molecule drugs
- Appreciate the impact and challenges of drug-target interaction on drug disposition
- Explain the impact of immunogenicity on the pharmacokinetics (PK) and pharmacodynamics (PD) of therapeutic proteins
- Identify factors in the PK and PD of therapeutic proteins that are modulated by childhood development

11/17/2021: Model-Informed Pediatric Drug Development: Application of Pharmacometrics to Define the Right Dose for Children

Lecture Speaker: Sander Vinks

Learning Objectives:

- Appreciate the FDA's Pediatric Study Decision Tree as a framework that can be a helpful starting point in determining the pediatric studies necessary for labeling based on the ability to extrapolate efficacy from adult or other data.
- Have a better understanding of how MIDD approaches are suited to address knowledge gaps including data leveraging to increase the success of pediatric studies.
- Highlight examples of successful pediatric model-informed drug development programs.

12/1/2021: Developmental Pharmacodynamics: Knowledge to be Gained in Pediatric Therapeutics

Lecture Speaker: Bridgette Jones

Learning Objectives:

- Understand the current knowledge base of pharmacodynamics in children
- Understand some areas of approach to increased knowledge of pharmacodynamics in children
- Understand research opportunities and needs to create more knowledge in the area

12/8/2021: High Frequency Clinical Data for AI/Machine Learning-Aided Biomarker Discovery and Enhancement of Clinical Trials: The Promise and Pitfalls

Lecture Speaker: Joseph Frassica

Learning Objectives:

- Understand the nature of available high frequency physiologic data
- Understand the possible benefits the use of large-scale data to clinical trials
- Recognize the pitfalls of the use of inadequately vetted and erroneous data in physiologic biomarker discovery

12/15/2021: Combining "Bedside" and Clinical Research Data to Inform Disease Progression and Outcomes/Biomarker Selection – Learning and Confirming

Lecture Speaker: Diane Mould

Learning Objectives:

- Understand the concept of disease progression versus disease activity
- Review the pharmacology of biologic agents and some of the issues associated with dosing metrics as applied to pediatric patients
- Understand the relationship between PK and PD commonly seen with biologic agents used to treat inflammatory disease
- Understand the concept of using Bayesian adaptive dosing and monitoring of individual PK parameters as a metric of disease activity for biologics

1/5/2022: Pharmaco-omics: Implications for Clinical Pharmacology

Lecture Speaker: Richard Weinshilboum

Learning Objectives:

- Briefly introduce the "omics" techniques being applied to clinical pharmacology
- Provide examples of the application of multiple omics to study drug response phenotypes
- Outline the use of multiple omics data to "guide" or "inform" genomic studies

1/12/2022: Systems Pharmacology and Translational Therapeutics

Lecture Speaker: Garret FitzGerald

Learning Objectives:

- Provide a view of clinical pharmacology that extends beyond modelling drug exposure and kinetics
- Incorporate contemporary technologies to understand mechanism of action
- Parse variability of drug response in an effort to achieve a more personalized approach to therapeutics.

1/19/2022: Pharmacotherapy of Pediatric Asthma

Lecture Speaker: Theresa Guilbert

Learning Objectives:

- Review national and international asthma guidelines and medications recommended by these groups.
- Present evidence for use of these recommended medications.
- Discuss future steps

1/26/2022: Pharmacotherapy of Viral Infections in Children

Lecture Speaker: Scott James

Learning Objectives:

- Describe clinical pharmacology principles of infectious disease agents
- List the drug development steps for infectious disease agents in children

2/2/2022: The Power of PK/PD and Monte Carlo Simulation (MCS): Pediatric Antimicrobial Drug Development and Recommendations for Clinical Use

Lecture Speaker: John Bradley

Learning Objectives:

- Review the various pharmacodynamic metrics for antibiotic activity
- Understand the rationale behind High/Infrequent dosing (aminoglycosides) and Low/Frequent dosing (beta-lactams)
- The antibiotic exposure needs to occur at the site of infection, and can vary tremendously from the serum concentration (e.g., CSF concentrations vs urine concentrations for aminoglycosides)
- Realize the “all susceptibilities are local” and the dosing/exposure need to match the susceptibilities in the institution of the clinician
- Consider how important, in children, it is to achieve the desired exposure, and the risk of failure you are willing to accept for a particular infection.

2/9/2022: Pharmacotherapy of Pediatric Cancer: Targeted New Agents

Lecture Speaker: Michael Ferguson

Learning Objectives:

- Review genetics of tumors
- Explain Precision Medicine (Precision Oncology/Precision Genomics/Personalized Medicine)
- Learn about different sequencing companies/techniques
- Garner knowledge about newer targeted therapy
- Apply new knowledge to case examples

2/16/2022: FDA Roundtable on Systems Pharmacology

Lecture Speaker: Gilbert Burckart + Team

Learning Objectives:

- Provide a current, and evolving overview of systems pharmacology
- Discuss specific research/case studies in systems pharmacology and drug development
- Engage a conversation in career opportunities as well as support for training in systems pharmacology

2/23/2022: COVID-19 - Pediatric Outcomes/MIS-C COVID Pediatric Therapeutics

Lecture Speakers: Anna Lin and Jeffrey Moss

Learning Objectives:

- Use consensus criteria to diagnose a pediatric patient with MIS-C
- Evaluate literature supporting use of immunomodulatory agents in MIS-C
- Provide recommendations for supportive care for pediatric patients with MIS-C

3/2/2022: Pharmacotherapy of Pain in Pediatrics

Lecture Speaker: Charles Berde

Learning Objectives:

- Improve understanding of the development of pain pathways and analgesic actions in newborns, infants, and children
- Increase knowledge of age-related changes in PK and PD for several commonly used classes of analgesics and implications for dose selection and assessment of benefits and risks
- Appreciate the challenges inherent in pediatric analgesic clinical trials and awareness of ongoing efforts to improve on pediatric analgesic study designs
- Appreciate the status of several areas of active research on pediatric pain and analgesic pharmacology

3/9/2022: Pediatric Psychopharmacology

Lecture Speaker: Adelaide Robb

Learning Objectives:

- Understand general concepts of pediatric psychopharmacology such as dosing, safety-side effect profiles from neurodevelopmental perspective, concentration-effect outcomes
- Understand the three main classes of psychotropics used in youth; stimulants, antidepressants, antipsychotics
- Describe key studies which illustrate the utility of psychotropics in children and youth

3/23/2022: New Developments in Developmental Pharmacology

Lecture Speaker: John van den Anker

Learning Objectives:

- Understand that growth and development have the largest impact on absorption, distribution, metabolism and excretion of frequently used drugs in neonates and young infants.
- Recognize that maternal-fetal pharmacology is one of the new developments in developmental pharmacology.
- Appreciate that to optimize pharmacotherapy in neonates, developmental pharmacokinetics need to be closely linked to developmental pharmacodynamics.

3/30/2022: Pharmacotherapy of Pediatric Cardiovascular Disease

Lecture Speaker: Christoph Hornik

Learning Objectives:

- Understand classes of commonly used heart failure pharmacotherapeutics, their mechanism of action, dosing, safety profile, and evidence supporting their use
- Have an overview of pediatric heart failure biomarkers and their potential application in clinical care and drug development
- Understand recent examples of successful and ongoing pediatric heart failure drug development programs.

4/6/2022: FDA Roundtable on Pharmacometrics and Clinical Trial Design

Lecture Speaker: Hao Zhu + Team

Learning Objectives:

- Promote and foster inter-agency/multi-contextual collaboration to strengthen the pace of research and encourage the development of innovative and groundbreaking strategies in clinical research.
- Discuss and evaluate the current state, challenges, opportunities, and future direction of utilizing model-based approaches to inform dosing recommendations in specific populations.

4/13/2022: Effective Aerosol Therapy

Lecture Speaker: Bruce Rubin

Learning Objectives:

- Understand how particle size, velocity, and size distribution all influence aerosol delivery
- Become familiar with the different aerosol devices (nebulizers, pressurized metered dose inhalers, dry powder inhalers) and accessory devices (valved holding chambers, breath tracking, flow monitors) and how these are used.
- Recognize the elements of effective aerosol inhalation as well as myths regarding the “best” aerosol delivery
- Appreciate the importance of adherence to effective aerosol therapy and how this may be improved.

4/20/2022: Pediatric Applications of Technology**Lecture Speaker:** Pending.**Learning Objectives:**

- Discuss and evaluate effective new technology and novel therapeutics, particularly drug eluting devices, for children and adolescents and that they are used optimally according to individual needs.
- Evaluate the use of peripherally- and/or coronary-placed stent in children and adolescents in the improvement coronary blood flow in a variety of clinical situations.

4/27/2022: 3D Printing and Bioprinting: Examples, Mechanism, Quality Control and Impact in Pharmaceutics**Lecture Speaker:** Mansoor Khan**Learning Objectives:**

- Understand different types of printers and bioprinters.
- Review the working principles of each printing method.
- Discuss examples from academia.
- Understand quality control: What it is, why it is important, and what affects the quality of the end product.
- Understand the impact of 3D printing and bioprinting on patients.

5/4/2022: Metformin and Glyburide during Pregnancy**Lecture Speaker:** Mary Hebert**Learning Objectives:**

- Understand pregnancy induced changes in glyburide pharmacokinetics
- Understand pregnancy induced changes in metformin pharmacokinetics
- Understand differences in metformin pharmacodynamics in pregnant women with GDM compared to non-pregnant women with T2DM
- Understand relative pharmacodynamics of glyburide monotherapy, metformin monotherapy and combination glyburide and metformin therapy in pregnant women

5/11/2022: Neonatal Drug Disposition and Renal Maturation**Lecture Speaker:** Jian Wang**Learning Objectives:**

- Explore the utilization of equations used to define pediatric renal function and how this relates to individualized drug exposure.
- Demonstrate several examples related to optimization of those models that incorporate renal function and utility of individual predictions using population pharmacokinetic models.
- Explore the impact of when estimating varying renal function and the impact on pharmacokinetic parameters such as drug clearance in neonates.

5/18/2022: Ethical Considerations in the Study of COVID Vaccines**Lecture Speaker:** John Lantos**Learning Objectives:**

- Analyze the justice implications of decisions about inclusion criteria
- Understand the value judgments that are required to define study endpoints
- Review debate about human challenge trials and allowable risk

5/25/2022: Neonatal Opioid Withdrawal Syndrome: Current and Emerging Evidence for Pharmacologic Management

Lecture Speaker: Julie Ross

Learning Objectives:

- Describe the growing burden of Neonatal Opioid Withdrawal Syndrome
- Discuss and evaluate evidence for the primary pharmacologic treatment options in Neonatal Opioid Withdrawal Syndrome
- Discuss and evaluate evidence for adjunctive pharmacologic therapy for Neonatal Opioid Withdrawal Syndrome