**WEDNESDAY MORNING WORKSHOP (8:30 am – 10:30 am)**

**E. (REAL WORLD EVIDENCE) The Role of Real World Evidence in Decision Making: Current Thinking and Practice**

**Organizer/Chair: Vipin Arora**

1. Methylation Quantitative Trait Loci and the Risk of Congenital Heart Diseases

 **Speaker:  Ming Li, Indiana University**

**TBA**

**2. Model-based evaluations of school-level interventions to mitigate infectious disease outbreaks**

 **Speaker:  Maria Litvinova, Indiana University**

Pre-emptive and reactive school closures are one of the frontline non-pharmaceutical measures aimed at mitigation of the spread of respiratory infectious diseases. However, statistical quantification of their effect is often challenging due to the heterogeneity in implementation and contexts. The effect may vary depending on which triggers are used for the closures, their timing, levels of community transmission or the epidemiological characteristics of the pathogen. In fact, there have been contrasting results concerning the effect of reactive school closures on SARS-CoV-2 transmission. Before COVID-19, we measured the changes in behavior of the population during reactive school closures, that allowed us to develop an innovative data-driven mechanistic modeling framework to reduce the uncertainty surrounding school-closure policies. In the COVID era we developed a data-driven computational model of SARS-CoV-2 transmission that incorporated the patterns of social interactions before and during reactive class/school closures. This framework allowed us to test alternative triggering mechanisms for class/school closures and estimate their potential to reduce COVID-19 burden in the community. The results of such modeling studies identified the importance of screening procedures and timely identification of infections for the effectiveness of school closures. This approach can also be beneficial to estimate direct and indirect effects of other interventions aimed at school-aged individuals including vaccination programs.

3. Molecular Epidemiology: Identifying biomarkers predictive of gestational age and neonatal morbidity

**Speaker: Kelli Ryckman, Indiana University**

Globally, approximately 15 million babies are born preterm each year and 1.1 million deaths are due to preterm birth (PTB), defined as delivery of an infant before 37 post-menstrual weeks. Accurate estimation of gestational age is important not only for improving critical care decisions but also for getting accurate estimates of preterm birth across the globe. The very preterm neonate (<32 weeks gestation) is at the highest risk of developing complications that can result in death or significant life-long disability. Among the most significant and common of the major neonatal morbidities are intraventricular hemorrhage (IVH), necrotizing enterocolitis (NEC), sepsis, and retinopathy of prematurity (ROP). While measures of neonatal illness severity have been successful in predicting the risk for mortality in very preterm neonates, our ability to identify newborns likely to develop significant morbidity remains limited. Neonatal illness severity indices have a variety of important clinical and research applications including risk stratification, family counseling, external benchmarking for inter-hospital performance comparisons, and determining individual treatments for infants with a specific risk profile. Our team has shown that metabolic biomarkers measured as part of routine newborn screening are novel predictors of gestational age, neonatal morbidity, and mortality. Topics covered in this talk include: 1) the importance of predicting gestational age and neonatal morbidity, 2) the contribution of molecular epidemiology to prediction of prematurity, and 3) using metabolic biomarkers measured as part of newborn screening to predict neonatal morbidity and mortality. Understanding the relationship between specific metabolites and neonatal morbidity and mortality will lead to the long-term goal of improved diagnostics, more effective therapeutic agents, and a precision approach to clinical management of the very preterm neonate.

4. Validation of real-world data-based outcomes: Concepts and applications

 **Speaker:  Sangmi Kim, Eli Lilly**

**TBA**