

Biostatistics and Epidemiology

Division Details

RESEARCH AND TRAINING DETAILS

Faculty	21
Joint Appointment Faculty	14
Research Fellows and Post Docs	2
Research Graduate Students	10
Total Annual Grant Award Dollars	\$7,304,535
Total Publications	168



Row 1: M Altaye, B Huang, M Macaluso, N Zhang

Row 2: K Bowers, R Ittenbach, J Woo, J Khoury, M Hossain

Row 3: H Sucharew, R Szczesniak, L Fei, B Zhang, N Ollberding, J Meinzen-Derr, E King

Research Highlights

Bench to Bassinet Program

[Eileen King, PhD](#), associate professor, in the Division of Biostatistics and Epidemiology, along with, [Peter White, PhD](#), professor and director of the [Division of Biomedical Informatics \(BMI\)](#), received a \$32.5 million, five-year grant to serve as the Administrative Coordinating Center, and data hub for the National Institutes of Health's ([NIH](#)) Bench to Bassinet Program ([B2B](#)). B2B is a national, multi-site, collaborative program designed to accelerate research into the molecular basis of congenital heart disease, from discovery and translational research to clinical testing.

The purpose of this federally funded program is to coordinate activities for the Cardiovascular Development Consortium and the Pediatric Cardiac Genomics Consortium, two leading scientific consortia dedicated to the discovery and modeling of genomic data for thousands of individuals with congenital and/or acquired heart disease and their influence on clinical outcomes. Division of Biostatistics and Epidemiology faculty and staff contribute to the conduct and administrative oversight of the project, including the design and development of databases capturing clinical and phenotypic data, statistical modeling and analysis of project data, and the management and tracking of biological specimens. We work in close collaboration with the Division of Biomedical Informatics in the design and development of a genomic data hub involving more than 150 terabytes of molecular and clinical cardiac data.

The B2B program is an important component of the Division of Biostatistics and Epidemiology and its collaborative ties with other divisions, highlighting many of the inherent strengths of the Division in the core areas of biostatistics, epidemiology, and data management. The B2B program offers the medical center a lead role in determining new directions for pediatric heart research leading to greater understanding of how patients' genetic profiles is something clinicians can use to better predict the course of illness, target

interventions, and result in novel cures for many of today's most challenging cardiovascular conditions. B2B is believed to be the largest single award ever received by Cincinnati Children's.

Methods Development

In FY 2016, faculty and staff from the division led independent research in many areas of methods development, nearly all with specific applications to pediatric science and medicine. Examples of such methodologies included new applications for analyzing zero-inflated repeated count data (see significant publication by Gupta), semiparametric mixed methods for nested repeated measures data (see significant publication by Szczesniak), as well as propensity score matching techniques with time-varying exposures. Other methods with direct applications to pediatrics included semiparametric regression modeling of multivariate panel count data with informative observation times, statistical analysis of metabolomics data, and novel methods for accelerated failure time models with incomplete predictors. Professional journals in which our methodological work appeared in FY 2016 include *Communication of Statistics*, *Journal of Multivariate Analysis*, *Lifetime Data Analysis*, *Annals of Epidemiology*, *Metabolomics*, and the *Journal of Modern Applied Statistical Methods*. This work is funded through both intramural and extramural awards. Two faculty members, in particular, Dr. Bin Huang, PhD, and Dr. Mi-Ok Kim, were recipients of PCORI Methods Awards designed specifically to foster the development of new approaches for advancing patient centered research. The Division formed shared interest groups in causal inference and adaptive clinical trials to promote additional work in these two important areas of pediatric research.

Population-based Research

The [Division of Biostatistics and Epidemiology](#) is the research hub for a variety of population-based cohorts aimed at understanding and improving child health in the context of where children and families live—in the community. These epidemiologic studies and collaborations allow our researchers to understand normal growth and development, the long-term impact of the environment or childhood lifestyle on health and disease, and intergenerational influences on child health.

There are four large Cincinnati-based cohorts directed from within the Division, led by Drs. [Patrick Ryan, PhD, MS](#); [Jane Khoury, PhD](#); [Jessica Woo, MHSA, PhD](#); and Alonzo Folger. Three of these cohorts represent traditional longitudinal epidemiologic cohorts, aimed at understanding the long-term role of early life exposures (e.g., in utero exposure to glucose or childhood exposure to air pollution or allergens) or measured risk factors (e.g., blood lipids, blood pressure, body mass index) on adolescent or adult outcomes, such as cardiovascular, renal, metabolic, allergy, asthma and neurodevelopment outcomes. These studies include the Cincinnati Childhood Allergy and Air Pollution Study (CCAAPS, PI: Dr. Patrick Ryan; see significant publications section by Brokamp), the Diabetes in Pregnancy study (PI: Dr. Jane Khoury), and the Princeton Lipid Research Study (PI: Dr. Jessica Woo), each of which has enrolled between 700 and 2,500 children and families. Some of these families have been followed and studied for 40 years. The fourth cohort is the research arm of a large regional parenting support home-visiting program, [Every Child Succeeds](#) (Lead Epidemiologist: Dr. Alonzo Folger; see featured publication), with robust databases designed to study such outcomes as pediatric injury, maternal depression, pediatric primary care, and the effects of maternal adversity on child development and the mediational role of epigenetics.

In addition to these large cohorts, the Division is involved in a number of other initiatives to study and improve the health of Cincinnatians. In an ongoing collaboration with [Hamilton County Public Health](#), Dr. Folger has provided epidemiologic and statistical expertise to support investigation and surveillance of the local syphilis epidemic. [Dr. Richard Ittenbach, PhD](#), collaborated with the Biodynamic Center at Cincinnati Children's to refine a county-wide screening of female athletes in Boone County, KY, to understand biomechanical profiles predisposing athletes to ACL injury. These and similar collaborations from our Division extends Cincinnati Children's research and impact beyond the clinical setting and situations that arise during clinical care, to truly understand and influence health in the communities we serve.

Team Science

The Division of Biostatistics and Epidemiology values tremendously its collaborative work with investigators throughout the medical center. In FY 2016, Division of Biostatistics and Epidemiology faculty and staff collaborated with investigators on funded studies from 34 of the 59 clinical and research divisions within the hospital, fully embracing the team science model. Divisional faculty and staff participated in 133 active research grants and contracts, with annual direct costs totaling \$152M (divisional direct costs: \$22M). Specific examples of successful team collaborations in which DBE faculty and staff participated in FY2016 were the Center for Clinical and Translational Science and Training in which 8 faculty and staff serve in active leadership positions, including statistical analysis and

study design, clinical research ethics, and clinical data management. Learning Networks represent another important area of collaborative involvement. In conjunction with the Anderson Center and a number of other clinical divisions, DBE members are helping reshape the way in which clinical data are used to inform and improve clinical care system-wide.

Significant Publications

Gupta R, Szczesniak RD, Macaluso M. Modeling repeated count measures with excess zeros in an epidemiological study. *Ann Epidemiol.* 2015 Aug;25(8):583-9

Valid and precise modeling of self-reported problems with condom use is necessary for research on condom safety and effectiveness. Traditional techniques may produce misleading estimates when modeling large proportion of zero values (perfect users or non-reporters) and discrete nonzero counts (at risk of reporting problems). Zero-inflated Poisson mixed regression allowed us to identify the characteristics of the two groups: that older women were significantly more likely to be non-reporters or perfect users. The nonzero problem rate decreased during follow-up, and was lower among women who believed in the benefits of condom use, and had no sexually transmitted diseases at baseline.

Length of hospital stay, and number of surgeries for children presenting with certain conditions, offer examples of excess numbers of zeros in pediatric research setting. Zero-inflated regression techniques can produce the mixture of correct probability distributions, examine the effects of study variables, and conclusively draw accurate inferences about child health.

Szczesniak RD, Li D, Amin RS. Semiparametric mixed models for nested repeated measures applied to ambulatory blood pressure monitoring data. *J Mod Appl Stat Methods.* 2016 May;15(1):255-75.

Researchers need flexible statistical approaches to reveal complex relationships between treatment and nonlinear outcomes in pediatric diseases and disorders, especially as intensive medical monitoring becomes a more powerful tool in research and care. It is particularly challenging to characterize hierarchical longitudinal correlations arising from long data sequences generated on multiple subjects before and after treatment. In this study, researchers applied a series of semiparametric mixed models, which provide a nonparametric representation of long data sequences over time while allowing for flexible covariance specification, to examine effects of a surgical intervention on the circadian rhythm of ambulatory blood pressure in children with sleep apnea. Unlike their traditional counterparts, the semiparametric mixed models estimated precise timing of clinical features, such as morning surge and nocturnal dipping, and demonstrated that intervention effects are strongest on nocturnal diastolic blood pressure. These models provide a sensitive, efficient means to analyze medical monitoring data in pediatric medicine.

Brunst KJ, **Ryan PH, Brokamp C**, Bernstein D, Reponen T, Lockey J, Hershey GKK, Levin L, Grinshpun SA, LeMasters G. **Timing and Duration of Traffic-related Air Pollution Exposure and the Risk for Childhood Wheeze and Asthma.** *Am J Respir Crit Care Med.* 2015 Aug 15;192(4):421-7.

Prior studies examining exposure to air pollution and childhood respiratory outcomes, including wheeze and new-onset asthma, have reported inconsistent results. Few studies, however, have examined the relationship between timing and duration of traffic-related air pollution (TRAP) exposure and childhood wheezing and asthma development. This study provides evidence that early-life exposure to high levels of TRAP associates with wheeze symptoms during childhood. Researchers associate exposure to high levels of TRAP over the first seven years of life with asthma development.

Woo JG, Herbers PM, McMahon RJ, Davidson BS, Ruiz-Palacios GM, Peng YM, Morrow AL. **Longitudinal Development of Infant Complementary Diet Diversity in 3 International Cohorts.** *J Pediatr.* 2015 Nov;167(5):969-74.

This paper provides novel information regarding infant complementary dietary diversity in three global predominantly-breastfed cohorts: Cincinnati, Mexico City and Shanghai, China. Complementary diet diversity may be an important precursor to both healthy dietary habits later in life, as well as improved health of infants regarding growth and metabolic outcomes. The major findings are that infants are more likely to achieve minimal dietary diversity, and achieve it earlier, than infants in Mexico City or Cincinnati, driven by greater intake in meats and eggs. By contrast, Cincinnati infants who are highly breastfed late in the first year of life have very low

dietary diversity scores, similar to low-income countries, potentially suggesting inappropriate or inadequate complementary feeding in this population. Exploration of the impacts of these findings on infant growth and health remain.

Brokamp C, LeMasters GK, Ryan PH. Residential mobility impacts exposure assessment and community socioeconomic characteristics in longitudinal epidemiology studies. *J Expo Sci Environ Epidemiol*. 2016 Jun;26(4):428-34.

Epidemiologic studies in pediatric research often use residential locations to estimate environmental exposures or community level characteristics, often with the assumption that a birth record address is constant throughout childhood. Using the Cincinnati Childhood Allergy and Air Pollution Study (CCAAPS) cohort, we found that over half of the cohort moved at least once before age seven. Overall, moves showed a separation by a median of four miles, and associated with a decrease in harmful environmental exposures and an improvement in community economic characteristics. We showed that ignoring residential mobility by only using the birth record address resulted in exposure misclassification leading to a bias towards the null when associating the exposures with asthma at age seven. Future studies should consider residential mobility to prevent biased conclusions in pediatric medicine and research.

Division Publications

1. Abdul-Rahim A, Fulton R, Sucharew H, Kleindorfer D, Khatri P, Broderick J, Lees K. **National Institutes of Health Stroke Scale Item Profiles as Predictor of Patient Outcome External Validation on Safe Implementation of Thrombolysis in Stroke-Monitoring Study Data.** *Stroke*. 2015; 46:2779.
2. Abu-El-Haija M, Palermo JJ, Fei L, Lin TK. **Variability in Pancreatitis Care in Pediatrics: A Single Institution's Survey Report.** *Pancreas*. 2016; 45:40-5.
3. Abu-El-Haija M, Wilhelm R, Heinzman C, Siqueira BN, Zou Y, Fei L, Cole CR. **Early Enteral Nutrition in Children with Acute Pancreatitis.** *J Pediatr Gastroenterol Nutr*. 2016; 62:453-6.
4. Adams DM, Trenor CC, 3rd, Hammill AM, Vinks AA, Patel MN, Chaudry G, Wentzel MS, Mobberley-Schuman PS, Campbell LM, Brookbank C, Gupta A, Chute C, Eile J, McKenna J, Mellow AC, Fei L, Hornung L, Seid M, Dasgupta AR, Dickie BH, et al. **Efficacy and Safety of Sirolimus in the Treatment of Complicated Vascular Anomalies.** *Pediatrics*. 2016; 137:e20153257.
5. Adeoye O, Sucharew H, Khoury J, Vagal A, Schmit PA, Ewing I, Levine SR, Demel S, Eckerle B, Katz B, Kleindorfer D, Stettler B, Woo D, Khatri P, Broderick JP, Pancioli AM. **Combined Approach to Lysis Utilizing Eptifibatid and Recombinant Tissue-Type Plasminogen Activator in Acute Ischemic Stroke-Full Dose Regimen Stroke Trial.** *Stroke*. 2015; 46:2529-33.
6. Akbari SH, Limbrick DD, Jr., McKinstry RC, Altaye M, Ragan DK, Yuan W, Mangano FT, Holland SK, Shimony JS. **Periventricular Hyperintensity in Children with Hydrocephalus.** *Pediatr Radiol*. 2015; 45:1189-97.
7. Ambroggio L, Sucharew H, Rattan MS, O'Hara SM, Babcock DS, Clohessy C, Steinhoff MC, Macaluso M, Shah SS, Coley BD. **Lung Ultrasonography: A Viable Alternative to Chest Radiography in Children with Suspected Pneumonia?** *J Pediatr*. 2016; 176:93-98 e7.
8. Ambroggio L, Test M, Metlay JP, Graf TR, Blosky MA, Macaluso M, Shah SS. **Beta-Lactam Versus Beta-Lactam/Macrolide Therapy in Pediatric Outpatient Pneumonia.** *Pediatr Pulmonol*. 2016; 51:541-8.
9. Ambroggio L, Test M, Metlay JP, Graf TR, Blosky MA, Macaluso M, Shah SS. **Comparative Effectiveness of Beta-Lactam Versus Macrolide Monotherapy in Children with Pneumonia Diagnosed in the Outpatient Setting.** *Pediatr Infect Dis J*. 2015; 34:839-42.
10. Anderson JB, Beekman RH, 3rd, Kugler JD, Rosenthal GL, Jenkins KJ, Klitzner TS, Martin GR, Neish SR, Brown DW, Mangeot C, King E, Peterson LE, Provost L, Lannon C, National Pediatric Cardiology Quality Improvement C. **Improvement in Interstage Survival in a National Pediatric Cardiology Learning Network.** *Circ Cardiovasc Qual Outcomes*. 2015; 8:428-36.

11. Antommaria AH, Ittenbach RF. **Quality Attestation's Portfolio Evaluation Is Feasible, but Is It Reliable and Valid?** *Am J Bioeth.* 2016; 16:35-8.
12. Auger KA, Jerardi KE, Simmons JM, Davis MM, O'Toole J, Sucharew HJ. **It's Complicated: Overcoming Statistical Challenges of Group Learning in Medical Education Research.** *J Grad Med Educ.* 2015; 7:326-30.
13. Averin K, Villa C, Krawczeski CD, Pratt J, King E, Jefferies JL, Nelson DP, Cooper DS, Ryan TD, Sawyer J, Towbin JA, Lorts A. **Initial Observations of the Effects of Calcium Chloride Infusions in Pediatric Patients with Low Cardiac Output.** *Pediatr Cardiol.* 2016; 37:610-7.
14. Backeljauw B, Holland SK, Altaye M, Loepke AW. **Cognition and Brain Structure Following Early Childhood Surgery with Anesthesia.** *Pediatrics.* 2015; 136:e1-12.
15. Badiga S, Siddiqui N, Macaluso M, Johanning G, Piyathilake C. **Homocysteinemia Is Associated with a Lower Degree of PbmC Line-1 Methylation and a Higher Risk of Cin 2c in the U.S. Post-Folic Acid Fortification Era.** *Nutr Cancer.* 2016; 68:446-55.
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22. Boyne P, Dunning K, Carl D, Gerson M, Khoury J, Rockwell B, Keeton G, Westover J, Williams A, McCarthy M, Kissela B. **High-Intensity Interval Training and Moderate-Intensity Continuous Training in Ambulatory Chronic Stroke: Feasibility Study.** *Phys Ther.* 2016.
23. Brady CC, Vannest JJ, Dolan LM, Kadis DS, Lee GR, Holland SK, Khoury JC, Shah AS. **Obese Adolescents with Type 2 Diabetes Perform Worse Than Controls on Cognitive and Behavioral Assessments.** *Pediatr Diabetes.* 2016.
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25. Brandt EB, Myers JM, Ryan PH, Hershey GK. **Air Pollution and Allergic Diseases.** *Curr Opin Pediatr.* 2015; 27:724-35.
26. Brokamp C, LeMasters GK, Ryan PH. **Residential Mobility Impacts Exposure Assessment and Community Socioeconomic Characteristics in Longitudinal Epidemiology Studies.** *J Expo Sci Environ Epidemiol.* 2016; 26:428-34.
27. Brown DW, Mangeot C, Anderson JB, Peterson LE, King EC, Lihn SL, Neish SR, Fleishman C, Phelps C, Hanke S, Beekman RH, Lannon CM, National Pediatric Cardiology Quality Improvement Collaborative. **Digoxin Use Is Associated with Reduced Interstage Mortality in Patients with No History of Arrhythmia after Stage I Palliation for Single Ventricle Heart Disease.** *J Am Heart Assoc.* 2016; 5.

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29. Chen H, Zhang N, Lu X. **Is Early Smoking a Causal Risk Factor for Later Cognitive Impairment? A 20-Year Prospective Study with Time-Varying Propensity Score Matching Based on Random Intercept and Slope.** *Commun Stat Simul Comput.* 2016; 45:2733-43.
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Grants, Contracts, and Industry Agreements

Annual Grant Award Dollars

Investigator	Title	Sponsor	ID	Dates	Amount
Cynthia L. Baker	REACH: Translational Telehealth HomeCare	Children's Hospital of Philadelphia (Lurie Children's Hospital of Chicago)	R01 NR002093	7/1/2014 - 6/30/2016	\$63,120
Shelley Ehrlich	Bisphenol A and Gestational Diabetes	National Institutes of Health (University of Cincinnati)	K12 HD051953	9/1/2014 - 6/30/2016	\$107,661
Shelley Ehrlich	Hospital Discharge Practices and Contaminants of Emerging Concern in Water	Water Research Foundation (American Water Works Company, Inc.)	Project 4616	1/1/2016 - 6/30/2017	\$43,186
Bin Huang, PHD	Patient Centered Adaptive Treatment Strategies (PCATS) using Bayesian Casual Inference	Patient-Centered Outcome Research Inst.	ME-1408-19894	9/1/2015 - 8/31/2018	\$459,635
Jane C Khoury, PHD	Recanalization Therapies and Markers of Outcomes in Acute Ischemic Stroke	National Institutes of Health (University of Cincinnati)	P50 NS044283	8/1/2008 - 4/30/2016	\$47,883
Jane C Khoury, PHD	Comparison of Hemorrhagic & Ischemic Stroke Among Blacks and Whites	National Institutes of Health (University of Cincinnati)	R01 NS030678	4/1/2015 - 3/31/2020	\$148,301

Mi-Ok Kim, PHD	Rigor of Multi-Registry CER Studies: Towards Patient-Centered Treatment Planning	Agcy for Healthcare Research and Quality	K18 HS022437	8/1/2014 - 7/31/2016	\$137,858
Mi-Ok Kim, PHD	Propensity Score-based Methods for CER Using Multilevel Data: What Works Best When	Patient-Centered Outcome Research Inst.	ME-1403-13922	1/1/2015 - 12/31/2017	\$349,176
Eileen King, PHD	Evaluation of Clinical and Safety Outcomes Associated with Conversion from Brand-Name to Generic Tacrolimus Products in High-Risk Transplant Recipients	Food and Drug Administration (University of Cincinnati)	HHSF223201310224C	9/26/2015 - 9/25/2016	\$98,370
Eileen King, PHD Peter S. White	Administrative Coordinating Center: Cardiovascular Development and Pediatric Cardiac Genomics Consortia	National Institutes of Health	U01 HL131003	1/1/2016 - 12/31/2020	\$3,252,500
Maurizio Macaluso, PHD	Cincinnati Center for Clinical and Translational Sciences and Training	National Institutes of Health (University of Cincinnati)	KL2 TR001426	8/14/2015 - 3/31/2019	\$37,119
Jareen K Meinzen-Derr, PHD	Early Language and Functional Expectations (LIFE) Study Of Infants and Toddlers	March of Dimes	#12-FY14-178	6/1/2014 - 5/31/2017	\$86,667
Jareen K Meinzen-Derr, PHD	Patterned Experience in Preterm Infants	National Institutes of Health (Ohio State University)	R01 NR012307	2/1/2016 - 1/31/2017	\$14,815
Patrick H Ryan, PHD	Efficiency of HEPA Air Purification in Reducing Traffic-Related Particle Exposure	US Depart of Housing & Urban Development (University of Cincinnati)	OHHHU0027	12/1/2014 - 11/30/2016	\$31,570
Patrick H Ryan, PHD	Neurobehavioral and Neuroimaging Effects of Traffic Exposure in Children	National Institutes of Health	R01 ES019890	4/1/2016 - 3/31/2017	\$593,219
Patrick H Ryan, PHD	Assessing Personal Exposure to Ultrafine PM Number and Respiratory Health	National Institutes of Health	R21 ES024713	3/1/2015 - 2/28/2017	\$192,730
Rhonda Szczesniak, PHD	Preventing Rapid Decline in CF: Statistical Research Career Commitment	National Institutes of Health	K25 HL125954	8/1/2015 - 3/31/2020	\$306,273

Jessica G Woo, PHD Elaine Urbina, MD	Childhood CV Risk and Adult CVD Outcomes: an International Long-term Follow-up	National Institutes of Health	R01 HL121230	12/1/2014 - \$1,279,814 11/30/2019
Bin Zhang, PHD	Mechanisms of Refractory Hypertension	National Institutes of Health (University of Alabama-Birmingham)	R01 HL113004	4/7/2014 - \$54,638 3/31/2019

Total Annual Grant Award Dollars **\$7,304,535**