# MAHARAJ, ANIL

#### CAREER OBJECTIVE

I am a pharmacist with graduate-level training in pharmacokinetics and pharmacodynamics. As a researcher, I have made important contributions towards the fields of pediatric pharmacology and biopharmaceutics. Notably, my research within the discipline of pediatric physiologically-based pharmacokinetic modeling has been cited by Food and Drug Administration guidance to assist sponsors in developing clinical drug investigations in neonates. My ongoing research interests are focused on the development and application of modeling and simulation techniques to support pediatric drug development. In particular, to support the advancement of mechanistic models in pediatrics, there is a need for research devoted to quantifying differences in physiological processes that drive developmental changes in pharmacokinetics between children and adults. My overarching career goal is to develop quantitative models that optimize the safe and effective use of medications in children.

#### **EDUCATION**

2012–2017 University of Waterloo (School of Pharmacy) Doctor of Philosophy (Pharmacy), 2017 Dissertation: Parameterization of In Silico Oral Disposition Models: Focus on Pediatrics

2002–2008 University of Manitoba (Faculty of Pharmacy) Bachelor's of Science (Pharmacy), 2008

#### **EXPERIENCE**

2020-current University of British Columbia Assistant Professor – Tenure Track (Pharmacokinetics)

Principal investigator: Pharmacokinetics Modeling and Simulation Laboratory

#### 2018–2020 Duke Clinical Research Institute

Postdoctoral Research Associate (Pharmacometrics)

- Lead pharmacokinetic/pharmacodynamic modeling efforts for clinical and preclinical investigations
- Generate Food and Drug Administration compliant population pharmacokinetic modeling reports
- Develop novel metrics for physiologically-based pharmacokinetic model evaluation
- Pediatric clinical trial support (e.g., protocol development, bioanalytical assay validation, and power analyses)

#### 2017 St. Jude Children's Research Hospital

Postdoctoral Research Associate (Pharmacometrics/Systems Modeler)

- Perform clinical and preclinical population pharmacokinetic analyses to support the development of novel therapies for treatment of pediatric brain tumor patients
- Communicate with sponsors and stakeholders throughout various stages of project development
- Design preclinical studies to assess brain penetration of antineoplastic drugs

#### 2016–2017 Design 2 Code Inc.

Pharmacometric consultant

- Develop a physiologically-based model for an orally administered endothelial receptor antagonist and its metabolite
- Provide educational seminars on physiologically-based pharmacokinetic modeling principles and software to client

Vancouver, British Columbia

Durham, North Carolina

Winnipeg, Manitoba

Waterloo, Ontario

Waterloo, Ontario

Memphis, Tennessee

- Perform preclinical pharmacokinetic assessments for different injectable formulations of an anesthetic agent to assess the feasibility for prospective human development
- Communicate with clients from project inception to delivery

2013–2014 Huron Perth Healthcare Alliance (Stratford General Hospital) Clinical Pharmacist

- Support allied healthcare professionals including physicians, nurses, and dietitians to ensure appropriate medication utilization
- Practice in both centralized and decentralized settings to provide pharmaceutical care to patients
- Validation of prepared chemotherapeutic products

# 2008–2011 Victoria General Hospital

Clinical Pharmacist

- Clinical teaching unit
  - Establish role for clinical pharmacists within a newly created clinical teaching unit
  - Provide patient-focused clinical support to teaching unit staff and patients
  - Practice within an interprofessional care team comprised of a diverse array of healthcare professionals
  - Mentor undergraduate pharmacy students
  - Provide academic detailing sessions to pharmacy and medicals students as well as medical residents
- Clinical trial pharmacy department coordinator
  - Develop protocols to support the pharmacy department's participation in clinical trials
  - Maintain and audit trial related financial records

# 2007 University of Manitoba

Research Assistant

- Devise microbiological studies to evaluate the effect of an ethanol-based catheter locking solution on isolates of Candida albicans
- Troubleshoot logistic issues with initial trial runs and implement changes to ameliorate issues
- Perform statistical analysis of study results

# PUBLICATIONS

# **Referred Journals**

- 1. Maharaj AR, Wu H, Hornik CP, Balevic SJ, Hornik CD, Smith PB, Gonzalez D, Zimmerman KO, Benjamin DK Jr, Cohen-Wolkowiez M. Simulated Assessment of Pharmacokinetically Guided Dosing for Investigational Treatments of Pediatric Patients With Coronavirus Disease 2019, JAMA Pediatr. 2020 Oct 1;174(10):e202422. doi: 10.1001/jamapediatrics.2020.2422. Epub 2020 Oct 5. PubMed PMID: 32501511; PubMed Central PMCID: PMC7275264.
- 2. Balevic SJ, Hornik CP, Green TP, Clowse MEB, Gonzalez D, Maharaj AR, Schanberg LE, Eudy AM, Swamy GK, Hughes BL, Cohen-Wolkowiez M. Dr. Balevic, et al reply. J Rheumatol. 2020 Oct 1;47(10):1587. doi: 10.3899/jrheum.200681. Epub 2020 May 25. PubMed PMID: 32451351.
- 3. Hill KD, Maharaj AR, Li JS, Thompson E, Barker PCA, Hornik CP. A Randomized, Controlled Pharmacokinetic and Pharmacodynamics Trial of Ambrisentan After Fontan Surgery. Pediatr Crit Care Med. 2020 Sep;21(9):e795-e803. doi: 10.1097/PCC.000000000002410. PubMed PMID: 32639468; PubMed Central PMCID: PMC7483887.
- 4. Maharaj AR, Wu H, Zimmerman KO, Autmizguine J, Kalra R, Al-Uzri A, Sherwin CMT, Goldstein SL, Watt K, Erinjeri J, Payne EH, Cohen-Wolkowiez M, Hornik CP. Population pharmacokinetics of olanzapine in children. Br J Clin Pharmacol. 2020 Jun 4;. doi: 10.1111/bcp.14414. [Epub ahead of print] PubMed PMID: 32497307.

Winnipeg, Manitoba

Stratford, Ontario

Winnipeg, Manitoba

- Maharaj AR, Wu H, Hornik CP, Arrieta A, James L, Bhatt-Mehta V, Bradley J, Muller WJ, Al-Uzri A, Downes KJ, Cohen-Wolkowiez M. Use of normalized prediction distribution errors for assessing population physiologically-based pharmacokinetic model adequacy. J Pharmacokinet Pharmacodyn. 2020 Jun;47(3):199-218. doi: 10.1007/s10928-020-09684-2. Epub 2020 Apr 22. PubMed PMID: 32323049; PubMed Central PMCID: PMC7293575.
- Balevic SJ, Hornik CP, Green TP, Clowse MEB, Gonzalez D, Maharaj AR, Schanberg LE, Eudy AM, Swamy GK, Hughes BL, Cohen-Wolkowiez M. Hydroxychloroquine in Patients with Rheumatic Disease Complicated by COVID-19: Clarifying Target Exposures and the Need for Clinical Trials. J Rheumatol. 2020 May 11;. doi: 10.3899/jrheum.200493. [Epub ahead of print] PubMed PMID: 32393664; PubMed Central PMCID: PMC7655510.
- Greenberg RG, Wu H, Maharaj A, Cohen-Wolkowiez M, Tomashek KM, Osborn BL, Clark RH, Walter EB. A Pharmacoepidemiologic Study of the Safety and Effectiveness of Clindamycin in Infants. Pediatr Infect Dis J. 2020 Mar;39(3):204-210. doi: 10.1097/INF.00000000002524. PubMed PMID: 31725114; PubMed Central PMCID: PMC7137351.
- Campagne O, Davis A, Maharaj AR, Zhong B, Stripay J, Farmer D, Roussel MF, Stewart CF. CNS penetration and pharmacodynamics of the CHK1 inhibitor prexasertib in a mouse Group 3 medulloblastoma model. Eur J Pharm Sci. 2020 Jan 15;142:105106. doi: 10.1016/j.ejps.2019.105106. Epub 2019 Oct 25. PubMed PMID: 31669383; PubMed Central PMCID: PMC6925336.
- Maharaj AR, Wu H, Zimmerman KO, Speicher DG, Sullivan JE, Watt K, Al-Uzri A, Payne EH, Erinjeri J, Lin S, Harper B, Melloni C, Hornik CP. Dosing of Continuous Fentanyl Infusions in Obese Children: A Population Pharmacokinetic Analysis. J Clin Pharmacol. 2019 Dec 8;. doi: 10.1002/jcph.1562. [Epub ahead of print] PubMed PMID: 31814149; PubMed Central PMCID: PMC7591270.
- Thompson EJ, Wu H, Maharaj A, Edginton AN, Balevic SJ, Cobbaert M, Cunningham AP, Hornik CP, Cohen-Wolkowiez M. Physiologically Based Pharmacokinetic Modeling for Trimethoprim and Sulfamethoxazole in Children. Clin Pharmacokinet. 2019 Jul;58(7):887-898. doi: 10.1007/s40262-018-00733-1. PubMed PMID: 30840200; PubMed Central PMCID: PMC6586496.
- Maharaj AR, Wu H, Hornik CP, Cohen-Wolkowiez M. Pitfalls of using numerical predictive checks for population physiologically-based pharmacokinetic model evaluation. J Pharmacokinet Pharmacodyn. 2019 Jun;46(3):263-272. doi: 10.1007/s10928-019-09636-5. Epub 2019 Apr 23. PubMed PMID: 31016557; PubMed Central PMCID: PMC6531337.
- Zhong B, Maharaj A, Davis A, Roussel MF, Stewart CF. Development and validation of a sensitive LC MS/MS method for the measurement of the checkpoint kinase 1 inhibitor prexasertib and its application in a cerebral microdialysis study. J Pharm Biomed Anal. 2018 Jul 15;156:97-103. doi: 10.1016/j.jpba.2018.04.018. Epub 2018 Apr 17. PubMed PMID: 29698863; PubMed Central PMCID: PMC5984718.
- Maharaj AR, Gonzalez D, Cohen-Wolkowiez M, Hornik CP, Edginton AN. Improving Pediatric Protein Binding Estimates: An Evaluation of α1-Acid Glycoprotein Maturation in Healthy and Infected Subjects. Clin Pharmacokinet. 2018 May;57(5):577-589. doi: 10.1007/s40262-017-0576-7. PubMed PMID: 28779462; PubMed Central PMCID: PMC5797516.
- Maharaj AR, Edginton AN. Examining Small Intestinal Transit Time as a Function of Age: Is There Evidence to Support Age-Dependent Differences among Children?. Drug Metab Dispos. 2016 Jul;44(7):1080-9. doi: 10.1124/dmd.115.068700. Epub 2016 Mar 14. Review. PubMed PMID: 26977099.
- 15. **Maharaj AR**, Edginton AN, Fotaki N. Assessment of Age-Related Changes in Pediatric Gastrointestinal Solubility. Pharm Res. 2016 Jan;33(1):52-71. doi: 10.1007/s11095-015-1762-7. Epub 2015 Jul 29. PubMed PMID: 26220249.

- Maharaj A, Fotaki N, Edginton A. Parameterization of small intestinal water volume using PBPK modeling. Eur J Pharm Sci. 2015 Jan 25;67:55-64. doi: 10.1016/j.ejps.2014.10.016. Epub 2014 Nov 6. PubMed PMID: 25444844.
- Maharaj AR, Edginton AN. Physiologically based pharmacokinetic modeling and simulation in pediatric drug development. CPT Pharmacometrics Syst Pharmacol. 2014 Oct 22;3:e150. doi: 10.1038/psp.2014.45. PubMed PMID: 25353188; PubMed Central PMCID: PMC4260000.
- Maharaj AR, Barrett JS, Edginton AN. A workflow example of PBPK modeling to support pediatric research and development: case study with lorazepam. AAPS J. 2013 Apr;15(2):455-64. doi: 10.1208/s12248-013-9451-0. Epub 2013 Jan 24. PubMed PMID: 23344790; PubMed Central PMCID: PMC3675728.
- 19. **Maharaj AR**, Zelenitsky SA, Vercaigne LM. Effect of an ethanol/trisodium citrate hemodialysis catheter locking solution on isolates of Candida albicans. Hemodial Int. 2008 Jul;12(3):342-7. doi: 10.1111/j.1542-4758.2008.00279.x. PubMed PMID: 18638091

# CONFERENCE ABSTRACTS

- Guimaraes M, Maharaj AR, Edginton AN, Vertzoni M, Fotaki N. Understanding the Impact of Age-Related Changes in Paediatric Gastrointestinal Solubility by Multivariate Data Analysis. AAPS PharmSci 360. 2018. Washington, DC. (Abstract T1130-05-037)
- Hill KD, Maharaj AR, Thompson E, Li JS, Pearson E, Hornik CP. A Double Blind, Randomized, Controlled Pharmacokinetic and Pharmacodynamics Trial of Ambrisentan After Fontan Surgery. AHA Scientific Sessions. 2018. Chicago, IL. (Abstract 14968)
- 3. **Maharaj AR**, Davis A, Zhong B, Roussel MF, Stewart CF. Plasma and CNS pharmacokinetics of the CHK-1 inhibitor prexasertib (LY-2606368) in mice bearing orthotopic group 3 medulloblastoma. AACR AM. 2018. Chicago, IL. (Abstract 4927)
- 4. **Maharaj AR**, Panetta C, Gajjar A, Stewart CF. The influence of age on the disposition of cyclophosphamide and its metabolites in infants and young children with brain tumors: A population pharmacokinetic analysis. ACoP8. 2017. Fort Lauderdale, FL. (Abstract M-025)
- 5. **Maharaj AR**, Edginton AN. Deconvolution of Gastrointestinal Permeability—Surface Area Using PBPK Modelling. AAPS AM. 2013. San Antonio, TX. (Abstract T3207)
- 6. **Maharaj AR**, Barrett JS, Edginton AN. Scaling Adult Physiologically-based Pharmacokinetic (PBPK) Models to Pediatrics: A Logical Workflow. AAPS AM. 2012. Chicago, IL. (Abstract W4300).

#### GRANTS

Thrasher Research Fund (2019-2020) Evaluation of the Effects of Childhood Obesity on Drug Dosing

#### PRESENTATIONS

# Invited Seminars

 Advancing Pediatric Pharmacotherapy: Pharmacokinetic Modeling and Simulation's Critical Role in Addressing Current Challenges. University of British Columba, Faculty of Pharmaceutical Sciences. 2019.

#### **Conference** Presentations

 Advances in Model Evaluation Methods for Pediatric Physiologically-Based Pharmacokinetics. American Conference on Pharmacometrics 6. 2015.

## DCRI Clinical Pharmacology Seminars

- Ceftazidime Pharmacokinetics in Obese Children. 2019.
- Olanzapine Pharmacokinetics in Children and Adolescents. 2019.
- Pharmacokinetics of Fentanyl in Obese Children. 2019.
- Use of Normalized Prediction Distribution Errors for Physiologically-based Pharmacokinetic Model Evaluation. 2018.

## Undergraduate Lectures

## University of British Columbia

- PHRM 100/ PHAR 502. Clinical Applications of PK Introduction. 2020.
- PHRM 100/ PHAR 502. Clinical Applications of PK Aminoglycosides . 2020.
- PHRM 100/ PHAR 502. Clinical Applications of PK Assessment of Renal Function. 2020.

## University of Waterloo

- Integrated Patient Focused Care 5. Vancomycin Clinical Pharmacokinetics. 2016.
- Integrated Patient Focused Care 5. Drug Prescribing in Renal Failure. 2016.
- PHARM 224. Extraction Ratio. 2015.
- Integrated Patient Focused Care 4. Digoxin Clinical Pharmacokinetics. 2015.
- PHARM 320. Nonlinear Pharmacokinetics/Phenytoin Clinical Pharmacokinetics. 2013.
- PHARM 223. Digoxin Pharmacokinetics. 2012.

#### MENTORSHIP

2016 University of Waterloo (School of Pharmacy) Undergraduate Mentor – PHARM 401

• Undergraduate student project: *Evaluation of Growth and Development on Drug Volume of Distribution*.

#### 2008-2011 Winnipeg Regional Health Authority Preceptor

 Provided mentorship and constructive feedback to undergraduate and PharmD students completing their clinical hospital rotations

# PROFESSIONAL DEVELOPMENT ACTIVITIES

2019-2020 **Therapeutic Drug Monitoring** *Editorial Board Member* 

2018-2020 **Journal Reviewer** *Clinical Pharmacokinetics Clinical Pharmacology & Therapeutics: Pharmacometrics & Systems Pharmacology Pediatric Drugs Therapeutic Drug Monitoring* 

#### PROFESSIONAL MEMBERSHIPS

- Ontario College of Pharmacist
- American Association of Pharmaceutical Scientists
- International Society of Pharmacometrics
- Canadian Pharmacists Association

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Waterloo, Ontario

Winnipeg, Manitoba

#### HONORS

- Reviewer of the Year Award Therapeutic Drug Monitoring (2019)
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- Outstanding Achievement in Graduate Studies Honour University of Waterloo (2017)
- W.B. Pearson Medal Faculty of Science, University of Waterloo (2017)
- NSERC Alexander Graham Bell Canada Graduate Scholarship Doctoral Program (2014)
- University of Waterloo School of Pharmacy Graduate Program: Best Student Presentation in the Research Seminar Series (2014)
- University of Waterloo School of Pharmacy Graduate Program: Award for Highest Standing in PHARM 610 (2013)
- Merck Canada Ltd. Postgraduate Pharmacy Fellowship Award (2013)
- Ontario Graduate Scholarship (2013)
- Health Research Foundation Pharmaceutical Sciences Research Scholarship (2012)
- NSERC Alexander Graham Bell Canada Graduate Scholarship Master's (2012)
- Procurity Pharmacy Services Inc. Prize (2008)
- McKesson Canada Scholarship (2008)
- Dean's Honor List (2003-2008)
- Guertin Centennial Scholarship (2002)