Curriculum Vitae

Fatemeh Akhlaghi, Pharm.D., Ph.D.

Summary: I am a pharmaceutical scientist with expertise in clinical pharmacology, translational sciences, drug metabolism, pharmacogenomics and pharmacokinetic/pharmacodynamic (PKPD) modeling. My research goal is to understand the sources of variability in drug disposition and effect specifically in patients with diabetes mellitus or non-alcoholic fatty liver disease (NAFLD). The long-term goal is to devise personalized medicine these disease state. I am proficient in design and implementation of clinical pharmacokinetic studies, quantification of drug concentration and metabolites using LC-MS/MS and data analysis by standard or population pharmacokinetics methods. Characterization of expression and activity of drug metabolism enzymes and transporters *ex vivo* or *in vitro* is another area of research practiced in my laboratory. diabetes mellitus on drug disposition, drug development in alcoholism and therapeutic drug monitoring of immunosuppressive agents in organ transplant recipients. In addition, I am the director of the graduate program in Pharmaceutics and Pharmacokinetics and Principal Investigator on two NIH grants.

Personal Information

Date of Birth: November 18th, 1966
Marital Status: Married with a 24-year old daughter
Residency Status: Naturalized Citizen of the United States

Work Address

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Website Brown University: https://vivo.brown.edu/display/fakhlagh
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EDUCATION

1984-1990	**University of Mashhad, Iran**	**Pharm.D.**
Project title:	Use of CD4 to CD8 ratio as a marker for kidney transplant rejection	
Major Professor:	Behrouz Nikbin M.D.	

1992-1997	**University of Sydney, Australia**	**Ph.D. in Pharmaceutical Sciences**
Project title:	Cyclosporine distribution in cardiopulmonary transplant recipients	

Major Professors: Kenneth F. Brown Ph.D. and Anne M. Keogh M.D.

EMPLOYMENT HISTORY

July 2014-	University of Rhode Island Pharmaceutics	Ernest Mario Distinguished Chair in
July 2014-	Brown University Medical School	Adjunct Professor of Medicine
July 2011-	University of Rhode Island	Full Professor
July 2010-	Brown University Medical School	Adjunct Associate Professor
2006-2010	University of Rhode Island	Associate Professor with Tenure
2001-2006	University of Rhode Island	Assistant Professor (Tenure Tack)
1998-2001	University of Cambridge, U.K.	Senior Clinical Scientist

(Advisor: Andrew K. Trull Ph.D.; Funded by Novartis, Roche Laboratories and Papworth Hospital Research Trust)

1996-1998	University of Sydney, Australia	Post-Doctoral Research Associate

(Advisors: Kenneth F. Brown Ph.D. and Andrew J McLachlan Ph.D.; Funded by Novartis and Janssen Cilag Australia)

FURTHER TRAINING

March 13, 2016
Design and Analysis of Quantitative Proteomic Experiments: Introduction to Statistical Methods and Practical Examples using Skyline, one-day workshop part of Human Proteomics Organization meeting in Boston, MA

July 6-10, 2015
Model-Based Drug Development: Incorporating Population Variability into Mechanistic Prediction of PK and Modelling PK-PD
A course on Simcyp, Certara Corporation

Aug 5-6, 2014
Transporters in Drug Discovery and Development
University of Rhode Island

Jan-March, 2013
Hands on data manipulation using R
Instructor: Dr. Kaori Ito, Pfizer Groton

May 1-5, 2012
Fisher / Shafer NONMEM Course
An Intermediate to Advanced NONMEM course with PLT tools
Bethesda, MD

March 19-21, 2012
The Introductory GastroPlus™ Simulation and Modeling Workshop
Cambridge, MA.

March 29-31, 2011
Triple Quadrupole System Training using Analyst® Software for Quantitation
AB Sciex, Framingham, MA.

October 4, 2009
Phoenix NLME - A Next Generation Tool for Population PK/PD Analysis
Instructor: Dan Weiner, Pharsight Corporation.

September 16, 2006
Course in Pharmacokinetic/Pharmacodynamic Modeling
Instructors: Drs William J. Jusko and Jogarao Gobburu.

September 12-14, 2005
A three-day hands-on course on "Wings for NONMEM Population Pharmacokinetics Modeling";
Instructors: Drs Nick Holford and Dianne Mould
Also organized the course with Dr. Sara Rosenbaum.
July 26-30, 2004

A weeklong hands-on course entitled "Molecular Genetic Methodologies for Pharmaceutical Scientists"; Department of Pharmaceutical Sciences, University of Buffalo;
Instructor: Dr. Dan Brazeau.

June 2002
A three full days hands-on course "Operator's Training on Sciex API2000 Liquid Chromatography Mass Spectrometer" University of Rhode Island, also organized the course.
Instructor: Dr. Bill Sawyers, Applied Biosystems.

September 27-29, 1999
Beginning level short course on "Population Pharmacokinetics using NONMEM Computer Program"
Instructors: Drs Lewis Sheiner and Stuart Beal; Uppsala Sweden.

January 9-15, 1999
"A course in Pharmacokinetic and Pharmacodynamic Modeling using WinNonlin" one credit point; Department of Clinical Pharmacology, Karoliniska Institute, Stockholm, Sweden;
Instructor: Dr. Ole Borga.

December 7-22, 1998
"A course in Pharmacokinetic and Pharmacodynamic with Clinical Applications"; four credit points; Department of Clinical Pharmacology, Karoliniska Institute, Stockholm, Sweden;
Instructors: Drs Gunnar Alvan, Ole Borga, Johan Gabrielsson, Lars Gustafsson.

HONORS AND AWARDS

1992	Levy Maill Pattinson Award, Faculty of Pharmacy, Uni. of Sydney
1993-96	Faculty of Pharmacy Postgraduate Scholarship, Uni. of Sydney
2002	University of Rhode Island New Faculty Development Award
2006	Outstanding Intellectual Property Award, University of Rhode Island
2008	Paul-Ehrlich Magic Bullet-Award 2008, Nurnberg Germany
2010	Outstanding Intellectual Property Award, University of Rhode Island

PROFESSIONAL SOCIETY MEMBERSHIP

1990-present	The Medical Council of Iran (Registered Pharmacist)
1993-1998	Australasian Society for Clinical and Experimental Pharmacology and Toxicology (ASCEPT)
1993-1998	Australasian Pharmaceutical Science Association (APSA)
1997-2001	International Society of Heart and Lung transplantation (ISHLT)
1998-2001	Transplantation Society
1996-present	International Association of Therapeutic Drug Monitoring and Clinical Toxicology (IATDM&CT)
1997-present	American Association of Pharmaceutical Scientists (AAPS)
2001-present	American Association of Colleges of Pharmacies (AACP)
2008-present	American Society for Clinical Pharmacology and Therapeutics (ASCPT)

CONSULTING ACTIVITIES

1996	Physicochemical characteristics of ingredients of an antacid suspension, consultant for Park Davis Pharmaceuticals in collaboration with Dr. Elizabeth Gipps, University of Sydney
1997-1998	Droplet size determination of nebulized solutions of Salbutamol and Ipratropium Bromide using Marple - Miller cascade impactor, in collaborating with Dr. Kim Chan, University of Sydney
2001-2003	Pharmacokinetics of intravenous immunoglobulin (IVIG), I have analyzed the pharmacokinetic data from several phase III studies conducted by Bio Products Limited, UK
2003	Member of Mycophenolic Acid TDM Advisory Board (Opticept clinical trial, an 800 patient trial conducted by Roche Laboratories to evaluate the need for mycophenolic acid therapeutic drug monitoring)
2005	Consulting on a case study conducted at the Department of Emergency Medicine, RI hospital on the elimination of carboxy hemoglobin
2005-2007	Expert witness in a personal injury case involving cyclosporine generic substitution and risk of organ rejection
2007	Expert witness in a patent dispute case between two major pharmaceutical companies

2008-2009	Pharmacokinetic and pharmacodynamic modeling of bortezomib in cynomongolus monkeys, Millennium Pharmaceuticals
2007-2010	Pharmacokinetic consultant for a clinical trial on the intra-nasal use of ketamine in children with laceration, Department of Emergency Medicine, Hasbro Children Hospital, Providence, RI.
2011	Consultant on concentration–projection of a modified release tablet by two different manufacturers.
2014	Expert witness for a non-infringement trial for two Canadian companies
2014	Consultant on bioequivalence studies on a generic versus a brand name drug
2016-2017	Consultant on a patent dispute case involving a combination anti-hyperglycemic agent
2017-	Consultant on a patent dispute case involving projection of pharmacokinetic parameters of controlled release formulations

INVITED PRESENTATIONS

DATE	PRESENTATION TITLE/LOCATION
Nov 1999	"Pharmacokinetics of cyclosporine in patients receiving metabolic inhibitors" Invited speaker at PKUK99 meeting, Oxford, UK.
Aug 16 2001	"Clinical pharmacology of immunosuppressive agents" Lecture to the Nephrology Residents, Department of Nephrology, Brown University Medical School, Providence, RI.
Oct 1 2001	"Novel strategies for monitoring immunosuppressive agents" invited speaker at the Department of Pediatrics Nephrology and Transplantation, the Boston's Children Hospital, University of Harvard Medical School, Boston, MA.
Oct 23 2001	"Monitoring cardiothoracic transplant recipients" Seminar to the Heart Transplant Group, the Brigham and Woman's Hospital, University of Harvard Medical School, Boston, MA.
Jan 25 2002	"Novel strategies for monitoring immunosuppressive agents" Seminar to Kidney Transplantation Services, Rhode Island Hospital, Providence, RI.
Jul 11 2003	"Pharmacokinetics and pharmacodynamics of immunosuppressive agents" oral presentation at RI-BRIN annual retreat, Alton Jones Campus, RI.
May 20 2004	Speaker at the workshop "Hot and alternative research funding" Title: How to Get Funding from the Industry, University of Rhode Island, Kingston, RI.
Apr 7 2005	"Pharmacokinetics of immunosuppressive agents in diabetic patients" Presentation to the Transplant Services, RI Hospital, Providence, RI.
Jan 25 2006	"Pharmacokinetics and –dynamics of immunosuppressive agents" Center for the New Stem Cell Biology Visiting Professors Seminar Series, COBRE program, Roger Williams Hospital, Providence, RI.
May 24 2006	Poster Judge at the Joint RI-COBRE symposiums, Providence, RI.

May 31 2007 "Review of transplant pharmacology" invited speaker at "Transplant Pharmacology: Keys to Medication Management in Organ Transplant Recipients"; Pharmacist CE program, Providence, RI.

Sept 11 2007 Research presentation "pharmacokinetic of immunosuppressive agents in diabetic patients" Millennium Pharmaceuticals, Boston, MA.

Oct 2 2007 "Novel monitoring methods for immunosuppressive agents PKPD" Research presentation at College of Pharmacy, University of Kentucky, Lexington, KY.

Oct 24 2007 "Immunosuppressive agents PK/PD and diabetes mellitus" Visiting professor program, Department of Pharmacology and Experimental Therapeutics, Tufts University School of Medicine, Boston, MA.

Jan 2 2008 "Effect of diabetes mellitus on drug metabolism and transporter" Hallett Center for Diabetes and Endocrinology Disorders, Brown University, Providence, RI.

July 25 2008 "Pharmacokinetics and –dynamic modeling of bortezomib in cynomonglous monkeys" Department of Clinical Pharmacology, Millennium Pharmaceuticals, Cambridge, MA.

Sept 3 2008 "Introduction to pharmacokinetic/pharmacogenomics modeling and application: a Velcade® case study" R&D presentation, Millennium Pharmaceuticals, Cambridge, MA.

Oct 5 2008 "Effect of diabetes mellitus on pharmacokinetics and pharmacodynamics of immunosuppressive agents: ciclosporin, tacrolimus and mycophenolic acid" Invited speaker at EHRLICH II, 2nd World Conference on Magic Bullets, Nurnberg, Germany.

May 20 2009 "Application of clinical pharmacology to improve the quality of use of medicines in diabetes and transplantation" invited speaker at Division of Clinical Pharmacology, Johns Hopkins University, Baltimore, MD.

May 2 2010 "Drug monitoring in distinct patient populations; pharmacokinetic differences between transplant recipients of different ethnicities", invited speaker at Sunrise symposium, the American Transplant Congress, May 2010, San Diego, CA.

Sept 7 2010 "Diabetes, reduced CYP3A4 activity and the possible role of statin lactone in statin induced myopathy"; presentation at the department of cardiology, Hartford Hospital, Hartford, CT.

Sept 28 2010 Invited participant in an FDA workshop on "Pharmacodynamic and Pharmacogenomics biomarkers in solid organ transplantation", Food and Drug Administration, White Oak Campus, MD.

Dec 14 2010 "Diabetes altering biotransformation and pharmacodynamics of immunosuppressive agents"; Invited speaker at the Department of Pharmaceutical Sciences, University of Colorado Health Science Center, Anschutz Medical Campus Aurora, CO.

Mar 23 2011	Diabetes and side effects of statins, American Heart Association Friends of Heart Luncheon, Center for Biotechnology and Life Sciences (CBLS) building, University of Rhode Island
Oct 8 2011	Influence of diabetes mellitus on the disposition of immunosuppressive agents and statins, PDM department, Pfizer Center Research, Groton, CT.
Aug 28, 2012	Impact of protein binding on drug disposition and action, College of Pharmacy, University of Technology, Sydney, Australia via Video conferencing.
Oct 22, 2012	Altered disposition of xenobiotics by diabetes mellitus, Division of Clinical Pharmacology, Johns Hopkins Medical Institute, Baltimore, MD.
Aug 8, 2013	Altered disposition of xenobiotics by diabetes mellitus and fatty liver, College of Pharmacy, University of Houston, Tx.
Nov 18, 2013	Effect of diabetes on pharmacokinetics and pharmacodynamics of immunosuppressive agents, Division of Transplantation, Methodist Hospital, Houston, Tx.
Mar 13, 2014	AACP Academic Research Fellows Program; Model of Team Science IV: Collaboration between academia, government, industry supported by NCATS; Rockville, MD.
Aug 7, 2014	Invited Speaker at "Pharmacogenomic Interplay in Biotransformation and Pharmacokinetics"; Pharmacokinetic consequences of metabolic syndrome; University of Rhode Island
Mar 12, 2015	Invited Speaker at the 30th Annual Seminar by the Sea; Northeast Regional Continuing Education Conference for Pharmacists "Statin Interactions: Food, Supplements and Other Drugs"
July 13, 2015	AACP Academic Research Fellows Program; Model of Team Science IV: Collaboration between academia, government, industry supported by NCATS; Potomac, MD.
Oct 20, 2015	Presentation of the result of phase 1b of PF-05190457 study in subjects with alcohol use disorders; NIH Clinical Center, Bethesda, MD.
Nov 5, 2015	Workshop leader on Mechanisms of Drug-Drug Interactions; International Congress of Quality, Safety and Rationale Use of Drugs, University of Mashhad, Mashhad, Iran
Nov 6, 2015	"Clinical Pharmacology and Therapeutic Monitoring of Immunosuppressive Agents" International Congress of Quality, Safety and Rationale Use of Drugs, University of Mashhad, Mashhad, Iran
Feb 2, 2016	Invited speaker in Connecticut Mass Spec Discussion group Title: Pharmacokinetic Consequences of Metabolic Syndrome: Challenges and Opportunities for Proteomic Mass Spectrometry
Dec 6, 2016	Invited speaker, Pfizer Cambridge

Title: Pharmacokinetics Consequences of Type 2 Diabetes (T2DM) and Non Alcoholic Fatty Liver Disease (NAFLD)

Feb 8, 2017 Invited speaker, department of gastroenterology, Beth Israel Deaconess Medical Center

AD HOC REVIEWER FOR SCIENTIFIC JOURNALS

2001-present	British Journal of Clinical Pharmacology
2003-present	Clinical Pharmacokinetics
2003-present	Journal of Chromatography B
2002	Pharmacoeconomics
2004	Transplantation
2006-present	Journal of Pharmacology and Experimental Therapeutics (JPET)
2006-present	Clinica Chemica Acta
2007-present	Clinical Pharmacology and Therapeutics
2009	European Journal of Clinical Pharmacology
2009	Liver Transplantation
2010-present	British Journal of Pharmacology
2010-	Journal of Pharmaceutical and Biomedical Analysis
2011-	European Journal of Medicinal Chemistry
2013-	Lancet
2016-	New England Journal of Medicine
2016-	Current Drug Metabolism
2016-	Pharmacotherapy
2016-	Alcohol and Alcoholism
2016	Medical Science Monitor

JOURNAL EDITORIAL BOARD

2013-present	Clinical Pharmacokinetics
2015-present	Journal of Pharmaceutics and Drug Research
2014-present	Journal of Research in Pharmacy Practice

GRANT REVIEWS

2007	Department of Defense, Chemical and Biological Defense Basic, Research Program
2009	The Czech Science Foundation, Czech Republic (GACR)
2013	National Science Center, Poland
2013-present	Qatar National Research Foundation (QNRF) Reviewing 2-3 grants in each grant cycle
2014 April	NIAID special emphasis panel; ZAI1 PA-I M1, ad hoc reviewer
2014 June	XNDA study section, ad hoc reviewer
2014 August	ZTR1 CI-6 (01) review of NCATS X02 grants
2015 March	ZTR1 CI-6 (02); Study section for review of NCATS UH2/UH3 grants

2015 Oct	CIDO Study section, ad hoc reviewer, Chicago, Illinois
2016 May	ZAI1-BDP-I-M4 study section, mail in reviewer
2016 June	BCHI study section, mail in reviewer
2017 Jan	ZAI1 PA-I (M2) 1 NIAID R34 review study section
2017 June	Nominated to be a standing member of Clinical and Integrative Diabetes and Obesity [CIDO] Study Section

TEACHING RESPONSIBILITIES

BPS403	Pharmacokinetics I (Basic Pharmacokinetics)	2002-2004, Team-taught (50%)
PHC427	4th year Interactive Learning	2002, Sole instructor
BMS540	Drug metabolism (experimental)	2003, Team taught
BPS502	Drug development *Pharmacokinetics in various phases of drug development*	2005-now, Team taught
BPS504	Pharmacokinetics II (Applied Pharmacokinetics)	2001- now, Sole instructor
BPS525	Experimental techniques in biomedical sciences *Use of mass spectrometry in quantitative analysis*	2004-now, Team taught
PHP516	Pharmacy practice laboratory II	2002-now, Team taught
BPS530	Topics in drug metabolism *Pharmacokinetics and drug-drug interaction studies*	2005, 2007, 2011, 2013, 2015, Team taught
PHC597	5th year Interactive Learning (1 section)	2003- 2007, 2015, Sole Instructor
BPS693/ 694	Graduate seminar	2002-2004, 2015-
APS670	Advanced pharmacokinetics	2001, 2003, 2009, 2014, 2016 Sole instructor

Average student evaluation of teaching score: 4.5 out of 5 in didactic courses

SERVICE ACTIVITIES IN THE UNIVERSITY OF RHODE ISLAND

2005	URI sabbatical review committee
2008-2011	URI president appointee at the "Intellectual Property Committee (IPC)"
2009-current	Member of "URI Institutional Review Board (IRB)"
2007-2008	Member of search committee for "Assistant Vice President for Research, Intellectual Property Management and Commercialization"
2009	Member of search committee for "Technology Transfer Specialist"
2010	Member of search committee for biostatistics faculty in the department of Computer Science and Statistics

2014	Member of search committee for biostatistics faculty in the department of Computer Science and Statistics
2015-current	Member of faculty Senate, URI

Service Activities in College of Pharmacy (COP) or Department of Biomedical and Pharmaceutical Sciences (BPS)

2006-current	Member of research and graduate studies committee, COP
2010-2013	Program assessment committee, vice chair, COP
2007-08	Member of ad-hoc promotion and tenure standards committee, BPS
2003, 05, 07	Member of various faculty search committees, BPS
2010	Search committee for two pharmaceutics positions, BPS
2011	Member of search committee for Pharmacogenomics faculty, BPS
2010-2011	Coordinator of INBRE seminar series, college of pharmacy
2012	Member of search committee for BPS departmental chair
2012-	Coordinator of College of Pharmacy College Wide Seminar series
2013-	Chair of liver and metabolic disorders working group, COP
2013-	Chair of faculty development committee, BPS
2013	Chair of promotion and tenure committee, COP
2013	Chair of full professors committee, COP
2013	Member of medicinal chemistry search committee, BPS
2014	Chair of Pharmaceutics faculty search committee, BPS
2015	Member of Pharmacogenomic faculty search committee, BPS
2016	Chair of two faculty searches in pharmaceutics
2017	Chair of search committee for Assistant/Associate Professor on Pharmaceutics

ORGANIZATION OF SCIENTIFIC CONFERENCES

2012	Co-chair of 1st International Conference on Frontiers in Pharmaceutical Sciences: Global Perspectives; September 28-30, 2012
2014	Member of organizing committee for Pharmacogenomic Interplay in Biotransformation and Pharmacokinetics, August 7th & 8th, 2014
2016	Member of organizational committee for Boston Society 2016 Applied Pharmaceutical Analysis conference
Sept 14, 2016	Session chair, Non-P450 Metabolism / Electron Pushing / Unusual Metabolism in 2016 Applied Pharmaceutical Analysis conference

STATEMENT OF RESEARCH

My research program is aimed at improving the quality of use of medications by means of identifying sources of variability in dose-concentration and concentration-effect relationships. Identification of new or improved biomarkers for drug effect is also another aim of this research. This type of research is usually identified as a branch of "Clinical/translational Pharmaceutical Sciences" within pharmacy schools but also is known as "Clinical Pharmacology" in the medical schools. During the drug development process (Phase I-III), Food and Drug Administration of United States (FDA) and other regulatory agencies avidly scrutinize a new agent for its safety and effectiveness; however many aspects of a new drug including side effects or drug-drug interactions are only discovered after the new drug is prescribed to a large number of patients. My research effort is focused on the evaluation of safety and effectiveness of post-marketed drugs (Phase IV)

with an emphasis on the immunomodulators. The three main objectives of my research program include:

Several projects are currently underway aiming to:

I. To characterize the effect of diabetic mellitus on immunosuppressive agents' disposition and concentration-effect relationship in kidney transplant recipients.
II. To study enzyme activity and protein expression for major phase I and phase II drug metabolizing enzymes in diabetic and non-diabetic tissues.
III. To study the disposition of statin lipid lowering agents in type 2 diabetic patients and to identify factors (i.e. CYP3A activity, genetic polymorphism, pro-inflammatory cytokines) in predisposing a diabetic patient to statin related myopathy.
IV. To validate the use of saliva as a non-invasive specimen for therapeutic drug monitoring of immunosuppressive agents.
V. Development of A Novel Compound for Alcoholism Treatment: a Translational Strategy

Other research areas include utilization of iodinated contrast media agents for precise assessment of kidney function and development of better/alternative dosage forms. I have elaborated on each of these areas in the following paragraphs:

(i) To characterize the effect of diabetic mellitus on immunosuppressive agents' disposition and concentration-effect relationship in kidney transplant recipients.

A kidney allograft transplant is the ultimate method of treatment for End Stage Renal Disease (ESRD). To prevent rejection, a transplant recipient will remain dependent on a life-long treatment with several immunosuppressive agents with unpredictable pharmacokinetics and numerous side effects. Approximately 30% of all kidney transplant recipients in the United States are diabetics before transplant and 15-20% develop new onset diabetes post-transplant (NoDAT). Data from UNOS and USDRS suggest that both graft and patient survival are reduced and the risk of serious infections is increased in transplanted diabetics. Although, in the current clinical practice, the immunosuppressive therapy is similar between the two groups, data on higher rate of infection imply that diabetics may be more immunosuppressed than their non-diabetic counterparts. Personalized immunosuppressive therapy, by means of devising appropriate diagnostic methods, may therefore reduce the occurrence of unwanted events thereby improving graft and patient survival. This project is aimed to estimate specific PK/PD parameters of immunosuppressive agents for patients with diabetes type (1 or 2) or with respect to the degree of glucose control. The hypothesis is that the effective concentration of some immunosuppressive agent is different between diabetic and non-diabetic patients as a function of diabetes type or glucose control. The other aim of this project is to evaluate the influence of diabetes type and glucose control on the cytochrome P450 3A (CYP3A) activity and metabolism of immunosuppressive agents.

To date, we have observed that diabetes significantly reduced the concentration of some of the cyclosporine metabolites (Dostalek et al. 2011), while the exposure to tacrolimus metabolites was not affected by diabetes (Chitnis et al. 2012). A clinical PKPD study is underway aiming to elucidate the metabolism of sirolimus in diabetic patients (funded by Pfizer). We have also observed altered concentrations of mycophenolic acid glucuronidated metabolites in diabetic patients (Akhlaghi et al. 2006; Patel et al. 2007), which may indicate an effect of diabetes on phase II metabolism or transporters. Altered concentrations of prednisolone and cortisol were also

observed in diabetic patients (Ionita et al. under review). These observations, have led us to study the expression and activity of drug metabolizing enzymes in diabetic livers and kidneys. Moreover, diabetes is associated with delayed gastric emptying time and altered GI pH. The effect of gastric residence time and GI pH was characterized on the disposition of immunosuppressive agents was characterized using an FDA approved system named SmartPill™ technology. The data analysis of this study that is funded by Novartis is currently ongoing.

(ii) To study enzyme activity and protein expression for major phase I and phase II drug metabolizing enzymes in diabetic and non-diabetic tissues.

Patients with diabetes mellitus require pharmacotherapy with numerous medications. However, the effect of diabetes on drug biotransformation is not well understood in human. This study was designed to investigate the effect of diabetes on liver cytochrome P450 3As, the most abundant phase I drug-metabolizing enzymes that oxidize numerous clinically, physiologically, and toxicologically important compounds. Using liver samples from diabetic and non-diabetic donors genotyped for CYP3A4*1B and CYP3A5*3 polymorphism, we have compared cytochrome P450 3A4, 3A5, and 2E1 mRNA expression, protein level, and enzyme activity between diabetic and non-diabetic subjects. The results showed pronouncedly lower P450 CYP3A4 activity in diabetic livers, whereas P450 3A5 protein level or mRNA expressions were comparable between the two groups. Concurrently, we observed increased P450 2E1 protein level and activity, characterized by higher chlorzoxazone 6-hydroxylation, in diabetic HLMs. The manuscript from this study (Dostalek et al. 2011) was published at the British Journal of Pharmacology. The result of this study also provides mechanistic explanation for reduced metabolite concentration of cyclosporine (a CYP3A4 substrate) but not tacrolimus that is also metabolized by CYP3A5. This study was funded by American Heart Association.

Moreover, MPA biotransformation and UDP-glucuronosyltransferases (UGTs) expression and activity were compared between liver and kidney from diabetic and non-diabetic donors. Glucuronidation of MPA as well as the expression and a probe substrate activity of UGTs primarily responsible for MPA phenol glucuronide (MPAG) formation (UGT1A1, 1A9), and MPA acyl glucuronide (AcMPAG) formation (UGT2B7). We have found both diabetic and non-diabetic human liver microsomes (HLM) and kidney microsomes (HKM) formed MPAG with similar efficiency; however, AcMPAG formation was significantly lower in diabetic samples. Supporting this finding, markedly lower glucuronidation of the UGT2B7 probe 3'-azido-3'-deoxythymidine, UGT2B7 protein and UGT2B7 mRNA was observed in diabetic tissues. UGT genetic polymorphism did not explain this difference since UGT2B7*2 or *1c genotype were not associated with altered microsomal UGT2B7 protein levels or AcMPAG formation. Furthermore, mRNA expression and probe activities for UGT1A1 or UGT1A9, both forming MPAG but not AcMPAG, were comparable between diabetic and non-diabetic tissues suggesting the effect may be specific to UGT2B7 mediated AcMPAG formation. These findings suggest that diabetes mellitus is associated with significantly reduced UGT2B7 mRNA expression, protein level, and enzymatic activity of human liver and kidney, explaining in part the relatively low circulating concentrations of AcMPAG in diabetic patients. This study is published in Drug metabolism and Disposition (Dostalek et al. 2011) and was funded by Novartis.

(iii) To study the disposition of statin lipid lowering agents in type 2 diabetic patients and to identify factors (i.e. CYP3A activity, genetic polymorphism, pro-inflammatory cytokines) in predisposing a diabetic patient to statin related myopathy.

Adverse drug reactions (ADRs) are the 4th major cause of death in the United States, the cost associated with drug-related morbidity, and mortality is estimated to be $136 billion per year. The incidence of ADRs is increased exponentially in patients who routinely take 4 for more medications. Individuals with diabetes mellitus are an example of such patients, although surprisingly, very little is known about the effect of diabetes mellitus on the pharmacokinetics and disposition of commonly used drugs. HMG-CoA reductase inhibitors (statins) are commonly used lipid lowering agents; however, up to 7% of patients treated with statins exhibit symptoms of muscle toxicity and ~0.5 percent develop potentially fatal rhabdomyolysis (severe muscle breakdown). Atorvasatin (ATV, Lipitor®, Pfizer) is the most frequently prescribed statin, yet to date, its pharmacokinetics has never been studied in diabetic patients. Epidemiological evidence suggests that the incidence of ATV induced rhabdomyolysis requiring hospitalization is three times higher in diabetic patients. Administered as an acid, ATV is converted to a lipophilic and more toxic lactone form. We have recently observed plasma concentration of ATV lactone was significantly elevated in diabetic patients, which may explain the higher incidence of ATV related side effects in diabetics. The broad long-term objective of this project is to optimize pharmacotherapy with statins to the individual need of each diabetic patient. The central hypothesis is that down regulation of CPY3A enzymes lead to elevated concentration of ATV-lactone. The rationale for this project is to identify patients' inherent propensity to develop myopathy so those patients can be administered statins (such as rosuvastatin) that are not CYP3A substrate. We have already developed and validated a very simple LC-MS/MS method for determination of ATV acid and five of its metabolites using 50-microL plasma (Macwan 2011, Macwan 2012). We have characterized ATV and metabolite concentration in 52 diabetic and non-diabetic transplant recipients and observed the concentration of ATV lactone to be 5-10 folds higher in diabetic patients. In vitro, diabetic livers were not capable of biotransforming ATV lactone to oxidative metabolites, which is in agreement with the theory of CYP3A4 down regulation in diabetes (Dostalek et al. 2012). This study was funded by a grant in aid from American Heart Association and is currently funded by a R15 grant from NIGMS.

(iv) To validate the use of saliva as a non-invasive specimen for therapeutic drug monitoring of immunosuppressive agents.

Saliva offers a non-invasive method to monitor the concentration of drugs including immunosuppressive agents. The use of immunosuppressive agents including cyclosporine, tacrolimus, sirolimus and mycophenolic acid is essential to prevent organ rejection after transplantation. These agents are also frequently used for the treatment of autoimmune diseases. Because of toxicity, the concentration of immunosuppressive agents in blood must be monitored routinely to allow dosage adjustment. However, the current monitoring method that includes measuring drug concentration before the next dose is proven inadequate in some patients therefore novel and alternative monitoring strategies are needed. To assess the total drug exposure, measuring several drug concentrations after the dose (i.e. before dose and at 1, 2, 3 and 4 hours post dose), followed by the calculation of Area Under the Concentration-Time curve (AUC) is an alternative strategy. The obvious drawback of this method is the need to keep the patient in the clinic for several hours and to perform venipuncture on each occasion.

Moreover, immunosuppressive agents are extensively bound to blood cells and plasma proteins leaving a small concentration free or pharmacologically active drug. An alternative strategy is to measure the free concentration instead of total drug concentration. However, complex methods are required to measure free drug thus prohibiting free concentration monitoring on a routine basis. We propose to develop diagnostic kits that will allow to non-invasively monitor the concentration of immunosuppressive agents in saliva. Saliva allows non-invasive specimen collection conveniently by the patient at home and the salivary concentration often reflects the free concentration. So far, we have developed two LC-MS/MS based assays to measure the salivary concentration of cyclosporine and mycophenolic acid and are currently working to expend this portfolio to measure tacrolimus and sirolimus concentrations. We also need to validate the use of saliva as a non-invasive alternative to blood monitoring of immunosuppressive agents.

This study is currently funded by Rhode Island Economic Development (RI-STAC). In addition, two patent applications have been filed with the USPTO with a European Union Patent that is approved recently.

(v) Development of A Novel Compound for Alcoholism Treatment: a Translational Strategy

Alcohol dependence (AD) afflicts ~10% of the US population and causes serious morbidity and mortality. Ghrelin is a 28-aminoacid peptide that stimulates appetite and food intake. It is an endogenous ligand for the growth hormone secretagogue receptor (GHSR1a). Preclinical studies suggest that ghrelin also modulates alcohol reward processing. Central ghrelin administration to mice significantly increased alcohol intake, and this increase was even more robust when ghrelin was administered bilaterally into specific brain reward nodes, e.g. the ventral tegmental area. Similarly, in alcoholic individuals, higher plasma ghrelin concentrations are associated with higher alcohol craving and consumption. This proposal will allow us to generate preliminary evidence on the safety and efficacy of such pharmacological agent via three projects, i.e.: (P1) a set of experiments testing the effect of this drug in well-validated animal models of alcohol-seeking behavior; (P2) a drug/alcohol interaction study to establish safety in humans (Phase 1b); and (P3) a human laboratory study to assess the efficacy of this drug on alcohol-seeking behavior via a set of well-validated procedures (alcohol cue-reactivity, alcohol self-administration, intravenous alcohol progressive ratio infusion) as well as characterization of the drug effect on reward processing neurocircuitry in the context of alcohol using fMRI (Phase 2a). These projects will be conducted in the NIAAA Intramural Program (PI: Leggio). Furthermore, all three projects will include pharmacokinetics (PK) and pharmacodynamics (PD) investigations conducted at University of Rhode Island (URI; PI: Akhlaghi). The PK/PD component will include (i) measuring total, unbound or tissue concentrations of the drug using liquid chromatography tandem mass spectrometry (LC-MS/MS) and evaluation of biomarkers of effect and (ii) estimation of PK and PD parameters in both animal and human studies by the use of conventional and semi-mechanistic modeling approaches to assist in identifying an optimal dosing regimen of the drug in AD. In summary, this research will investigate the tolerability, efficacy and mechanism of this novel pharmacological approach for AD thus leading to the potential identification of a new treatment for AD. This project that is funded by NCATS provides a unique opportunity for my lab to be involved in a real life drug development project.

Maintaining a Clinical Pharmacokinetics Laboratory

The basic requirement for a research laboratory in clinical pharmacokinetics is the availability of

sensitive, specific and reproducible analytical methods for drug concentration measurement. Currently, such assays require the use of a very expensive and difficult to maintain liquid chromatography mass spectrometry system (LC-MS/MS). The operation of these instruments requires specialized personnel and highly controlled environment (i.e. restricted user access). In addition, every assay either chromatography or immunoassay based, must be validated according to the guidelines set forth by the FDA and preferably published in a peer reviewed journal. The requirement is so fundamental that a clinical study performed using non-validated assays is usually not publishable in a reputable journal. Because of this requirement, much of our effort is devoted to the development and validation of analytical methods using HPLC and LC-MS/MS.

The following assays are now available in my laboratory all of that have been validated according to the FDA "Guidance for Industry: Bioanalytical Method Validation" and were published as manuscript or conference abstract.

CONCENTRATION OF TOTAL DRUG AND METABOLITES

The basic requirement for a research laboratory in clinical pharmacokinetics is the availability of sensitive, specific and reproducible analytical methods for the measurement of total or unbound concentration of drugs and their major metabolites. Every assay, either chromatography or immunoassay based, must be validated according to the guidelines set forth by the FDA and preferably published in a peer reviewed journal. The requirement is so fundamental that a clinical study performed using non-validated assays is usually not publishable in a reputable journal. Because of this requirement, my lab devotes considerable effort to the development and validation of analytical methods using HPLC-UV and LC-MS/MS. The following assays are now available in the laboratory, all of which have been validated according to the FDA "Guidance for Industry: Bioanalytical Method Validation" and were published as manuscript or conference abstract:

- Acetaminophen concentration for determination of gastric emptying time (HPLC-UV)
- Acetaminophen glucuronide and sulfate concentrations (LC-MS/MS)
- Atorvastatin and metabolites [atorvastatin (ATV) lactone, o-hydroxy ATV, o-hydroxy ATV lactone, p-pydroxy ATV, p-hydroxy ATV lactone (LC-MS/MS)
- AZT (3'-azido-3'-deoxythymidine) glucuronidation as a probe for UGT2B7 activity (LC-MS/MS)
- Chlorzoxazone hydroxylation as a probe for P450 2E1 activity (LC-MS/MS)
- Cortisol metabolite (6 β hydroxy cortisol) and free cortisol concentration in urine (HPLC-UV)
- Cyclosporine; total concentration (LC-MS/MS)
- Estradiol-glucuronidation as a probe for UGT1A1 activity (HPLC-UV)
- Iodixanol concentration for determination of GFR (HPLC-UV)
- Iohexol concentration for determination of Glomerular Filtration Rate (GFR) (HPLC-UV)
- Ketoconazole concentration in human plasma (LC-MS/MS)
- Midazolam, 1'-OH and 4-OH midazolam (LC-MS/MS)
- Mifepristone concentration in rabbit plasma
- Mycophenolic acid (MPA) metabolites; concentration of MPAG and Acyl MPAG (HPLC-UV)
- Mycophenolic acid (MPA), total concentration (HPLC-UV)
- Oseltimivir and carboxylate (LC-MS/MS)
- PF-05190457 concentration in human and rat plasma and rat brain

- Pioglitazone and keto pioglitazone metabolite in human plasma (LC-MS/MS)
- Prednisolone, prednisone, cortisol and cortisone concentrations (LC-MS/MS)
- Propofol glucuronidation as a probe for UGT1A9 activity (HPLC-UV)
- Rosuvastatin acid, n-desmethayl rosuvastatin and rosuvastain lactone in plasma (LC-MS/MS)
- Sirolimus; total concentration (LC-MS/MS)
- Tacrolimus; total concentration (LC-MS/MS)
- Testosterone and 6-beta-testostrone (HPLC)
- Thyroid hormones, T3 and T4 (LC-MS/MS and ICP-mass spec.)

Unbound (free) concentration of drugs

- Cyclosporine; unbound concentration (equilibrium dialysis using [^{3}H] cyclosporine as tracer)
- Mycophenolic acid, unbound concentration (ultrafiltration followed by LC-MS/MS)
- Tacrolimus; unbound concentration (equilibrium dialysis using [^{3}H]tacrolimus as tracer)
- Prednisone, prednisolone and cortisol concentrations (ultrafiltration followed by LC-MS/MS)

Concentration of drugs in saliva

- Cyclosporine, saliva concentration (LC-MS/MS)
- Mycophenolic acid, saliva concentration (LC-MS/MS)
- Tacrolimus, saliva concentration (LC-MS/MS)
- Sirolimus, saliva concentration (LC-MS/MS) (under development)

Pharmacodynamic assays for immunosuppressive agents

- Measurement of inosine 5'-monophosphate dehydrogenase type–II (IMPDH-II) activity in peripheral blood mononuclear cells; this method is a pharmacodynamics marker for mycophenolic acid (enzymatic reaction followed by LC-MS/MS)
- mRNA expression using Taqman and SYBR green methods (rtPCR).
- Measurement of intracellular cytokine (IL-2, TNF-α, IFN-gamma) production in mitogen stimulated peripheral blood T-lymphocytes (intracellular immunostaining followed by flow cytometer; this method is one of the Pharmacodynamics assays to access the immunosuppressive activity of calcineurin inhibitors at T-cell level).
- Measurement of phenotypic markers (CD86, CD54 and CD95) expression in mitogen stimulated peripheral blood B-lymphocytes ($CD19^+$ cells); immunostaining followed by flow cytometer.
- ImmuKnow™ test (Cylex Inc): this test detects cell-mediated immunity by measuring the concentration of ATP from CD4+ cells following stimulation. The assay is the only FDA-cleared assay that directly assesses the cell-mediated immune response.

Preclinical studies

To explain many observations originated from clinical PKPD studies, one has to utilize various techniques commonly used in the basic biomedical science or the preclinical stages of drug development. Among these techniques employed in my laboratory are the followings:

- Characterization of metabolic capacity of human liver microsomes in metabolizing CYP or UGT substrates.
- Western blot and rtPCR.
- Pharmacokinetics and drug-drug interaction studies in Sprague Dawley rat.

- Isolation and fractionation of lipoproteins from plasma to access plasma distribution of drugs among lipoprotein fractions.
- Plasma protein studies of new drugs and binding of drugs to different blood cells (i.e. red blood cells and lymphocytes).
- Transwell assay using MDCK cell lines transfected with human MDR1 (*ABCB1*) or MRP2 (*ABCC2*) genes. This assay is employed to characterize the drug-drug interaction at transporter level.
- Caco-2 transwell assay
- HepG2 culture to evaluate the effect of diabetes

CURRENT AND PAST COLLABORATORS

Anders Åsberg Ph.D.; College of Pharmacy, University of Oslo, Norway
Andrew Bostom M.D.; Brown University Medical School, Providence, RI
Anne Keogh MBBS; St. Vincent's Hospital, Sydney, NSW, Australia
Ayman El-Kattan, Ph.D., Pfizer, Cambridge, MA.
Bingfang Yan Ph.D.; BPS department, URI
Gideon Koren M.D.; Rhode Island Hospital, Providence, RI
Jack Wands, M.D., Dept. of Gastroenterology, Brown University
Jean Daley M.D.; Rhode Island Hospital, Providence, RI
John Marshall, Ph.D.; Brown University, Providence, RI
Li Yu Ph.D.; Roche Pharmaceuticals
Lorenzo Leggio M.D., Ph.D.; NIAAA, NIH
M. Liliana Gonzalez Ph.D.; Department of Computer Science and Statistics, URI
Michael Court D.V.M Ph.D.; Washington State University, WA
Paul D. Thompson, M.D., Department of Cardiology, Hartford Hospital
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Rebecca Boyd Ph.D.; Pfizer Pharmaceuticals, Groton, CT
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Sara Rosenbaum Ph.D.; BPS department, URI
Susie Hu M.D.; Brown University Medical School, Providence, RI
Suzanne DeLaMonte M.D., MPH, Liver Research Unit, Brown University
Tim Flanigan, M.D., Brown University, Providence, RI
Uwe Christians M.D.; Ph.D.; Uni. of Colorado, Denver, CO

RESEARCH STUDENTS

Current graduate students

Name	Degree candidate	Title of project
Anitha Sravankumar, M.Sc.	Ph.D.	Generation of an in vitro hepatocyte model for diabetes mellitus and NASH
Armin Sadighi, M.Sc.	Ph.D.	Effect of alcohol and diabetes on gastrointestinal permeability
Benjamin Barlock, B.Sc.	Ph.D.	Drug Development in alcohol use disorder

Enoch Cobbina, M.Sc.	Ph.D.	Pharmacokinetics interaction of PF-05190457 and alcohol
Ghadah Alghaith, Pharm.D.	M.Sc.	
Rohitash Jamwal, M.Sc.	Ph.D.	Pharmacokinetic drug interactions with Cannabinoids
Sravani Adusumali, M.Sc.	Ph.D.	Altered hepatic metabolism of statins

Former graduate students/post docs

Graduate Name	**Degree and year**	**Present employment**
Abdullah AlJutayli	M.Sc. (2016)	Academia in Saudi Arabia
Dr. Mohammad Al Zaabi, MD, Ph.D.	Sabbatical fellow (2015-2016)	Professor, Sultan Qaboos University, Oman
Mwlod Ghareeb	PhD graduate (2015)	University of Cincinnati, Ohio
Dr. Arial Topletz	Post-doctoral fellow supported by grant # 5T32DA013911; PI Flannigan	University of Maryland at Guam
Dr. Amir Mohammad Pour	Sabbatical fellow (2012-2013)	Professor, University of Mashhad, Iran
Dr. Ken Ogasawara	Postdoctoral research associate (2011-2013)	Eli Lilly, Kobe, Japan
Ileana Ionita	Ph.D. graduate (2013)	Pfizer Pharmaceuticals, CT
Joyce Macwan	Ph.D. graduate (2013)	Simulation Plus Inc, CA
Shripad Chitnis	Ph.D. graduate (2012)	Novartis Pharmaceuticals, MA
Dr. Miroslav Dostalek	Postdoctoral research associate (2009-2011)	Genentech, San Francisco, CA
Karen Thudium	PharmD/MSc graduate (2010)	Novartis Pharmaceuticals, NJ
Dimple Pabla*	Ph.D. graduate (2009)	Impax Laboratories, Inc
Rajesh Narwal*	Ph.D. graduate (2008)	MedImmune Pharma
Shripad Chitnis	MSc graduate (2008)	Novartis Pharmaceuticals, MA
Komal Paryani	MSc graduate (2008)	CVS Pharmacy
Anisha Mendonza	Ph.D. graduate(2007)	Novartis Pharmaceuticals, MA
Chirag Patel	Ph.D. graduate (2006)	Takeda/Millennium, MA
Dr. Wei-Johhn Sam*	Postdoctoral research associate (2005-2007)	National Institutes of Health
Dr. Hamim Zahir	Postdoctoral research associate (2003-2004)	Daiichi-Sankoyo, NJ
Rohit Soman	MSc graduate (2005)	Retail Pharmacist
Jenana Maker (Halilovic)	Pharm. D. (2005)	Associate Professor, Uni. of the Pacific
Anisha Mendonza	MSc graduate (2004)	Novartis Pharmaceuticals, MA

Chirag Patel	MSc graduate (2004)	Takeda/Millennium MA
Julie Jones*	Ph.D. graduate (2003)	Jjo, Inc
Ghatem Baheti*	MSc graduate (2003)	Parexel

* Co-advisor with other pharmaceutics faculty

Undergraduate/Pharm.D. Research Students

Ido Preis, BA	Medical student, Brown Uni, 2004
Matthew Harmon	Biology student, Brown Uni, 2005
Karen Thudium	Pharm.D. student, URI, 2006-
James Rebbello	Pharm.D. student, URI, summer 2008
Shayan Gates	BSc student, URI, summer 2009
Elyse Kim	PharmD student, 2012
Alyssa Dantonio	BSPS student 2013
El-Araby, Nermeen	Pharm.D. student, 2013-2014
Meghan Kelly	Pharm.D. Student, Summer 2014
Benjamin Barlock	BSPS student, Summer 2014
Julia Suits	INBRE summer student 2015
Anthony Giuliani	PharmD student, Summer 2015
Julia Scott	BSPS student, Fall 2015
Xin Bush	BSPS student, since summer of 2016
Rachel Ryu	PharmD student, since Fall 2016

Thesis committee advising/membership in the University of Rhode Island
Anasuya Ghosh; MSc student (BMS)
Major Professor: Roberta King; Defense chair, Graduated Fall 2002.

Vishwasenani Balasubramanyam; MSc Student (BMS)
Major Professor: Nasser Zawia; Defense chair, Graduated Spring 2002.

Gutam Jha; MSc Student (BMS)
Major Professor: Roberta King; Defense chair, Graduated Fall 2002.

Julie Jones; PhD student (APS)
Major Professor: Sara Rosenbaum; Graduated Spring of 2003.

Ghatem Baheti; MSc Student (APS),
Major Professor: Dr. Sara Rosenbaum, Graduated Summer of 2003.

Chandra Vemavarapu; PhD student (APS),
Major Professor: Dr. Tom Needham, Graduated Spring 2003

Yuxin Li; PhD student (BMS),
Major Professor: Dr. Bingfang Yan, Graduated Fall 2003

Rina Chokshi; PhD student (APS)

Major Professor: Dr. Hussain Zia, Graduated Spring 2004.

Karuna Sachdeva; PhD Student (BMS),
Major Professor: Dr. Clinton Chichester, Graduated Fall 2004.

Rajesh Narwal; PhD Student (BPS)
Major Professor: Dr. Sara Rosenbaum; graduated July 2008

Sandy Weiner; PhD Student (BPS), Major Professor: Dr. Bingfang Yan.
Member of graduate committee, PhD Comprehensive exam, May 7th, 2004.

Dimple Pabla; Ph.D. student (BPS),
Major Professor: Dr. Hussain Zia; graduated Dec 2009.

Guofeng Ye; Ph.D. student (BPS), Major Professor: Dr. Keykavous Parang
Member of graduate committee.

Carolyn Higgins; MSc candidate,
Department of Chemistry, Major Professor Dr. Jimmie Oxley, graduated April 2008.

Jason Simione; MSc candidate,
Department of Pharmacy Practice, Major Professor Dr. Brian Quillam, graduated April 2008.

Vijay More; MSc candidate, Department of Biomedical and Pharmaceutical Sciences, Major Professor, Dr. Angela Slitt, Defense Date Nov 2009.

Brian Corbett; Ph.D. candidate, Department of Chemistry
Major Professor: Jacoda Major, Defense date Jan 2010.

Jae Joon Song; MSc candidate, Department of Computer Science and Statistics, Major professor: Dr. Gonzalez, July 2010.

Aderemi Dosunmu; Ph.D. student (BPS), Major Professor: Dr. Nasser Zawia.
Member of graduate committee; defended Ph.D. in Aug 2010.

John Yanusas; Ph.D. student (BPS), Major Professor: Dr. Thomas Needham
Member of graduate committee; PhD defense, May 2012

Dale Steele MD; MSc student in biostatistics
Member of graduate committee; MSc defense, Dec 2011

Ruohan Wang; MSc student in biostatistics
Member of graduate committee; MSc defense, Dec 2011

Hong Lu; PhD student in Pharmaceutical Sciences
Member of graduate committee; PhD defense, July 2013

Yu Seon Jung; MSc student in Pharmacy Practice
Member of graduate committee; MSc defense, July 2014

External examiner of Ph.D. thesis:

Aug 2004: external examiner for Ph.D. thesis by Hamim Zahir, University of Sydney, Australia; Major professor: Andrew J. McLachlan

Nov 2008: external examiner for Ph.D. thesis by Hongmei Xu, University of Sydney Australia; Major professor: Andrew J. McLachlan

Oct 2009: external examiner for Ph.D. thesis by Lily Zhang, University of Sydney Australia; Major professor: Andrew J. McLachlan

Feb 2012: external examiner for Ph.D. thesis by Lisa Longato, Brown University; Major professor: Suzanne de la Monte

Aug 2012: external examiner for Ph.D. thesis by Michael Hanley, Pharm.D., Tufts University; Major professor: David Greenblatt

GRANTS AND FUNDING

Ongoing Research Support

National Institutes of Health, NCATS Novel Strategies for Treating Alcoholism: A Translational Approach 1UH2TR000963 [TR12-004] - limited competition for NIH-industry pilot program: discovering new therapeutic uses for existing molecules (UH2/UH3) PI: Akhlaghi, Fatemeh (Contact); Leggio, Lorenzo (NIAAA, NIH)	**2013-2018** $1,665,126 Akhlaghi portion
National Institutes of Health, R15 GM101599 Altered Hepatic Disposition of Statins by Diabetes mellitus Role: PI	**2012-2017** $323,000
National Institutes of Health, SBIR proposal to NIMH NMDA receptor NR2D subtype-selective allosteric modulator for the treatment of impulsivity disorders (1R43MH098467-0) Collaboration with Chinglu Pharmaceutical Research LLC	**2013-2015** $ 76,792 Akhlaghi portion

Completed Research Support

Pfizer Pharmaceuticals Inc. (0468X1-4536) Investigator initiated grant program Pharmacokinetics and -dynamics of sirolimus in diabetic kidney transplant recipients Role: PI	**2009-2013** $190,170

Novartis Pharmaceuticals, IIRP-1027 **2010-2013**
SmartPill technology for exact evaluation of gastrointestinal residence time in diabetic kidney transplants after conversion to EC-MPS $232,042
Role: PI

Rhode Island Science and Technology Council (RI-STAC) **2010-2012**
Novel oral fluid based methods for non-invasive determination of total exposure to active immunosuppressive agents $111,878
Role: PI

Novartis Pharmaceuticals (CERL080-US68) **2008- 2012**
Investigator initiated grant program $198,458
Effect of diabetes mellitus on pharmacodynamics of immunosuppressive agents and characterization of UGT activity in diabetic liver and kidney
Role: PI

American Heart Association (0855761D) **2008-2011**
Grant-in-aid, Founders Affiliate, $60,000/year direct cost for three years $198,000
Individualized statin therapy in type 2 diabetics
Role: PI

Millennium Pharmaceuticals **2008-2009**
Pharmacokinetics and pharmacodynamics modeling of bortezomib $40,000
Role: PI

Investigator initiated grant, Novartis Pharmaceuticals **2005-2008**
Pharmacokinetics and –dynamics of mycophenolate sodium in diabetes $160,500
Role: PI

Investigator initiated grant, Roche Pharmaceuticals **2004-2007**
Monitoring mycophenolic acid in saliva $107,500
Role: PI

Proposal development grant, Uni. of Rhode Island Council for Research **2006**
Biomarkers of immunosuppression in diabetic kidney transplant recipients $10,000
Role: PI

Investigator initiated grant, Roche Laboratories **2003-2005**
Pharmacokinetics of mycophenolic acid in diabetes $139,700
Role: PI

Novartis Pharmaceuticals NJ **2003-2004**
Clinical evaluation of cyclosporine C-2 in lung transplant recipients $35,313
Role: PI

Rhode Island Foundation Medical Research Grant Monitoring of cyclosporine in saliva Role: PI	**2003-2004** $10,000
National Center for Research Resources (NIH) New Investigator's support as part of the RI-BRIN program PI: Zahir Shaikh, 3P20RR016457-02S1 Pharmacokinetics and pharmacodynamics of immunosuppressive agents Role: Junior Investigator	**2002-2004** $100,671
National Center for Research Resources (NIH) Pilot/feasibility study grant to RI-BRIN program Distribution and metabolism of immunosuppressive agents	**2002** $19,982
Bio Products Limited, UK Pharmacokinetics of intravenous immunoglubulins	**2002** $20,000
University of Rhode Island Proposal development fund	**2002** $9,958
Novartis Pharmaceuticals, U.K. Unbound concentration of prednisolone and heart allograft rejection	**2000** £9,723
Roche Educational Grant Pharmacokinetics of Cellcept in heart or lung transplant recipients	**2000-2001** £25,000
Transplant Charitable Fund, Papworth Hospital PKPD of corticosteroids after heart and lung transplantation Evaluating various risk factors for organ rejection following heart transplantation	**1998-2000** £96, 253
Janssen-Cilag Pty. Ltd, Australia Distribution of Tacrolimus in heart transplant recipients: A determinant of immunosuppressant efficacy	**1997-1999** A$151,788

PENDING GRANT APPLICATIONS

National Institutes of Health, NIDDK Role of MRP2 Polymorphism in Tacrolimus Disposition and Adverse Effects; 1 R21 DK095208-01A1 Scored 30 but not funded, to be submitted as an R01 PI: Akhlaghi, Fatemeh
National Institutes of Health Clopidogrel resistance in diabetes and NASH To be submitted as R01

PI: Akhlaghi, Fatemeh

National Institutes of Health, NCCAM
Natural Product Drug Interaction Research and Education Center (NP-DIREC); 1 U54 AT008910
Application for center for excellence in natural products drug interaction
Amount requested: $10.7 Million
Scored, not funded

PATENTS

1. **European Union Patent** 1996067; **Akhlaghi F** and Mendonza AE; Monitoring Cyclosporine in Saliva; patent granted in 2013
2. **United States Patent Application** 20080255765; **Akhlaghi F** and Mendonza AE; Monitoring cyclosporine in saliva - 10-16-2008
3. **United States Patent Application** 20080318322; **Akhlaghi F** and Mendonza AE; Analysis of mycophenolic acid in saliva using liquid chromatography tandem mass spectrometry - 12-25-2008
4. **United States Patent Application** 62311667. **Akhlaghi F** and Ghareeb M. Systems and methods for the measurement of tacrolimus in oral fluids by liquid chromatography tandem mass spectrometry

PEER-REVIEWED PUBLICATIONS

https://www.ncbi.nlm.nih.gov/pubmed/?term=(Akhlaghi+F)+AND+(rhode+OR+sydney+OR+cambridge+OR+transplant)

SUBMITTED OR IN REVISION

1. Ghareeb M, Gohh RY, **Akhlaghi F**. Tacrolimus concentration in oral fluid of kidney transplant recipients: factors influencing the relationship with whole blood. Submitted to *Clinical Pharmacokinetics*
2. Tang, Qi; Cai, Ang; Bian, Ke; Chen, Fangyi; Delaney, James; Adusumalli, Sravani ; Bach, Alvin; **Akhlaghi, Fatemeh**; Cho, Bongsup; Li, Deyu. Quality Control of Oligonucleotide Chemical Synthesis: A Systematic Strategy to Identify Products and Byproducts Generated from Modified Structure Incorporation; Submitted to *the Journal of the American Chemical Society*
3. Jamwal R, Barlock BJ, Adusumalli S, Ogasawara K, Simons BL, **Akhlaghi F**. A multiplex and label-free relative quantification approach for studying protein expression of drug metabolizing enzymes in human liver microsomes using SWATH-MS. Submitted to *Journal of Proteomic Research*

PUBLISHED

4. Jamwal R, Topletz AR, Ramratnam B, Akhlaghi F. Ultra-high performance liquid chromatography tandem mass-spectrometry for simple and simultaneous quantification of cannabinoids. J Chromatogr B Analyt Technol Biomed Life Sci. 2017 Feb 6;1048:10-18. doi: 10.1016/j.jchromb.2017.02.007. [Epub ahead of print] PubMed PMID: 28192758.
5. Lee MR, Scheidweiler KB, Diao XX, **Akhlaghi F**, Cummins A, Huestis MA, Leggio L, Averbeck BB. Oxytocin by intranasal and intravenous routes reaches the cerebrospinal fluid

in rhesus macaques: determination using a novel oxytocin assay, Accepted to *Molecular Psychiatry, Jan 2017*

6. Cobbina E, Akhlaghi F. Non-alcoholic fatty liver disease (NAFLD) - pathogenesis, classification, and effect on drug metabolizing enzymes and transporters. Drug Metab Rev. 2017 Mar 17:1-15. doi: 10.1080/03602532.2017.1293683. [Epub ahead of print]
7. Haass-Koffler CL, Akhlaghi F, Swift RM, Leggio L. Altering ethanol pharmacokinetics to treat alcohol use disorder: Can you teach an old dog new tricks? J Psychopharmacol. 2017 Jan 1:269881116684338. doi: 10.1177/0269881116684338. [Epub ahead of print] PubMed PMID: 28093021.
8. **Akhlaghi F**, Matson KL, Mohammadpour AH, Kelly M, Karimani A. Clinical pharmacokinetics and pharmacodynamics of antihyperglycemic medications in children and adolescents with type 2 diabetes mellitus; Clin Pharmacokinet. 2016 Nov 10. [Epub ahead of print] Review. PubMed PMID: 27832452
9. Ghareeb M and **Akhlaghi F**. Development and validation of a Sensitive and selective LC-MS/MS method for determination of tacrolimus in oral fluids; Accepted for Publication *Journal of Chromatography B*
10. Lin S, Henning AK, **Akhlaghi F**, Reisfield R, Vergara-Silva A, First MR. Interleukin-2 receptor antagonist therapy leads to increased tacrolimus levels after kidney transplantation. *Ther Drug Monit*. 2015 Apr;37(2):206-13. PubMed PMID: 25162212.
11. Ghareeb M, Leggio L, El-Kattan A, **Akhlaghi F**. Development and validation of an UPLC-MS/MS assay for quantitative analysis of the ghrelin receptor inverse agonist PF-5190457 in human or rat plasma and rat brain. *Anal Bioanal Chem*. 2015 Jul;407(19):5603-13. PubMed PMID: 25943263. PMCID: 4499019.
12. Ghareeb M, **Akhlaghi F**. Alternative matrices for therapeutic drug monitoring of immunosuppressive agents using LC-MS/MS. Bioanalysis. 2015;7(8):1037-58. PubMed PMID: 25966013. PMCID: 4480919.
13. Robertsen I, Asberg A, Granseth T, Vethe NT, **Akhlaghi F**, Ghareeb M, et al. More potent lipid-lowering effect by rosuvastatin compared with fluvastatin in everolimus-treated renal transplant recipients. Transplantation. 2014 Jun 27;97(12):1266-71. PubMed PMID: 24521776. PMCID: 4127422.
14. Ionita IA, Ogasawara K, Gohh RY, **Akhlaghi F**. Pharmacokinetics of total and unbound prednisone and prednisolone in stable kidney transplant recipients with diabetes mellitus. Ther Drug Monit. 2014 Aug;36(4):448-55. PubMed PMID: 24452065. PMCID: 4109138.
15. Patel CG, Ogasawara K, **Akhlaghi F**. Mycophenolic acid glucuronide is transported by multidrug resistance-associated protein 2 and this transport is not inhibited by cyclosporine, tacrolimus or sirolimus. Xenobiotica. 2013 Mar;43(3):229-35. PubMed PMID: 22934787. PMCID: 4116557.
16. Ogasawara K, Chitnis SD, Gohh RY, Christians U, **Akhlaghi F**. Multidrug resistance-associated protein 2 (MRP2/ABCC2) haplotypes significantly affect the pharmacokinetics of tacrolimus in kidney transplant recipients. Clin Pharmacokinet. 2013 Sep;52(9):751-62. PubMed PMID: 23633119. PMCID: 3755037.
17. Mohammadpour AH, **Akhlaghi F**. Future of cholesteryl ester transfer protein (CETP) inhibitors: a pharmacological perspective. Clin Pharmacokinet. 2013 Aug;52(8):615-26. PubMed PMID: 23658137. PMCID: 3720705.

18. Dostalek M, Gohh RY, **Akhlaghi F**. Inosine monophosphate dehydrogenase expression and activity are significantly lower in kidney transplant recipients with diabetes mellitus. Ther Drug Monit. 2013 Jun;35(3):374-83. PubMed PMID: 23666569. PMCID: 4109137.
19. Chitnis SD, Ogasawara K, Schniedewind B, Gohh RY, Christians U, **Akhlaghi F**. Concentration of tacrolimus and major metabolites in kidney transplant recipients as a function of diabetes mellitus and cytochrome P450 3A gene polymorphism. Xenobiotica. 2013 Jul;43(7):641-9. PubMed PMID: 23278282. PMCID: 4116556.
20. Tsze DS, Steele DW, Machan JT, **Akhlaghi F**, Linakis JG. Intranasal ketamine for procedural sedation in pediatric laceration repair: a preliminary report. Pediatr Emerg Care. 2012 Aug;28(8):767-70. PubMed PMID: 22858745.
21. Macwan JS, Ionita IA, **Akhlaghi F**. A simple assay for the simultaneous determination of rosuvastatin acid, rosuvastatin-5S-lactone, and N-desmethyl rosuvastatin in human plasma using liquid chromatography-tandem mass spectrometry (LC-MS/MS). Anal Bioanal Chem. 2012 Jan;402(3):1217-27. PubMed PMID: 22108655.
22. Longato L, Ripp K, Setshedi M, Dostalek M, **Akhlaghi F**, Branda M, et al. Insulin resistance, ceramide accumulation, and endoplasmic reticulum stress in human chronic alcohol-related liver disease. Oxid Med Cell Longev. 2012;2012:479348. PubMed PMID: 22577490. PMCID: 3347750.
23. Dostalek M, Sam WJ, Paryani KR, Macwan JS, Gohh RY, **Akhlaghi F**. Diabetes mellitus reduces the clearance of atorvastatin lactone: results of a population pharmacokinetic analysis in renal transplant recipients and in vitro studies using human liver microsomes. Clin Pharmacokinet. 2012 Sep 1;51(9):591-606. PubMed PMID: 22775412.
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PUBLICATION IN PREPARATION (SUCCESSIVELY NUMBERED FROM PREVIOUS SECTION)

The following manuscripts are currently in preparation (undergoing revision) for submission to scientific journals; most of the work is already completed and/or presented at scientific meetings:

1. Shripad D. Chitnis, Miroslav Dostalek, Fatemeh Akhlaghi. Influence of Diabetes Mellitus on the Pharmacokinetics and Pharmacodynamics of the Immunosuppressive Agents used in Organ Transplantation. To be submitted to Clinical Pharmacokinetics.
2. Kim JH, Maker J, El-Araby N, Akhlaghi F. Pharmacokinetic drug interactions with mTOR inhibitors: sirolimus, everolimus and temsirolimus (invited review article) to be submitted to *Clinical Pharmacokinetics.*
3. **Akhlaghi F**, Chitnis SD, Mendonza AE, Ionita IA, Gohh RY. Reduced level of biomarkers of immunosuppressive activity in diabetic kidney transplant recipients is related to diabetes type and glucose control; to be submitted to *Transplantation.*
4. **Akhlaghi F**, Monbaliu J, Kadambi V, Yu L. Blood and plasma pharmacokinetics of bortezomib in relation to blood 20s proteasome activity after single and multiple dosing in cynomongolus monkeys; to be submitted to *Journal of Pharmacology and Experimental Therapeutics.*
5. **Akhlaghi F**, Monbaliu J, Kadambi V, Prakash S, Lee F, Yu L. Development of an integrated pharmacokinetic and pharmacodynamic model for bortezomib to allow predication of 20s proteasome activity from plasma concentrations; to be submitted to *Cancer Chemother Pharmacol.*
6. Chitnis SD, Gohh RY, **Akhlaghi F**. Diabetic renal transplant recipients maintained on sirolimus therapy exhibit lower expression of CD95 pharmacodynamic marker with minimal effect on sirolimus pharmacokinetics; to be submitted to *Transplantation.*

CONFERENCE ABSTRACTS
(IN REVERSE CHRONOLOGICAL ORDER)

1. **Akhlaghi F**, Ogasawara K, Cobbina E, Sravankumar A, Barlock B, Puggioni G, DeLaMonte S. Creation of a Repository of Human Liver to Study the Effect of Diabetes and Non Alcoholic Fatty Liver Disease (NAFLD) on Drug Disposition. Poster presentation at Gordon Research Conference: Drug Metabolism, July 10-15, 2016, Holderness School, NH.
2. Cobbina E, **Akhlaghi F**; Activity of Cytochrome P450 2B6 in Liver from Subjects with Diabetes and Non-Alcoholic Fatty Liver Disease (NAFLD). Poster presentation at Gordon Research Conference: Drug Metabolism, July 10-15, 2016, Holderness School, NH.
3. Jamwal R, **Akhlaghi F**; Impact of Diabetes and Non Alcoholic Fatty Liver Disease (NAFLD) on CYP3A Activity and Clint and Preliminary PBPK Modeling. Poster presentation at Gordon Research Conference: Drug Metabolism, July 10-15, 2016, Holderness School, NH.
4. Macwan JS, Lukacova V, Fraczkiewicz G, Bolger MB, **Akhlaghi F**, Woltosz WS. Physiologically Based Pharmacokinetic Modeling of Rosuvastatin and Prediction of Transporter-Mediated Drug-Drug Interactions Involving Gemfibrozil; Journal of Pharmacokinetics and Pharmacodynamics 2015, Volume 42 Pages S39-S39.
5. Tapocik JD, Pilling A, Pincus A, Frable C, **Akhlaghi F**, Heilig M, Leggio L. A Novel Ghrelin Receptor Antagonist May Serve as a Therapeutic Target for Alcoholism. Poster presentation in American College of Neuropsychopharmacology, Dec 7-11, 2014, Phoenix, Arizona; published in Neuropsychopharmacology (2014) 39, S597.
6. Ogasawara K, Chitnis SD, Gohh RY, Christians U, and **Akhlaghi F**. Haplotypes of Multidrug Resistance-Associated Protein 2 (MRP2) affect the pharmacokinetics of tacrolimus in kidney

transplant recipients; Oral presentation at Up Close and Personalized (UPCP 2013), July 2013, Paris, France.

7. Macwan JS, Bolger MB, **Akhlaghi F.** Physiologically-based pharmacokinetic modeling of atorvastatin acid and major metabolites in stable kidney transplant recipients with diabetes mellitus. Poster Presentation at the American College of Pharmacometrics, May 2013, Orlando, FL.
8. Macwan JS, Sam WJ, Gohh RY, **Akhlaghi F.** Development of a complex combined parent-metabolite population pharmacokinetic model for atorvastatin acid and its lactone metabolite: implication of renal transplantation. Poster Presentation at the American College of Pharmacometrics, May 2013, Orlando, FL.
9. Dostalek M, Gohh RY, **Akhlaghi F.** Inosine monophosphate dehydrogenase (IMPDH) gene and protein expression and activity is markedly lower in kidney transplant recipients with diabetes mellitus. Poster presentation at the American Society for Clinical Pharmacology and Therapeutics, 113th Annual Meeting, Abstract Published in Clinical Pharmacology and Therapeutics, Vol 91, Suppl. 1, S87, March 2012.
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11. **Akhlaghi F**, Chitnis SD, Ionita I, Christians U, Asberg A. Impact of diabetes mellitus on metabolism of immunosuppressive agents: cyclosporin, tacrolimus and prednisone. Poster Presentation at the International Association of Therapeutic Drug Monitoring and Clinical Toxicology (IATDM&CT), Oct 2011, Stuttgart, Germany. Abstract was published in Ther Drug Monit: 2011; 33 (4).
12. **Akhlaghi F**, Dostalek M, Mendonza AE, Chitnis SD, Gohh RY. Reduced levels of biomarkers of immunosuppressive activity in diabetic kidney transplant recipients. Poster/Podium Presentation at the International Association of Therapeutic Drug Monitoring and Clinical Toxicology (IATDM&CT), Oct 2011, Stuttgart, Germany. Abstract was published in Ther Drug Monit: 2011; 33 (4).
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14. Norris DC, Gohh RY, **Akhlaghi F**, Morrissey PE. Kalman Filtering for tacrolimus dose titration in the early hospital course after kidney transplant, poster presentation in the American Transplant Congress, May 1-4, 2011, Philadelphia, PA.
15. Macwan JS, **Akhlaghi F**. Development of a simple method for analysis of atorvastatin (ATV) and metabolites in acid and lactone forms by liquid chromatography-tandem mass spectrometry (LC-MS/MS); Poster presentation at the FIP Pharmaceutical Sciences 2010 World Congress/AAPS Annual Meeting and Exposition, November 14 - 18, 2010, New Orleans, LA.

16. Chitnis SD, **Akhlaghi F**. Development and validation of a simple method for quantitative estimation of sirolimus in human whole blood using liquid chromatography-tandem mass spectrometry (LC-MS/MS); Poster presentation at the FIP Pharmaceutical Sciences 2010 World Congress/AAPS Annual Meeting and Exposition, November 14 - 18, 2010, New Orleans, LA.
17. Chitnis SD, Moll V, Schniedewind B, Christians U, **Akhlaghi F**. Diabetic kidney transplant recipients exhibit elevated levels of tacrolimus metabolites; Poster presentation at the FIP Pharmaceutical Sciences 2010 World Congress/AAPS Annual Meeting and Exposition, November 14 - 18, 2010, New Orleans, LA.
18. Thudium KE, **Akhlaghi F**. Development and validation of an assay for determination of urinary 6 beta hydroxycortisol to cortisol ratio, a noninvasive marker for CYP3A activity; Poster presentation at the FIP Pharmaceutical Sciences 2010 World Congress/AAPS Annual Meeting and Exposition, November 14 - 18, 2010, New Orleans, LA.
19. Ionita IA, Gohh RY, **Akhlaghi F**. Pharmacokinetics of prednisolone and cortisol suppression in diabetic and nondiabetic stable kidney transplant recipients; Poster presentation at the FIP Pharmaceutical Sciences 2010 World Congress/AAPS Annual Meeting and Exposition, November 14 - 18, 2010, New Orleans, LA.
20. **Akhlaghi F**, Gohh RY, Mendonza AE, Flack P, Åsberg A. Reduced cyclosporine Metabolism in Diabetic Stable Kidney Transplant Recipients; Poster presentation at the FIP Pharmaceutical Sciences 2010 World Congress/AAPS Annual Meeting and Exposition, November 14 - 18, 2010, New Orleans, LA.
21. Dostalek M, Yan B, **Akhlaghi F**. Significantly reduced cytochrome P450 3A4 expression and activity in liver from human with diabetes mellitus; Poster presentation at the FIP Pharmaceutical Sciences 2010 World Congress/AAPS Annual Meeting and Exposition, November 14 - 18, 2010, New Orleans, LA.
22. Hu S, **Akhlaghi F**, Chitnis SD, Chiu R, Go S, Rout R, Steffes M, Abbott JD, Dworkin L, Bostom A. Accurate prediction of true glomerular filtration rate (GFR) by both immediate post–angiography iodixanol clearance, and pre–angiography estimated GFR. Poster presentation at the American Society of Nephrology (ASN), 43rd Annual Meeting and Scientific Exposition, November 18–21, 2010, Denver, CO.
23. **Akhlaghi F**, Chitnis SD, Mendonza AE, Ionita IA, Gohh RY. Utilization of B- and T-cell activity markers to evaluate the degree of immunosuppression in diabetic kidney transplant recipients. Invited poster presentation at "Pharmacodynamic and Pharmacogenomic Biomarkers in Solid Organ Transplantation", September 28, 2010; Food and Drug Administration, White Oak Campus.
24. Lin S, Henning AK, **Akhlaghi F**, Reisfield R, Vergara-Silva A, First MR. Interleukin-2 receptor antagonist induction therapy leads to increased tacrolimus levels after kidney transplantation. Presented as Mini Oral Presentation at the XXIII International Congress of The Transplantation Society (TTS 2010) August 15 – 19, 2010, Vancouver, BC, Canada.
25. **Akhlaghi F**, Chitnis SD, Mendonza AE, Ionita IA, Gohh RY. Reduced level of biomarkers of immunosuppressive activity in diabetic kidney transplant recipients is related to diabetes type and glucose control, Poster presentation at American Transplant Congress May 1-5, 2010, San Diego, CA.

26. Pabla D, **Akhlaghi F**, Zia H. Intestinal permeability enhancement of levothyroxine sodium by medium chain fatty acids studied in MDCK epithelial cell line. Poster presentation at the AAPS Annual meeting and exposition, Nov 2009, Los Angles; also abstract published at AAPS Journal (2009).

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31. **Akhlaghi F**, Chitnis SD, Mendonza AE, Patel CG, Gohh RY. Effect of diabetes mellitus on pharmacokinetics and pharmacodynamics of immunosuppressive agents: ciclosporin, tacrolimus and mycophenolic acid; Invited speaker at EHRLICH II, 2nd World Conference on Magic Bullets, October 3-5, 2008, in Nürnberg, Germany.

32. Pabla D, **Akhlaghi F**, Zia H. A comparative pH-dissolution profile study of selected commercial levothyroxine products using inductively coupled plasma mass spectrometry (ICP-MS) assay, Poster presentation at the AAPS Annual meeting and exposition, Nov 2008, Atlanta also abstract published at AAPS Journal, 10(S2), Abstract No. T2063 (2008).

33. Patel CG, **Akhlaghi F**. Evaluation of transporter mediated drug interactions for mycophenolic acid and metabolites using MDCK-II/MRP-2 cells. Poster presentation at the AAPS Annual meeting and exposition, Nov 2007, San Diego.

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35. Pabla D, Zia H, **Akhlaghi F**. Development and validation of an ICP-MS method for quantification of levothyroxine in dissolution studies. Poster presentation at the AAPS Annual meeting and exposition, Nov 2007, San Diego.

36. **Akhlaghi F**, Sam WJ, Rosenbaum SE, A population pharmacokinetic model for mycophenolic acid and metabolites in kidney transplant recipients; Poster presentation in American Transplant Congress, May 5-9 2007, San Francisco.

37. **Akhlaghi F**, Mendonza AE, Caldarusa M, Gohh RY, Diabetic kidney transplant recipients exhibit reduced biomarkers of T- and B-cell activity; Poster presentation in American Transplant Congress, May 5-9 2007, San Francisco.

38. Jones J, Narwal R, **Akhlaghi F**, Rosenbaum S. Population pharmacokinetics of prednisolone in heart and lung transplant patients. Poster presentation at 2006 AAPS Annual Meeting and Exposition, Oct 28-Nov 2, 2006, San Antonio, Texas.

39. Paryani K, **Akhlaghi F**. Development of an LC-MS/MS method for determination of atorvastatin and its acid and lactone metabolites in human plasma, Poster presentation at 2006 AAPS Annual Meeting and Exposition, Oct 28-Nov 2, 2006, San Antonio, Texas.

40. Patel C, Richman K, Gohh R, **Akhlaghi F**. Pharmacokinetics and pharmacodynamics of mycophenolic acid (MPA) in diabetic kidney transplant recipients. Poster presentation at 2006 AAPS Annual Meeting and Exposition, Oct 28-Nov 2, 2006, San Antonio, Texas.

41. Mendonza AE, Richman K, Gohh R, **Akhlaghi F**. Effect of diabetes mellitus on pharmacokinetics and pharmacodynamics of calcineurin inhibitors cyclosporine and tacrolimus. Poster presentation at 2006 AAPS Annual Meeting and Exposition, Oct 28-Nov 2, 2006, San Antonio, Tx.

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