

Yan Li

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Education

College of Pharmacy, University of Florida	Feb 2019
Ph.D. in Pharmaceutical Outcomes and Policy	
Specialty: Pharmacoepidemiology	
Advisor: Almut Winterstein, PhD, FISPE	
School of Pharmaceutical Sciences, Peking University	Jul 2013
M.Sc. in Clinical Pharmacy	
School of Pharmaceutical Sciences, Peking University	Jul 2011
B.Sc. in Pharmacy	

Professional Experience

U.S. Food and Drug Administration, Center for Drug Evaluation and Research

Office of Surveillance and Epidemiology

Senior Staff Fellow, RG-0601 (Epidemiologist)

July 2022 – current

Staff Fellow, RG-0601 (Epidemiologist)

June 2020 – June 2022

- Providing epidemiology expertise and assistance in the scientific review of new drug and biologic applications
- Conducting in-depth review of drug safety or real-world evidence (effectiveness) related epidemiologic study protocols/reports to aid the regulatory decision making and provide comments to applicants.
- Contributing to the development and review of post-marketing safety surveillance plans, post-marketing requirement/commitment plans, and risk evaluation and mitigation strategies.
- Serving as the lead instructor for the FDA internal training courses “Epidemiology in Drug Regulation” and “Essentials in Postmarket Drug Safety.”
- Serving as epidemiology consultant to FDA funded external research projects and public/private partnerships
- Leading studies in the FDA’s Sentinel System to examine disease epidemiology, drug utilization, and drug effectiveness or safety issues to inform the regulatory decision making
- Providing epidemiology expertise to address drug safety related citizen petitions

University of Florida, College of Pharmacy

Adjunct Instructional Assistant Professor

July 2022 – current

- Instructor for the 3-credit graduate level course [PHA6891 Introduction to Pharmacoepidemiology](#)
Offering semester: Fall
Annual enrollment: 20-25 students

U.S. Food and Drug Administration, Center for Drug Evaluation and Research

Office of New Drugs

Apr 2019 – May 2020

ORISE Fellow

- Led a multidisciplinary team on an initiative to explore the potential of using real-world data/evidence to support regulatory decisions about product effectiveness in patients with COPD and asthma.
- Won the best poster award at 2019 Office of New Drug ORISE Research Day (3 winners out of 50+ participants).

University of Florida, College of Pharmacy

Aug 2013 -May 2019

Research Assistant

- Designed and conducted multiple observational studies on diverse research topics: drug utilization and

safety study, comparative effectiveness study, predictive modelling, and database validation.

- Gained extensive experience with different types of large healthcare databases: administrative claims data, electronic health records, and surveys.
- Had research experience with multiple therapeutic areas/topics: psychiatry, pain medicine, cardiology, drug-drug interaction, and medication adherence.
- Research projects:
 1. Epidemiology and safety of skeletal muscle relaxant and concomitant opioid or psychotropic medication use.
 2. Internal validation of Medicaid Analytic eXtract data capture for comprehensive managed care plan enrollees.
 3. ADD/ADHD treatment patterns in adult Medicaid beneficiaries.
 4. Development and validation of a complexity score to identify hospitalized patients at high risk for preventable adverse drug events.

Amgen Inc.

Jun 2018 – Sep 2018

Global Health Economics

Graduate Intern

- Assessed the real-world treatment pattern and resource utilization for one oncology product using the IQVIA Hospital Discharge Database.
- Analyzed patient-reported outcome data in clinical trials to support market access strategies for one oncology product.
- Conducted the analysis of (and co-authored) four conference abstracts, one was selected as an oral presentation in 2019 Transplantation and Cellular Therapy Meetings of ASBMT and CIBMTR
- Interacted with vendors regarding ongoing and upcoming projects
- Participated and contributed in cross-functional team meetings.

University of Florida, Center for Quality Medication Management

Sep 2016 – May 2018

Research Fellow

- Provided support to center's various data analytic needs to improve the efficiency of operation.
- Developed an automated algorithm to identify poorly performing beneficiaries as targets for telephonic medication adherence enhancement service.

University of Florida, College of Pharmacy

Aug 2013 - Aug 2016, Jun – Oct 2018

Teaching Assistant & Instructor

- Responsibilities: give lectures, develop tutoring materials, write and grade exam questions, host Q&A sessions, record keeping
- Course experience: Principles of Pharmacoeconomics; Evidence Based Practice & Evidence Based Pharmacy; Introduction to Pharmacy, Pharmaceuticals & the Health Care System; Pharmaceutical Microeconomics

Peking University Third Hospital

Mar 2011- Jun 2013

Intern Clinical Pharmacist

- Responsibilities: outpatient and inpatient pharmacy dispensing, patient education and counseling, ward round (mainly in the division of cardiology), adverse drug reaction reporting.
- Research projects: 1. Evaluate the role of genetic test in clopidogrel antiplatelet therapy; 2. Evaluate the development of hospital pharmacy in China.

Publications

Peer-reviewed articles

1. **Li Y**, Delcher C, Reisfield GM, Wei YJ, Brown J, Winterstein AG. Utilization patterns of skeletal muscle relaxants among commercially insured adults in the United States from 2006 to 2018. Pain Medicine. 2021; 22(10): 2153–2161.

2. Dong SJ, Qi HH, Li Y, Men P, Alifu M, Zhang YT, Li YJ, Zhao RS. A systematic review and meta-analysis of anticoagulation therapy for portal vein thrombosis in patients with cirrhosis: to treat or not to treat? *Hepatology International*. 2021;15:1356–1375.
3. Dong SJ, Zhang YT, Li Y, Li YJ, Miao YQ, Zhao RS, Zhai SD. Direct oral anticoagulant for the treatment of VTE in cancer patients: a systematic review and meta-analysis. *Annals of Pharmacotherapy*. 2021; 55(4): 430-439.
4. Winterstein AG, Li Y, Gerhard T, Linden S, Shuster J. Medication use for attention-deficit/ hyperactivity disorder and the risk of driving citations and crashes among teenage drivers: a population- based cohort study. *Journal of Attention Disorder*. 2021; 25(11): 1511-1518.
5. Li Y, Delcher C, Wei YJ, Brown J, Reisfield GM, Tighe P, Winterstein AG. Risk of opioid overdose associated with concomitant use of opioids and muscle relaxants: a retrospective cohort study. *Clinical Pharmacology and Therapeutics*. 2020; 108(1): 81-89.
 - Commentary by Staffa JA. Keeping the Pharmacology in Pharmacoepidemiology. *Clinical Pharmacology and Therapeutics*, 2021, 109(6):1393-1394.
 - Spotlighted by the University of Pennsylvania Real-World Evidence on Drug Interactions Newsletter, July edition, 2020.
6. Choi Y, Park H, Hampf C, Brumback B, Meissner C, Li Y, Roussos-Ross D, Zhu Y, Henriksen C, Winterstein AG. Usability of encounter data for Medicaid comprehensive managed care vs traditional Medicaid fee-for-service claims among pregnant women. *Pharmacoepidemiology and Drug Safety*. 2020; 29(1): 30-38.
7. Li Y, Delcher C, Brown J, Wei Y, Reisfield GM, Winterstein AG. Impact of Schedule IV controlled substance classification on the use of carisoprodol in the United States: an interrupted time series analysis. *Drug and Alcohol Dependence*. 2019; 202: 172-177.
8. Wang Y, Delcher C, Li Y, Goldberger BA, Reisfield GM. Overlapping prescriptions of opioids, benzodiazepines, and carisoprodol: "Holy Trinity" prescribing in the state of Florida. *Drug and Alcohol Dependence*. 2019; 205: 107693.
9. Li Y, Staley B, Henriksen C, Xu D, Lipori G, Winterstein AG. Development and validation of a dynamic inpatient risk prediction model for clinically significant hypokalemia using electronic health records data. *American Journal of Health-System Pharmacy*. 2019; 76(5): 301-311.
10. Li Y, Zhu Y, Chen C, Wang X, Choi Y, Henriksen C, Winterstein AG. Internal validation of Medicaid Analytic eXtract data capture for comprehensive managed care plan enrollees from 2007 to 2010. *Pharmacoepidemiology and Drug Safety*. 2018; 27(10): 1067-1076.
11. Wang X, Winterstein AG, Li Y, Zhu Y, Antonelli PG. Inappropriate use of systemic antibiotics for acute otitis externa: impact of a clinical practice guideline. *Otology and Neurotology*. 2018; 39(9): 1088-1094.
12. Zhu Y, Liu W, Li Y, Wang X, Winterstein AG. Prevalence of ADHD in publicly insured adults. *Journal of Attention Disorders*. 2018; 22(2): 182-190.
13. Winterstein AG, Staley B, Henriksen C, Xu D, Lipori G, Jeon N, Choi Y, Li Y, Hincapie-Castillo J, Soria-Saucedo R, Brumback B, Johns T. Development and validation of a Complexity-Score to rank hospitalized patients at risk for preventable adverse drug events. *American Journal of Health-System Pharmacy*. 2017; 74(23): 1970-1984. **(2018 ASHP Foundation Pharmacy Practice Research Award)**
14. Li Y, Liu W, Zhu Y, Liu X, Winterstein AG. Determinants of pharmacological treatment initiation and persistence in publicly insured adults with attention-deficit/hyperactivity disorder. *Journal of Clinical Psychopharmacology*. 2017; 37(5): 546-554.
15. Dong SJ, Li Y, Zhai SD. Role of pharmacists in the management of cardiovascular diseases. *Chinese Journal of Cardiology*, 2016; 44(11): 998-1000.
16. Dong SJ, Zhang T, Li Y, Zhai SD. Pharmaceutical care of serious bleeding induced by tramadol-warfarin interaction: a case report. *Journal of Peking University, Health sciences*. 2014; 46(5): 809-813.
17. Penm J, Li Y (co-first author), Zhai S, Hu Y, Chaar B, Moles R. The impact of clinical pharmacy services in China on the quality use of medicines: a systematic review in context of China's current healthcare reform.

Health Policy and Planning. 2014; 29(7): 849-872.

18. Penm J, Wang H, **Li Y**, Chaa B, Moles R. Factors affecting the implementation of clinical pharmacy services in China. Qualitative Health Research. 2014; 24(3): 345-356.
19. Dong SJ, **Li Y**, Zhai SD. Discussion on the methods to improve medication adherence among low health literacy patients. Pharmaceutical Care and Research. 2014; 14(2): 93,128,141.
20. Tang HL, **Li Y**, Hu YF, Xie HG, Zhai SD. Effects of CYP2C19 loss-of-function variants on the eradication of H. pylori infection in patients treated with proton pump inhibitor-based triple therapy regimens: A meta-analysis of randomized clinical trials. PLoS ONE. 2013; 8: e62162.
21. **Li Y**, Tang HL, Hu YF, Xie HG. The gain-of-function variant allele CYP2C19*17: a double-edged sword between thrombosis and bleeding in clopidogrel-treated patients. Journal of Thrombosis and Haemostasis. 2012; 10(2): 199-206.
22. **Li Y**, Hu YF, Zhou HH. The role of genetic test in clopidogrel antiplatelet therapy. Chinese Journal of Clinical Pharmacology. 2012; 28(9): 694-697.

Manuscripts under review

None

Books and reports

1. Winterstein AG, Zhu Y, **Li Y**, Liu W. ADD/ADHD Treatment Patterns in Adult Medicaid Beneficiaries, 2017. Report to Florida Agency of Health Care Administration (56 pages).
2. Delcher C, Moga D, **Li Y**, Munoz M, Sohn M, Bae J. Chapter 53. Pharmacoepidemiology and Pharmacovigilance. In: Adejare A, ed. Remington - The Science and Practice of Pharmacy, 23rd edition. Cambridge: Academic Press; 2021: 899-913.

Letters

1. **Li Y**, Dong S, Soria-Saucedo R. Drug interactions with non-vitamin K oral anticoagulants. JAMA. 2018; 319(8): 827-828.

Technical Capabilities

Experience with healthcare database:

Sentinel Distributed Database

Medicaid Analytic eXtract (MAX)

The Transformed Medicaid Statistical Information System (T-MSIS) Analytic Files (TAF)

IBM MarketScan Research Database

IQVIA Hospital Discharge Database

US hospital administrative and clinical databases (Electronic Health Records of UF Health)

Pharmacy claim database of a Florida based Medicare advantage plan

Nationwide Inpatient Sample (NIS)

Statistical software: SAS, R

Language: English, Chinese

Professional affiliations

International Society for Pharmacoepidemiology

Member (2014 -)

Chair, Education Committee (2022-2024)