BIOGRAPHICAL SKETCH

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NAME: Setoguchi-Iwata, Soko

eRA COMMONS USER NAME (credential, e.g., agency login): SOKOSET

POSITION TITLE: Professor of Medicine, Department of Medicine, Rutgers Robert Wood Johnson Medical School; Professor of Epidemiology, Department of Epidemiology, Rutgers University School of Public Health

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Miyazaki Medical College, Miyazaki, Japan	M.D.	1994	Medicine
Kameda Medical Center, Chiba, Japan	Residency	1996	General Medicine
Kyushu University Hospital, Fukuoka, Japan	Fellowship	1999	Cardiology
Harvard School of Public Health, Cambridge, MA	M.P.H.	2002	Health Care Management
Harvard School of Public Health, Cambridge, MA	Sc.M.	2003	Health Policy
Harvard School of Public Health, Cambridge, MA	Dr.P.H.	2005	Epidemiology
University of North Carolina, Chapel Hill, NC	Residency	2016	Internal Medicine
Robert Wood Johnson University Hospital, New Brunswick, NJ	Residency	2017	Internal Medicine

A. Personal Statement

As a practicing internist with doctoral training in epidemiology and biostatistics, I am committed to contributing my expertise to produce solid clinical science evidence supporting clinical and policy decisions and to raise next generation clinical scientists. My research builds and uses large data to perform pharmacoepidemiologic research, health services and outcomes research as well as comparative effectiveness research for medications and implantable medical devices in patients with chronic disease. I have worked extensively on such studies in populations with a range of chronic conditions, including cancer, cardiovascular disease, and . Using my clinical background and advanced training in epidemiology and statistical methods, I have established a strong track record in health services/outcome research, pharmacoepidemiology, and comparative effectiveness research (CER) utilizing large databases including claims data, linked registry data, and linked Medicare–electronic health records (EHR), producing over 150 publications. I have also conducted applied statistical methods studies by developing and evaluating design-based methods, analytic methods in pharmacoepidemiology, and CER to combat bias in observational studies. I have also led outcomes validation studies that are relevant to the sophisticated design and statistical analysis considerations that need to be taken into account when using large databases to investigate questions as in this proposal.

Selected Ongoing Research Support
NIH/NIA 1R01AG060232-01A1   **Setoguchi-Iwata (PI)**   06/2019-03/2024
Disease Outcomes in Older adults under extreme Heat, Air pollution and Medication use (DO-NO-HARM)
NIH/NIMHD P50MD017356   **Setoguchi-Iwata (PI)**   09/2021-06/2026
Rutgers-NYU Center for Asian Health Promotion and Equity
Cystic Fibrosis Foundation   **Setoguchi-Iwata (PI)**   06/2020-05/2023
An Integrated Clinical Research Database for CF Children and Families
NIH/NCATS UL1TR003017   **Panettieri (PI)**   03/2019-02/2024
New Jersey Alliance for Clinical and Translational Science: NJ ACTS
Role: Director, Degree Programs, TL1

Selected Completed Research Support
NIH/NIA Asian Research Center for Minority Aging Research   Setoguchi-Iwata(PI)   2019-2021
Health Outcomes in Asian Older Adults under Extreme Heat and Medication Use.

NIH/NIA 1R21AG044294-01A1   **Setoguchi-Iwata (PI)**   2013-2015
Climate Change and Health: Heat Wave and Drug Adverse Events in the Elderly
PCORI Method RFA   **Setoguchi-Iwata (lead MPI)**   2014-2016
Developing Methods for Linking Large Databases and Registries
AHRQ KO2-HS017731   **Setoguchi-Iwata (PI**   2008-2013
Improving Methods for Comparative Effectiveness Research in Cardiovascular Care
AHRQ   HHSA290-2005-0016-I   **Setoguchi-Iwata (PI)**   2009- 2012
Real World Effectiveness of Implantable Cardioverter Defibrillators and Carotid Stenting in Medicare Patients
NIH/NICHD 1R21-HD055479-01   **Setoguchi-Iwata (PI)**   2007-2010
Utility of a New Database to Study Drug Safety during Pregnancy

B. Positions and Honors

Positions and Employment

2020-	Professor of Medicine and Epidemiology, Rutgers Robert Wood Johnson Medical School, Rutgers School of Public Health & Institute for Health, Health Care Policy and Aging Research
2017-2020	Associate Professor of Medicine, Department of Medicine, Rutgers Robert Wood Johnson Medical School; Associate Professor of Epidemiology, Department of Epidemiology, Rutgers School of Public Health; and Institute for Health, Health Care Policy and Aging Research, Rutgers University
2016-2020	Adjunct Associate Professor of Epidemiology, Department of Epidemiology, Rutgers School of Public Health & Institute for Health, Health Care Policy and Aging Research, Rutgers University
2014-2016	Adjunct Associate Professor of Medicine, Department of Medicine, Duke Clinical Research Institute & Duke University School of Medicine
2010-2014	Adjunct Associate Professor of Pharmacoepidemiology, University of Tokyo Graduate School of Medicine, Japan
2010-2014	Associate Professor of Medicine, Department of Medicine, Duke Clinical Research Institute & Duke University School of Medicine
2009-2010	Assistant Professor of Epidemiology, Department of Epidemiology, Harvard School of Public Health
2009-2010	Assistant Professor of Medicine, Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital & Harvard Medical School
2005-2009	Instructor in Medicine, Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital & Harvard Medical School

Other Experience and Professional Memberships

2023	NIH Clinical Informatics and Digital Health (CIDH) Study Section, Reviewer
2022	NIH Health Services Quality and Effectiveness (HSQE) Study Section, Reviewer
2021-current	PCORI Peer Review, Associate Editor
2020	NIEHS Special Emphasis Panel/Scientific Review Group 2020/05 ZES1 LAT-K (K9), Reviewer
2018	NIH NCATS Special Emphasis Panel/Scientific Review Group UG3/UH3, Reviewer
2017-2021	FDA Drug Safety and Risk Management Advisory Committee (DSaRM), Member
2017	AHRQ Special Emphasis Panel/Scientific Review Group 2018/01 ZHS1 HSR-X (01), Reviewer
2016	AHRQ Special Emphasis Panel/Scientific Review Group 2017/05 ZHS1 HSR-X (01), Reviewer
2015-2016	PCORI CTAP Post-Award Expert Advisory Subcommittee, Member
2015	PCORI CDRN Phase II, Reviewer
2014	PCORI Methodology Consultation Review Panel for Pragmatic Trial Proposals, Review Panel Member
2014	AHRQ R21(HS14-07 Deliberative approaches), Reviewer
2013	The Swiss National Science Foundation, Reviewer
2012	PCORI RFA Phase I (Cycle II), Reviewer
2011	Member, Advisory Committee for FDA Medical Device Epidemiology Network
2003-	Member, International Society of Pharmacoepidemiology

2020	Mentoring Award, Department of Medicine, Robert Wood Johnson Medical School
2011	Fellow of the International Society of Pharmacoepidemiology (FISPE)
2008	Highlights of the Year Journal of American College of Cardiology
2006	1st place poster at International Conference for Pharmacoepidemiology in Lisbon, Portugal, 'The Risk of Statins on Breast, Colorectal and Lung Cancer'
2003	Pharmacoepidemiology Training and Research Scholarship, Harvard School of Public Health, Department of Epidemiology
2000	Exchange Fellowship in Epidemiology, St. Luke's Life Science Institute, Japan
1994	MD with Distinction (top 5%)
1989	Training Scholarship, Japan Scholarship Foundation

C.   Contribution to Science

1. **Cancer pharmacoepidemiology**: Cancer is one of the major unintended consequences of treatments, including medications, biologics, radiation therapies. Identifying and quantifying cancer risks as adverse events can be rarely done in premarket randomized trials but require a larger patient population with longer term follow-up in postmarket settings. I have conducted multiple cancer pharmacoepidemiologic studies assessing the utilization and safety of medications and biologics related to cancer outcomes. To advance this line of research in pharmacoepidemiology (cancer pharmacoepidemiology), I have developed large database algorithms to identify cancers, which have been used in many other cancer pharmacoepidemiology studies. I have also linked state cancer registries to state Medicare data to assess the debated association between statin use and cancer after many studies showed protective effect of statins on cancer including a naïve case control study published in New England Journal of Medicine causing debates. My study showed null effect of statins on cancer using the linked Medicare and cancer registry data in NJ and PA and many subsequent carefully conducted studies reached the same conclusion.

   a. **Setoguchi S**, Glynn RJ, Avorn J, Mogun H, Schneeweiss S; Statins and the Risk of Lung, Breast, and Colorectal Cancer in the Elderly; Circulation, 115(1): 27-33, 2007. PMID:17179016.
   b. **Setoguchi S**, Solomon DH, Avorn J, Weinblatt ME, Katz JN, Glynn RJ, Cook EF, Schneeweiss S; Tumor necrosis factor alpha antagonist use and cancer in patients with rheumatoid arthritis; Arthritis Rheum, 54(9): 2757-64, 2006. PMID: 16947774.
   c. **Setoguchi S**, Solomon DH, Glynn RJ, Cook EF, Levin R, Schneeweiss S; Agreement of Diagnosis and its Date for Hematologic Malignances and Solid Tumors between Medicare Claims and Cancer Registry Data; Cancer Causes Control, 18(5): 561-9, 2007. PMID: 17447148.
   d. Cheung WY, Lai EC, Ruan JY, Chang JT, **Setoguchi S**; Comparative adherence to oral hormonal agents in older women with breast cancer; Breast Cancer Res Treat., 152(2): 419-27, 2015. PMID: 26070268.

2. **End of life care in cancer and heart failure:** I have contributed to understanding the quality of end-of-life care in cancer and heart failure patients using large databases. The goal of care is not always prolonging a life but sometimes is ensuring good quality of life at the end-of-life. We compared prospective and retrospective indicators for the quality of end-of-life cancer care in large databases and also applied the method in understanding the quality of care in heart failure patients whose prognosis is as poor as that in patients with metastatic colorectal cancer.

   a. **Setoguchi S**, Earle CC, Glynn RJ, Stedman M, Polinski JM, Corcoran CP Haas JS; Comparison of Prospective and Retrospective Indicators of the Quality of End-of-Life Cancer Care; Journal of Clinical Oncology, 26(35): 5671-8, 2008. PMID: 19001333; PMCID: PMC2650390.
   b. **Setoguchi S**, Glynn RJ, Steadman M, Flavell CM, Levin R, Stevenson LW; 'Hospice, Opiates, and Acute Care Utilization Among the Elderly Prior to Death From Heart Failure or Cancer'; Am Heart J., 160(1): 139-44, 2010.
   c. Cheung W, Stevenson LW, Stewart G, **Setoguchi S**; Enrollment and Events of Hospice Patients with Heart Failure versus Cancer; Journal of Pain and Symptom Management, 45(3): 552-560. 2013. PMID: 22940560.

d. Unro KT, Greiner MA, Johnson KS, Curtis LH, **Setoguchi S**; Racial Differences in Hospice Use and Patterns of Care After Enrollment in Hospice Among Medicare Beneficiaries With Heart Failure; Am Heart J, 163(6): 987-993, 2012. PMID: 22709751.

3. **CER for Cardiovascular Patients and Outcomes**: I have contributed to comparative effectiveness research (CER) by producing solid evidence for comparative/clinical safety and effectiveness of medications and devices in real-world patients with cardiovascular disease or assessing cardiovascular outcomes; this has been accomplished through leveraging existing large databases through record linkage, supplementing studies by conducting validation studies, and using tested methods to control bias in observational studies. My studies are primarily conducted in vulnerable populations, mostly in older adults with chronic conditions but also in low-income pregnant women. The results have been published in the following journals: American Journal of Epidemiology, British Medical Journal, Archives of Internal Medicine, New England Journal of Medicine, Canadian Medical Association Journal, American Heart Journal, Journal of American College of Cardiology, and Circulation.

   a. Huybrechts, KF, Palmsten K, Avorn J, Cohen, LS, Holmes LB, Franklin JM, Mogun, H, Levin R, Kowal M, **Setoguchi S**, Hernandez-Diaz S; Antidepressant Use in Pregnancy and the Risk of Cardiac Defects; N Eng J Med, 370(25): 2397-407, 2014. PMID: 24941178; PMCID: PMC4062924.

   b. Chen CY, Stevenson LW, Stewart GC, Bhatt DL, Epstein AE, Desai M, Williams L, **Setoguchi S**. Real-World Effectiveness of Primary ICDs Implanted during Hospitalizations for Heart Failure Exacerbation or Other Acute Comorbidities: a Cohort Study of Older Patients with Heart Failure. BMJ. 2015 Jul 14;351:h3529.

   c. Jalbert JJ, Gerhard-Herman MD, Nguyen LL, Jaff MR, Kumamaru H, Williams LA, Chen CY, Liu J, Seeger JD, Rothman AT, Schneider P, Brott TG, Tsai TT, Aronow HD, Johnston JA, **Setoguchi S**; Comparative Effectiveness of Carotid Artery Stenting versus Carotid Endarterectomy Among Medicare Beneficiaries; Circ Cardiovasc Qual Outcomes, 9(3): 275-85, 2016. PMID: 27116974.

4. **Health services and outcomes research for cardiovascular disease and outcomes**: I have contributed to studies using large databases to understand the utilization of health services and medications as well as outcomes in patients with cardiovascular diseases, especially those with coronary artery disease, heart failure, and cerebrovascular diseases. My work has been published in major cardiology and general medicine journals.

   a. **Setoguchi S**, Glynn RJ, Avorn J, Mittleman MA, Levin R, Winkelmayer WC; Improvements in Long-term Mortality after Myocardial Infarction and Increased Use of Cardiovascular Drugs after Discharge: A 10-Year Trend Analysis; Journal of American College of Cardiology, 51(13): 1247-54, 2008. PMID: 18371553.

   b. **Setoguchi S**, Stevenson LW, Schneeweiss S; Repeated Hospitalizations Predict Mortality in the Community Population with Heart Failure; Am Heart J, 154(2): 260-6, 2007. PMID: 17643574.

   c. Kumamaru H, Jalbert JJ, Nguyen LL, Gerhard-Herman MD, Williams LA, Chen CY, Seeger JD, Liu J, Franklin JM, **Setoguchi S**. Surgeon Case Volume and 30-day Mortality after Carotid Endarterectomy among Contemporary Medicare Beneficiaries: Before and After National Coverage Decision for Carotid Artery Stenting. Stroke. 2015 May;46(5):1288-94. PMID: 25791713

   d. Chen CY, Stevenson LW, Stewart GC, Seeger JD, Williams L, Jalbert JJ, **Setoguchi S**. Impact of baseline heart failure burden on post-implantable cardioverter-defibrillator mortality among medicare beneficiaries. J Am Coll Cardiol. 2013 May 28;61(21):2142-50. PMID: 23541973; PMCID: PMC5587185.

5. **Applied Method in CER and Epidemiology**: Multiple challenges exist in conducting comparative effectiveness studies (CER) using observational data. I use, promote, and develop/test design-based methods as well as advanced statistical methods to conduct valid observational studies. I have contributed to the field of CER and pharmacoepidemiology by conducting applied methods studies to improve drug safety/CER methods. I assessed the impact of various biases such as confounding bias, collider stratification bias, healthy user bias, and immortal person time bias. Finally, I tested new/existing methods to assess or control such bias in observational studies.

a. **Setoguchi S**, Schneeweiss S, Brookhart MA, Glynn RJ, Cook EF. Evaluating Uses of Data Mining Techniques in Propensity Score Estimation: A Simulation Study. Pharmacoepidemiology and Drug Safety. 2008; 17(6):546-55. PMID: 18311848; PMCID: PMC2905676.
b. Liu W, Brookhart MA, Schneeweiss S, Mi X, **Setoguchi S**. Implication of Collider Stratification Bias in Epidemiologic Studies: A Simulation Study. Am J Epidemiol; 2012 Nov 15;176(10):938-48.
c. **Setoguchi S**, Stevenson LW, Stewart GC, Bhatt DL, Epstein AE, Desai M, Williams L, Chen CY. Healthy candidate bias limits assessment of clinical effectiveness for implantable cardioverter-defibrillators: a cohort study of older patients with heart failure. BMJ. 2014 May 8;348: g2866. PMID: 24812112; PMCID: PMC4014056.
d. Mi X, Hammill BG, Curtis LH, Lai CC, **Setoguchi S**. Use of the Landmark Method to Address Immortal Person-Time Bias in Comparative Effectiveness Research: A Simulation Study. Statistics in Medicine, 2017. PMID: 27350312.

Complete List of Published Work in My Bibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/soko.setoguchi-iwata.1/bibliography/41161437/public/?sort=date&direction=ascending