Kaiser Permanente
Research

Kaiser Permanente Southern California

The Center for Vaccine Safety and Effectiveness Research

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Contents

About the Center for Vaccine Safety and Effectiveness Research

The Kaiser Permanente Southern California Center for Vaccine Safety and Effectiveness Research engages in innovative research with real-world implications.

Investigators leverage the rich resources of Kaiser Permanente's integrated health system to conduct a wide range of studies, from the incidence and outcomes of vaccine-preventable disease to the safety and effectiveness of widely used vaccines.

Through partnerships with clinicians, academics, federal funders, and industry sponsors, researchers ask and answer health questions that benefit the organization's members and the public at large.

The Kaiser Permanente Southern California Difference

The Center for Vaccine Safety and Effectiveness Research efficiently conducts high-quality research involving large, diverse populations, providing timely evidence to decision-makers and the public.

Integrated care delivery

Kaiser Permanente's unique integrated care delivery system is a model for the future. The delivery system connects care and health services across a variety of settings, spanning outpatient and inpatient care, and includes ancillary services such as pharmacies and laboratories. This model offers the ability to completely capture the total health care information about each member, unlike fee-for-service models.

Large, diverse, and stable population

Kaiser Permanente is one of the nation's largest not-for-profit health plans. Southern California is the organization's largest region, with 4.5 million members who broadly represent the diversity of age, sex, and race/ethnicity in the California population. This population is highly stable, facilitating longitudinal research. The large, diverse, and stable population permits the rapid accrual of a representative sample size and offers the ability to evaluate long-term implications of immunization.

Electronic health record

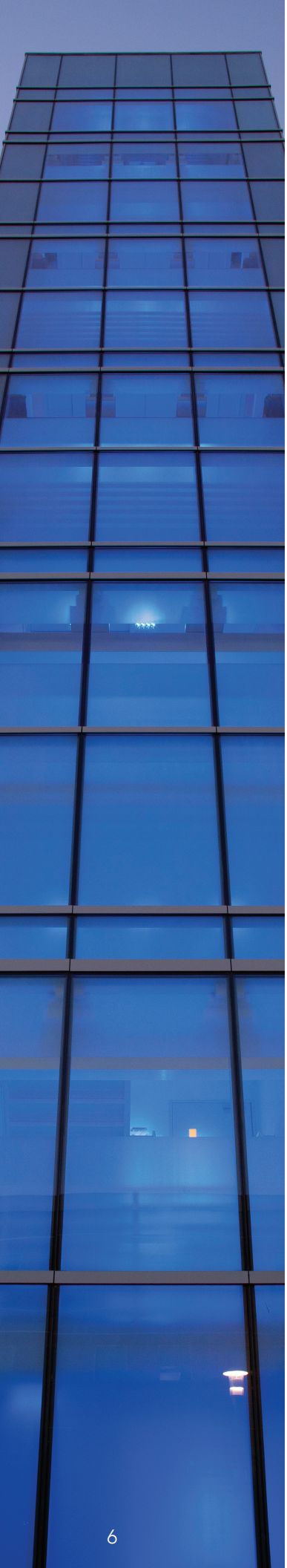
Kaiser Permanente uses certified electronic health records technology as part of the Health Information Technology for Economic and Clinical Health (HITECH) Promoting Interoperability program (formerly known as Electronic Health Records Meaningful Use). Kaiser Permanente HealthConnect® is the largest and most advanced civilian electronic health record system available in the United States. In addition to supporting patient care, this robust system facilitates research, providing access to electronic medical records for the Center for Vaccine Safety and Effectiveness Research team. Details of care are available at the fingertips of researchers in real time.

Focus on prevention

Immunizations are an important part of Kaiser Permanente's overall focus on preventive care. The organization is one of the top-rated health maintenance organizations for meeting national standards of care, which include measures of childhood and adult immunization. Recommended vaccines are provided at no cost to Kaiser Permanente members. Kaiser Permanente Southern California thus provides an excellent real-world setting in which to understand the safety and effectiveness of vaccines.

Scientific expertise

The Center for Vaccine Safety and Effectiveness Research team includes investigators with expertise in vaccine safety and effectiveness, epidemiology, pharmacoepidemiology, biostatistics, infectious diseases, and clinical care. Combining this diverse scientific expertise with a resource-rich environment creates an unparalleled opportunity to advance knowledge about widely used vaccines.



Regional Overview

As an integrated health care system, Kaiser Permanente Southern California provides an ideal environment for population-based epidemiologic, clinical, and health services research. The health plan's population includes more than 4.5 million Southern California residents who represent 260 different ethnicities and speak about 118 different languages. Facilities include hospitals and medical offices, all linked by an information infrastructure that supports both clinical practice and business needs. Health information from this infrastructure can be leveraged for research purposes.

Approximately 90 percent of members remain in the health plan after one year; more than three-quarters remain after three years. Membership is strikingly similar to California census estimates in terms of age, sex, and race.

Kaiser Permanente Southern California at a Glance

Medical Centers
(hospitals)
15

Medical Offices
234

Physicians
7,650

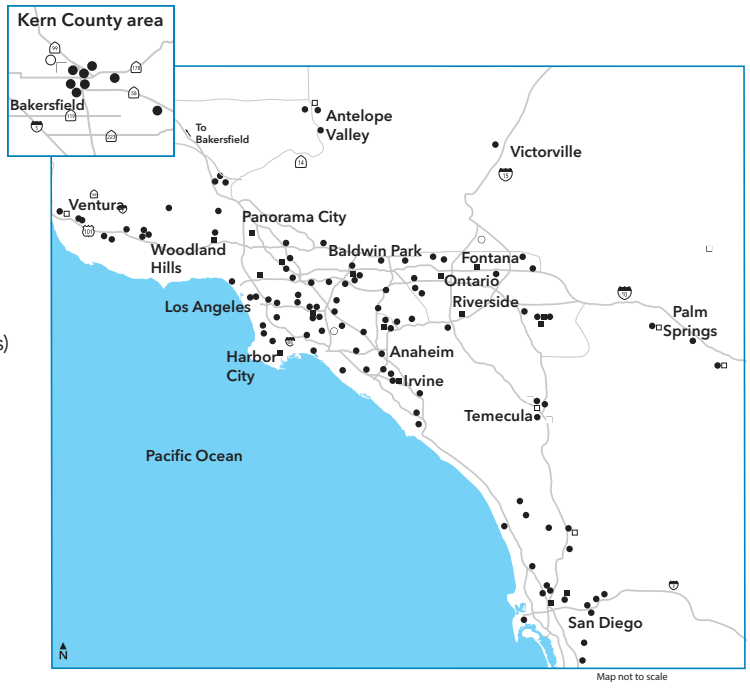
Nurses
26,900

Total staff
74,500

Births per year
41,000

Kaiser Permanente Southern California

- ■ Kaiser Permanente medical centers (hospital and medical offices)
- □ Kaiser Permanente medical offices
- ● Affiliated hospitals
- ○ Affiliated medical offices



Demographic Characteristics of the Kaiser Permanente Southern California Membership on January 1, 2020, Compared With the California Census Population

	Membership #	Membership %	CA Census %
Total population	4,536,414	100.0	100.0
Sex:			
Male	2,201,661	48.5	49.7
Female	2,334,753	51.5	50.3
Age:			
Under 5 years	233,093	5.1	6.3
5 to 9 years	252,748	5.6	6.4
10 to 14 years	277,793	6.1	6.5
15 to 19 years	285,432	6.3	6.6
20 to 24 years	317,668	7.0	7.2
25 to 34 years	671,494	14.8	15.1
35 to 44 years	629,725	13.9	13.2
45 to 54 years	602,605	13.3	13.2
55 to 59 years	305,835	6.7	6.3
60 to 64 years	279,337	6.2	5.6
65 to 74 years	420,666	9.3	7.8
75 to 84 years	193,789	4.3	4.0
85 years and over	66,229	1.5	1.8
Race:			
One race	4,353,374	96.0	95.2
White	2,522,389	55.6	60.1
Black/African American	486,761	10.7	5.8
American Indian & Alaska Native	28,326	0.6	0.8
Asian	676,123	14.9	14.3
Native Hawaiian & Other Pacific Islander	31,278	0.7	0.4
Other race	608,496	13.4	13.8
Two or more races	183,043	4.0	4.8
Ethnicity:			
Hispanic or Latino (of any race)	1,914,756	42.2	38.9

Research in Kaiser Permanente Southern California

The Center for Vaccine Safety and Effectiveness Research is part of the Department of Research & Evaluation, based in Pasadena, California. The department leads and collaborates on research projects with clinicians and with partners from government, academia, and industry.

The Department of Research & Evaluation employs more than 30 full-time staff scientists, 290 research staff (statisticians, programmers, project managers, research associates), and 95 support staff (administration, business office, operations, information technology, and communications). The computing infrastructure consists of a local area network and a high-performance computing environment.

Research Files

The medical record number serves as a unique identifier linking all medical encounters for each member. Care received in the outpatient, inpatient, and emergency settings is documented in the electronic medical record and captured in research databases. Care received outside the Kaiser Permanente Southern California system is captured through claims. The files are updated near real time.

The following are examples of files that can be used for research:

- **Membership:** Includes demographic information such as name, sex, date of birth, race/ethnicity, address, phone number, e-mail address, and Medicaid coverage.
- **Diagnosis:** Includes International Classification of Diseases, 9th revision (ICD-9), and 10th revision (ICD-10) codes.
- **Procedure:** Includes ICD-9 and ICD-10, Current Procedural Terminology (CPT), and Systematized Nomenclature of Medicine (SNOMED) codes.
- **Immunization:** Includes vaccine name, date of vaccination, route of administration, facility where vaccine was administered, dose, manufacturer, and lot number.
- **Laboratory:** Includes laboratory orders and results.
- **Pharmacy:** Includes National Drug Codes (NDCs) and Generic Product Identifier (GPI) codes. About 98% of members have a drug benefit with minimal copayments.
- **Mortality:** Includes deaths from hospital and membership databases, as well as from state and national death files. Also includes cause of death.
- **Birth:** Includes pregnancy-related information such as gestational age, birth weight, and Apgar scores.
- **Registries:** Includes cancer and HIV registries containing information such as patient demographics, utilization, disease history, and risk factors.

Research & Evaluation leads and collaborates on research projects with clinicians and with partners from government, academia, and industry.

Vaccine Research Capacity

The research team has expertise and experience in performing a vast array of vaccine research studies, ranging from epidemiologic studies of vaccine-preventable diseases to Phase IV post-licensure studies.

The organization's unique infrastructure allows the team to:

- Identify subjects with particular exposures or diagnoses through electronic medical records.
- Ascertain outcomes through health care utilization files.
- Validate diagnoses, determine symptom onset, and evaluate disease severity through medical record review.
- Estimate incidence rates through the identification of persons with new disease onset and the person-time denominator from the membership files.
- Evaluate the natural history and clinical course of disease through passive follow-up of cohorts that are assembled retrospectively or prospectively on the basis of disease incidence or exposure.
- Minimize recall bias by using information captured in the medical records before disease onset rather than relying on patient recall.
- Follow cohorts actively with a prospective assessment of outcomes (e.g., patient-reported outcomes, satisfaction, quality of life) by taking advantage of current patient contact information.
- Identify and screen potential subjects according to prespecified eligibility criteria, minimizing effort in the field.
- Evaluate participation bias by using background information for persons agreeing to participate in a study as well as those who do not.

The center's capabilities span the entire process, from the inception of a project through dissemination of findings. Capabilities include:

- Training in Good Pharmacoepidemiology Practices and familiarity with best practices for conducting and reporting pharmacoepidemiologic studies using electronic health care data.
- Using real-world data and analytic strategies that are fit-for-purpose to generate real-world evidence to support regulatory and policy decisions.
- Conducting Phase IV observational safety and effectiveness studies to fulfill regulatory post-marketing requirements and commitments.
- Determining the appropriate study design and analytic approach to answer the research question of interest.
- Developing study protocols independently or collaboratively.
- Expediting Institutional Review Board (IRB) and Health Insurance Portability and Accountability Act (HIPAA) processes while ensuring human subjects protection and data privacy.
- Developing standard documents to ensure quality and consistency.
  - Project Management Plan.
  - Vaccine Management Plan.
  - Risk Management Plan.
  - Data Management Plan.

  - Case Identification Algorithms.
  - Case review/Adjudication Standard Operating Procedure.
  - Statistical Analysis Plan.
  - Scientific Review Committee Standard Operating Procedure.
  - Data Monitoring Committee Standard Operating Procedure.
- Establishing procedures for ensuring data integrity and data quality.
- Assembling large cohorts of subjects rapidly, comprehensively capturing exposures and outcomes.
- Studying special populations, such as people who are immunocompromised, pregnant, or of diverse racial/ethnic or socioeconomic backgrounds.
- Conducting long-term effectiveness and safety studies.
- Distributing and tracking vaccines (including nonformulary vaccines) provided as part of post-licensure studies.
- Developing case identification algorithms using diagnosis codes, laboratory tests, and medications to identify outcomes of interest (e.g., autoimmune, rheumatologic, endocrine, neurologic, cardiac).
- Conducting medical record review using the electronic health record system, Kaiser Permanente HealthConnect.
- Managing case review and adjudication processes, including assembling committees of physician specialists.
- Employing secure electronic data collection methods.
- Collecting patient-reported information through mailed questionnaires, phone surveys, and in-person interviews.
- Collecting clinical specimens for research.
- Using natural language processing of clinical notes to identify outcomes not easily identified through structured data or to facilitate medical record review.
- Performing analyses according to a prespecified analysis plan.
- Using study design and analytic strategies to minimize bias and confounding.
- Coordinating an independent Scientific Review Committee or Data Monitoring Committee.
- Preparing interim and final reports for regulatory agencies.
- Presenting results at scientific meetings and to national advisory groups.
- Publishing results in peer-reviewed journals.
- Coordinating kick-off meetings, site visits, and monitoring visits.
- Coordinating regular conference calls, including scheduling meetings and preparing agendas and minutes summarizing discussion, decisions, and action items.
- Working with international collaborators.
- Providing strong project management support, including managing resources, communicating proactively, reporting on progress, tracking timelines, and maintaining documentation.
- Ensuring all deliverables are of high quality and completed according to the scope of work, within budget, and on time.

Research Topics

The research team partners with clinicians, public health officials, universities, and vaccine manufacturers to conduct important research on the following topics:

- Safety of newly licensed vaccines and new recommendations for existing vaccines.
- Effectiveness of vaccines in a real-world setting.
- Vaccines in special populations such as pregnant women, the immunocompromised, and older adults.
- Epidemiology of vaccine-preventable diseases.
- Vaccine coverage, uptake, and adherence with recommendations.
- Methodologies for assessing vaccine safety and effectiveness.

The following research projects highlight the center's capabilities and illustrate the Kaiser Permanente Southern California difference:

- Using almost 10 years of electronic health records for more than 35,000 Kaiser Permanente Southern California members, the research team collected **real-world evidence** on the effectiveness of concomitant vaccination with the live shingles vaccine and the pneumonia vaccine. The research findings can be used to inform regulatory decision-making and revise product labels.
- To address physicians' and patients' safety concerns about inpatient flu vaccination, researchers evaluated the **safety of flu vaccination before discharge** in more than 250,000 hospitalized patients over three flu seasons.
- Through a retrospective cohort study conducted among pregnant women, researchers concluded that **Tdap vaccination during pregnancy** is not associated with increased risk for autism spectrum disorder in children.
- Research conducted by the center has provided physicians the **evidence needed to recommend immunizations to their most vulnerable patients,** such as shingles vaccine to patients with end-stage renal disease.
- Leveraging the diverse health information in Kaiser Permanente's electronic health record, the research team disentangled the effects of body mass index, race/ethnicity, associated comorbidities, time, neighborhood-level sociodemographic factors, and other factors on the **risk of death from COVID-19.**
- Researchers contributed important data on the real-world **disease burden of herpes zoster (HZ)** among immunocompetent and unvaccinated adults ages 50 years and older.
- The research team collected data on the morbidity and mortality of **respiratory syncytial virus (RSV) disease in older hospitalized adults.** Increased recognition of adult RSV disease burden is important in the evaluation of new RSV vaccines and antivirals.

Research Team

Investigators

Steven Jacobsen, MD, PhD | Steven.J.Jacobsen@kp.org

Dr. Jacobsen is the senior director of research for Kaiser Permanente Southern California's Department of Research & Evaluation. He has been the Kaiser Permanente Southern California site principal investigator for the Vaccine Safety Datalink since 2007. He has led post-licensure safety studies of measles, mumps, rubella, and varicella (MMRV), human papillomavirus (HPV), and hepatitis B vaccines. He has served on the editorial board of the American Journal of Epidemiology since 1997 and of Vaccine since 2011. He is a chronic disease epidemiologist with a long-standing interest in vaccine research, men's urologic health, and cardiovascular disease. He is a professor of health systems science at the Kaiser Permanente Bernard J. Tyson School of Medicine. Dr. Jacobsen received his medical degree from the Medical College of Wisconsin and his doctorate in public health sciences (epidemiology) from the University of Illinois at Chicago.

Hung Fu Tseng, PhD | Hung-Fu.X.Tseng@kp.org

Dr. Tseng is a senior scientist in the Department of Research & Evaluation. He is the principal investigator of several post-licensure studies, including the safety of meningococcal vaccine, safety of Tdap vaccine in pregnant women, and effectiveness of recombinant zoster vaccine. He led Vaccine Safety Datalink studies on the safety of zoster vaccine live, safety of the pneumococcal conjugate vaccine (PCV13) in children and older adults, and safety of Tdap vaccine in older adults. He led studies of the epidemiology of respiratory syncytial virus in hospitalized older adults and the effectiveness of cell-based versus egg-based influenza vaccine. He led several other NIH- and CDC-funded studies. He has presented his findings to the Advisory Committee on Immunization Practices. He is a Fellow of the American College of Epidemiology, a professor at the Kaiser Permanente Bernard J. Tyson School of Medicine, and an adjunct professor at the University of Southern California. Dr. Tseng received his doctorate in epidemiology from the University of California, Los Angeles.

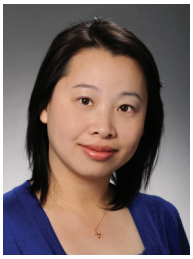
Chun Chao, PhD | Chun.R.Chao@kp.org

Dr. Chao is a cancer epidemiologist who is interested in cancers that tend to affect young people. She has led studies examining the trend and pattern of HPV vaccine uptake, as well as correlates for HPV vaccine initiation and series completion. She was the lead author for the publication of the autoimmune safety surveillance of HPV vaccine. She has evaluated multilevel factors within HPV vaccine and cervical cancer research including patient-level factors (e.g., adherence to the recommended HPV vaccine series and screening), provider-level factors (e.g., in-depth interviews of immunization providers), and system-level factors (e.g., patient reminder interventions). Dr. Chao received her doctorate in epidemiology from the University of California, Los Angeles.

Darios Getahun, MD, PhD | Darios.T.Getahun@kp.org

Dr. Getahun is a perinatal and pediatric epidemiologist with experience in basic and translational research. His research focuses on exploring and understanding potential etiologic factors for adverse pregnancy outcomes, especially among high-risk pregnancies and in vulnerable pregnant women. He led several studies, including two NIH R01 studies (Flame Retardants and Adverse Perinatal Outcomes and Impact of Elective Induction of Adverse Perinatal Outcomes). He published on the effect of maternal influenza vaccination during pregnancy on adverse pregnancy outcomes. He also published on universal SARS-CoV-2 screening in women admitted for delivery at Kaiser Permanente Southern California. He serves as a co-investigator on the Vaccine Safety Datalink project. He has been reviewing articles for the journal Vaccine for more than 10 years. Dr. Getahun received his medical degree from University of Leipzig, Germany, and his doctorate in epidemiology from Rutgers-Robert Wood Johnson Medical School, New Jersey.

Rulin Hechter, MD, PhD | Rulin.C.Hechter@kp.org



Dr. Hechter is an infectious disease epidemiologist. She has led studies examining uptake and correlates for initiation and completion of HPV4 vaccine among males, coverage of zoster vaccine in the elderly, hepatitis B screening and vaccination among high-risk populations, and vaccine safety in HIV patients. Her research focuses on the prevention and treatment of HIV and other sexually transmitted infections. She also studies the impact of psychiatric disorders and substance use on health outcomes and care engagement among patients affected by other chronic comorbidities, including HIV/AIDS. She serves as a co-investigator on the Vaccine Safety Datalink project. She is an adjunct assistant professor of epidemiology at the University of California, Los Angeles. She is also an assistant professor of clinical science at the Kaiser Permanente Bernard J. Tyson School of Medicine. Dr. Hechter received her medical degree from Suzhou Medical College in China and her doctorate in epidemiology from the University of California, Los Angeles.

Sara Tartof, PhD | Sara.Y.Tartof@kp.org

Dr. Tartof is an infectious disease epidemiologist who studies vaccine safety and effectiveness, antimicrobial resistance and stewardship, hospital infections, and coccidioidomycosis, among other areas. She has published on the safety of influenza vaccination administered during hospitalization and the safety of meningococcal conjugate vaccine in children. She led a study on risk factors for severe outcomes among patients with COVID-19, as well as a study looking at the impact of pneumococcal vaccination on COVID-19 outcomes. She is a principal investigator on several federally funded studies, including a large multi-site study evaluating the impact of California Senate Bill 27 on antibiotic-resistant infections, a study to improve screening and treatment for latent tuberculosis infection, and a study evaluating hospital-based antibiotic stewardship programs. She serves as a co-investigator on the Vaccine Safety Datalink project. Dr. Tartof received her doctorate in epidemiology from the University of California, Berkeley.

Jaejin An, PhD | Jaejin.X.An@kp.org

Dr. An is a pharmacoepidemiologist and outcomes researcher whose work focuses on understanding medication utilization, medication adherence, and disease management patterns. She also has interests in drug efficacy, safety, and pharmacoeconomics. Her research has applications for patient quality of care and outcomes. Her clinical focus is in the treatment, prevention, and comorbidity management of cardiovascular diseases, including hypertension, dyslipidemia, atrial fibrillation, and diabetes. She has conducted analyses on the cost of hospitalization associated with respiratory syncytial virus infection versus influenza infection in hospitalized older adults. She is leading a study on the risks associated with taking antihypertensive medications in patients with confirmed COVID-19 infection and high blood pressure. Dr. An received her doctorate in pharmaceutical economics and policy from the University of Southern California, Los Angeles.

Clinical Investigators

Bradley Ackerson, MD | Bradley.K.Ackerson@kp.org

Dr. Ackerson is an infectious disease pediatrician at Kaiser Permanente Southern California. He has helped develop and conduct vaccine safety and efficacy studies including a Phase III trial of Hib vaccine and five large post-licensure safety studies. He has published on severe morbidity and mortality associated with respiratory syncytial virus versus influenza infection in hospitalized older adults. He has been reviewing articles for Vaccine, American Journal of Epidemiology, American Journal of Public Health, Open Forum of Infectious Diseases, and American Journal of Managed Care for more than 10 years. As an associate clinical professor of pediatrics and pediatric infectious diseases at University of California, Los Angeles, he teaches medical students, residents, and pediatric infectious disease fellows. He has been named to the list of Southern California Super Doctors for many years. Dr. Ackerson received his medical degree from the University of California, San Diego.

Bruno Lewin, MD | Bruno.J.Lewin@kp.org

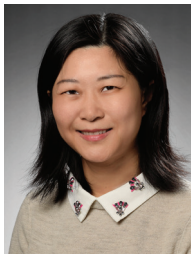
Dr. Lewin is a family medicine physician, director of the Travel Advisory Service at Kaiser Permanente Los Angeles, and the chairman of the Regional Immunization Practice Committee for Kaiser Permanente Southern California. As chairman, he coordinates appropriate use of vaccination and implementation of new immunization recommendations within Kaiser Permanente Southern California. He is a clinical co-investigator on the Vaccine Safety Datalink project, and is leading a Vaccine Safety Datalink study on the safety of travel vaccines. He published on the risk of postherpetic neuralgia in patients who developed herpes zoster despite having received zoster vaccine. He holds several teaching positions, including core faculty for the Kaiser Permanente Los Angeles Family Medicine Residency, volunteer assistant clinical professor at Charles Drew University and the David Geffen School of Medicine at University of California, Los Angeles, and preceptor of the Longitudinal Integrated Clerkship at the Kaiser Permanente Bernard J. Tyson School of Medicine. Dr. Lewin received his medical degree from the University of California, Los Angeles.

Biostatistician Investigators

Stanley Xu, PhD | Stan.Xu@kp.org

Dr. Xu is a senior research scientist biostatistician in the Department of Research & Evaluation. He has served as principal investigator, co-investigator, and lead biostatistician on randomized trials and observational studies funded by the National Institutes of Health, Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, and the U.S. Food and Drug Administration. He has published novel statistical methods in longitudinal data analyses, count data analyses, self-controlled studies, survival analyses, confounder adjustment, outcome misclassification, probabilistic bias analyses, missing data, multiple imputation, and sequential analyses. He has contributed to studies of vaccine safety, substance use, cardiac outcomes, diabetes, hypertension, pharmacoepidemiology, health care utilization, heath care disparities, social needs, mental health, prediction models, and surveillance of the COVID-19 pandemic. He serves as a co-investigator on the Vaccine Safety Datalink project. Dr. Xu received his doctorate in biostatistics from the University of Colorado, Denver, and his doctorate in applied chemistry from Beijing Agricultural University, Beijing.

Lei Qian, PhD | Lei.X.Qian@kp.org



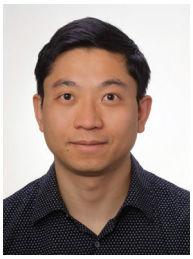
Dr. Qian is a collaborative biostatistician research scientist in the Department of Research & Evaluation. Her methodological research focuses on bias assessment for observational data, propensity score analysis, sequential analysis, self-controlled case series, nonlinear trends analysis, and machine learning methods, with applications in vaccine, infectious disease, and cardiovascular disease research. She is a co-investigator on several post-licensure studies, including the safety of Tdap vaccine in pregnant women, safety of hepatitis B vaccine, and effectiveness of recombinant zoster vaccine. She serves as a co-investigator on the Vaccine Safety Datalink project. Dr. Qian received her doctorate in biostatistics from the University of California, Los Angeles.

Jeff Slezak, MS | Jeff.M.Slezak@kp.org

Mr. Slezak is a collaborative biostatistician research scientist in the Department of Research & Evaluation. He has extensive experience with vaccine safety methods, predictive modeling, and identification of high-risk populations. He contributed to the design and analysis of studies of the safety of HPV vaccine, meningococcal vaccine, and hepatitis B vaccine, as well as studies examining the uptake and completion of the HPV vaccine. He contributed to a randomized trial of patient reminder letters to improve completion rates for the HPV vaccine. Other areas of interest include prostate cancer and bladder cancer. Mr. Slezak received his master's degree in statistics from Iowa State University.

Natural Language Processing Specialist

Chengyi Zheng, PhD | Chengyi.X.Zheng@kp.org



Dr. Zheng is a natural language processing (NLP) specialist in the Department of Research & Evaluation. He serves as a co-investigator on the Vaccine Safety Datalink project, and has led studies using NLP to identify local reactions, anaphylaxis, and shoulder injury related to vaccine administration. He also developed an NLP algorithm to identify cases of herpes zoster ophthalmicus. He has led NLP efforts for a study on outcomes in patients with suspected acute coronary syndrome and another study on surveillance of patients with small pulmonary nodules. Dr. Zheng received his doctorate in computer science from the Oregon Health & Science University, Portland.

Post-Doctoral Research Fellow

Katia Bruxvoort, PhD | Katia.Bruxvoort@kp.org

Dr. Katia Bruxvoort is an infectious disease epidemiologist and post-doctoral research fellow. She is a co-investigator on several post-licensure vaccine safety and effectiveness studies (hepatitis B vaccine, shingles vaccine, influenza vaccines). Other current research includes understanding patterns of antimicrobial use and resistance in urinary tract infections and improving uptake and adherence to pre-exposure prophylaxis (PrEP) for HIV. She has broad interests in infectious disease prevention, screening and diagnostics, and the intersection of social needs and health. She also contributes to several studies on COVID-19. Dr. Bruxvoort received her doctorate in epidemiology from the London School of Hygiene and Tropical Medicine, London.

Scientific Program Manager

Lina Sy, MPH | Lina.S.Sy@kp.org

Ms. Sy is a scientific program manager in the Department of Research & Evaluation. She is the program manager and a co-investigator for the Kaiser Permanente Southern California site of the Vaccine Safety Datalink project, and for several large post-licensure vaccine studies of recombinant zoster vaccine, hepatitis B vaccine, Tdap vaccine, meningococcal conjugate vaccine, HPV vaccine, and MMRV vaccine. Her research interests include real-world evidence for vaccine safety and effectiveness, vaccine uptake and adherence with recommendations, and epidemiology of vaccine-preventable diseases. Ms. Sy received her master's degree in public health from the University of California, Berkeley.

Support Staff

The Department of Research & Evaluation has a pool of programmers, biostatisticians, project managers, and research associates. This work unit model facilitates the ability to obtain well-qualified and trained study staff in a timely manner.

Biostatistics and Programming Support

Programmers extract and manage data, provide quality control, and generate reports. They have extensive experience extracting data from clinical care systems for research.

Biostatisticians consult on study design, calculate sample size, determine appropriate analytic methods, conduct analyses, and interpret results. The department's doctoral and master's-level biostatisticians have expertise in traditional epidemiologic study designs, such as cohort and case-control studies, as well as designs often used for vaccine safety research, including self-controlled case series (SCCS), case-centered approach, rapid cycle analysis (RCA), and propensity score analyses with inverse probability of treatment weighting (IPTW).

Research Support

Project managers provide overall study coordination support, make sure studies comply with IRB and HIPAA requirements, manage resources and budgets, and ensure timely completion of deliverables. Our master's-level project managers have extensive experience managing large vaccine post-licensure studies.

Research associates perform medical record abstraction and validation and collect patient data through mailed questionnaires, phone surveys, and in-person interviews. Our research associates have performed thousands of medical record abstractions and patient interviews to collect information on vaccine exposures and outcomes of interest.

Publications

Findings from the center's studies guide national immunization regulatory and policy decisions and provide the public with the best available information regarding the risks and benefits of immunization.

Authors from Kaiser Permanente Southern California are in boldface.

Safety

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