

HARVARD
PILGRIM
HEALTH CARE
INSTITUTE

Annual Report

2021

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PHOTOGRAPHY:
Institute staff & family, Elisif Photography

MISSION

The Institute's mission is to improve health care delivery and population health through research and education, in partnership with health plans, delivery systems, and public health agencies.

WHO WE ARE

The Department of Population Medicine (DPM) in the Harvard Pilgrim Health Care Institute is a research and teaching partnership between Harvard Pilgrim Health Care and Harvard Medical School. The Department is housed in the Harvard Pilgrim Health Care Institute, a limited liability corporation of Harvard Pilgrim Health Care that includes the Department and the Office of Sponsored Programs. We are one of 15 Harvard Medical School affiliates. In 2021, Harvard Pilgrim Health Care combined with Tufts Health Plan, creating Point32Health. The Institute is also part of Point32Health and now partners with both health plans.

As the nation's first medical school appointing department based in a health plan, we're strategically positioned to improve population health and health care delivery locally, nationally, and internationally. We're distinctive for our scope, expertise, and collaborations.

Our mission and activities are highly consonant with the National Academy of Medicine's advocacy for a national Learning Health System — one that incorporates evidence-based practices into routine care, captures new knowledge as part of the ongoing delivery of care, and then applies new knowledge in a timely manner

We're made up of nearly **300** personnel, including **44** core faculty, **19** research scientists, and **24** fellows, working with hundreds of institutional and individual collaborators around the globe.



DEAR COLLEAGUES,

As you will see in this report, the second year of COVID was a remarkably productive one. Our ability to accomplish so much, especially while working remotely, speaks volumes about the talent and commitment of the more than three hundred people who comprise the Institute. These contributions, at every level, highlight the value of scholarship embedded in a health plan.

Those in our line of work aim to make change. As the nation's first medical school appointing department based in a health plan, we see it as our responsibility to understand the impact of ongoing and emerging issues on the health plan's members and on society and to produce real world evidence that drives changes to improve health and equity.

As rapidly evolving COVID-19 variants challenged what we thought we knew, we kept pace, producing scholarship that strengthened the knowledge base even as new strains emerged (see page 8). Our increased attention to health equity began to bear fruit and promises to be especially productive in the future. For more on our commitment to reducing health disparities, see page 13. Maintaining focus on the many problems

we wrestled with before COVID-19 emerged also remains mission-critical, and we continue to produce in areas like precision medicine, lifecourse, surveillance, and more (see page 17).

Of course, there are key resources that make our work possible. The fact that so many major federal funders of research — National Institutes of Health, Centers for Disease Control and Prevention, Agency for Healthcare Research and Quality, the Food and Drug Administration, and the Patient Centered Outcomes Research Institute — support our work is further confirmation of the value of our work to society as a whole.

As for sharing this knowledge, our faculty's ability to adjust curriculum—in format, scope, and subject—highlights their dedication to training the next generation of population health researchers, clinicians, and educators. For more on that, see page 24. Their expertise and bodies of work also attracted numerous trainees; we are lucky to call some new permanent colleagues; others, lifelong collaborators (see page 28).

As we look toward returning to in-person collaboration, we reflect back on a year distinctive for highlighting what we do best: harness our collective talents to focus on the greater good.

Sincerely,

A handwritten signature in black ink that reads "Richard Platt". The signature is written in a cursive, slightly slanted style.

Richard Platt | Professor and Chair, Department of Population Medicine
President, Harvard Pilgrim Health Care Institute

Faculty + Staff

~300

TOTAL
PERSONNEL

44

NEW HIRES
IN 2021

18

AFFILIATED
FACULTY

44

CORE
FACULTY

38

AFFILIATED CLINICAL
FACULTY

19

RESEARCH
SCIENTISTS

24

FELLOWS

PREP

FA

Research

We conduct research on individuals' behaviors and environments as well as the structures, processes, and outcomes of the health care and public health systems. Our work blends a population and public health focus, is anchored in health care delivery, and leverages unprecedented data resources derived from health care delivery systems along with methodologic expertise in analyzing those resources.

Keeping Pace With the Rapidly Evolving Pandemic

Institute members are working on the front lines of clinical care delivery and on research and public health projects to add to the growing and evolving body of knowledge on COVID-19. As this body of knowledge grows, so do our publications — visit www.populationmedicine.org/COVID for the latest list.

COMPARATIVE EFFECTIVENESS

Rui Wang is co-leading the Vitamin D for COVID-19 (VIVID) trial¹ to determine the effect of vitamin D supplementation on COVID-19 disease progression and post-exposure prophylaxis. Noting that vitamin D deficiency is a risk factor for COVID-19, the team suggests that improvement in vitamin D blood levels by supplementation may mitigate COVID-19 risk for clinical progression. Their national clinical trial, conducted remotely with a study population of more than 1,500 participants, consists of dispensing 3,200 IU/d daily for 4 weeks to persons with newly diagnosed COVID-19 infection to reduce disease severity and to prevent infection in household members of newly infected individuals. Because COVID-19 disproportionately affects racial/ethnic minority groups that experience higher rates of vitamin D deficiency, vitamin D has the potential to help reduce health disparities if shown to be efficacious.

¹ Wang, R, DeGruttola, V, Lei, Q, et al. The Vitamin D for COVID-19 (VIVID) Trial: A Pragmatic Cluster-Randomized Design. *Contemporary Clinical Trials* Vol. 100, 2021-01-01.

DELIVERY SYSTEMS

COVID-19 has had a profound, and still evolving, impact on the health care landscape. **Michael Klompas**, **Chanu Rhee**, and **Meghan Baker** lead the Infection Control Program at Brigham and Women's Hospital (BWH) and the Dana Farber Cancer Institute in Boston. In this capacity, they have been responsible for overseeing the hospitals' preparations and policies to safely manage COVID-19 as well as to detect and control clusters of infection. Their national profiles have grown as they continued reporting from the front lines of the pandemic by way of publishing a number of influential studies, narrative reviews, and editorials (see page 12) informed by real-world evidence and firsthand experience. This work includes a highly cited narrative review² in *Annals of Internal Medicine* of current insights into respiratory virus transmission in health care settings. They argue that new research demonstrates that individuals generate the full range of respiratory particles, not just either

² Klompas M, Milton DK, Rhee C, Baker MA, Leekha S. Current Insights Into Respiratory Virus Transmission and Potential Implications for Infection Control Programs: A Narrative Review. *Ann Intern Med*. Vol. 174 (12), 2021-12-01.

droplets or aerosols, suggesting that hospital-based infection control policies in place at the beginning of the pandemic were outdated. Additional research has focused on hospital-based transmission³, or lack thereof⁴. **Sanjat Kanjilal** is the Associate Medical Director of Clinical Microbiology at BWH. He has continued to work in close collaboration with other microbiology laboratory directors at BWH and Massachusetts General Hospital to ensure COVID-19 testing and genome sequencing capacity was able to meet the demands of clinical care and employee testing, despite many challenges faced with staff shortages. Additionally, he completed validations of three rapid antigen tests for Mass General Brigham and ensured they were suitable for use for patient triage and employees returning to work during the Omicron wave.

Michael Klompas and **Richard Platt** lead the Centers for Disease Control and Prevention (CDC)-funded Prevention Epicenter, “Harvard Pilgrim Health Care Institute Center for Excellence in HAI Surveillance and Prevention”. In 2021, this Epicenter was renewed for the next five years, which will take it through over 20 years of continuous funding—one of only two continuously funded centers in the country. Epicenter COVID-19 projects included an analysis of the impact of COVID-19 on healthcare-associated infections across 148 HCA Healthcare hospitals in 2020, led by **Meghan Baker**. Results⁵ showed that COVID-19 surges were associated with increases in non-COVID-19 healthcare-associated infection rates and clusters of infections within hospitals, emphasizing the need for balancing COVID-19-related demands with routine hospital infection prevention.

3 **Klompas M, Baker MA**, Griesbach D, Tucker R, Gallagher GR, Lang AS, Fink T, Cumming M, Smole S, Madoff LC, **Rhee C**. Transmission of SARS-CoV-2 from Asymptomatic and Presymptomatic Individuals in Healthcare Settings Despite Medical Masks and Eye Protection. *Clin Infect Dis*. 2021-03-11.

4 **Rhee C, Baker M**, Tucker R, **Klompas M**. Absence of Long-Range SARS-CoV-2 Transmission from a Highly Infectious Patient with Undiagnosed COVID-19 in a Positive Pressure Room. *Infect Control Hosp Epidemiol*. 2021-07-21.

5 **Baker MA**, Sands KE, Huang SS, Kleinman K, Septimus EJ, Varma N, Blanchard J, Poland RE, **Coady MH**, Yokoe DS, Fraker S, Froman A, Moody J, Goldin L, Isaacs A, Kleja K, Korwek KM, Stelling J, Clark A, **Platt R**, Perlin JB; CDC Prevention Epicenters Program. The Impact of COVID-19 on Healthcare-Associated Infections. *Clin Infect Dis*. 2021-08-09.



In addition to their Institute research roles, Michael Klompas, Chanu Rhee (pictured here), and Meghan Baker lead the Infection Control Program at Brigham and Women’s Hospital. They have played a central role during the pandemic in developing policies to protect patients and staff from COVID-19 and contributed to the growing body of knowledge around its epidemiology, transmission, and prevention.

Additionally, **Michael Klompas, Meghan Baker, Rui Wang,** and **Chanu Rhee** assessed the impact of airborne infection isolation room utilization rates on health care worker infection rates at Mass General Brigham by comparing two similar hospitals with different utilization rates. Airborne infection isolation rooms are hospital spaces with enhanced ventilation and negative pressure designed to minimize the quantity of airborne pathogens. Results⁶ showed no difference in health care worker infection rates between a hospital that used negative pressure rooms for almost all COVID-19 patients and one that only used negative pressure rooms for a minority of COVID-19 patients. Additional Epicenter COVID publications can be found at www.populationmedicine.org/COVID.

6 **Klompas M**, Ye S, Vaidya V, Ochoa A, **Baker MA**, Hopcia K, Hashimoto D, **Wang R, Rhee C**. Association between Airborne Infection Isolation Room Utilization Rates and Healthcare Worker COVID-19 Infections in Two Academic Hospitals. *Clin Infect Dis*. 2021-10-02.

COVID-19 RESEARCH/ MEDIA STATISTICS



46

PUBLICATIONS
in the medical literature



33

NEWS ARTICLES



2

PODCASTS



1

OP-ED



4

RADIO APPEARANCES



1

TELEVISION APPEARANCE



MORE AT

www.populationmedicine.org/COVID

POLICY

In a PCORI-funded supplement to the Asthma in Families Facing Out-of-pocket Requirements with Deductibles (AFFORD) project, **Alison Galbraith** and her study team are testing a navigation intervention for people with asthma who lost their jobs and coverage during the COVID-19 pandemic to help them find coverage and manage the costs of asthma care. Qualitative interview data have demonstrated the financial and health challenges faced by families as they try to find new coverage and manage the costs of asthma care in the shadow of the pandemic.

SURVEILLANCE AND PUBLIC HEALTH

Institute investigators continue to work within a national research network of health care systems, the National Patient-Centered Clinical Research Network (PCORnet), on innovative projects in clinical epidemiology and population health surveillance. **Jason Block** leads several large-scale projects in PCORnet including a CDC-funded COVID-19 surveillance program in 44 health care systems. The work provides up-to-date information on COVID-19 infections and vaccinations to the CDC to facilitate national reporting on this information on their public-facing COVID-19 Tracker site and to investigate priority topics. Recently, the group has published studies on racial and ethnic disparities⁷ in the use of monoclonal antibody treatments for COVID-19, the incidence of myocarditis and pericarditis after COVID-19 infection and COVID-19 vaccination⁸, and the prevalence of symptoms and conditions that develop after COVID-19⁹. Additional Institute PCORnet COVID-19 work includes a collaboration in the National Institutes of Health RECOVER projects that are investigating post-acute sequelae of COVID-19.

7 Wiltz JL, Feehan AK, Molinari NM, ...**Block JP**, et al. Racial and Ethnic Disparities in Receipt of Medications for Treatment of COVID-19 — United States, March 2020–August 2021. *MMWR Morb Mortal Wkly Rep* Vol. 71, 2022.

8 **Block JP**, Boehmer TK, Forrest CB, et al. Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 Vaccination — PCORnet, United States, January 2021–January 2022. *MMWR Morb Mortal Wkly Rep* 2022;71:517-523.

9 Hernandez-Romieu AC, Carton TW, Saydah S, ...**Draper C**...**Nagavedu K**...**Block J**. Prevalence of Select New Symptoms and Conditions Among Persons Aged Younger Than 20 Years and 20 Years or Older at 31 to 150 Days After Testing Positive or Negative for SARS-CoV-2. *JAMA Netw Open* Vol. 5 (2), 2022.



Institute team members hold a hybrid seminar.

The U.S. Food and Drug Administration (FDA) Sentinel Operations Center, based in the Harvard Pilgrim Health Care Institute and led by **Richard Platt**, is a national program that allows the FDA to monitor the safety and effectiveness of marketed medical products. Sentinel was actively involved in the FDA's response to COVID-19, providing data on natural history and management of the disease. The Sentinel COVID-19 response team, led by **Judy Maro, Noelle Cocoros, and Candace Fuller**, has created a longitudinal dataset with over 221,000 adult COVID-19 cases and 2,200 pediatric cases within the electronic health record system of HCA Healthcare. This work allows monitoring the use of drugs in the inpatient setting in general, description of the course of illness among hospitalized COVID-19 patients, and the evaluation of the treatment impact of therapies actively being used under real-world conditions. The Sentinel team also worked with several health plans to obtain more timely data to conduct studies examining arterial and thrombotic events among individuals with COVID-19, natural history and treatments of COVID-19 among pregnant women, and the utilization of medications being used to treat COVID-19. See page 23 for more detail on Sentinel in general, and the Sentinel website¹⁰ for detail on the many activities that are completed or ongoing in response to the pandemic.

Institute researchers continued their longstanding partnership with the Massachusetts Department of Public Health (MDPH) to build and maintain MDPHnet, a distributed

network that allows MDPH to track conditions of public health interest using electronic health record data drawn from delivery systems across the state. In 2021, the team, led by Institute members **Michael Klompas, Noelle Cocoros, and Sarah Willis** continued to develop the system's capacity to monitor COVID-19. MDPHnet identifies potential COVID-19 cases using diagnostic codes, vital signs, and laboratory tests, and creates weekly reports for MDPH on incidence, testing patterns, comorbidities, and outcomes of COVID-19 and other respiratory viruses. Analyses assessing COVID-19 among people living with HIV is underway. This year, an additional project was kicked off to identify adverse events related to COVID-19 vaccines using the same platform — this work is being led by Institute members **Meghan Baker, Michael Klompas, and Sarah Willis**. See page 21 for more detail on MDPHnet.

Few population-level studies have examined the effects of COVID-19 on childhood obesity prevalence. Using MDPHnet, a research team led by fellow **Allison Wu** with **Izzuddin Aris, Noelle Cocoros, Marie-France Hivert, Michael Klompas**, and colleagues, examined obesity prevalence in a fixed cohort of children and adolescents in three periods ranging from 2018 to 2020. Results, published in *JAMA Pediatrics*¹¹, showed that while childhood obesity was on the rise before the emergence of COVID-19, the pandemic was associated with an accelerated increase in obesity.

¹⁰ <https://www.sentinelinitiative.org/>

¹¹ Wu AJ, Aris IM, Hivert M, Rocchio C, Cocoros NM, Klompas M, Taveras EM. Association of Changes in Obesity Prevalence With the COVID-19 Pandemic in Youth in Massachusetts. *JAMA Pediatr.* 2021-12-13.

COVID-19 Thought Leadership

As the COVID-19 pandemic continues to shape infection control and public health policy, faculty contribute their epidemiological and clinical expertise to think pieces about the public health response to the virus.

NAVIGATING THE LANDSCAPE OF RISK AFTER VACCINATION

Julia Marcus continued to discuss the difficulties of navigating evolving public health messaging in *The Atlantic*¹². She kicked off 2021 with a piece about how the rollout of the vaccine affected the behavior and risk-benefit calculus of the public, and how this rivaled the public health messaging at the time. As time would (and continues to) tell, the pandemic has proved a much more complex problem than vaccines alone can solve, and public health messaging should support responsible decision-making.

SHINING THE POSSIBLE LIGHT AT THE END OF THE TUNNEL ON BREAKTHROUGH COVID-19 INFECTIONS IN FULLY VACCINATED INDIVIDUALS

In a pre-Omicron *JAMA*¹³ editorial from early November, **Michael Klompas** discusses breakthrough infections in individuals fully vaccinated against COVID-19. As the pandemic has endured, the data and understanding of coronavirus has evolved greatly, including that surrounding breakthrough infections. Evidence shows that fully vaccinated individuals are less prone to carry COVID-19, shed less virus when they are infected (despite having viral loads as high as unvaccinated individuals), and that disease severity among those vaccinated individuals who do become infected is less severe.

NEW OPPORTUNITIES TO EXAMINE OLD FRAMEWORKS

Michael Klompas, Chanu Rhee, and colleagues published a Viewpoint¹⁴ in *BMJ Quality & Safety* regarding issues tangential, but still important, to COVID-19. They posit that changes wrought in hospitals by the COVID-19 pandemic provide a fresh opportunity to rethink our frameworks for measuring and benchmarking healthcare-associated infections.

EIGHT REASONS MANDATING THE COVID-19 VACCINE FOR HEALTH CARE WORKERS IS MORE CRITICAL THAN THE INFLUENZA VACCINE

Michael Klompas has spent much of his time during the pandemic on the front lines treating patients and evaluating how to best keep health care workers safe as the body of knowledge of COVID-19 evolved. In this Ideas and

Opinions piece¹⁵ in *Annals of Internal Medicine*, he and colleagues support the notion of making SARS-COV-2 vaccines mandatory for health care workers, comparing against the mandating of influenza vaccines 15 years ago. Though a hotly debated topic, the team discusses eight reasons in favor of a mandate, arguing their belief that the case is significantly stronger than was the case for mandating influenza vaccines. Reasons include the mortality rate and post-COVID-19 symptoms, threat to essential workers' lives, common transmission by asymptomatic and presymptomatic individuals, the need to protect patients, the safety and efficacy of the vaccines, and COVID-19's disruption of the hospital operations community and workforce overall.

RECOGNIZING THE NEED FOR NUANCED MASKING GUIDANCE FOR HEALTH CARE WORKERS

In a commentary¹⁶ from **Michael Klompas, Chanu Rhee**, and **Meghan Baker** in *Clinical Infectious Diseases*, they suggest that new CDC guidance—that all providers seeing patients with suspected or confirmed COVID-19 wear N95 respirators—be broadened during periods of high community transmission. They reason that because SARS-COV-2 is most contagious before the onset of symptoms, and because the likelihood of patients or health care workers having occult infections is greater during periods of high community incidence, universal use of N95s for all patients—not just those with suspected or confirmed COVID-19—may help decrease nosocomial transmission.

DECONSTRUCTING IMPROVEMENTS AND HOSPITAL VARIATION IN COVID-19 MORTALITY RATES DURING THE EARLY PANDEMIC WAVE

An editorial¹⁷ by **Chanu Rhee**, published in *BMJ Quality & Safety*, advocates for rigorously examining trends in COVID-19 outcomes and the contribution of potentially modifiable hospital factors to mortality to prepare for potential future surges. He highlights this through a discussion of a study that appears in the same issue of the journal that suggests that strains on hospitals' staff and other resources may have contributed to worse outcomes. Dr. Rhee stresses the importance of coordinated regional approaches to mitigate increased numbers of patients, and that though these approaches have improved greatly throughout the pandemic, there is more room for improvement. He closes by stressing that we must take both the positive and negative lessons of the early response to COVID-19 to plan for future waves and pandemics.

DROPLETS VERSUS AEROSOLS: THE PANDEMIC QUESTIONS OLD DEFINITIONS

In a *CHEST* editorial¹⁸ from October, **Michael Klompas** and **Chanu Rhee** discuss two studies highlighted in the issue, which look closely at aerosol generation and mitigation during exercise. They note there is little distinction between droplet- and aerosol-based transmission, as people produce respiratory particles in a range of sizes even in the absence of procedures classically thought to be “aerosol-generating”, with no clear line between droplets and aerosols. What does this mean for protecting health care workers? Drs. Klompas and Rhee say the implication is that N95s and negative-pressure rooms should be prioritized based on patients’ viral load, symptoms, and activities rather than on the basis of specific procedures.

12 <https://www.theatlantic.com/ideas/archive/2021/01/giving-people-more-freedom-whole-point-vaccines/617829/>

13 **Klompas M.** Understanding Breakthrough Infections Following mRNA SARS-CoV-2 Vaccination. *JAMA* Vol. 326 (20), 2021.

14 Salmasian H, Beloff J, Pimentel MP, Resnick A, **Rhee C, Baker MA, Klompas M.** Rethinking Standardised Infection Rates and Risk Adjustment in the COVID-19 era. *BMJ Qual. Saf.* 2021-01-08.

15 **Klompas M,** Pearson M, Morris C. The Case for Mandating COVID-19 Vaccines for Health Care Workers. *Ann Intern Med.* Vol. 174 (9), 2021.

16 **Michael Klompas, Chanu Rhee, Meghan A Baker,** Universal Use of N95 Respirators in Healthcare Settings When Community Coronavirus Disease 2019 Rates Are High. *Clin. Infect. Dis.* 2021.

17 **Rhee C.** Deconstructing Improvements and Hospital Variation in COVID-19 Mortality Rates During the Early Pandemic Wave: The Effects of Wave Evolution and Advances in Testing, Treatment, and Hospital Care Quality. *BMJ Quality & Safety* 2021-08-05.

18 **Klompas M, Rhee C.** Aerosol Generation During Exercise: Implications for Preventing Viral Transmission In and Out of the Exercise Laboratory. *Chest* Vol. 160 (4), 2021-10-01.

Health Equity

Addressing health equity is central to solving many of our greatest public health issues. Our cross-cutting research examines equity and disparities across the lifespan. By leveraging our position within both a medical school and a health plan, we continue to expand our portfolio of work in health equity and disparities in hopes of making long-lasting impact.

LIFECOURSE

Project Viva is an Institute-based landmark study of life-course influences on health and disease. Vitamin D, which can be obtained via diet or synthesized by the body in response to UVB light, is one such influence and may contribute to programming future bone health, adiposity, and cardiometabolic risk. Although the importance of adequate vitamin D status in childhood is well-established, suboptimal vitamin D status is common among children and gaps exist in our understanding of factors associated with vitamin D status in early life. A team led by **Karen Switkowski**, with **Sheryl Rifas-Shiman, Emily Oken**, and colleagues, characterized relations of early-life factors with plasma 25-hydroxyvitamin D concentrations—the measure which reflects both vitamin D intake and synthesis—in early and mid-childhood among children in Project Viva, and explored potential differences in these associations between White and Black children (categorized based on mother report of child’s race/ethnicity). Factors independently associated with childhood vitamin D status included season of blood collection, vitamin D supplementation, birth season, prenatal exposure, and higher dietary intake of vitamin D. Results¹⁹, published in *The Journal of Nutrition*, suggest that race, likely as a proxy for skin pigmentation, is a strong predictor of plasma 25-hydroxyvitamin D concentrations even after

19 **Switkowski KM, Camargo CA, Rifas-Shiman SL, Fuller H, Oken E.** Early-Life Factors Are Associated with Vitamin D Status in Early and Mid-Childhood and May Differ between White and Black Children. *J Nutr.* Vol. 151 (5), 2021-05-11.



Alison Galbraith's research focuses on the effects of new health insurance strategies on health care decision making and use of health care services; she leads the RECOVER project with HPHC operational leaders.

accounting for many other factors and that other predictors of vitamin D status may differ between White and Black children. These findings can help identify children potentially at risk of vitamin D deficiency and inform potential recommendations on how to improve vitamin D status in childhood. See page 22 for more information about Project Viva.

POLICY

In a unique collaboration with Harvard Pilgrim Health Care (HPHC) operational leaders, **Alison Galbraith** and former Institute faculty member Frank Wharam are leading a team of Institute investigators (**Olesya Baker, Laura Garabedian, Mei-Sing Ong, Alon Peltz, Anita Wagner, Hefei Wen, and Hao Yu**) assessing the impact of the COVID-19 pandemic on commercial health insurance enrollment, health outcomes, and disparities among HPHC members. This program, titled RECOVER: Understanding COVID-19 Impacts on Health Outcomes and Equity in the New England Region, focuses especially on elucidating differential impact on health plan members from racial and ethnic minority groups.

Alon Peltz was recently appointed to the role of Medical Director for Health Equity at Point32Health. In this role, Dr. Peltz reports to the Chief Medical Officer and supports efforts to improve quality of care and reduce health care inequities across the organization. Dr. Peltz continues to lead two research studies related to health equity. The first study, supported by Dr. Peltz's Institute faculty grant, is a collaboration between the Institute and

Point32Health focused on identifying racial bias in data algorithms used for enrolling members in care management programs. Bias in data algorithms often reflects historic imbalances in access to care and use of medical services. Dr. Peltz is working to identify if any such bias exists in the heritage Harvard Pilgrim Health Care population and if so, to identify potential mitigation steps. The second study, sponsored by the Massachusetts Association of Health Plans, examines racial, ethnic, and age-based differences in telehealth use during the COVID-19 pandemic. Preliminary results have revealed lower rates of telehealth use for primary care services among older adults, individuals insured by Medicaid, and among those residing in predominately Black communities in Massachusetts. Results have also showed that racial and ethnic disparities differ by insurance type prompting additional inquiry which is underway. The final report is planned for fall 2023 and will help identify policy recommendations that can apply across the entire health care sector to promote equitable access to telehealth.

Advances in immunotherapies and targeted therapies have greatly increased survival rates for those with melanoma, lung cancer, and breast cancer. While these therapies are promising, cancer experts including **Maryam Asgari** emphasize the need in a new *JAMA Oncology Viewpoint*²⁰ to more closely examine their underuse, which has been attributed to cost, racial/ethnic, socioeconomic, and geographic factors. These novel therapies may offer great hope to patients with cancer and their families, but if barriers to their use remain, their actual efficacy is greatly diminished. The team examines the commonly speculated barriers that may contribute to differential use of immunotherapies and targeted therapies across different patient groups and proposes calls to action to reduce these disparities. The authors advocate for the oncology community to explore every measure to improve their equitable use and conduct real-time analyses of their use.

Hao Yu is leading three federally funded projects examining health workforce related disparities and equity. An Agency for Healthcare Research and Quality funded project has found²¹ that the Medicaid expansion

20 Ashrafzadeh S, **Asgari MM**, Geller AC. The Need for Critical Examination of Disparities in Immunotherapy and Targeted Therapy Use Among Patients With Cancer. *JAMA Oncol.* Vol. 7 (8), 2021.

21 Escarce JJ, Wozniak GD, Tsipas S, Pane JD, Brotherton SE, **Yu H**. Effects of the Affordable Care Act Medicaid Expansion on the Distribution of New General Internists Across States. *Med Care.* Vol. 59 (7), 2021-07-01.

under the Affordable Care Act has attracted more new primary care physicians to practice in the expansion states, especially in disadvantaged areas in those states. A project funded by National Institute on Minority Health and Health Disparities is examining²² whether increasing health care providers in health professional shortage areas helps reduce disparities in health care and health outcomes between health professional shortage areas and other areas. For another project, which is funded by National Institute of Mental Health, he is examining the supply and distribution of mental health workforce and health care for children with autism overall, and especially for those who live in underserved areas, such as rural, low-income, and minority communities²³.

PREVENTION

Black women are disproportionately impacted by HIV, accounting for nearly 60% of new HIV infections among U.S. women while making up less than 15% of the female population. A new formulation of preexposure prophylaxis (PrEP), with long-acting injections every 8 weeks, was approved in December 2021 and could improve uptake among Black women, but little is known about PrEP product preferences among Black women. Led by **Whitney Irie**, with **Julia Marcus** as senior author, a study team assessed preferences for PrEP products, including injectable PrEP and daily oral PrEP, in a national sample of Black cisgender women. The study²⁴ contributes some of the first data on Black women's preferences for PrEP products, finding that injectable PrEP is preferred over oral PrEP in a subset of Black women, particularly those with anticipated stigma or cost concerns related to PrEP use. The study was published in *AIDS and Behavior*.

Joshua Petimar is the co-PI of a grant from Center for Science in the Public Interest to examine socioeconomic disparities in the effects of supermarket food marketing on food choice. In-store food marketing activities, such as displays, signage, and price discounts, are widespread in food retailers and aim to influence food

22 **Yu H, Klompas M**, Kofner A, Horvitz-Lennon M, **Zhang F**, McKernan S. COVID-19 Vaccination: Concerning Trends in Primary Care Health Professional Shortage Areas. *Am J Prev Med*. 2022-02-20.

23 **McBain RK**, Cantor JH, Kofner A, Stein BD, **Yu H**. Ongoing Disparities in Digital and In-Person Access to Child Psychiatric Services in the United States. *J Am Acad Child Adolesc Psychiatry* 2021-12-21.

24 **Irie WC**, Calabrese SK, Patel RR, ... **Marcus JL**. Preferences for HIV Preexposure Prophylaxis Products Among Black Women in the U.S. *AIDS Behav* 2022.

Harvard SOGIE and Medical Education



Brittany Charlton (pictured above) co-directs the Harvard SOGIE (Sexual Orientation and Gender Identity and Expression) Health Equity Research Collaborative. While Harvard SOGIE brings together experts from across the university, the Harvard Pilgrim Health Care Institute is now its new administrative home with the support of both faculty and staff. In 2021, Harvard SOGIE celebrated its 10th anniversary and remains committed to promoting the health of diverse LGBTQ+ communities in terms of sexual orientation, gender identity and expression, age, race/ethnicity, geography, and other axes of social inequality.

Dr. Charlton is also leading efforts with Harvard Medical School's Sexual and Gender Minority Health Equity Initiative. This multi-year effort enhances the ability of medical school students and faculty to provide evidence-based care by integrating sexual and gender minority health content across the curriculum, and features a unique mentorship program created by Dr. Charlton that helps faculty to foster a supportive learning environment, particularly when teaching about sexual and gender minority health or when teaching LGBTQ-identified trainees.

See page 24 for additional information on our Teaching Programs.

Thought Leadership

As authorities in their areas of research, faculty often pen think pieces on timely, relevant topics in health care and medicine in high-impact journals and media.

EMBEDDED PRAGMATIC TRIALS AS A TOOL TO ENGAGE HEALTH CARE SYSTEM PARTICIPATION IN RESEARCH

The pace of traditional medical research is not on track to keep up with real-world demands for evidence, according to a *New England Journal of Medicine Perspective*²⁵ led by **Richard Platt**. The COVID-19 pandemic highlighted this for certain. Instead, embedded pragmatic clinical trials (ePCTs) can produce this evidence without the limitations of observational studies, having the added benefit of being integrated into standard care, involving existing clinicians, and using data already being routinely collected. The team demonstrates the feasibility of using ePCTs by citing experience gained from working in the coordinating center of the NIH Health Care Systems Research Collaboratory.

REFLECTING ON THE MEDICARE SEPSIS PERFORMANCE MEASURE

In an *Annals of Internal Medicine* Editorial²⁶, **Michael Klompas** and **Chanu Rhee** take a look at what the way forward might be for the Medicare Sepsis Performance Measure. They suggest that there are two paths to follow: better diagnostic tools to rapidly identify the acutely ill in need of antibiotics; and secondly, shifting sepsis reporting from debatable process measures to objective outcomes using standardized, clinically meaningful, electronically definable, risk-adjusted indicators.

25 **Platt R**, Simon GE, Hernandez AF. Is learning Worth the Trouble? - Improving Health Care System Participation in Embedded Research. *N Engl. J Med.* Vol. 385 (1), 2021-06-26

26 **Klompas M, Rhee C**. Has the Medicare Sepsis Performance Measure (SEP-1) Catalyzed Better Outcomes for Patients With Sepsis? *Ann Intern Med.* Vol. 174 (7), 2021-07-01.

choices to increase sales. These practices tend to promote unhealthy foods and often target shoppers with lower socioeconomic status. Dr. Petimar's study will determine differences in the effects of these practices by household-level measures of socioeconomic status such as poverty status, food assistance, and housing insecurity. He is conducting this work alongside collaborators at Harvard T.H. Chan School of Public Health, Massachusetts General Hospital, and Johns Hopkins Bloomberg School of Public Health.

REPRODUCTIVE HEALTH DISPARITIES

Brittany Charlton launched a 5-year NIH funded grant focused on sexual orientation-related disparities in obstetrical and perinatal health. Her research over the last decade has revealed that, compared to heterosexual women, sexual minority women are vulnerable to poor gynecological health; for example, they are more likely to experience sexual assault and to encounter barriers to health care. Despite the mounting evidence of these gynecological disparities, little is known about the extent to which obstetrical and perinatal health differ across sexual orientation groups. Dr. Charlton and her team aim to address the knowledge gaps in sexual orientation-related obstetrical and perinatal health by collecting and analyzing national data from three unique, longitudinal, intergenerational cohorts including the Growing Up Today Study and the Nurses' Health Studies. In 2021, Dr. Charlton and her team also leveraged other data sources to examine additional obstetrical and perinatal health inequities arising not only from homophobia but also racism. They published the first paper²⁷ to quantify intersectionality in the area of sexual orientation-related obstetrical disparities; findings revealed that sexual minority women, particularly those who are also women of color, are more likely to have an unintended pregnancy compared to their white, heterosexual peers. In another paper²⁸, her team revealed that among women of color, sexual minorities had strikingly worse birth outcomes than their heterosexual peers.

27 Reynolds CA, Beccia A, **Charlton BM**. Multiple Marginalization and Unintended Pregnancy Among Racial/Ethnic and Sexual Minority College Women: Incorporating Multiplicative and Additive Interaction into Health Disparities Research. *Paediatr Perinat Epidemiol* Vol. 35 (4), 2021-07-01.

28 Everett B, Limburg A, **Charlton BM**, Downing J, Matthews A. Sexual Identity and Birth Outcomes: A Focus on the Moderating Role of Race/Ethnicity. *J Health Soc Behav* Vol. 62 (2), 2021-06-01.

Additional 2021 Research Highlights

THE FUTURE OF PRECISION MEDICINE

Rapid advances in genomic technologies and the availability of increasing amounts of genomic information influence how health care is provided. Institute researchers identify and evaluate genomics practices to improve individual and population health, with much of this work focused on improving outcomes for asthma. A study²⁹ led by **Joanne Sordillo** and **Sharon Lutz** with **Ann Chen Wu** used findings from a large multi-ancestry genome-wide association study (GWAS) of asthma to compute a polygenic risk score for asthma with relevance for racially diverse populations. The study found that polygenic risk scores across multiple racial/ethnic groups were associated with an increased asthma risk. This suggests that polygenic risk scores have the potential to help predict disease development.

In 2020, Institute researchers developed the Precision Medicine Policy and Treatment (PreEMPT) Model, a sophisticated computer model capable of simulating short- and long-term clinical benefits and estimating the cost-effectiveness of integrating different genome screening strategies into clinical care for healthy or high-risk newborns for a wide variety of heritable conditions. A new study led by **Ann Wu**, **Kurt Christensen**, **Natasha Stout**, and colleagues, utilized the PreEMPT model to examine the benefits and costs of genetic testing of the siblings of newborns found to have mutations in the 11 genes most commonly associated with childhood-onset cancers. Study results showed that testing

siblings of newborns could reduce deaths from these rare cancers by about 50%, and save nearly \$17,000 per year for each year of life gained among the siblings, compared to not testing for the mutations.

Marie-France Hivert is leading the efforts of four Precision Medicine in Diabetes Initiative working groups, focusing on Precision Medicine for Gestational Diabetes Mellitus. The Precision Medicine in Diabetes Initiative was initiated by the American Diabetes Association and the European Association for the Study of Diabetes in collaboration with experts in diabetes across the world. The overall objective of the initiative is to improve diabetes care by realizing the promise of precision medicine for diabetes, in the hope to offer custom delivery of health care, with medical practices, testing, decisions, and treatments tailored to the individual patient level. Dr. Hivert contributed to the first consensus report that was published in 2020.³⁰ The evidence will be summarized into a second consensus report that will pave the way for clinical applications of precision medicine for gestational diabetes mellitus, in addition to other types of diabetes. Dr. Hivert also helped organize the Precision Medicine in Diabetes virtual symposium in 2021³¹, where she was one of the key speakers, outlining the work of the GDM working groups and promises of precision medicine for gestational diabetes mellitus.

30 Chung WK, Erion K, Florez JC, Hattersley AT, **Hivert MF**, ... Franks PW. Precision medicine in diabetes: A Consensus Report from the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetologia*. Vol. 63 (9), 2020-09-01.

31 Nolan JJ, Kahkoska AR, Semnani-Azad Z, **Hivert MF**, ...Franks PW. ADA/EASD Precision Medicine in Diabetes Initiative: An International Perspective and Future Vision for Precision Medicine in Diabetes. *Diabetes Care* Vol. 45 (2), 2022-02-01.

29 **Sordillo JE**, **Lutz SM**, Jorgenson E, Iribarren C, McGeachie M, Dahlin A, Tantisira K, Kelly R, Lasky-Su J, Sakornsakolpat P, Moll M, Cho MH, **Wu AC**. A polygenic risk score for asthma in a large racially diverse population. *Clin Exp Allergy*. 2021 Nov;51(11):1410-1420.





• • •
Pi-I Debby Lin's work examines the impact of per- and polyfluorinated Substances (PFAS) on population health.

LIFECOURSE

Puberty is a key stage during child development. Prior research indicates that early pubertal onset—concerningly, on the rise in the United States and other countries—may increase risk of long-term chronic disease later in life. A better understanding of the early life factors related to puberty is important to develop intervention strategies to prevent earlier pubertal onset. In a nationwide multi-cohort study through the NIH Environmental Influences on Child Health Outcomes program, new work³² by **Izzuddin Aris** with **Emily Oken**, **Marie-France Hivert**, and colleagues examined the importance of early life factors in pubertal development. They found that male children who gained weight or grew faster than their peers in the first five years of life were associated with entering puberty at a younger age. The researchers found similar results in female children but only among those with faster weight

gains during early childhood (two to five years of age). Female children with faster weight gains during infancy (six months to two years of age) and early childhood started their periods earlier and had more advanced pubic hair development. The findings suggest that there are sex-specific associations of faster growth in early life with earlier pubertal onset, indicating that children with faster growth in early life should be monitored closely for earlier onset of pubertal development.

PREVENTION

Institute researchers lead work examining the health impact of per- and polyfluorinated substances (PFAS), a large group of synthetic chemicals nicknamed “forever chemicals” because of their persistence in humans and the environment. PFAS pose high public health concerns due to their universal detection in human blood and potential health risks. Understanding the trends and change of blood concentrations of PFAS is important to evaluate the health impact of PFAS at both the individual- and population-level. New work³³ led by **Pi-I Debby Lin** with **Marie-France Hivert**, **Emily Oken**, and colleagues, examined trends and rate of change of the blood PFAS concentrations for six of the most frequently detected PFAS in overweight or obese U.S. adults and evaluated variations by sex, race/ethnicity, and age. Study results found a downward trend in blood concentrations for all PFAS, except perfluorononanoic acid, that was consistent with the timing for U.S. manufacturers’ phaseout. Male and Black participants consistently showed higher concentrations of perfluorooctanesulfonic acid and perfluorononanoic acid than female and white participants, likely due to differences in exposure patterns, metabolism or elimination kinetics. The findings suggest that national policies, industrial compliance, and stewardship efforts have a large considerable effect on population-level PFAS exposure and highlights the success of addressing chemical exposures in partnership with multiple sectors.

³² **Aris IM**, Perng W, Dabelea D, Ganiban JM, Liu C, Marceau K, Robertson, OC, Hockett CW, Mihalopoulos NL, Kong X, Herting MM, O’Shea M, Jensen ET, **Hivert MF**, **Oken E**, the Program Collaborators for Environmental Influences on Child Health Outcomes. Analysis of Early-Life Growth and Age at Pubertal Onset in US Children. *JAMA Netw Open* Vol. 5 (2), 2022.

³³ **Lin PD**, Cardenas A, Hauser R, Gold DR, Kleinman KP, **Hivert MF**, Calafat AM, Webster TF, Horton ES, **Oken E**. Temporal Trends of Concentrations of Per- and Polyfluoroalkyl Substances Among Adults with Overweight and Obesity in the United States: Results from the Diabetes Prevention Program and NHANES. *Environ Int.* Vol. 157, 2021-12-01.

Davene Wright launched a 2-year NIH grant to design and field a study that aims to identify and prioritize the characteristics of childhood obesity that parents care most about. Her team hypothesizes that focusing risk communication on the specific obesity-related issues that are important to parents may encourage families to address their child's weight status earlier.

STUDY DESIGNS

Robust and flexible methods are crucial in modeling longitudinal, repeated measured biomarkers, especially in the multivariate setting with complex non-linear trajectories. For example, to understand disease progression in primary HIV infection, CD4+ T cell counts and HIV-1 RNA levels are two important biomarkers to observe and analyze simultaneously. **Rui Wang, Tom Chen,** and collaborators proposed³⁴ a joint modeling approach that allows for flexible trajectories for each biomarker, accounts for the potentially time-varying correlation between markers, and can be applied to multiple outcomes of mixed types. They also proposed an implementation procedure to fit such models using standard software.

Researchers are often interested in treatment effects on an event of interest that is subject to competing events. Supposing the event of interest is kidney injury, a competing event (such as death) would make it impossible for the event of interest to subsequently occur. In this case, the effects of treatment on the competing event may indirectly contribute to the total treatment effect on kidney injury, complicating its interpretation. **Jessica Young** and collaborators proposed³⁵ a general theory for alternatives to the total effect in this setting—the *separable effects*. These are effects of modified versions of the study treatment that may equate to effects of the study treatment only through isolated pathways of interest to investigators. They define and clarify how to reason about conditions under which the separable effects can be interpreted as direct,

34 Zhao L, **Chen T**, Novitsky V, **Wang R**. Joint Penalized Spline Modeling of Multivariate Longitudinal Data, with Application to HIV-1 RNA Load Levels and CD4 Cell Counts. *Biometrics* Vol. 77 (3), 2020-07-19.

35 Stensrud MJ, Hernán MA, Tchetgen Tchetgen EJ, Robins JM, Didelez V, **Young JG**. A Generalized Theory of Separable Effects in Competing Event Settings. *Lifetime Data Anal.* Vol. 27 (4), 2021-09-01.

Executive Director Sheila Fireman and Sr. Manager of Operations Vickie Pagliuca plan for the Institute Return to Office.

Our research is focused in the following areas:

COMPARATIVE EFFECTIVENESS

Which strategies are best to optimize outcomes for individuals and populations?

DELIVERY SYSTEMS

How best to improve clinical care processes and outcomes?

PREVENTION

How to modify the risk of acquiring diseases and/or to prevent their secondary consequences?

POLICY

What is the impact of different approaches to health policy, financing, or administering health care insurance?

SURVEILLANCE AND PUBLIC HEALTH

How can health care data be used to support public health?



indirect, or path-specific effects of the study treatment on the event of interest not containing, or only containing, pathways that are mediated by competing events and give statistical estimation procedures. They stress that, unlike previous definitions of direct, indirect, or path-specific effects in the causal inference literature, the separable effects can be subject to empirical scrutiny in future studies.

SURVEILLANCE AND PUBLIC HEALTH

“Real-world data” such as electronic health record data and administrative claims data is increasingly playing a role in studies that support regulatory and health care decisions. Challenges arise because these data sources were not specifically designed for such use and therefore may not always represent or capture the information needed to answer the scientific question at hand. A fundamental question in using real-world data for decision-making is: How certain must we be that the data used to identify an exposure, outcome, or other study variable is what the study intends it to be? When is real-world evidence good enough for decision-making? A new White Paper³⁶ led by **Noelle Cocoros** with **Darren Toh** and international colleagues provides a

36 **Cocoros NM**, Arlett P, Dreyer NA, Ishiguro C, Iyasu S, Sturkenboom M, Zhou W, **Toh S**. The Certainty Framework for Assessing Real-World Data in Studies of Medical Product Safety and Effectiveness. *Clin Pharmacol Ther.* Vol. 109 (5), 2021-05-01.

practical guide to help researchers and regulators assess the “fit-for-purpose” of variables in such situations. They propose three levels of certainty (optimal, sufficient, and probable) to be considered in the context of each study variable, the specific question being studied, the study design, and the decision at hand. The use of real-world data for clinical or regulatory decision-making requires assessing the balance between feasibility and scientific validity—and the framework helps with making that assessment.

Sepsis is a leading cause of death, disability, and cost worldwide. In October 2015, the Centers for Medicare & Medicaid Services began requiring U.S. hospitals to report adherence to the Severe Sepsis and Septic Shock Early Management Bundle (SEP-1) that emphasizes time-sensitive processes of care for patients with suspected sepsis, including lactate measurements, blood culture orders, broad-spectrum antibiotics, intravenous fluids, and vasopressors for persistent hypotension. Understanding if or how these guidelines have affected patient care and outcomes is critical. As part of a portfolio of Institute research to improve our nation’s capacity to monitor sepsis incidence, outcomes, and quality of care, new work led by **Chanu Rhee** with **Michael Klompas**, **Rui Wang**, **Tingting Yu**, and colleagues through the CDC Prevention Epicenters Program examined the association of SEP-1 implementation with sepsis treatment patterns and outcomes in 114 hospitals between 2013 and 2017³⁷. This study showed that SEP-1 implementation was associated with an immediate increase in diagnostic testing but no change in already-increasing rates of broad-spectrum antibiotic use, and no improvements in the combined outcome of in-hospital death or discharge to hospice. These findings suggest that alternate approaches to improving mortality for patients with sepsis are warranted.

37 **Rhee C, Yu T, Wang R**, Kadri SS, Fram D, Chen HC, **Klompas M**; CDC Prevention Epicenters Program. Association Between Implementation of the Severe Sepsis and Septic Shock Early Management Bundle Performance Measure and Outcomes in Patients With Suspected Sepsis in US Hospitals. *JAMA Netw Open* Vol. 4 (12), 2021-12-01.



Noelle Cocoros reviews the RiskScape tool, which provides population-level summaries of specific conditions of interest to public health officials as part of MDPHnet.



Major Institute Programs

MDPHNET: INFECTIOUS AND CHRONIC DISEASE SURVEILLANCE

Institute researchers have a longstanding partnership with the Massachusetts Department of Public Health (MDPH) to build and maintain a distributed data network that uses large practices' electronic health record data to support next-day detection of notifiable diseases such as hepatitis, HIV, and tuberculosis, weekly assessment of influenza-like illness, and near real-time monitoring of chronic illness and its treatment. The network covers approximately 50% of the Massachusetts population. Faculty member **Michael Klompas** leads this work along with **Noelle Cocoros** and **Sarah Willis**. In 2021, Institute researchers worked closely with MDPH in the implementation of electronic case reporting at multiple sites, including the first site located in western Massachusetts. Thirteen sites now report cases of notifiable diseases to MDPH via this system. In addition, Institute researchers collaborated with MDPH to develop and implement a weekly syndromic surveillance report for COVID-19 like illness and a COVID-19 case reporting algorithm for participating sites. See page 11 for more detail. Institute researchers continue working with chronic disease epidemiologists at MDPH to conduct population-level analyses, with recent work focused on understanding the impact of COVID-19 on ambulatory care. Finally, a project led by **Julia Marcus**, **Jessica Young**, and **Douglas Krakower** uses data from various sites to estimate the HIV pre-exposure prophylaxis use needed to reduce HIV incidence to targeted levels among men who have sex with men.

NEXT-D

As part of the Natural Experiments in Translation for Diabetes (NEXT-D) consortium, **Dennis Ross-Degnan**, **Laura Garabedian**, **Christine Lu**, **Anita Wagner**, and

Mei-Sing Ong, along with former faculty member Frank Wharam, lead a series of studies examining the impact of reductions in patient cost sharing on diabetes care and longer-term complications as well as adherence to medications for management of diabetes and related cardiometabolic disorders. The NEXT-D consortia have been funded by the CDC, National Institute of Diabetes and Digestive and Kidney Diseases, and PCORI since 2010, with the Institute team receiving three consecutive 5-year awards.

In 2021, work led by **Dr. Garabedian** published in *BMJ Open*³⁸ found that enrollment in high deductible health plans has increased markedly since 2005. High deductible health plan members with diabetes, cardiovascular disease, and low morbidity had higher annual out-of-pocket costs than corresponding low deductible members. High deductible health plan enrollment coupled with high out-of-pocket costs associated with high deductible health plans may be particularly detrimental to the financial well-being of people with diabetes and cardiovascular disease, who have more health care needs than healthier populations.

The Affordable Care Act (ACA) mandates that primary preventive services have no out-of-pocket costs but does not exempt secondary prevention from out-of-pocket costs. Most commercially insured patients with diabetes have high deductible health plans that subject key microvascular disease-related services to high out-of-pocket costs. Brief treatment delays can significantly worsen microvascular disease outcomes. Work led by Frank Wharam published in *Diabetes Care*³⁹ in 2021 found that high deductible health plan enrollment among people with diabetes was associated with delayed retinopathy diagnosis and vision loss diagnosis and treatment compared with low-deductible plan enrollees. Findings raise concerns about visual health among high deductible health plan members and call attention to discrepancies in ACA cost sharing exemptions.

38 **Garabedian LF, Zhang F, LeCates R, Wallace J, Ross-Degnan D, Wharam JF.** Trends in High Deductible Health Plan Enrollment and Spending Among Commercially Insured Members With and Without Chronic Conditions: a Natural Experiment for Translation in Diabetes (NEXT-D2) Study. *BMJ Open* 2021.

39 **Wharam JF, Wallace J, Argetsinger S, Zhang F, Lu CY, Stryjewski TP, Ross-Degnan D, Newhouse JP.** Diabetes Microvascular Disease Diagnosis and Treatment After High-Deductible Health Plan Enrollment. *Diabetes Care* 2021.



The Project Viva team celebrates the end of the mid-teen research visits.

The NEXT-D consortium has actively engaged junior colleagues during 2021. Felipe Marcondes is a current General Internal Medicine fellow at Mass General Hospital conducting a high-impact study describing delays in diabetes diagnosis among high deductible health plan members. Elise Tremblay is a junior faculty member at Boston Children’s Hospital who has initiated a NEXT-D study about disparities in insulin out-of-pocket costs and use. Jake Quinton, a General Internal Medicine fellow at UCLA mentored by **Dr. Ross-Degnan**, examined a new segmentation strategy for identifying Medicaid patients who would most benefit from a complex case management program.⁴⁰

PROJECT VIVA

Led by Institute faculty, Project Viva is a landmark study of lifecourse influences on health and disease. Continuously funded by the NIH since 1998, Viva has followed a cohort of pregnant women and their (now young adult) offspring for more than two decades. In 2016, Viva investigators received a highly competitive 7-year grant from the NIH Office of the Director to join the Environmental Influences on Child Health Outcomes (ECHO) Program,

a consortium of pregnancy and birth cohort studies around the U.S. **Emily Oken** and **Marie-France Hivert** are the Principal Investigators of Project Viva. Other Viva investigators based at the Institute include **Izzuddin Aris**, **Brittany Charlton**, **Peter James**, **Josh Petimar**, **Joanne Sordillo**, **Karen Switkowski**, **Ann Wu**, and **Jessica Young**.

2021 Project Viva highlights include:

- Completion of the “Mid-Teen” visit. Despite the many challenges related to COVID-19, the Viva team saw 835 Moms and 806 Teens.
- **48** publications, many of which were led by fellows and junior faculty and mentored by more senior investigators on Project Viva. For example:
 - › A study⁴¹ showing that adolescents who have increasing central adiposity (“belly fat”) during childhood are likely to have worsening cardiometabolic health⁴². This study was led by **Allison Wu**, a pediatric gastroenterologist at Boston Children’s and fellow in the Harvard Pediatric Health Services Research Fellowship, for which the Institute is one of the core training sites.

⁴⁰ Quinton JK, Duru OK, Jackson N, Vasilyev A, **Ross-Degnan D**, O’Shea DL, Mangione CM. High-Cost High-Need Patients in Medicaid: Segmenting the Population Eligible for a National Complex Case Management Program. *BMC Health Serv Res.* Vol. 21 (1), 2021-10-23.

⁴¹ **Wu AJ**, **Aris IM**, **Rifas-Shiman SL**, **Oken E**, Taveras EM, Chavarro JE, **Hivert MF**. Associations of Mid-childhood to Early Adolence Central Adiposity Gain with Cardiometabolic Health in Early Adolence. *Obesity (Silver Spring)* Vol. 29 (11), 2021-11-01.

⁴² <https://www.healio.com/news/endocrinology/20211115/central-adiposity-gain-during-childhood-associated-with-worse-cardiometabolic-profile>

- › **Dr. Aris** led work showing that more favorable neighborhood opportunities in mid-childhood predicted better cardiometabolic health from mid-childhood to early adolescence⁴³. In 2021 Dr. Aris received an Institute faculty grant, and also an Opportunity and Infrastructure Fund award from the NIH ECHO program to conduct further research related to neighborhood environments and child health.
- › Postdoctoral fellow **Marcia Pescador Jimenez** published several papers examining how exposure to nature and green space can influence health, including one showing that greater greenspace exposure in early childhood was associated with behaviors in mid-childhood⁴⁴. Dr. Jimenez received a highly competitive K99/ROO award from the National Institute on Aging (NIA) and has recently started a faculty position at Boston University School of Public Health.

THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) SENTINEL SYSTEM

The Harvard Pilgrim Health Care Institute led the development in 2009, and continues a leadership role, of the FDA Sentinel System, a program that allows the FDA to work with the nation's leading health care organizations to monitor the safety and effectiveness of marketed medical products. Sentinel uses a distributed electronic health data network. Curated data covering tens of billions of hospital stays, outpatient visits, and pharmacy dispensings remains with the participating organizations to provide the privacy and security of patients' health information. Sentinel has performed more than **600** queries for the FDA in support of its regulatory decision-making responsibilities, including **103** active query requests⁴⁵ in 2021. Institute investigators were authors of **40** Sentinel presentations and publications⁴⁶ in 2021.

43 **Aris IM, Rifas-Shiman SL, Jimenez MP, Li LJ, Hivert MF, Oken E, James P.** Neighborhood Child Opportunity Index and Adolescent Cardiometabolic Risk. *Pediatrics* Vol. 147 (2), 2021-02-01.

44 **Jimenez MP, Aris IM, Rifas-Shiman S, Young J, Tiemeier H, Hivert MF, Oken E, James P.** Early Life Exposure to Greenness and Executive Function and Behavior: An Application of Inverse Probability Weighting of Marginal Structural Models. *Environ Pollut.* Vol. 291, 2021-12-15.

45 <https://www.sentinelinitiative.org/studies/drugs>

46 <https://www.sentinelinitiative.org/news-events/publications-presentations>

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Darren Toh is the Chief Scientist for the Operations Center of the FDA Sentinel System.

In collaboration with partners at Brigham and Women's Hospital, the Harvard Pilgrim Health Care Institute also co-leads the Sentinel Innovation Center⁴⁷, which is building a new, complementary data system that contains electronic health records from 10 million lives and developing cutting-edge methods and analysis tools to query structured and unstructured electronic health data. Guided by the Sentinel System Five-Year Strategy Plan laid out by the FDA, the Operations and Innovation Centers, together with a Community Building and Outreach Center, are developing and implementing plans to increase the efficiency and responsiveness of the Sentinel System, develop new data sources and more sophisticated methods, broaden the community of users, and extend Sentinel capabilities to allow multi-national collaboration to support assessment of the safety and effectiveness of marketed medical products.

In 2021, the FDA conducted numerous activities within the Sentinel System to protect and promote public health during the COVID-19 pandemic. See page 11 for more detail.

Institute President **Richard Platt** serves as the Principal Investigator of the FDA Sentinel System. Other Sentinel investigators based at the Institute include **Darren Toh, Judith Maro, Noelle Cocoros, Sruthi Adimadhyam, John Connolly, Candace Fuller, Jane Huang, Sheryl Kluberg, Christine Lu, Jennifer Lyons, Ashley Martinez, Ashish Rai, Mayura Shinde, Katherine Yih, Anita Wagner, and Jenna Wong.**

47 <https://www.sentinelinitiative.org/about/sentinel-structure/sentinel-innovation-center-ic>



THE

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Teaching

Our mission includes educational programs that give physicians and population scientists-in-training the tools they need to become health care leaders of the future. We take education beyond the classroom and into the types of settings where these trainees will eventually practice. Our teaching programs are enriched by our focus on the health of populations and our understanding of the kinds of diverse health issues that face our society in the 21st century.

Classroom Teaching

HARVARD MEDICAL SCHOOL

Clinical Epidemiology and Population Health

Institute faculty have led the Clinical Epidemiology and Population Health curriculum at Harvard Medical School (HMS) since 1996. This longitudinal curriculum spans three required courses in the pre-clerkship and post-clerkship phases of the HMS curriculum: Essentials of the Profession I, Transition to the Principal Clinical Experience, and Essentials of the Profession II.

These courses are led by **Laura Garabedian**, **Jason Block**, and **Izzuddin Aris**, and combine teaching of core skills of clinical epidemiology (biostatistics, study design, and critical reasoning) as they apply to the care of individuals and populations with an introduction to key public and population health topics. The curriculum provides students with the skills to critically evaluate evidence and use it appropriately in clinical decisions and population health management. In pre-clerkship courses, students are introduced to key clinical epidemiological concepts and then apply these concepts to make evidence-based decisions for clinical cases. In the post-clerkship course, students employ clinical epidemiological concepts to critically appraise population health research studies and explore and improve population health problems. **Thirteen** faculty, **eight** research scientists, and **four** research fellows participated in teaching the courses in 2021.

Infectious Diseases

Sanjat Kanjilal serves as Director of *Mechanisms of Microbial Pathogenesis*, a core course for second-year MD students in the Harvard-MIT Health Sciences and Technology program. The course introduces students to cutting-edge research ranging from next

generation single cell sequencing platforms for antibiotic susceptibility to artificial intelligence models for early identification of patients with sepsis to vaccine development for SARS-CoV-2. In 2021, Dr. Kanjilal updated the course structure, content, content delivery, diversity of lecturers, and sociocultural context. The course structure shifted from podium lectures to interactive flipped-classroom formats, and problem sets focused on solving challenging real-world cases and “Grand Challenges” in infectious diseases. Content review led to the removal of that which implicitly supported racist and discriminatory practices, replaced with that which recognizes the contributions of under-represented minorities in understanding problems in microbiology and infectious disease. A diverse group of young physician scientists were recruited as lecturers and case discussants. Students gave the course a perfect evaluation.



Izzuddin Aris (pictured above) is the Co-Director of the Essentials 1 Clinical Epidemiology and Population Health course along with Laura Garabedian.



Sanjat Kanjilal leads *Mechanisms of Microbial Pathogenesis*. He revamped the entire curriculum in his first year as Course Director in 2021.

COURSE LEADERSHIP AND TEACHING AT THE HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH

Institute faculty also bring their analytical and statistical methods expertise to lead several courses at the Harvard T.H. Chan School of Public Health (HSPH).

Statistical Inference II

Rui Wang leads this advanced statistical course offered by the Department of Biostatistics. Geared toward doctoral students across the university, the course addresses several advanced topics in statistical inference including limit theorems, multivariate delta method, properties of maximum likelihood estimators, asymptotic relative efficiency, robust and rank-based procedures, resampling methods, and nonparametric density estimation. **Jessica Young** serves as a guest lecturer, discussing causal inference.

Introduction to Statistical Genetics

Sharon Lutz co-leads this course in the Department of Biostatistics with Martin Aryee. Topics include the basic molecular biology underpinnings of genetics, principles from population genetics, family-based and population-based association testing, genome wide association studies, expression QTL analysis and epigenome-wide association studies. **Kurt Christensen** served as a guest lecturer.

Built Environment, Nature, and Health

Peter James leads this course in the Department of Environmental Health, in which students learn how to study the influence of built and natural environments on an array of health outcomes, critically assess the evidence behind associations observed in the literature, and explore the policy and decision-making processes that facilitate built and natural environment changes. **Jason Block** guest lectured in this class on the relationship between the food environment (access and availability of food stores in neighborhoods) and diet and health.

Analysis of Multivariate and Longitudinal Data

Tom Chen leads this course, offered by the Department of Biostatistics. The course presents classical and modern approaches to the analysis of multivariate observations, repeated measures, and longitudinal data.

Gender and Health

Brittany Charlton leads this course, which is the first of six core courses in the Women, Gender, and Health Concentration sequence. It introduces students to gender as a theoretical concept and a category of analysis in public health—specifically, the ways in which gender differentially structures health for women, men, and people of all genders. This course emphasizes the epidemiological aspects of gender analysis and the interactions among gender, class, race/ethnicity, and sexuality.

Fellowships and Mentoring

A productive fellowship can be a catalyst into a successful research career. Institute research fellows receive strong mentorship, support, and regular feedback on their work including how to achieve their desired goals and steps to increasing career trajectory both at the Institute and beyond. We wish the best of luck to the following individuals who completed their fellowships in 2021:

Mohammad Alrawashdeh

Current position: Assistant Professor, Jordan University of Science Technology, Jordan

Diana Contreras Soria

Current position: Postdoctoral Research Fellow, Epidemiology, Harvard T.H. Chan School of Public Health

Alessandra Ferrario

Current position: Technical Officer, World Health Organization (WHO) Regional Office for the Eastern Mediterranean, Cairo, Egypt

Diana Juvinao-Quintero

Current position: Postdoctoral Research Fellow, Epidemiology, Harvard T.H. Chan School of Public Health

Dongdong Li

Current position: Instructor, HMS Department of Population Medicine, Harvard Pilgrim Health Care Institute

Marcia Pescador Jimenez

Current position: Assistant Professor, Epidemiology Department, Boston University School of Public Health

Joshua Petimar

Current position: Research Scientist 1, HMS Department of Population Medicine, Harvard Pilgrim Health Care Institute

Whitney Irie

Current position: Lecturer, HMS Department of Population Medicine, Harvard Pilgrim Health Care Institute

Jenny Sun

Current position: Senior Manager, Global Medical Epidemiology, Pfizer

Jeremy Weinberger

Current position: Assistant Professor of Medicine, Tufts University School of Medicine; Attending Physician, Tufts Medical Center Division of Pulmonary, Critical Care, and Sleep Medicine

Jiebing Wen

Current position: Assistant Professor, Department of Healthcare Leadership & Management, Medical University of South Carolina

Alison Wu

Current position: Instructor, Boston Children's Hospital Division of Gastroenterology and Nutrition



Diversity, Equity, and Inclusion (DEI)

The Institute remains committed to addressing the systemic and structural racism and other causes of inequity that are so prevalent in our society. Despite the challenges of the pandemic, Institute members have maintained engagement in much-needed conversation about the legacy of racial injustice in the United States through a variety of new initiatives and increased participation in standing programs. In 2021, we focused our efforts on improving communication, expanding disparities research, deepening our commitment to service, and welcoming experts to the Institute for educational programs:

Our portfolio of health equity research continues to expand with new and important topics (detailed on page 13).

The DEI Reading & Discussion group met 6 times, discussing 5 written works, and 1 documentary by artists of color.

The DEI Recruitment and Retention subcommittee developed more inclusive job descriptions and postings.

14 Institute mentors and 5 students/participants took part in the Job Shadowing program, a half-day program in partnership with Boston Bottom Line. In this program, which helps diverse first-generation college students gain insight and experiences into industries of interest before entering the workforce, the students learned about the Institute, took part in a career panel and mock interviews, and had their resumes reviewed.

The Institute engaged 3 speakers: Keith Marion, who spoke about Healthy Conversation, Pam Garramone who spoke about positive psychology, and Jackie Glenn, who spoke about Unconscious Bias.

The DEI Communications subcommittee launched an internal monthly newsletter highlighting upcoming events and trainings at the Institute and beyond; funding opportunities for researchers; and news.

Welcome to the Institute: Introducing New 2021 Fellows

HARVARD MEDICAL SCHOOL FELLOWSHIP IN GENERAL MEDICINE AND PRIMARY CARE

The Institute is one of six sites for HMS's Fellowship Program in General Medicine and Primary Care, one of the leading training programs in the nation. For over two decades, the Fellowship has provided research training and experience under the direction of highly qualified mentors. The new Institute fellow in 2021 is:

Bryant Shuey

Mentor: Hefei Wen

Focus: Substance use disorders in vulnerable populations and health outcomes related to cost-sharing; learning how to analyze the effects of health policies on health outcomes.

HARVARD-WIDE PEDIATRIC HEALTH SERVICES RESEARCH FELLOWSHIP

The Institute is one of three sites for the Harvard-wide Pediatric Health Services Research Fellowship, which trains pediatric generalists and subspecialists to address critical questions about how to improve the capacity of the U.S. health care system to meet the needs of children and families, including socioeconomically disadvantaged and minority populations. The new Institute fellow in 2021 is:

Isdin Oke

Mentor(s): Alison Galbraith, Ann Wu

Focus: Identifying disparities in vision care and surgical outcomes; cost-effectiveness analysis of novel screening strategies for eye disease.

FELLOWSHIP IN HEALTH POLICY AND INSURANCE RESEARCH

As health care delivery and health insurance systems rapidly change, the need for individuals trained in novel methods to produce sound evidence—the kind that

“Our fellowship programs are not just about training junior investigators, we build connections. We maintain those collaborations and develop long-term relationships.”

LAURA GARABEDIAN

Institute Director of Teaching and
Co-Director, Fellowship in Health Policy
and Insurance Research

will inform policy and program changes for the betterment of population health—grows more urgent. Founded in 2001, the fellowship celebrated its 20th anniversary in 2021. Fellows who entered the program in 2021 include:

Natalia Kunst

Mentor: Ann Wu

Focus: Weighting tradeoffs among costs, benefits, and risks in cancer prevention and treatment policies, and designing and prioritizing clinical research when resources are limited.

Yang Liu

Mentor(s): Natasha Stout, Hao Yu

Focus: Social determinates of healthy ageing, injury prevention and cost burden of fall related injuries.

Yanlei Ma

Mentor: Hao Yu

Focus: The Affordable Care Act and the health care workforce.

Yue (Ariel) Zhou

Mentor: Hao Yu

Focus: Assessing policy impacts on cancer therapy approvals, access, and use in China.

THOMAS O. PYLE FELLOWSHIP

Endowed by Harvard Community Health Plan to honor its former Chief Executive Officer, the Thomas O. Pyle Fellowship Fund provides funding for individuals studying critical topics in domestic health policy and health care systems. Individuals receiving Pyle fellowships in 2021 include:

Whitney Irie

Mentor: Julia Marcus

Focus: Preexposure prophylaxis access and implementation for HIV prevention.

Natalia Kunst

Mentor: Ann Wu

Focus: Weighting tradeoffs among costs, benefits, and risks in cancer prevention and treatment policies, and designing and prioritizing clinical research when resources are limited.

Yanlei Ma

Mentor: Hao Yu

Focus: The Affordable Care Act and the health care workforce.

Joshua Petimar

Mentor: Jason Block

Focus: The effects of public health nutrition policies on diet quality.

Mahnum Shazhad

Mentor(s): Christine Lu, Mei-Sing Ong, Anita Wagner

Focus: Provider decision making in the context of pharmaceuticals with a focus on accelerated approvals and deadoption decisions.

Nicolas Trad

Mentor: Anita Wagner

Focus: The impact of high-deductible health plans on metastatic cancer care.



Institute fellows, along with Health Policy and Insurance Research Fellowship co-Director Anita Wagner, meet for lunch on the Institute balcony.

Honors/ Awards

GORDON MOORE AWARD FOR EXCELLENCE IN MENTORING

The Harvard Pilgrim Health Care Institute strives to provide its staff, fellows, faculty, and leadership with strong mentoring to facilitate their development. Over the past 3 decades, we have evolved an active internal mentoring program through multiple processes. The annual Gordon Moore Award for Excellence in Mentoring celebrates outstanding Institute members who inspire, support, and catalyze a colleague's development to become the best they can be in their careers and lives. A nomination for excellence in mentoring appreciates individuals who have had a transformative role in the professional or personal development of one or more mentees.



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Dennis Ross-Degnan, along with staff, fellows, and faculty from the Health Policy and Insurance Research division, stands in front of a map showing all of the places around the world from which he had fellows.

Ann Wu, Associate Professor

Dr. Wu was the 2021 recipient of the Gordon Moore Excellence in Mentoring Award. Dr. Wu embodies all qualities of outstanding mentors through developing others' talents, serving as a role model, coach, and supporter, and through advocating for work-life balance.

WILLIAM SILEN LIFETIME ACHIEVEMENT IN MENTORING AWARD, HARVARD MEDICAL SCHOOL

Established in 1997, the William Silen Lifetime Achievement in Mentoring Award, presented by the Office for Diversity, Inclusion & Community Partnership, honors and acknowledges the lifetime commitment Dr. Silen made to mentoring students, residents and faculty. Recipients of this award have contributed a minimum of 20 years of service in mentorship to support professional and personal development at all stages of career development.

Dennis Ross-Degnan, Associate Professor

Dr. Ross Degnan was the 2021 recipient of the William Silen Lifetime Achievement in Mentoring Award from Harvard Medical School. Dr. Ross-Degnan received the award for his lifetime commitment to a career marked by inspiring, supporting, and catalyzing the professional and personal development of generations of colleagues.

THE SUZANNE AND ROBERT FLETCHER PRIZE IN POPULATION MEDICINE

In 2021, the Institute awarded the fourth annual Suzanne and Robert Fletcher Prize in Population Medicine, named for Professors Emeriti Suzanne and Robert Fletcher, who have been national leaders in advancing the field of clinical epidemiology. An expert panel of Institute faculty

Robert H. Ebert Career Development Awards

The Robert H. Ebert Career Development Award, named for the founder of Harvard Community Health Plan and former Dean of Harvard Medical School, supports the work of Institute faculty who demonstrate exceptional promise in the area of ambulatory care, primary care, or preventive medicine.

These awards provide resources to develop leading-edge programs in teaching and research and to pursue scientific and professional activities consistent with the Institute's mission. Congratulations to 2021's new awardees:

LAURA GARABEDIAN | Building Capacity For Research Using All-Payers Claims Databases

State all-payers claims databases (APCDs) are a unique source of data for the evaluation of health insurance policies and include data on health care enrollment and claims for most residents in a state over time across coverage types, allowing for the longitudinal study of insurance transitions and health care utilization and outcomes. Dr. Garabedian will use her Ebert Award to acquire Massachusetts APCD data and build the Institute's capacity to use APCD for externally-funded projects.

SHARON LUTZ | Developing Novel Statistical Methods To Account For Heterogeneity Due To Sex In Genetic Association Studies

Dr. Lutz will use her Ebert Award to develop novel statistical methods to account for heterogeneity due to sex in genetic association studies. These methods can be applied to a wide range of phenotypes in multiple studies both within and outside of the Institute, including ADAPT, PREDICT, and Gen3G.

JUDITH MARO | Adapting Case-Based Signal Detection For Medication In Pregnancy Studies

Dr. Maro's Ebert Award, focused on developing and testing methods for longitudinal signal detection, will offer her the ability to demonstrate the value of signal identification in outcomes and disease surveillance settings, such as outcome-indexing and COVID-19. Such demonstration projects will open up new networks and relationships and provide new funding opportunities.

JESSICA YOUNG | Estimands In Longitudinal Causal Inference: Interpretation, Causal Diagrams, And Simulation Studies

Dr. Young's Ebert Award will support her work towards improved statistical methods for policy-relevant causal inference in real-world data under transparent assumptions.

reviewed submissions from Harvard Medical School and Harvard School of Dental Medicine students, judging each by the importance of the topic for population health, clarity of expression, and quality of writing.

Maya Behn, Erika Lynn-Green, and Inam Sakinah, Harvard Medical School students

Their winning submission "Early COVID-19 Vaccination for Incarcerated Populations: Prioritizing Population Health", makes the case for prioritizing highly impacted populations inside carceral facilities and their home communities from the perspectives of social justice, equity, prevention, and vulnerability.

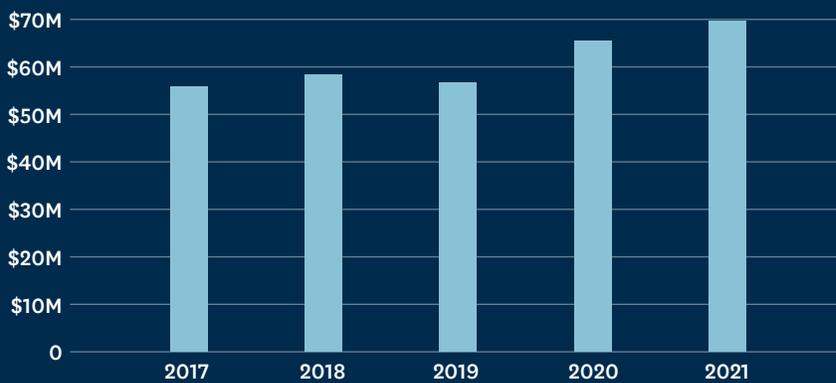
EBERT FELLOWSHIP, HARVARD MEDICAL SCHOOL ELEANOR AND MILES SHORE FACULTY DEVELOPMENT AWARD

Alon Peltz, Assistant Professor

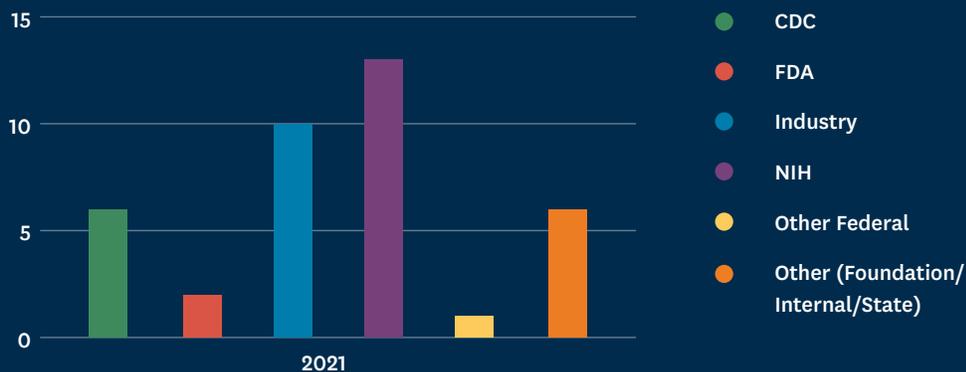
The Ebert fellowship is awarded to junior faculty to support research and career development in population medicine. For his Ebert Fellowship project, Dr. Peltz is conducting a mixed-methods study in the health plan setting to identify racial bias in data algorithms used for enrolling members in care management programs.

2021 by the Numbers

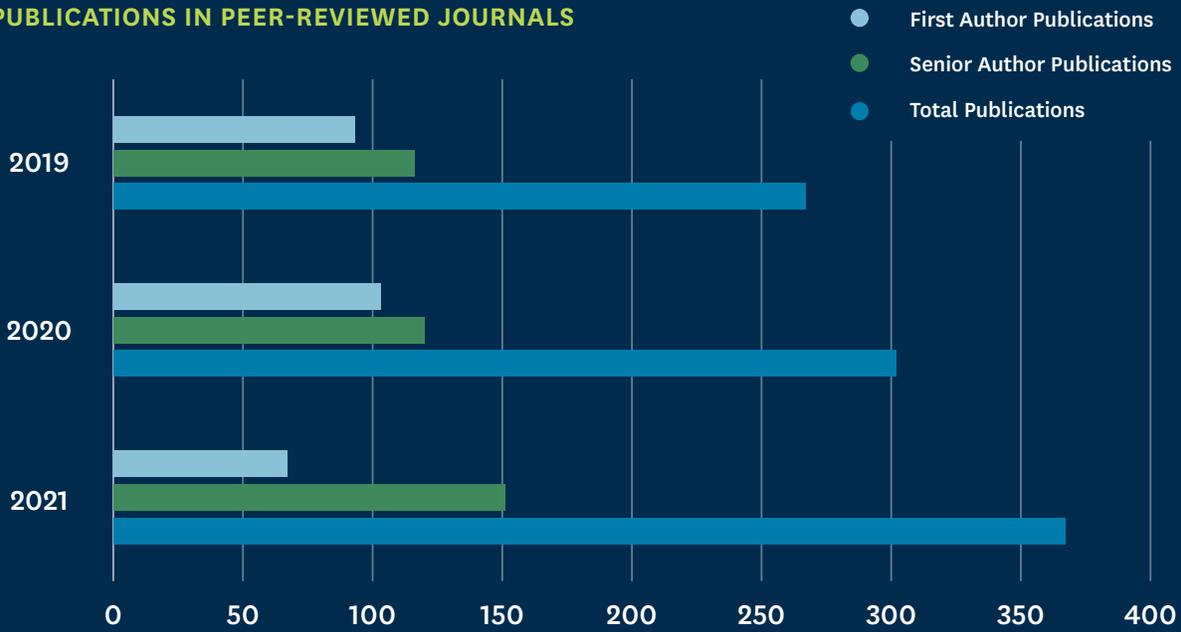
TOTAL RESEARCH INCOME (IN MILLIONS)



NUMBER OF NEW AWARDS (BY FUNDER)



PUBLICATIONS IN PEER-REVIEWED JOURNALS



AWARDS + GRANTS



129
ACTIVE GRANTS/
CONTRACTS



109
NEW PROPOSALS
SUBMITTED



38
NEW AWARDS



367
PUBLICATIONS



\$69.7M
IN GRANT/CONTRACT REVENUE

Mission

The Institute's mission is to improve health care delivery and population health through research and education, in partnership with health plans, delivery systems, and public health agencies.

