February 23, 2024

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Positions

Dr. Lachin is Research Professor of Biostatistics and Bioinformatics, and of Statistics, who has held various positions during his 50+ years of service to the George Washington University.

Dr. Lachin received his B.S. in experimental psychology from Tulane University in 1965 under the mentorship of the late Arnold Gerall and Davis Chambliss, and his Sc.D. in Biostatistics from the University of Pittsburgh in 1972. In 1973 Dr. Lachin joined George Washington University as Assistant Research Professor of Statistics (100% research, no teaching) at The Biostatistics Center, then a research facility in the Department of Statistics, predating the later founding of the School of Public Health and Health Services in 1997. He was promoted to Associate Research Professor in 1977 and Research Professor in 1982. In 1984 he was appointed Professor of Statistics, and tenure was awarded in 1987. Dr. Lachin first taught a course in 1978 and from then until 2006 Dr. Lachin divided his efforts between the Department of Statistics (and later the School of Public Health) and the Biostatistics Center.

In 2000 Dr. Lachin's faculty appointment was shifted from the Department of Statistics to the Department of Epidemiology and Biostatistics in the recently established School of Public Health and Health Services. In 2006 he stopped teaching and in 2014 he relinquished his tenured appointment to become Research Professor, devoting all of his effort to direct nationwide medical research programs in diabetes. He is now partially retired.

Dr. Lachin also served as Director of The Biostatistics Center from 1988-2000, and as Assistant Director from 1980-1985, as Co-Director from 1985-1988 and 2000-2010, and as Interim Director from 2010-2012. The Biostatistics Center is the largest research program in the University with over 120 staff and funding exceeding $40-60 million annually, almost all from the National Institutes of Health (NIH).

Contributions to Academics:

From 1984 – 2006 Dr. Lachin was in a regular faculty teaching position, first in the Department of Statistics and later in the School of Public Health and Health Services. While teaching in the Department of Statistics, Dr. Lachin introduced graduate courses into the department curriculum on data analysis, the design of clinical trials, survival analysis and biostatistical methods, all core subjects in Biostatistics.

Dr. Lachin chaired the establishment of a Masters of Science Program and a PhD program in Biostatistics, and like programs in Epidemiology. The program was launched in 1995 as a joint initiative of the Department of Statistics and the then-named Graduate Program in Public Health. That in turn led to establishment of the Milken Institute School of Public Health on July 1, 1997. Dr. Lachin was the graduate Program Director from 1995 – 2004.

Dr. Lachin also mentored the dissertation research of 16 doctoral students in Statistics, Biostatistics or Epidemiology. Dr. Lachin no longer teaches but continues to supervise doctoral student dissertation research.

Sponsored Research:

Dr. Lachin has served as the Principal Investigator (PI) or co-PI for 12 studies funded by the National Institutes of Health. Here are the most important.

Diabetes Control and Complications Trial (DCCT: 1982-1998): In 1981 the National Institute of Diabetes, Digestive and Kidney Disease issued a request for proposals to serve as the Data Coordinating Center for the DCCT. The GWU Biostatistics Center with Dr. Lachin as PI was selected to fill this role. The research group of 28 clinical centers and five laboratories enrolled a cohort of 1441 subjects with type 1 diabetes who were treated and followed for a mean of 6.5 years. The objective was to test the glucose hypothesis that microvascular complications were a result of extended periods of hyperglycemia. Participants were randomized to intensive therapy with near normal glucose levels versus standard of care with no glucose target. The primary outcome was the appearance or progression of retinopathy (eye lesions).

The trial was stopped early by the study's Data Safety Monitoring Board (DSMB) for clear evidence of efficacy of the intensive therapy, reducing microvascular complications by 26-63% over the 6.5 years. These results established glycemia as a major causal risk factor and mechanism for the onset of Type 1 diabetes complications, and set a ***new worldwide standard for Type 1 diabetes care***. The DCCT led to therapeutic interventions that drastically reduced diabetes-related blindness, renal failure, and amputation, from 30%, 35%, and 12% pre-DCCT to 1%, 1%, and 1% post-DCCT, respectively.

The DCCT spurred development of clinical guidelines for Type 1 diabetes by the American Diabetes Association (ADA), spurred creation of the ***National Diabetes Education Program*** to disseminate the findings to the public (www.ndep.nih.gov), stimulated research efforts to develop tools and therapies that aid patients in achieving control of blood glucose levels, and incentivized many states to provide mandatory coverage of supplies for intensive therapy.

The primary publication for the DCCT has been cited more than 23,000 times, the most frequent citation in the diabetes treatment literature. The Harvard Health Letter named the DCCT in 1993 as the most significant advancement in medicine, “because it asked important questions, was carried out with great care, and generated clear-cut answers. Its results will help millions of people with diabetes live longer and healthier lives.” The DCCT Research Group was awarded the ***Charles H. Best Medal*** in 1994 by the American Diabetes Association for "Distinguished Service in the Cause of Diabetes.” As the Principal Investigator of the DCCT Coordinating Center, Dr. Lachin was a Co-recipients of the Best Medal.

Epidemiology of Diabetes Interventions and Complications (EDIC,1994 to 2027): Previously, Dr. Lachin was also the PI for the EDIC study that is a longitudinal follow-up study of 1441 participants originally enrolled in the DCCT. The DCCT established that intensive therapy to control glucose levels markedly reduced the risk of various complications of diabetes. The EDIC also showed that reductions in glycemia during the DCCT had long lasting beneficial effects during EDIC, a phenomenon termed ***metabolic memory***. Dr. Lachin served as Principal Investigator of DCCT/EDIC from the inception in 1982 through 2020 at which time he relinquished that responsibility to colleagues.

Diabetes Prevention Program (DPP; 1994–2003, Co-PI 1994-96 and 1999-2002): The DPP was a randomized clinical trial designed to evaluate interventions for the prevention of diabetes in people with impaired glucose tolerance. Participants were randomized to: (i) the intensive lifestyle intervention (weight loss and increased calorie expenditure), (ii) metformin, or (iii) placebo. During the study, 3,234 participants from 27 US sites, with 45% from minority groups, disproportionately affected by type 2 diabetes were enrolled. Trial participants were followed for 2-5 years with quarterly visits. The lifestyle intervention reduced the risk of developing diabetes by 58% over a 3-year period. The corresponding risk reduction for metformin was 31%. The primary publication for the DPP trial was co-authored by Dr. Lachin and has been cited more than 24,000 times, the most frequent citation in the diabetes prevention literature. The trial was selected as one of ***"Drazen's Dozen"*** by Jeffrey Drazen, Editor-in-Chief of the *New England Journal of Medicine*, as one of the 12 most impactful studies published during his 19-year tenure, and was cited as an example of comparative effectiveness research from the ***Federal Coordinating Council for Comparative Effectiveness Research*** in a report to the President of the United States and the U.S. Congress.

Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE). From 2010 to December, 2023 Dr. Lachin was the PI of the Coordinating Center. Another colleague now serves as PI. The project is now in the analysis and publication stage and is funded until early 2025. Since January 1, 2024 Dr. Lachin has served as co-investigator and another colleague now serves as Principal Investigator. GRADE evaluated the relative effectiveness and safety of four pharmaceuticals for the treatment of subjects with recently-diagnosed type 2 diabetes. In 45 clinical centers nationwide, 5047 participants were treated and followed for an average of 5 years. All four treatments were able to lower glucose levels initially but after 4 years those treated with liraglutide or insulin glargine were able to maintain better glucose control. In 2023 the GRADE study received a ***Top 10 Clinical Research Achievement Award*** from the Clinical Research Forum.

Previously Dr. Lachin was Co-investigator and/or co-PI for the biostatistical coordinating centers for the ***Type 1 Diabetes Trial Network*** (2001-2008), the ***Study of Plasmapheresis in Severe Lupus Nephritis*** (1981-1988), and the ***National Cooperative Gallstone Study*** (1980-1984), among others. He was also the initial co-PI for the ***Study of Captopril (Angiotension Converting Enzyme Inhibition) Treatment in Diabetic Nephropathy***, later transferred to another colleague. In the design of the study, Dr. Lachin established ***"doubling of serum creatinine"*** as an outcome, later FDA-approved in treatment trials for nephropathy.

Almost all of Dr. Lachin's research was funded by the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health. The total funding from the NIH to Dr. Lachin's research was ***$471,569,626*** since 1985. There are no records prior to 1985.

Honors and Awards:

Additional honors and awards since 2003 include

- Distinguished Alumni Award for Research. University of Pittsburgh School of Public Health, December 2022
- Lifetime Achievement Award, 25th Anniversary Celebration of the George Washington University Milken Institute School of Public Health, October, 2022.

- Co-recipient with Barbara Braffett and Ionut Bebu, 2020 American Diabetes Association Michaela Modan Memorial Award, presented by the Public Health & Epidemiology Interest Group.
- Second Annual Robert F. Woolson Lecture, Department of Biostatistics, College of Public Health, University of Iowa, 2011.
- 2010 Oscar and Shoshana Trachtenberg Prize for Scholarship, The George Washington University, May, 2010.
- 2010 Distinguished Researcher Award, The George Washington University Medical Center, March, 2010.
- Inaugural Fellow, Society for Clinical Trials, 2006

Bibliometrics:

Dr. Lachin is the author or co-author of 5 books on biostatistics and clinical trials. The graduate reference text, with Dr. William Rosenberger, ***Randomization in Clinical Trials: Theory and Practice***, John Wiley and Sons (First Edition, 2002, Second Edition, 2016), received the American Association of Publishers award for "***The Professional and Scholarly Title of 2002 In Mathematics and Statistics.***"

He is also the author of the graduate reference text ***Biostatistical Methods, The Assessment of Relative Risks,*** John Wiley and Sons (First Edition, 2000, Second Edition, 2011), that remains in print over the past 25 years and has been published in Japanese. He is also a co-editor of the book ***The Randomized Clinical Trial and Therapeutic Decisions***, Marcel-Dekker, 1982.

Dr. Lachin's bibliography below classifies papers according to subject matter, statistical (methodological) or medical (clinical), and whether or not the paper was peer reviewed (referred).

	Refereed	Non-refereed	Total
Statistical	77	18	95
Medical	322	12	334
Total	399	30	429

Among statistical papers, 77 were referred and 18 non-referred for a total of 95. For medical, 322 were referred and 12 not for a total of 334. Combined, nearly 400 (399) papers were referred for a total of 429 papers. These include 20 papers in The *New England Journal of Medicine* as a named author or un-named member of the writing team, and one as the Chair of the writing team (first author).

Per Google Scholar as of February 16, 2024, Dr. Lachin's H-Index is 101, meaning that 101 of his peer reviewed papers have been cited at least 101 times. His i10 Index is 233, and his papers had received 103,576 citations. Further, per a 2020 report from the Meta-Research Innovation Center at Stanford University (METRICS), among 8 million authors world-wide since 1960, the number of citations to Dr. Lachin's work was ranked at the 99.94th percentile over his career, or in the top 6/100th of a percent, in the fields of Endocrinology & Metabolism, Clinical Medicine, and Statistics & Probability.

Per the Exaly Search Engine, as of 02/24/2023, Dr. Lachin is cited as the:

Most cited author in *Contemporary Clinical Trials* from articles published in 1981 and in 1988.
Most cited paper in *Contemporary Clinical Trials* from 1981 and 1988
Most published author in *Contemporary Clinical Trials* during 1988 and Lifetime.
Most cited author in *The New England Journal of Medicine* (2002)
Most cited paper in *The New England Journal of Medicine* (2002, 2015)
Most cited author in *Gastroenterology* (1982)

Medical Scholarship and Impact

Dr. Lachin is an internationally recognized scholar in all aspects of diabetes and its various vascular complications, and his medical publications have established the primacy of hyperglycemia (elevated glucose levels) as the principal determinant of risk of these complications, especially in type 1 diabetes. As a result, intensive control of glucose is now accepted world-wide as the goal of therapy in type 1 diabetes. The Diabetes Control and Complications Trial Research Group was awarded the Charles H. Best Medal in 1994 by the American Diabetes Association for "Distinguished Service in the Cause of Diabetes."

His recent co-authored medical papers include the demonstration that intensive treatment of type 1 diabetes leading to near normal levels of glucose during the DCCT can reduce mortality and the progression of retinal and renal microvascular complications during the DCCT/EDIC study. This phenomenon called ***metabolic memory*** was first reported in a landmark paper in the *New England Journal of Medicine* in 2000 for which Dr. Lachin was the first author. He has since published other papers as sole or lead author that describe the long-term waning of this phenomenon, called ***metabolic amnesia***.

Dr. Lachin also was the second author of two recent landmark papers in the *New England Journal of Medicine* on the principal results of the GRADE study that evaluated the 5 – 7 year relative effectiveness and safety of 4 established glucose lowering agents, for all of which there was no long-term data. All agents were safe with different degrees of success in the ability to maintain near normal levels of glycemia.

Dr. Lachin also contributed to the evaluation of the effects of Type 2 diabetes medications on cardiovascular disease risk. In the study of sitagliptin there was no increased risk, and in the study of empagliflozin the risk was significantly reduced.

Biostatistical and Methodology Impact

Dr. Lachin is recognized as one of the world's experts on the evaluation of sample size and power for medical studies, the theory and application of methods of random treatment assignment (randomization) in clinical trials, for methods of interim (e.g. group sequential) analysis, the role of a Data and Safety Monitoring Board, and various aspects of event-time (survival analysis), among others.

Dr. Lachin's recent methodological publications include papers on the Wei-Lachin multivariate one-directional test for multiple outcomes and event-times, on the fallacies of analyses using Last Observation Carried Forward, and the evaluation of sample size and power for survival analyses with multiple groups, strata and quantitative covariates in a Cox Proportional Hazards regression model.

Also noteworthy are two joint papers with colleague Dr. Ionut Bebu and others from the EDIC study. The first paper describes the statistical methods that were developed to estimate the optimal schedules for detection and treatment of disease progression from successive examinations. The second paper then describes the application to the frequency of retinal examinations for surveillance of progression of diabetic retinopathy.

Bebu I, Lachin JM. Optimal screening schedules for disease progression with application to diabetic retinopathy. *Biostatistics*. 2018;19(1):1-13.

The DCCT/EDIC Research Group (Writing Committee: Nathan DM, Bebu I, Hainsworth D, Klein R, Tamborlane W, Lorenzi G, Gubitosi-Klug R, Lachin JM). Frequency of evidence-based screening for retinopathy in type 1 diabetes. *N Engl J Med* 2017, 376(16):1507-16.

We also provide an online tool to assist physicians to provide the optimal schedule for individual patients.

Dr. Lachin has been a member of virtually every major national or international society in statistics/biostatistics/clinical trials and diabetes. He has been elected a Fellow of the Society for Clinical Trials, the American Statistical Association and the Royal Statistical Society, and a member of the International Statistical Institute. He has held offices in various societies and was President of the Society for Clinical Trials for 2002-2003.

He has lectured widely on his research on Diabetes and statistical methodology at meetings of the American Diabetes Association, the World Diabetes Congress of the International Diabetes Federation (IDF), the European Association for the Study of Diabetes, the American Statistical Association, the International Biometrics Society and the Society for Clinical Trials; and at workshops and symposia organized by the National Institutes of Health, the Juvenile Diabetes Association, and the National Academy of Sciences, among many venues.