### **BIOGRAPHICAL SKETCH**

NAME: Sarit Polsky

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

POSITION TITLE: Assistant Professor of Medicine and Pediatrics at the Barbara Davis Center for Childhood Diabetes and University of Colorado School of Medicine

#### EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion MM/YYYY	FIELD OF STUDY
Brandeis University	B.A.	1999	Comparative Literature
Johns Hopkins University, Bloomberg School of Public Health	M.P.H.	2002	Master of Public Health
Medical School for International Health & Medicine in Collaboration with Columbia University Medical Center	M.D.	2004	Medicine

### A. Personal Statement

In my career, I have had two main research foci: metabolic diseases (diabetes mellitus and obesity) and women's health. My early research examined the risk to develop Type 2 Diabetes (T2D) and obesity. I completed my Internal Medicine residency training in the Women's Health track. I joined the staff at the Barbara Davis Center (BDC) for Diabetes in 2014. Since that time, I focused my clinical and research activities on type 1 diabetes (T1D) and have been the director of the Pregnancy and Women's Health Clinic at the BDC, Adult Clinic. I have been a principal investigator or co-investigator on numerous clinical trials evaluating technologies and therapeutics in individuals with T1D. These studies include advanced diabetes technologies such as continuous glucose monitoring (CGM) systems, insulin pumps, and artificial pancreas therapies and the therapeutics include new insulin formulations, delivery of new insulins through insulin pumps, and treatments for prevention of diabetes complications. Some of these clinical trials evaluated efficacy of said therapies in adults (men and women) with T1D and some were focused exclusively on pregnant women. I was a site-PI in the PERL Study (Preventing Early Renal Loss in Diabetes), an international, multi-site randomized controlled trial that investigated if administration of a uric acid-lowering medication could help prevent or decrease the progression of kidney problems in individuals with T1D. Since 2014, I have received continuous funding for numerous clinical trials for diabetes technologies and therapies in adults with T1D. I have been a writing group member for multiple manuscripts from the T1D Exchange Clinic Network and Registry, which was the only real-world and largest registry of individuals with T1D in the U.S.A., and the T1D Exchange QI (Quality Improvement) Collaborative. I am the PI for the first study in the United States approved by the FDA to examine artificial pancreas technology in pregnancies associated with T1D.

ACTIVITY/ OCCUPATION	START (mm/yy)	END (mm/yy)	FIELD	INSTITUTION/ COMPANY	SUPERVISOR/ EMPLOYER
Teaching Assistant	08/01	10/01	Epidemiology I	Johns Hopkins Bloomberg School of Public Health	Dr. Jonathan Samet
Internship and Residency	07/04	06/07	Internal Medicine	Jacobi Medical Center	Dr. Charles Nordin
Fellowship	07/07	06/08	Clinical Research	Montefiore Medical Center	Dr. Andrea A. Howard
Hospitalist	02/08	03/08	Internal Medicine	Montefiore Medical Center	Dr. John Loehner
Fellowship	07/08	09/12	Endocrinology and Clinical Research	University of Colorado*	Dr. Bryan Haugen
Instructor	10/12	02/14	Endocrinology	University of Colorado*	Dr. Bryan Haugen

B. Positions and Honors

Assistant	02/14	present	Type 1 DM and	Barbara Davis Center	Dr. Satish Garg
Professor			Endocrinology		
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\*University of Colorado, Anschutz Medical Campus

### **Certification and Licensure**

- 2007 State of New York, Medical License
- 2007 American Board of Internal Medicine
- 2008 State of Colorado, Medical License
- 2010 State of New Mexico, Medical License
- 2011 American Board of Endocrinology, Diabetes, and Metabolism

## Academic and Professional Honors

- 1999 Magna Cum Laude Graduate, Brandeis University
- 1999 Highest Honors Graduate, Brandeis University
- 2009 Abstract Travel Grant Award, Trainee Day at Endocrine Society Annual Meeting
- 2017 Chosen for the T1D Exchange Clinic Network and Registry Steering Committee (18 month term)

## **Professional Memberships**

2007-current American Medical Association 2015-current The American Diabetes Association

## C. Contributions to Science

1. Early on, I focused on risk factors for developing T2D. I studied how alcohol affected risk of developing T2D among 3,175 adults with impaired fasting glucose, impaired glucose tolerance, and a body mass index ≥24 kg/m<sup>2</sup> in the Diabetes Prevention Program (DPP). Moderate alcohol consumption reduced the risk for diabetes in individuals with prediabetes. I worked on study design, interpreting data, and manuscript writing. One risk factor for hyperglycemia is taking anti-viral medications for HIV. In 377 adults with or at-risk for HIV who had 2 oral glucose tolerance tests over time, 7% screened positive for DM at baseline. On follow-up (18.6 months), 5% developed DM and 16% developed prediabetes based on elevated fasting plasma glucose (52% of cases), 120-minute glucose (33%), or both (15%). Incident hyperglycemia was independently associated with higher age and body mass index. I conducted the statistical analysis, interpreted the data, and led manuscript writing.

- a) Crandall JP, **Polsky S**, Howard AA, Perreault L, Bray GA, Barrett-Connor E, Brown-Friday J, Whittington T, Foo S, Ma Y, Edelstein SL; Diabetes Prevention Program Research Group. Alcohol consumption and diabetes risk in the Diabetes Prevention Program. *Am J Clin Nutr.* 2009 Sep; 90(3): 595-601. [doi: 10.3945/ajcn.2008.27382. PMID: 19640960. PMCID: PMC2728644]
- b) Polsky S, Floris-Moore M, Schoenbaum EE, Klein RS, Arnsten JH, Howard AA. Incident hyperglycemia among older adults with or at-risk for HIV infection. *Antivir Ther.* 2011; 16(2): 181-8. [doi: 10.3851/IMP1711. PMID: 21447867. PMCID: PMC3552387]
- 2. I identified strategies to address overweight/obesity. I examined a profile of 12 hormones and cytokines related to adiposity, satiety/hunger, and inflammation in 61 adults. Participants who lost ≥8% body weight had changes related to less fat mass and unfavorable hunger signals. I contributed to the sub-study design, data interpretation, and led manuscript writing. I conducted 3 studies examining effects of herbs/spices on food consumer liking. Adults (n=150) consumed an entrée with side dishes and were randomized to order of full fat, plain reduced fat, and reduced fat plus spice. Adding herbs and spices to reduced-fat foods did not compromise food liking for most meal items. I was lead study coordinator, created databases, performed some study visits and data entry, and contributed to study design and manuscript writing. I examined a low-cost weight loss program (Take Off Pounds Sensibly, TOPS) among different groups. I was involved in a cohort study with 10 health care systems across the U.S. in SPAN (Scalable Partnering Network) for comparative effectiveness research on bariatric surgery. Among 7,457 individuals who underwent adjustable gastric banding (AGB) or Roux-en-Y gastric bypass (RYGB) over a period of 5 years with follow-up for another year, the risk of a 30-day major adverse event was low (hazard ratio 0.46, p=0.006), of a subsequent intervention was higher for AGB (3.31, p<0.001), and of subsequent hospitalization was greater for RYGB (0.73, p<0.001). Weight loss was greater with RYGB. I contributed to study concept and design, data analysis and interpretation, and manuscript revision. Care management intensity (CMI) among 9 centers was evaluated in a retrospective cohort study supplemented by surveys. 4,433 individuals underwent RYGB or AGB between 2005 and 2009. Preoperative CMI was low in 2 sites, moderate in 5, and high in 2. Postoperative CMI was low in 5 sites and high in 4. There

was no association between CMIs and postoperative change in BMI. This study elucidated the heterogeneity across sites. I contributed to study concept/design, data analysis/interpretation, and manuscript writing/revision.

- a) Polsky S, Ogden LG, MacLean PS, Giles ED, Brill C, Wyatt HR. Biomarker Profile Does Not Predict Weight Loss Success in Successful and Unsuccessful Diet-Reduced Obese Individuals: a Prospective Study. *ISRN Obes.* 2013 Jan 1; 2013. pii: 804129. [doi: 10.1155/2013/804129. PMID: 24363955. PMCID: PMC3867982]
- b) Polsky S, Beck J, Stark RA, Zhaoxing P, Hill JO, Peters JC. The Influence of Herbs, Spices, and Regular Sausage and Chicken Consumption on Liking of Reduced Fat Breakfast and Lunch Items. *J Food Sci*, 2014 Oct; 79(10): S2117-26. [doi: 10.1111/1750-3841.12643. PMID 25219391. PMCID: PMC4197100]
- c) Arterburn DE, Powers JD, Toh S, **Polsky S**, Butler MG, Portz JD, Donahoo WT, Herrinton L, Williams R, Vijayadeva V, Fisher D, Bayless EA. Comparative effectiveness of laparoscopic adjustable gastric banding versus laparoscopic gastric bypass. *JAMA Surgery*. 2014 Dec 1; 149(12): 1279-87. [doi: 10.1001/jamasurg.2014.1674. PMID: 25353723]
- d) Polsky Ś, Donahoo WT, Lyons EE, Funk KL, Elliott TE, Williams R, Arterburn D, Portz JD, Bayliss E. Evaluation of Care Management Intensity and Bariatric Surgical Weight Loss. Am J Manag Care, 2015 Mar; 21(3): 182-9. [PMID 25880623]
- 3. T1D is the current focus of my research. One of my research interests in the investigation of new medications, novel uses of old medications, and advanced diabetes technologies for T1D care. I summarized the literature on new medications for the treatment of diabetes. These reviews included the use of sodium-glucose co-transporter 2 (SGLT-2) inhibitors, glucagon antagonists, insulin therapies, and newer agents for DM. I reviewed the recent studies and contributed to manuscript writing. I reviewed data on the new inhaled insulin and contributed to the manuscript writing. Finally, I was a contributing author on an invited review of the effects of chronic device use on skin among people with diabetes, which included guidelines for preventing and treating adhesive-related skin conditions based on the expert opinions of the authors.
  - a) Garg SK, **Polsky S**, Shah VN. New Medications for the Treatment of Diabetes. *Diabetes Technol Th*er, 2016; 18 Suppl 1:S112-29. [doi: 10.1089/dia.2015.1514. PMID 26836424]
  - b) Dailey G, Ahmad A, **Polsky S**, Shah VN. A novel option for prandial insulin therapy: inhaled insulin. *Postgrad Med*, 2016 Nov; 128(8): 839-847. [doi: 10.1080/00325481.2016.1229555. PMID 27580306]
  - c) Messer LH, Berget C, Beatson C, Polsky S, Forlenza GP. Preserving Skin Integrity with Chronic Device Use in Diabetes. *Diabetes Technol Ther*. 2018 Jun;20(S2):S254-S264. [doi: 10.1089/dia.2018.0080.
    PMID: 29916740; PMCID: PMC6011799]
- 4. I have evaluated complications of T1D, including obesity with insulin resistance, cardiovascular diseases (CVD), substance abuse, and nephropathy. I reviewed 18 months of literature on obesity, insulin resistance, and T1D. These studies reported high prevalence rates of overweight/obesity among adults and children with T1D, increased risk for developing T1D and comorbidities among obese individuals, potential roles for adjunctive therapies such as metformin, glucagon antagonists, and SGLT-2 inhibitors among individuals with T1D for glucose control or insulin resistance, and effects of bariatric surgery on glucose control, comorbidity management, and obesity among adults and adolescents with T1D. I examined the associations between alcohol consumption, DM risk, and CVD in an invited review (first author). The T1D Exchange Registry was used to evaluate the frequency of use and problem use of psychoactive substances in T1D adults, as well as determinants of kidney disease in people with T1D. I contributed to the data interpretation and manuscript writing for both manuscripts. The PERL (Preventing Early Renal Loss) Study was an international, randomized controlled trial investigating the use of allopurinol to slow down progression of early renal decline in people with T1D. I was a co-first author on the baseline and methods paper and co-author on the pivotal findings paper.
  - a) Polsky S, Akturk HK. Alcohol Consumption, Diabetes Risk, and Cardiovascular Diseases within Diabetes. *Curr Diab Rep*. 2017 Nov 4; 17(12): 136. [doi: 10.1007/s11892-017-0950-8. PMID 29103170]
  - b) Petry NM, Foster NC, Cengiz E, Tamborlane WV, Wagner J, Polsky S. Substance Use in Adults With Type 1 Diabetes in the T1D Exchange. 2018 Dec; 44(6): 510-518. [doi: 10.1177/0145721718799088.
    PMID: 30203721]
  - c) McGill JB, Wu M, Pop-Busui R, Mizokami-Stout K, Tamborlane WV, Aleppo G, Gubitosi-Klug RA, Haller MJ, Willi SM, Foster NC, Zimmerman C, Libman I, **Polsky S**, Rickels MR. Biologic and social factors predict incident kidney disease in type 1 diabetes: results from the T1D exchange clinic

network. *J Diab Complications*. 2019 Oct; 33(10): 107400. [PMID: 31279735, doi: 10.1016/j.jdiacomp.2019.06.005]

- d) Doria A, Galecki AT, Spino C, Pop-Busui R, Cherney DZ, Lingvay I, Parsa A, Rossing P, Sigal RJ, Afkarian M, Aronson R, Caramori ML, Crandall JP, de Boer IH, Elliott TG, Goldfine AB, Haw JS, Hirsch IB, Karger AB, Maahs DM, McGill JB, Molitch ME, Perkins BA, **Polsky S**, Pragnell M, Robiner WN, Rosas SE, Senior P, Tuttle KR, Umpierrez GE, Wallia A, Weinstock RS, Wu C, Mauer M; PERL Study Group. Serum Urate Lowering with Allopurinol and Kidney Function in Type 1 Diabetes. *N Engl J Med*. 2020 Jun 25: 382(26): 2493-2503. [PMID: 32579810, doi: 10.1056/NEJMoa1916624]
- 5. I have evaluated the effects of T1D on women's health. I was a primary manuscript writer for literature reviews on technology use for the management of T1D in women and on invited commentaries on pregnancy management in T1D. Using data from the T1D Exchange Clinic Registry, I wrote a manuscript examining technology use in women based on parity (first author) and gender differences in diabetes self-care in adults with T1D. I was the PI of a study on the use of remote monitoring technology (Dexcom Share™) with continuous glucose monitoring (CGM) therapy in pregnancies associated with T1D. I presented 4 posters at the American Diabetes Association (ADA) Scientific Sessions on interim and complete analyses and 1 poster at the Advanced Technologies & Treatments for Diabetes conference on complete analyses. There were 8 women who did not use CGM, 13 who used CGM alone, and 15 who used CGM with Share. The hemoglobin A1C was significantly lower for both CGM groups compared to no CGM use over time (p=0.0042 over time). Median sensor glucose was lower (p=0.0331) and time spent in hyperglycemia (<180 mg/dL) was lower (p=0.0228) among CGM Share users. There was less fear and worry of hypoglycemia among CGM Share users. Glycemic indices were worse among women who developed preeclampsia compared to women who did not. I wrote the IRB documents for the study, conducted the study, created the database, and wrote the abstracts and paper. Finally, I was a contributing reviewer for a chapter on pregnancy management among women with T1D.
  - a) Polsky S, Wu M, Bode BW, DuBose SN, Goland RS, Maahs DM, Foster NC, Peters AL, Levy CJ, Shah VN, Beck RW. Diabetes Technology Use among Pregnant and non-Pregnant Women with T1D in the T1D Exchange. *Diabetes Technol Ther*, 2018 Jul 10. [doi: 10.1089/dia.2018.0033. PMID: 29990438]
  - b) Polsky S, Akturk H. Case series of a hybrid closed-loop system used in pregnancies in clinical practice. *Diabetes Metab Res Rev.* 2019 Nov 22: e3248 [PMID: 31758630, doi: 10.1002/dmrr.3248]
  - c) Polsky S, Garcetti R, Pyle L, Joshee P, Demmitt JK, Snell-Bergeon JK. Continuous glucose monitor use with and without remote monitoring in pregnant women with type 1 diabetes: a pilot study. *PLoS One*. 2020 Apr 16; 15(4): e0230476. doi: 10.1371/journal.pone.0230476. eCollection 2020. [PMID: 32298269]
  - d) Castorino K, Polsky S, O'Malley G, Levister C, Nelson K, Farfan C, Brackett S, Puhr S, Levy C. Performance of the Dexcom G6 Continuous Glucose Monitoring System in Pregnant Women With Diabetes. *Diabetes Technol Ther*. 2020 Apr 23. [PMID: 32324061, DOI: 10.1089/dia.2020.0085]

For complete publication list in MyBibliography, please go to: http://www.ncbi.nlm.nih.gov/sites/myncbi/1n\_Kmm5G1jUAG/bibliography/40769101/public/?sort=date&directio n=ascending

## D. Additional Information: Research Support and/or Scholastic Performance (does not include all studies)

### Ongoing Research Support 1. PDY15083: GEMELLI

Sanofi US Services, Inc. Garg (PI) 05/01/2018 to 4/30/2021 Prospective, multicenter, randomized, open-label, crossover to evaluate safety of SAR341402 (an ultra-rapid acting insulin) vs insulin aspart using an external continuous subcutaneous insulin infusion system in adult patients with T1D.

Role: Site Principal Investigator

#### 2. **2-SRA-2018-666-M-R: "Hybrid closed-loop insulin therapy in pregnancies complicated by T1D**" JDRF Polsky (PI) 09/01/2018 to 12/31/2021

This two-site, prospective, open-label, randomized controlled pilot study compares hybrid closed-loop therapy to sensor augmented pump therapy in pregnancies associated with T1D throughout gestation and the early post-partum period for safety, glycemic control, quality of life, and gestational outcomes. Rose: Principal Investigator

#### 3. T1D Exchange, Unitio, Inc. "T1D Exchange QI Collaborative"

The Quality Improvement (QI) Collaborative uses data from >12 clinics across the United States to identify unmet needs for people with T1D, engage in QI projects for clinical care and research, create best practices, and disseminate lessons learned from real-world evidence in order to improve the clinical practices and quality of life for individuals with T1D.

Role: Site Principal Investigator

# 4. PTL-903652, DexCom, Inc.

"Performance of the Dexcom G6 Continuous Glucose Monitoring (CGM) System in Pregnant Women with **Diabetes Mellitus**"

Goal: Prospective, observational study to establish safety and performance of the Dexcom G6 CGM System utilized for up to 10 days of wear in pregnant women with diabetes mellitus in the 2<sup>nd</sup> and 3<sup>rd</sup> trimesters. Role: Site Principal Investigator

5. NIH, NIDDK UC4 DK108612 01 Damiano (PI) 03/01/2020 to 02/29/2021 "The insulin-only bionic pancreas pivotal trial: testing the iLet in adults and children with type 1 diabetes" This multicenter randomized control trial compares efficacy and safety using an insulin-only configuration of the iLet Bionic Pancreas System vs usual care (UC) over 13 weeks, with an extension phase for those in UC. Role: Co-Investigator

6. IIS-2019-096, Dexcom, Inc. 04/01/2020 to 03/31/2021 "Triple C Pregnancy Study (Clinical effectiveness and Cost-benefit analysis with CGM in PREGNANCY Study" Retrospective chart review of type 1 diabetes pregnancies managed for glycemic control at the Barbara Davis Center for Diabetes over a 6-year period to evaluate clinical effectiveness and cost-benefit of CGM use in pregnancy compared to self-monitoring of blood glucose in pregnancy. **Role: Principal Investigator** 

## Completed Research Support (last 3 years, does not include all studies)

1. Investigator-Initiated Pilot Prospective CGM Quality Improvement (QI) Project

DexCom, Inc. Polsky (PI) 07/01/2015 to 12/31/2018 This QI pilot study evaluated the role of CGM use either alone or with remote monitoring capabilities that enable subjects to share CGM date with family and friends among pregnant women with T1D. Role: PI

# 2. PERL: Preventing Early Renal Function Loss in Type 1 Diabetes

NIH, NIDDK UC4 DK101108 Doria (PI) 09/30/2013 to 11/30/2019 This three-year, multi-center randomized controlled trial in 13 US and 4 international centers tested the hypothesis that lowering uric acid slows decline in glomerular filtration rate in adults with T1D. Role: Investigator through 8/31/2016, Site PI 9/1/2016 until Study End

# 3. PERLage: Preventing Early Renal Loss Follow-Up Study

JDRF Doria (PI) 11/01/2017 to 10/31/2020 Long-term follow-up of PERL participants to assess the residual effects of allopurinol treatment on GFR, cardiovascular complications, and eve complications, to identify predictors of diabetic kidney disease progression, and to identify novel biomarkers of GFR loss, progression to renal failure, and complications. Role: Site PI

## 4. Performance of the Dexcom G6 Continuous Glucose Monitoring (CGM) System in Pregnant Women with Diabetes Mellitus

DexCom. Inc.

04/17/2019 to 03/22/2020

Prospective, observational study to establish safety and performance of the Dexcom G6 CGM System utilized for up to 10 days of wear in pregnant women with diabetes mellitus in the 2<sup>nd</sup> and 3<sup>rd</sup> trimesters. Role: Site PI

04/17/2019 to 03/22/2020

Rioles (PI)

Polsky (PI)