

Dear Friends,

I am writing what has become an irregular newsletter from The Center for Clinical Trials (CCT), summing up the 2010 activities of the “core” faculty and students in the clinical trials concentration.

The year 2010 was marked by some sad events, both personally and collectively. The Center lost from its core faculty **Harry Marks**, who died of prostate cancer in January 2011, and 2010, the year preceding his death, was both an opportunity to celebrate Harry’s life and a period of collective mourning at the tremendous loss we were going to experience. Harry was a unique individual who added much to the Center’s scholarly work. His range and depth of knowledge was legion and encompassed far more than the history of medicine, public health, and clinical trials that were his “official” domain. His book, *The Progress of Experiment: Science and Therapeutic Reform in the United States, 1900–1990* is surely one that all clinical trialists should have on their bookshelves. At our monthly seminars, Harry was always the first to raise his hand with a question for the speaker, and the question was frequently one that taught us a new way of thinking about a problem, and almost always taught us something we did not already know. In October 2010, many of us had an opportunity to share in “HarryFest,” a celebration in his honor. Although Harry was quite ill at the time, he designed the topics for discussion, chose the presenters and the readings they were to discuss, and, as was his wont, always asked the first questions. Harry is much missed by me, the Center for Clinical Trials Faculty, and many other friends and colleagues around the world.

Highlights for the year

We asked each faculty member to note highlights of their year. This is what we heard (alphabetical order by surname) .

I had the good fortune to be included on two National Academy of Sciences committees this year, both concerned with quite interesting topics. The first was the *Committee on Handling Missing Data in Clinical Trials*, and we published a useful little book on the subject, *The Prevention and Treatment of Missing Data in Clinical Trials*. I also served on the Institute of Medicine’s *Committee on Standards for Systematic Reviews of Clinical Effectiveness Research*, with the standards published in March 2011.

Barbara Hawkins completed her current research project to compare visual acuity and patient-reported outcomes between sham and no-treatment controls from clinical trials of choroidal neovascularization in age-related macular degeneration.

Janet Holbrook, Elizabeth Sugar and Dave Shade, all of whom are investigators for The American Lung Association Asthma Clinical Research Network Data Coordinating Center, completed and presented a study that evaluated the sensitivity and specificity of methacholine challenge test for detecting asthma and presented the findings at the American Thoracic Society

meeting in New Orleans in May 2010. The Network also launched two new trials – SOYA (placebo-controlled trial of effect of soy genistein on lung function in asthma) and STAN (placebo controlled trial of effect of nasal steroids on asthma symptoms in patients with sinusitis). In addition, they have completed follow-up for phase 1 of the MUST (multicenter uveitis steroid treatment) Trial.

Tianjing Li completed her PhD in Epidemiology and a MHS in Biostatistics and joined the Center Faculty as an Assistant Scientist. She was invited to be one of the co-convenors of the Cochrane Comparing Multiple Interventions Methods Group, an international oversight committee for setting standards and the research agenda for network meta-analysis.

Milo Puhan, with **Aynur Ünalp-Arida** as co-lead, guided the launch of the CCT Study Design Consulting Service, supported through the Johns Hopkins Institute for Clinical and Translational Research (ICTR). CCT faculty members offer a consulting service on questions relating to study design and conduct. The goal of this consulting service is to provide intellectual and methodological input into clinical research studies and research synthesis initiated by faculty of Johns Hopkins University. The service has been quite successful, with a number of new collaborations established.

Finally, many congratulations to **Aynur Ünalp-Arida**, promoted to Associate Scientist in 2010.

Honors and awards

Steve Goodman was elected a 2010 Fellow of the Society for Clinical Trials. Congratulations Steve!

Editorial boards and journals

Our faculty and students continued to serve on a number of editorial boards this year. The centerpiece of our activities was *Clinical Trials*. *Journal of the Society for Clinical Trials*, edited by **Steve Goodman**. **Barbara Hawkins** serves as Deputy Editor, and **Roberta Scherer** as Managing Editor; **Karen Robinson**, **Milo Puhan** and I are Associate Editors, and **Harry Marks** served on the Editorial Advisory Board. Many or most of Center faculty have served as peer reviewers.

Faculty have editorial responsibilities with other journals as well. **Steve Goodman** is Associate Editor at *Annals of Internal Medicine*. Journals at which Center faculty serve in an editorial advisory or associate role include *Ophthalmic Epidemiology* (**Barbara Hawkins**); *Cochrane Methodology Review Group* (**Karen Robinson**); *Cochrane Eyes and Vision Group* (**Roberta Scherer**, **Barbara Hawkins**, **Kay Dickersin**); *PloS One* (**Roberta Scherer**); *Health and Quality of Life Outcomes*, *Cochrane Airways Group* (**Milo Puhan**), *BMJ*, *Health Expectations*,

Research Synthesis Methods, and Trials (Kay Dickersin).

Our faculty frequently serve as journal peer reviewers, and of particular note, our students have been gaining this critical experience as well. Although now a CCT faculty member, as a student, **Tianjing Li** served as a peer reviewer for *JAMA*, *BMJ*, *Ophthalmology*, *PloS Medicine*, and *Ophthalmic Epidemiology*. **Dolly Chang** served as a peer reviewer for *Ophthalmology* and for *Ophthalmic Epidemiology*, **Lynn Huynh** served as a peer reviewer for *JAMA* and **Swaroop Vedula** as a peer reviewer for *Bipolar Disorders* and *JAMA*.

Data and Safety Monitoring Boards

Our faculty continue to be active on data and safety monitoring boards (DSMBs). I chair the DSMB for the Pelvic Floor Disorders Network (PFDN) (Chair), sponsored by the National Institute of Child Health and Human Development. I also serve on the Risperidone Treatment for Military Service Related to Chronic Post-Traumatic Stress Disorder, sponsored by the Veterans' Administration Cooperative Studies Program. **Janet Holbrook** is a member of the DSMB for two clinical trials, a placebo controlled trial for lovastatin in adolescents with Lupus, and an evaluation of the effects of genetic variation on response to asthma medications.

Barbara Hawkins completed her service as Chair of the DSMB for the Oral Cleft Prevention Trial, sponsored by the National Institute of Dental and Craniofacial Research (NIDCR). She was newly appointed to the Data Monitoring and Oversight Committee for the Los Angeles Latino Eye Study. **Aynur Ünalp-Arida** serves on the DSMB for the Acute Liver Failure Research Group. **Marie Diener-West** serves on DSMBs for The Pediatric Eye Disease Investigator Group, sponsored by the NEI; and the Chemotherapy After Prostatectomy for High Risk Prostate Carcinoma, sponsored by the Department of Veterans Affairs.

Advisory boards

We also continue to serve on advisory boards. **Barbara Hawkins** is a member of the Steering Committee of an FDA-NEI-DoD sponsored study (subject and study name are currently confidential). **Marie Diener-West** is on the Study Advisory Board for the Macular Telangiectasia (MacTel) study; **Steve Goodman** is on the Medical Advisory Panel of the National Blue Cross/Blue Shield Association Technology Assessment Program; and **Milo Puhan** serves on the Advisory Committee for CanCOLD (Canadian Cohort of Obstructive Lung Disease).

In 2010, I served on the Scientific Advisory Committee for the Love/Avon Army of Women. I also served the IOM Oversight Committee for the Workshop on Handling Missing Data in Clinical Trials; and the IOM Committee on Standards for Systematic Reviews of Clinical

Effectiveness Research. I had the good fortune to continue to serve on the PRISMA Group (Preferred Reporting Items for Systematic Reviews and Meta-analysis) and the SPIRIT (Standard Protocol Items for Randomized Clinical Trials) Initiative.

Societies - leadership roles

A number of faculty served key roles in professional societies in 2010.

Ann-Margaret Ervin was appointed to the Diversity Issues Committee for the Association for Research in Vision and Ophthalmology (ARVO); **Roberta Scherer served on the** Education Committee for the Society for Clinical Trials; and **Barbara Hawkins** continued to serve as a member of the Society for Clinical Trials Fellows Selection Committee.

In addition, a number of Center faculty were involved in the organization of major conferences. The Cochrane Collaboration's annual Colloquium was in the United States in 2010, so a number of us were tapped to help organize this international meeting, for the first time held jointly with the Campbell Collaboration. **Karen Robinson** headed up the Colloquium Workshop Committee and I headed up the Scientific Committee. Karen is also on the Planning Committee for the 2011 CMTP Comparative Effectiveness Research (CER) Institute meeting. For the past few years I have been involved in the Planning Committee for the 2011 North American Epidemiology Congress. While serving on planning committees for major meetings requires a major time commitment, it is always fun to contribute to the scientific milieu of a meeting. Also into meeting planning, **Steve Goodman** served as Co-Chair of the NIH-AHRQ conference Methodologic Challenges in Comparative Effectiveness Research, held in December 2010. And Tianjing Li organized the international invitational meeting, Network Meta-analysis Meeting and Workshop hosted by the US Cochrane Center.

Study sections, including leadership roles

We served on a number of grant study sections in 2010. Among our contributions, **Milo Puhan** served as a reviewer for a National Institutes of Health (NIH) RFA, Smoking Cessation in Hospitalized Patients. **Roberta Scherer was a** reviewer for the Canadian Institutes of Health Research, "Knowledge Synthesis" program. Although not strictly a study section, the National Eye Institute (NEI) External Protocol Review Committee for the Diabetic Retinopathy Clinical Research Network (DRCRNet) is an ongoing project involving periodic external review of new protocols submitted by a NEI-funded research network; I serve as Chair of the committee reviewing the protocols.

New grants/contracts

Center for Clinical Trials faculty enjoyed another successful year in terms of grant funding. I received a new U01 from the NEI for the Cochrane Eyes and Vision Group: US Coordination of Contributors. **Tianjing Li** and I also began work on a clinical trial, Strategy To Reduce the Incidence of Post-operative Delirium in Elderly participants (STRIDE), funded by the National Institute of Aging (Principal Investigator is Fritz Sieber). **Janet Holbrook and Dave Shade** were funded to conduct a new trial, BESTT, which is a phase 2 placebo controlled RCT for broccoli sprout extracts (sulforaphane) for COPD. **Milo Puhan** received renewal of his grant for the COPD cohort study ICE COLD ERIC, conducted in collaboration with the Universities of Zurich (Switzerland) and Amsterdam (Netherlands). The study is supported by the Swiss National Science Foundation, the Zurich Lung League and the Dutch Asthma Fund. He also started on a new award, Methods for Balancing Harms and Benefits in Systematic Reviews from the Agency for Healthcare Research and Quality (AHRQ) (Cynthia Boyd, Principal Investigator). **Karen Robinson** had a very good year. She was funded by the Cystic Fibrosis Foundation Development of Evidence-based Guidelines, and also by AHRQ for Research Needs Methods Projects: Frameworks for Determining Research Gaps. In addition, she serves in a major role on four other grants in her role as Co-Director of the Johns Hopkins Evidence-based Practice Center.

Teaching

The strong teaching commitment of the Center faculty is evident from our list of courses taught in 2010. **Marie Deiner-West** will continue to teach Fundamentals of Epidemiology I and II as one of the special courses the Center has provided for the FDA fellows. **Marie, Tianjing Li,** and I taught a short version of our Systematic Reviews and Meta-analysis course at the Health Policy and Management Fall Institute in Barcelona, Spain. Now that she is faculty, **Tianjing** has been promoted to co-instructor in the third term Systematic Reviews and Meta-analysis course for which I am responsible. The course, started by **Steve Goodman** and me in 1994, has numerous contributors from our faculty and students: **Steve Goodman** and **Karen Robinson as faculty,** and **Swaroop Vedula** and **Dolly Chang** who serve as stellar teaching assistants.

Our core clinical trials curriculum is ably taught by **Janet Holbrook and Lea Drye** (“Introduction to Clinical Trials”, offered 1st and 2nd quarters, and for the FDA Fellows). Janet also directs the Topics in Clinical Trials course we have provided annually for the FDA Fellows. **Roberta Scherer** and **Aynur Unap-Arida** offered “Clinical Trials Management” in the fourth term and **Dave Shade** taught “Clinical Trial Data Management”. **Milo Puhan** and **Steve Goodman** teach the recommended fourth quarter course, “Evaluation of Tests for Diagnosis, Prediction and Screening”. Outside our 2-year clinical trials sequence but with the Department of Epidemiology, **Steve Goodman** directs the “Epidemiology Doctoral Seminar.”

Center for Clinical Trials faculty served as guest lecturers in the Epidemiology Winter Institute

and offer courses in the Summer Institute (**Milo Puhan's** "Comparative Effectiveness Research: Outcome Measures" and **Aynur Ünalp-Arida** and **Roberta Scherer's** "Managing Clinical Trials"). Faculty also provide teaching in core Department courses, for example **Milo Puhan** has a major responsibility for the second term doctoral epidemiology course in the Department (340.752). We also provide numerous lectures in one another's courses, and for the FDA Fellows courses Janet oversees, as well as special lecturers in the Department of Epidemiology and other Departments.

Ann-Margret Ervin and **Roberta Scherer** serve as co-facilitators of the CCT journal club, held monthly throughout the school year. About 30 students and faculty engage in spirited discussion about articles presenting timely or controversial issues related to clinical trials

Our seminars continue to be a big success and of interest well beyond the CCT. Last year's speakers included both those external to Johns Hopkins (Susan Ellenberg, Bob Curley and James Kaylor (all three from Penn), Keith Baggerly (MD Anderson), Tom Greene (Greene LLP), and Julian Higgins (Cambridge, UK), as well as speakers from Hopkins (**Harry Marks**, Maria Wawer, Steve Gange, Ruth Faden, Gary Rosner, and Taha Taha).

Keeping in touch

I look forward to providing annual updates on our graduates and in-depth reporting about our research. So send us your suggestions and news, we are contributing to the Department blog and just as soon as the School's new website software is installed, our website will be entirely revamped. Check out our website in the interim for seminars, journal club and other information (<http://cct.jhsph.edu>). Thank you for your interest in and your contributions to the Center.

With very best wishes,



Kay Dickersin, MA, PhD
Professor
Director, Center for Clinical Trials

2010 Publications of the Core CCT Faculty

Marie Deiner West:

1. Caffo B, **Diener-West M**, Punjabi NM, Samet J: A novel approach to prediction of mild obstructive sleep disordered breathing in a population-based sample: the Sleep Heart Health Study. *Sleep* 2010; 33:1641-8.
2. Gottlieb DJ, Yenokyan G, Newman AB, O'Connor GT, Punjabi NM, Quan SF, Redline S, Resnick HE, Tong EK, **Diener-West M**, Shahar E: Prospective study of obstructive sleep apnea and incident coronary heart disease and heart failure: the sleep heart health study. *Circulation* 2010; 122:352-60.
3. Redline S, Yenokyan G, Gottlieb DJ, Shahar E, O'Connor GT, Resnick HE, **Diener-West M**, Sanders MH, Wolf PA, Geraghty EM, Ali T, Lebowitz M, Punjabi NM: Obstructive sleep apnea-hypopnea and incident stroke: the sleep heart health study. *American Journal of Respiratory and Critical Care Medicine* 2010; 182:269-77.

Kay Dickersin:

1. Li T, Ervin A-M, Scherer R, Jampel H, **Dickersin K**. Setting priorities for comparative effectiveness research: a case study using primary open-angle glaucoma. *Ophthalmology* 2010; 117:1937-1945.
2. **Committee on National Statistics, Division of Behavioral and Social Sciences and Education**. The Prevention and Treatment of Missing Data in Clinical Trials. National Research Council. Washington, DC: National Academies Press, 2010.
3. **Dickersin K**, Chalmers I. Recognising, investigating and dealing with incomplete and biased reporting of clinical research: from Francis Bacon to the World Health Organisation. *JamesLind Library* (www.jameslindlibrary.org) 2010.
4. **Dickersin K**. To reform US health care, start with systematic reviews (Policy Forum). *Science* 2010; 329: 516-7.
5. Lindsley K, Nichols JJ, **Dickersin K**. Interventions for acute internal hordeolum. *Cochrane Database of Systematic Reviews* Issue 9. Art. No.: CD007742. DOI: 10.1002/14651858.CD007742.pub2. PMID: 20824865. 2010.
6. Sox HC, Helfand M, Grimshaw J, **Dickersin K**, PLoS Medical Editors, Tovey D, Knottnerus JA, Tugwell P. Comparative effectiveness research: challenges for medical journals. (Multiple simultaneous publications): *Am J Manag Care* 2010;

16:e131-3. *Croat Med J* 2010; 5:191-4, 2010. *J Clin Epidemiol* 2010 ePub May 10; 63:862-4. *Med Decis Making* 2010 Epub Apr 27; 30:301-3. *PLoS Med* 2010; 7:e1000269. *Trials* 2010; 11:45. *The Cochrane Library*
<http://www.thecochranelibrary.com/details/editorial/687971/Comparative-Effectiveness-Research-Challenges-for-Medical-Journals.html>. 2010 April 29.

7. **Dickersin K**, Fredman L, Flegal KM, Scott J, Crawley B. Female editorship is an important indicator of gender imbalance (letter). *J Roy Soc Med* 2010; 103:5.
8. Li T, **Dickersin K**, Scherer R, Wieland S. Registering systematic reviews (online letter). *Can Med Assoc J* 2010; 6 April.

Leah Drye:

1. Rosenberg PB, **Drye LT**, Martin BK, Frangakis C, Mintzer JE, Weintraub, Porsteinsson AP, Schneider LS, Rabins PV, Munro CA, Meinert CL, Lyketsos, CG, for the DIADS-2 Research Group. Sertraline for the treatment of depression in Alzheimer's disease. *Am J Geriat Psych*. 2010; 18:136-45.
2. Weintraub D, Rosenberg PB, **Drye LT**, Martin BK, Frangakis C, Mintzer JE, Porsteinsson AP, Schneider LS, Rabins PV, Munro CA, Meinert CL, Lyketsos CG, for the DIADS-2 Research Group. Sertraline for the treatment of depression in Alzheimer's disease: Week-24 outcomes. *Am J Geriat Psych*. 2010; 18:332-340.
3. **Drye LT**, Meinert JL, Meinert CL. Gender indexing in publications of clinical trials: 1991-2008. *Clinical Trials* 2010; 7: 677-85.

Ann-Margret Ervin:

1. **Ervin AM**, Wojciechowski R, Schein O. Punctal occlusion for dry eye syndrome (Review). *Cochrane Database of Systematic Reviews* 2010, Issue 9. Art. No.: CD006775. DOI: 10.1002/14651858.CD006775.pub2.
2. Li T, **Ervin AM**, Scherer R, Jampel H, Dickersin K. Setting priorities for comparative effectiveness research: A case study using primary open-angle glaucoma. *Ophthalmology*, 2010 October;117:1937-45.
3. Baldwin CM, **Ervin A**, Mays M, Silva G, Shafazand S, Boland L, Walsleben J, Weaver T. Sleep Disturbances, Quality of Life and Ethnicity: The Sleep Heart Health Study. *JCSM*; 2010; 6: 176-183.

Steve Goodman:

1. **Goodman SN.** On making clinical trials possible. *Clin Trials* 2010;7:621.
2. Goodman SN. Commentary. *Biostatistics.* 2010;11:389-90.
3. Gerson J, **Goodman SN.** An absence of evidence in "evidence-based rulemaking". *Am J Bioeth* 2010;10:22-3.
4. Luznik L, Bolaños-Meade J, Zahurak M, Chen AR, Smith BD, Brodsky R, Huff CA, Borrello I, Matsui W, Powell JD, Kasamon Y, **Goodman SN**, Hess A, Levitsky HI, Ambinder RF, Jones RJ, Fuchs EJ. High-dose cyclophosphamide as single-agent, short-course prophylaxis of graft-versus-host disease. *Blood* 2010; 115: 3224-30.
Brodsky RA, Chen AR, Dorr D, Fuchs EJ, Huff CA, Luznik L, Smith BD, Matsui WH, **Goodman SN**, Ambinder RF, Jones RJ. High-dose cyclophosphamide for severe aplastic anemia: long-term follow-up. *Blood.* 2010;115:2136-41.
5. **Goodman S**, Berry D, Wittes. Bias and trials stopped early for benefit (letter). *JAMA.* 2010; 304:157; author reply 158-9.

Janet Holbrook:

1. Multicenter Uveitis Steroid Treatment Trial Research Group. The Multicenter Uveitis Steroid Treatment Trial: Rationale, Design, and Baseline Characteristics. *Am J Ophthalmol* 2010;149:550-561.

Tianjing Li:

1. **Li T**, Ervin A, Scherer R, Jampel H, Dickersin K. Setting Priorities for Comparative Effectiveness Research: A Case Study Using Primary Open-Angle Glaucoma. *Ophthalmology* 2010; 117:1939-45.

Milo Puhan:

1. **Puhan M.A.**, Van Natta ML, Palella FJ, Addessi A, Meinert C, for the Studies of the Ocular Complications of AIDS Research Group. Excess Mortality in Patients with AIDS in the Era of Highly Active Antiretroviral Therapy: Temporal Changes and Risk Factors. *Clin Infect Dis* 2010;51(8):947-56.
2. **Puhan M.A.**, Gimeno-Santos E, Scharplatz M, Troosters T, Walters EH, Steurer J. Pulmonary rehabilitation following exacerbations of chronic obstructive pulmonary disease. *Cochrane Database of Systematic Reviews* 2010; Issue 11. CD005305

3. Béchir M; **Puhan M.A.**, Neff S.B., Guggenheim M., Wedler V. Stover J.F., Stocker R., Neff T.A. Early fluid resuscitation with hyperoncotic HES 200/0.5 (10%) in severe burn injury. *Critical Care* 2010; 14:R123.
4. Mahfud M, Breitenstein S, El-Badry AM, **Puhan M.A.**, Rickenbacher A, Samaras P, Pessaux P, Lopez-Ben S, Jaeck D, Figueras J, Alain-Clavien P. Impact of preoperative bevacizumab on complications after resection of colorectal liver metastases: case-matched control study. *World J Surg* 2010; 34: 92-100.
5. Sahrman P, **Puhan M.A.**, Attin T, Schmidlin PR. Systematic review on the effect of rinsing with povidone-iodine during nonsurgical periodontal therapy *J Periodont Res* 2010; 45:153-64.

Karen Robinson:

1. **Robinson KA**, Mckoy N, Saldanha I, Odelola OA. Active cycle of breathing technique for cystic fibrosis. *Cochrane Database of Systematic Reviews* 2010; Issue 11. Art. No.: CD007862. PMID: 21069699.
2. Flume PA, Mogayzel, PJ, Robinson KA, Rosenblatt RL, Quittell L, Marshall BC, and the Clinical Practice Guidelines for Pulmonary Therapies Committee. Cystic Fibrosis Pulmonary Guidelines: Pulmonary Complications: Hemoptysis and Pneumothorax. *Am J Respir Crit Care Med* 2010; 182:298-306. PMID: 20675678
3. Tyus NC, Gibbons MC, **Robinson KA**, Twose C, Guyer B. In the shadow of academic medical centers: A systematic review of urban health research in Baltimore City. *J Community Health* 2010; 35: 433-52. PMID: 20422444
4. Moran A, Brunzell C, Cohen RC, Katz M, Marshall BC, Onady G, **Robinson KA**, Sadosky KA, Stecenko A, Slovis B; the CFRD Guidelines Committee. Clinical Care Guidelines for Cystic Fibrosis-Related Diabetes: A position statement of the American Diabetes Association and a clinical practice guideline of the Cystic Fibrosis Foundation, endorsed by the Pediatric Endocrine Society. *Diabetes Care* 2010; Dec; 33: 2697-2708. PMID: 21115772
5. Shamliyan, TA, Kane RL, Ansari MT, Raman G, Berkman N, Grant M, Janes G, Maglione M, Moher D, Nasser M, **Robinson KA**, Segal JB, Tsouros S. Developing quality criteria to evaluate nontherapeutic studies of incidence, prevalence, or risk factors of chronic diseases: pilot study of new checklists. *J Clin Epidemiol* 2010; PMID: 21071174

Roberta Scherer:

1. Li T, Ervin A-M, **Scherer R**, Jampel H, Dickersin K. Setting priorities for comparative effectiveness research: a case study using primary open angle glaucoma. *Ophthalmology* 2010; 117:1937-45.
2. Crocetti M, Amin DD, **Scherer R**. Assessment of risk of bias among pediatric randomized controlled trials. *Pediatrics*; 2010. epub July 12,. DOI: 10.1542/peds.2009-3121

Elizabeth Sugar:

1. The Multicenter Uveitis Steroid Treatment Trial Research Group; Kempen JH, Altaweel MM, Holbrook JT, Jabs DA, Sugar EA. The Multicenter Uveitis Steroid Treatment (MUST) Trial: Rationale, Design, and Baseline Characteristics. *Am J Ophthalmology* 2010; 149: 550-561.
2. Lutz E, Yeo CJ, Lillemoie KD, Biedrzycki B, Korbin B, Herman J, **Sugar E**, Piantadosi S, Cameron JL, Solt S, Onners B, Tartakovsky I, Choi M, Sharma R, Illei PB, Hruban RH, Abrams RA, Le D, Jaffee E, Laheru D. A Lethally Irradiated Allogeneic Granulocyte-Macrophage Colony Stimulating Factor-Secreting Tumor Vaccine for Pancreatic Adenocarcinoma: A Phase II Trial of Safety, Efficacy, and Immune Activation. *Ann Surg* 2010; Dec 17 [Epub ahead of print].
3. Fakhry C*, **Sugar E***, D'Souza G, Gillison M. Two-week versus six-month sampling interval in a short-term natural history study of oral HPV infection in an HIV-positive cohort. *PLoS One*; 2010; 5: e11918. *Authors contributed equally.
4. Redmond KJ, Wolfgang CL, **Sugar EA**, Ahn J, Nathan H, Laheru D, Edil BH, Choti MA, Pawlik TM, Hruban RH, Cameron JL, Herman JM. Adjuvant Chemoradiation Therapy for Adenocarcinoma of the Distal Pancreas. *Ann Surg Oncol*; 2010; 17: 3112-9.

Aynur Ünalp-Arida:

1. Writing Committee member. Lavine JE, Schwimmer JB, Molleston JP, Scheimann AO, Murray KF, Abrams SH, Rosenthal P, Sanyal AJ, Robuck PR, Brunt EM, **Ünalp A**, Tonascia J for the NASH CRN. Treatment of non-alcoholic fatty liver disease in children: TONIC trial design. *Contemp Clin Trials* 2010; 31:62-70.
2. Kistler KD, Molleston JP, **Ünalp A**, Abrams SH, Behling C, Schwimmer JB, and the NASH CRN Research Group. Symptoms and quality of life in obese children and adolescents with nonalcoholic fatty liver disease. *Aliment Pharmacol Ther* 2010; 31: 396-406.
3. Abdelmalek MF, Suzuki A, Guy G, **Ünalp-Arida A**, Colvin R, Johnson RJ, Diehl AM.

Increased fructose consumption is associated with fibrosis severity in patients with NAFLD. *Hepatology* 2010; 51:1961-1971.

4. Writing Committee member. Sanyal AJ, Chalasani NP, Kowdley KV, McCullough AJ, Diehl AM, Bass NM, Neuschwander-Tetri BA, Lavine JE, Tonascia J, **Ünalp A**, Van Natta ML, Clark JM, Brunt EM, Kleiner DE, Hoofnagle JH, Robuck PR. Pioglitazone, vitamin E, or placebo for nonalcoholic steatohepatitis: PIVENS trial primary results. *N Engl J Med* 2010; 362: 1675-1685.
 5. Sanyal AJ, **Ünalp A** for the NASH CRN investigators. Pioglitazone, vitamin E, or placebo for nonalcoholic steatohepatitis: PIVENS trial primary results [authors' response to letters to the editor]. *N Engl J Med* 2010; 363: 1185-1186.
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