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Mei Sheng Duh, a Managing Principal of Analysis Group, is a pharmacoepidemiologist and outcomes researcher specializing in the safety, health economics and outcomes of pharmaceutical or biological agents. Dr. Duh has conducted and directed numerous medical records review studies, claims data analyses, patient surveys, and clinical trials data analyses to investigate adverse events, prevalence and incidence, resource utilization patterns, patient-reported outcomes (eg, quality of life, work productivity loss), clinical effectiveness (eg, responder analysis), direct medical and indirect productivity costs of a disease burden, and cost-effectiveness associated with the use of pharmaceuticals or biologics. Prior to joining Analysis Group, Dr. Duh was a Senior Associate Epidemiologist at Ingenix Pharmaceutical Services where she was a principal investigator for several epidemiological studies using large automated medical insurance databases and medical records to address drug safety issues in response to the FDA's public health concerns. She also served as a pharmacoepidemiologist at Astra Pharmaceuticals, LP (now AstraZeneca) in charge of drug safety data for New Drug Applications and post-marketing surveillance.

Dr. Duh has conducted studies in the following therapeutic areas: liver disease, anemia, oncology, renal diseases, osteoporosis, irritable bowel syndrome, gastroesophageal reflux disease, acnes, psoriasis, dermatitis, HIV, fungal infections, asthma, ocular hypertension, pregnancy outcomes, depression, and hematological disorders.

Dr. Duh has also been responsible for special tasks in assisting pharmaceutical, biotech, and medical device companies in preparation for FDA and CMS committee meetings, critical review of the planned study protocols, establishment of liaison with clinical community, CMS reimbursement analyses, development of standard operating procedures for health economics and outcomes research group, and strategic discussions on study ideas in support of Phase III clinical trials, Phase IV pharmacoecconomics and outcomes research, and safety issues. Dr. Duh was appointed to an expert panel convened by the Foundation for the National Institutes of Health's Observational Medical Outcomes Partnership (OMOP) to develop methodologies for studying drug-induced liver injuries on a national scale. She served as a chairperson for Drug Information

Association annual meetings, was an adjunct assistant professor of Pharmacoeconomics and Pharmacoepidemiology at Massachusetts College of Pharmacy and Allied Health Sciences. She is currently a Guest Lecturer at the Harvard School of Public Health, an elected member with American Society of Hematology, and a journal reviewer for *Pharmacoeconomics*, *American Journal of Hospital-System Pharmacists*, *Chest*, *Managed Care Interface*, *Pharmacoepidemiology and Drug Safety*, and *Therapeutics and Clinical Risk Management*.

Dr. Duh is a graduate of the Harvard School of Public Health, where she received a Doctor of Science degree with a concentration in Pharmacoepidemiology, Biostatistics, and Health Policy and Management. She received a Masters' degree in Public Health in the area of chronic disease epidemiology from Yale School of Medicine, and a B.S. in pharmacy from Taiwan.

EDUCATION

Sc.D. in Pharmaco-Epidemiology, Harvard School of Public Health, 1996

M.P.H. in Chronic Disease Epidemiology, Yale School of Medicine, New Haven, Connecticut, 1992

B.S. in Pharmacy, Kaohsiung Medical College, Taiwan, 1990

PREVIOUS EMPLOYMENT

1999-2001 Senior Associate Epidemiologist, Ingenix Pharmaceutical Services

4/99-9/99 Pharmacoepidemiology Consultant, AstraZeneca R&D

1997-1999 Pharmacoepidemiologist, Astra Pharmaceuticals, L.P.

1996-1997 Clinical Scientist/Project Manager, Astra USA, Inc.

1996-1997 Epidemiology Session Chairperson, Drug Information Association

1992-1996 Research Fellow in Pharmacoepidemiology Program, Harvard School of Public Health

PROFESSIONAL AFFILIATIONS

Guest lecturer, Epidemiology Department, Harvard University School of Public Health

Adjunct Assistant Professor of Pharmacoepidemiology and Pharmacoeconomics, Massachusetts College of Pharmacy and Allied Health Science

Reviewer, *Pharmacoeconomics*

Reviewer, *American Journal of Hospital-System Pharmacists*

Reviewer, *Chest*

Reviewer, *Therapeutics and Clinical Risk Management*

Reviewer, *American Journal of Kidney Diseases*

Reviewer, *Managed Care Interface*

Reviewer, *Pharmacoepidemiology and Drug Safety*

Reviewer, *American Journal of Managed Care*

Reviewer, *Nephrology Dialysis Transplantation*

Reviewer, *PharmacoEconomics*

Member, International Society of Pharmacoepidemiology

Member, International Society of Pharmacoeconomics and Outcomes Research

Elected Member, American Society of Hematology

PUBLICATIONS

Mei-Sheng Duh: “ The Effectiveness of Surgery on the Treatment of Acute Spinal Cord Injury and the Relationship with Pharmacological Therapy.” A Master’s Thesis Presented to the Faculty of Yale University School of Medicine, 1992.

Mei-Sheng Duh: “ The Application of Artificial Neural Networks in the Epidemiology of Liver Diseases” A Doctoral Thesis Presented to the Faculty of Harvard University, 1996.

Duh M-S, Shepard MJ, Wilberger JE, and Bracken MB. The effectiveness of surgery on the treatment of acute spinal cord injury and its relationship with pharmacological treatment. *Neurosurgery* 35:240-249, 1994.

Duh M-S, Walker AM, Pagano M, Kronlund K. Prediction and cross-validation in modeling incident cases of hepatic disorders using automated medical data. *American Journal of Epidemiology* 1998; 147:407-13.

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Duh M-S, Walker AM, Kronlund K. Descriptive epidemiology of acute liver enzyme abnormalities in the general population of central Massachusetts. *Pharmacoepidemiology and Drug Safety* 8: 275-283, 1999.

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Corwin HL, Gettinger A, Levy MM, Fink MP, Pearl RG, Abraham E, MacInyre NR, Shabot M, Duh MS, Shapiro MJ. Anemia and blood transfusion in the critically ill: current clinical practice in the United States-The CRIT Study. *Critical Care Medicine* 2004; 32:39-52.

Shorr AF, Duh MS, Kelly KM, Kollef MH. Red blood cell transfusion and ventilator-associated pneumonia: a potential link? *Critical Care Medicine* 2004; 32 (3): 666-74.

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Sands BE, Duh M-S, Ajene A, Walker AM. Computerized algorithms for the identification of irritable bowel syndrome, colonic ischemia, and complications of constipation: validation through medical records. *Pharmacoepidemiology and Drug Safety* 2005 May 24

Duh MS, Mark TL. Cost-effectiveness of epoetin alfa and darbepoetin alfa in patients with chemotherapy related anemia. *Expert Rev Pharmacoeconomics Outcomes Res.* 2005;5(4):383-394.

Duh MS, Lefebvre P, Fastenau J, Piech CT, Waltzman RJ. Assessing the clinical benefits of erythropoietic agents using area under the hemoglobin change curve. *The Oncologist* 2005; 10: 438-448.

Campos SM, Duh MS, Lefebvre P, Rosberg J. Benefits associated with an early hemoglobin response to epoetin alfa therapy in the treatment of chemotherapy-related anemia. *J Natl Compr Canc Netw.* 2005 Nov;3(6):807-16.

Ben-hamadi R, Duh MS, Aggarawal J, Henckler A, Mckenzie RS, Tak Piech C. The cost-effectiveness of weekly epoetin alfa relative to weekly darbepoetin alfa in patients with chemotherapy-induced anemia. *Curr Med Res Opin* 2005 Oct; 21(10): 1677-82.

Smith MR, Boyce SP, Moyneur E, Duh MS, Raut M, Brandman J. Assessing the risk of clinical fracture in men with non-metastatic prostate cancer receiving gonadotropin-releasing hormone agonist therapy. *J of Urology* 2006 Jan;175(1):136-9; discussion 139.

Fowler JF, Ghosh A, Sung J, Emani S, Chang J, Den E, Thorn D, Person J, Duh MS. The Impact of chronic hand dermatitis on quality of life, work productivity, activity impairment, and medical costs. *J Am Acad Dermatol.* 2006 Mar;54(3):448-57.

Stang PE, Greenberg PE, Birnbaum HG, Kessler RC, Hoffman L, Duh M-S. Chapter 12. A regulatory perspective on productivity claims: implications for future productivity research. In Kessler RC, Stang PE. Chicago: The University of Chicago Press, pp. 242-252, 2006.

Fowler JF, Duh MS, Chang J, Person J, Thorn D, Raut M, Ghosh A, Den E, Emani S. A survey-based assessment of the prevalence and severity of chronic hand dermatitis in a managed care organization. *Cutis* 2006; 77:385-392.

Mincey BA, *Duh MS*, Thomas SK, Moyneur E, Marychencko M, Boyce SP, Mallett D, Perez EA. Risk of cancer treatment-associated bone loss and fractures among women with breast cancer receiving aromatase inhibitors. *Clin Breast Cancer* 2006 June; 7(2): 127-32.

Clancy TE, Sengupta TP, Paulus J, Ahmed F, *Duh MS*, Kulke MH. Alkaline phosphatase predicts survival in patients with metastatic neuroendocrine tumors. *Dig Dis Sci* 2006 May; 51(5): 877-84. Epub 2007 Jun 7.

Lefebvre P, Gosselin A, McKenzie RS, Mody SH, Piech CT, *Duh MS*. Dosing patterns, treatment costs, and frequency of physician visits in adults with cancer receiving erythropoietic agents in managed care organizations. *Current Medical Research and Opinion* Vol 22, No 9, 2006: 1623-31.

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Lefebvre P, *Duh MS*, Buteau S, Bookhart B, Mody SH. Medical costs of untreated anemia in elderly patients with predialysis chronic kidney disease. *J Am Soc Nephrol* 2006 Dec;17(12):3497-502

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Duh MS, Latypova A, Greenberg P. Impact and treatment of anemia in the elderly: clinical, epidemiological, and economic perspectives. *Expert Rev Pharmacoeconomics Outcomes Res.* 2006;6(5):383-394.

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Oh WK, Proctor K, Nakabayashi M, Evan C, Tormey LK, Daskivich T, Antras L, Smith M, Neary MP, *Duh MS*. The risk of renal impairment in hormone-refractory prostate cancer patients with bone metastases treated with zoledronic acid. *Cancer.* 2007 Mar 15;109(6):1090-6.

Andermann F, *Duh MS*, Gosselin A, Paradis PE. Compulsory generic switching of antiepileptic drugs: high switchback rates to branded compounds compared with other drug classes. *Epilepsia.* 2007 Mar;48(3):464-9.

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Wu WK, *Duh MS*, Lefebvre P. Is there a difference in the cost-effectiveness of erythropoietic therapies for the treatment of anemia in patients receiving HCV combination therapy? *Hepatology* 2007 Jul; 46(1): 283.

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Vekeman F, McKenzie RS, Lefebvre P, Watson SH, Mody SH, Piech CT, Duh MS. Dose and cost comparison of erythropoietic agents in the inpatient hospital setting. *Am J Health Syst Pharm* 2007 Sep 15; 64(18): 1943-9.

Moyneur E, Bookhart BK, Mody SH, Fournier A, Mallet D, Duh MS. Medical and work loss burden of pre-dialysis chronic kidney disease and related anemia: an employer's perspective. *Journal of Health & Productivity* 2007 (Oct): 3-9.

Chen L, Antras L, Duh MS, Levy N, Neary M, O'Brien ME, von Pawel J. Psychometric validation of the Patient Symptom Assessment in Lung Cancer instrument for small cell lung cancer. *Curr Med Res Opin.* 2007 Nov;23(11):2741-52.

Sikand H, Decter A, Greco T, Watson SH, Kang YJ, Mody SH, Piech CT, Duh MS, Naeem A. Cost analytic model to determine the least costly inpatient erythropoiesis stimulating therapy regimen. *Ann Pharmacother.* 2007 Nov 20.

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- Fowler JF, *Duh MS*, Rovba L, Buteau S, Pinheiro L, Lobo F, Sung J, Doyle JJ, Swensen A, Mallett DA, Kosicki G. The direct and indirect cost burden of atopic dermatitis: an employer-payer perspective. *Manag Care Interface*. 2007 Oct;20(10):26-32.
- LeLorier J, *Duh MS*, Paradis PE, Lefebvre P, Weiner J, Manjunath R, Sheehy O. Clinical consequences of generic substitution of lamotrigine for patients with epilepsy. *Neurology*. 2008 May 27;70(22 Pt 2):2179-86.
- Faught E, *Duh MS*, Weiner JR, Guérin A, Cunnington MC. Nonadherence to antiepileptic drugs and increased mortality. Findings from the RANSOM Study. *Neurology*. 2008 Jun 18 [Epub ahead of print]
- Chen L, Antras L, *Duh MS*, Neary M, O'Brien ME. Symptom assessment in relapsed small cell lung cancer: cross-validation of the patient symptom assessment in lung cancer instrument. *J Thorac Oncol* 2008 Oct; 3(10): 1137-45
- Diel IJ, Weide R, Koppler H, Antras L, Smith M, Green J, Wintfeld N, Neary M, *Duh MS*. Risk of renal impairment after treatment with ibandronate versus zoledronic acid: a retrospective medical records review. *Support Care Cancer* 2008 Dec 17 [Epub ahead of print]
- Fowler JF, *Duh MS*, Rovba L, Buteau S, Pinheiro L, Lobo F, Sung J, Doyle JJ, Swensen A, Mallett DA, Kosicki G. The impact of psoriasis on health care costs and patient work loss. *J Am Acad Dermatol* 2008 Nov; 59(5): 772-80
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- Vekeman F, Bookhart BK, White J, McKenzie RS, Duh MS, Piech CT, Lefebvre P. Impact of limiting erythropoiesis-stimulating agent use for chemotherapy-induced anemia on the United States blood supply margin. *Transfusion*. 2009 May;49(5):895-902. Epub 2009 Jan 19.
- Faught RE, Weiner JR, Guérin A, Cunnington MC, Duh MS. Impact of nonadherence to antiepileptic drugs on health care utilization and costs: Findings from the RANSOM study. *Epilepsia*. 2009 Mar; 50(3): 501-9. Epub 2008 Oct 3.
- Laliberte F, Bookhart BK, Vekeman F, Corral M, Duh MS, Bailey RA, Piech CT, Lefebvre P. Direct all-cause health care costs associated with chronic kidney disease in patients with diabetes and hypertension: a managed care perspective. *J Manag Care Pharm* 2009 May; 15(4): 312-22.
- Vekeman F, McKenzie RS, Bookhart BK, Laliberté F, Duh MS, Tak Piech C, Lefebvre P. Drug utilization and cost considerations of erythropoiesis stimulating agents in oncology patients receiving chemotherapy: observations from a large managed-care database. *J Med Econ*. 2009;12(1):1-8.

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Heaney ML, Toy EL, Vekeman F, Laliberté F, Dority BL, Perlman D, Barghout V, Duh MS. Comparison of hospitalization risk and associated costs among patients receiving sargramostim, filgrastim, and pegfilgrastim for chemotherapy-Induced neutropenia. *Cancer.* 2009 Jul 27. [Epub ahead of print]

Duh MS, Cahill KE, Paradis PE, Cremieux PY, Greenberg PE. The economic implications of generic substitution of antiepileptic drugs: a review of recent evidence. *Expert Opin Pharmacother.* 2009 Oct;10(14):2317-28.

Raptis A, Duh MS, Wang ST, Dial E, Fanourgiakis I, Fortner B, Paley C, Mody-Patel N, Corral M, Scott J. Treatment of transfusional iron overload in patients with myelodysplastic syndrome or severe anemia: data from multicenter clinical practices. *Transfusion.* 2009 Aug 28. [Epub ahead of print]

HONORS

- | | |
|-----------|--|
| 1992-1996 | Harvard University: Pharmacoepidemiology Teaching and Training Award |
| 1994 | Harvard University: Teaching Fellow (honorary award) |
| 1992 | Yale University: National Collaborative Spinal Cord Study Training Award |
| 1992 | Yale University: Scholarship Award for Distinctive Doctoral Applicant |

INVITED SPEECHES

- | | |
|------|--|
| 2003 | “Application of pharmacoepidemiology to drug safety litigation”,
Pharmacoepidemiology Seminar Series, Harvard School of Public Health,
Boston, Massachusetts |
|------|--|

2006

“A new dimension of disease burden- work absenteeism and presenteeism”
Health economics and outcomes research seminar series, Harvard School of
Public Health, Boston, Massachusetts