

HEALTH MATTERS, INC

CAROLE ALISON CHRVALA, PHD

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<http://www.healthmattersmedwriting.com>

PROFESSIONAL QUALIFICATIONS

Independent epidemiologist, healthcare researcher, and writer with extensive experience in epidemiology, health economics and outcomes research, strategic and competitive analysis, medical writing, research design and interpretation, biostatistics, and health affairs

- Proficiency in all components of competitive strategic analyses, medical intelligence, and publication plans
- Expertise in disease surveillance and screening, exposure assessment, risk factor exposure, economic impact of disease and interventions, study design, sampling, program evaluation, analysis plans, and data interpretation
- Extensive experience in writing and editing scientific manuscripts for peer-reviewed journals
- Skilled in the preparation of abstracts, posters, and slide sets
- Substantial experience and expertise in health economics and outcomes research
- Proficiency in the synthesis of key findings from complex medical literature to prepare monographs, white papers, and comprehensive literature reviews
- Experience in the preparation of programs and materials for continuing education and sales training
- Skilled in the development of executive summaries for conference proceedings and advisory boards
- Proficiency in the preparation of all components of research proposals for submission to government agencies, non-government organizations, and commercial firms for grants, contracts, and cooperative agreements
- Skilled in the development of consumer education materials
- Accustomed to fast-paced, deadline-oriented work, develops and adheres to project timelines, handles multiple assignments simultaneously, and works collegially with project teams

THERAPEUTIC AREAS / SUBJECT MATTER EXPERTISE

- **Cardiovascular:** acute coronary syndrome, anticoagulant therapy, aortic stenosis, atherosclerosis, atrial fibrillation, dyslipidemia, heart failure, hypertension, mitral valve regurgitation, myocardial infarction, peripheral artery disease, pulmonary hypertension, stroke, unstable angina, venous thromboembolism
- **Diabetes:** diabetes self-management, hyperglycemia, hypoglycemia, microvascular and macrovascular complications, self-monitoring of blood glucose
- **Infectious diseases:** acute bacterial skin and skin structure infections, bacteremia, *Clostridium difficile*, hepatitis B, hepatitis C, HIV/AIDS, hospital-acquired pneumonia, influenza, *Legionella pneumophila*, MRSA, respiratory syncytial virus, sepsis, sexually transmitted infections, ventilator- and nonventilator hospital-acquired pneumonia
- **Musculoskeletal:** fractures, joint replacement, osteopenia, osteoporosis, skeletal-related events, work-related musculoskeletal injuries
- **Neurologic:** Alzheimer's disease, dementia, migraine, multiple sclerosis, non-malignant brain tumors, Parkinson's disease
- **Oncology:** bladder, brain and central nervous system, breast, cervical, colon, endometrial, esophageal, gastric, lymphoma; head/neck, hepatocellular, leukemia, lung, lymphoma, melanoma, mesothelioma, multiple myeloma, oral, ovarian, pancreatic, prostate, renal cell, rectal, skin, and urologic cancer; cancer-associated thrombosis
- **Psychiatric:** anorexia, attention deficit hyperactivity disorder, autism spectrum disorders, binge eating disorder, bipolar disorder, bulimia, depression, generalized anxiety disorder, post-traumatic stress disorder, schizophrenia
- **Respiratory:** allergies, asthma, chronic obstructive pulmonary disease, idiopathic pulmonary fibrosis, nontuberculous mycobacteria
- **Rheumatologic:** ankylosing spondylitis, gout, osteoarthritis, psoriatic arthritis, rheumatoid arthritis, scleroderma, Sjögren's syndrome, soft tissue rheumatism
- **Women's health:** contraception, endometriosis, fibromyalgia, hormone replacement therapy, peri- and post-menopausal health issues, prenatal testing, reproductive health, sexual health, vasomotor symptoms
- **Other:** acute and chronic pain, chronic kidney disease, Crohn's disease, hereditary angioedema, hidradenitis suppurativa, inflammatory bowel disease, long-term care, irritable bowel syndrome, obesity, opioid use and abuse, overactive bladder, plaque and pustular psoriasis, ulcerative colitis

EMPLOYMENT EXPERIENCE

Health Matters, Inc, Chatham County, NC

2004 to Present

Epidemiologist and Medical Researcher/Writer

- Strategic competitive analysis and medical intelligence
- Medical communications strategy and publication planning
- Epidemiologic research and statistical consulting
- Health economics and outcomes research
- Print and interactive training programs and materials
- Manuscripts for peer-reviewed journals
- Abstracts, posters, and slide presentations
- White papers, monographs, and literature reviews
- Continuing medical education materials and programs
- Conference and advisory board summaries
- Consumer health education materials

Valid Insight

2016 to present

Epidemiologist, HEOR Researcher, and Market Access Medical Writer

- Market access consulting to help companies navigate the challenges faced by drug developers seeking market access for new and innovative therapeutics

TTC Group

2014 to present

Strategy and Scientific Communications

- Providing life sciences management advisory and multidisciplinary strategic communications services

Rho, Incorporated, Chapel Hill, NC

2004 to 2005

Senior Research Scientist

- Co-Principal Investigator on a contract with National Institutes of Health for the Statistical and Clinical Coordinating Center for Autoimmune Centers of Excellence and Stem Cell Research with award amount totaling more than \$17 million
- Developed relationships with autoimmune disease thought leaders, clinicians, and cooperative group members
- Drafted and edited research proposals and related study materials including IRB submissions, Manuals of Operational Procedures, participant consent forms, data collection forms, and data validation procedures

- Prepared routine and special study reports for the sponsoring agency and supported coordination of a series of meetings and teleconferences with various members of the research consortium

CODA, Incorporated, Durham, NC

2003 to 2004

Senior Study Director

- Collaborated with study investigators, breast cancer clinicians, and laboratory researchers to refine the design of a study examining lifestyle and environmental risk factors for breast cancer among sisters of women with breast cancer
- Directed the design and development of a comprehensive, Web-based study management system
- Coordinated pilot test of computer-assisted telephone interviews, various self-administered questionnaires, and in-home biological specimen collection
- Drafted and edited study materials including IRB submissions, data collection instruments, data collection procedures, and participant education materials
- Developed and tested communication materials and strategies for participant recruitment and retention
- Completed quality-control review of all project deliverables and coordinated a staff of 15 professionals

CSR, Incorporated, Arlington, VA

2001 to 2003

Director, Health Research and Analysis Division

- Co-Principal Investigator and Project Director for 3 separate contracts with the National Institutes of Health that focused on HIV/AIDS, drug and alcohol use, and drug-related deaths with award amounts totaling more than \$6,000,000
- Coordinated in-depth reviews of the scientific literature on drug use, alcohol use, and drug-related deaths
- Coordinated the design, testing, implementation, and modification of a Web-based data collection system for Ryan White CARE Act grantees
- Developed methods and materials for the provision of technical assistance and training for recipients of funds under the Ryan White CARE Act
- Prepared routine and special summary reports on results of data submitted by Ryan White CARE Act grantees as well reports on the evaluation of technical assistance and training activities

- Developed detailed work plans and timelines for all project deliverables, completed quality-control review of all project deliverables, and coordinated a staff of 25 professionals

National Academy of Sciences, Washington, DC
2001

1998 to

Senior Program Officer

- Collaborated with committees of national experts and opinion leaders to respond to congressionally mandated research topics while adhering to strict reporting timelines
- Completed comprehensive reviews of relevant scientific literature, regulations, and protocols
- Collaborated with committee members to integrate key findings from reviews and develop conclusions and recommendations
- Prepared draft and final report manuscripts and responded to external peer review of these manuscripts and implemented strategies for dissemination of final reports
- Provided briefings on key conclusions and recommendations for congressional committees and the Office of the Surgeon General

Food and Drug Administration, Bethesda, MD

1997 to 1998

Senior Scientist

- Conducted studies of patterns and predictors of mammography utilization among diverse groups of women
- Examined barriers and incentives to compliance with mammography quality assurance regulations
- Conducted training for health professionals on the epidemiology of breast cancer and aspects of mammography quality assurance regulations

Colorado Department of Public Health and Environment, Denver, CO

1989 to 1996

Director, Cancer Prevention and Control Program

- Principal Investigator on 5 grants and cooperative agreements with cumulative award amounts totaling \$20 million
- Co-principal Investigator on 7 grants and cooperative agreements with cumulative award amounts totaling \$10 million
- Developed and coordinated a web-based statewide mammography surveillance system

- Developed and evaluated materials and interventions tailored for health professionals to improve patterns of referral for cancer screening and diagnostic evaluation of screen-detected abnormalities
- Developed and evaluated materials and interventions tailored for diverse consumer groups to promote adherence to screening exams for breast, cervical, colorectal, skin, and prostate cancer
- Prepared and provided testimony to state and federal legislative bodies on issues relevant to cancer prevention and control
- Served on state and national advisory boards addressing a broad range of public health issues
- Served on special grant review panels for the National Institutes of Health
- Developed detailed work plans and timelines for all project deliverables, completed quality-control review of all project deliverables, and coordinated a staff of 50 professional and administrative staff

GRANTS AND FUNDED RESEARCH

Principal Investigator: Breast Cancer Surveillance Research in Colorado. Grant No. 1U01 CA63736, National Institutes of Health, National Cancer Institute, Division of Cancer Prevention and Control, 1994 to 1999. Total award: \$2,500,000

Principal Investigator: Breast Cancer Educational Interventions for Worksites. Grant No. 1R25CA66873, National Institutes of Health, National Cancer Institute, Division of Cancer Prevention and Control, 1994 to 1997. Total award: \$398,779

Principal Investigator: Colorado Women's Cancer Control Initiative. US Centers for Disease Control and Prevention, Division of Cancer Prevention and Control, 1991 to 1996. Total award: \$15,000,000

Principal Investigator: Behavior Change Achieved by Different Breast Self-Examination Educational Techniques. Grant No. RFA87-CA-37; National Institutes of Health, National Cancer Institute, Division of Cancer Prevention and Control, 1989 to 1991. Total award: \$35,000

Principal Investigator: Assessment of Physicians Attitudes and Practices Concerning Breast Cancer Screening Exams. Cancer League of Colorado, 1989 to 1990. Total award: \$19,240

Co-Principal Investigator: Statistical and Clinical Coordinating Center for Autoimmune Diseases and Stem Cell Transplant Therapy. Division of Allergy, Immunology, and Transplantation, National Institutes of Health, DHHS, 2002 to 2007. Total Award: Approximately \$18,000,000

Co-Principal Investigator: A Public Health Study of Mammogram Interpretation. National Institutes of Health, National Cancer Institute, Division of Cancer Prevention and Control, 1997 to 2000. Total award: \$750,042

Co-Principal Investigator: Opportunities to Promote Screening Mammography under the Mammography Quality Standards Act of 1992. Jacobs Institute, 1998. Total award: \$19,500

Co-Principal Investigator: Breast and Cervical Cancer Screening Interventions for Latinas in Colorado. Grant No. RFA-89-CA-15, National Institutes of Health, National Cancer Institute, Special Populations Branch, 1990 to 1995. Total award: \$2,500,000

Co-Principal Investigator: Breast Cancer Screening Surveillance: The Colorado Mammography Advocacy Project. US Centers for Disease Control and Prevention, Division of Cancer Prevention and Control, 1988 to 1992. Total award: \$1,600,000

Co-Principal Investigator: Colorado Women's Cancer Prevention and Control Program: A Model Program. US Centers for Disease Control and Prevention, Division of Cancer Prevention and Control, 1990 to 1991. Total award: \$600,000

Co-Investigator: CIS Initiated Outcalls to Promote Screening Mammography Among Low-Income Women. National Institutes of Health, National Cancer Institute, Division of Cancer Prevention and Control, 1993 to 1998. Total award: \$5,000,000

OTHER PROFESSIONAL ACTIVITIES

Member of the 2017-18 Ethics and Standards Committee of the International Society for Medical Publication Professionals

Abstract reviewer for the 2017 International Society for Pharmacoeconomics and Outcomes Research 20th annual European Congress

Abstract reviewer for the 2017 International Society for Pharmacoeconomics and Outcomes Research 6th Latin America Conference

Abstract reviewer for the 2017 33rd annual international meeting of the International Conference on Pharmacoepidemiology and Therapeutic Risk Management

Abstract reviewer for the 2017 22nd annual international meeting of the International Society for Pharmacoeconomics and Outcomes Research

Abstract reviewer for the 2017 50th annual meeting of the Society for Epidemiologic Research

Abstract reviewer for the 2016 semi-annual Student Novel Methods Web Conference of the Society for Epidemiologic Research

Abstract reviewer for the 2016 19th annual European Congress of the International Society for Pharmacoeconomics and Outcomes Research

Abstract reviewer for the 2016 32nd International Conference on Pharmacoepidemiology & Therapeutic Risk Management of the International Society for Pharmacoepidemiology

Abstract reviewer for the 2016 annual meeting of the Society for Epidemiologic Research

Faculty for the 2016 Health Economics and Outcomes Research Writing Workshop, Comparative effectiveness and real-world evidence research: Understanding and using data and evidence in HEOR writing, March 2016

Faculty for the 2nd annual Health Economics and Outcomes Research Writer Workshop Webinar, Comparative effectiveness and real-world evidence research, December 2015

Abstract reviewer for the 2015 annual meeting of the Society for Epidemiologic Research

Abstract reviewer for the 2014 annual meeting of the Society for Epidemiologic Research

Reviewer for the *American Journal of Epidemiology*, 2014

Reviewer/Commentator on the Good Publication Practice 3 (GPP3) Initiative for the International Society for Medical Publication Professionals, 2014

Member of the Steering Committee for Stem Cell Transplantation Investigations for Autoimmune Diseases, National Institute on Allergy and Infectious Disease, Division of Allergy, Immunology, and Transplantation (2004 to 2006)

Member of the Steering Committee for Academic Centers of Excellence for Immunology and Transplantation, National Institute on Allergy and Infectious Disease, Division of Allergy, Immunology, and Transplantation (2004 to 2006)

Member of the Cellular Manufacturing Process Monitoring Committee, National Institute on Allergy and Infectious Disease, Division of Allergy, Immunology, and Transplantation (2004 to 2006)

Member of the Recruitment and Retention Advisory Board, Sister Study: Gene-Environment Interaction in the Etiology of Breast Cancer (2003 to 2004)

Member of the Scientific Advisory Board, Sister Study: Gene-Environment Interaction in the Etiology of Breast Cancer (2003 to 2004)

Chair of a review panel to author a white paper on the final Mammography Quality Standards Act for states involved in the National Breast and Cervical Cancer Early Detection Program (Spring 1996)

Member of the Grants Review Board for the Susan G. Komen Foundation, Colorado Division (1996)

Chair of the National Breast Cancer Screening Surveillance Consortium (1995 to 1996)

Consultant to Dartmouth Medical School concerning methods and strategies for design, implementation, and evaluation of breast cancer screening surveillance systems (Fall 1995)

Chair of a review panel to author a white paper on the issue of screening mammography reimbursement for women 40 to 49 for states involved in the National Breast and Cervical Early Detection Program (Spring 1995)

Member of the Minority Clinical Trials Advisory Board, University of Colorado Health Sciences Center, Division of Cancer Prevention and Control (1995 to 1996)

Special Grant Review Panel on Specialized Program of Excellence in Breast Cancer Research, National Institutes of Health, National Cancer Institute (1995)

Special Grant Review Panel on Community Prevention and Control, National Institutes of Health, National Cancer Institute (1994 to 1996)

Member of the Ad Hoc Advisory Group on Physician Reminder Systems, American Cancer Society, National Office (1993 to 1997)

Member of the Osteoporosis Advisory Board, Colorado Department of Public Health and Environment (1993 to 1996)

Program Director for the Secondary Prevention Program, Division of Cancer Prevention and Control, University of Colorado Health Sciences Center (1993 to 1994)

Expert Witness testifying to the United States House of Representatives, Sub-Committee on Health and the Environment, Committee on Energy and Commerce concerning re-authorization of Public Law 101-345 (April 1993)

Consultant to state Departments of Public Health (Maryland, New Jersey, Michigan, North Dakota, Kansas, and New York) on project design, implementation, and evaluation for the CDC-funded National Breast and Cervical Cancer Early Detection program (1992 to 1996)

Member of the Prostate Cancer Task Force, American Cancer Society, Colorado Division (1992 to 1996)

Special Grant Review Panel on Data-based Intervention Research Programs, Public Health Initiative, National Institutes of Health, National Cancer Center, Public Health Applications Branch (1992 to 1994)

Member of the CDC Training Program Advisory Committee, National Program for Breast and Cervical Cancer Early Detection Program, Division of Cancer Prevention and Control, US Centers for Disease Control (1992 to 1993)

Member of the Colorado Mammography Fund, Board of Directors (1991 to 1996)

Member of the Rocky Mountain Cancer Information Service Advisory Board, Rocky Mountain Region (1991 to 1996)

Member of the Office of Cancer Communications Planning Board, National Institutes of Health, National Cancer Institute, Office of Cancer Communications (1991 to 1994)

Member of the Mammography Training Advisory Committee, Community College of Denver (1991 to 1992)

Special Grant Review Panel on Public Health Approaches to Breast and Cervix Screening, National Institutes of Health, National Cancer Center, Public Health Applications Branch (1991)

Member of the Diabetes Prevention and Control Advisory Group, Diabetes Control Program, Colorado Department of Public Health and Environment (1990 to 1996)

Member of the state Cardiovascular Disease Prevention Coalition, Cardiovascular Disease Prevention and Control Program, Colorado Department of Public Health and Environment (1990 to 1994)

Member of the National Black Leadership Initiative on Cancer, Southwest Region (1990 to 1994)

Member of the Colorado Breast Cancer Task Force, American Cancer Society, Colorado Division (1989 to 1996)

Member of the Health and Human Services State Advisory Committee, Latin American Research and Service Agency (1989 to 1993)

PROFESSIONAL AFFILIATIONS

- American Diabetes Association
- American Heart Association
- American Medical Writers Association
- American Society of Clinical Oncology
- European Medical Writers Association
- International Society for Medical Publication Professionals
 - Member of Ethics and Standards Committee
 - Member of the Case Studies Subcommittee
 - Member of the Standards Handbook Subcommittee
- International Society for Pharmacoeconomics and Outcomes Research

- International Society for Pharmacoepidemiology
- Society for Epidemiologic Research

EDUCATION

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| University of Colorado, Boulder, CO | PhD | Behavioral Medicine/Epidemiology |
| | MA | Behavioral Medicine/Epidemiology |
| College of Wooster, Wooster, OH | BA | Psychology |

HONORS AND AWARDS

- Phi Beta Kappa
- Recipient of Reaching People through Partnerships Award, National Institutes of Health, National Cancer Institute
- Recipient of Women's Health Award, Community Coalitions of the Colorado Women's Cancer Control Initiative

SELECTED PUBLICATIONS

Ballard-Barbash R, Taplin SH, Yankaskas BC, Ernster VL, Rosenburg RD, Carney PA, Barlow WE, Geller BM, Kerlikowske K, Edwards BK, Lynch CF, Urban N, Chrvala CA, Key CR, Poplack SP, Worden JK, Kessler LG. Breast Cancer Surveillance Consortium: A national mammography screening and outcomes database. *AJR Am J Roentgenol*. 1997;169(4):1001-8.

Chrvala CA. The changing landscape of treatment options for metastatic castrate-resistant prostate cancer: challenges and solutions for physicians and patients. *Pharmacy & Therapeutics Journal*. 2012;37(8):453-63.

Chrvala CA. Breast cancer risk status as a predictor for breast cancer screening behaviors. *Prog Clin Bio Res*. 1990;339:239-51.

Chrvala, CA. The Colorado Women's Cancer Control Initiative: A comprehensive effort to address breast and cervical cancer in Colorado. *Colorado Medicine*. 1993;90(4):141-2.

Chrvala CA, Bulger R, eds. *Leading Health Indicators for Healthy People 2010*. Washington, DC: National Academy Press; 1999.

Chrvala CA, Crepeau FM, Todd WW, Hurlburt GA. and Webb W. The Colorado Mammography Advocacy Project: Breast Cancer Screening Surveillance in Colorado. *Colorado Medicine* 1992;89(5):179-81.

Chrvala CA, Crepeau FM, Todd WW, Webb W, Hurlburt GA, Nadel M. Breast cancer screening. Results and follow-up for Colorado women. *Colorado Medicine*. 1992;89(5):179-81.

- Chrvala CA, Iverson DC. Predictive models for proficiency and frequency of BSE performance. *Prog Clin Bio Res*. 1989;293:159-73.
- Chrvala CA, Iverson DC. A smoking history analysis of former and current smokers. *Prog Clin Bio Res*. 1989;293:197-210.
- Chrvala CA, Klein SA, Hurlburt GA. Patterns and predictors for physician compliance with breast cancer screening guidelines. *Colorado Medicine*. 1995;92:101-03.
- Chrvala CA, Scrimshaw S, eds. *Speaking of Health: Assessing the Effectiveness of Health Communications for Diverse Populations*. Washington, DC: National Academy Press; 2002.
- Chrvala CA, Sharfstein S, eds. *Definitions for Serious and Complex Medical Conditions*. Washington, DC: National Academy Press; 1999.
- Chrvala CA, Sherr D, Lipman RD. Diabetes self-management education for adults with type 2 diabetes mellitus: a systematic review of the effect on glycemic control. *Patient Education and Counseling*. 2015 Nov 22. [Epub ahead of print]
- Eagly AH, Chrvala CA. Sex differences in conformity: Status and gender role interpretations. *Psychol Women Q*. 1986;10:203–220.
- Hendrick RE, Chrvala CA, Plott C, Cutter GR, Jessop NW, Wilcox-Buchalla P. Improvement in mammography quality control: 1987–1995. *Am J Radiol*. 1998;207(3):663–8.
- Kaplan RM, Navarro AM, Castro GG, Elder JP, Mishra SI, Hubbell A, Chrvala CA, Flores E, Ramirez A, Fernandez-Esquer ME, Ruiz E. Increased use of mammography screening among Hispanic women: Baseline results from the National Cancer Institute cooperative group on cancer prevention in Hispanic communities. *Am J Prev Med*. 1996;12(6):467–71.
- Riedl M, Gower RG, Chrvala CA. Current medical management of hereditary angioedema: results from a large survey of US physicians. *Ann Allergy Asthma Immunol*. 2011;106(4):316–22.

VOLUNTEER ACTIVITIES

- Member of the Program Committee for the Chatham County Literacy Council
- Consultant to the Chatham County Literacy Council on the design, conduct, analysis, and interpretation of results from a needs assessment on literacy in Chatham County