

Summary of Epidemiology and Biostatistics Projects

Carole Alison Chrvala, PhD

919.545.2149 (Work) 919.951.5230 (Mobile)

cchrvala@centurylink.net

www.healthmattersmedwriting.com

- Systematic literature review on the frequency, risk factors, and severity of tooth staining and discoloration associated with tetracycline
- Systematic literature review on the efficacy and safety of immunotherapy in the treatment of cancer
- Literature review to characterize global prevalence and incidence rates for chronic thromboembolic pulmonary hypertension
- Development of a statistical data plan and interpretation of results to evaluate the impact of an online continuing medical education and quality improvement intervention to improve remission rates in patients with major depressive disorder
- Development of clinical study protocol, statistical analysis plan, data management, analysis, and interpretation, and research monitoring for a prospective, randomized, controlled trial comparing a wearable insulin delivery device to standard insulin optimization for type 2 diabetes mellitus
- Research, data analysis, and writing for a risk management plan submission to the European Medicines Agency for authorization of a novel antibacterial agent for the treatment of community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections
- Systematic and structured literature reviews of the prevalence of dyslipidemia, lipids and cardiovascular events, lipid monitoring, effects of anti-retroviral regimens on lipid profiles, and management of dyslipidemia in patients with HIV-1
- Systematic literature review on the neuropsychiatric safety, tolerability, toxicity, and discontinuation of integrase strand transfer inhibitors for the treatment of HIV-1
- Systematic literature review on the incidence of and predictors for chronic opioid use following surgery
- Preparation of slide presentations and supporting materials for submission to a Food and Drug Administration Advisory Committee to review the efficacy and safety of a humanized, anti-eosinophil monoclonal antibody for the treatment of severe uncontrolled asthma with eosinophilic phenotype
- Disease area review to identify unmet needs and develop a value proposition to support a selective monoclonal antibody for moderate-to-severe hidradenitis suppurativa

- Literature review, summary, and interpretation of findings regarding current and emerging therapies for renal cell carcinoma
- Global value dossier on first- and second-line therapies for metastatic renal cell carcinoma
- Clinical study protocol, statistical analysis plan, data collection, and analysis for a prospective case-control study to assess the impact of arteriovenous fistula or graft dysfunctions on health-related quality of life in patients undergoing hemodialysis
- Research proposal to evaluate interventions for the prevention of renal failure in hemodynamically unstable patients in the critical care setting
- Data collection, analysis, and strategic direction on the economic burden and patient-reported outcomes associated with primary and secondary patency loss of arteriovenous fistula access in patients with chronic kidney disease and peripheral artery disease
- Development of a research protocol for a longitudinal observational registry study to assess the clinical outcomes of patients with advanced solid and hematologic malignancies tested by standardized next-generation genomic sequencing and treated with provider-determined standard of care
- Preparation of an investigational new drug briefing package for submission to the Food and Drug Administration to change the marketing status of an emergency contraceptive product from prescription to over-the-counter status for women of childbearing potential
- Benefit-risk analysis to support a feasibility analysis for FDA submission to approve over-the-counter access for an emergency contraceptive
- Evaluation of global health status and quality of life in patients randomized to chemotherapy or EGFR-directed therapy for *EGFR* mutation-positive lung cancer
- Review of patient and disease profiles associated with increased risk of cardiovascular event to support a feasibility analysis for FDA submission to approve over-the-counter status for short-term use of nonsteroidal anti-inflammatory drugs and cyclooxygenase-2 selective inhibitors currently prescribed for mild pain attributed to arthritis and musculoskeletal pain
- Literature review and summary on the prevalence, incidence, and risk factors for injuries associated with high-risk movements in healthcare workers

- Analysis of an administrative research database to describe the baseline characteristics of patients with ALK-positive non-small cell lung cancer, identify anti-cancer therapy prior to initiation of ALK+ therapy, and analyze treatment patterns including discontinuations and dose modifications associated with ALK+ therapy
- Review of health conditions characterized by vasomotor symptoms and a feasibility analysis for FDA submission to approve over-the-counter status of a prescription medication for moderate-to-severe vasomotor symptoms
- Research consultant and biostatistician for a quasi-experimental study to evaluate the impact of a patient safe-handling intervention on rates of healthcare worker injuries and identify barriers and incentives to worker adherence to the intervention
- Research consultant and biostatistician on a grant submitted to the Agency for Healthcare Research and Quality for a prospective study to evaluate safety, efficiency, accuracy, and user satisfaction associated with 4 types of intravenous smart pump devices
- Interactive training module on research design, statistical principles, statistical analysis and interpretation, data presentation, and health economics and patient-reported outcomes for healthcare professionals
- Comprehensive analysis of overactive bladder syndrome including incidence, prevalence, symptoms, risk factors, diagnosis, disease progression, comorbid conditions, physical and psycho-emotional consequences, direct and indirect economic costs, and an historical overview of current and emerging treatments
- Analysis of the role of an investigational, oral tyrosine kinase inhibitor for advanced malignancies, including ALK-positive non-small cell lung cancer with and without brain metastases, compared with crizotinib, ceritinib, and alectinib
- Analysis of the association between nonalcoholic steatohepatitis and risk factors for cardiovascular disease, including obesity, dyslipidemia, hypertension, and insulin resistance
- Statistical analysis plan and randomization strategy to compare the impact of a community-based diabetes self-management intervention with and without ongoing structured support

- Research proposal and statistical analysis plan for an evidence-based intervention to assess current practices regarding the management of mitral valve disease
- Analysis of results from surveys, interviews, and focus groups conducted with primary care physicians, interventional cardiologists, imaging cardiologists, and cardiothoracic surgeons to assess current knowledge, skills, and practices regarding the evaluation and management of mitral valve regurgitation
- Development and validation of a risk prediction model for recurrent *Clostridium difficile*
- Analysis and interpretation of findings from the international Diabetes Attitudes, Wishes, and Needs (DAWN2) study and development of recommendations to support patient-centered care for people with diabetes, with a focus on policies, interventions, follow-up, and evaluation to improve healthcare, clinical outcomes, and quality of life
- Systematic review of the impact of diabetes self-management education on clinical outcomes, quality of life, healthcare resource utilization, and indirect costs
- Evaluation of the incidence, risk factors, current treatment strategies, clinical outcomes, and healthcare utilization for *Clostridium difficile* in residents of long-term care facilities
- Analysis of differences in risk factors for hospital-acquired versus community-acquired *Clostridium difficile*
- Analysis of risk factors for hospital readmission for recurrent *Clostridium difficile*
- Analysis of trends in healthcare resource utilization and costs among hospitalized patients with *Clostridium difficile*
- Analysis of the clinical and economic burden of *Clostridium difficile*-associated diarrhea among high-risk populations during hospitalization
- Analysis of the healthcare resource utilization and economic burden of *Clostridium difficile*-associated diarrhea among populations at high risk of recurrence following hospital discharge
- Data collection and analysis to support a medication use evaluation tool to improve clinical outcomes in *Clostridium difficile*

- Evaluation of the epidemiology, pharmacologic interventions, healthcare utilization, and costs associated with the treatment of *Clostridium difficile* in hospital and outpatient settings
- Evaluation of hospital readmission rates and predictors associated with *Clostridium difficile*
- Analysis of the epidemiologic burden, risk factors, diagnosis, treatment patterns, and health consequences of endometriosis in adolescents
- Substantive writing and edits for a research proposal to evaluate an intervention to reduce the risk of prediabetes and diabetes among airforce personnel for submission to the National Institutes of Health by the Diabetes Center of Excellence, United States Air Force
- Analysis of the epidemiologic burden, risk factors, treatment patterns, and prognosis of glioma to support an application for submission to the European Medicines Agency for approval of orphan drug designation
- Evaluation of US and international databases to characterize trends in the staging of newly-diagnosed breast cancer in western European countries
- Analysis of the worldwide epidemiologic burden of non-small cell lung cancer, associated risk factors, and emerging treatments through 2020
- Analysis of the epidemiologic burden, risk factors, treatment implications, and prognosis for chemotherapy-induced peripheral neuropathy in response to treatment for non-small cell lung cancer
- Projection of the worldwide epidemiologic burden of hepatocellular cancer and associated risk factors through 2015 and 2020
- Evaluation of US and international databases and research on non-Hodgkin lymphoma to characterize the epidemiologic burden, risk factors, prognostic indicators, and the safety and efficacy of current and emerging therapies
- Evaluation of US and international databases and research on chronic lymphocytic leukemia to characterize the epidemiologic burden, risk factors, prognostic indicators, and the safety and efficacy of current and emerging therapies
- Evaluation of US and international databases and research on multiple myeloma to characterize the epidemiologic burden, risk factors, prognostic indicators, and the safety and efficacy of current and emerging therapies
- Retrospective analysis of the indications, prevalence, and outcomes associated with liver transplantation for hepatocellular cancer

- Evaluation of US and international databases and research on central nervous system metastases including epidemiologic burden, risk factors, prognostic indicators, and the safety and efficacy of current and emerging therapies
- Evaluation of US and international data and research on hepatocellular cancer to characterize the epidemiologic burden, risk factors, prognostic indicators, and the efficacy and safety of current and emerging therapies
- Summary report on current classification systems, diagnosis, induction therapy regimens by patient age, consolidation therapy, relapse interventions, and salvage regimens for acute myeloid leukemia
- Analysis of the epidemiologic burden, risk factors, treatment patterns, and prognosis of pediatric solid tumors to support applications for submission to the European Medicines Agency and the US Food and Drug Administration for approval of orphan drug designation
- Review of the epidemiologic burden, trends, efficacy and safety of current and emerging therapies, and prognosis for acute myeloid leukemia
- Evaluation of the strengths and limitations of methods to identify, recruit, and maintain a cohort of patients with relapsed diffuse large B cell lymphoma
- Evaluation of the strengths and limitations of methods to identify, recruit, and maintain a cohort of patients with metastatic melanoma
- Comparative analysis of epidemiologic trends among adult and pediatric populations worldwide for acute myeloid leukemia and myelodysplastic syndromes
- Comparative review of the efficacy and safety of therapeutic interventions for breakthrough cancer pain
- Analysis of the epidemiologic burden, risk factors, therapeutic options, and prognosis of ovarian cancer to support applications for submission to the European Medicines Agency and the US Food and Drug Administration for approval of orphan drug designation
- Analysis of the epidemiologic burden, risk factors, treatment patterns, and prognosis of glioblastoma multiforme to support applications for submission to the European Medicines Agency and the US Food and Drug Administration for approval of orphan drug designation
- Comparative review of the efficacy and safety of pharmacologic interventions for acute exacerbations of hereditary angioedema

- Research proposal for the development and implementation of a tracking and follow-up surveillance system for patients with hereditary angioedema and individuals at risk of hereditary angioedema
- Analysis of the strengths and limitations of biomarkers for new drug development in oncology
- Development of case report forms and data collection procedures for multiple myeloma treated with pegylated liposomal doxorubicin
- Substantive writing and edits to the General Research and Clinical Center competitive renewal application submitted by the University of North Carolina, Chapel Hill to the National Institutes of Health (funded)
- Systematic analysis of hyperuricemia as a biomarker for rheumatologic, metabolic, and hemodynamic abnormalities
- Preparation of a global statistical analysis plan for evaluation of device interventions for cardiovascular disease
- Epidemiologic analysis of *de novo* coronary lesion length, stent length, and evaluation of the efficacy and safety of drug-eluting and bare metal stents
- Epidemiologic analysis reviewing the safety profile of selective factor Xa inhibitors for a risk management plan for venous thromboembolism and stroke
- Epidemiologic analysis on treatments for platinum-sensitive, taxane-sensitive ovarian cancer
- Comprehensive literature review on the efficacy, safety, and tolerability of progestins
- Literature review, data analysis, and summary of sources of epidemiologic bias interpretation of results from population-based registries to determine the efficacy of pharmacologic interventions
- Consultant to medical device company on percutaneous coronary interventions with drug-eluting stents for coronary artery disease including reviews of published literature and conference proceedings on basic pharmacology, randomized controlled trials, patient registries, and observational studies
- Analysis of the epidemiologic burden, risk factors, treatment patterns, and prognosis of acute myeloid leukemia to support applications for submission to the European Medicines Agency and the US Food and Drug Administration for orphan drug designation

- Comprehensive literature review on strategies for primary care providers to provide patient education and counseling about low-dose oral contraceptives
- Assisted with the research and development of the cancer prevention and control plan for the state of North Carolina
- Substantive writing and edits for a proposal on telehealth for submission by the Federation of State Medical Boards to the Health Services Resource Administration (funded)
- Substantive writing and edits for a proposal on pediatric epilepsy for submission by the University of California, San Francisco to the National Institutes of Health
- Review of published and fugitive literature for the development of a research proposal on pharmacologic interventions for schizophrenia
- Review of published and fugitive literature and interviews with subject matter experts regarding the epidemiologic burden, risk factors, treatment, and prognosis for various respiratory conditions
- Development of the Annual Cancer Review for the state of North Carolina
- Assisted with the development and conduct of a survey of health insurers regarding benefits for the primary and secondary prevention of cancer