AMY S. KENDRICK

Summary of Professional Experience

Amy S. Kendrick, in the Management and Operations group of the Environmental and Health Sciences Division at RTI International, is currently a clinical research manager within the Center for Clinical Research Network Coordination (CRNC). As a study manager within the Management and Operations Group, she is responsible for facilitating the centralization and standardization of safety reporting procedures across coordinating centers. In addition, she serves as the clinical research manager on studies conducted in the Chronic Effects of Neurotrauma Consortium (CENC).

Ms. Kendrick has 14 years of patient care experience and more than 13 years of clinical research experience. Her patient care experience, primarily in pediatrics, ranged from outpatient to inpatient and then to Intensive Care Unit (ICU) settings. Her research experience has spanned from hospital site coordinator, to Clinical Research Office (CRO) coordinator and pharmacovigilance specialist, ultimately becoming project director of a coordinating center performing government-funded research on infectious disease and autoimmune disorders. Before joining RTI, she served for 6 years, as the clinical research manager of an Evidence Synthesis Group (ESG), which included an Evidence-based Practice Center (EPC), at Duke University. In that capacity, she managed between five and 15 employees. Her work has been published in many technical reports and peer-reviewed journals, including *Annals of Internal Medicine, Clinical Infectious Diseases,* and *Clinical Trials*.

Education

Post-Masters, Clinical Research Management, Duke University, Durham, NC, 2004.
MSN, Pediatric Nursing, University of Virginia, Charlottesville, VA, 1991.
BSN, Nursing, Simmons College, Boston, MA, 1988.

Professional Experience

2015 to date	RTI International, Research Triangle Park, NC.
	Clinical Research Manager. Facilitates the centralization and standardization of safety reporting procedures across coordinating centers. Serves as the clinical research manager for studies conducted in the CENC.
2009 to 2015	Duke Clinical Research Institute, Durham, NC.
	Clinical Trials Manager. The sponsors for the Duke Evidence Synthesis Group (ESG) duties included the Agency for Healthcare Research and Quality (AHRQ)/ Evidence-based Practice Center (EPC III, EPC V, and American Recovery and Reinvestment Act funded), Patient-Centered Outcomes Research Institute (PCORI), and professional societies. For literature reviews, developed project scopes, screened literature search results, abstracted data points, and prepared summaries of findings. For report writing, summarized methodologies from large

systematic reviews. Prepared summaries of findings for health care and research administration topics and for horizon scans and topic brief documents across body systems and disease processes. Prepared reports and journal manuscripts, participated in meetings, and discussed project status, ongoing scope, and timelines with sponsors. Communicated the status of projects within Duke (the Duke Clinical Research Institute and School of Medicine). Reviewed contracts and budgets for accuracy (project and functional group levels), facilitated scope and timeline modifications, and monitored expenditures and invoicing. For business development, wrote proposal sections (primarily project management sections) and assisted with project budgets (reviewed staffing levels and provided non-staff expenses). Supervised between five and 15 staff members, conducted performance evaluations, approved time cards and vacation requests, and evaluated overall utilization rates. As the hiring manager, reviewed resumes, conducted interviews, prepared job descriptions. Fostered ongoing team communication through policies and other administrative messages. Conducted weekly meetings with the team across entire ESG project portfolio, coordinated staff resources, and ensured consistent and systematic procedures through coordination. Directly provided in-services and ongoing mentoring to all staff levels across the project portfolio.

Project Leader. Provided ongoing coordination of 20 projects at any given time. Coordination tasks included performing systematic reviews, prioritizing future research prioritization, and conducting other types of projects. Database and software implementation involved the general use of an electronic database for conducting systematic reviews, including programming data forms, training users on how to utilize the software, and managing the database (approximately 60 projects). Adjusted resources to meet timelines and produce high-quality reports. Provided oversight and forecasting of project-specific funds. Authorized invoicing.

2004 to 2009 Rho, Inc., Chapel Hill, NC.

Project Director. Sponsors for work while at Rho, Inc. included two National Institute of Allergy and Infectious Diseases (NIAID) clinical trials networks: Bacteriology and Mycology Biostatical and Operations Unit (BAMBU) and Autoimmunity Centers for Excellence (ACE). Communicated regularly with the BAMBU sponsor. Coordinated personnel resources across the portfolio of projects and provided oversight of project timelines, with ongoing team and sponsor updates. Provided reports about project status per contract requirements and as needed to discuss any ongoing issues. Increased monitoring for overall project compliance, including appropriate archiving of study documents at the coordinating center and in the sponsor's master file.

Senior Study Coordinator. Worked on both BAMBU and ACE projects. Supervised and mentored coordinating center staff and mentored new staff. Monitored site initiation and ongoing (on-site and in-house) and close-out visits. Developed proposals by preparing sections that were specific to study coordination items. Reviewed proposal sections prepared by others (data management, regulatory, and safety reporting sections primarily). For procedural documents, developed coordination manuals of operations across projects (both within the coordinating center and across two coordinating centers for NIAID).

Nurse Coordinator. In the area of safety reporting, reviewed materials provided by sites, prepared serious adverse event reports for medical monitor, followed up with sites to resolve data queries, and participated in safety summary preparations for project reports (data safety, progress, and end of study). Provided general study coordination by preparing materials for manuals of operations, as well as tools to facilitate study implementation (i.e., inclusion or exclusion quick guides, study visit reminders, and screening and drug accountability logs). Prepared draft data collection forms (both paper based and electronic) and worked with statisticians and data managers to develop univariate and multivariate data checks. Reviewed data queries and worked with site staff regarding ongoing training and resolving data issues. Worked with coordinating center staff to teach protocol-specific items and how to use general management tools, trained site staff about protocols, the operations manual, and regulatory and Good Clinical Practice (GCP) items. Served as the point person for scientific and operational issues. For regulatory documents, prepared informed consent form (ICF) templates, reviewed site ICFs for regulatory compliance, and coordinated regulatory packet reviews and follow-up with coordinating center groups to facilitate site initiations and master file completeness. Disseminated scientific data by coordinating and participating in end-of-study reports, developing manuscripts for peer-reviewed journals, and participating at conferences.

2004 PPD, Morrisville, NC.

Nurse Consultant (January to April). Was a post-marketing call center responder for safety reporting and for consumer and health care professional inquiries duties.

2003 to 2004 Duke Clinical Research Institute, Durham, NC.

Research Externship. Developed study tools for case report forms, drafted ICFs and Institutional Review Board submissions, conducted feasibility surveys, and performed archiving per GCP and International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines.

2001 to 2003 Duke University Medical Center, Durham, NC.

Registered Nurse, Pediatric ICU and Interventional Radiology.

1988 to 2001 University of Virginia Medical Center, Charlottesville, VA.

Registered Nurse. Was a staff nurse on the inpatient Infant and Toddler/Medical and Surgical Unit, then a pediatric surgery coordinator, and then a staff nurse in the Newborn ICU (NICU). Additional roles during the 10 years as a NICU nurse included charge nurse, very low birthweight (VLBW) specialist, new staff preceptor (for 17 new nurses), and extracorporeal membranous oxygenation specialist.

1992 to 1995 University of Virginia, Charlottesville, VA.

Research Coordinator. Coordinated multiple protocols across the Cardiology and Neonatology Departments.

Honors and Awards

Nursing Curriculum Tutor, Simmons College, 1985 to 1988.

Professional Service

Chairperson, Professional Advisory Committee for Camp Holiday Trails, 1989 to 1991.

Peer-Reviewed Journal Articles

Al-Khatib, S. M., Gierisch, J. M., Crowley, M. J., Coeytaux, R. R., Myers, E. R., Kendrick, A, et al. (2015). Future research prioritization: Implantable cardioverter-defibrillator therapy in older patients. *Journal of General Internal Medicine.* May 27. [Epub ahead of print].

Gierisch, J. M., Myers, E. R., Schmit, K. M., McCrory, D. M., Coeytaux, R. R., Crowley, M. J., … Kendrick, A. S., et al. (2014). Prioritization of patient-centered comparative effectiveness research for osteoarthritis. *Annals of Internal Medicine, 160*(12) 12, 836–841.

Crowley, M. J., McCrory, D. M., Chatterjee, R., Gierisch, J. M., Myers, E. R., Schmit, K. M., … Kendrick, A. S., et al. (2014) Prioritization of research addressing antipsychotics for adolescents and young adults with bipolar disorder. *Annals of Internal Medicine, 160*(7), 492–498.

Gierisch, J. M., Myers, E. R., Schmit, K. M., Crowley, M. J., McCrory, D. M., Chatterjee, R., … Kendrick, A. S., et al. (2014). Prioritization of research addressing management strategies for ductal carcinoma in situ. *Annals of Internal Medicine, 160*(7), 484–491.

Jackson, G. L., Powers, B. J., Chatterjee, R., Bettger, J. P., Kemper, A. R., Hasselblad, V., … Kendrick, A. S., et al. (2013). Improving patient Care. The patient-centered medical home a systematic review. *Annals of Internal Medicine, 158*(3), 169–178.

Bettger, J. P., Alexander, K. P., Dolor, R. J., Olson, D. M., Kendrick, A. S., Irvine, J. R., et al. (2012). Transitional care after hospitalization for acute stroke or myocardial infarction: A systematic review. *Annals of Internal Medicine, 157*(6), 407–416.

Bright, T. J., Wong, A., Dhurjati, R., Bristow, E., Bastian, L., Coeytaux, R. R., … Kendrick, A. S., et al. (2012). Effect of clinical decision-support systems: A systematic review. *Annals of Internal Medicine, 157*(1), 29–43.

Powers, B. J., Coeytaux, R. R., Dolor, R. J., Hasselblad, V., Patel, U. D., Yancy, Jr., W.S., … Kendrick, A. S., et al. (2012). Updated report on comparative effectiveness of ACE inhibitors, ARBS, and direct renin inhibitors for patients with essential hypertension: much more data, little new information. *Journal of General Internal Medicine, 27*(6), 716–729.

Anekthananon, T., Manosuthi, W., Chetchotisakd, P., Kiertiburanakul, S., Supparatpinyo, K., Ratanasuwan, W., … Kendrick, A. S., et al. (2011). Predictors of poor clinical outcome of cryptococcal meningitis in HIV–infected patients. *International Journal of STD & AIDS, 22*(11), 665–670.

Sungkanuparph, S., Filler, S., Chetchotisakd, P., Pappas, P., Nolen, T.L., Manosuthi, W., … Kendrick, A. S., et al. (2009). Cryptococcal immune reconstitution, inflammatory syndrome after antiretroviral therapy in AIDS patients with cryptococcal meningitis: a prospective multicenter study. *Clinical Infectious Diseases, 49*(6), 931–934.

Pappas, P., Chetchotisakd, P., Larsen, R., Manosuthi, W., Morris, W., Anekthananon, T., … Kendrick, A. S., et al. (2009). A phase II randomized trial of amphotericin B alone or combined with fluconazole in the treatment of HIV–associated cryptococcal meningitis. *Clinical Infectious Diseases, 48*(12), 1775–1783.

Nolen, T. L., Dimmick, B., Ostrosky-Zeichner, L., Kendrick, A. S., Sable, C., Ngai, A., et al. (2009). A Web-Based Endpoint Adjudication System (WEBEAS) for interim analyses in clinical trials. *Clinical Trials, 6*(1), 60–66.

Presentations and Proceedings

Ostrosky-Zeichner, L., Sobel, J., Pappas, P., Shoham, S., Barron, M., Reboli, A., … Kendrick, A. S., et al. (2007, September). *Pilot study of risk-based caspofungin (CFG) prophylaxis in the ICU: Lessons from a multicenter, randomized, double-blind trial and insights into diagnostic performance of surrogate markers.* Poster presented at the 47th Annual Interscience Conference of Antimicrobial Agents and Chemotherapy, Chicago, IL.

Kendrick, A. S., Nolen, T. L., Zimmer, L. O., & Wallace, D. (2007, May). *Trials and their tribulations: The importance of reality checks when planning a clinical trial*. Poster presentation at the Annual Meeting of the Society for Clinical Trials, Montreal, Quebec, Canada.

Technical Reports

Williams, J. W., Jackson, G. L., Powers, B. J., Chatterjee, R., Bettger, J. P., Kemper, A. R., … Kendrick, A. S., et al. (2012, July). *Closing the quality gap series: Revisiting the state of the science. The patient-centered medical home*. Evidence report. Prepared by the Duke Evidence-based Practice Center. Contract number 290-2007-10066-I. Rockville, MD: Agency for Healthcare Research and Quality. *Evidence Report/Technology Assessment,* (208.2), 1–210.

Lobach, D., Sanders, G. D., Bright, T. J., Wong, A., Dhurjati, R., Bristow, E., … & Kendrick, A. S. (2012, April). *Enabling health care decision making through clinical decision support and knowledge management.* Evidence report. Prepared by the Duke Evidence-based Practice Center. Contract number 290-2007-10066-I. Rockville, MD: Agency for Healthcare Research and Quality. *Evidence Report/Technology Assessment,* (203), 1–784.

Olson, D. M., Bettger, J. P., Alexander, K. P., Kendrick, A. S., Irvine, J. R., Wing, L., et al. (2011, October). *Transition of care for acute stroke and myocardial infarction patients: From hospitalization to rehabilitation, recovery, and secondary prevention*. Prepared by the Duke Evidence-based Practice Center. Contract number 290-2007-10066-I. Rockville, MD: Agency for Healthcare Research and Quality. *Evidence Report/Technology Assessment,* (202), 1–197.

Kemper, A. R., Coeytaux, R., Sanders, G. D., Van Mater, H., Williams, J. W., Gray, R. N., … & Kendrick, A. S. (2011, September). *Disease-modifying antirheumatic drugs (DMARDS) in children with juvenile idiopathic arthritis (JIA)*. Prepared by the Duke Evidence-based Practice Center. Contract number HHSA 290 2007 10066-I. Rockville, MD: Agency for Healthcare Research and Quality.

Sanders, G. D., Coeytaux, R., Dolor, R. J., Hasselblad, V., Patel, U. D., Powers, B., … & Kendrick, A. S. (2011, June). *Angiotensin-converting enzyme inhibitors (ACEIs), angiotensin II receptor antagonists (ARBs), and direct renin inhibitors for treating essential hypertension: An update*. Prepared by the Duke Evidence-based Practice Center. Contract number 290-02-0025. Rockville, MD: Agency for Healthcare Research and Quality.