

# epidemiology pharmacoepidemiologist

## A TRUE TALE

“I was born into public health,” says Elizabeth Andrews, MPH, PhD. When she was a child growing up in North Carolina, her father was in charge of milk and food sanitation control for the state. “He was one of those very dedicated old-school public health officials,” she says. “We did not go into a restaurant without looking at the sanitation rating, and we never ate anything from the refrigerator without smelling it first.” Dr. Andrews has never lost this perspective on protecting the health of a community.

After graduating from the University of North Carolina (UNC), Dr. Andrews attended the UNC School of Public Health (UNCSPH) where she focused on health policy and administration. Her first official job was as health planner for the Secretary of the Department of Human Resources (now the Department of Health and Human Services) in North Carolina. The job entailed



Elizabeth Andrews, MPH, PhD

conducting needs assessments for health care services for the entire state. It also meant that she would play an important role in the strategic plan for delivery of health care in the state by working with North Carolina’s first legislative panel on health maintenance organizations. Her position as health planner was followed by a job at the North Carolina State Health Department, where she ran the state school health program as well as the statewide regionalized perinatal care program.

As her career advanced, Dr. Andrews realized her interests lay in epidemiology rather than health administration, “because I wanted to be more involved in conducting research and developing more of a specialized focus,” she says. When Dr. Andrews heard about an opening in epidemiology at a pharmaceutical company, she immediately applied, and was hired. The work was intellectually challenging, and Dr. Andrews relished the opportunity to work with so many bright, capable people who were leaders in their field. While on the job, she earned her PhD in epidemiology.



### Pharmaco- epidemiologist Checkpoint


Does applying the principles of epidemiology to pharmaceuticals sound interesting to you?

Are you interested in a scientific career path with a research focus?

Would you enjoy knowing that the results of your research will make a measurable difference to populations of people?

*If so, read on*

As a series of mergers increased the company's size, scope and complexity, Dr. Andrews' responsibilities also grew. "The pharmaceutical industry provided a fabulous setting for practicing public health epidemiology," she



"I describe epidemiology as 'the language of public health,' because, in this population-based field, we use numbers, rates and measures of associations to describe the impact of risk factors, behaviors, and health care interventions. These are the measures that guide public health priorities and policies."

says. Epidemiology can help shape drug development priorities by quantifying unmet medical need, and can help evaluate the safety of products when in general use outside of the structured research setting. Eventually, Dr. Andrews was ready for new challenges and found exactly what she was looking for when she joined RTI International, a global research organization, to head an epidemiology group, and was promoted to Vice President of RTI-Health Solutions.

### **Profiling the job**

Dr. Andrews is a public health research epidemiologist specializing in pharmacoepidemiology. Research epidemiologists work primarily with data collected by field epidemiologists or with secondary databases, such as electronic medical records databases. They monitor trends in diseases, identify etiologic factors, find relationships between exposures and clinical outcomes, model data and design appropriate public health programs. Field epidemiologists work on the front lines of potential and actual epidemic outbreaks. Both occupations are essential to the health of the public and, as might be expected, frequently overlap.

Though public health and private sector research epidemiologists work in largely the same ways, there are still significant differences between the two groups. "In the private sector, we sometimes may have the luxury of more resources, but at the same time the review process is often far more stringent and focused. All in all, however, the process takes less time, because the study usually addresses a practical and often urgent issue," Dr. Andrews says. Her company, RTI International, is a not-for-profit independent institute geared toward the social and health sciences. RTI has conducted health, medical and pharmaceutical research for the government and the private sector for over 40 years. Its multidisciplinary expertise covers all phases of

research, from initial study design through publication of study findings. Typical studies conducted by the organization address important issues such as undiagnosed asymptomatic sexually transmitted diseases, evaluation of the safety of antimicrobial therapy for anthrax exposure, measuring the prevalence and correlates of drug abuse in a large, representative sample of the U.S. population, reproductive toxicology studies, preclinical studies and a host of other concerns

As director of Health Solutions — RTI’s first large-scale strategic initiative focused on public health research largely for the commercial sector — Dr. Andrews leads a team of epidemiologists, statisticians, pharmacists, health economists, survey researchers and people experienced in market research and business strategy. The team focuses on health outcomes and the population impact of medicines, biologics and medical devices. “We do economic analysis of the value of medicines, help clients study the costs and benefits of therapy and develop systems that assess the value of a pharmaceutical company’s product in the marketplace,” she says. This work is extremely important to providers, payors and patients as the need to appropriately utilize innovative technologies grows. Studies utilize large databases that resemble the real world of clinical practice. A managed care organization (MCO) claims database, for example, shows all of a patient’s medical care claims, including when a patient visits his or her provider or fills a prescription. “We look at the records over time and develop a picture of what happened to that patient. If you do that with all the members of an MCO, which could number in the millions, then you can clearly evaluate a drug’s usefulness.” By studying large and broad-based data sets, epidemiologists attempt to characterize the long-term outcomes of care and identify key technologies and management strategies to provide better levels of care. “Of course we do this work with information that has been completely de-identified and we never have access to the individual patient or physician’s identity,” she says. All such research is reviewed by an Institutional Review Board to assure the confidentiality needs of all individuals are appropriately protected.

As a pharmacoepidemiologist, Dr. Andrews concentrates on different aspects of drug therapy in real world settings. She investigates the use and effectiveness of drug therapy in specific populations to help guide better clinical decision-making. These studies span a wide variety of diseases as well as care settings. The impact on public health, including critical conditions such as HIV and other viral infections, cancer, cardiovascular disease, diabetes



**Did you know?**  
The presence of diseases such as AIDS, TB, STDs, and other acute and chronic diseases has created shortages of research epidemiologists.<sup>1</sup>

and hemophilia, is significant. Other RTI studies have focused on other important non-disease-specific areas such as environmental and occupational exposures, including medical radiation, inadequate nutrition, and alcohol and cigarette use.

One of the studies Dr. Andrews' group has recently completed was a naturalistic randomized trial, designed to compare the effectiveness and tolerability of three different antidepressants. In this study, the treatments were randomized,



but after the initial randomization, the patients received the same care they would have otherwise received. Other naturalistic studies work by following extant treatments of patients rather than working through randomized clinical trials. Dr. Andrews' team often follow patients by telephone interviews. "In these totally naturalistic studies, we don't have the interventional requirements of a clinical trial, such as lab tests and physical examinations at pre-determined intervals. Since these are not randomized, these patients have already been placed on whatever treatments their physicians chose and we study

them after the fact," she says. Another current study uses an existing database to evaluate treatment-resistant depression. These studies are important because they describe, in an academically rigorous way, the outcomes of drug treatments under "real world" conditions. This real-world data is increasingly important to health planners, as they augment traditional controlled-clinical trials as a tool for developing strategies to optimize patient care.

RTI-Health Solutions' studies exemplify the many ways in which pharmacists, public health specialists and various other professionals interrelate. "One of our most valued researchers in the growing world of epidemiology is a pharmacist with a PhD in epidemiology," Dr. Andrews says, adding, "It's just a great combination." For example, public health specialists bring research methodology and a population-based perspective to the study, and pharmacists bring a clinical perspective, an understanding of pharmacologic properties of drugs, and knowledge of the practical aspects of how patients receive their medications. Dr. Andrews' faculty appointments at both the school of pharmacy and the school of public health further illuminate the

dual nature of pharmacoepidemiology, an exciting career path for a pharmacist who wants to work in public health.

Dr. Andrews speaks of epidemiology as a primarily quantitative discipline that helps health care professionals understand risks and benefits before taking action. “Although my area is largely research,” she says, “the specialty encompasses a wide range of proficiencies, including disease knowledge, research design, data analysis, communications skills and the ability to enlist the help of numerous other disciplines for any given study.” To succeed in this field, Dr. Andrews says, specialized training and graduate level courses in epidemiologic methods and biostatistics are required. “Having an MPH or PhD in epidemiology is absolutely essential.”

### **A day in the life**

At RTI, Dr. Andrews devotes much of her time to planning new projects or troubleshooting existing ones. Each day brings a heady mix of challenges — scientific, strategic and administrative.

She begins one typical morning on a conference call with representatives of a pharmaceutical company concerning a health outcomes study that RTI-Health Solutions has been commissioned to design and implement.

“Providing technical advice to clients is one of my chief responsibilities,” Dr. Andrews notes. “But I’m also involved in managing RTI’s resources in a way that ensures that work gets done on time and on budget.”

Never averse to rolling up her sleeves and immersing herself in hard research, Dr. Andrews squeezes in two hours of work on a CDC study examining the safety of antibiotics used for anthrax prophylaxis. “We’ll be meeting with the CDC in a few days to work out a plan for collecting data and setting up interviews,” she explains. “The interviews themselves begin at the end of the month, so we’re on a very rapid turnaround.”

Around midmorning, she breaks away from the CDC project to confer with another pharmaceutical company. This time, the conversation is about designing and evaluating the success of methodologies for targeting its drugs at the appropriate recipients and ensuring proper usage. “I find these kinds of consultative assignments especially challenging and rewarding,” she says. “Primarily it’s because they involve working with a team of experts from many different fields, and getting everyone focused on a specific research question. There’s a tremendous amount of intellectual challenge.” In this case,



*“Doing epidemiology research in a private setting is perfect for me because here, if I have an idea, I can frequently just run with it.”*

**Elizabeth Andrews, MPH, PhD**

multiple questions need to be addressed: “What are the side effects of the drug and how can they be assessed? How can we ensure their proper use?”

As an adjunct faculty member of UNC’s School of Pharmacy, Dr. Andrews spends her afternoon working with colleagues and several students on potential study designs and discussing several proposed RTI-UNCSPH research collaborations with university faculty members. Back in her office by late afternoon, she meets with RTI-Health Solutions researchers to review data that have been gathered as part of a current study relating to new drugs for a poorly understood gastrointestinal disorder. She finishes her day conferring with RTI colleagues about several new strategic initiatives, as well as general management and finance issues.

“The days can be long and demanding,” says Dr. Andrews. “But because they’re so varied, and the projects so meaningful, the work is extremely satisfying.”



## career at a glance

### Elizabeth Andrews, MPH, PhD

2001–Present	<b>Division Director</b> Epidemiology and Clinical Research, RTI Health Solutions, Research Triangle Park, N.C.
2001–Present	<b>Vice President</b> RTI Health Solutions
2001–Present	<b>Adjunct Associate Professor</b> University of North Carolina at Chapel Hill, School of Pharmacy
1991–Present	<b>Adjunct Associate Professor</b> Epidemiology University of North Carolina at Chapel Hill, School of Public Health
2001	<b>Vice President</b> Worldwide Epidemiology, GlaxoSmithKline
1995–2000	<b>Director</b> Worldwide Epidemiology, Glaxo Wellcome
1994–1995	<b>Head</b> International Department of Epidemiology, Burroughs Wellcome
1993–1994	<b>Head</b> Department of Epidemiology, Burroughs Wellcome
1986–1993	<b>Head</b> Epidemiology Section, Burroughs Wellcome
1982–1986	<b>Epidemiologist</b> Department of Product Surveillance and Epidemiology, Burroughs Wellcome
1981–1982	<b>Chief</b> Office of Purchase-of-Care Services, North Carolina Department of Human Resources
1979–1981	<b>Manager</b> Statewide Perinatal Care Program, North Carolina Department of Human Resources
1977–1979	<b>Health Planner</b> North Carolina Department of Human Resources

1 <http://owl.ben.edu/departments/mph/volemp.htm>