

Careers in Cardiovascular Outcomes Research

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To best understand the field and goals of outcomes research, it is important to appreciate the challenges that confront our healthcare system. Although considerable advances in patient care have been made over the last several decades, patients, physicians, and payers continue to struggle with rising costs and inefficiencies, poor application of evidence to clinical care, fragmentation, misaligned incentives, disparities, suboptimal patient safety, and lack of patient-centeredness. In its seminal 2001 report, *Crossing the Quality Chasm: A New Health System for the Twenty-first Century*, the Institute of Medicine concluded that the US healthcare system has fallen far short of its potential to deliver care in a safe, timely, equitable, efficient, evidence-based or patient-centered manner.¹ They called for a complete redesign of the way in which we currently practice and deliver care. The field of outcomes research is ideally positioned to address most of these challenges.

Outcomes research focuses on what is ultimately achieved by our efforts in healthcare. It seeks not only to describe the “end-result of healthcare” (patient outcomes) and its determinants but also to develop solutions to improve the outcomes by aligning the needs of patients with the performance of physicians and the healthcare system with the use of available resources.^{2,3} The field of outcomes research ranges from everyday clinical decision making that affects individual physicians and patients to population science, health economics, and policy. As such, outcomes research lies at the interface of multiple scientific disciplines, including clinical epidemiology, biostatistics, qualitative research, behavioral science, organizational theory, ethics, decision analysis, health system economics, health policy, health informatics, and the sciences of quality improvement and implementation research. Understanding and integrating these multiple disciplines can accelerate the pace and application of insights into practice.

Therefore, to be a successful outcomes researcher, one should ultimately be contributing toward the process of improving clinical care. Although the full cycle of improvement requires multiple stages and participants, a prospective investigator must be able to identify critical issues in patient care and health policy, crystallize these issues and possible solutions, study the identified components of care, summarize and disseminate the findings, and then contribute toward the implementation of potential solutions, often studying the

impact of these novel approaches to care. An outcomes researcher is often first an astute clinician who can appreciate the subtleties and nuances of patient care but also someone who can subsequently measure and analyze these aspects of care, interpret the results so that opportunities for improvement may be gleaned, and develop and test interventions that can affect patient outcomes in a meaningful way.

The need for a national focus on outcomes research is great. Because cardiovascular disease is the leading cause of death⁴ and healthcare costs⁵ for men and women in the United States, the field of cardiology has a particularly pressing need to advance the field of outcomes research. A critical initial step in this direction is to expand the infrastructure for training cardiovascular outcomes researchers.

Training the Cardiovascular Outcomes Researcher

To position oneself for a career in outcomes research, formal training, mentorship, and experience are critical. All trainees benefit from intense exposure to the “tools” of their trade, a well-chosen mentor, an independent research experience, and fiscal support. A recent report on careers in cardiovascular research provides an in-depth overview of mentorship, funding, and pathways for success in the basic, translational, and clinical sciences.⁶ As it relates to outcomes research, the training needs to be aligned with the goals and priorities of a prospective outcomes investigator.

The main mission of an outcomes researcher is generating knowledge to improve clinical decision making and healthcare delivery with the goal of optimizing patients’ outcomes. Because outcomes research lies at the interface of multiple scientific disciplines, well-trained cardiovascular outcomes scientists must possess a broad range of methodological expertise to understand and communicate with scientists in similar and complementary fields, including the basic, medical, and social sciences. Furthermore, they must acquire practical experience in applying this expertise in a hands-on “outcomes laboratory” environment by conducting mentored and independent research projects. One of the critical goals to be garnered from training is how to formulate and answer important clinical questions. Through education and mentored research, trainees will be able to formulate important scientific questions, design mechanisms to validly address

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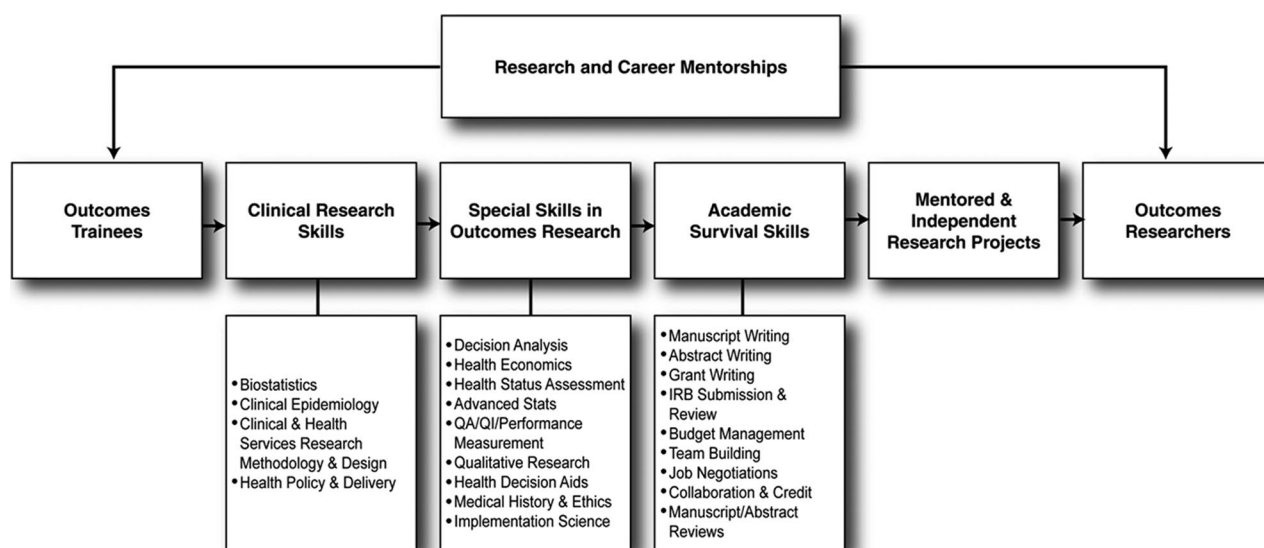


Figure. Conceptual model of the transition from a trainee to an independent outcomes investigator. QA/QI indicates quality assessment/quality improvement; IRB, institutional review board.

existing gaps in knowledge, communicate their findings to relevant parties, and design and test interventions to overcome existing gaps in care.

It is important to appreciate that training in outcomes research is a life-long endeavor. New techniques and skills are constantly being introduced, and new study designs continually provide new methodological challenges. However, an initial foundation for outcomes research can be formed through traditional training programs. An ideal training environment for future outcomes investigators should provide a combination of a well-structured, formal curriculum that will enable trainees to acquire methodological expertise, ample opportunity for testing their skills in mentored and individual research projects, and 1-on-1 mentoring (research mentoring), as well as academic career and “survival” (career mentoring) support. A conceptual model for transitioning from a trainee to an outcomes researcher is presented in the Figure. Although no specific sequence for acquiring these skills is mandated, over one’s career, exposure to all of these areas will be helpful to the emerging scientist.

Because of its emphasis on patient care, the field of outcomes research is ideal for clinically oriented researchers who have the ability to ask and answer critically important questions with direct clinical implications. Without a doubt, any successful outcomes research environment needs a multidisciplinary team with participation of nurses, statisticians, economists, psychologists, decision scientists, and others. Prospective investigators in each of these disciplines could benefit from the scope of training that we propose. Although many of these emerging scientists will have had extensive training within their respective disciplines, acquiring insight into the full spectrum of skills necessary for a successful career in outcomes research will be an important strength in their development. Thus, although the clinician-scientist is a key member of such a team, and it is the training of these clinician-investigators that is the primary focus of this article,

all members of a multidisciplinary outcomes research team may benefit from the concepts addressed in this review.

For clinician trainees, the first critical step in the process of outcomes research training is superb clinical training. The ability to identify the key clinical questions and deficiencies in healthcare delivery is not possible without first obtaining fundamental skills in clinical medicine. However, the transition from a knowledgeable clinician to an outcomes researcher requires a commitment to obtain additional skills and the willingness to continually expand and master the techniques needed to better address one’s research interests.

Once a clinician chooses to pursue a career in outcomes research, a critical step in the training process is to acquire the general skills of clinical research. Just as a basic scientist would not be capable of launching a research career without focused training in the skills of laboratory science, an outcomes researcher cannot succeed without mastering the skills of clinical investigation. This part of the training forms the basic foundation of a clinical and outcomes research skills set. It should provide the depth and breadth of instruction commensurate with a master’s degree (such as a Master of Public Health or Master of Science degree). The fundamental disciplines to be covered should include biostatistical concepts and applications (such as 1- and 2-way analyses including ANOVA and simple linear regression, nonparametric analysis, multivariable analyses [linear regression, logistic regression, survival analyses], hierarchical analyses, Poisson regression, general linear models, repeated-measures and longitudinal analyses, weighting, factor analyses, Bayesian analysis, and meta-analysis); principles of clinical epidemiology and clinical and health services research (including quantitative and qualitative study methodology and design, sampling strategies, data collection and measurement approaches, and data analysis); health policy (including healthcare financing and delivery systems, policy agenda setting, evaluation of policy alternatives, and policy implementation); and detailed exposure to the responsible conduct of research.

To complement this initial foundation, trainees will also require additional, specialized skills in outcomes research. Several key areas have emerged as fundamental components in the outcomes research and quality of care field, and understanding their importance and role in research and patient care is an essential component of training. These areas include an emphasis on patient-centered care (such as understanding the difference between surrogate and patient-centered end points and health status assessment), the science of implementation research, quality assessment and improvement, healthcare economics and cost-effectiveness analysis, the role of observational research (including patient registries) and clinical trials in generating evidence, performance measurement and appropriateness criteria, health decision aids and decision analysis, as well as cultural competence and an understanding of healthcare disparities. Although all trainees should be introduced to this broad array of topics, extensive instruction in all of these specialized areas is not feasible for all outcomes researchers. However, being able to communicate with and understand colleagues who have mastered such skills will be a valuable tool for success. Most often, trainees choose certain career “tracks” within outcomes research, such as clinical research, health policy, or quality improvement, among others.

Furthermore, to successfully confront the many challenges in launching their careers (both as researchers and clinicians), trainees will need basic “academic survival” skills. A complete outcomes research training program should provide instruction in manuscript and abstract writing, presentation skills, intrainstitutional and interinstitutional collaborations, identifying funding opportunities and grant writing, peer review, academic ethics, intellectual property, team building and leadership, budget management, and job negotiations. Although many of these are developed over years and with experience, an orientation to these issues can be instrumental in preparing trainees for their future.

Just as “real laboratory experience” is an essential component of training for the basic sciences, applying newly acquired skills in practice by participating in specific research projects is an invaluable, and possibly the most important, part of outcomes research training. Moreover, there is no better enticement to trainees than the challenge and thrill of developing their research projects from conception to publication and, ultimately, translation into practice. Hence, the primary objective of any outcomes training program is to provide a rich research experience.

Outcomes researchers employ both prospective studies and analysis of existing data sets, depending on the research question being addressed. When supporting prospective data collection, an outcomes research training program should be able to support critical evaluation of study designs, creation of data collection forms, mechanisms for data collection, data management and cleaning, and support for analyses and interpretation. When clinical questions are best addressed through secondary data analysis, an outcomes research training program should have abundant data resources (ideally both observational and clinical trials databases), statistical analysis support, and access to a diverse body of mentors and consultants with various areas of expertise (both within the

program and through collaborative relationships with other institutions) and should provide on-site opportunities for quality improvement initiatives and implementation of research into clinical practice. Beyond institutional databases, several large national registries can provide access to data and serve as potential resources for trainees. A list of some national resources and how to access them is provided in Table 1.

Throughout the training period, it is critical for trainees (as well as their instructors) to be engaged in a formal, continuous mentorship process. A close, mutually supportive relationship between a mentor (or group of mentors) and a trainee is needed to better understand a trainee’s research interests, learning and working style, and needs. An ongoing mentoring process not only allows a mentor to periodically evaluate and provide guidance to ongoing research projects (research mentoring) but permits feedback about time management, communication skills, conflict resolution, team building, management of research teams, consultants, and collaborators, academic ethics, and career development (career mentoring). Excellent reviews of academic mentoring are available through the American Heart Association Web site⁷ and in an earlier publication of this series entitled “Choosing a Research Project and a Research Mentor.”⁸ Although many aspects of mentoring for outcomes researchers are similar to those of most scientific disciplines,⁶ particular traits to identify in an outcomes research mentor are the ability to ask and address stimulating and clinically relevant research questions, methodological expertise in the trainee’s area of interest, and demonstrated success in mentoring other outcomes-oriented scientists.

Because clinical exposure provides the natural “laboratory” experience for a clinician-scientist and frequently highlights relevant knowledge gaps and opportunities for improvement in patient care, the research and clinical experiences should be considered equally important and complementary components of training for an outcomes research investigator. Although the training in outcomes research can be obtained through various pathways, on average, 2 years of additional training are required to build the necessary skill sets. In the current healthcare environment, with its continuous evolution of technology and diagnostic and therapeutic modalities that can each affect the training period necessary for clinical competency, careful coordination between outcomes and clinical training is often needed to enable the trainee to launch a career within a reasonable period of time. As an example, trainees in the field of cardiology may be faced (depending on their clinical focus) with the need to complete their general training, followed by additional years of instruction in various imaging and/or procedural modalities. Superimposed on this background, 2 more years of research training may add substantial time and financial burden. Although the time commitment to research is essential, the unique clinical focus of outcomes research frequently allows for ways of combining the clinical subspecialty and research training, so that this additional time burden is minimized without compromising the quality of either research or clinical experience. Achieving this requires

Table 1. Potential Resources for Data Analysis

Data Set Categories	Examples	Additional Information
Publically available governmental data resources	Behavioral Risk Factor Surveillance System	http://www.cdc.gov/brfss/index.htm
	National Health and Nutrition Examination Survey	http://www.cdc.gov/nchs/nhanes.htm
	National Hospital Discharge Survey	http://www.cdc.gov/nchs/about/major/hdasd/nhdsdes.htm
Large administrative data sets	Federal (Centers for Medicare and Medicaid Services), state (United States), and provincial (Canada) hospital discharge databases, insurance carrier databases (eg, Kaiser-Permanente), Veterans Health Administration data sets	Permission required for data access
Registries administered by national foundations	National Registry of Cardiopulmonary Resuscitation (American Heart Association)	http://www.nrcpr.org/
	National Cardiovascular Data Registry (American College of Cardiology)	http://www.ncdr.com
	Get With the Guidelines (American Heart Association)	http://www.americanheart.org/presenter.jhtml?identifier=1165
	Society of Thoracic Surgeons National Database	http://www.sts.org/sections/stsnationaldatabase/ ; permission required for data access
Epidemiological databases	Framingham Heart Study	http://www.framinghamheartstudy.org/research/index.html ; permission required for data access
Clinical trials databases	Many of the large cardiovascular clinical trials' databases can be leveraged to study variations in patient outcomes	Permission required for data access
Publically available databases from previously conducted clinical studies	Cardiovascular Health Study	http://www.chs-nhlbi.org/

flexibility and innovative approaches on the part of both trainees and directors of various subspecialty and research training programs.

Many successful investigators acquire components of their training through the resources, expertise, and mentoring at their local institutions, using well-established channels, including career development awards (administered by the National Institutes of Health, American Heart Association, Veterans Health Administration, and others). However, several structured, formal training programs have been established that focus specifically

on training future outcomes research investigators. Table 2 provides a sample of such training programs.

Beyond an intensive, formal education, numerous opportunities for lifelong learning exist. These are important because outcomes research is a dynamic and ever-changing field. For example, new analytical techniques are constantly being introduced to more accurately extract important knowledge from observational data (eg, propensity scores, hierarchical models for handling clustered data), new sources and types of data (eg, electronic medical records databases,

Table 2. Training Opportunities for Cardiovascular Outcomes Researchers

Program Name	Institution(s)	Web Address
American Heart Association – Pharmaceutical Roundtable Outcomes Research Postdoctoral Fellowships	Duke University, Mid America Heart Institute, UCLA, Stanford University	http://www.americanheart.org/presenter.jhtml?identifier=3064953
AHRQ Health Services Research Training Programs	National program; multiple sites available, focus of the programs varies by site	http://www.ahrq.gov/fund/training/t32.htm
Postdoctoral Training in Quality of Care and Outcomes Research for Cardiovascular Disease and Stroke	NHLBI and Wake Forest University offer a T-32 focused on cardiovascular outcomes research	http://www.phs.wfubmc.edu/public/edu_cvd.cfm
Robert Wood Johnson Clinical Scholars Program	Yale University, UCLA, University of Michigan, University of Pennsylvania	http://rwjcsp.unc.edu/
VA National Quality Scholars Fellowship Program	National program; program coordination at Dartmouth University	http://www.dartmouth.edu/~cecs/fellowships/vaqs.html
VA Advanced Fellowship Program in Health Services Research and Development	VA national program	http://www.va.gov/OAA/SpecialFellows/programs/SF_HSRD.asp

AHRQ indicates Agency for Healthcare Research and Quality; VA, Veterans Affairs; UCLA, University of California at Los Angeles; and NHLBI, National Heart, Lung, and Blood Institute.

genomic and proteomic data, administrative data with linkages to long-term outcomes data such as the Social Security death master file) are becoming available, and the rapid evolution of new treatments mandates continuing evaluation and understanding. To stay abreast of new and evolving research methods, both annual conferences (eg, the American Heart Association Annual Scientific Forum on Quality of Care and Outcomes Research, which offers travel fellowships for trainees) and seminars (eg, the National Institutes of Health Summer Institute on Design and Conduct of Randomized Clinical Trials⁹ or the Summer Institute for Informed Patient Choice at Dartmouth¹⁰) are available and can be considered avenues in advancing the outcomes researcher's ability to address the latest research questions. By leveraging such training, both at the start and throughout one's career, potential outcomes researchers are well positioned to launch and sustain their careers.

Career Opportunities in Outcomes Research

As a well-trained outcomes researcher, one has valuable skills to critically evaluate the medical literature and its generalizability to patient care, understand methodological challenges in digesting new data, evaluate the structure and processes of the healthcare environment, understand how to implement change in the system to deliver care more aligned with evidence, appreciate healthcare financing and how to incentivize better care, and understand how to define new gaps in knowledge that need to be addressed. This knowledge is invaluable in elevating the quality of medical care and positions an outcomes researcher to pursue a broad range of career opportunities.

A traditional career path for the outcomes research is as a member of an academic department. Like all academic positions, it is critically important that an outcomes researcher launch his or her career at an institution that provides the infrastructure for success. This includes the availability of committed mentorship from more senior investigators. Ideally, given the multidisciplinary nature of outcomes research, there should be a number of mentors with different skill sets that can inspire and support the growth of a young researcher. It is also critically important that the department chairperson be exceedingly supportive and committed to the young academician's career. Although for a basic scientist there is a pervasive expectation that he or she needs a substantial amount of protected time (often 80%) and money to launch a research program, there may be a perception that a similar amount of time and resources is not needed for an emerging outcomes researcher. This would be a mistake. Although a laboratory bench and equipment may not be necessary, the ability to obtain and analyze data, quantify and improve the quality of care, and initiate prospective data collection to generate new knowledge or to formulate and pilot test clinical interventions all require substantial time and resources. Thus, outcomes researchers seeking new appointments in academic departments must aggressively negotiate to secure the necessary resources to support their success.

A particularly exciting academic opportunity for outcomes researchers is in the terminal phase of translational research.

Buoyed by the evolving redesign of the National Institutes of Health toward translational science,¹¹ there is a pressing need for institutions to determine how best to move basic science discoveries to the bedside. This involves several steps for which an outcomes researcher is ideally positioned to contribute. First, the clinical significance of basic science discoveries needs to be established. This requires defining the association of a basic science discovery (eg, a gene, protein, or biomarker) with clinical outcomes. Moreover, the incremental contribution of this discovery, over and above already established clinical markers of outcomes, is needed. As such, sophisticated analytical techniques, the use of derivation and validation cohorts, and insight into how these discoveries might be implemented and valued is a requirement that the outcomes researcher is well trained to fulfill. Once a clear opportunity for a novel basic science discovery is established, the process of delivering this innovation in care must be developed. For example, if a new gene is determined to have an important pharmacogenetic association with outcome (eg, one variation in a gene is associated with significant survival benefit from the use of a β -blocker after a myocardial infarction, and another variation is associated with harm),¹² how will the routine care of patients be altered? An outcomes researcher is ideally trained to consider how the routine processes of care might be changed to enable that genetic test to be run and to incorporate that result in medical decision making while also considering the multitude of other patient characteristics that might influence the benefits of β -blocker therapy and how to communicate this information to patients so that their individualized care plan might be sustained after discharge.¹³

Beyond a traditional academic appointment, the outcomes researcher has the skills to pursue a broad range of other career opportunities. These could include leading quality improvement activities within a practice or hospital, supporting a health plan in quantifying and rewarding quality, guiding the pharmaceutical or device industry in designing clinically important trials that incorporate a broad range of clinical and economic outcomes, serving as science officers for nonprofit foundations or governmental entities (such as the National Institutes of Health), providing guidance for future research directions and funding programs, creating new research programs and providing leadership for independent research institutes, and serving important roles in public health and policy. Each of these positions demands the ability to fully understand and interpret the strengths and limitations of study designs, the ability to evaluate a broad range of clinical and economic outcomes, and an in-depth appreciation of healthcare delivery. Thus, the training in clinical epidemiology, outcomes assessment, biostatistics, healthcare policy, and economic analysis that the outcomes researcher has mastered is exceedingly important in pursuing these careers.

An important part of career development for any prospective or current outcomes investigator in cardiovascular disease is to become a part of the cardiovascular outcomes research community. Becoming involved in the work of the American Heart Association's Scientific Council on Quality of Care and Outcomes Research (<http://www.american-heart.org/presenter.jhtml?identifier=3016540>), including its

Young Clinicians and Investigators Committee, attending the American Heart Association Annual Scientific Forum on Quality of Care and Outcomes Research, as well as reading and submitting contributions to the journal of the Council, *Circulation: Cardiovascular Quality and Outcomes*,¹⁴ will allow trainees extraordinary opportunities for learning new skills, networking, building collaborative relationships with other investigators, and finding mentors. The cardiovascular outcomes research community is known for being exceedingly inclusive, collaborative, and nurturing, and the potential benefits of getting involved cannot be overestimated.

Although not the focus of this article, the funding of outcomes research is an integral part of career development for the young clinician-scientists in this field. Potential funding opportunities for the early career investigators have been outlined in an earlier publication of this series, entitled "Funding Opportunities for Investigators in the Early Stages of Career Development."¹⁵

Future Directions and Opportunities

Outcomes research is an exceedingly exciting and dynamic field. Its focus on identifying opportunities to improve the clinical outcomes of patients and to reorganize the practice of medicine to leverage these opportunities has never been more in demand. Outcomes research training positions an individual to rigorously consider the determinants of patient outcomes, from patient-centered factors to treatments, and to determine how best to redesign the structure and processes of healthcare to optimize those outcomes. Currently, much work is needed to address challenges in applying evidence-based therapy, supporting the coordination of care over time, and creating the economic incentives for a more optimal healthcare system. As new knowledge and the era of personalized medicine evolve,¹⁶ there is an ever-growing need for scholars not just to generate new knowledge but to translate this knowledge into a safe, timely, equitable, and evidence-based healthcare system in which routine care can be aligned with patients' individualized goals and values. Outcomes research is ideally positioned to meet this challenge and to support the evolution of high-quality healthcare. Although the training may be long and challenging, the rewards are great, and outcomes researchers will have a growing opportunity to shape the healthcare environment so that we all may benefit from the explosion of new knowledge occurring within all disciplines of medicine.

Disclosures

Dr Kosiborod serves as the fellowship program director and Dr Spertus as the director of the American Heart Association Pharma-

ceutical Roundtable Outcomes Research Center at Saint Luke's Mid America Heart Institute.

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