University of Cincinnati

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I, Jacqueline M. Knapke, hereby submit this original work as part of the requirements for the degree of Doctor of Philosophy in Educational Studies.

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Improving Physician Research Training at the University of Cincinnati: A Mixed Methods Phenomenological Evaluation

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Improving Physician Research Training at the University of Cincinnati:

A Mixed Methods Phenomenological Evaluation

A dissertation submitted to the

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College of Education, Criminal Justice, and Human Services

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By

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Abstract

This study was a mixed methods interpretive phenomenology with qualitative emphasis that evaluated the Master of Science program in Clinical and Translational Research (MSCTR) at the University of Cincinnati. The purpose of the study was to allow students to articulate their expectations, needs, and experiences in the MSCTR and to develop novel training methods and/or curriculum modifications to improve physician-scholar training. The sequential study design included document review and a group level assessment in phase I, followed by interviews, participant journal entries, and a survey in phase II. Group level assessment data were analyzed using group level assessment analysis, document review, interview, and journal entry data were analyzed using a modified seven stage hermeneutic analysis, and survey data were analyzed using descriptive statistics. Findings suggest five major areas for improvement: curriculum, mentorship/relationships, program structure and organization, instructional methods, and ancillary student perspectives on MSCTR experiences. Concluding recommendations from these five patterns include: update the overall curriculum, improve statistical training, invest in online courses to make them better and continue to develop new coursework for online learning, consider more creative ways of integrating both online and in-person work into the curriculum, and create a more structured mentorship program within the MSCTR program.
Acknowledgments

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I am extremely grateful to the 12 students who participated in this study. I understand how frenetic your schedules and lives already are, and I appreciate your willingness to take on
this additional burden. Most of you volunteered because of your deep commitment to improving research training for future clinicians, but I know many of you also did it as a personal favor to me, and I’m thankful to enjoy such cordial working relationships with you all. I feel a burden to carry your recommendations forward and put them into practice.

Finally, thank you to my family. I would not be who I am without each and every one of you, and I feel so fortunate to be surrounded by such wonderful people. To Jay, for simply being my everything. To Leo, my sweet baby boy. To my furry little loves, Henry, Rosie, Grover, and Mama. To Dad and Georgene, for their truly unconditional love and support. To my mom, whom I wish could be here to share this joyful experience with me. And to all my siblings, siblings-in-law, and their children: Kim, Roger, Claire, Ethan, Audrey, Dan, Laurie, Kelly, Joe, Zach, Alex, Maddie, Traci, Kevin, Allison, Nolan, Ashleigh, Alexa, Abbi, Doug, Sara, Noah, and Mia. And to my Uncle Chuck, who is a second father and mother to me, and one of my very best friends. Thank you all for your strength, love, and encouragement.
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Chapter 1: Background and Introduction

For several decades, the academic medical community has been concerned about the reluctance of young physicians to prepare for and undertake careers in clinical research (Bartels et al., 2010; Wyngarden, 1979). As recently as 2013, Gottesman wrote, “The shortfall of new physician-researchers is a national, if not global, concern, and its remedy requires a coherent and cooperative approach among biomedical research and teaching institutions” (p. 2250). As the demand at academic health centers for physician-faculty members to provide clinical care to patients increases, clinicians have less time to focus on a research career (Nathan, 1998). Equally troubling is the high attrition rate of accomplished clinical investigators within academic medical centers (Dickler, Fang, Heinig, Johnson, & Korn, 2007; Nathan, 1998; Rivkees & Genel, 2007). Numerous factors have contributed to the dearth of clinician-investigators: increased competition for National Institutes of Health (NIH) grant funding (particularly from non-MD applicants) (Nathan, 1998), deficient research training (Goldstein, 1986), ineffective mentorship (Shafer, 2010), inefficient institutional infrastructure (Shafer, 2010), and outmoded promotion and tenure guidelines that do not reward team science (Shine, 1998). In an era characterized by potentially enormous biomedical discoveries, all of these factors limit progress.

In response, the federal government has taken strides over the last several decades to try to bolster the numbers of well-trained clinical researchers. In 1995, the Director of the NIH organized the “NIH Director’s Panel on Clinical Research” to assess the current state of clinical research and offer suggestions for improving it (Nathan & Wilson, 2003). The panel’s recommendations instigated many new changes to the clinical research environment. Suggestions included educational debt relief, creating a clear clinical research career path,
improving mentorship, investing in clinical research institutes across the country, and emphasizing training and education programs across the spectrum of clinical and translational research.

### Medical School Debt

According to the Association of American Medical College’s 2012 report on medical education debt (Youngclaus & Fresne, 2013), 86% of medical school graduates report having some education debt, and the median amount was $170,000. In general, a post-residency monthly payment on such a debt is between $1,400 and $2,200, lasting for 7-25 years (Youngclaus & Fresne, 2013). This level of debt places serious restrictions on the freedom of recent medical school graduates to choose career paths that are financially limited, but that might be more appealing and satisfying to them. A strictly clinical job in a private practice or hospital setting is much more lucrative than a research position at an academic center, so many young physicians are naturally drawn to job opportunities that are primarily clinical.

To combat this trend, Congress passed a bill in 2000 to offer educational loan relief to clinical researchers who fulfill eligibility requirements (Nathan & Wilson, 2003), aiming to reduce the financial strain that prevents some physicians from pursuing a research career. The purpose of the loan repayment program administered by the NIH is specifically “the recruitment and retention of highly qualified health professionals as research investigators to careers in research: ("K30 Clinical Research Curriculum Award (CRCA)," 2006). If awarded, the NIH will pay up to $35,000 per year of a clinical researcher’s loans, and researchers can apply for annual renewals. The NIH also offers loan repayment programs in clinical research fields that are considered high priority, such as pediatrics, health disparities, contraception
and infertility, and research serving individuals from disadvantaged backgrounds ("Policy & Guidance," 2013). According to the loan repayment program, “a short-term program evaluation has shown that participants in these programs stay in research careers longer, apply for and receive more research grants, and are more likely to become independent investigators than their peers who do not receive LRP [loan repayment program] funding” ("NIH Repays Your Student Loans," 2012).

**Career Development and Mentorship for Young Investigators**

Numerous studies have demonstrated that mentorship can greatly impact the career success of physician-scientists (Buddeberg-Fischer, Stamm, & Buddeberg, 2009; Feldman, Arean, Marshall, Lovett, & O'Sullivan, 2010; Jackson et al., 2003; Shollen, Bland, Finstad, & Taylor, 2009; Straus, Chatur, & Taylor, 2009). As Rubio et al. (2011) summarize, “effective mentoring is associated with high research productivity (Steiner, Curtis, Lanphear, Vu, & Main, 2004), increased professional socialization and interactions(Shollen et al., 2009), and greater satisfaction with salaries and promotions (Chung et al., 2010; Sambunjak, Straus, & Marusic, 2006). In a meta-analysis of mentorship in a corporate setting, Underhill (2006) found that effective mentorship was tied to higher rates of job satisfaction, self-esteem, organizational commitment, and promotion opportunities and lower rates of work stress and work-family conflict (as quoted in Rubio, 2011).

Since mentorship can have such a profound influence on the decisions and successes of young clinician-researchers, many institutions of clinical research around the country are placing a heavier emphasis on formalizing their mentorship processes, both in terms of training mentors and matching new investigators with excellent mentors. Recommendations have now
been published on selecting, training, and supporting mentors (Abedin et al., 2012; Burnham & Fleming, 2011; Burnham, Schiro, & Fleming, 2011), evaluating mentors (Anderson, Silet, & Fleming, 2011; Meagher, Taylor, Probsfield, & Fleming, 2011), and mentoring clinical investigators (Fleming, Burnham, & Huskins, 2012; Silet, Asquith, & Fleming, 2010).

Locally, the University of Cincinnati (UC) has taken steps to improve the mentorship of early-career physician-scientists within the Academic Health Center (AHC). The University of Wisconsin - Madison’s Institute for Clinical and Translational Research developed a workshop on how to facilitate research mentor training. The workshop is offered for free, either at Madison, Wisconsin or on-site at the organization seeking training. It uses a train-the-trainer model, meaning those who attend and receive training should then be prepared to train others at their home institution. The Cincinnati Center for Clinical and Translational Science and Training (CCTST) invited Madison workshop presenters to Cincinnati in December, 2012, for a training workshop and for a series of lectures on their mentoring research and training programs. Since then, the CCTST has facilitated mentorship workshops using the Madison model and also maintains a list of senior researchers with appropriate areas of expertise and mentorship.

The CCTST co-directors also drafted new guidelines for UC’s Appointment, Reappointment, Promotion, and Tenure (ARPT) guidelines to place more value on mentorship. Their suggested changes were unanimously approved by the College of Medicine Faculty Council in 2008, and the new language about mentorship includes: “Achievements in mentoring are evidenced by obtaining federal funding for mentorship, by serving as mentor on others’ mentored research grants, by receiving local or national mentorship awards, by teaching
workshops on mentorship, or through letters of support from current or past trainees whom the candidate has mentored” (Heubi & Tsevat, 2008, p. 405). All of these efforts are aimed at improving the capability and effectiveness of research mentorship at the AHC, thereby better fostering the success of young clinician-investigators.

In 1999, the NIH introduced new patient-oriented research career development awards, supporting both young investigators and their mentors (Kotchen, Lindquist, Malik, & Ehrenfeld, 2004; Nathan & Wilson, 2003). Part of a larger “K” award series, the K08, K23, and K24 are specifically meant for physician-scientists just getting started in their research careers (“Advice on Mentored Career Development Awards,” 2012). The K08 and K23 award mechanisms are geared towards young clinician investigators in the early stages of their research careers, supporting them for 3-5 years to conduct research that is supervised by a more senior research mentor (“Mentored Patient-Oriented Research Career Development Award (Parent K23),” 2014). The K24 award, then, is a more “midcareer” funding mechanism that provides researchers the protected time to conduct their own patient-oriented research, but also to mentor residents, fellows, and junior faculty who are pursuing research careers (“Midcareer Investigator Award in Patient-Oriented Research (Parent K24),” 2014). Both mechanisms are intended to provide a clearly charted path for young investigators who do not yet have a lot of research experience, but who also show promising potential for successful research careers. The K24 award is especially interesting in that it not only allows young researchers (generally at the associate professor level) the time they need for their own research studies, but it also encourages them to contribute to the cycle of researcher development by committing to mentorship.
At the institutional level, the CCTST created the “KL2 Research Scholars Mentored Career Development Award.” The KL2 award “provides 75% salary support (up to $75,000/year) plus $25,000 in expenses for up to two consecutive years to highly qualified MD, PhD, or PharmD junior faculty pursuing careers in clinical and translational research” (“KL2 Research Scholars Mentored Career Development Award,” 2014). It is essentially an in-house funding program that provides young faculty members at UC, CCHMC, or Cincinnati Veterans Affairs Medical Center (VAMC) with support to get their early research projects off the ground. By protecting 75% of their work time from being overtaken by clinical duties, young investigators have more time to learn the ropes of research, including navigating the Institutional Review Board, collecting data, working with a biostatistician, and writing and presenting results (Young, Dehaven, Passmore, & Baumer, 2006). Without this early salary support, most young faculty members are taxed with heavy clinical schedules that severely limit the time they’re able to dedicate to research activities (Young et al., 2006). In addition to the KL2 institutional award, the CCTST has also formed a “K Club,” a group of junior faculty who have applied for and/or received K awards. The K Club meets once a month to discuss and support group members’ research projects.

In 2011, adding one more step to the physician-investigator career path, the NIH created the NIH-Lasker Clinical Research Scholars Program (Gottesman, 2013). This program offers clinically-trained researchers support for up to 12 years, with the first five to seven years occurring in the NIH Intramural Research Program, and possible additional years (up to five) at a research institution (Gottesman, 2013). In addition to the long-term financial commitment this program provides, researchers also benefit from participating in the largest research
institution on the globe, with over 1,200 principle investigators and 4,000 postdoctoral fellows ("What is the IRP?," 2014). The long-term goal for the NIH-Lasker Clinical Research Scholars Program is to maintain a group of at least 20 researchers “at various stages in their careers benefiting from the proximity to NIH laboratory facilities, mentors, and role models” (Gottesman, 2013).

**Clinical and Translational Science Awards**

One of the most dramatic investments in clinical and translational research by the federal government is the Clinical and Translational Science Award (CTSA) program, which was launched in 2006. The awards are institutional awards, and the overall goal of the program is to create identifiable homes for clinical and translational research across the country. Since 2006, 62 CTSA have been awarded, creating a network of medical research institutions that work together to “transform the local, regional, and national environment to increase the efficiency and speed of clinical and translational research across the country” ("About the CTSA Consortium," 2014). Essentially, CTSA are meant to provide organizational centers for institutional clinical research activities, making it easier for researchers to collaborate and access training and consultation services. CTSA centers are also expected to facilitate clinical research with community and industry partners ("About the CTSA Program," 2014). The goals of CTSA centers are generally organized around education and career development, regulatory knowledge, research networking, research design (biostatistics and epidemiology), community engagement, comparative effectiveness research, and evaluation ("Best Practices and Recommendations," 2014). CTSA sites are also expected to contribute to the consortium as a
whole, sharing best practices, research findings related to improving clinical research, and working together to move the field forward.

The University of Cincinnati was awarded an institutional Clinical and Translational Science Award in 2009. UC created the CCTST in 2005 already, partly in preparation for the rollout of the CTSA program the following year. The CCTST serves as the main hub for all levels of researchers: high school students, medical students, community members, post-doctoral fellows, junior faculty members, and senior researchers. It organizes many of the research events around the Academic Health Center, including talks, workshops, information sessions, seminars, and forums. In addition, it maintains a list of funding opportunities, both internal and external, and it even provides grants for junior faculty (as mentioned above) or for pilot studies.

In addition, the CCTST brings innovations from the CTSA consortium to the local research population. For example, ResearchMatch is a tool that matches volunteer study participants (often community members) with current or ongoing research studies at the Academic Health Center (“ResearchMatch,” 2014). Another excellent tool the CCTST brought to UC and its research affiliates is an application called Research Electronic Data Capture (REDCap). REDCap was originally developed by Vanderbilt University and “is a secure, web-based application designed exclusively to support data capture for research studies, allowing users to build and manage online surveys and databases quickly and securely” (“REDCap,” 2014). It’s free, secure (e.g., HIPAA- and IRB-approved), and flexible. In just one other example of how the CCTST has improved the flow of research, it facilitated the conversion of the UC IRB submission system to the same online system used by Cincinnati Children’s Hospital Medical Center. This drastically simplified the process undergone by many clinical research projects that
are submitted to and approved by the review boards at both institutions, lessening the inconvenience for the researchers and effectively speeding up the entire research process.

**Training and Education**

In its report on the status of clinical research in U.S. medical education, the Association of American Medical Colleges ("Promoting translational and clinical science: The critical role of medical schools and teaching hospitals. Report of the AAMC’s Task Force II on Clinical Research," 2006) cited insufficient training as one of the primary hindering factors in accelerating clinical research. In conjunction with the many other investments in clinical research described above, the NIH also began investing more in clinical research training programs. In 1998, the NIH created an institutional Clinical Research Curriculum Award, or K30, to improve the quality of training in clinical research by funding educational programs at many U.S. academic institutions (Mullikin, Bakken, & Betz, 2007; "Promoting translational and clinical science: The critical role of medical schools and teaching hospitals. Report of the AAMC’s Task Force II on Clinical Research," 2006). The K30 program supported developing and/or improving didactic curricula in clinical research theory, methodology, application, and ethics ("K30 Clinical Research Curriculum Award (CRCA)," 2006). The University of Cincinnati received a K30 award in 2005, prompting the development of a new research training program as well as the creation of multiple new courses geared specifically towards young clinician-investigators. In addition, when the CTSA program launched, a key component involved fostering graduate and postgraduate programs in clinical and translational science in order to provide a knowledge base for clinical and translational researchers ("Strategic goal committee 2 - Training and career development of clinical/translational scientists," 2013). UC received a CTSA in 2009.
UC’s Department of Environmental Health has been training physicians in epidemiology, biostatistics, research design, and ethics since the mid-1980s, primarily through its MS and PhD programs in Epidemiology. In the mid-2000s, with the increased emphasis on clinical research training, several new courses were developed for the physician-scientist audience. For example, a course called Study Design and Analysis was offered by a combined physician-epidemiologist instructor team. The course still exists today, and its goals are to provide instruction on matching study designs with the appropriate statistical analyses, all within the context of a clinical research study. Another unique course, Design and Management of Field Studies in Epidemiology, was created to provide instruction in designing (and then managing) a clinical research study from start to finish, and students work together to develop their hypotheses, specific aims, and research methods, emerging with an NIH grant proposal at the end of the term.

The training program for physician-scientists was formalized during this time as well, beginning with a Master of Science degree approved by the Ohio Board of Regents in January 2009. As stated in its program proposal (Full Proposal: Master of Science in Clinical and Translational Research, 2008):

The educational objective of the Master of Science in Clinical and Translational Research is to train clinical professionals (physicians, nurses and other terminal degree clinical professionals) to become independent investigators and to provide them with training in clinical epidemiology, clinical effectiveness, molecular epidemiology, clinical trials, and translational research necessary to prepare successful career development and independent investigator awards. The disciplinary purpose and ultimate goal of the
The program is to move practitioners from the realm of personal clinical experience to objective evidence. (p. 5)

The MS program’s stated student outcomes are that, upon graduation, students should be able to:

- Practice responsible conduct of research according to NIH standards.
- Evaluate scientific literature for appropriateness of study design, analysis techniques, and findings.
- Interpret and communicate a variety of biostatistical approaches and sources of error in quantitative data analyses.
- Formulate well-defined research questions, hypotheses, specific aims, and appropriate methodology to implement clinical research.

The MS degree is comprised of 30 credits, 20 of which are directed and 10 of which are electives or independent research credits. The 20 core requirements include Introduction to Biostatistics, Introduction to Epidemiology, Introduction to SAS Programming, Ethics in Research, Design and Management of Field Studies, an advanced biostatistics class, a regression class, two Division of Epidemiology and Biostatistics Seminars, the Clinical Research Scholars Seminar, and thesis research ("Core Courses," 2014). To fulfill the remaining 10 credits, students can either take approved electives or research credits, or they can choose from one of seven focus areas: clinical epidemiology, clinical trials, quality improvement, molecular epidemiology, translational research, translational research informatics, and clinical research informatics ("Focus Areas," 2014).
Later in 2009, both a land-based Certificate and an online Certificate in Clinical and Translational Research were launched. One of the goals of the CTSA program is to increase research awareness and participation across a spectrum of users, from young students interested in science, technology, engineering, and math (STEM) fields to advanced researchers to community members with little to no scientific or research background ("About the CTSA Program," 2014). The MS degree in Clinical and Translational Research at UC serves one of the highest levels of this spectrum: those with a doctorate degree in the sciences who are pursuing clinical research careers. The Certificate programs in Clinical and Translational Research serve a much broader audience. Although they are graduate level and require a baccalaureate degree, they are open to people with a broader range of disciplinary backgrounds and career interests.

The purpose of the online Certificate is to provide introductory training in clinical and translational research to fellows and junior faculty interested in collaborating in research, fellows/junior faculty just launching their career as clinical/translational researchers; health science students in the Colleges of Medicine, Pharmacy, Nursing, and Allied Health Sciences; basic science researchers crossing over into clinical translation; residents; post-doctoral fellows from within the CCHMC/UCCOM community to other similar groups across the nation (Full Proposal: Certificate in Clinical and Translational Research, 2008). The Certificate program is comprised of six core credits (Introduction to Biostatistics, Introduction to Epidemiology, and Ethics in Research), and then students take an additional four elective credits of their choice. It does not require a thesis project, but students eligible for and interested in continuing on to the MS degree can count all earned credits earned under the Certificate towards the MS.
Core Competencies

As new training programs began to emerge at more institutions around the country, the NIH National Center for Research Resources (NCRR), which has since been supplanted by the National Center for Advancing Translational Sciences (NCATS), began developing core clinical research educational competencies in 2008 ("Core Competencies for Clinical and Translational Research," 2011). The CTSA Education and Career Development Key Function Committee collaborated with NCATS to form an Education Core Competency Work Group to “define the training standards for core competencies in clinical and translational research” ("Core Competencies for Clinical and Translational Research," 2011). The core competencies provide guidelines for MS training in fourteen thematic areas, including research question formulation, literature critique, study design, research implementation, identification of sources of error, statistical approaches, informatics, scientific communication, diversity, translational teamwork, leadership, cross-disciplinary training, and community engagement in research ("Core Competencies for Clinical and Translational Research," 2011). The final Core Competencies were approved in November, 2011 ("Core Competencies for Clinical and Translational Research," 2011). Table 1 provides details on the fourteen thematic areas of the Core Competencies, along with the competencies themselves.

Table 1: Core Competencies in Clinical and Translational Research

<table>
<thead>
<tr>
<th>1. Clinical and Translational Research Questions</th>
<th>1. Identify basic and preclinical studies that are potential testable clinical research hypotheses.</th>
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<td></td>
<td>2. Identify research observations that could be the bases of large clinical trials.</td>
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<td></td>
<td>3. Define the data that formulate research hypotheses.</td>
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<td></td>
<td>4. Derive translational questions from clinical research data.</td>
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<tr>
<td></td>
<td>5. Prepare the background and significance sections of a research proposal.</td>
</tr>
<tr>
<td></td>
<td>6. Critique clinical and translational research questions using data-based literature searches.</td>
</tr>
<tr>
<td></td>
<td>7. Extract from the scientific literature scientific insight for research innovation.</td>
</tr>
</tbody>
</table>
### II. Literature Critique

1. Conduct a comprehensive and systematic search of the literature using informatics techniques.
2. Summarize evidence from the literature on a clinical problem.
3. Describe the mechanism of a clinical problem reviewed in a manuscript.
4. Use evidence as the basis of the critique and interpretation of results of published studies.
5. Assess sources of bias and variations in published studies.
7. Identify the unknown knowledge within a research problem.

### III. Study Design

1. Formulate well-defined clinical or translational research question.
2. Propose study designs for addressing a clinical or translational research question.
3. Assess the strengths and weaknesses of possible study designs for a given clinical or translational research question.
4. Design a research study protocol.
5. Identify a target population for a clinical or translational research project.
6. Identify existing measures of clinical or translational research.
7. Design a research data analysis plan.
8. Determine resources needed to implement a clinical or translational research plan.
9. Prepare an application to an IRB.

### IV. Research Implementation

1. Compare the feasibility, efficiency, and ability to derive unbiased inferences from different clinical and translational research study designs.
2. Assess threats to internal validity in any planned or completed clinical or translational study, including selection bias, misclassification, and confounding.
3. Incorporate regulatory precepts into the design of any clinical or translational study.
4. Integrate elements of translational research into given study designs that could provide the bases for future research, such as the collection of biological specimens nested studies and the development of community-based interventions.

### V. Sources of Error

1. Describe the concepts and implications of reliability and validity of study measurements.
2. Evaluate the reliability and validity of measures.
3. Assess threats to study validity (bias) including problems with sampling, recruitment, randomization, and comparability of study groups.
4. Differentiate between the analytic problems that can be addressed with standard methods and those requiring input from biostatisticians and other scientific experts.
5. Implement quality assurance systems with control procedures for data intake, management, and monitoring for different study designs.
6. Assess data sources and data quality to answer specific clinical or translational research questions.
7. Implement quality assurance and control procedures for different study designs and analysis.

### VI. Statistical Approaches

1. Describe the role that biostatistics serves in biomedical and public health research.
2. Describe the basic principles and practical importance of random variation, systematic error, sampling error, measurement error, hypothesis testing, type I and type II errors, and confidence limits.
3. Scrutinize the assumptions behind different statistical methods and their
4. Generate simple descriptive and inferential statistics that fit the study design chosen and answer research question.
5. Compute sample size, power, and precision for comparisons of two independent samples with respect to continuous and binary outcomes.
6. Describe the uses of meta-analytic methods.
7. Defend the significance of data and safety monitoring plans.
8. Collaborate with biostatisticians in the design, conduct, and analyses of clinical and translational research.
9. Evaluate computer output containing the results of statistical procedures and graphics.
10. Explain the uses, importance, and limitations of early stopping rules in clinical trials.

**VII. Biomedical Informatics**

1. Describe trends and best practices in informatics for the organization of biomedical and health information.
2. Develop protocols utilizing management of information using computer technology.
3. Describe the effects of technology on medical research, education, and patient care.
4. Describe the essential functions of the electronic health record (EHR) and the barriers to its use.
5. Explain the role of health information technology standards have on the interoperability of clinical systems, including health IT messaging.
7. Retrieve medical knowledge through literature searches using advanced electronic techniques.
8. Discuss the role of bioinformatics in the study design and analyses of high dimensional data in areas, such as genotypic and phenotypic genomics.
9. Collaborate with bioinformatics specialists in the design, development, and implementation of research projects.

**VIII. A. Regulatory Support and Knowledge Competencies**

1. Describe the fundamental principles of the protection of human subjects, the main authoritative bodies, key codes, and scope of enforcement.
2. Describe the Food and Drug Administration requirements for drug biologic products.
3. Prepare an application for IRB approval.
4. Critique a proposal for risks to human subjects and protections of vulnerable populations.
5. Describe the essential elements of voluntary informed consent.
6. Describe the principles of research documentation, validation and audit.

**VIII. B. Responsible Conduct of Research**

1. Explain the ways in which the principles of research ethics are integrated into the design, conduct, oversight and dissemination of research.
2. Describe the authority for and professional standards for the responsible conduct of research.
3. Explain the procedures for reporting and investigating misconduct in research.
4. Explain conflict of interest management in research.
5. Outline criteria for determination of authorship.
6. Describe the role of peer review in funding and publication.
7. Explain the purpose, policies and procedures to ensure ethical use, care, and
animal safety in research.

**IX. Scientific Communication**

1. Communicate clinical and translational research findings to different groups of individuals, including colleagues, students, the lay public, and the media.
2. Translate the implications of clinical and translational research findings for clinical practice, advocacy, and governmental groups.
3. Write summaries of scientific information for use in the development of clinical health care policy.
4. Translate clinical and translational research findings into national health strategies or guidelines for use by the general public.
5. Explain the utility and mechanism of commercialization for clinical and translational research findings, the patent process, and technology transfer.

**X. Cultural Diversity**

1. Differentiate between cultural competency and cultural sensitivity principles.
2. Recognize the demographic, geographic, and ethnographic features within communities and populations when designing a clinical study.
3. Describe the relevance of cultural and population diversity in clinical research design.
4. Describe cultural and social variation in standards of research integrity.
4. Critique studies for evidence of health disparities, such as disproportional health effects on select populations (e.g., gender, age, ethnicity, race).

**XI. Translational Teamwork**

1. Build an interdisciplinary/ intradisciplinary/ multidisciplinary team that matches the objectives of the research problem.
2. Manage an interdisciplinary team of scientists.
3. Advocate for multiple points of view.
5. Demonstrate group decision-making techniques.
7. Manage a clinical and/or translational research study.

**XII. Leadership**

1. Work as a leader of a multidisciplinary research team.
2. Manage a multidisciplinary team in across its fiscal, personnel, regulatory compliance and problem solving requirements.
3. Maintain skills as mentor and mentee.
4. Validate others as a mentor.
5. Foster innovation and creativity.

**XIII. Cross Disciplinary Training**

1. Apply principles of adult learning and competency-based instruction to educational activities.
2. Provide clinical and translational science instruction to beginning scientists.
3. Incorporate adult learning principles and mentoring strategies into interactions with beginning scientists and scholars in order to engage them in clinical and translational research.
4. Develop strategies for overcoming the unique curricular challenges associated with emerging scholars from diverse backgrounds.

**XIV. Community Engagement**

1. Examine the characteristics that bind people together as a community, including social ties, common perspectives or interests, and geography.
2. Appraise the role of community engagement as a strategy for identifying community health issues, translating health research to communities and reducing health disparities.
3. Summarize the principles and practices of the spectrum of community-engaged research.
4. Analyze the ethical complexities of conducting community-engaged research.
5. Specify how cultural and linguistic competence and health literacy have an impact on the conduct of community engaged research.
Evaluation Efforts

In 2010 and 2012, the UC clinical and translational research training program conducted focus groups with students enrolled in the Clinical Research Scholars Seminar to garner feedback about student experiences in the program and possible improvements. Students broached issues that included more pre-enrollment advising sessions, occasions to interact with fellows who are more advanced in the MS program, clarification on tuition funding opportunities, a more cohesive curriculum, and more applied statistics instruction. We\(^1\) have worked to address all of these issues as much as possible, instituting open information sessions that include new and advanced students, working with the CCTST to clearly publish institutional reimbursement/remission policies and funding opportunities, and revising our curriculum to include courses that are relevant and of interest to our physicians.

Few studies have quantitatively evaluated the success of training provided through a K30 or CTSA, although using an alumni survey, Goldhamer et al. (2009) did correlate reception of NIH grant funding with starting the training program at a younger age, being a generalist, and successfully publishing projects from coursework. A number of more qualitative tools and frameworks for assessing clinical researchers’ success after completing a training program have been developed over the last five years. The first, called the Clinical Research Appraisal Inventory (CRAI), aims to measure trainees’ perceived self-efficacy in a variety of related conceptual areas such as conceiving of and designing a study, funding and managing a study, collaborating with peers, responsible conduct of research, collecting and interpreting data, and

\(^{1}\) I use the pronoun “we” throughout this section because, in my role as program director of UC’s Clinical and Translational Research training program, I work with a team of faculty members and administrators. I am the primary administrator of program evaluation efforts, but many others are involved.
reporting study results (Lipira et al., 2010; Mullikin et al., 2007). More recently, the CTSA program’s Key Function Committee (KFC) on Evaluation published a comprehensive model for career success that can be used to “theoretically explore determinants of career success among physician-scientists” (Rubio et al., 2011). This model includes both extrinsic (financial success, promotion, grants, and publications) and intrinsic (satisfaction with job, career, and life) factors in its conceptualization of overall career success.

While assessment tools such as the CRAI and the comprehensive career-success model are important and helpful approaches for program directors to consider, neither offers pragmatic methods for empirically evaluating the contributions of investigators who are trained through CTSA-funded programs. Assessing trainees’ perceived self-efficacy using the CRAI is not directly correlated to their actual or potential success in a research career (Hacker, Bol, Horgan, & Rakow, 2000). It is possible that clinical researchers feel very confident about their skills post-training, but that they have not actually achieved skill mastery. Hence, the CRAI is typically viewed as a “short-term indicator of program impact,” rather than long-term (Lipira et al., 2010). The personal and organizational factors described in the career-success model are intended primarily for theoretical use, not “empiric validations” (Rubio et al., 2011). The comprehensive career-success model does, however, include a few quantifiable measurements in its list of “extrinsic” success indicators, including financial success, promotion, leadership positions, grants, and publications. The first three are most difficult to measure, given that data on trainees’ current salary levels and career trajectories are not readily available. The last two, however – publications and grants – can be found rather easily through open access databases available online. Publications, in particular, are easily collected and verified. All one needs is a
full name, and often an institution or research area helps, and one can quickly obtain an updated list of all publications produced by a person over many decades.

With the training goals of the CTSA program and evaluation models from the field of physician-scientist training programs in mind, UC undertook an empirical evaluation study to evaluate the effectiveness of our MS in Clinical and Translational Research (MSCTR) by comparing alumni publications to a non-alumni comparison group. While more traditional methods of training program evaluation typically include post-training survey data from graduates that attempt to measure everything from course and curriculum quality to faculty and mentor interaction to perceived usefulness of program content, our goal was to consider the program’s success from a purely empirical standpoint.

In 2013, we completed a study that compared publication track records of MS fellows and non-MS fellows to evaluate program effectiveness ("The CTSA Program at NIH: Opportunities for Advancing Clinical and Translational Research. Committee to Review the Clinical and Translational Science Awards Program at the National Center for Advancing Translational Sciences," 2013; Knapke et al., 2013). We found that MS fellows publish more first-authored articles, and more articles overall, than non-MS fellows. Additionally, men in the non-MS group outpace their women colleagues, but the gender gap is eliminated in the MS group. More recently, we completed a similar study that compared grant awards in MS and non-MS fellow groups (Knapke, Haynes, Kuhnell, & Tsevat, 2015). This study showed that when controlling for age and sex, MS fellows are three times more likely to have at least one grant than non-MS fellows. MS fellows are also significantly more likely to have obtained at least one K, R, or M grant award than non-MS fellows. Interestingly, older fellows are more likely to have
a least one grant of any kind, and sex was only significant when looking at R grants, with men more likely than women to have at least one R grant. Although these preliminary, quantitative studies strongly indicate a high degree of program success in training the next generation of clinical researchers, they also raise important questions related to sex, age, and research productivity.

The research projects detailed above are part of our ongoing efforts to improve clinical research training at UC. Effective program evaluation needs to be ongoing, consistent, and open to the potential for major innovations. Due to a confluence of multiple factors, including shrinking budgets both in terms of institutional and federal funding, a renewed focus on online training, and the innovation charge in the IOM’s report on the CTSA Program ("The CTSA Program at NIH: Opportunities for Advancing Clinical and Translational Research. Committee to Review the Clinical and Translational Science Awards Program at the National Center for Advancing Translational Sciences," 2013), momentum is building towards a new paradigm for training physician-scientists. Successful evaluation that fosters innovative improvements requires a more in-depth, personal, and systematic approach to identify the subtle nuances impacting trainees' performance in their pursuit of a career in academic medicine. A mixed methods approach that incorporates both quantitative measures and qualitative exploration can fill these gaps in our knowledge.
Chapter 2: Theoretical Frameworks

Although clinical and translational research students come to the field as adults with expertise in one or more areas of medicine, in many ways, they are embarking on an entirely new branch of their careers, and they have much to learn in terms of the research process and the norms within their chosen discipline of clinical research. Because of these unusual student traits and the unique challenges of the clinical research field in general, Bruner’s (1960) constructivism theory for curriculum development, disciplinary socialization theory (Bess, 1978; Lave & Wenger, 1991; Merton, 1949), and Knowles’ (1973, 1980, 1984) learning theory of andragogy can serve as useful frameworks when conducting educational research within clinical and translational research education.

Bruner’s Constructivism Theory for Curriculum Development

Jerome Bruner was a leader in the fields of cognitive learning theory and educational philosophy from the 1960s through the 1990s. Although he generally embraced a constructivist approach to understanding human learning (Bruner, 1960; Goodman, 1978; Piaget, 1970), he allowed for the inclusion of many other possible learning theories, including:

- **Tabula rasa**, or the “premise that experience writes on the wax tablet of the mind” (Bruner, 1985),
- **Hypothesis generation**, the idea that learners come to experiences with hypotheses already in place, and that these hypotheses act as a filter which “selects and organizes what gets through the senses into the mind” (Bruner, 1985),
- **Nativism**, which views the powers of the mind as innate characteristics that organize our experiences into categories and hypotheses (Bruner, 1985),
• and *Novice-to-expert*, a more pragmatic approach to cognitive development that views
the learner as simply a novice in need of an expert to mimic in order to attain expertise
(Bruner, 1985).

It’s important to note that while this chapter focuses on the “spiral curriculum” concept, which
is primarily situated in a constructivist theoretical framework, Bruner (1985) recognized all of
these other learning theories as valuable and possible. He clearly states, “There is not one kind
of learning . . . Any learner has a host of learning strategies at command . . . . Perhaps the best
choice is not a choice of one, but an appreciation of the variety that is possible” (p. 8).

Bruner’s constructivism relies heavily on the work of Jean Piaget (1970). As Bruner
(1985) succinctly summarizes, “The tenet of Piaget’s constructivism is that the world is not
found, but made, and made according to a set of structural rules that are imposed on the flow
of experience” (p. 6). Constructivism emphasizes the importance of a larger structure that
influences the ways we perceive and process knowledge. According to Bruner (1985), learners
come to experiences with knowledge about a larger structure, or system, at work in their
worlds, and this structure provides bounds for any new knowledge acquired from learning
experiences. Existing knowledge of the structure of things and new knowledge interact,
changing the learners’ perceptions and understanding of the larger structure. As a result,
learners go through stages of cognitive development, with the structure providing a framework
that bounds understanding, new knowledge informing that structure and changing it, and a
revised structure emerging, “accommodating” the new knowledge (Bruner, 1985, p. 7). As
Bruner (1985) states, “Learning is bound within the limits of the rules of the system; it consists
of realizations of the general rules in application to particulars” (p. 6-7).
Bruner’s Spiral Curriculum

Bruner first discusses his spiral curriculum model in one of his earliest books, *The Process of Education* (1960). Essentially, Bruner (1960) introduces the idea that children should be presented with “the great issues, principles, and values that a society deems worthy of the continual concern of its members” (p. 52). Any subject matter beyond this fundamental charge is gratuitous. A key aspect of the spiral curriculum is the belief that a very young child can understand relatively complex concepts, as long as they are presented properly within the child’s larger structural framework, or, in other words, in a way appropriate to the child’s current stage of structural development (Bruner, 1960). The spiral curriculum model then advocates for further development of the same core issues and topics in later grades, cultivating and expanding students’ understanding of both the larger structural framework under which the concepts operate, and the specifics of the concepts themselves (Bruner, 1960).

Use of the term “spiral” is appropriate because of the model’s characterization of teaching and learning as an iterative process. Children are given a simple introduction to concepts at an early age and they use their own experiences and cognitive stages to inform that introduction. In later grades, then, the same topics are re-examined, but with more complexity as the learners’ structural understandings develop and progress. As learners move through a curriculum, they are repeatedly exposed to the same core ideas, but with increasing complexity and specialization, just as their structural scaffolding evolves and becomes more nuanced (Figure 1). “Structure,” to Bruner, is an understanding “that permits many other things to be related to it meaningfully. To learn structure, in short, is to learn how things are related”
(Bruner, 1960, p. 7). One’s structure, then, could be viewed as one’s “cognitive capacity (or its limit)” to perceive connections among different aspects of one’s experiences (Takaya, 2008).

Harden and Stamper (1999) summarize four key features of a spiral curriculum:

1. Topics are revisited.
2. As topics are revisited, the level of difficulty increases.
3. New knowledge and experiences are related to existing knowledge and experiences.
4. Student competency increases with each visit until overall learning objectives are achieved.

It is worth noting a few additional qualities to each of the four features. First, although topics are revisited, they are not simply repeated (Harden & Stamper, 1999). Although instruction may return to particular themes, skills, or contexts, new information should be included with each return to a topic. The second feature listed above, the increasing level of difficulty with each visit, relates to the first in that a return to a topic should include new, additional learning outcomes for students and provide more sophisticated applications of the topic, typically with more practical relevance. The third feature, relating new learning to previous learning, lies at the heart of Bruner’s spiral curriculum model, because it ties directly back to the constructivist framework in which Bruner operates. Effective learning happens when students are able to build upon their existing understanding of a discipline within a larger culture, and teachers should be mindful of the limits of a learner’s structure at any given cognitive stage. Finally, the fourth feature of the spiral curriculum model wraps up the cycle of learning, with the learner accomplishing the desired proficiency after repeated exposure and development of key topics.

The spiral curriculum model offers several unique benefits, as well: topics are reinforced over time by continued exposure, students progress from a more simplistic grasp of topics to a complex, deep understanding, integration occurs across the curriculum, without the
compartmentalization that often comes with other approaches to curriculum design, key topics are sequenced in a logical way, both in terms of scope and timing, as they relate to students’ cognitive stages, higher level learning objectives guide the curriculum, and students are encouraged to understand information and, eventually, use their knowledge and skills in applied practice, and finally, the spiral curriculum model offers flexibility to meet students where they are at each stage, and to sometimes move them more fluidly through a curriculum if knowledge is mastered early on (Harden & Stamper, 1999).

**Figure 1: Constructivist Learning: The Spiral Curriculum**

The Spiral Curriculum in Higher Education

Although Bruner’s theoretical interests primarily focused on primary and secondary education, his spiral curriculum model can be easily adapted to a post-secondary educational context. Knight (2001) wrote an article on curriculum planning in higher education that emphasizes the importance of coherence in curriculum, using Bruner’s spiral model as a
foundation. Educators and researchers in higher education have, in fact, already applied the model to a variety of fields including chemistry (Gravert, 2006; Grove, Hershberger, & Bretz, 2008; Minter & Reinecke, 1985; Sartoris, 1992), interdisciplinary sciences (Chen, Hsu, & Wu, 2009), online education (Masters & Gibbs, 2007), nursing (Chambers, Thiekotter, & Chambers, 2013; McCormack, 1993), and medical education (Davis, 2003; Davis & Harden, 2003; Harden & Stamper, 1999; Howe, Campion, Searle, & Smith, 2004; Jones, Higgs, de Angelis, & Prideaux, 2001; Malik & Malik, 2002). The theory behind Bruner’s (1960) spiral curriculum model is particularly applicable to higher education because across all disciplines, from the sciences to literature and history, instructors build on previously learned material and skills.

**Disciplinary Socialization Theory**

Disciplinary, or professional, socialization theory has percolated within the field of higher education, particularly graduate education, since the 1950s (Bess, 1978; Merton, 1949; Pavalko, 1971). Essentially, the theory states that once students have chosen their professional occupation, they experience “a shift of psychological orientations and energies from the self-concept of neophyte/apprentice to one of fledgling professional” (Bess, 1978, p. 292; Caplow, 1964; Gross, 2011). Bess (1978) further explains that “professionalization is the process by which students learn the skills, values, and norms of the occupation or profession, while socialization refers herein to the process of adopting the values, norms, and social roles which constrain behavior in an organizational setting” (p. 292). Both processes are social learning processes, comprised of observation, imitation, feedback, modification, and finally, internalization (Bess, 1978; Bragg, 1976).
Bess’s (1978) theory of disciplinary socialization is specific to the field of higher education, focusing on the indoctrination of new classes of faculty members through a series of learning processes. The process of choosing an occupation typically begins during a student’s undergraduate studies, takes many years, and involves a number of small and large decisions (Bess, 1978). Throughout the process, students are influenced socially by a variety of people, and they might engage in internal visualizations of what types of positions they can imagine themselves thriving. Bess (1978) states that, “As they interact in diverse interpersonal situations, take on part-time work, meet persons in a variety of vocations, they ‘experience’ different parts of their skills and potential” (p. 291). This psychologically formative process leads some students to pursue graduate school degrees, often as a result of cultural and family influence, or out of a strong self-concept tied to academic success in college (Wallace, 1966).

Once in graduate school, the student begins to more fully commit him or herself to the profession, “which involves a total investment of the ego in the ideological bases and career opportunities of a particular field” (Hershenson, 1968). Graduate students learn the values and norms of academia, as communicated to them by the faculty and the organizational structure under which they work. Clark and Corcoran (1986) state that professional socialization is an essential aspect of a successful graduate school program. Not only do these norms “collectively embody the professional nature of the occupation,” but they also “convey the range of opportunities and constraints on the behaviors which describe the occupation and the career of a faculty member” (Bess, 1978, p. 294). Finally, Bess (1978) argues that once students complete graduate training and undertake junior faculty positions, they undergo a fuller process of professional socialization. This stage typically occurs during their untenured years, when they
“are more fully socialized into the profession in general and the employing organization in particular. Norms and values, more than skills, sink in and become an integral part of the faculty members’ conscious rationale for and unconscious stimulus to expected role behaviors” (Bess, 1978, p. 297).

As the research around disciplinary socialization has matured over the last 10-20 years, scholars have begun to formulate specific phases or stages that constitute the socialization process. Tinto (1993) and Gardner (2007) suggest three stages of socialization, whereas other research teams have suggested four (Lovitts, 2001; Stein & Weidman, 1989, 1990; Weidman, Twale, & Stein, 2001). Stein and Weidman’s (1989, 1990) four stage model is based on empirical evidence and takes into account the huge variety of experiences that contribute to the graduate student process, from the academic experiences of students (coursework, exams, etc.), to the “relational” aspects of graduate school (evolving relationships with other students, faculty mentors, and professionals within a particular field), and from the group level of socialization involving member and role performance to the individual level, meaning how an individual student perceives and engages in social life within his or her field. Stein and Weidman’s (1989, 1990) four stage model (Figure 2) includes:

*Stage I - Anticipatory:* This early stage of disciplinary socialization, usually associated with the period when students are applying to, gaining admission, and just beginning their graduate programs, is when students begin to anticipate the types of attitudes and behaviors expected of them within their chosen discipline. Their initial impressions of their fields are often stereotypical and vague. Gardner (2010) characterizes this phase as “impress[ing] greatly upon
the rest of [students’] program” and being “integral to the rest of the students’ experience” (p. 64).

Stage II - Formal: This stage consists of formal instruction in students’ chosen disciplines. Students are novices at this stage, but they carefully (often subconsciously) observe their faculty members and older peers “to learn normative role expectations and how they are carried out” (Weidman et al., 2001, p. 13). The relationships formed with faculty members and graduate student peers during this stage are essential to students’ understanding of their selected profession.

Stage III - Informal: This stage builds on the formal instruction students received in Stage II, further indoctrinating students into what types of behaviors are acceptable and valued within their field. As the novice from Stage II gains a more nuanced understanding of the role requirements specific to a field, he or she also becomes more aware of flexibility within those roles.

Stage IV – Personal: This final stage of disciplinary socialization is when students fully internalize the expectations of their field, “form[ing] a professional identity and reconcil[ing] the dysfunction and incongruity between their previous self-image and their new professional image as they assume their new role” (Weidman et al., 2001, p. 14).

As Daresh and Playko (1995) state:

At the culmination of the socialization process, students should be able to answer three key questions: (1) What do I do with the skills I have learned? (2) What am I supposed to look like and act like in my professional field? and (3) What do I as a professional look
like to other professionals as I perform my new roles? (as quoted in Weidman et al., 2001)

Figure 2: The Four-Stage Model of Disciplinary Socialization (based on Stein & Weidman, 1989)

Communities of Practice

Lave and Wenger (1991) developed a theory of social learning based around the concept of “communities of practice.” Simply put, a community of practice is a group of people who share and participate in a regular, common endeavor. Communities of practice are unique from other social units of individuals in that they are not based on proximity of location to each other or class, gender, or other demographic characteristics. Instead, a community of practice develops shared “ways of doing things, views, values, power relations, ways of talking,” all with a shared commitment to making meaning within their specific area of interest (Eckert, 2006). Also important to the theory of communities of practice is the notion that participants within a
community situate themselves, as individuals within the group, in a particular place in the world around them.

Lave and Wenger (1991) based their theory of communities of practice within larger “situated learning” framework. Criticizing the classroom instruction model that values instruction of abstract knowledge without an applied context, Lave and Wenger (1991) instead argue that learning is “situated,” meaning that when it occurs most naturally, learning is often unintentional and rooted in an activity, a context, and a culture. As Elkjaer (2009) points out, Lave and Wenger’s (1991) “understanding of learning as participation in communities of practice took learning out of the clutches of individualism . . . . The key issue is the relation between the institutional order and the participants’ experience” (p. 87). It is important to note, as Wenger (2009) does, that in the context of situated learning, “participation” “refers to a more encompassing process of being active participants in the practices of social communities and constructing identities in relation to these communities” (p. 210). In later writings on situational learning, Lave (2009) challenges the idea that learning is “a process contained within the mind of the learner” because such a notion “ratifies a dichotomy of mind and body,” essentially ignoring the practical reality of the interplay between individuals and the world in which we live (p. 202).

**Andragogy Model**

Although college application and enrollment numbers have been up all over the country for several years now, one particular student population has seen huge growth over the last couple decades: adult learners (Moore & Kearsley, 2005). Adult learners are typically characterized by age and life experience. Almost a decade ago, the National Center for
Educational Statistics ("Reasons for Adults' Participation in Work-Related Courses, 2002-2003 (NCES 2005-088)," 2005), under the U.S. Department of Education, described adult learners as people at least 16 years old; however, adult learners are more commonly identified as people between the ages of 25 and 50 (Kimmel, Gaylor, Grubbs, & Hayes, 2012; Moore & Kearsley, 2005; Osgood-Treston, 2001). Adult learners form a unique student population, and they bring their own interests, attitudes, and expectations to a classroom.

Malcolm Knowles (1970, 1973, 1980) developed the andragogy theory, which attempts to provide a framework for understanding the distinctive needs of an adult student population. A more familiar term in traditional education is pedagogy, with the Greek root “paid,” or child and “agogus,” meaning leader of. In contrast, andragogy’s root word “aner” translates as man (instead of boy), so the term itself is an appropriate alteration of a well-known tradition. Knowles (1973) makes clear that he is “not talking about a clear-cut differentiation between children and adults as learners. Rather, [he is] differentiating between the assumptions about learners that have traditionally been made by those who practice pedagogy in contrast to the assumptions made in andragogy” (p. 43). Knowles (1973) then goes on to describe four main assumptions of andragogical theory:

1. **Changes in Self-Concept:** Children maintain a self-concept of total dependency, but adulthood is characterized by a self-concept of self-direction. Once this psychological maturation occurs, the adult naturally feels most comfortable in situations that allow him or her to self-direct, independently. As Knowles (1973) states, when a person’s ability to self-direct is inhibited (e.g., he is treated like a
child), “he experiences a tension between that situation and his self-concept” (p. 45).

2. *The Role of Experience:* Compared to children, adult learners bring a wealth of life experiences to their learning. These experiences form the very essence of who a person is. Unlike children, who define themselves in terms of other people (teachers, parents, etc.), adults define themselves by their experiences. “Andragogues convey their respect for people by making use of their experience as a resource for learning” (Knowles, 1973, p. 46).

3. *Readiness to Learn:* Adult learners’ life situations increase their readiness to learn. In other words, adult learners want to learn “those things they ‘need’ to because of the developmental phases they are approaching in their roles as workers, spouses, parents,” etc. (Knowles, 1973, p. 47). Knowles (1973) also discusses a “critical implication” of assumption three, which is that whenever possible, learning experiences should be timed to “coincide with the learners’ developmental tasks” (p. 47).

4. *Orientation to Learning:* Traditional pedagogy assumes that young students approach learning based on subject areas. Andragogy assumes that adults approach learning with a problem-based orientation. Knowles (1973) believes most adults pursue education because of a perceived “inadequacy” in their lives, so they seek learning experiences that directly apply to their areas of inadequacy (p. 48).

In general, andragogical theory asserts that adult learners typically seek information they feel is valuable to them, both intrinsically and extrinsically, and that can be applied within
their lives (Knowles, 1973). They also appreciate self-directed educational experiences, and they prefer to work independently towards their own defined educational and professional needs (Kimmel et al., 2012; Knowles, 1970, 1973, 1980). They value knowledge that can be immediately used in their lives, personally or professionally, and they view life experience as an important contributing factor to expertise (Knowles, 1980).

Often, adult learners are also balancing numerous commitments outside of school and their educational goals are based on well-defined needs (Kimmel et al., 2012; Osgood-Treston, 2001). Compared to their younger counterparts, adult learners are typically more motivated to do well in their studies and more oriented towards task completion (Merriam & Caffarella, 1999). In many cases, adult learners have chosen to advance their education so that they can retain a competitive edge in the workplace, especially during times of economic recession (Kimmel et al., 2012). Although often described as non-traditional students in higher education, adult learners are redefining the conventional image of a college student. College enrollment numbers among adult learners are expected to increase at almost twice the rate of traditional students (e.g., students under 25 years old) between 2009 and 2017 ("Digest of Education Statistics," 2010).

As more adults have chosen to pursue higher education degrees, researchers have worked to refine learning theories to make them more applicable to adults. Older learners often come to the classroom, whether in-person or virtually, with very different expectations and life experiences. Many adults are accustomed to the standard method of instruction, with an instructor actively delivering content and directing discussions and students more passively listening and responding (Cercone, 2008; Tweedell, 2000). The differences between adult
learners and their younger classmates can be especially manifested in an online course, where the method of delivery itself can be new and challenging to older students (Cercone, 2008). However, the desire to work independently and flexibly and to achieve specific, task-oriented goals could also work especially well with adult learners participating in online courses.

Process Model of Curriculum Design

The four assumptions outlined above led Knowles to eventually outline a “process model” of educational program design. Knowles first described the andragogical process model in his 1984 book, Andragogy in Action. During the time between his initial presentation of andragogy (1970) and his conception of the process model (1984), his conception of andragogy evolved. For example, early on, Knowles (1970) tended to emphasize the way the content of an educational experience was structured; e.g., adult learners respond to content that is relevant to their lives and presented experientially. Later, though, Knowles (1984) stressed instead the process of adult learning, meaning how the teacher involves learners in the educational process. This model outlines eight elements of curriculum planning within an andragogical context, contrasting these to a pedagogical context (Table 2, adapted from (Knowles, Holton III, & Swanson, 2011, p. 115).

Table 2: Process Elements of Andragogy

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<tr>
<th>Process Elements</th>
<th>Pedagogical Approach</th>
<th>Andragogical Approach</th>
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<tbody>
<tr>
<td>1. Preparing Learners</td>
<td>Minimal</td>
<td>Provide information</td>
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<td></td>
<td></td>
<td>Prepare for participation</td>
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<td></td>
<td></td>
<td>Help develop realistic expectations</td>
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<td></td>
<td></td>
<td>Begin thinking about content</td>
</tr>
<tr>
<td>2. Climate</td>
<td>Authority-oriented</td>
<td>Relaxed, trusting</td>
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</table>
Each of the eight steps outlined in the above process model takes into account the unique needs of adult learners. In order for all of these steps to successfully guide the learning process, Knowles et al. (2011) note that often a preparatory activity that exposes adult learners to the principles of self-directed learning may be necessary. Although andragogical theory recognizes that adult learners thrive in an educational atmosphere characterized by self-direction and independence, frequently, adults have not yet learned to direct their own educational experiences. In fact, “they often experience a form of culture-shock when first exposed to adult educational programs that require them to participate in the planning” (Knowles et al., 2011, p. 116). The authors recommend providing a brief “experiential encounter” with the ideas behind educational self-direction before fully immersing adult students in a class organized according to the andragogical process model (p. 116).
My Own Theoretical Situation

My choice of theoretical frameworks reflects a lot of the theoretical assumptions I bring to most aspects of my work as an academic program director, including my research. All of the theories described above are firmly grounded within a constructivist paradigm, which aligns itself well within a qualitative research approach. Constructivism posits that instead of there being one, true, objective reality (more of a positivist approach), reality is relative to each individual, and is constructed within the mind, through experiences (Hansen, 2004; Ponterotto, 2005). Schwandt (1994, 2000) stresses the importance of understanding the everyday “lived experiences” of individuals, from their own points of view. And Dilthey (1977), another constructivist, emphasizes that these experiences happen within a historical social reality. My own epistemological perspective is well-matched to constructivism, especially with regard to my research. The motivations and hindrances to both pursuing and achieving a successful clinical research career are ambiguous and shifting, as I believe is true for most reality and truth in human experience. A more quantitative, positivist approach to studying clinical research scholars’ educational experiences might uncover basic trends, but it will not provide a deeper and more textured understanding of the lived experiences young clinical researchers encounter in the day to day. This kind of understanding is essential to improving their overall training, and possibly in effect, their desire to pursue (and their ability to succeed) in such a highly competitive field.

It is important to note that my particular epistemology placed in the larger context of medical research and education is challenging. Convincing students and faculty alike that my proposed methodology is appropriate and valuable will be difficult at times. Most clinical
researchers are firmly grounded in the sciences, or more specifically, in a positivist paradigm. For many of them, research findings that do not include $p$ values and standard deviations are considered questionable, at best. On the other hand, qualitative and mixed methodologies are gaining ground in the medical and health sciences, and participants will undoubtedly recognize that their life experiences have contributed to their educational and career choices. These factors will help me to persuade them of the value of a mostly qualitative approach, with its constructivist theoretical underpinnings.

Stein and Weidman’s (1989, 1990) four stage model of disciplinary socialization is appealing because his stages are not a simple timeline from start to completion of an advanced graduate degree. Instead, they are flexible and characterize logical psychological and social developments in graduate students. They provide a framework for understanding how students begin in a field as novices and move through typical stages of psycho-social development to see themselves as professionals in a field, but they don’t impose strict frames of time or academic milestones on an ambiguous, organic process. Disciplinary socialization, in my mind, is especially pertinent to young clinical investigators in training. Clinical researchers are a very unique type of physician – one that operates within a clinical setting dedicated to patient care, but that also views the clinic as a means of conducting research to improve clinical care. The possibilities in terms of defining a research question, designing a study, collecting data, analyzing data, and producing a meaningful research article are truly infinite, so a clinical and translational research trainee’s early indoctrination into the field is especially imperative. Without strong formal didactics and informal, individual mentorship throughout stages II-IV in Stein and Weidman’s (1989, 1990) four stage process, the trainee will likely falter in his or her
early research projects, leading to personal frustration with the whole research enterprise. Perhaps more importantly, in a high-stakes field like clinical and translational research where funding is paramount, inadequate socialization to the behavioral and procedural norms in the field can lead to professional failure in launching a successful research career.

Interestingly enough, Stein and Weidman’s (1989, 1990) four phases of disciplinary socialization interact nicely with Bruner’s (1985) spiral curriculum model because both rely upon an interpretive approach that recognizes the role of the individual’s experiences and preconceptions in the process of growth and learning. As Ongiti (2008) states, in a discussion of Stein and Weidman’s (1989, 1990) socialization framework, “the new entrant comes with her values, and as she goes through the process of socialization, changes or maintains the inherent values upon entry” (p. 54). This description could also be readily applied to Bruner’s (1985) spiral curriculum model, where the learner comes to experiences with a structural understanding of the world already in place, and as she moves through the curriculum, the revisiting of core topics deepens her understanding and changes her structure.

Bruner’s (1985) spiral curriculum model could potentially bring major benefits to a clinical and translational research training curriculum. Most of our students come in with extensive clinical experience and knowledge, but they lack research experience and formal research training. Consistency and revisitation of core topics related to conducting research would serve them extremely well. In fact, faculty members often complain that students do not remember fundamental epidemiological study designs or basic biostatistical principles from semester to semester. Adopting an approach that introduces students to core concepts in the introductory courses and then revisits them regularly and consistently throughout the more
advanced courses, building on and reinforcing earlier learning, could really strengthen students’ understanding of the key topics, topics Bruner (1960) would characterize as, “the great issues, principles, and values that a society [or a clinical research community of practice] deems worthy of the continual concern of its members” (p. 52). Students themselves complain that courses sometimes feel disjointed from each other, with no common threads to guide the entire program. A spiral curriculum model would also help unify the curriculum for the students, giving them repeated exposure to the most important principles of clinical research in a variety of courses and contexts.

Knowles’ (1973, 1980, 1984) andragogy model is also particularly relevant to a student population comprised of medical doctors who balance busy clinical schedules with the time-consuming demands of beginning a research career. As Knowles (1973) asserts in his model, adult learners value independence and self-direction in their learning experiences, view experience as an important aspect of knowledge, seek information they can directly apply to their own personal and/or professional lives, and take a problem-based approach to learning (as opposed to subject-based). Andragogy is a perfect theoretical lens through which to view physician-scholars who are pursuing post-doctoral graduate degrees in clinical research (Fordis et al., 2005). With busy clinical schedules and clearly defined training goals that must be applicable and relevant to their work, Knowles’ portrait of an adult learner matches the typical physician-scholar very well. They appreciate the ability to apply course objectives and assignments directly to their own ongoing research projects, they value being able to earn academic credit for independently conducted research activities, and they view their own experiences and the experiences of their peers and the faculty as indispensable learning tools.
Knowles (1973) states, “It is my observation that a good deal of professional education is totally out of phase with the students’ readiness to learn. For example, a new medical student needs to have direct experience with hospitals, patients, and practicing doctors before he is ready to learn facts about pathology, anatomy, biochemistry, and other content” (p. 47). I think this is an interesting aspect of andragogy that could really improve the curricular structure of UC’s clinical and translational research program. For example, students often do not fully grasp the importance of the statistical principles they learn about in their first semester of the master’s program. Because they are not often not immersed in a research project yet, or even beginning to formulate a study, their learning about statistical theories or formulae, or even practical applications of statistics, is devoid of meaningful context. I can imagine it would be immensely helpful if students first “dip their feet” into a research study to begin to understand the types of problems researchers face at different steps in the process. Some students already have this when they begin, but many do not. After this, they could then begin the more formal didactic training in epidemiology and biostatistics, but within a context of some initial research experience.

The assumptions behind a constructivist learning theory and the spiral curriculum model described by Bruner (1960), disciplinary socialization theory (Bess, 1978; Lave & Wenger, 1991; Merton, 1949), and Knowles’ (1973, 1980, 1984) andragogy model all share some basic common ground, and they all will inform my own interpretations as a primarily qualitative researcher. These theories operate within a constructivist paradigm that assumes knowledge and truth are not absolute, but instead are relative to one’s background and current situation. They place high value on previous experiences, and they tend to emphasize the practical
applications produced by the theories. Context is an essential element of all three, because context can shape learners’ experiences, interpretations, and adaptations. The assumptions underlying these theories fit within my own epistemological and ontological approach to research, and they lend themselves especially well to the phenomenon I plan to explore in my dissertation research.
Chapter 3: Methods

The next generation of Clinical and Translational Science Award (CTSA) education programs must be individualized, flexible, and innovative ("The CTSA Program at NIH: Opportunities for Advancing Clinical and Translational Research. Committee to Review the Clinical and Translational Science Awards Program at the National Center for Advancing Translational Sciences," 2013). Typically, Clinical and Translational Research (CTR) training programs are evaluated through course evaluations and student exit surveys. The University of Cincinnati CTR training program has utilized these methods and others and identified a high level of satisfaction from its students; however, if the purpose of program evaluation is to enhance and tailor an educational program to fit the needs of its students, these methods are limited. Successful evaluation requires a more in-depth, personal approach to identify the subtle nuances impacting trainees’ performance in their pursuit of careers in academic medicine. A mixed methods research approach can fill this gap in the knowledge. In addition, the use of phenomenological research enables the program user, i.e., the trainee, to inform the development of next-generation approaches in educating clinical scholars. The phenomenological design used in this research and the educational advances identified through this project could serve as a model for CTSA programs across the country.

Clinical researchers need a robust background in study design, statistical analysis, grant writing, and research ethics in order to be effective researchers. The ultimate goal of the CTR training program at UC is to move practitioners from the realm of personal clinical experience to objective evidence. The combination of didactic course work, seminars, and individual mentoring is meant to enable clinicians to develop the analytic and quantitative skills necessary
to conduct research within their own particular specialty, improving clinical practice, and ultimately, improving human quality of life by understanding the causes of human health issues and identifying effective methods of prevention and treatment. This study is the first step towards improving educational methods to better meet clinical and translational research trainee expectations and needs. Its findings will produce new innovations that will change the way UC trains local clinicians to do research, potentially changing the way other CTSA programs train their physicians.

Interpretive Phenomenology

Phenomenology is an umbrella term for a variety of phenomenological approaches with different philosophical underpinnings. For the purposes of this study, I used an interpretive, or hermeneutic, phenomenological approach. The philosophical work of Martin Heidegger (1962) serves as the basis for this approach, which includes the core idea that individuals exist within a “lifeworld,” or contextual reality, and they cannot fully remove themselves from this context. The idea of “situated freedom” (Leonard, 1999) is also central to Heidegger’s philosophy, and to the practice of interpretive phenomenology. Lopez and Willis (2004) summarize Heidegger’s contention that, “humans are embedded in their world to such an extent that subjective experiences are inextricably linked with social, cultural, and political contexts” (p. 729). Essentially, this means humans do not have absolute freedom in their decisions, but instead are limited to varying degrees by the context in which they live. The assumptions behind interpretive phenomenology work well within the larger theoretical frameworks I discussed in Chapter 2 because all account for the important role context and experience play in individual perceptions of reality, choice, and experience. As Ray (1994) explains, interpretive
phenomenology involves understanding the everydayness of a phenomenon through the
interpretation of the participant, the researcher intuiting meaning in the data analysis phase,
and then interpreting implications.

**Mixed Methods Research: Definition**

Because mixed methods research (MMR) is a relatively new field that is still evolving and
defining itself, it is important to first define my own understanding and use of the phrase.
Johnson and Christensen’s (2008) simple but inclusive definition of the approach most
resonates with me: “Mixed research involves the mixing of quantitative and qualitative
research methods, approaches, or other paradigm characteristics. The exact mixture that is
considered appropriate will depend on the research questions and the situational and practical
issues facing the researcher” (p. 34). This definition appeals to me for a number of reasons.
First, it includes what I consider to be a fundamental premise of mixed methods research: the
presence of both qualitative and quantitative methods in the same study. It mentions a few
specific aspects of mixing methods I also consider essential: the methods themselves, which
include data collection and analyses, approaches, which I interpret as study design, and “other
paradigm characteristics,” which to me, is a wonderfully open statement that could include
everything from ontological and epistemological beliefs to interpretive frameworks to
methodological traditions.

Johnson and Christensen’s (2008) definition also includes two subtler nuances that I find
appealing. First, it suggests there is a continuum of mixed methods, leaving room for studies
that incorporate both quantitative and qualitative methods, but possibly with an emphasis or
priority placed on one or the other. The phrase “exact mixture” indicates that there is not a
strict formula for how much of either approach should be included in a mixed methods study (Johnson & Christensen, 2008, p. 34). Combined with the idea that the appropriate mixture “depend[s] on the research questions and the situational and practical issues facing the researcher” is, to me, a direct nod to the flexibility inherent to qualitative research, and so also very important (Johnson & Christensen, 2008, p. 34). The language of this definition aligns well with the “situationalist position” briefly described by Greene, Caracelli, and Graham (1989), which I also identified with as I wrestled with the idea of mixing paradigms (p. 257). As Greene et al. (1989) state, the situationalist position is a “middle-ground” position between the purists and the pragmatists, contending that “our understanding of a given inquiry problem can be significantly enhanced by exploring convergences from alternate paradigms” (p. 257). I found this compromise to be a happy middle ground in the debate over mixing philosophical assumptions because it acknowledges the purists’ rejection of mixing paradigms as legitimate, but it also recognizes that mixing methods (and, in effect, paradigms) can yield important new understandings of complex research problems.

**Mixed Methods Research in CTR/Graduate Medical Education Research**

Before designing this mixed methods study, it was important to first examine the relevant literature for existing research models and findings. However, because CTR training programs have only been formalized over the last five to ten years, there are no mixed methods studies available yet that are specific to the field of clinical research training. Instead, I performed a brief literature review on mixed methods studies related to graduate medical education program development and evaluation. While development and evaluation are two different aspects of an educational program, as Nastasi et al. (2007) discuss, program
evaluation is often an iterative process whereby monitoring and evaluation data inform and improve program processes, which are then evaluated again for further improvements, and so on. Graduate medical education research is a good match to clinical research training because it focuses on adult-learner/professional student populations in the context of the medical sciences. The purpose of this brief literature review was to examine the ways researchers have used mixed methods designs to evaluate educational programs in graduate medical education. A secondary goal was to develop some best practices for mixed methods research in this field to determine how best to apply these practices to CTR training program evaluation and development.

My analysis focused on eight articles that met my criteria of having a true mixed methods design, reasonably integrating the qualitative and quantitative strands, and working with a graduate medical student population. All eight of the articles were published very recently, in either 2013 or 2014. I read and analyzed these eight articles to determine the specific type of mixed methods design the authors used, the purpose of their study, methods incorporated, sampling techniques, integration methods, priority given to the qualitative and quantitative strands, and inferences made. Table 3 provides a summary of my findings.
<table>
<thead>
<tr>
<th>Source</th>
<th>Purpose</th>
<th>Sample</th>
<th>Constructs/ Metrics</th>
<th>MM Design</th>
<th>Methods Used</th>
<th>Findings</th>
</tr>
</thead>
</table>
- Participant preferences | QUAN  
Explanatory sequential: Longitudinal! | Quan: Pre- and post-test  
Qual: phone interviews | EIDM knowledge increased immediately after workshop, but not long-term. Participant preferences also changed from post-test to six month follow-up. |
- Learner views  
- Experiences of TBL | Quan + Qual  
Concurrent | Quan: questionnaire  
Qual: interviews | Generally positive findings regarding TBL effectiveness. Only downside to TBL was preparing for class. TBL did not change participant views about teamwork. |
- Attitudes  
- Behaviors | Quan + Qual  
Concurrent | Quan: survey  
Qual: survey, debriefing session | HBH program brought about positive changes on all outcomes. |
- Training needs  
- Perceived | Multi-phase:  
1. Quan + Qual  
2. Quan + Qual  
3. Quan + Qual | Quan: surveys, audit notecards  
Qual: focus group, surveys, audit cards | Multi-phase mixed methods approach allowed authors to validate curriculum content taken from experts and |
<table>
<thead>
<tr>
<th>Teacher, doi:10.3109/0142159X.2013.877126</th>
<th>obstacles and solutions</th>
<th>consensus in the field. Allowed them to identify gaps in training and barriers to development.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audcent, T. A., et al. (2013). Development and evaluation of global child health educational modules. <em>Pediatrics</em>, 132(6), e1570-e1576. Evaluate a 4-module educational program on global child health Residents 3 of Kirkpatrick’s 4-level model: • Reactions • Learning • Behaviors QUAL + quan Concurrent Quan: satisfaction questionnaire, knowledge test Qual: focus groups Both quan and qual data demonstrated high levels of student satisfaction and knowledge gained. Program directors agreed modules were relevant and interesting and could be integrated into existing curriculum.</td>
<td></td>
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<td>MacDonald, C. J., Archibald, D., Baltz, J. M., &amp; Kidder, G. M. (2013). The REDIH experience: An emerging design to develop an effective training program for graduate students in reproductive science. <em>Advances in Medical Education and Practice</em>, 4, 201-216. Evaluate reproductive science educational program Trainees and mentors • Participant reactions QUAL + quan Concurrent Quan: survey Qual: focus groups Both quan and qual findings suggest the program and curricular design is working well.</td>
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| Evaluate a draft of resident milestones from accrediting agency | Faculty/residency directors | Participant reactions | QUAL + quan Concurrent | Quan: survey Qual: focus groups | Milestones were viewed as helpful for assessing residents, but made specific recommendations and identified need for faculty development. |
From this brief review of relevant literature, I derived a short list of best practices that informed my efforts to evaluate and improve how we teach physicians advanced research methods in UC’s CTR program. First, the overwhelming preference for a concurrent design suggests that it serves as the prevailing model in the field at this time. Having worked in graduate medical education for several years, I would suggest there are several reasons for this. First, efficient pragmatism is a driving force in the field, and it is much simpler to collect both quantitative and qualitative data all in one phase. Including a second phase of data collection and analysis not only adds time to the process, but also money and faculty or staff effort. In a fast-paced environment that revolves around clinical rotations, grant cycles, and new research innovations, both the students in these programs and the faculty conducting these studies do not have ample time to complete sequential studies over longer periods. For better or for worse, teaching and educational program administration are not often primary duties of the medical faculty, so studies within this field must be relatively succinct and feasible.

Another potential best practice taken from this literature review is to rely upon well-known methods when conducting mixed methods research in graduate medical education. The authors of these eight studies primarily used quantitative surveys and tests and qualitative surveys, interviews, and focus groups. Both the participant population and the audience of these studies operate in a mostly positivist paradigm, so using methods that are known to that audience and that are recognized as reasonably reliable, valid measures is important when trying to secure support and cooperation. Because of the positivist context in which the research is taking place, this best practice particularly applies to the qualitative methods a researcher chooses. While it is possible that more experimental methods will be tolerated as
mixed methods gains acceptance, and even esteem, in the field, for now, incorporating qualitative methods such as PhotoVoice or found poetry would certainly raise some critical eyebrows among trainees and practitioners working in graduate medical education.

Another potential best practice in the field, which is not well-represented in this literature review, is to consider the possibilities of a longitudinal study. This recommendation potentially works against the first one listed here, which is to adopt a concurrent design when possible, but both can be incorporated into program evaluations that are ongoing and iterative. Only one study in this review attempted a longitudinal design (Yost, Ciliska, & Dobbins, 2014), and the inclusion of longitudinal follow-up data actually changed the authors’ findings. In six month follow-up phone interviews, participants responded differently than they originally had immediately after completing the education program. I think the opportunities provided by longitudinal follow-ups are particularly helpful in program evaluation because effects and perceptions of a program can dramatically change between the time immediately after completion and several months or even years later, after time and experience have tempered participants’ reactions.

**Design**

This is a mixed methods research study with qualitative priority that primarily utilizes a phenomenological research design to explore CTR trainees’ educational needs. The phenomenological approach is useful when it is important to understand a group of individuals’ common experiences around a phenomenon (in this case, their research training) in order to better understand the phenomenon itself. The goal is to develop a composite description of the “essence” of the group’s experiences, and to then improve practices or policies that influence
the phenomenon (Creswell, 2013) This approach has historically been used in the fields of psychology and human sciences but has increasingly gained favor in education and even the health sciences (Creswell, 2013; Moustakas, 1994; van Manen, 1990). In order to be at the forefront of CTR training, I want students’ ideas about how we can best meet their needs to guide future steps. This study was not just part of regular program evaluation; it serves as the groundwork for future innovations in the field.

Recruitment and Sampling

I originally anticipated recruiting approximately 10-20 students, with equal representation by gender and proportional institutional affiliation according to the breakdown of the MS student population. The MS program’s student body is almost equally split by gender, but approximately 65%-75% of our students come from CCHMC, with the remainder primarily coming from UC. In the end, I enrolled 12 students in this study, eight (66%) from CCHMC and four (33%) from UC. Participants were equally split by gender, with six women and six men. All 12 participants were affiliated with different departments and divisions, giving me the broadest range of backgrounds possible, both in terms of organizational culture and medical/research specialization. The MS student population is primarily comprised of clinical fellows, but we do train a small number of junior faculty members. The sample for this study reflected that aspect of the larger student body as well, with two of the 12 participants being assistant professors and the remaining 10 being clinical fellows. Additionally, there was some variation in participants’ status in the program. Two participants were new trainees, only 1-2 semesters into their coursework. Eight were advanced in their studies, with 1-2 semesters left of course/thesis work. The remaining two participants were alumni, having graduated from the
MS in the last 1-2 years. I employed a stratified sampling approach, which worked well; after seven participants responded to my open email invitation, I then followed up with the remaining five to achieve appropriate representation across each stratum.

**Data Collection**

Keeping in mind the best practices described in the review of the literature described above, this study was a sequential mixed methods study, the second phase of which employed an embedded design. I prioritized the qualitative strands, I used qualitative methods that are well-known in the field, and I included a primarily quantitative survey tool. Methods of data collection included document review, a group level assessment (GLA), interviews, student journals, and a survey.

**Phase I: Group Level Assessment and Document Review**

**Phase I: Group Level Assessment**

In October, 2014, I held the first meeting of the study. Eight participants attended: five women and three men, six from CCHMC and two from UC. First, we went over the study plan and consent process. Next, everyone introduced themselves and I explained the GLA procedure. There were 10 large sheets of white paper posted around the room, each with one question written on it. Students were instructed to go around the room and write their answers to each question. If someone else had already written something they agreed with, they made a checkmark next to that comment. The purpose of the group level assessment was to gather broad, group-level data about student expectations and experiences in the MS program. The 10 questions of the GLA were:

1. Why did you enroll in the program?
2. What specific skills did you hope to gain from the MS?

3. What has been the one most positive experience of your training?

4. What has been the one most negative experience?

5. What hurdles did you face at the beginning of the program (applying, getting started)?

6. What hurdles have you faced in getting to graduation?

7. What method of instruction do you feel is most effective (lecture, applied, journal club, team/groupwork, online, etc.)?

8. Name one way the MSCTR program could be improved.

9. If the CTR program were a person, how would you describe its personality?

10. Why would you not recommend this program to others?

Once students had finished writing their answers/checkmarks on the large sheets of white paper (Figure 1), we spent a few minutes reading through what everyone had written. Then, I split the room into two groups, giving each group five sheets of paper. Each group was responsible for reading the questions and answers again, discussing the responses, and distilling 1-3 themes from each sheet of paper. Once this was completed, we came back together as one large group to discuss emerging themes.
The group level assessment is a participatory method that interactively engages participants and uses their expertise to inform the research process (Vaughn, Jacquez, Zhao, & Lang, 2011; Vaughn & Lohmueller, 2014). Vaughn and Lohmueller (1998) describe the purpose of the GLA as “generat[ing] valid data through a process where group members have the opportunity to talk with each other about what occurs in their groups” (p. 100). Reddy (1996) contends “that a group level assessment allows the problem to be defined with the group and from the group’s perspective” (as quoted in Vaughn & Lohmueller, 1998, p. 100). I used the modified GLA process described by Vaughn et al. (2011), which includes seven steps instead of Reddy’s (1996) ten step Group Level Team Assessment. In brief, the seven steps are: 1. Climate setting, 2. Generating ideas, 3. Appreciating responses, 4. Reflecting on the responses, individually, 5. Understanding in subgroups, 6. Selecting data to prioritize, and 7. Considering next action steps as a group (Vaughn et al., 2011).

The GLA method offers several benefits when compared to a more individual assessment. First, because the group is responsible for really generating, organizing, and prioritizing the main ideas, issues or concerns specific to one individual should not receive undue attention (Vaughn & Lohmueller, 1998, 2014) A related benefit is that the facilitator gathers both positive and negative feedback, whereas individuals tend to provide more negative feedback, “in confidence” (Vaughn & Lohmueller, 1998). Although focus groups tend to be the better known and more commonly used group method, the GLA also offers a couple benefits over the focus group. Focus groups sometimes allow one individual or a small group of individuals to dominate and guide the discussion, shutting out the quieter or less opinionated participants (Vaughn & Lohmueller, 2014). In GLA, everyone contributes their ideas on paper.
first, and then reflects on all the responses before working in smaller groups to determine what themes are most prevalent and important and should be prioritized. Focus groups can also be heavily influenced by the researcher/facilitator, but the GLA empowers participants to direct the process, conclusions, and actions steps in a much more interactive way (Vaughn & Lohmueller, 2014).

**Phase I: Document Review**

Applicants to the MS program are required to include a Personal Statement and a statement of Career Goals, both aimed to give the Admissions Committee a better idea of why the applicant is pursuing a graduate degree in clinical research and to ascertain what the applicant’s expectations are, in terms of his or her educational experiences and professional objectives. The purpose of these documents is to ensure the program is a good match for the student and that the student’s expectations fall within the range of the program’s outcomes. These statements tend to be one paragraph to two pages long, and they provide an initial picture of each applicant, before he or she begins the program.

In terms of this study, these documents were a rich source of data written in the student’s own words. Although the topics they addressed were highly relevant to this study, students had written them without any prior knowledge of the study or its goals, lending their statements purity from bias or intention to deliver a message they think is expected of them. After the GLA, I also obtained signed consent forms from the remaining four participants who could not attend. Then, I pulled each participant’s graduate application to the CTR program from his or her file and reviewed it for potential information on educational goals, motivations, and
expectations. Trainees’ stated aims prior to starting the program provided insight into relevant questions for the interviews and journal prompts (Phase II).

Document review is a valuable method within qualitative research because it can provide unique knowledge of the history and context of a phenomenon, without actually disturbing the setting (Marshall & Rossman, 2006). As Creswell (2012) notes, documents “provide the advantage of being in the language and words of the participants, who have usually given thoughtful attention to them. They are also ready for analysis without . . . transcription” (p. 223). Negative aspects include needing to travel to obtain them (or lack of access at all), accuracy, and completeness of documents. Many of the usual limitations of document review did not apply in my case. I had very easy access to the documents, and they were complete. One potential issue was the accuracy of the students’ statements. Although applicants did not write the statements for the purposes of this study, they did write them with the goal of gaining admission to the MS program. Many of them are fully aware of the program’s stated outcomes, so it is possible they tailored their statements to align with what they think the Admissions Committee wanted to read.

**Phase II: Interviews, Journal Submissions, and Survey**

**Phase II: Interviews**

Using the themes identified in Phase I, I then developed a series of flexible interview questions and journal prompts. When designing these questions, I had three primary goals in mind:

1. Follow up on themes that emerged at the GLA for further clarification.
2. Consider research questions not yet addressed in Phase I.
3. Allow space for new thematic developments not yet discovered.

At the start of each interview, I reminded each participant about the purpose of the study and the themes that arose in Phase I, both from the GLA and my own analysis of their application documents. Interview questions ranged in focus from students’ barriers to starting the program, experiences in their coursework thus far, thoughts about the MS curriculum and faculty, mentorship, and feedback about the MS program’s methods of instruction. See Appendix B for the full interview guide.

Between mid-November and mid-December, 2014, I conducted one-on-one interviews with all 12 participants. Interviews ranged in length from approximately 24 minutes to approximately one hour and seven minutes. Eleven of the 12 interviews were conducted in-person, either in the Rainbow Café in the S building of Cincinnati Children’s Hospital Medical Center, in a conference in the Kettering Labs Complex at the University of Cincinnati, or in participants’ offices. One interview was conducted over the phone because the participant had recently moved to Albuquerque, New Mexico. All 12 participants received a $50 Amazon gift card for their time spent being interviewed. All interviews were recorded using the Audio Memos application on an Apple iPad. I then transcribed all 12 interviews between December, 2014 and late January, 2015.

Interviews are one of the most well-known and accepted methods of qualitative data collection. I used the responsive interviewing technique described by Rubin and Rubin (2012), which emphasizes the conversational, relational aspects of an interview. Responsive interviewing takes on a friendly, supportive tone without confrontation, and the interviewee is treated as a partner in the process, rather than a subject. Because of this, the questions were
flexible, and the interviewee’s answers could change the path of the interview (Rubin & Rubin, 2012). Rubin and Rubin (2012) describe five key characteristics of high quality, naturalistic interviews: fresh and real, balanced, thorough, credible, rich and nuanced. Interviews do have some limitations, though. They can be very time-consuming, and as a result, costly to the research project (Creswell, 2012). Prosser (2013) also notes that verbal interviews often have rather “narrow parameters of responses” and they “favor the articulate,” meaning interviewees who are better able to verbally articulate their thoughts and experiences will be better captured by the interview method (p. 195).

Phase II: Student Journal Submissions

Between late November, 2014 and mid-January, 2015, I also collected four written journal responses from 11 of 12 participants. I gave an approximate guideline of one page per journal entry, but stated that students should write as little or as much as they felt necessary for each particular prompt. I sent out journal prompts once a week via email with the general (but admittedly flexible) request that participants respond by the end of that week. Most participants followed this timeline, but others took their time and submitted journal entries irregularly or in batches. All participants submitted their journals via email. Three of the four journals were guided, i.e., I provided students with a writing prompt. One week was open. See Appendix C for each journal prompt.

Student journals are excellent sources of qualitative data for a number of reasons. First, compared to in-person interviews and GLAs, written journals give participants (especially those who may not be as verbally expressive or eloquent) time to think about and compose their responses more carefully, allowing them to state more clearly and accurately what they wish to
communicate about their experiences. Journals also come in written form, saving the researcher the time-intensive work of transcription. The process of student journals can also be flexible; as the researcher receives and begins to analyze early journal submissions, the prompts for future weeks can be adjusted, if necessary, to address any interesting themes that unexpectedly arise. James, Milenkiewicz, and Bucknam (2008) note that “the degree of insight that [student journals] offer is directly tied to frequency and quantity of the writing. For instance, a single entry in a student journal might not be as indicative of an overall theme as entries where one or several students mention the theme regularly” (p. 74). The four weeks of journals generated valuable insight that I could not have acquired from just one GLA or individual interview.

**Phase II: Survey**

Finally, I administered a mostly quantitative survey that attempted to measure students’ satisfaction with major aspects of the program. The survey collected current demographic data, asked Likert-scaled questions related to how well the students felt the MS program was meeting stated educational outcomes, asked students to assess the value of specific courses (both required and elective), and asked students to rate their level of satisfaction as far as variety of courses, availability of courses in their fields of interest, quality of teaching, level of intellectual rigor, and number of requirements. Surveys were administered using REDCap, an online and secure data collection and storage system sponsored by the CCTST.

Surveys conducted online are fast and efficient forms of data collection (Creswell, 2012). They are relatively simple to create and track using online tools, such as REDCap, and data can often be quickly exported and analyzed. They are also fast and accessible for participants, many
of whom spend hours online and are comfortable using web-based applications. Many of the limitations that Creswell (2012) highlights about survey research were not issues for me. For example, I did not have a low response rate problem because students had volunteered to participate. I was also able to send the survey out to additional students and recent alumni, whose email addresses I had readily available. Security issues, technological problems, and changes to email addresses, all problems cited by Creswell (2012), were not major factors in my research. Surveys are limited in terms of generating thick descriptions of phenomena, though, so quantitative results from the survey primarily served as supplementary data to the qualitative strand.

**Data Analysis**

Data collection in qualitative research should be reflective and involve immersion, disclosure, and authenticity. Throughout the data analysis, I maintained a researcher’s notebook disclosing my points of view and/or biases as they related to my interpretation of student responses. All data was included in the analysis, whether participants completed all portions of the study or not. For example, one student only participated in the interview, but not the GLA, journals, or quantitative survey; I still included his interview data in my analysis and results.

**Modified Seven Stage Hermeneutic Analysis (Diekelmann et al., 1989)**

Using the seven stage process described by Nancy L. Diekelmann and David G. Allen in Diekelmann et al. (1989) as a foundation, I made some modifications to better fit the goals and context of my particular research project. This structured analysis guides the researcher to develop categories into themes into patterns (Figure 4).
Before beginning analysis, I first checked all application materials, transcripts, and journals for completeness and accuracy. Then, Table 4 provides details of the seven stage hermeneutic data analysis process in its original form, along with the modifications I found necessary.

**Table 4: Modifications made to Seven Stage Hermeneutic Analysis (Diekelmann et al., 1989)**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Original Process</th>
<th>My Modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 – Immersion</td>
<td>The research team reads through all documents to obtain an overall understanding.</td>
<td>None.</td>
</tr>
<tr>
<td>2 – Identification of Categories</td>
<td>Each team member summarizes sections of the documents and identifies categories. Members meet to discuss their interpretations, provide evidence from the text, clarify categories, and reach consensus.</td>
<td>I was the sole researcher.</td>
</tr>
<tr>
<td>3 – Refinement of Categories</td>
<td>Members of the research team revisit the documents for more independent analysis and further clarification of any discrepancies in the group’s interpretation.</td>
<td>I was the sole researcher.</td>
</tr>
<tr>
<td>4 – Identification</td>
<td>The research team works to collapse refined categories into relational themes (a relational</td>
<td>I was the sole researcher.</td>
</tr>
</tbody>
</table>
of Themes

The research team revisits the documents to look for meanings that support or contradict the themes.

5 – Patterns Emerge

The research team interprets the data further, and constitutive patterns emerge. Patterns express the relationships of the relational themes and are the highest level of hermeneutical analysis.

6 – Consult with Peers to Validate Conclusions

The principle investigator allows the research team and outside researchers (familiar with the context and method) to review the entire analysis for validation.

7 – Final Report

The research team prepares its final report of the project and includes excerpts to support conclusions.

I was the sole researcher.

I was the sole researcher, and I shared my findings with all participants, my peer advising group, and my manager for their validation of my conclusions.

I was the sole researcher.

I include more specific details about my data analysis process in Chapter 4: Findings/Results.

Analysis was ongoing from the start of data collection to completion of the project. After data collection and analysis, I incorporated member checking by sharing the identified themes and categories with my manager and my peer advising group, as well as with participants in the study via email for their confirmation or revision.

Payment for Participation

All participants were invited to participate in all aspects of the study (document review, GLAs, interviews, journals, and survey). Participants were offered a total of $200 for their participation: $50 after the GLA, $50 after their individual interview, and $100 upon submission of their final journal. There was no incentive payment for completion of the brief survey.

Credibility

This study employed multiple techniques to ensure credibility of results. First, it employed well-established methods of data collection and data analysis (Lincoln & Guba, 1985;
Shenton, 2004). All five data collection techniques in this study are well-known methods and are supported by the literature. Additionally, triangulation across a variety of data collection tools also supports credibility of the study findings (Brewer & Hunter, 1989; Guba, 1995; Lincoln & Guba, 1985). In this case, using five different methods of data collection across two phases of the study suggests strong credibility. The primary focus was on the qualitative strand, with the survey results serving as corroboration. In addition to methods, familiarity with the culture of participants can also ensure credibility (Lincoln & Guba, 1985; Shenton, 2004). While most methodologists recommend researchers spend prolonged periods of time with the groups or individuals under study in order to better understand them and to gain their trust, in this study, I was fortunate to have worked with the study population for over seven years, enjoying friendly professional relationships with individuals in the group and benefitting from a deep understanding of the group’s culture. Additionally, I encouraged participants to be candid and honest in their observations, free from fear of consequences or exposure for any negative comments, which contributes to informant honesty (Shenton, 2004). And finally, I employed member checking in three different ways (key stakeholder, peer researchers, and participant review) to help establish credibility (Lincoln & Guba, 1985).

Conclusion

Innovation is a key area of emphasis in the second generation of CTSA programs, particularly with regard to education ("The CTSA Program at NIH: Opportunities for Advancing Clinical and Translational Research. Committee to Review the Clinical and Translational Science Awards Program at the National Center for Advancing Translational Sciences," 2013). This study will lead the charge to innovate in several ways. First, qualitative studies are not the norm in a
clinical research context. Leaders and faculty in the field have a thorough understanding of the knowledge and skills that training programs such as UC’s CTR degree need to impart to young scholars. However, no one has invited the trainees themselves to help define the future areas of training improvement within their programs. This study identified training issues that prevent some of our graduates from reaching their full potential, providing direction for educational interventions and a curricular redesign, both of which could transform the paradigm that currently informs many clinical research training programs at CTSA institutions across the country.
Chapter 4: Findings/Results

This chapter is organized by Phase I and Phase II findings. Presentation of Phase II findings follows the seven stage analysis process, first with a brief overview of the themes and patterns, followed by a more detailed exploration of each pattern with themes, including supporting quotations.

Phase I: Group Level Assessment and Document Review

Phase I: Group Level Assessment

The purpose of the group level assessment was to gather broad, group-level data about student expectations and experiences in the MS program. It was a unique opportunity for students to both generate their own data, and then analyze it, all in one session. A summary of the large-scale themes the group identified is found in Table 5.

Table 5: Themes from the Group Level Assessment

<table>
<thead>
<tr>
<th>Question</th>
<th>Themes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Why did you enroll in the program?</td>
<td>Fellowship Requirements</td>
</tr>
<tr>
<td></td>
<td>Research Skills</td>
</tr>
<tr>
<td>2. What specific skills did you hope to gain from the MS?</td>
<td>Study Design/Analysis/Implementation Collaboration</td>
</tr>
<tr>
<td>3. What has been the one most positive experience of your training?</td>
<td>Publication &amp; Proposal Completed Basic Research Skills</td>
</tr>
<tr>
<td>4. What has been the one most negative experience?</td>
<td>Required Classes aren’t that Helpful</td>
</tr>
<tr>
<td>5. What hurdles did you face at the beginning of the program (applying, getting started)?</td>
<td>No Hurdles</td>
</tr>
<tr>
<td>6. What hurdles have you faced in getting to graduation?</td>
<td>Balancing Clinical Responsibilities</td>
</tr>
<tr>
<td>7. What method of instruction do you feel is most effective (lecture, applied, journal club, team/groupwork, online, etc.)?</td>
<td>Interactive and Participatory</td>
</tr>
<tr>
<td>8. Name one way the MSCTR program could be improved.</td>
<td>More Physician-Oriented Classes (Especially Statistics) Offer More Classes More Often</td>
</tr>
<tr>
<td>9.</td>
<td>If the CTR program were a person, how would you describe its personality?</td>
</tr>
<tr>
<td>----</td>
<td>---------------------------------------------------------------------</td>
</tr>
<tr>
<td>10.</td>
<td>Why would you not recommend this program to others?</td>
</tr>
</tbody>
</table>

After the two groups reported their themes from each of the 10 questions, the group discussed all of the issues as a whole and established three major themes:

1) Students wanted more physician-specific courses, especially in statistics. Participants felt that the professors who taught statistics taught too much from a statistician’s perspective, i.e., they focused too heavily on the theory and formulae behind statistical concepts rather than the application of these concepts. If the MS could offer more classes that are specifically geared towards the physician-scientist audience, the content and instructional methods would be more appropriate for students training to be principle investigators.

2) Students wanted a more directed curriculum. While participants appreciated the flexibility of the current core curriculum, they also would appreciate more direction when choosing their “selective” classes. A selective class is one class students choose to take from a list of options. For example, to fulfill their “advanced biostatistics” requirement, students can select one class from a list of four classes. GLA participants noted that although they did know some of the gaps in their own knowledge base, they were still early in their research careers and they “did not know what we did not know.” Most come from medical school backgrounds where their coursework was dictated to them, and at this stage of their education, they wanted the core curriculum to be clearly and simply spelled out.

3) Unity and cohesion throughout the MS training was a problem – the classes often felt disconnected from each other.
Participants expressed a desire for a series of courses that are better connected to each other, or that flow together more seamlessly. At the time of the study, the core curriculum worked as a series of nine classes that operated independently of each other, although there was somewhat of a built-in sequence enforced by prerequisites. Students would have liked to take courses in a sequence that better reinforced and built upon prior learning.

The discussion at the GLA was very positive, overall, but the three problematic themes above surfaced in a variety of ways as participants discussed the 10 questions. For example, in the discussion of question 9, “If the CTR program were a person, how would you describe its personality?” participants initially focused on the positive traits they associated with the MS program: the flexibility of its faculty, staff, and curriculum, the friendliness of the people involved, and its openness to most qualified applicants. However, participants then commented on the negative sides of these characteristics, such as being perhaps too flexible in the curriculum and not giving enough guidance on the specific courses students should complete. Throughout the GLA, there were many moments where the group would be discussing some positive aspect of the MS, but then someone would clarify that the statistics courses were the exception, e.g., “I feel like the professors would try really hard to use clinical examples in class to make it relevant to my research . . . except in the Intro to Biostats course, where all he would talk about was rolling a die.”

**Phase I: Document Review**

After the GLA, I analyzed all 12 participants’ application documents using a modified version of the hermeneutic analysis described by Diekelmann et al. (1989) (see Chapter 3 for details).
From this analysis, I found five consistent patterns related to the reasons participants sought to improve and expand their research skills through the MS program:

1) **Personal experiences had intensified their interest in research.**

Many students had had powerful personal experiences with their patients that made them want to pursue research training. As one pediatric oncologist described,

> Even though the battle of cancer is unique and personal to each patient, cancer is not one child. This disease is pernicious; it invades every possible organ system, it invades families, communities, and nations . . . Unless I, as a physician, have the tools to interpret data, discover new connections, take risks and ultimately see the much bigger picture, I am not really doing my job.

2) **They wanted to improve their care for patients in the clinic.**

Students in the MSCTR program maintained deep connections to the patients they care for in their roles as clinicians: “Thus, I am applying to obtain a Master of Science in Clinical andTranslational Research . . . to ultimately impact the lives of the critically ill children I treat on a daily basis.”

3) **They wanted to better mentor and/or teach others in their divisions and/or fellowships.**

This was perhaps one of the more surprising themes, given that the MSCTR does not currently attempt to develop students’ own mentorship and teaching skills. As one participant said in his application materials, after completing the MSCTR, he aimed to “educate younger generations to follow in the gratifying footsteps of innovation and progress.”

4) **They wanted to collaborate more effectively with their colleagues.**

Clinical research is inherently team-oriented, and these participants often described a desire to improve their abilities to collaborate with colleagues on research projects: “I also hope that I can be a benefit to my colleagues in clinic with this new skill set . . . I would like to be able to
help [my colleagues] pursue research and improvement projects within our clinic, patient
population and community.”

5) They wanted to further their own professional goals.

Students brought their own professional goals to their MS training as well, stating, “ . . . I
believe the [MSCTR] can begin to provide the foundation for my pursuit of a career as an
independent investigator in translational research,” and, “After using the literature to make
clinical decisions, I now want to have some of my own publications.”

**Phase II: Interviews, Journal Submissions, and Survey**

Using the results from Phase I, I then designed questions for the interviews and journal
submissions in Phase II. As I mentioned in Chapter 3, when designing these questions, I had
three primary goals in mind:

1. Follow up on themes that emerged at the GLA for further clarification.

2. Consider research questions not yet addressed in Phase I.

3. Allow space for new thematic developments not yet discovered.

**Phase II Qualitative Results:**

Working with 120 pages of text data from the interviews and journal submissions was a
challenge at first. However, using the modified hermeneutic analysis process described in
Chapter 3, I was able to incrementally make sense of the data. First, after second-level coding, I
organized the information into relatively indistinct categories. With these in mind, I revisited
the data and refined the categories into relational themes. Finally, I connected the themes and
constructed patterns from them. Although I analyzed all of the textual (interview and journal)
data using the same method, I initially organized their categories and themes separately.
Journal prompts were often about very specific aspects of the program, whereas interview conversations covered a wide variety of topics. Because of this, it was most useful to me to consider the journal submissions separately from the interviews at first, when I was just beginning to construct categories. It wasn’t until I had a sense of the themes from both sets of data that I could then connect them across methods and merge them into overall patterns.

**Categories**

I included two key processes in the first step of data analysis, immersion. First, I considered the interview transcription an early part of the immersion process, since I spent many hours listening to audio and typing words into text, familiarizing myself with the data again. Next, I simply read all of the materials through and used a yellow highlighter for line-by-line coding. In coding, I marked passages of text that seemed important and worth revisiting. Sometimes these early highlights would be several words or a sentence, but just as often, they were an entire paragraph.

After immersing myself in the Phase II data, I moved on to step two of the seven step process described by Diekelmann et al. (1989): summarizing sections of the text for the purpose of identifying categories. Using hand-written notes in the margins of participant interview transcripts and journal submissions, I began with close to 100 original categories, including intro classes, audio quality, flexibility, physician study groups, and scheduling. Some of these, if they were copiously noted, would go on to become their own themes, but others would be wrapped into larger themes that captured similar categories.

**Themes**
Once I noted the categories based on my first line-by-line coding, I moved to steps three and four, which entailed revisiting and analyzing the data based on the categories previously identified, and further refining those categories to develop relational themes. After almost two months of data immersion and early analysis, the major themes emerging from the categories were relatively clear. Details on individual themes are provided in Table 6.

Patterns

Step five was probably the most exciting step in the data analysis process, because finally, I was at a point where I could make sense of some high-level patterns. This is also the step where I combined both the interview and the journal data into one set. After reading the transcripts and journal submissions multiple times, I was prepared to move the themes into their next stage, patterns. With the patterns I had in mind, I began coding the themes (written in the margins of my hard copy data) with different colored highlighters to signify possible patterns. The actual names for some of the patterns eluded me at first, but others were obvious. In an effort to properly characterize the patterns that were at first difficult to label, I revisited the data and identified quotations that best represented what I felt the participants were describing. Two unusual issues also emerged that did not exactly fit into any of the four major patterns, so these were grouped into a fifth, “ancillary” pattern. The two ideas under this fifth pattern are loosely tied together as students’ reflections on their research and training experiences. Step six of the analysis process entails member checking, which I detail more below. In brief, I discussed my early interpretations with the MS program’s faculty director, a peer advising group, and study participants themselves, incorporating their input into my later analysis. The final patterns upon which I settled are provided in Table 6.
### Table 6: Phase II Patterns and Themes

<table>
<thead>
<tr>
<th>Pattern</th>
<th>Themes in this Pattern</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Curriculum</strong></td>
<td>Participants appreciate the flexibility of the curriculum.</td>
</tr>
<tr>
<td></td>
<td>Participants want a stronger sequence of core courses.</td>
</tr>
<tr>
<td></td>
<td>Participants want better, more in-depth statistical instruction.</td>
</tr>
<tr>
<td></td>
<td>Participants want more integration of biostatistics and epidemiology/study design in their coursework.</td>
</tr>
<tr>
<td></td>
<td>The CR Scholars Seminar and Design &amp; Management of Field Studies are the two classes that have the biggest positive impact. Both could benefit from expansion.</td>
</tr>
<tr>
<td></td>
<td>Participants want a journal club-type class that critiques articles.</td>
</tr>
<tr>
<td></td>
<td>Participants find the Introduction to SAS Programming class frustrating and not beneficial. They instead want a programming class that gives a broad overview of multiple software programs.</td>
</tr>
<tr>
<td><strong>Mentorship/Relationships</strong></td>
<td>Although most participants have strong mentorship through their home departments/divisions, most think additional mentorship coordinated by the MS program would be welcome and helpful.</td>
</tr>
<tr>
<td></td>
<td>The earlier students can be connected with a mentor, the better.</td>
</tr>
<tr>
<td></td>
<td>Participants highly value other types of relationships nurtured by the MS program: faculty members, research collaborators, and other students.</td>
</tr>
<tr>
<td><strong>Program Structure and Organization</strong></td>
<td>Fitting classes in around their clinical schedules is a major challenge for all participants. Courses that are offered rarely (every other year, or even just once a year) make it very difficult to take classes in which they’re interested.</td>
</tr>
<tr>
<td></td>
<td>All participants spoke very highly of the MS program administrators and emphasized how critical they are to the program’s continued success.</td>
</tr>
<tr>
<td></td>
<td>Participants want more individualized academic advising, more frequently.</td>
</tr>
<tr>
<td><strong>Instructional Methods</strong></td>
<td>Participants want more physician-centered coursework.</td>
</tr>
</tbody>
</table>
The seventh and final stage of the hermeneutical analysis described by Diekelmann et al. (1989) entails writing a final report and providing sufficient excerpts to demonstrate the validity of findings. This next section is organized according to the five patterns: curriculum, mentorship, program structure and organization, instructional methods, and ancillary student perspectives on MSCTR experiences.

**Pattern 1 – Curriculum**

The curriculum pattern was the most discussed at the GLA, in the interviews, and in the journal submissions. This pattern encompasses the most themes, and it provides the biggest opportunity to greatly improve the MS training program. The curriculum pattern includes both broad themes related to the organization of the curriculum and more specific themes related to content and particular courses.

Flexibility was a key theme under the curriculum pattern; although all MS students are required to take specific core classes, there is flexibility built into both the MS core and its electives. Participants greatly appreciated this, saying things like, “I really appreciated the
flexibility of the coursework, the ability to recognize that we do work that can count towards these credits outside of being in a classroom” and, “the thing I like most about the MS program is the flexibility.” Although flexibility was key, in Phase II, participants described wanting a stronger sequence of core courses. As one participant put it, “I value flexibility because of the job. But to be honest, it would be nice to have sequential classes so that you have to take them one right after the other, so that one class reinforces the next.” In a similar vein, one participant, when asked about the most positive aspects of his training so far, responded,

This is sort of a cop out, but I think for me it was just the structured curriculum. You know what I mean? Because I feel like I needed help and when I started this, you probably know more about this than I do - theories of adult learning and how we have a framework and adults put things in whereas kids start with zero and you build up, adults come with a framework. So I think the biggest thing that this gave me was okay, let’s start from the beginning: statistics one, epi one, research design one and this reinforced that framework so I feel like that’s what I really got out of it. I am a big believer in the importance of learning the fundamentals and I think a lot of physicians and especially emergency physicians want to jump to the finish line. And that’s what had happened - I’ve been pushed to the finish line: do this project, and a couple years later I’m like I don’t know what the hell I’m doing.

Participants wanted better, more in-depth statistical instruction. Statistics classes came up frequently in interviews and in the participant journals. Although a few participants had very positive experiences in their statistics classes, most thought the statistics curriculum needed work. When asked if the coursework had addressed the skills and knowledge she wanted to obtain from the MS, one participant said,

I think yes, but on a very basic level. I feel like was all very sort of skimming the surface of it. So I have a better understanding of statistics and study design and things like that, but I think it’s still very on a superficial level. I would [like more depth]. I just expected it to be a little more challenging. I didn’t feel challenged through the whole thing and would have liked it to be a little tougher and more detailed.
In the GLA from Phase I, participants concluded that unity across the curriculum was a problem. This was the only theme from Phase I that was not supported by Phase II follow-up collection and analysis. When asked about cohesion in the curriculum, individual participants reported, “No, I thought it went pretty smooth. Taking Biostats before Regression, taking SAS before Study Design & Analysis, taking Epi before Design & Management. It was fairly cohesive as far as I was concerned.” Or, “I think it’s not as bad as – it’s not a big problem, to be honest . . . There are requirements and prerequisites, so you do end up doing one thing before the other.” However, the cohesion issue did manifest itself in another, more subtle way related to improving the integration of different aspects of the curriculum at the course level. Many participants talked about how they want more integration of biostatistics and epidemiology/study design in their coursework. Quotations ranged from, “I think you also need more integrated classes – not just stats, not just epi, but something that combines all of them. Because once you take the basics, you need to integrate it” to,

Design a study without the stats stuff, and you still have to figure out a sample size, have to figure out statistical testing that’s appropriate and when you’re writing your grant, it’s not one without the other. I think that’s also another fallacy and the way we’re taught it – the design and the stats are not combined, but you have to apply them together.

One student touched on this issue by mentioning the need for an advanced class that pulls all the previous learning in other classes together:

I think that one [class] could maybe be required because that’s one thing I didn’t get – I got the pieces, but I didn’t get the whole thing put together. Because, like, you’re going to do a research project, here’s how you start, you know, how you ask your question all the way through to data collection and forms to collect . . . Having a capstone, like putting it all together at the end, if you took that and broke it all down into what you needed and what you’ve already done here, the epi, the introduction to stats, programming, and QI, then kind of putting it all together . . . You get parts and pieces here and there, and then you’re kind of on
your own to put it all together and I think most people can do that, but it would be nice to reinforce that.

Themes related to the actual content provided in specific courses were both positive and negative. On the positive side, the Clinical Research Scholars Seminar and Design & Management of Field Studies were the two classes that had the biggest positive impact. Participants thought both could benefit from expansion. As one participant said,

The Design & Management class was by far the best class I had. You know, we wrote a grant, there was a lot of people that came in that gave guest lectures that were very helpful. . . . we got timely feedback on our writing, we learned how to give each other feedback on our writing, and I feel like more interactive classes like that, and even in the CR Scholars Seminar, we’d do that – we’d pass around our abstracts and critique each other, and I feel like that’s real life, that’s what you do, you critique each other’s, you might critique an article for a journal, that’s the stuff we’ll really be doing.

Another stated, “One [of the most positive experiences in the MS program] would be the Design & Management of Field Studies course. That put me really on the right track with developing my thesis and overall, then my manuscript. It was very well paced within the class so I could get everything developed.”

One potential new course that many participants stated they would appreciate is a journal club-type class that critiques articles. One participant from pediatric cardiology said . . . to look specifically at people in pediatrics and looking at articles from their fields and breaking those down in terms of what the study design was, what the results were, ultimately what the findings are and how do you interpret that . . . at this point in my career, what I really need to do is sit down, read an article, and see what they did, what they found, and interpret their results and decide if it’s a good or a bad study . . . And to be able to do it quickly. To learn tips from people who have done this a lot, like this is a quick way to get what you need from an article.
And another participant echoed this, saying, “Just like a one hour class where you meet, read a journal article, and you go through it and pick it apart. You do five or eight of those. That would definitely nail some of those skills home.”

One major negative that almost all participants commented on was the Introduction to SAS Programming class, which falls within the core curriculum. Participants found this class frustrating and not beneficial. They instead wanted a programming class that gave a broad overview of multiple software programs. Participants were very quick to express gratitude to the instructors of the class, who were well-liked and appreciated. But the course itself did not meet student needs, and participants were blunt about this fact:

SAS was hands-down the worst class. *laughs* I’m sure I’m not the only one to say that. It was incredibly difficult, incredibly time-consuming, and I didn’t feel like I understood what was going on . . . I think you probably do need a programming course, but I don’t know if a programming course should be an overview of here’s what R is, here’s what SAS is, here’s how they’re different, here’s how they’re the same. Kind of just so you know what’s out there, because I feel like after this class, I still didn’t know how to use SAS and then I had to do my own statistics. And you know Rao uses R, Jun, uses SAS. Personally, I use SPSS because it’s very easy to use. So I think maybe a class that compares and contrasts those and gives you a very basic introduction to what they look like and how to use them might be better. Because I think a lot of us aren’t going to be doing our own stats, in the long run. And so it kind of was a little bit of a waste of time. You need at least an introduction to programming because then you can appreciate it. Otherwise, I had no idea how you take raw data and analyze it so I think that’s really important, but maybe a different approach.

Another participant, when I specifically asked her about Introduction to SAS Programming laughed before saying,

I don’t know what to say about that . . . I will never do it in my life, and I feel like it’s a hard thing so I don’t even know what to say about it. I didn’t understand one word that they said the whole time that we were in that class, I was like, they’re speaking French. And I got all the work done, but only because I would stay after class and they would help me write it.
And finally, a different participant also did not have a positive experience in the course: “Um, I think SAS was not . . . it was another like hoop I jumped through that I never really used it again, and the other classes use R. The basics of programming was not useful really.”

**Pattern 2 – Mentorship/Relationships**

Although most participants had strong mentorship through their home departments/divisions, most thought additional mentorship coordinated by the MS program would be welcome and helpful. One participant said if the MS could, . . . have a system where there should be regular meetings between mentor and mentee. I just feel like I could have benefited from a relationship a lot more and I think I didn’t go seeking it because I do have it in my fellowship program but I think it would have been a great addition to have it in the MS program as well . . . you leave it up to us and I think when you’re just starting the program, you don’t know – it’s better to just be assigned to somebody.

In a journal entry related to the creation of a course on professional, career topics, another participant wrote,

An alternative to having classes regarding some of these topics [related to a career planning course] would be providing mentors as part of the program – they would be able to help guide us in our career-planning and search for funding . . . actually this would be a great opportunity regardless of whether there are dedicated classes or not – definitely like the idea of mentors! Any and all guidance welcome!

Demonstrating the huge negative impact poor mentorship can have on a young researcher, one participant wrote, “The lack of strong mentorship throughout fellowship training has made me question the academic model [of research].”

Many participants commented that the earlier students can be connected with a mentor, the better. As one participant summarized, If there could be an option to [meet with a mentor], have a 1 credit thing to have a second mentor just to go over things and get feedback . . . That might be
helpful getting started . . . I feel like it would be an advantage to have [mentorship] early on. Because you don’t realize that early on. You realize it later, that oh, I could have used more help. Or other than getting six rejections, I could have talked to someone, I would have known what the medicine side thinks compared to the rheumatology side.

And another student, from a different institution and field echoed this idea in one of her journal reflections:

Mentorship is key to a successful research career. I feel that in my training I have not had great mentorship and it has resulted in less success . . . I feel that if I had better mentorship, someone at the beginning would have said – hey, start with one retrospective study (guaranteed, publishable, and can be finished in 1-2 years) and then work on a prospective study that will be pilot data for a bigger project that you want to do after fellowship. In addition do a review article and a case report. I think I would be in a much better place now if someone had given me that advice . . . If there would have been a mentor in the master’s program that could have steered me differently it would have been helpful. I think it is a role that needs to be assigned and started early though because as mentee, we don’t always know that we should be asking these questions in the beginning.

Aside from wanting more assigned, formal mentorship, participants highly valued other types of relationships nurtured by the MS program: faculty members, research collaborators, and other students. When discussing some of the positive impacts the MS has had on her research career, one participant concluded, “I guess that’s part of it – having access to those people [epidemiology and biostatistics faculty members]. I don’t know if I would have known about them or if it’s just harder, I don’t know . . . the one on one stats training was really great.”

And another participant, when asked what advice she would give to a new trainee, said “Get involved with the program – get to know the people and identify a mentor early. The unique thing about mentors from the program is that they will have your best interest at heart and they will be a good compliment to the mentorship from your fellowship/division . . .”
Pattern 3 – Program Structure and Organization

Fitting classes around their clinical schedules was a major challenge for all participants. Courses that were offered rarely (every other year, or even just once a year) made it very difficult for students to take classes in which they were interested. As one student said, “I think the biggest barrier for me has been finding time to get away from clinical work. Because even though they say we have more research time, we take a lot of call and still have a lot of expectations as far as our clinical stuff, so it’s just trying to find a good balance. It was a bit challenging.” And another participant expressed disappointment with not being able to take the courses about which she was so excited:

I couldn’t wait to take courses including the genetics of complex disease, molecular epi, molecular and cell biology, the biology of cancer and human genetics. By no fault of the masters, but more by being a clinician while obtaining a degree, I did not get to take any of those courses. The courses were offered at times that either conflicted with other classes or were many days a week that would interfere with my clinical duties.

One participant commented in her journal that, “Courses that are only offered every other year can get frustrating,” and another said,

I mean, I don’t remember specific details but I do remember a couple times that classes were interesting but they were offered every other year or met at bad times, so while they sounded good, I just wasn’t able to take them because of when they were offered.

On the positive side, all participants spoke very highly of the MS program administrators and emphasized how critical they were to the program’s continued success. One participant liked how actively program faculty and staff worked to improve students’ educational experiences:

It was constantly clear to us that this was a relatively novel thing that – there was a constant search for improvement. It’s a very fluid program and it was
always clear that everyone’s pushing for feedback, wanting to know whether it was, from all aspects, from the top down, everyone was always trying to make it better.

Another participant laughingly admitted: “Yeah, [the advising and administration of the MS] is obviously one of the best things. And I wouldn’t have known anything if you guys wouldn’t have told us.” Participants also appreciated the flexibility of program administrators. When asked about one of her most positive experiences in the MS thus far, one participant stated, “definitely how flexible you are – you were able to accept some of my credits that I had done before, and with my move, you guys have helped support and guide me so I can finish. That’s a really, really big asset, as far as I’m concerned.”

Another area of possible improvement in terms of program administration was academic advising. Basically, participants wanted more individualized academic advising, more frequently. One student commented, “. . . we should probably meet with you or Erin once a month or something. I think that’s not a bad idea.” Another had a different idea about how to advise students more regularly:

I do think that without a strong program director, the details and scheduling process would be overwhelming for some people. I would suggest a group meeting once at the start of every semester and once at the end. This way large things could be conveyed to the group like how to physically enroll in classes, if any basic requirements had changed (like during the transition from quarters to semesters), thesis requirements, etc. Then each person, if time allowed, should schedule a meeting with the program director every semester to make sure they were staying on track, getting credits completed appropriately, and planning for graduation. One area of improvement in regards to advisement of course scheduling would be to attempt to suggest courses based on each participant’s needs.
Pattern 4 – Instructional Methods

Another area ripe for innovation concerned the program’s methods of instruction. The themes in this pattern suggested that the faculty and administrators of MS program should reevaluate current teaching methods to better meet the needs of this specific student audience. To start, participants wanted more physician-centered coursework. This was one of the primary themes from the GLA, and I regretted not exploring it further, explicitly, in the interviews and journals. This conclusion from the GLA was decisive and, although it did come up several times in the interviews, it was usually tangential to another topic under discussion. As one student stated in her interview,

I think having some of the physician only classes would be helpful. I mean, because we got, even in the Design [and Management of Field Studies] class, when everyone’s talking about their grants, the medical ones were so different from the others that having them separate might be helpful. They’re totally different.

Another admitted, “I think I would agree with others who have said that more clinically focused would be preferred. Just because that’s the way we think and if we had classes that were more specialty focused, that would be especially helpful.” Another example is the student who, when discussing the need for more specialized, physician-centered classes, said,

. . . at this point in my career, what I really need to do is sit down, read an article, and see what they did, what they found, and interpret their results and decide if it’s a good study or a bad study. I think as you get to become an adult learner (laughs), I have to do stuff that’s more relevant and directed towards what I do, just because learning just overall general stuff isn’t as helpful to me anymore.

In a somewhat related theme, participants also wanted more applied statistical instruction. Too often, the statistics classes the MS students took were taught for more of a statistician audience, using theory and formulas as the basis. Participants, however, needed
only the basics behind the theory of a statistical method. What participants really wanted and
needed was applied instruction in statistics. As one student stated in his interview,

I think doing is key . . . it’s true that you learned a lot more, once you started
doing it, the thing that you thought was so obvious, and you’re like wait, what?
The first time you read it and you’re like, oh yeah, I got it, I got it. But then you
do it and you’re like what? . . . I think the more doing, the better. Doing is good.
It’s painful and I’ll complain about it and so will everyone else but at the end of
the day, it really is what forces you to learn.

As another student put it,

Statistics, it’s like, it felt like they were teaching to statisticians, not clinicians. I
don’t care what the theorem behind developing that equation was, like, I don’t
care. (Laughs.) I don’t have any desire to know that, nor do I want to derive it
from scratch. Do I need to know how to use it? Yes.

Participants valued the flexibility online courses provided. Many students commented
that the online coursework made it possible for them to even do the MS:

I think in terms of the biggest success, I think the online coursework has been
the thing that – I don’t think I’d be able to do this without that. A lot of my
daytime stuff is tied up, so a lot of it’s going to be happening at night. At the
night, there’s a challenge to it as well. It’s nice to have the classes at a certain
time during the day, but it’s just been hard to make that time . . . . I approach it a
little differently than others because I don’t want to miss the clinical
opportunities, so that puts me a little further behind in terms of coursework. But
at the same time, if it’s online, I can have a wider range of dates – it’s better for
me. I think that’s more of an adult learning style anyways – knowing what I have
to do, and finding the time to do it, and sort of learning it on my own.

Or as another stated, “For flexibility and timing, I really like the online part. I would not have
been able to take as many credits as I have without the online classes.” One student noted that
online courses worked particularly well for the introductory topics: “I think online is good for
the basics, for how it was, which was good, but I feel like it would be more difficult for the
advanced kind of things. And I liked the classes that were lecture mixed with discussion.”
On the other hand, participants definitely valued the learning that took place in-class. Many participants acknowledged that in an online class, you “lose something” that only occurs with face-to-face interaction. One student commented, “... I think you do learn a lot from talking to people. I think sometimes you’re sitting in class and some of your understanding comes from talking to the person next to you.” Again, recognizing there needed to be a balance between online classes and in-person classes, another participant said,

And for me, the online classes were basic introduction classes that lend themselves very well to being online. And then the more interactive, difficult classes – I don’t think grant writing could be online. Plus it’s nice to be in class and work on projects together.

One participant who was completing her MS mostly online from New Mexico stated,

... it might have been nice to have a bit more interaction with my colleagues. Quite a few of my classes were online and I felt a little bit isolated. Even though there were discussion boards, there wasn’t really a forum that would have allowed us to learn from each other. So you kind of lose that learning experience.

And in a written journal response, yet another participant plainly said, “There are also a great many topics/classes that I wouldn’t want to be online, that require the ability to ask real-time questions and get real-time help, or that benefit greatly from group work.”

Given the two previous themes under this pattern, students obviously recognized how valuable both online and in-person coursework was for their learning. And partly because of this, many participants recommended more hybrid/blended instructional methods. One class in particular already did this, utilizing online instruction but also incorporating several in-person group sessions throughout the term: “Ethics was good – I liked those. Online was fine, and the group meetings – I liked the design of this class the most. I liked the ability to do online stuff and then attend those meetings.” And another student, when asked what method he prefers
most, said, “Well, I like the mix, personally. I like being in class, but it was also nice that all my
time wasn’t spent in classes so it was nice that there was a mix of online, in the afternoon,
evening, to kind of fit the schedule based on what I have going on personally and clinically.”

**Pattern 5 – Ancillary Student Perspectives on MSCTR Experiences**

The fifth and final pattern consisted of two ideas that did not fit neatly into any other
patterns. Admittedly, these two notions did not meet the criteria for “themes,” in that very few
participants mentioned them. However, both were important to mention because they strongly
influenced the students who did have experiences with them. Both related to students’ general
perspectives on their MSCTR experiences.

The first student perspective in this pattern was that academic integrity and rigor should
be priorities that undergird all other MS training activities. Only three participants discussed
this issue at some length in interviews, and one again in a student journal submission. In order
to protect participants’ anonymity and the specific courses and faculty members, I will discuss
this perspective only loosely. In one case, a participant recounted disappointing and inequitable
classroom practices connected to one particular required class. This participant recalled that
during the final exam, other students in this class openly worked together, even though the
final was not a group exam, and the professor was sitting nearby. Additionally, final grades did
not seem to at all correlate with grades received throughout the semester (final grades were
much higher). As this participant described:

> I think [the professor] just rounded up, to be honest. I wonder about that. I don’t
think our grades on our exams matched our final grades. Our homework, all we
had was a check – like if we got the same answer. So basically all we had to do
was turn in a paper with a check on it saying you got the same answer. I mean,
that’s a master’s? . . . [In this class], I saw people working on the final exam
together. And I was like . . . it was so clear. [The professor] was sitting right up there and I’m like, you have to see that, right? I was so blown away . . .

Another student echoed this concern, stating that “nobody fails out of the MS,” and classes were often much easier than she had hoped or expected. Another participant felt that the thesis process was much too lax. This person’s perspective was that students can graduate with little to no oversight over a final project that is supposed to demonstrate all the knowledge they have mastered in their graduate studies, a policy which did not reflect well on the MS degree. As the participant stated:

I was surprised with the lack of oversight as it related to my thesis. Essentially, my thesis was accepted, sent forward, and accepted again, within a span of like 20 minutes . . . That was a little surprising to me . . . I think the program puts a lot of faith in the PI to make sure that – we’re still students with this type of stuff – and you’re putting a lot of stock in letting the PI be responsible for making sure we’re putting out quality projects . . . I was just surprised there wasn’t someone more to read it and make me defend it a little bit. Can I ask you some questions about your research and make sure you understand it . . . It was just surprising to me that nobody really cared what I submitted.

These students’ reflections indicated that in some areas of the MS, faculty and administrators were giving trainees too much flexibility and autonomy. In the end, issues like this can lead not just to a decrease in student learning, but to a devaluing of the MS degree itself, as one participant summarized in a journal entry:

When I pictured myself with a Master’s Degree I thought it would be something I was proud to have, that it would make me more marketable and knowledgeable. I’m not sure it did those things. Knowing multiple people who cheated have the same degree, knowing that my tests were open book and didn’t reflect what I learned, knowing that my academic work doesn’t reflect my true research makes me less proud of my degree. So while I did gain from the program and it will help me take better care of my patients, it is not exactly what I had hoped for.
Statements such as this indicated that students wanted to be challenged in their graduate studies, and they expected the MS program to hold them accountable to a high level of quality and integrity, goals which the MS did not always meet.

The second notion under this ancillary pattern was that previous and current research experiences can radically enrich (or diminish) students’ CTR training experiences in ways that were unique from the course experiences provided by the MS program. Only a few participants discussed this idea either in interviews or in journal submissions, but because it changed their educational experiences quite a bit, it was important to include it in these results. For example, one student did an extra year of basic science research as part of his fellowship program before deciding to pursue the clinical research path and beginning the MS. His experiences in the lab had a positive effect on his learning experiences in the MS, he said, giving him a better perspective on the spectrum of research and giving different meaning and value to some of his coursework:

I think that I had a very great experience with my year in the lab and I was working in an incredible lab. And in that lab, I had already written a grant and gotten to do some writing that relates to . . . so the PI in that lab made me do some things that the [Design & Management of Field Studies] course tries to teach you. So I had already done it in real life, which is an experience that most people don’t get. So I think I was able to see what the curriculum was trying to do. It’s hard for me to sometimes separate out . . . I think I got more out of it because I had already written a grant and I could see that this is why they’re trying to teach this because this is important to do so I think that insight helped me to appreciate what the purpose of the course was.

Or in the case of another participant, she had the unusual experience of having already applied for grant funding. Although she was not awarded the grant she had applied for, she considered the grant writing process a positive experience, one that directly informed her course studies and motivated her to choose electives that would be especially useful to her for the future. On
the negative side, another participant had experienced multiple “failures” with previous research projects she had undertaken immediately before beginning her MS, and continuing into her MS studies. Partly because of this, in one of her journal entries, she explained that she did not expect to continue into a serious research career track because she was disillusioned with the process and with the academic medicine model as a whole. First-hand research experiences such as these before beginning the MSCTR degree, and even during the MSCTR, had both positive and negative effects on students’ training experiences.

**Member Checking**

Stage six of the seven step hermeneutical analysis process entails providing your full analysis and summary findings to the research team and to researchers outside of the research team for validation. Outside reviewers should be familiar with both the context and the research methods. Because I am the sole researcher on this study, I had to modify this step. My goal was to stay true to the purpose of this stage, which is primarily to ensure validity (credibility) of findings. To do this, I made three efforts to obtain feedback from informed stakeholders. First, as I mentioned above, I discussed the data analysis process and findings with my direct supervisor, who was the faculty director of the MS program and very familiar with the curriculum and the students. Although she did not look at the data directly, she supported my methods of analysis and confirmed that, knowing the MS curriculum and its students well, my conclusions seemed valid. I also shared my initial findings with a peer advisory group. This group was organized and attended by a faculty advisor and comprised of doctoral students specializing in qualitative and action research methods. The group met twice a month and regularly reviewed group members’ research projects, offering feedback or insight.
on all aspects of the research process. The group’s feedback was immensely helpful in clarifying, condensing, and naming patterns. For example, the “Program Structure and Organization” pattern was originally named “Administration,” but the group did not think this was an accurate label for the kinds of themes under that pattern. Group members helped to devise the more descriptive and appropriate name “Program Structure and Organization” instead.

Additionally, I employed member checking directly with study participants. Member checking was part of my original research plan, and it was included in the protocol and consent form. I sent my patterns with themes (essentially, an early version of Table 6 above) to all 12 study participants via email (Appendix D). I gave a brief explanation of the purpose of member checking in qualitative research and invited them to respond with further feedback. I heard back from just one participant, who commented that I was “right on.” I interpreted the non-response from other participants as agreement with my conclusions. As Diekelmann et al. (1989) state,

The multiple stages of interpretation [stages 1-6] provided a means of bias control. The purpose of the multiple stages was to expose conflicts and inconsistencies by allowing for reappraisals and comparisons. The goal was to expose unsubstantiated meanings and inaccurate interpretations not supported by the text. Expert consensual validation was also included in this process. (p. 12)

**Survey Results**

A survey was distributed to all 12 participants via email. Nine of 12 participants completed the survey. The survey was also sent to all students enrolled in the MS program who had completed at least one year of coursework (n=22), as well as graduates from the last two years with a current email address (n=13). In total, 47 current students and recent alumni were
invited to participate in the survey. Of the 22 current students, 14 completed the survey, and of the 13 recent alumni, 4 completed the survey (Table 7). Among the 27 respondents, 14 (52%) were women and 13 (48%) were men, 16 (59%) were fellows and 11 (41%) were faculty, 19 (70%) were affiliated with CCHMC, and 8 (30%) were affiliated with UC (Table 8).

Table 7: Survey Responses

<table>
<thead>
<tr>
<th>Student Group</th>
<th>Invited (n=47)</th>
<th>Responded (n=27)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Participants</td>
<td>12</td>
<td>9</td>
</tr>
<tr>
<td>Current Students</td>
<td>22</td>
<td>14</td>
</tr>
<tr>
<td>Recent Alumni</td>
<td>13</td>
<td>4</td>
</tr>
</tbody>
</table>

Table 8: Descriptive Statistics of Survey Respondents (n=27)

<table>
<thead>
<tr>
<th>Sex</th>
<th>Women</th>
<th>14 (52%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Men</td>
<td>13 (48%)</td>
</tr>
<tr>
<td>Position</td>
<td>Fellow</td>
<td>16 (59%)</td>
</tr>
<tr>
<td></td>
<td>Faculty</td>
<td>11 (41%)</td>
</tr>
<tr>
<td>Institutional Affiliation</td>
<td>CCHMC</td>
<td>19 (70%)</td>
</tr>
<tr>
<td></td>
<td>UC</td>
<td>8 (30%)</td>
</tr>
</tbody>
</table>

Appendix E provides the full survey. After collecting basic demographic information, the second section of questions asked participants to indicate the extent to which they felt the MS program’s stated educational objectives had been met, for them. Using a Likert scale, students could move a slider from “Not at All” (0) to “Very Much” (100). If they had no opinion, they could leave the slider in its place at 50. Responses that were left at 50 were later dropped from the analysis. The four stated objectives of the MS are provided in Table 9, along with the means and standard deviations of responses.

Table 9: Participant Responses to Program Objective Statements

<table>
<thead>
<tr>
<th>Educational Objectives of the MSCTR</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Be a critical consumer of the medical literature</td>
<td>27 (100%)</td>
<td>73.19</td>
<td>19.01</td>
</tr>
</tbody>
</table>
In the next section of the survey, students were asked to assess the value of the core curriculum courses, again using a Likert scale. Students could move a slider from “Not at all Valuable” (0) to “Extremely Valuable” (100). If they had no opinion, they could leave the slider in its place at 50. Responses that were left at 50 were later dropped from the analysis. The specific courses included in the survey are provided in Table 10, along with the means and standard deviations of student responses.

Table 10: Participant Responses to Curriculum Statements

<table>
<thead>
<tr>
<th>Core Requirements</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Division of Epidemiology Seminar</td>
<td>26 (96%)</td>
<td>40.04</td>
<td>21.71</td>
</tr>
<tr>
<td>Introduction to Epidemiology</td>
<td>27 (100%)</td>
<td>86.78</td>
<td>13.23</td>
</tr>
<tr>
<td>Introduction to Biostatistics</td>
<td>26 (96%)</td>
<td>71.81</td>
<td>24.50</td>
</tr>
<tr>
<td>Introduction to SAS Programming</td>
<td>27 (100%)</td>
<td>49.63</td>
<td>26.22</td>
</tr>
<tr>
<td>Ethics in Research/Scientific Integrity</td>
<td>26 (96%)</td>
<td>74.35</td>
<td>16.96</td>
</tr>
<tr>
<td>Design &amp; Management of Field Studies</td>
<td>26 (96%)</td>
<td>84.69</td>
<td>17.25</td>
</tr>
<tr>
<td>Clinical Research Scholars Seminar</td>
<td>26 (96%)</td>
<td>76.04</td>
<td>20.57</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Electives/Selectives</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regression Analysis</td>
<td>17 (63%)</td>
<td>67.59</td>
<td>21.12</td>
</tr>
<tr>
<td>Advanced Biostatistics</td>
<td>11 (41%)</td>
<td>78.91</td>
<td>19.98</td>
</tr>
<tr>
<td>Meta-Analysis</td>
<td>6 (22%)</td>
<td>74.17</td>
<td>19.19</td>
</tr>
<tr>
<td>Biostatistics in Research</td>
<td>8 (30%)</td>
<td>74.38</td>
<td>17.94</td>
</tr>
<tr>
<td>Decision Analysis &amp; Cost-Effectiveness Analysis</td>
<td>13 (48%)</td>
<td>87.08</td>
<td>16.08</td>
</tr>
<tr>
<td>Study Design &amp; Analysis</td>
<td>15 (56%)</td>
<td>73.60</td>
<td>22.07</td>
</tr>
<tr>
<td>Principles of Clinical Trials</td>
<td>8 (30%)</td>
<td>68.25</td>
<td>15.22</td>
</tr>
</tbody>
</table>

Finally, participants were asked to indicate their level of agreement with quality statements regarding their coursework. Using a Likert scale, students could move a slider from
“Do not Agree” (0) to “Agree” (100). If they had no opinion, they could leave the slider in its place at 50, but all participants provided opinions, so no responses were dropped. The statements of quality are provided in Table 11, along with the means and standard deviations of responses.

Table 11: Participant Responses to Quality Statements

<table>
<thead>
<tr>
<th>Quality Statements about the MSCTR</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>I was very satisfied with the variety of courses that were offered.</td>
<td>27 (100%)</td>
<td>72.96</td>
<td>19.92</td>
</tr>
<tr>
<td>The course schedule worked well with my schedule, allowing me to take the courses I wanted.</td>
<td>27 (100%)</td>
<td>71.37</td>
<td>26.83</td>
</tr>
<tr>
<td>Teaching in the program was high-quality.</td>
<td>27 (100%)</td>
<td>75.59</td>
<td>17.62</td>
</tr>
<tr>
<td>Coursework was appropriately challenging for a master’s degree.</td>
<td>27 (100%)</td>
<td>78.67</td>
<td>18.88</td>
</tr>
<tr>
<td>The number of courses required was appropriate.</td>
<td>27 (100%)</td>
<td>78.93</td>
<td>18.41</td>
</tr>
</tbody>
</table>

When asked, “Would you recommend this MS program to others?” 100% of respondents (27/27) said yes.
Chapter 5: Discussion and Implications

The purpose of this phenomenological study was two-fold: to allow students to articulate their expectations, needs, and experiences in the MS in Clinical and Translational Research program, and to develop novel training methodologies and/or curriculum to improve physician-scholar training. The research questions associated with this study were:

1. Why do trainees choose to pursue CTR training?
2. What knowledge or skills do students wish to obtain from their MS training?
3. What have students’ experiences been like thus far?
4. What areas of their educational program do trainees feel are lacking?
5. What changes would students make to the program’s curriculum and/or methods?

Although not explicitly planned in the design at the outset of the study, questions 1 and 2 above were primarily addressed in Phase I and questions 3, 4, and 5 above were primarily addressed in Phase II. This was not overly surprising, because questions 1-2 dealt with student expectations prior to starting the program, and questions 3-5 dealt with student experiences after beginning the program. Chapter 4 was organized primarily by the two phases of the study and the data analysis process. This chapter, Chapter 5, begins with a discussion of the results from the two phases, followed by a discussion about the interplay between the research process, findings, and theoretical frameworks, before concluding with final implications and recommendations.

Phase I

Results from the document review and GLA of Phase I provided the most insight into research questions 1 and 2. There was some overlap in themes from participants’ application
documents and the GLA, but there were also interesting differences. After analyzing participants’ application documents, which included personal statements and career goals, five major themes emerged:

1. Personal experiences had intensified their interest in research.
2. They wanted to improve their care for patients in the clinic.
3. They wanted to better mentor and/or teach others in their divisions and/or fellowships.
4. They wanted to collaborate more effectively with their colleagues.
5. They wanted to further their own professional goals.

Although some of these themes (personal experiences, the desire to teach, the desire to further their own professional goals) have been identified in the literature as reasons physicians pursue careers in academic medicine (Borges, Navarro, Grover, & Hoban, 2010), it seems the wish to improve clinical care and collaborate with colleagues is unique to the research-specific career path. In the GLA, the group’s analysis produced different overall reasons for enrolling in the MS program: fulfilling fellowship requirements and acquiring research skills. While fulfilling fellowship requirements is an acceptable and practical reason for pursuing the MS degree, virtually no one actually wrote that in their application documents. Presumably, applicants realized the MS Admissions Committee would want to see more of a personal commitment to a research career than just a basic desire to satisfy one of many fellowship requirements.

Research suggests that methods that rely upon a group setting and group interaction can actually open participants up to speak candidly on topics they might otherwise consider taboo (Kitzinger, 1994), and in the more laid-back group setting, students determined that fulfilling fellowship goals was a major reason for pursuing the MS. The second theme from the GLA –
acquiring research skills – was inherent in all of the five themes from the document review. Students wanted to acquire and improve their research skills because personal experiences had intensified their interest in research and so that they could improve their clinical care, better mentor and teach others, collaborate with colleagues, and further their own professional goals. The desire to effectively carry out research studies is consistent with previous reviews of the literature on why physicians pursue careers in academic medicine (Goldacre, Stear, Richards, & Sidebottom, 1999; Sanders, Fulginiti, & Witzke, 1992; Straus, Straus, & Tzanetos, 2006).

Although the MS program addressed four of these five expressed goals somewhere in its curriculum, one rather surprising reason students enrolled in the MS was because they wanted to mentor and/or teach others (specifically, residents and junior fellows) in their fields. Currently, the MSCTR does not attempt to instruct students in issues such as being a mentor or developing a fellowship curriculum, so these are interesting areas for potential development. The desire to teach and mentor has been documented in other areas of the literature that look at why physicians choose the academic medicine career path (Borges et al., 2010; Donnelly et al., 1996; Sanders et al., 1992; Straus et al., 2006), but UC’s MSCTR has never addressed this issue in its program structure or curriculum.

When asked about skills or knowledge they wished to gain from their MS studies, participants expressed strong agreement about broad areas of interest. Almost all participants mentioned wanting to acquire skills in designing research studies, implementing studies, analyzing and interpreting data, and collaborating with others in their research. These themes did not vary between the GLA and document review, and although they aligned well with the competencies described by NCRR (Abedin et al., 2012; "Core Competencies for Clinical and
Translational Research," 2011), they were also much less sophisticated, which was understandable. Many students did express more specific areas of interest as well, such as designing and managing clinical trials, quality improvement methodology, and molecular epidemiology, but several areas of the defined core competencies seemed to be of little interest or just simply unknown: biomedical informatics, regulatory affairs and responsible conduct of research, scientific communication, cultural diversity, leadership, and community engagement ("Core Competencies for Clinical and Translational Research," 2011). The uniformity of the reported knowledge and skills students hoped to obtain through their MS studies demonstrates that they were aware of the gaps between their own capabilities and the capabilities they would need to hone if they wanted to successfully design and lead research studies. Most MS students have discussed and observed, (or, at minimum, read about) research studies under the mentorship of a senior colleague or director, and so they often acutely sensed the hole in their own knowledge of statistics and research methodologies. Consistent with Knowles’ (1970, 1973, 1980) andrologogical theory of adult learning, physicians come to the MSCTR with a strong, general idea of the types of things they need to learn that will directly apply to their research careers.

**Phase I Results ➔ Phase II Results**

As stated in Chapter4, one purpose of Phase II was to follow up on issues raised by the GLA in Phase I. Participants reached three conclusions by the end of the GLA:

1) Students wanted more physician-specific courses, especially in statistics.

2) Students wanted a more directed curriculum.
3) Unity and cohesion throughout the MS training was a problem – the classes often felt disconnected from each other.

Phase II allowed for further investigation of the three main themes from the GLA. The Phase II data analysis process confirmed two of the three GLA themes: students wanted more physician-specific courses (especially in statistics) and students wanted a more directed curriculum. Having worked with this particular student audience for over seven years, I was familiar with their desire to be taught and mentored by other physicians, when possible. The literature suggests that physicians bring a distinctive viewpoint to clinical research, different from PhD researchers, and essential to changing healthcare at the bedside (Shine, 1998). Although participants were not explicitly asked about creating more physician-specific courses in Phase II, the issue still arose in the one-on-one interviews and in journal submissions. Often, when I asked participants about their most negative experiences in the program, the conversation would turn towards statistics classes. Participants often felt as if professors were teaching to statisticians instead of physicians with limited math backgrounds. Students also often felt that the physician viewpoint in research is so unique, only other physicians can understand it and approach the content and instructional methods of a course appropriately, a suggestion that is supported in the literature (Miles, Price, Swift, Shepstone, & Leinster, 2010; Paes, 2010).

Similarly, while participants made it clear they wanted and needed a high level of flexibility in the curriculum, they also consistently expressed a desire for a stronger sequence of courses. At first, this finding was surprising because according to Knowles’ (1973, 1980, 1984) theory of andragogy, adult learners tend to be highly self-directed, bringing their unique experiences and needs to their educational goals. However, after further reflection, physician-
scholars are accustomed to the typical medical school model, where their curriculum is so
directed, they rarely even register for the courses themselves; the courses are assigned to them. Physicians in the MS program also maintained exceedingly busy schedules, and so they did not often have time to look carefully through course listings. Participants in this study usually had a general idea about the types of things they needed to learn in order to start their research careers, but they did not understand the specifics yet. For example, they might have known they wanted to learn about methods of statistical analysis, but they didn’t know if they needed to learn regression, structural equation modeling, or nonparametric statistics. This desire for a straightforward curriculum structure is characteristic of adult learners as well. As Ross-Gordon (2011) states, “This body of research [on adult learners in college classrooms] suggests that while adult learners desire flexibility, they also often desire structure” (p. 26).

Participants suggested it would be much easier and more effective for them if the program would tell them what is most important for them to learn, while still allowing some flexibility and choice for those who do have specific things in mind or who are working around difficult clinical schedules.

The third theme from Phase I’s GLA (the curriculum lacks unity and cohesion) was not supported by Phase II follow-up. The interview guide included one question about this specific issue: “At the group meeting, unity and cohesion throughout the curriculum seemed to be an issue. Was this an issue for you, and if so, do you have any ideas for how we could improve the sense of connectedness throughout your entire MS program?” All 12 interviewees stated this was not a problem for them, which was interesting because eight of the 12 were participants in the GLA that concluded it was a problem. When questioned about curricular cohesion at the
individual level, students generally thought the curriculum was smooth and cohesive, primarily thanks to prerequisites and the scheduling of more advanced courses in the spring semester.

However, a related issue did emerge in Phase II: participants wanted more integration of biostatistics and epidemiology in combined classes. Several participants stated the need for a capstone type class that pulls together all the elements of clinical research learned in previous classes. This indicated that while students did not think overall cohesion was a major problem, they did want better integration of biostatistics and epidemiology and/or a capstone-type course that pulled everything together, both of which hinted at the idea that, as the curriculum was organized during their studies, with most biostatistics and epidemiology courses being taught separately, the topics were at least a little disjointed. Several good examples of integrated curricula exist within the CTSA consortium already. Although their introductory courses are separated by topic, the Weill Medical College at Cornell University has developed several advanced courses that integrate biostatistics and epidemiological training, such as Foundations of Clinical Research and Research Grant Writing (Clinical and Translational Science Center, 2015; Supino & Borer, 2007). The University of Southern California teaches introductory biostatistics and epidemiology separately, but has also developed three 4-credit courses called Clinical Translational Research I, II, and III. Each course incorporates aspects of research methodology, scientific communication, team science, and ethics (Keck School of Medicine, 2015). Harvard Medical School has also developed a course that explicitly combines instruction in study design and analysis called Principles and Practices of Clinical Research (Harvard Medical School, 2015).
Phase II Results

The results from Phase II fell into five patterns: curriculum, mentorship/relationships, program structure and organization, instructional methods, and ancillary student perspectives on MSCTR training. While participants cited many positive aspects of the MS program under these five patterns, areas of improvement also arose under each one. The purpose of this mixed methods program evaluation study was to allow students to have a voice in their training experiences and to use their feedback to develop novel training methodologies and/or curriculum improvements to enhance physician-scholar training at UC. With that agenda in mind, Phase II results provided numerous opportunities for growth and improvement.

Pattern 1 – Curriculum

The curriculum pattern included the biggest number of themes and frankly, the biggest opportunity to comprehensively improve the MSCTR training program. Participants made clear that they not only wanted the existing courses to be made better, but they also wanted new courses that incorporate new content not covered in current coursework. Two themes from this pattern were connected: participants appreciated the flexibility of the curriculum, but they also wanted a stronger sequence of core courses (Ross-Gordon, 2011). This recommendation from participants could be relatively easy to accommodate, requiring only some minor tweaks to the existing curriculum to make it clearer which classes should be taken, and in what sequence.

A more difficult issue that came up again and again in the GLA, individual interviews, student journal submissions, and even in the survey was statistical instruction. Students’ responses to their statistical training were mixed. Although a few participants reported that
they were very pleased with the approach and content of their statistical classes, the majority of participants felt that professors did not teach statistics in ways that were relevant for physicians, in terms of both content and method. Of the 12 total participants in this study, nine had taken enough statistical coursework to offer feedback. Of those nine, six characterized their overall experiences with statistics as negative, with only three offering positive feedback. All three students who had positive experiences specifically commented on one particular professor’s classes being very good. Negative aspects of the current statistics courses included: lack of applied instruction, superficiality of topic coverage, and too much emphasis on programming in SAS. As Supino and Borer (2007) note, “purely theoretical discourse tends to be of limited interest to [an audience of clinicians and other health professionals]. Accordingly, we advise our faculty to present all concepts and principles so that their relation to clinical practice is clear” (p. 350). Most of these problems in UC’s MSCTR statistics courses stemmed from the courses being taught by biostatisticians who taught for a more statistical audience. By bringing in different types of instructors – clinicians who are strong in statistics and even epidemiologists or other types of researchers with strong quantitative backgrounds – we can better meet the needs of our physician student audience.

Almost universally, the Introduction to SAS Programming course was reviled. All students agreed that a programming class was necessary, but that the SAS class was too bogged down by the details of computer programming instead of providing a more general overview of the SAS program itself. In their discussion of tailoring research training to a physician audience, Supino and Borer (2007) state, “Statistics are taught as tools for answering specific clinical research questions” (p. 347), and this should be the guiding principle at UC as well. Several students
would have preferred a course that provided an overview of all or some of the major programming software: SAS, R, SPSS, JMP, and STATA. Although the MS Curriculum Committee approved a list of programming “selective” courses in the Fall of 2013, giving students a few more course options to fulfill this requirement, the majority of students still take the Introduction to SAS Programming course. Given the vehemently negative feedback on this course, and the explicit request for a course that does not focus on one programming software alone, it is time to change the requirement altogether. Since the vast majority of the MS students will not be analyzing their own data, but instead will work with a biostatistician to interpret results, they do not need such detailed instruction in programming. They would benefit much more from a class that introduces them to the variety of analysis software available, and gives them a basic introduction to acquiring and using each software. As the curriculum is currently set up, students do have a choice of programming classes, but this assumes they know which software they or their statistician will use, and many students do not know that in the early semesters of their MS studies, when they take their introductory courses.

Several participants suggested more integration of the epidemiology and biostatistics components in the coursework, better reflecting the real process behind designing a research study. As the curriculum is currently designed, only two classes explicitly integrate study design topics with statistical analysis: Study Design and Analysis (selective) and Design and Management of Field Studies (required). Because Study Design and Analysis is included on a list of selectives, not all students take it. And Design and Management of Field Studies doesn’t actually teach students how to integrate design and analysis techniques, but instead requires
students to do so as they prepare a grant application. Given this, integration is definitely an area within the curriculum that could be improved, but this would require a complete overhaul of the core courses, ideally at the introductory level. Instead of two separate Introduction to Biostatistics and Introduction to Epidemiology courses, the program could offer broader courses such as Clinical and Translational Research I and Clinical and Translational Research II, somewhat similar to the University of Southern California’s approach to teaching clinical research (Keck School of Medicine, 2015) and Harvard Medical School’s combined Principles and Practices of Clinical Research course (Harvard Medical School, 2015). These two core required courses could address study design and analysis techniques together, reflecting, for example, on the ways students can design their studies and set up their data collection methods to better answer the research questions they have, using appropriate analysis techniques, or calculating an appropriate sample size before designing a study so that they can then recruit and collect data from the necessary number of participants. Because so many aspects of the design of a study have direct effects on the analysis and interpretation, it certainly makes sense to teach the two more in tandem.

When asked about topics they thought were missing from the curriculum, participants had a variety of responses, but three gaps consistently arose:

- Expand Design and Management of Field Studies to be a year-long course that covers more topics related to study design and implementation.
- Expand the Clinical Research Scholars Seminar to include several more topics related to professionalism and the job search.
• Create a “journal club” type of class where students learn about a type of design and/or statistical analysis and then scrutinize journal articles that demonstrate that topic (both good and bad).

In the core curriculum, Design & Management of Field Studies and the Clinical Research Scholars Seminar were the two classes that had the biggest positive impact. Both could benefit from expansion, both in terms of time and topics covered. Many participants suggested expanding these two courses so that they meet more frequently and/or over a longer period of time and cover more topics, in more depth. Many participants also specifically noted the value of varied faculty viewpoints being included in these classes’ discussions (Supino & Borer, 2007).

Regarding Design and Management of Field Studies, participants suggested stretching it over two semesters and beginning with conception of a research idea, framing research questions, and developing a study design and analysis plan, then continuing on to the current course content, which walks students through writing a grant application. This recommendation echoes training efforts at other CTSA sites (Harvard Medical School, 2015; Keck School of Medicine, 2015). Similarly, participants thought that the Clinical Research Scholars Seminar should meet twice as often and include many additional topics related to careers and professionalism such as: the job search, writing a CV, writing an NIH biosketch, writing a Letter of Intent, preparing for a research interview (both how to present yourself and what questions to ask), evaluating an organization’s culture, spending more time on the topic of mentorship, negotiating clinical vs. research responsibilities (both at the start of your job and down the road), finding funding, the funding process, developing a research career plan, different pathways to funding, multi-center consortium research, manuscript submission, and
education debt. A recent report from the Association of American Medical Colleges identified professionalism as one of several key areas of development for physician training ("Optimizing graduate medical education: A five-year road map for America's medical schools, teaching hospitals and health systems," 2015). And finally, many students suggested a journal club style class that would specifically focus on clinical research literature and introduce them to a variety of methods and designs, giving both good and bad examples. A class like this would be fairly easy for faculty members to teach because much of the class time would be devoted to discussing an assigned article or articles, potentially even articles the students provide. Given that one of the fundamental learning outcomes of the MS program is that students be able to evaluate scientific literature for appropriateness of study design, analysis techniques, and findings, a class like this would directly address that outcome. Many other physician scientists preparatory programs incorporate a journal club into their curricula as well ("The New Jersey Medical School Physician Scientist Skills Program for 2013-14," 2015; "Physician Scientist Development Program," 2015; "Physician Scientist Training Program," 2015; "Physician Scientist Training Program in Pediatrics (PSTP2)," 2015).

**Pattern 2 – Mentorship/Relationships**

In its current state, the MS program does not provide formal mentorship. Applicants are required to have one letter of recommendation from a research mentor in their field that is committed to meeting with them regularly and guiding their thesis research projects, and our faculty director is available for mentorship, should students request it. Other than that, students discuss mentorship in the Clinical Research Scholars Seminar, including expectations of both mentors and mentees, how to mend an unproductive mentoring relationship, and when
to move on to a new mentor. The literature on mentorship strongly suggests that fellows with mentors are more likely to publish one or more papers a year, and are more likely to secure early funding as a principle investigator (Steiner et al., 2004; Steiner, Curtis, Lanphear, Vu, & Reid, 2000; Steiner, Lanphear, Curtis, & Vu, 2002). Mentorship is imbued in the culture of most research institutions, and all MSCTR students have mentors through their department or division appointments. However, anecdotal evidence suggests these mentoring relationships are not always effective or even existent, in any practical sense. In the past, MS fellows have complained that their mentors pressured them to work on research that served the mentor’s career better than the fellow’s, that their mentors were passive-aggressive or even competitive, or that they never actually met. Sambunjak et al. (2006) suggest that while mentors and mentees recognize the value of mentorship, the demands on their time from clinical, research, and administrative duties make it more challenging to have effective mentoring relationships.

So although most participants reported having strong mentorship through their home departments or divisions, all were open to additional mentorship coordinated by the MS program. Mentors assigned by the program need not be in the student’s area of specialization. Because their mentoring relationships with the people in their own fields were often complex and affected by the unique organizational cultures within their own disciplines, many participants suggested that a “neutral” third-party mentor would be very helpful. Many studies connect mentorship from multiple, diverse mentors with career success, personal satisfaction, and achievement of organizational goals (Baugh & Scandura, 1999; de Janacz & Sullivan, 2004; Higgins, 2000; Higgins & Kram, 2001). Participants envisioned this person serving in a variety of
ways: most often in one-on-one meetings between just mentee and mentor, but also attending group meetings where the trainee’s other mentors are also present. Participants felt that a third party mentor would provide more unbiased guidance on projects that would best serve the trainees at their current career stage, rather than possibly being swayed by department or fellowship politics or the mentor’s own career goals. Students also felt that mentors provided by the MS program could offer a valuable “outsider’s” perspective, so that students would get a sense of what is normal or expected in other fields (Baugh & Scandura, 1999; Higgins, 2000; Schapira, Kalet, Schwartz, & Gerrity, 1992).

Participants suggested that the earlier they can be connected with a mentor, the better, because fellows or junior faculty members who were just beginning their research careers often did not know where to begin. Literature suggests strong mentorship in the early stages of one’s career is essential to a successful launch into a profession (Kay, Hagan, & Parker, 2008; Scandura, 1992). Some participants acknowledged that when they were beginning, they did not know enough about clinical research to be aware of what they did not know, and meeting regularly with a mentor from their first semester on could have eliminated a lot of the frustration and confusion that often arose as they learned what they did not know. Many participants suggested that the MS program maintain a list of faculty members who have track records of excellent mentorship and are willing to mentor new clinical researchers pursuing (and possibly beyond) the MS degree. Program administrators could then match trainees to a mentor from the list, or trainees could even choose their own. Many other CTSA programs incorporate formal mentorship into their training programs as well (Clinical and Translational Science Center, 2015; "Degree and Certificate Programs: Advising and Mentoring," 2015; Keck
School of Medicine, 2015). While some participants suggested program mentorship be mandatory and enforced (i.e., program administrators track mentor-mentee meetings), others thought it should be strongly recommended but not required. The data was not conclusive on this issue, so further research and discussion is needed before developing a program mentorship policy.

Another interesting theme under the Mentorship/Relationships pattern concerned the relationships students formed with faculty and program staff while in the MS program. Frankly, outside of regular coursework, the MS program did little to formally encourage connections between teaching faculty members and trainees. Many trainees naturally began working with faculty members outside of their coursework if their research interests overlapped, or if the trainees needed biostatistical guidance on a class project that turned into a publication. Many participants noted how helpful and productive these relationships were, not only increasing their learning, but also giving them deeper insight into the process and interpersonal connections that must occur in order for clinical research projects to be successful (Bess, 1978; Gross, 2011; Merton, 1949; Pavalko, 1971). Students also felt that the informal conversations they had with program administrators and program faculty were often just as important as the formal instruction they received in class, for a number of reasons: receiving course recommendations that were personalized to their situations and interests, learning from the anecdotal lessons told by more seasoned clinical researchers, discovering resources available to them that might not have been widely publicized, and growing their network of people involved in clinical research who were able to contribute to their research goals in countless ways (de Janacz & Sullivan, 2004; Haworth & Conrad, 1997; Higgins & Kram, 2001). Given the warmth
with which students discussed their relationships within their training, the MS program could do more to promote these kinds of interactions among students, faculty, and staff.

**Pattern 3 – Program Structure and Organization**

This pattern was the most difficult to classify, because it encompassed a few issues that were distinct from one another. However, all of the themes under this pattern related to the way the MSCTR is organized, administratively. Beginning with the positive, all participants spoke very highly of the program administrators and emphasized how critical they were to the program’s continued success (Haworth & Conrad, 1997). The student population of the MS is unique because the vast majority of students are medical doctors who maintain busy clinical schedules, including day-long and overnight service call shifts. In other words, MSCTR trainees lead stressful lives that revolve around their very important medical work, and they frequently have little time to peruse course listings or figure out registration issues. Study participants relied heavily on program administrators to walk them through the admissions and graduation processes, send regular reminders about deadlines, serve as liaisons to other university offices, and suggest courses that were most appropriate for student needs (Bowden & Merritt, 1995). Participants clearly recognized the dedicated work of the MS program administration to make student experiences as relevant, supportive, problem-free, and accessible as possible. Many participants bluntly stated they could not complete the MS without the assistance of the program directors and coordinator.

In spite of the highly positive feedback about program administration, there were areas with room for improvement. One major issue with the structural organization of the MSCTR that came up with almost all of the participants was scheduling, a very common concern among
adult learners (Berling, 2013; Ross-Gordon, 2011), but one that is intensified in the clinician student population. The physician-scholars in this study were clearly struggling to maintain their clinical responsibilities with their MS studies and their home lives. Many of the participants in this study expressed disappointment that they could not take particular classes they were really interested in because the times the classes were offered conflicted with students’ clinic time, or the classes were offered every other year and didn’t work within students’ overall time frame. Many participants thought that the MS program should offer more classes more frequently, some even suggesting that core courses should be offered every semester, every year. While this last option is infeasible for faculty members, the MSCTR can certainly do more to better accommodate student schedules. Currently, core introductory courses (Introduction to Epidemiology, Introduction to Biostatistics, Introduction to SAS Programming, Scientific Integrity/Ethics in Research, and the Division of Epidemiology Seminar) are offered at least two semesters out of three each year. However, the elective courses that address unique, specific topics that tend to be more relevant to student areas of medical and research specialization, are offered much less frequently: sometimes once a year, but just as often, only once every other year. The MS program could conduct a needs assessment to determine which elective courses are of the greatest interest to students, and then offer those courses at least once each academic year. In addition, the MS program can continue to move courses online, either conducting them entirely on the web or providing at least some instruction online and decreasing the amount of in-person time required. The hybrid class, which includes both online and in-person instruction, and which will be discussed in the next
section on Instructional Methods, also offers a great deal of flexibility and should be explored more by MS faculty and staff.

Finally, while participants were satisfied with the work done by program administrators, some participants wished they had had more advising on coursework and their thesis research projects. Participants would like administrators to be familiar with each student’s unique situation, interests, and goals so that advising can be as individualized as possible. Bland (2003) suggests that advising for adult learners be less “prescriptive” and more “developmental,” making academic advising more of an interpersonal, facilitating process instead of simple dictatorial direction. For example, some participants expressed disappointment that they were not informed of other course options that could have taken the place of Introduction to SAS Programming. One participant said he wished an advisor would have informed him he could have done a retrospective chart review or meta-analysis for his thesis, which would have been much more feasible than the prospective study he undertook instead (and that delayed his graduation by a year). While it is difficult to maintain intimate familiarity with each student’s very particular set of circumstances, it is certainly possible to meet with students regularly and to check in with them over email. For many years, the MS faculty director and program director would meet with students individually every summer to assess progress, answer questions, and address any issues. These meetings have not occurred since 2012, but this study clearly shows students would appreciate an annual check-in. The annual one-on-one meeting gives administrators a chance to look carefully at each student’s record up to that point, including Statement of Intent and Institutional Review Board progress, and to red flag any areas where a student seems to be falling behind or missing some key aspect of the MS program (Bland,
Perhaps more importantly, it provides an opportunity for students to air their concerns and questions, and to receive guidance on how to plan out their remaining coursework, in many cases all the way to graduation (Light, 2001).

**Pattern 4 – Instructional Methods**

Participants were eager to discuss the instructional methods currently used in the MSCTR because in some ways, the methods of instruction available to them had the biggest impact on their daily lives, at least in terms of scheduling. One request many participants made was that classes be more physician-centered. As the curriculum is currently organized, some classes are explicitly geared towards physicians (summer Introduction to Epidemiology and summer Introduction to Biostatistics, Clinical Research Scholars Seminar, Decision Analysis and Cost-Effectiveness Analysis, and Design and Management of Field Studies). Even in those classes that were developed specifically for doctors, the professors were well aware of the physician students in their classes and tried to accommodate their needs and interests. However, the MSCTR program incorporates many traditional biostatistics and epidemiology courses that include a large number of non-physicians on the class roster (Full Proposal: Master of Science in Clinical and Translational Research, 2008), and professors also must teach to those students. In Advanced Biostatistics, for example, the professor is a biostatistician, and the audience includes many MS and PhD students in Biostatistics, whose needs and interests are very different. MSCTR physician-scholars in this study noticed this disconnect, and so the instructional methods and content of some courses did not meet their needs. Previous research indicates that physicians approach research differently than other types of researchers, such as those trained through PhD programs (Shine, 1998).
While talking with participants about this theme, it became clear that the implications of this recommendation were two-fold: not only should the student list be limited to mostly physicians, but the professors themselves should ideally be physicians also. Participants felt that having more physician-only classes would be more efficient because the time taken up in class by other types of students working through their questions or talking about their research was not productive for the physician-scientists in the room. Trainees in the MSCTR program hoped to be principle investigators on their own clinical research studies, so their approach to research was different from that of an epidemiology student, who might be involved in studies that were better characterized as pure field epidemiology. Field epidemiological research has different goals, starting with recruitment and data collection methods all the way through to findings and outcomes (Gregg, 2008; Portney & Watkins, 2009; Rothman, Greenland, & Lash, 2008). In addition, participants would like more physicians who are actively involved in research teaching their courses, since those instructors would naturally understand what physician-scientist students need to know. While this is an excellent idea, it is very challenging to find physician faculty who have the time to teach regularly.

Knowledge of statistics is essential for physicians who are designing, conducting, and interpreting good clinical research (Castles, 1979; Marks, 1982; Supino & Richardson, 1999). In this study, participants frequently stated that the teaching methods in many of their statistics courses were not effective. Too often, professors focused on the theory behind various statistical concepts and provided in-depth instruction on formulas and programming, none of which was relevant for physicians. Instead, physician-scientist trainees need statistical instruction that is more applied (Supino & Borer, 2007). Many participants commented that a
brief introduction to a concept with an overview of its history and theoretical/mathematical underpinnings would be helpful, followed by a much more intensive application of the concept to clinical research problems. Supino and Borer (2007) note that “examination and comparison of a variety of alternative study design and statistical analysis options is helpful to the clinical investigator whose efforts may be limited by practical considerations” (p. 346). Students said if they can bring in their own data to work with as part of the learning process, that would be even more useful (Knowles, 1973). At this stage of their studies and their careers, MS trainees need extremely practical instruction on how to actually use the statistical analyses they are learning. They will work with biostatisticians who understand the mathematical theories behind the formulas, but the physician’s role is to be familiar with the more pragmatic aspects of biostatistical analyses: calculating sample size, sources of error, correctly interpreting P values, random variation, and understanding common methods such as regression modeling and Bayesian inference. Physicians need statistical instruction that, at minimum, enables them to critically read and interpret the scientific literature (Altman, 2002; Hawkins, 2004; Marks, 1982; Supino & Borer, 2007). Many participants also wanted to be able to run their own very basic data analyses for pilot studies, before they begin working with a biostatistician.

The final three themes under the Instructional Methods pattern were highly related:

- Participants valued the flexibility online courses provide.
- Participants also valued the learning that takes place in-class.
- Many participants recommended more hybrid/blended instructional methods.

Given their difficult schedules, participants highly valued the flexibility provided by online coursework. However, many students commented that the quality of current online courses
varied quite a bit; some online classes were quite good but others were not. Students wanted their online coursework to be high-quality, first and foremost. Some commented that they were able to just click through modules in some online courses without paying much attention, which, while easier, did not deliver the information they needed in a meaningful way. Students also complained that some online courses were just voiceovers of slides, without any real engagement with the material or elaboration on the topics. Online courses worked very well for students’ schedules, and students greatly valued the flexibility of doing the work on their own time. However, they wanted the material to be presented in clear, thoughtful, and interesting ways.

On the other hand, most participants recognized that something was “lost” in courses that were taught entirely online. Contrary to a discussion of online learning by Kassop (2003) that includes interaction and intimacy in three of its top ten reasons online learning is as good, and even better, than in-person learning, participants in this study felt that interpersonal interactions were not as powerful in an online educational setting, where the professors and students primarily communicated in writing. Not only did they feel the interaction was lacking, but many participants felt that the actual transmission of knowledge was also weakened in an online setting. In many cases, students said that online coursework lent itself to distractions because they had the internet at their fingertips while watching the instructional modules, or colleagues or family members would walk in the room as they were typing a discussion board response. The vulnerability towards distraction and disengagement is a common theme in the literature on distance learning (Carr-Chellman & Duchastel, 2000; Stacey, Smith, & Barty, 2004) However, research also suggests that instructors can effectively create interactive classrooms
online, which can lead to higher levels of student engagement and learning (Arbaugh, 2000; Finlay, Desmet, & Evans, 2004; Swan, 2001, 2002; Ussher, 2004). Other participants said that unless they were required to be in a room at a certain time for class, they simply could not find or create the openings in their schedules to give the course the time it deserved. Sitting in a room with other like-minded individuals nearby, who were also trying to learn the fine points of cross-sectional or quasi-experimental study designs, seemed to have a large impact on participants’ perceptions of their own understanding and retention of knowledge. Many researchers within the field of online learning have found the opposite to be true: high-quality distance learning courses can result in “deep and meaningful understandings and communities of inquiry,” (Garrison & Kanuka, 2004, p 98) particularly when they include some synchronous interactions ((Garrison & Kanuka, 2004; Hiltz, 1997; Marjanovic, 1999; Rimmershaw, 1999; Williams, 2002). However, for all of the reasons discussed above, participants in this study also valued traditional, in-class instruction and learning.

Because they valued both online coursework and traditional face-to-face interaction, many participants in this study recommended the MS program offer more courses that utilize hybrid and/or blended instructional methods. Although they wanted the continued flexibility of online learning, they suggested that it be combined with in-person meetings. Two models were suggested for this approach: hybrid classes at all levels that provide some instruction online with additional meetings in a classroom, or online introductory classes followed by in-person coursework for more advanced classes. The latter is the current model in the MS, with Introduction to Biostatistics, Introduction to Epidemiology, Scientific Integrity/Ethics in Research, and many introductory or intermediate electives all offered online. Culmination
courses like the Clinical Research Scholars Seminar, Design and Management of Field Studies, and more advanced biostatistics courses like Advanced Biostatistics, Meta-Analysis, and Decision Analysis and Cost-Effectiveness Analysis are offered in-person only. However, this study suggests that the current model does not meet the needs of students, both in terms of scheduling and learning. Program faculty and administrators should consider the possibilities of a hybrid instructional model, which would combine online didactics and in-person follow-up in every class. Research suggests that blended learning can enhance both the effectiveness and the efficiency of learning experiences in higher education (Garrison & Kanuka, 2004; Ginns & Ellis, 2007; Lopez-Perez, Perez-Lopez, & Rodriguez-Ariza, 2011; Osguthorpe & Graham, 2003; Singh, 2010).

**Pattern 5 – Ancillary Student Perspectives on MSCTR Experiences**

As discussed in Chapter 4, the two ideas included in this pattern were not true themes, in that they were only referenced by a few participants. However, these two perspectives struck me as not just compelling, but also of high importance to these particular participants, and therefore worth mentioning and exploring further in future program research and administration. Two students discussed disappointing experiences within the MSCTR related to academic integrity and rigor. One student observed blatant cheating in one class with no intervention from the faculty member present, and others felt that the MS program was not challenging enough for a graduate-level degree. Some research indicates that academic dishonesty in U.S. colleges is pervasive and influenced by perceived peer behavior and peer and faculty acceptance (Elliott, Deal, & Hendryx, 2014; McCabe, Butterfield, & Trevino, 2006, 2012; McCabe & Trevino, 1993). One participant who witnessed unprincipled student and faculty
actions in her coursework felt her degree was cheapened, because other students who had
earned the same degree had done so while cheating. Others felt that the coursework was too
easy and the thesis process was too lax, two perceptions which also diminished the value of the
degree, at least in the eyes of these particular students. While I hope that these were singular
experiences in an otherwise scrupulous academic program that maintains high standards of
quality and integrity, student perspectives such as these, uncommon or not, are certainly
upsetting and cause for re-appraisal of program curriculum and processes.

The second notion under this “ancillary” pattern related to the role previous and current
research experience played in students’ training. A few participants noted both positive and
negative experiences they had before or early in their MS studies that influenced the way they
approached their coursework or the way the MS curriculum worked for them. This is not
surprising, given both the constructivist theory of learning discussed in Chapter 2 (Bruner, 1960,
1985, 1991) and the importance adult learners place on previous experience (Knowles, 1970,
1973, 1980). However, it introduces interesting possibilities in terms of curriculum
development. Many MS students begin formal research training in the second or even third
year of their fellowship training, since their first years are often clinic-heavy. If the MS program
could reach this population of future students prior to matriculation into the MS program and
potentially get them involved in even a small, introductory research project before they begin
their studies, it could transform their educational experiences once they begin.

The importance of experience in one’s development of knowledge ties back to both
Bruner’s (1960) constructivist theory for curriculum development and Dewey’s (1938)
pragmatist approach to education. In writing about teacher education, Dewey (1938) argued
that first-hand experience in schools is critical to prospective teachers’ development because it informs and challenges what they already know – as Gallego (2001) explains, “about themselves, the context, and their profession” (p. 313). Although there is little existing research about research exposure within the clinical research field at the level of training studied in this project, the literature does indicate that early exposure to research careers beginning in undergraduate and medical education programs contributes to physician interest in clinical research careers (Bartels et al., 2010; Guba, 1995; Ley & Rosenberg, 2005; Moskowitz & Thompson, 2001). Extending this principle to the post-medical school/fellowship student audience makes sense because although most fellows pursue a fellowship because they are interested in specialized clinical and research training, many of them do not have first-hand experience with research before they begin their fellowship. As a few participants in this study demonstrated, such experience was valuable to their formal education in clinical and translational research. This finding could provide direction for future research within the UC MSCTR program.

Survey

Finally, the survey results corroborated much of the qualitative findings. Survey respondents were well distributed in terms of sex (almost equal at 52% women and 48% men), current position (59% fellow and 41% faculty), and institutional affiliation (70% CCHMC and 30% UC). In general, these numbers matched well when compared to descriptive characteristics of the current MS student body.

When asked to indicate their agreement, on a scale of 0% to 100%, with how well they felt the MS program met its four student learning outcomes, respondents strongly agreed all
four were met, with the mean responses ranging from 73% to 84%. Interestingly, the outcome that students indicated was least met was “Be a critical consumer of the medical literature,” a theme that did not come up in the qualitative strand very much, other than the suggestion that the program include a journal club class that critiques articles. This learning outcome is not explicitly covered in any class, but instead students are expected to gather the necessary skills to read and evaluate scientific literature throughout all of their coursework. Since it scored the lowest in terms of students’ perceived learning, this outcome should be addressed more intentionally and specifically in one or several courses. Many other similar CTR training programs include a journal club that meets regularly, ("The New Jersey Medical School Physician Scientist Skills Program for 2013-14," 2015; "Physician Scientist Development Program," 2015; "Physician Scientist Training Program," 2015; "Physician Scientist Training Program in Pediatrics (PSTP2)," 2015) and creating such a class here at UC would address this outcome more effectively.

Given the qualitative findings of this study, it is not surprising that the outcome with the second-lowest rating from students related to their understanding of biostatistics. When asked if they felt the MS program prepared them to “understand biostatistical approaches and sources of error in order to successfully interpret and communicate quantitative data analyses,” survey respondents indicated that this outcome was met with almost 77% satisfaction, which is still a pretty high level of agreement for an aspect of the program that was frequently criticized. However, statistical training was clearly an area in need of improvement. Strong knowledge of statistics is essential for physician-scientists (Castles, 1979; Marks, 1982; Supino & Richardson, 1999), and statistical instruction needs to be applied and relevant (Supino & Borer, 2007).
Next, students rated their satisfaction with being able to “formulate well-defined research questions, hypotheses and specific aims, and appropriate methodology to implement clinical research” at almost 83%. This was not terribly surprising, since this learning outcome is directly addressed in a required course, Design and Management of Field Studies. The skills included in this learning outcome encapsulate many of the core competencies described by NCATS for clinical and translational research training, so they are essential (Abu-Zaid, 2014; "Core Competencies for Clinical and Translational Research," 2011; "Core competencies for clinical and translational research," 2013).

Finally, students rated highest satisfaction with the fourth learning outcome, “understanding responsible conduct of research according to NIH standards.” The mean level of agreement with this learning outcome was 84%, demonstrating that the Scientific Integrity/Research in Ethics course, along with other courses that discuss issues related to responsible conduct of research, is very effective. Ethics are fundamental when conducting research in a clinical setting, particularly on a human subject population. Although trainees receive ethics training as part of their medical degrees, research ethics are unique and require special treatment within a CTR training program ("Core Competencies for Clinical and Translational Research," 2011; Ezekiel, Wendler, & Grady, 2000; "Patient Recruitment: Ethics in Clinical Research," 2011).

Student responses to the next set of questions in the survey supported the qualitative data in this study as well. When asked to indicate how valuable specific courses were for them, students ranked the MS core requirements as follows, starting with least valuable: Division of Epidemiology Seminar (40.04), Introduction to SAS Programming (49.63), Introduction to
Biostatistics (71.81), Ethics in Research/Scientific Integrity (74.35), Clinical Research Scholars Seminar (76.04), Design and Management of Field Studies (84.69), and Introduction to Epidemiology (86.78). The two highest rated classes, Design and Management of Field Studies and Introduction to Epidemiology, utilize very applied, engaging instructional methods, and the topics they cover are both interesting and useful for beginning researchers (Knowles, 1970, 1973, 1980). The professors of both classes are also very well-liked. The third most highly rated core class, Clinical Research Scholars Seminar, is a unique seminar taught by two physicians with years of research experience. This course covers unusual topics such as job negotiation, getting the most out of national meetings, and mentorship. Most students found this class helpful and interesting, but a few complained that they received this type of information elsewhere, so it was not as useful for them (Knowles, 1970, 1973, 1980). It was promising, and frankly, a little surprising, to see Introduction to Biostatistics rated so highly, given the push-back students expressed about their biostatistical training being too theoretical (Supino & Borer, 2007). However, the program has invested a lot of time and resources in this course over the last three years, so perhaps those investments have paid off. There was a big jump down to Introduction to SAS Programming’s rating of just under 50%, but this was not surprising, given the qualitative data that demonstrated students found this course troublesome and ineffective (Supino & Borer, 2007). And finally, the Division of Epidemiology Seminar is a class that most students choose to present at once, rather than attend, so as it is currently offered, it does not serve a major purpose in the MS curriculum. Most students report that they considered it just a box they have to check before graduation, without getting anything out of it.
Next, students were asked to rate the value of any elective and selective courses they completed. These courses were rated fairly highly, with Decision Analysis and Cost-Effectiveness Analysis leading with 87.08%. This course is taught by a physician, and students often comment on his excellence as a teacher. Students also reported that the course changed their clinical practice for the better (one of their stated reasons for seeking MSCTR training), and that they could come away with an article manuscript, which was extremely valuable (Knowles, 1970, 1973, 1980). The next two most highly rated courses, Advanced Biostatistics (78.91%) and Biostatistics in Research (74.38%) are both taught by the same instructor mentioned above, Dr. Marepalli Rao. Dr. Rao is a beloved instructor, and students enjoy his classes not just because he teaches biostatistical concepts in understandable ways, but also because he is a charming and humorous individual, characteristics that can affect student learning (Brady, 1994; Torok, McMorris, & Lin, 2004). Meta-Analysis was next with a mean score of 74.17, a strong rating. Students often reported enjoying this class because it was applied, well-taught, and they could also develop an article manuscript in it (Knowles, 1970, 1973, 1980). Study Design and Analysis was next, rating a mean score of 73.6. This course was helpful to students because it built upon the concepts they learned in Introduction to Epidemiology and Introduction to Biostatistics, giving students more in-depth information about specific study designs, and then pairing those designs with appropriate biostatistical methods. It is also one of the few advanced courses that was offered online, which students found helpful (Kassop, 2003; Stacey et al., 2004). Finally, the two lowest-rated courses on the electives/selectives list were Principles of Clinical Trials (68.25) and Regression Analysis (67.59). Principles of Clinical Trials had a new instructor as of Fall 2014, so most respondents likely took
the course under the previous instructor, who was not a good fit for the material. Regression Analysis also struggled for several years because of health issues with the professor, but it has since been taken over by a new instructor, so its future is optimistic (Brady, 1994; Torok et al., 2004). Both of these final two are heavy statistical classes, so it is no surprise that students rated them lower than the others, given their qualitative feedback on the statistics classes overall.

Finally, students were asked to indicate their agreement with five “quality” statements related to their overall academic experiences in the MS program. Respondents rated all five statements in the 70s. Students agreed least with the statement, “The course schedule worked well with my schedule, allowing me to take the courses I wanted,” echoing student complaints about scheduling from the qualitative strands, and reflecting participants’ struggle to make their personal, clinical, and academic schedules mesh (Berling, 2013; Ross-Gordon, 2011; Young et al., 2006). Next, students least agreed with, “I was very satisfied with the variety of courses that were offered,” an issue that did not come up very much in the qualitative strands. If anything, students suggested they would like a more directed curriculum with a more specific sequence of courses. However, the lower rating on this question could have been connected to participant complaints about courses that are offered only every other year. Also, the MS program could consider conducting needs assessments regularly to determine what types of classes students would like to take, and developing new content as new fields and methods become popular (Kimmel et al., 2012; Osgood-Treston, 2001). The remaining three statements were all rated above 75%: teaching in the program was high-quality (75.59), coursework was appropriately challenging for a master’s degree (78.67), and the number of courses required
was appropriate (78.93). These were strong ratings that did not indicate a need for major change. 100% of respondents said they would recommend the MS program to others, which was extremely encouraging.

The Interplay of Theory, the Research Process, and Results

Chapter 2 discussed three theoretical frameworks that supported this study: Bruner’s (1960) constructivism theory for curriculum development, disciplinary socialization theory (Bess, 1978; Lave & Wenger, 1991; Merton, 1949), and Knowles’ (1973, 1980, 1984) learning theory of andragogy. All three of these frameworks for approaching clinical and translational research training proved extremely useful in the planning and implementation of this study, but especially in the interpretation of the findings and the concluding recommendations and implications. In designing the study, understanding the ideas behind Bruner’s spiral curriculum model, disciplinary socialization theory, and andragogy affected the development of questions that would speak to the issues unique to each theoretical framework. For example, two of the three key themes from the GLA were that students wanted a more directed curriculum and that unity throughout the training program is an issue. Both of these relate to Bruner’s spiral curriculum model, and interview questions 4a and 4b directly followed up on these themes: “4a. Tell me your thoughts about a more directed curriculum (this could mean a stricter list of requirements/less flexibility or possibly a specific sequence of courses). 4b. Unity and cohesion throughout the curriculum seems to be an issue. Was this an issue for you, and if so, do you have any ideas for how we could improve the sense of connectedness throughout your entire MS program?” Similarly, many of the questions about the curriculum and instructional methods were prompted by the principles underlying Knowles’ learning theory of andragogy, and other
questions addressed program mentorship as a way to touch upon disciplinary socialization theory. In fact, virtually every theme that resulted from this study can be tied back to one or more of the three theoretical frameworks, either directly or indirectly.

**Bruner’s Spiral Curriculum**

As discussed in Chapter 2, Bruner’s theories of learning generally adopted a constructivist outlook on learning, proposing that learners come to experiences with knowledge about a larger structure, or system, at work in their worlds, and this structure provides bounds for any new knowledge acquired from learning experiences. Bruner (1985) imagined stages of cognitive development as a learner brings new knowledge to what he or she already understands about a known structure, and then adapts that existing knowledge to accommodate the new information. The spiral curriculum is essentially a curriculum of iterative phases of learning. Although originally developed with school age children in mind, it is equally appropriate for an adult learner population, where experience arguably plays an even more important role in learning. In an academic program designed using Bruner’s spiral curriculum model, basic, core ideas are introduced at the start. As students move from the introductory coursework into the more advanced coursework, the same ideas are presented, but with increasing difficulty and specialization.

This model could serve a curriculum in clinical research very well. For example, because clinicians often struggle with biostatistics, a spiral curriculum would first introduce them to basic statistical concepts, such as probability. Once students have a strong grasp of this fundamental concept, instructors could revisit it, but also build on it by discussing Bayesian probability. In a more advanced class, students could again relearn the basics of probability and
Bayes’ theorem, but also build further to include Bayesian linear regression. Instructors should take care throughout the process to ensure that students are making connections between their early learning of probability and their later learning of more complex uses of probability. Finally, a student could take actual output from a data analysis that uses Bayesian linear regression and interpret it appropriately, demonstrating a basic mastery over the concept.

Although students in this study eventually concluded that cohesion was not a major problem in the MSCTR program, they did affirm that they want a stronger sequence of core courses and they want better integration of biostatistics and epidemiology in their coursework. These two themes indicate that there is some disconnect between the learning that takes place across their individual courses. As the curriculum is currently designed, professors from different fields and departments teach their specific classes with little direction from the program administration, outside of basic guidelines on topics that should be covered. Professors who teach advanced statistics courses have a general idea of what students learn in their introductory courses, but much of that understanding is assumed. It would be much more effective for the MSCTR program leadership team to present a unified approach to teaching the training program’s goals, and then work with faculty members to ensure that the same core topics are revisited over time and with increasing difficulty. Under its current curriculum model, students do report they obtained understanding of many core ideas related to clinical research. But student learning would certainly be enhanced, perhaps radically, by adopting a more intentionally iterative curriculum model.
As Malcolm Knowles (1970, 1973, 1980) described in his learning theory of andragogy, adults bring different assumptions than children to their learning experiences. He theorized that typically, adults seek information they feel is valuable to them, both intrinsically and extrinsically, and that can be applied within their lives (Knowles, 1973). They appreciate self-directed educational experiences, and they prefer to work independently towards their own defined educational and professional needs (Kimmel et al., 2012; Knowles, 1970, 1973, 1980). Adults also tend to view life experience as an important contributing factor to expertise (Knowles, 1980). Using Knowles’ theory of andragogy as an interpretive lens in this study was very appropriate. Participants’ concerns and responses matched up well with the characteristics attributed to adult learners. Physicians who seek research training do so for very specific reasons, such as improving their clinical care or improving their ability to collaborate with other researchers in their field. Because of this, they want instruction on very specialized topics, related to both their current research projects and their future research goals. Many of them come with previous experiences, both clinical and often research-related, that serve as strong motivators for their educational goals. They appreciate coursework that makes itself compatible with their current research. For example, students love a class such as Meta-Analysis where they can take a topic of their choosing, learn about how to choose and analyze previous studies within that topic, and at the end of the class, have a publication manuscript almost ready for submission. Or, in a class like Regression Analysis, students can learn the principles of different types of regression models while also analyzing their own clinical data.
Interestingly, in interviews and journal submissions, unprompted by the interviewer or by journal prompts, many students recognized their own tendency to approach their training as a typical adult learner would. This awareness of their own learning style came up most often in discussions about the curriculum or instructional methods. Two participants specifically mentioned adult learning, in the context of providing a formal framework of study that includes more specialized, physician-centered coursework that gives students the practical training they need. One student perfectly expressed a very specific need he has in order to do his job better; he stated that he comes to the classroom with a structural understanding of the way clinical research works, and where the gaps in his knowledge lie, and he wants coursework that will address those gaps. Another student talked about the formal training framework the MS provided him, which was exactly what he needed as an adult learner. Here again, the andragogy theory directly applied to this students’ training interests and goals. Many physicians came to the program having a strong sense of what they need to learn, but not knowing where or how to start.

Knowles’ andragogical theory of learning also played a strong role in the instructional methods pattern. Because adult learners in the MSCTR program do manage heavy demands, both professionally and personally, online courses were frequently cited as a major factor that contributed to students’ success. Knowles (1970, 1973, 1980) and Kimmel et al. (2012) describe adult learners as self-directed students who prefer to work independently towards their own defined educational and professional needs. As one participant described, the online coursework allowed him to complete coursework on his own time, which was essential given his work and family commitments. He specifically characterized his approach as an adult
learning style, encapsulating Knowles’ outline of the adult student: a person with very specific educational goals, limited time, and lots of motivation to learn independently.

**Disciplinary Socialization Theory**

The field of clinical and translational research is very unique and although it has been around for several decades, it has undergone significant changes over that time. Because formal degree programs have only recently been developed, many older researchers did not complete official research training, but instead learned “on the job” or from mentors and older colleagues. Only a very small subset of clinicians achieve long-term research success in the form of grant funding, and so culturally, these physicians develop their own values, behaviors, ways of thinking, networks of affiliations, even their own argot. To increase the likelihood of physician-scientists receiving grant awards for well-designed scientific studies, much of the culture of the field has been codified through training programs such as the UC MSCTR, mentorship programs, and a clear career path of investigator awards that starts with early career awards that are heavily mentored and leads to fully independent awards that often entail some form of built-in, return mentoring.

Disciplinary (or professional) socialization theory describes the process by which trainees learn the culture of their chosen field. Disciplinary socialization is a learning theory, but it relates to more social learning than academic training, and its final result is internalization of a discipline’s unique norms. It means transforming one’s professional self-image as simply a physician treating patients into a new professional identity, one in which they fully identify with the role a clinical researcher plays in changing public health. This theoretical framework suggests that students look to older colleagues, professors, and mentors for guidance as they
work to understand what’s expected of them. Mentorship was a clear pattern in this study – students want more of it, and they want it as early in their academic studies as possible. In the context of disciplinary socialization theory, mentorship is essential for setting students up for successful research careers. The more and the better mentorship students receive from successful clinical researchers, the better they understand the field’s expectations and the better prepared they are for obtaining grants and managing successful research studies.

In this study, it was interesting to include students from both ends of the training spectrum: students in their first semester or two of coursework, students much more advanced in their MS studies, and then even a couple of alumni who are now into the early stages of their research careers. Generally, students just beginning their training hadn’t yet fully grasped how the field of clinical research works. They were able to talk about what they liked about their courses and often had a vague sense of research projects they would be working on over the next couple years, but they did not yet understand the process of research, from idea formation to finding and obtaining funding all the way through to publication. Using the four-stage model of disciplinary socialization from Figure 2 in Chapter 2, these students fall somewhere between Stage I: Anticipatory and Stage II: Formal. They had some sense of the field and were beginning to interact with their older colleagues who were involved in research, but they were still novices about much of the culture of clinical and translational research. The more advanced students who had not yet graduated from the MS program had much more to say about how the MS program could better meet their research training needs, and they spoke with some ease about their current research projects and their future research goals. They were clearly at a later stage of psycho-social development in terms of understanding their chosen discipline,
probably around Stage III: Informal, sometimes even into Stage IV: Personal, according to Chapter 2’s Figure 2. And finally, the alumni participants were well into Stage IV of the disciplinary socialization process described by Stein and Weidman (1989). They were reflective about the ways in which their academic studies would contribute or were already contributing to their research studies, and they had a full understanding of the expectations and norms within the field of clinical research. Many of the advanced students and alumni in this study seemed to be connected to “communities of practice” (Lave & Wenger, 1991), as well. Many of them met regularly with like-minded research colleagues and knew where to find the resources they needed for their research projects.

**Conclusion: Implications and Recommendations**

Although participants in this study indicated high levels of satisfaction with most of their educational experiences in the MSCTR program at UC, they also offered many suggestions for improving the program for future trainees. Some of these suggestions were relatively simple fixes, while others will require more thoughtful consideration before moving ahead. This final section will lay out overall implications of this research study in the form of recommendations.

1. **Update the overall curriculum.**

Participants reported that the MS curriculum needs some updates, and there are two main options when considering these changes. One approach entails a complete overhaul of the core classes, and the other approach involves more minor tweaks and additions. When planning these curricular modifications, Bruner’s spiral curriculum (1985) design and the tenets of Knowles andragogy learning model (1970, 1973, 1980) should be considered.
a. **Curriculum Overhaul:** Because students want a stronger sequence of classes, better and more applied statistical instruction, more physician-centered coursework, and better integration of epidemiology and biostatistics, the MS program core could be completely redesigned to address all of these issues. Essentially, this would involve restructuring all of the core classes into much larger, more comprehensive courses that would incorporate topics taken from the current core classes and teach them in a more integrated way. For example, instead of requiring Introduction to Epidemiology, Introduction to Biostatistics, Introduction to SAS Programming, a regression class, Scientific Integrity/Ethics in Research, and Design and Management of Field Studies, all of the topics within those courses would be combined into two major courses, totaling 8-12 credits and spanning two semesters. These two courses could simply be called “Clinical and Translational Research I” and “Clinical and Translational Research II” (CTR I and CTR II), and they would be taught explicitly for physician students in the MSCTR program, ideally by physicians or at least with significant physician input. Because participants asked for a new journal club-type class, that course could also either be rolled into the CTR I and CTR II classes, or it could meet separately. Students could then take one additional advanced biostatistics course of their choosing, along with an expanded Clinical Research Scholars Seminar and the Division of Epidemiology Seminar to round out the core requirements. In addition, they would still have at least 10 remaining credits that could be
fulfilled through electives of their choosing and/or independent research credits.

b. **Minor Curriculum Updates:** Instead of redesigning the curriculum entirely, more minor changes could be made to the existing curriculum. For example, statistical programming could be wrapped into the Introduction to Biostatistics course, perhaps as a one credit hour “lab,” where students use the information they are learning in Introduction to Biostatistics and apply it using one or more programming software programs. Advanced biostatistics courses could be reviewed, and changes in instructors and foci could be made to better suit the needs of the physician students and to connect the study design and analysis principles more purposefully across individual courses. Design and Management of Field Studies and the Clinical Research Scholars Seminar could each be increased by one credit, giving more time to cover the additional material students requested. Finally, a journal club class could be added, possibly even framed as an advanced biostatistics course that focuses on different types of quantitative analysis techniques.

2. **Improve statistical training.**

The majority of participants were unsatisfied with their statistical training, often starting with Introduction to Biostatistics and continuing on through to the advanced biostatistics classes. The MS statistics courses would benefit from instructors who teach more to a physician-scientist’s needs, essentially going in-depth into statistical concepts, but keeping the instruction
applied, and not overly theoretical or mathematical. Additionally, Introduction to SAS Programming is definitely not working well in its current model. Students would get more out of a statistical programming class that provides an overview of the different programs available to them, without deeper examination of the minutiae of any one program.

3. **Invest in existing online courses to make them better, and continue to develop coursework for online learning.**

Participants in this study almost universally lauded the move to online coursework, primarily because of the increased flexibility and accessibility it allows. However, they also recognized that something is lost when a classroom is entirely online. Participant experiences in existing online courses were mostly positive, but also problematic at times. The MSCTR program should address issues in existing courses to make them as good as possible. Students also support additional online course development, but again, with quality being the primary goal.

4. **Consider more creative ways of integrating both online and in-person work into the curriculum.**

Students recognized they often gained a better understanding of content when professors and students came together in a more traditional classroom-instructional model. But, demonstrating some of the principles of andragogy (Knowles, 1970, 1973, 1980), participants also wanted the flexibility and self-directed learning inherent to online courses. Because of this, the MSCTR program should consider hybrid course models that include both independent, online instruction and in-person discussion of topics. With regard to recommendation #1a.
above, the two new CTR I and CTR II courses could be conducted partly online and partly in-person, easing the burden of in-class meetings for students and faculty alike.

5. **Create a more structured mentorship program within the MSCTR.**

Although most students indicated the mentorship they received through their home departments was good enough, they welcomed more mentorship from different types of people. The MSCTR program should develop a list of capable mentors who are agreeable to meeting with early clinical researchers 2-4 times a year. The MS program should connect mentees with mentors within the first semester of their training, arrange for a mentoring relationship contract, and strongly recommend regular meetings, possibly even making them compulsory using documentation. The MSCTR should also evaluate its mentorship program annually to ensure that both mentors and mentees are meeting their obligations.

These five concluding recommendations succinctly summarize the implications of this study’s findings. Previous quantitative research demonstrates that the MSCTR program at UC is successfully training physicians for careers in clinical and translational research, and this mixed methods study supports those findings. However, results of this study also reveal that the program could do more to better educate its students and to transform itself into a leading training program in the U.S. Since its formal establishment in 2009, and even long before, program administrators and faculty have striven to provide effective, valuable training to physicians looking to transform their own fields through research. Students come to their graduate studies with a passion for learning how to design and conduct research studies that
will help them practice better medicine, and it is our responsibility to meet their passion with training excellence.
References


correlates at a small, Midwestern liberal-arts school. *Journal of Academic and Business
Ethics, 9.*

283(20), 2701-2711.

matter: Results from a survey of faculty mentees at a large health sciences university.
*Medical Education Online, 15.*

Finlay, W., Desmet, C., & Evans, L. (2004). Is it the technology or the teacher? A comparison of
online and traditional english composition classes. *Journal of Educational Computing

*Journal of the American Medical Association, 308*(19).

http://eh.uc.edu/Clinicalresearch/curriculum_focus.html

Fordis, M., King, J. E., Ballantyne, C. M., Jones, P. H., Schneider, K. H., Spann, S. J., . . . Greisinger,
interactive CME workshops: A randomized controlled trial. *Journal of the American
Medical Association, 294*(9), 1043-1051.

College of Medicine. Cincinnati, OH.


*Degrees and Programs*, (2015).

Kitzinger, J. (1994). The methodology of focus groups: The importance of interaction between research participants. *Sociology of Health & Illness, 16*(1), 103-121.


Malik, A. S., & Malik, R. H. (2002). The undergraduate curriculum of Faculty of Medicine and Health Sciences, University Malaysia Sarawak in terms of Harden's 10 questions. *Medical Teacher, 24*(6), 616-621.


Singh, T. (2010). Creating opportunities for students in large cohorts to reflect in and on practice: lessons learnt from a formative evaluation of students' experiences of


http://www.col.org/pcf3/Papers/PDFs/Ussher_Bill.pdf


Appendix A: Consent Form

IRB #: 2013-7614
Approved:
3/15/2014
Do Not Use After:
3/14/2015

Informed Consent Document

Title of Study: Clinical and Translational Research Participatory Study
Principal Investigator: Jackie Knapke, EdM
University of Cincinnati Department: Department of Environmental Health
Date: December 2013

WHAT IS THE PURPOSE OF THIS FORM?
This consent form gives you the information you will need to help you decide whether to participate in this research study or not. Please read the form carefully. You may ask any questions about the research, the possible risks and benefits, your rights as a volunteer, and anything else that is not clear. When all of your questions have been answered, you can decide if you want to participate or not.

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?
The purpose of this project is to allow you, a student in the Clinical and Translational Research training program, to contribute to future research in the field by giving them the opportunity to articulate your expectations, needs, and actual experiences in the our training program.

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH STUDY?
You are invited to take part in this study because you have matriculated into the Clinical and Translational Research training program at the University of Cincinnati.

WHAT WILL HAPPEN DURING THIS RESEARCH STUDY AND HOW LONG WILL IT TAKE?
This study is comprised of five key aspects:

1. We will first meet for a focus group to discuss the study. Once you understand the study and sign this informed consent document, we will discuss your experiences in the training program as a group and ask if you have suggestions for research ideas related to the your training. The focus group will take approximately hour.

2. I will access your application materials to the training program, including your personal statement and career goals.

3. We will meet once for a one-on-one interview to discuss your experiences in the program as an individual and ask if you have suggestions for research ideas related to your training. The interview will last approximately 30-90 minutes.

4. You will submit 6-8 journal entries. I will provide a prompt for about half of the journal submissions, but the other half will be open for you to reflect on your clinical research training experiences. Journal entries should be at least 1 typed page and can be submitted via email.

5. I will provide the results of this study to you via email and invite your comments.

We will use a digital recorder so that I can collect what is said during the focus group and interviews. You should not agree to take part in this study if you do not wish to be recorded. The study will be conducted in 2014.

WHAT ARE THE RISKS OF THIS RESEARCH STUDY?
This study poses no risk to your health. There is a small risk of loss of privacy. Your identity will be kept confidential and all information collected will be stored in a locked file and/or password-protected computers. We will ask members of the focus group to avoid talking outside the group about anything they heard during the discussion. However, there is a risk that comments you make during the discussion may be shared outside of the group. We plan to present and publish the results of this work, and we might find it useful to include information
or a quotation from your interview. Your real name will not be used, but your gender, age, and affiliation might allow people who know you to identify you.

**WHAT ARE THE BENEFITS OF THIS RESEARCH STUDY?**
This study will help us know if there are any areas that you feel need further research within the field of Clinical and Translational Research training. You could personally benefit from improved training, or our future students could benefit from improvements.

**WILL YOU BE PAID FOR PARTICIPATING?**
You will be paid a total of $200 for your participation: $50 after your first focus group, $50 after your individual interview, and $100 upon submission of your final journal.

**WHO WILL SEE THE INFORMATION YOU GIVE?**
Only the research staff involved in this project will be able to see the information. The information will be kept in locked filing cabinets or in a secure computer. Any data will be retained in an identifiable state for potential future unspecified research. Secondary analysis could occur for collected data to identify future areas of research.

If the results of this project are published, your identity will not be made public. We will not identify you in any way. We will not identify you if we quote your comments in a publication.

**DO YOU HAVE A CHOICE TO BE IN THE RESEARCH STUDY?**
If you decide to participate, you are free to discontinue participation at any time with no adverse effects. We want you to be comfortable in this project, which includes the ability to leave at any time, if you decide to do so.

**WHAT IF YOU HAVE QUESTIONS?**
If you have any questions about this research project, please contact: Jackie Knapke, University of Cincinnati, email: jackie.knapke@uc.edu, phone: 513-558-0809.

If you have questions about your rights as a participant, please contact the University of Cincinnati Institutional Review Board (IRB) Office, at (513)558-5259 or by email at irb@ucmail.uc.edu.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Participant’s Name (printed):

__________________________________________

(Signature of Participant) (Date)
Appendix B: Interview Guide

Introduction: Some of the major themes that came from our group level assessment and then my review of your application documents (personal statements and career goals) are:

- Students are looking to improve and expand their research skills for a variety of reasons: personal experiences, to improve clinical care, to mentor and/or teach others, to collaborate better with their colleagues, to make a difference, and to further their own professional goals.
- Students want more physician-centered coursework, especially when it comes to statistics.
- Students potentially want a more directed curriculum.
- Unity and cohesion throughout the MS training is a problem – the classes often feel disconnected from each other.

The questions I’ll ask you today try to study these themes in more detail, with the goal of improving our training in the future. Do you have any questions about the study so far?

1. As you considered the MS degree, applied and have now since begun the coursework, what barriers have you faced?

2. Tell me about your experiences in the MS program so far.
   a. Has the coursework addressed the research skills and knowledge you were interested in obtaining when you began?
   b. Have you noticed a difference in your ability to consider a research question within your own field and address that question? Work with other colleagues on research projects more effectively?
   c. If you had to name the single biggest contributor to your success in the program and in your research so far, what would that be?
   d. What challenges have you faced in the program? If you had to name your single biggest challenge so far, what would that be?

3. What areas of your educational program do you feel are lacking?
   a. Teaching?
   b. Faculty involvement/accessibility?
   c. Mentorship?
   d. Advising?

4. If you could change the list of course requirements and electives, what changes would you make?
   a. Tell me your thoughts about a more directed curriculum (this could mean a stricter list of requirements/less flexibility or possibly a specific sequence of courses).
   b. At the group meeting, unity and cohesion throughout the curriculum seemed to be an issue. Was this an issue for you, and if so, do you have any ideas for how we could improve the sense of connectedness throughout your entire MS program?
   c. Tell me about your experiences as far as the method of instruction is concerned (e.g., online courses, traditional courses, seminars, etc.). What suggestions do you have to improve our teaching methods, at the course level?
   d. Are there any challenges or needs that the program currently overlooks that are most important? This could be with regard to organization of the program, curriculum, specific research skills you think are important that aren’t addressed, etc.
5. Is there anything else you’d like to share with me about your training goals or educational experiences that we haven’t covered?
Appendix C: Journal Prompts

Journal 1

For your first journal submission, I'd like to hear your thoughts on the MS program providing more specific preparation for your job searches and career planning. Many have mentioned that you would appreciate a class about navigating the job market, interviewing techniques, finding funding, thinking about or writing your research career plan, etc. Please let me know what you think of this possibility.

- Do you think a class like this is appropriate and/or necessary in the MS curriculum?
- How extensive should the coverage be (e.g., how many credits should the course be worth)?
- What topics would you want covered?
- Should the class be required or optional?
- Have you or will you receive this type of information in another way, outside the MS?

I'm looking for an approximately 1 page response, but only write as little or as much as you feel necessary. If you can email your response to me before Thanksgiving next week, I'd appreciate it.

Journal 2

A few of you are still working on the first journal submission, and that’s fine. I’m trying to spread them out week to week so you’re not writing them all at once, but whatever you prefer is okay with me. The overall goal is to have everything submitted by the end of the year.

For your second journal, please tell me whether or not you plan to pursue a research career. As you write about your decision, please consider the following questions:

- If so, why, and if not, why not?
- Has your research training impacted your decision at all?
- What other contributing factors or people have helped you reach this decision?

Please provide a good amount of detail about your thought process around this issue and all the different circumstances and experiences that have influenced your decision.

If you can send me responses by this Friday, 12/5, that’ll help keep us on track.

Journal 3

This week’s journal submission is open-ended. Write about whatever you feel is relevant to your MS training in clinical research – things we can improve (especially if it’s something we didn’t talk about during your interview), things that work really well, complaints you have about any aspect of the training, etc. I know some of you might have trouble coming up with
something to write about, but just let your brain wander a bit with regard to your research education and I bet you’ll come up with something. 😊

If you can send me responses by this Friday, 12/12, that would be great!

Next week will be our last journal week, and I’ll provide a prompt again. The sooner you submit all four of your responses, the sooner you’ll receive your final $100 Amazon gift card!

**Journal 4**

One final journal response for you: If you were to meet with a new fellow or junior faculty member who was interested in pursuing the MS in Clinical & Translational Research, what would you tell them?

If you can send me responses by this Friday, 12/19, that would be great!

Once I’ve received your final submission, you can expect the $100 gift card to be emailed to you within a day.

Thank you so much for your participation! The final steps of this project are an optional survey that I’ll send out soon and then, probably several months down the road, I will email you with the initial results of the study for your comments.
Appendix D: Member Checking Email

Hello everyone,

Thanks again for your participation this past fall and winter in the qualitative evaluation of our MS program. As promised, after analyzing the qualitative data from your interviews and journals, I’d like to present my initial findings to you and welcome your feedback.

“Member checking” is common practice in qualitative research. Qualitative researchers will sometimes provide their interpretations and conclusions to the group of people who provided the data in the first place for review and comment. It’s one technique for establishing the credibility (qualitative’s term for validity) of research findings.

Having said that, here are my summary findings, in their briefest format. My full report includes many more specific details about each theme.

If you agree with the interpretations below, you do not need to respond (unless you’d like to, or you’d like to provide further comment/clarification). If it seems I’ve misconstrued the things we discussed and the things you wrote in your journal responses, I definitely want to hear from you!

<table>
<thead>
<tr>
<th>Pattern</th>
<th>Themes in this Pattern</th>
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<tbody>
<tr>
<td>Curriculum</td>
<td>Participants want more physician-centered coursework.</td>
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<tr>
<td></td>
<td>Participants appreciate the flexibility of the curriculum.</td>
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<td></td>
<td>Participants want a stronger sequence of core courses.</td>
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<td></td>
<td>Participants want better, more in-depth, and more applied statistical instruction.</td>
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<tr>
<td></td>
<td>Participants want more integration of biostatistics and epidemiology/study design instruction.</td>
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<td></td>
<td>The CR Scholars Seminar and Design &amp; Management of Field Studies are the two classes that have the biggest positive impact. Both could benefit from expansion.</td>
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<td></td>
<td>Participants want a journal club-type class that critiques articles.</td>
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<td></td>
<td>Participants find the Introduction to SAS Programming class frustrating and not beneficial. They instead want a programming class that gives a broad overview of multiple software.</td>
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<tr>
<td>Mentorship/Relationships</td>
<td>Although most participants have strong mentorship through their home departments/divisions, most think additional mentorship coordinated by the MS program would be welcome and helpful.</td>
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<td></td>
<td>The earlier students can be connected with a mentor, the better.</td>
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<tr>
<td></td>
<td>Participants highly value other types of relationships nurtured by the MS program: faculty members, research collaborators, and other students.</td>
</tr>
<tr>
<td>Administration</td>
<td>Fitting classes in around their clinical schedules is a major challenge for all participants.</td>
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<tr>
<td></td>
<td>Courses that are offered rarely (every other year, or even just once a year) make it very difficult to take classes in which they’re interested.</td>
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</table>
All participants spoke highly of the MS program administrators and emphasized how critical they are to the program’s continued success.

Participants want more individualized academic advising, more frequently.

Participants appreciate the flexibility of program administrators.

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<tr>
<th>Instructional Methods</th>
<th>Participants want more physician-centered coursework.</th>
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<tr>
<td></td>
<td>Participants value the flexibility online courses provide.</td>
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<td></td>
<td>Participants also value the learning that takes place in-class.</td>
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<td></td>
<td>Many participants recommend more hybrid/blended instructional methods.</td>
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Thanks again,
Jackie

Jackie Knapke
Program Director
Clinical and Translational Research Training Program
University of Cincinnati
160 Panzeca Way, Kettering Labs
PH: 513-558-0809
FX: 513-558-4838
http://www.eh.uc.edu/clinicalresearch
Like us on facebook!
### MS in CTR Program Evaluation

Please provide your most current contact information.

1) First and Last Name
   
2) Title
   
3) Institutional Affiliation
   
4) Email Address
   
5) Secondary Email Address

The MS in Clinical & Translational Research lists the following educational objectives for all graduating students. To what extent do you feel that the following objectives have been met during your studies in the MS program?

6) Be a critical consumer of the medical literature
   
7) Understand biostatistical approaches and sources of error in order to successfully interpret and communicate quantitative data analyses
   
8) Formulate well-defined research questions, hypotheses and specific aims, and appropriate methodology to implement clinical research
   
9) Understand responsible conduct of research according to NIH standards

Please assess the value of the following required courses to your academic experience and your career goals.

If you did not take the course or transferred a substitute course from another institution, please leave the slider at "No Opinion."

10) Thursday Division Seminar

11) Introduction to Epidemiology

12) Introduction to Biostatistics

13) Introduction to SAS Programming

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Appendix E: Survey
14) Ethics in Research/Scientific Integrity

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Valuable</th>
<th>No Opinion</th>
<th>Extremely Valuable</th>
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15) Design & Management of Field Studies

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<th>Valuable</th>
<th>No Opinion</th>
<th>Extremely Valuable</th>
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16) Clinical Research Scholars Seminar

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<th>No Opinion</th>
<th>Extremely Valuable</th>
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Please assess the value of the following elective/selective courses to your academic experience and your career goals.

If you did not take the course, please leave the slider at "No Opinion."

17) Regression Analysis

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<th>Not at all</th>
<th>Valuable</th>
<th>No Opinion</th>
<th>Extremely Valuable</th>
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18) Advanced Biostatistics

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<th>No Opinion</th>
<th>Extremely Valuable</th>
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19) Meta-Analysis

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<th>No Opinion</th>
<th>Extremely Valuable</th>
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20) Biostatistics in Research

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<th>Not at all</th>
<th>Valuable</th>
<th>No Opinion</th>
<th>Extremely Valuable</th>
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21) Decision Analysis and Cost-Effectiveness Analysis

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<th>Not at all</th>
<th>Valuable</th>
<th>No Opinion</th>
<th>Extremely Valuable</th>
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22) Study Design & Analysis

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<th>No Opinion</th>
<th>Extremely Valuable</th>
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23) Principles of Clinical Trials

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<th>No Opinion</th>
<th>Extremely Valuable</th>
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(Place a mark on the scale above)

24) Please offer comments on any additional elective courses you took that are not listed above.

Please indicate your level of agreement with the following statements regarding your coursework.

25) I was very satisfied with the variety of courses that were offered.

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<th>Do not Agree</th>
<th>No Opinion</th>
<th>Agree</th>
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(Place a mark on the scale above)

26) The course schedule worked well with my schedule, allowing me to take the courses I wanted.

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<th>Do not Agree</th>
<th>No Opinion</th>
<th>Agree</th>
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(Place a mark on the scale above)
27) Teaching in the program was high-quality.

28) Coursework was appropriately challenging for a master's degree.

29) The number of required courses was appropriate.

30) If you were not satisfied with your coursework at UC, please offer suggestions on how we can improve student experiences.

31) Would you recommend this MS program to others?  
   ○ Yes  ○ No

32) How do you recommend we advertise our program to your directors and colleagues?

33) Please include any additional comments here.