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DESIGN AND IMPLEMENTATION OF A CAREER DEVELOPMENT PROGRAM FOR PHYSICIAN-SCIENTISTS: LESSONS LEARNED

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Abstract

Importance: While skills in health services research (HSR) and data science have great potential to advance the field of urogynecology, few clinical researchers obtain such training.

Objectives: The aim of the R25 UrogynCREST Program is to prepare the next generation of physician-scientists for a successful career in urogynecologic HSR through skilled mentoring and advanced training. The purpose of this report is to describe program implementation and lessons learned.

Study Design: Administered through the program institution and in partnership with AUGS, this program provided junior faculty with advanced online training and, through a core facility, access to healthcare databases for research projects. Participants received individualized mentoring and biostatistical support. Anonymous surveys captured actionable, real-time feedback from participants as they moved through the program.

Results: Despite a limited budget, UrogynCREST maintained a core of excellent faculty, high-quality biostatistical support, and engaged, knowledgeable advisors and mentors. This allowed for similar experiences across cohorts while permitting program improvements between cohorts in faculty-participant interactions, team dynamics, and data and regulatory support. Administrative management by a single institution facilitated responses to fiscal and regulatory changes. Asynchronized learning and partnering with a society attracted a diverse group of physician-scientists.

Conclusions: Career development programs that incorporate online education, mentoring, database access, and biostatistical support must be prepared for mid-program changes. Regular communication among stakeholders was vital. Working with a core facility provided efficient database access, but evolving regulatory and administrative processes and costs presented challenges. Our experiences implementing this program can benefit similar programs that train early-career physician-scientists.

Keywords

career development; educational program implementation; on-line learning; health services research

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INTRODUCTION

Need for Physician-Scientists in Urogynecology in Health Services Research

Pelvic floor disorders (PFD) are common and become more prevalent with age. Urogynecologists are uniquely empowered to lead the effort to maximize the value of health care and shape policies to improve the lives of women with PFD. Health services research (HSR) plays a vital role in advancing the field of urogynecology and our understanding and development of effective treatments for urogynecologic disorders. In this era of value-based healthcare, it is critical to incorporate population-based research and take advantage of data science and predictive analytics to help shed light on real-world patterns of care. However, while HSR is growing and has enormous implications for healthcare, physician-scientists have few opportunities to expand their expertise in the area.

Barriers to a Successful Research Career

There are multiple challenges that can prevent physician-scientists from transitioning to independent research careers, particularly in HSR. Common across a broad range of medical disciplines, these barriers include lack of training in research methods[1,2] and advanced statistics,[1,3,4] difficulty identifying appropriate mentors,[1,4,5,6,7] few opportunities for collaboration,[2,6,8] and challenges accessing data.[2] NIH's R25 and T32 career development programs are intended to address these challenges. However, many programs accept only individuals from the parent institution, are of short duration, or address only one or two barriers. None are tailored specifically to support research in urogynecology. Additionally, few if any provide the vital support team of administrative, mentoring, database, and statistical expertise that reduces cost and time burden for program participants.

How can we address these barriers in order to cultivate and sustain the next generation? The UrogynCREST Program addresses these challenges through implementation of in-depth, hands-on instruction, expert mentoring, and biostatistical and administrative support. Here, we discuss the implementation of this R25 program and offer lessons learned, anticipating that this program may be mirrored for physician-scientists in other medical subspecialties desiring to set up an educational and research program.

IMPLEMENTATION OF THE UROGYNCREST PROGRAM

Program Goals

The aim of the R25 Duke University/American Urogynecologic Society Clinical Research Educational Scientist Training (UrogynCREST) program is to prepare the next generation of physician-scientists for a successful career in health services research through skilled mentoring and advanced training. During the 2-year program, participants complete online coursework, attend discussion groups, meet with their assigned mentors and biostatisticians, and conduct research using large beneficiary-level databases. At the completion of the program, participants are expected to have the essential skills to conduct and publish their independent analyses and to pursue HSR collaborations and grant submissions to advance the field.

Organizational Structure

Leadership and Administrative Support.—Previous studies have found that proper administrative support is vital to program success.[6] UrogynCREST was led by a Principal Investigator/Program Director and since some tasks required coordination with the partnered organization, the American Urogynecologic Society (AUGS), it was prudent to have a coordinator at each organization. The coordinator from the program institution was responsible for developing and maintaining the online educational platform, shepherding participants through data access, serving as liaison with the biostatistical core, tracking participant progress, and preparing and submitting regulatory documentation. The AUGS coordinator was responsible for maintaining the program content on the AUGS website, opening the call for applications, organizing the application and selection process, and recording meeting minutes.

Advisory Committee.—Although an online educational program could potentially enroll an unlimited number of participants, the intense individual attention provided by this program limited the number of participants per cohort and required a selection process. The Advisory Committee (AC) reviewed applications and selected participants, provided feedback to participants and mentors during semiannual AC meetings, and provided oversight and feedback to leadership. It was comprised of six members from US institutions who were nationally recognized for their leadership, educational, clinical, and research contributions in urogynecology. Because we were partnering with AUGS, we sought advisors who were either well-published academicians in health services research (HSR) as it pertained to pelvic floor disorders and/or AUGS leaders from the research registry, educational committee, or the grant review committee. All advisors had a successful history of independent research and mentoring. There was no financial incentive and advisors were asked to commit their expertise and time without pay. The AC membership was diverse in gender, subspecialty training, academic institutions, and content expertise, which was invaluable when we encountered unanticipated issues such as participant project changes or providing an individual enhanced performance plan. The composition of the AC worked well and did not change over time.

Mentors.—Critical to maintaining a pipeline of trained HSR physician-scientists is providing mentorship. Since HSR was relatively new in PFD research, we conducted a literature search during grant preparation to identify potential mentors with publications that used large, national databases and whose expertise would align with three main areas of PFDs; epidemiology, diagnostic testing and technologies, and medical and surgical treatment outcomes. Potential mentors were approached and biosketches and mentoring information obtained to ensure that they had substantial and successful mentoring experience. At the time of selection, our mentors had mentored 132 postdoctoral trainees (86% continuing in research-related careers) and 37 junior faculty (an average of 6 per mentor). All were MDs and eight out of the nine mentors had master’s degrees in either Clinical Research Design, Epidemiology, Education, Health Sciences, Public Health, and/or Predictive Analytics and one had a Certificate in Human Investigations. A strong commitment to education and mentoring, along with HSR expertise proved extremely important since the mentors could not be financially supported by the grant (as outlined in the requirements of the

Funding Opportunity Announcement) and the mentees relied heavily on their guidance. As the number of HSR researchers in PFD increase and information on which mentor characteristics may be most important for such a program, future emphasis will be placed on recruitment via a standardized application process with the intent to continue to diversify the mentor pool.

Faculty.—The program director worked with leadership in Duke's Clinical Research Training Program and departmental chairs to identify faculty with area expertise (see Online Curriculum), the capability to develop a solid educational online curriculum, and a willingness to deliver engaged virtual discussion sessions and offer individual participant feedback for assignments. All faculty had academic appointments within the program institution (Departments of Medicine, Obstetrics/Gynecology, Population Health Sciences, and Biostatistics/Bioinformatics). Faculty were paid a stipend per session taught.

Program Participants.—The partnership with AUGS allowed for national exposure for the program. With no cost for participants to take part in this program, the financial burdens that often plague departments and institutions to train and support junior faculty development were mitigated. Since the goal of the program was to attract individuals determined to pursue careers as physician-scientists, the application process was similar to the requirements for other NIH-funded career development programs. The AC review process included evaluation of their career development plan, prior research, and concept proposal. The AC also considered candidates' potential to advance their careers through participation in the program.

To strive for a critical mass, the program sought to support 15–18 individuals over the 5-year grant period. To provide a small group educational experience, the 5-year funding period was divided into three 2-year cycles with each cycle having a cohort of up to six participants. This allowed for individualized mentoring assignments, manageable biostatistical support, and the development of peer mentoring and collaboration across cohorts.

Program Structure Overview

In their first year, participants completed coursework comprised of asynchronized learning and synchronized group discussions. This format allowed busy surgeon/physicians to work at their own pace. Based on their proposed projects, participants were matched with a primary and a secondary mentor. Mentors and participants were required to sign a compact covering the expectations for both parties. The mentor/mentee team developed a detailed Statistical Analysis Plan (SAP) that gave structure and definition to their projects. Participants utilized training from their coursework and other resources to complete a well-drafted SAP. Other activities in the first year included data access training and obtaining IRB approval from their own institutions. During their 2nd year, participants worked directly with their assigned biostatistician and mentors to complete their analyses, presented their research at scientific meetings, and submitted their manuscript.

Program Components

Online Curriculum.—The curriculum content was developed based on the results of a survey to AUGS junior faculty, using a modified Delphi procedure to elicit specific knowledge gaps. Consensus was established after two rounds. This resulted in four learning modules with 3–6 sessions each (see Table 1). Participants had two weeks to complete each session, and one week to complete each assignment. There was a 2-week break between modules. Session evaluations indicated that the time commitment was reasonable.

The faculty received best practice guidelines for delivering online courses and recorded their presentations using the institution's media studio or their own professional equipment. Faculty provided learning objectives, reading materials, and final assignments. All course content was posted on the Sakai[9] learning platform. This platform was chosen for its proven ability to support similar programs, and because it was free and well-supported at the authors' institution.

Session Evaluations.—At the completion of each session, participants anonymously evaluated the session topic, reading materials, video presentation, group discussions, access to faculty member, assignments, and overall value. Evaluations were reviewed by program leadership and course faculty. Real-time feedback from the participants allowed for adjustments for the subsequent educational sessions.

Data Access and Analysis

Central to the program was the ability to access large health-related databases to conduct a research project. To make this possible in the time allowed, we partnered with the institute's PopHealth DataShare™ core facility, a collection of secure electronic health data supported by a dedicated staff, which had a streamlined process for accessing and working with a variety of healthcare databases. DataShare provided both regulatory and analytics support to obtain coverage under a Data Use Agreement, set up the protected workspace for data analysis, and access the data. A Data Use Acknowledgement was also set up between the program institution and the participant's institution.

The following steps were required before participants could access the database:

- Statistical Analysis Plan fully developed and vetted by mentors and biostatistician
- Required training (e.g., Working with Healthcare Databases, HIPAA, Data Integrity and Security)
- Data Use Acknowledgement
- Data Transfer Agreement (if applicable)
- IRB approval from participant's institution

Meetings

Participating in online courses with only email communication among program members can feel quite siloed. Therefore, participants met quarterly with the Program Director

and Program Coordinator to discuss their research projects and receive feedback from the director and their peers. Participants discussed potential collaborations. Mandatory mentee-mentor-biostatistician meetings (scheduled one to two times per month during data analysis) helped participants define and achieve feasible program goals. During biannual Advisory Committee meetings, participants presented updates to the AC, their mentors, and their cohort on their project. Mentors provided assessment of their mentee's progress. A question-and-answer period after each presentation offered opportunity for participants to receive valuable feedback from the committee and their peers. Participants who had a time conflict submitted written or pre-recorded updates prior to the meeting for the AC to review.

Program Success

Overall academic growth during UrogynCREST program.—Career progress was tracked via REDCap which gathered data on participants' presentations, publications, grant submissions, and RCR training. This information was provided to the AC prior to meetings and included in annual reports to NIH.

At the time of this writing, Cohort 1 has recently completed the 2-year program, Cohort 2 has completed the curriculum (Year 1) and started on their projects, and Cohort 3 has begun Module 1 of the curriculum. This shows a continual flow of productivity. We include here progress to date.

After finishing all coursework, completing their database project, and submitting their manuscript to a peer-reviewed journal (FPMRS, J. of Urology, Urology, and American J. of Obstetrics and Gynecology, International Urogynecology), all six Cohort 1 participants received certificates for their successful program completion. All Cohort 1 participants presented their UrogynCREST research at national meetings (e.g., AUGS, SUFU, Society of Gynecologic Surgeons, American Urogynecologic Society). During their time in the program, Cohort 1 published 42 papers (average, 7). Of the seven UrogynCREST project manuscripts submitted by Cohort 1, six have been accepted and one is under review. Recently, one of these papers was highlighted in *This Week in Urology*.

In addition to disseminating their work through publications and presentations, participants have begun new collaborations across cohorts and are making plans for joint research. Participants are also preparing to submit grant proposals (NIH, private, and institutional) to continue the research begun during their time in the UrogynCREST program. Three Cohort 1 participants have expressed interest in serving as secondary mentors to Cohort 3, which will not only hone their mentoring skills but could also extend their collaborations.

Reasons for success.—Based on program evaluations, we identified four areas contributing to the success of the program.

Organized leadership.: The principal investigator/program director and the program coordinator have a strong, collaborative working relationship that effectively supports participants throughout the program. Weekly meetings enabled the leadership to identify issues and make effective decisions based on changing circumstances. An organized activity-tracking system and quarterly meetings with participants helped maintain open

communications. Posting resources and documents on a central system established consistent messaging.

Dedicated mentors.: Mentors were dedicated to participant success, and engaged beyond what was stipulated in the mentor-mentee compact. For example, several participants needed a greater time commitment from their mentors than was initially planned to assist with statistical strategies and revamping of their study designs. In their evaluation of the program, participants expressed appreciation for their mentors' advice and guidance throughout the 2-year period, from project development and analysis through manuscript submission.

Skilled faculty.: Faculty were eager to share their expertise with participants and dedicated time beyond the percent effort received from the grant. Faculty provided useful feedback on assignments and were available for group discussions and 1–1 tutoring. When course evaluations showed that the session "Statistics in Health Services Research" was challenging for some participants. the faculty member restructured the module to help those with less statistical background and set up additional 1–1 meetings to walk them through the first assignments.

Database access.: The leadership team diligently worked with DataShare to ensure that participants obtained access to databases in an efficient manner. The Data Use Agreement was set up early, and training and documentation requirements were determined. Working with the contracts office, we developed the Data Use Acknowledgement between the participant's institution and the program's institution.

Lessons Learned

Despite establishing standard processes for sharing information, accessing databases, and communicating with key players, it was necessary to revise processes upon implementation of the program. Data was gathered both formally and informally. For assessing the curriculum, we required participants to evaluate each session. These anonymous evaluations used a 5-point scale from 'strongly disagree' to 'strongly agree' and included areas for qualitative responses. In addition, we elicited real-time feedback from participants via email and quarterly meetings regarding program logistics, mentor relationships, and working with the biostatisticians. Changes were made during Cohort 1, and adjustments continue as Cohorts 2 and 3 move through the program. These changes include:

Dissemination of ongoing program information.—Over the course of the first year, we found that having a central place to share information across cohorts was needed. We made use of the "Resources" feature in Sakai to upload meeting minutes and slides, biostatistical hours, IRB language, templates and forms, and articles. The "Announcements" feature alerted participants to newly uploaded resources. Group discussions with faculty via Zoom were set up on Sakai, which automatically saved the recordings for later review by participants. In addition, the program coordinator periodically sent reminder emails to participants about unfinished tasks.

Structure of group discussions.—Initially, the synchronized group discussions were deemed of marginal benefit, as no particular topic was discussed in depth. Therefore, a structured approach was initiated with participants emailing questions to the faculty member ahead of time and the faculty member creating an agenda based on participant needs. Comparing Cohorts 1 and 2, the anonymous session evaluations showed improved ratings in every session for "opportunities for group communication and discussion."

Course content updates.—Improvements based on these evaluations included changing the session order, posting slides in addition to videos, providing more relevant assignments and readings, and re-recording lectures to enhance audio quality. For example, based on participants' evaluation of the session in instrumental variables, the faculty member provided extra reading, changed the assignment, and met individually with participants which led to marked improvement in overall knowledge assessment (see Figures 1 and 2).

Accessing data.—Since participants were not part of the program institution, there were challenges using healthcare datasets. Holders of healthcare databases require participants to work on the data in a secure environment. We initially relied on the DataShare core to handle much of these regulatory requirements for access, however, the process was more cumbersome and lengthier than we had originally thought. Additional steps included HIPAA training, Data Security and Integrity training, live training with DataShare staff for initial set-up, and a background check. A tracking sheet that delineated all the required steps helped, but the process posed additional regulatory efforts. Additionally, the variety of databases was more limited than we had planned. Barriers to using a variety of databases included biostatisticians' lack of familiarity with certain datasets, no established data use agreement, and the absence of relevant variables for the proposed research. As the program evolved, bringing publicly available datasets into the program institution's secure environment became possible; however, increased time and cost constraints ultimately limited these opportunities. Nevertheless, the biostatisticians' support for the development of the analysis plan for these datasets and their consultations during analysis were invaluable.

Flexibility in response to change in biostatistical support.—Immediately after the grant was awarded, the program's biostatistical support transitioned from a percent effort allocation to an institutional "core" that billed by the hour. Because of the variability in project complexity, uncertainty in time requirements for data extraction, and the diverse needs for analytical support for each participant, it was challenging to equitably allocate biostatistical hours among participants. Initially, we estimated 90 hours per participant, but as Cohort 1 began their database work, we realized that more time was needed for some projects. Therefore, leadership and DataShare worked together to enact detailed procedures for estimating and tracking biostatistical hours per participant. Beginning with Cohort 2, we required the mentor-mentee-biostatistician team to complete a form that delineated a proposed amount of time for each activity, resulting in a range of 70–120 hours per participant.

Conclusion

This educational research career development program was designed to address some of the challenges faced by early career physician-scientists. Enhanced engagement between participants and faculty is vital for the success of online coursework, particularly in cases where participants have differing abilities. Structured communication among all key players is beneficial for participant progress. Additionally, administrative management by a single institution is essential for providing effective faculty support and handling regulatory and fiscal changes. Addressing the barriers of skill development, mentoring, data access, and administrative support at this critical career stage can help increase the pool of talented physician-scientists who can advance the biomedical field. Many of the successes and lessons learned here can be implemented in other early career physician-scientist programs where both education and research activities are planned.

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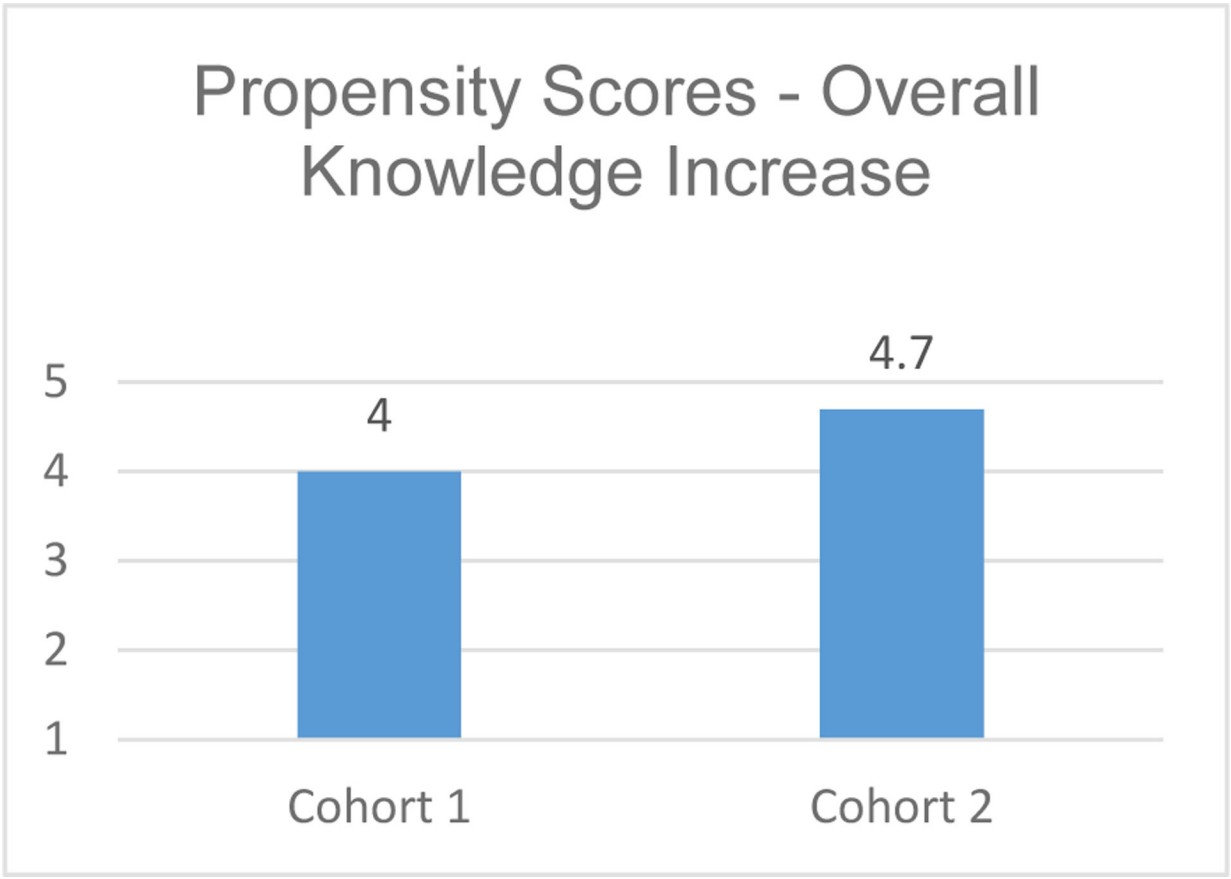

Figure 1:
Propensity Scores - Overall Knowledge Increase

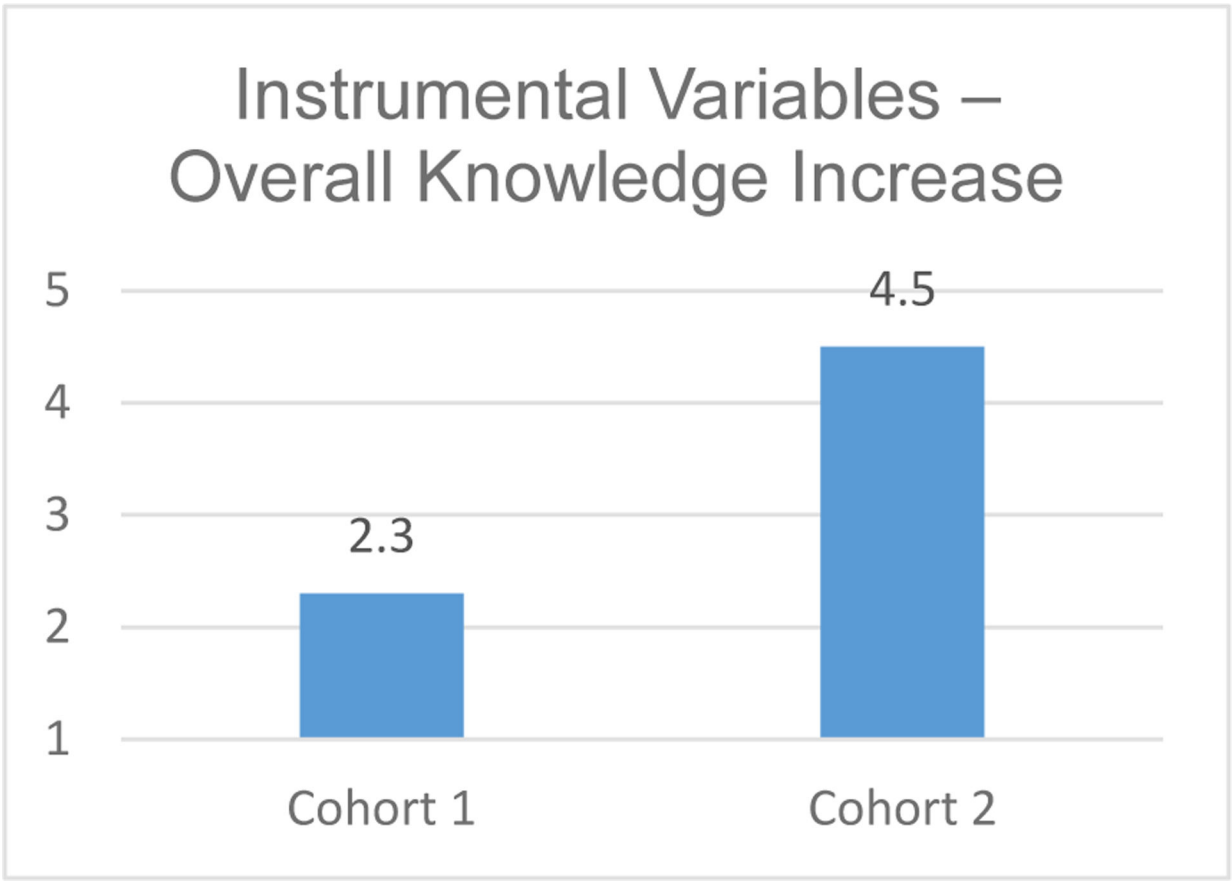

Figure 2:
Instrumental Variables – Overall Knowledge Increase

Table 1:

UrogynCREST Program Online Curriculum

Module I: Study Design	Randomized Clinical Trials Observational Studies Comparative Effectiveness Studies Systematic Reviews and Meta-Analysis Retrospective Analysis using Healthcare Databases Implementation Science
Module II: Economic, Psychometric, and Decision-Analytic Studies	Patient-Reported Outcomes Economic Analyses Decision-Analytic Modeling
Module III: Statistics in Health Services Research	Descriptive Statistics Bivariate Analysis Multivariable Inferential Statistics Propensity Score Matching Instrumental Variables
Module IV: Advanced Statistical Methods	Linear and polynomial regression Logistic regression Cross validation Model selection, nonlinear models Splines and generalized additive models Tree-based methods