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Mentoring for Success in Tobacco Regulatory Science: A Qualitative Study

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None to report.

Abstract

Objectives—Our study explores the experiences of early career and senior scientists regarding mentorship and career trajectories in tobacco regulatory science (TRS).

Methods—We conducted 22 phone interviews with early career and senior tobacco regulatory scientists from July 2015 to January 2016. All interviews were conducted using a structured interview guide and analyzed using a thematic approach by 2 independent coders.

Results—TRS presents specific opportunities and challenges to scientists due to its focused goal of informing tobacco regulation. An understanding of US Food and Drug Administration (FDA) research priorities and how science can inform tobacco regulation are essential for effective mentorship in TRS. Careers in TRS can be pursued in various academic and non-academic professional roles; both offer the distinct ability to conduct science that impacts public policy. Early career and senior scientists identified the importance and challenge of providing broad training across the diverse disciplines of TRS.

Conclusions—Effective mentorship in TRS requires that mentors possess an in-depth understanding of the scientific, regulatory, and legislative processes inherent to tobacco regulatory policy-making. A training program for mentors specific to TRS has the potential to meet diverse professional needs of mentors and mentees aiming to impact tobacco policy.

Keywords

mentorship; policy; tobacco regulatory science; tobacco; researcher training; qualitative research

Tobacco regulatory science (TRS) is “the scientific discipline that supports the evaluation of the risks and benefits of tobacco regulatory decisions and provides a robust scientific foundation for regulatory policies.” The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) provided the United States (US) Food and Drug Administration (FDA) with the authority to regulate how tobacco products are manufactured, marketed, and distributed in the US, and to carry out public education. In response, the FDA developed the Center for Tobacco Products, whose Office of Science assesses the existing scientific evidence and supports research to inform tobacco regulatory actions to protect public health.

TRS research directly informs how the FDA regulates tobacco product advertising, marketing, promotion, distribution, and sales; enforces regulations; and develops public education. Providing the FDA with useful information to regulate tobacco products requires both scientific expertise and attention to the FDA’s regulatory authority. Though our paper focuses on TRS relative to FDA regulation, TRS research also may inform local, state, national, and international policy, including clean indoor air laws or taxes that are outside the FDA’s authority. Thus, the field of TRS is more expansive than the TRS funding priorities identified by the FDA and National Institutes of Health (NIH).¹

A mentoring relationship is defined as one in which a mentor with relevant knowledge and experience supports and guides a mentee’s professional development. Evidence supports that structured, purposeful mentorship is critical to prepare future researchers. In biomedical

research, training programs are well-established, such as those available through the Clinical and Translational Science Awards Program at the NIH.² Although there is a vast body of literature on best practices in mentoring for academic science generally,^{3–6} there is little available evidence to guide effective mentorship within TRS. The Society for Research on Nicotine and Tobacco Trainee Network aims to facilitate professional development and networking among tobacco scientists, but does not focus specifically on TRS.

In September 2013, the NIH Tobacco Regulatory Science Program coordinated the trans-NIH collaborative effort with the FDA, that funded 14 US-based Tobacco Centers of Regulatory Science (TCORS) to increase knowledge across a broad spectrum of TRS research topics. Each center provides early career investigator training, education, and mentoring to develop the next generation of tobacco regulatory scientists. The centers complement FDA-funded Centers for Excellence in Regulatory Science and Innovation that focus on medical product development and food safety and quality.⁷ To promote cross-TCORS collaboration, a TCORS Training Workgroup was formed with representation from all 14 TCORS, the FDA, and the NIH. The TCORS Training Workgroup developed a curriculum for training TRS researchers, the description of which can be found elsewhere.¹

The purpose of our study was to explore the views and experiences of early career and senior scientists as they relate to mentorship and career trajectories in TRS. Using a *grounded theory* approach, we sought to identify the characteristics of TRS that make it distinct from other research areas, understand the challenges of mentoring within this field, and depict lessons learned and recommendations for best practices in TRS mentoring. We also investigated if and how the FDA-funded TCORS impacted mentorship and career development in the field of TRS.

METHODS

Sample

The sample included 2 cohorts of TRS respondents: (1) senior scientists; and (2) early career scientists. Senior scientist participants were nominated by the TCORS Training Workgroup. TRS senior scientists were defined as leaders of TRS research efforts who were considered by members of the TCORS Training Workgroup to be authorities in TRS, and who currently or in the past served as a mentor to at least one TRS mentee. Senior scientists were selected to reflect diverse geographies and professional institutions, including universities, federal government agencies, and non-academic research institutes. TRS early career scientists were defined as those who had recently graduated from a doctoral or post-doctoral training program and were actively employed in some TRS capacity in US universities, federal government agencies, and non-academic research institutes. Early career scientists were nominated by senior scientist participants during the interview process.

Recruitment and Consent

Participants were sent a recruitment email that introduced the research study and requested their voluntary participation, without incentives. A second follow up email was sent to non-respondents of the initial recruitment email.

Prior to the telephone interview, each participant was read a consent statement explaining the nature of the research and their rights as research participants. Additionally, written consent was obtained from participants to report their data without use of identifiers.

Procedure

Two semi-structured interview instruments (one for each cohort) were designed to cover themes relevant to mentorship and career advancement in TRS, while leaving opportunities for unanticipated information.^{8–10} Themes across both instruments included examination of the novel aspects of the field of TRS, how scientists contribute to regulatory decision-making, TRS career paths, and effective TRS mentoring methods. The interview instrument development process included iterative feedback within the TCORS Training Workgroup, cognitive testing of the guide during pilot interviews with 2 senior scientists in TRS, and revision of specific interview questions after each cognitive test to ensure optimal clarity and flow. The content of the items did not change substantively after the cognitive testing, and thus, responses of the senior scientists who tested the guide were included in our analysis.

The primary method of data collection was phone interview, a method that enabled us to gather qualitative data from scientists across the country. The first author conducted all phone interviews between July 2015 and January 2016. TRS senior scientist interviews lasted approximately 45–60 minutes, and early career scientist interviews lasted approximately 30 minutes. During each interview, the interviewer recorded detailed notes. Early career scientists also were video- and audio-recorded using Cisco WebEx technology with their consent. Interview guides for both cohorts are provided in the Appendix.

Analysis

We implemented a *grounded theory* approach.^{8–10} Two coders developed a thematic code frame based on the questions in the senior scientist interview instrument. The initial code frame was designed such that each question had one corresponding code. The first author then reviewed the interview notes and applied the code frame to abstract the interview data using the qualitative software NVivo (QSR International, Version 11, 2015). During the coding process, a small number of additional codes were created, corresponding to unanticipated themes that emerged from the interviews. Using the early career scientist interview instrument, the first author repeated the same code development and coding process. An additional author (MCC) undertook a thorough second coding of the interview data set to ensure inter-rater reliability of coding.

Inter-rater reliability was calculated for each coded interview using percentage agreement. Reliability between the 2 coders was adequate; agreement was 70% or higher (mean = 80%) on all senior scientist interviews, and was 70% or higher (mean = 80%) for 11 out of 12 early career scientist interviews. Agreement for the remaining early career scientist interview was 60%. Due to the low reliability rating for this interview, the 2 coders met to reach consensus and ensure that only correctly coded data were used in the analysis.

The first author identified recurring themes related to each code for both participant groups, and reported on the frequency of identified themes. The first author also identified illustrative quotes that synthesized opinions from multiple participants. We used the Critical

Appraisal Skills Programme Qualitative Research Checklist as a guide for ensuring the rigor and quality of our research methods.¹¹

Systematic Review

To place our findings in context we conducted a systematic review by consulting a medical librarian to review the literature on mentoring and regulatory science. We restricted our search to English language articles and searched on various terms for mentoring, and regulatory science and translational medical research. The methods are reported in the Appendix.

RESULTS

Table 1 summarizes participant characteristics. All 10 TRS senior scientists who were nominated participated in our research (100% response rate). Of the 15 TRS early career scientists nominated, 12 participated in our research (80% response rate). Their formal education backgrounds included chemistry, epidemiology, pharmacology, anthropology, communication science, plant biology, molecular biology, biochemistry, health behavior, and psychology.

Table 2 highlights illustrative quotes from senior scientist interviews. Table 3 highlights illustrative quotes from early career scientist interviews across relevant themes.

Challenges of Mentoring in the Field of TRS

Senior scientists and early career scientists agreed that TRS is different from other scientific fields and that standards for TRS training programs are still emerging.

TRS Differs from Other Scientific Fields

Senior scientist perspective—Senior scientists emphasized that the regulatory focus distinguishes the TRS field from other scientific fields, with 2 distinct themes. Senior scientists highlighted a tension between providing cross-disciplinary training to provide trainees a broad base of knowledge and skills consistent with career development and the narrower focus on TRS. Senior scientists identified that the diverse career paths available to TRS trainees presented a challenge to traditional mentoring, especially as it related to mentees potentially pursuing careers in tobacco companies.

First, the scientific approach necessary in TRS differs from other scientific research areas because it requires framing research questions according to regulatory needs. Specifically, conducting TRS research requires an understanding of the Tobacco Control Act and the ability to address research questions that are responsive to FDA funding priorities to regulate tobacco. Results revealed a shift in how senior scientists developed their research agendas.

“It’s made me think more about how what I do might have policy relevance, and how my research aims might fold back into this bigger picture of what we need to know to reduce the burden of tobacco on society.”

Multiple senior scientists specifically mentioned that they recently shifted their research agendas away from such topics as tobacco cessation or specific types of mechanistic

research because the topics did not address the FDA's regulatory needs. One senior scientist said:

“As I think of research questions, I often think about whether the question is or could be relevant to regulatory science, since the FDA has a dedicated funding stream to address regulatory science. But I'm not going to encourage a fellow to not pursue a question of interest because it doesn't apply to regulation. But for the ones who do have interest, we're aware that they have a better chance of getting it funded if they can clearly show the relevance to FDA.”

Second, TRS makes a clear impact on public policy and population health, requiring navigation of political and legal issues.

“With TRS, I can't think of a clearer picture where all of the science comes forward together to inform policy. Oftentimes that's an afterthought in science.”

Early career scientist perspective—The majority of early career scientists interviewed reported entering the TRS field through circuitous routes without a TRS background. Most reported shifting their research foci at some point in their careers and applying their training in other scientific areas to TRS. Some early career scientists reported that their shift was due to their skills being better suited for TRS research than for clinical work, whereas others shifted from research in other health areas to a focus in tobacco. A few early career scientists cited the lack of freedom to determine their own research direction, and having to change research directions during their training, as career setbacks.

Despite the challenges, early career scientists reported that engaging in TRS was particularly meaningful because it enabled them to directly impact a significant public health issue and work at the intersection of science and policy. Multiple early career scientists working in government found career satisfaction in the significance and scope of their work at the federal level intersecting research and policy.

Emerging TRS Training Program Standards

Senior scientist perspective—The majority of senior scientists reported that broad training in and outside TRS is critical for long-term career success and marketability. One senior scientist remarked that because tobacco regulatory scientists have historically received formal training in diverse scientific disciplines before entering TRS, developing a training program that provides a common knowledge core while simultaneously enabling each mentee to develop his/her own strengths was a challenge. Similarly, multiple senior scientists expressed that more scientists are being trained in TRS than there are positions to employ them, so it is essential that mentees receive broadly applicable scientific training to support their long-term career development and job marketability.

Early career scientist perspective—The aforementioned aspects of TRS standards and training were corroborated independently by the early career scientists.

Other TRS Mentoring Issues

Results also revealed challenges of TRS mentorship that were described by only one of the 2 cohorts.

Senior scientist perspective—The majority of senior scientists indicated that they had not encountered conflicts of interest as scientists and mentors in TRS. The potential conflicts of interest that were reported included determining the acceptability of consulting with pharmaceutical companies, partnering with the tobacco industry, pursuing careers with companies that sell e-cigarettes or harm reduction products, and participating in litigation involving big tobacco companies. A few senior scientists strongly emphasized that the changing landscape of tobacco products and regulation raises new potential challenges and conflicts.

Senior scientists also reported that they faced challenges in their TRS mentoring roles including helping early career mentees distinguish between regulatory and non-regulatory tobacco science, helping mentees find funding opportunities within the FDA authority, and encouraging the professional flexibility and collaboration necessary to succeed in TRS.

Early career scientist perspective—Early career scientists were not asked directly about conflicts of interest experienced. However, one early career scientist reported receiving backlash from tobacco companies after publishing a paper as a challenge encountered specifically in TRS.

Early career scientists had a number of recommendations about how TRS mentors could have been more effective. Multiple early career scientists reported that past mentors could have been more helpful if the mentors had better understood and engaged with the various methods and scientific fields of study within TRS. Additionally, multiple early career scientists emphasized that successful mentors teach mentees how to develop and nurture a broad professional network across scientific fields and disciplines.

Overcoming the Challenges: Effective TRS Mentorship Methods

We use the following phases of mentorship, relevant to any career path, to provide a framework for TRS mentorship: (1) onboarding a mentee with a mentor; (2) aligning mentee goals, roles, and expectations; (3) cultivating opportunities for mentee growth; and (4) mentee-mentor relationship transition or closure. Figure 1 summarizes our results relating to TRS mentorship methods reported by senior and early career scientists by framework phase, identifying general mentorship skills versus those specific to TRS.

Onboarding Mentees

Onboarding includes typical orientation activities, but more comprehensively involves ensuring that mentees understand the organization's culture, structure, and how to accomplish goals effectively.¹² The majority of senior scientists conduct a needs assessment with potential mentees at the beginning of the relationship. The needs assessment enables the mentor to understand the mentee's goals and appropriately support the mentee's success.

For many mentees, the results of this needs assessment mature into an Individual Development Plan (IDP) that evolves over time.

Multiple early career scientists cited either a family history of tobacco-related disease or being matched with an effective mentor working in TRS as catalyzing their initial entry into TRS. The majority of early career scientists also mentioned specific mentors who impacted their choice to work in TRS through such actions as involving them in tobacco-related studies, role modeling successful careers, and expressing confidence in the early career scientist's abilities.

Aligning Goals

The majority of senior scientists reported that major mentoring challenges in TRS include helping mentees to think and communicate in regulatory terms and providing mentees with a cross-disciplinary academic foundation in TRS. Many senior scientists said that their primary mentoring goal is to assist mentees in developing scientific research skills and the mentee's vision for his/her own career. Specific skills include developing strong research design and methodological skills, grant writing, and academic writing skills. Multiple senior scientists reported aiming to help mentees understand the broad scope of TRS as a field, including a common core understanding across relevant disciplines.

“...Primary goal is having people answer a question that will improve tobacco policies so that they will reduce the disease and public health burden of tobacco... Learn what policies are effective and ineffective, or how to tweak a policy to make it work.”

Senior Scientist Respondent

During the goal alignment phase, senior scientists also orient TRS trainees by exposing them to TRS resources (eg, Tobacco Control Act; FDA Research Priorities; Surgeon Generals' reports) and involving their mentees in relevant professional meetings. Other initiation steps include providing program-specific orientation lectures and readings, encouraging participation in journal clubs, and helping mentees file public comments with the FDA.

Early career scientists reported a few career challenges faced at this stage of mentorship, including changing research directions or advisors and struggling to find help during their doctoral studies outside of their laboratories.

Cultivating Opportunities

In the Cultivating Opportunities phase, the mentor and mentee continue to monitor expectations to achieve the agreed upon goals. Senior scientists named networking and accessing job opportunities as critical means for mentees to meet their career goals. The steps they take to assist mentees in these critical activities include connecting mentees with other TRS colleagues, enabling mentees' participation at national meetings, sharing knowledge of relevant resources with mentees, helping mentees practice for presentations and interviews, providing career counseling, and guiding mentees through grant writing.

The majority of early career scientists corroborated that many of the networking strategies mentioned by senior scientists were useful. Multiple early career scientists emphasized that connections made through their mentors were essential to securing their current positions. Additional methods of networking mentioned by early career scientists included conducting informational interviews with professionals whose careers they admired and reaching out to alumni of their training programs.

Transition

In the transition phase, the majority of senior scientists indicated that academia and government agencies (including the FDA) were the most common career paths for scientists trained in TRS. The majority of senior scientists also stated that non-academic research institutions, health departments, non-profit organizations, industry, and clinical work draw smaller numbers of TRS scientists. Interviews with early career scientists confirmed a diversity of career paths in TRS, including opportunities for positions leading or managing research.

Early career scientists shared that effective mentors were those who challenged and motivated them, including enabling them to pursue opportunities of interest. Multiple early career scientists shared that effective mentors expressed confidence in their abilities, helped them broadly visualize their future careers, shared “insider” knowledge of the field, and strategized with them around long-term career goals.

Systematic Review

The details of our systematic review of mentoring in Regulatory Science are reported in the Appendix. No articles were excluded by virtue of being non-English language. We identified no manuscripts that described regulatory science mentor training within the tobacco field, or in other regulatory science fields.

Recommendations for a TRS Mentor Training Program

The majority of senior scientists indicated that they do not participate in formal ongoing mentor training to maintain or enhance their mentoring skills.

Multiple senior and early career scientists indicated that a mentor training program specific to TRS would be valuable and suggested elements to include in a structured training: ensuring that mentors have a comprehensive understanding of the scope of TRS and the Tobacco Control Act; training scientists to handle potential conflicts of interest; case studies highlighting diverse career paths in TRS; a model IDP; a core set of lectures and readings in TRS; and clarification around the definition and history of TRS. Scientists also mentioned that a comprehensive list of contacts in TRS would be helpful. One early career scientist also brought up the importance of addressing diversity in a mentor training, indicating that mentorship across scientific fields is stronger when mentors and mentees represent diverse sex, cultural, race/ethnicity, class, and regional backgrounds.

DISCUSSION

The principal findings of our interviews revealed that TRS mentoring shares many themes with mentoring in other scientific disciplines, such as an emphasis on core competencies. Other similarities include adapting mentoring as the mentee transitions from onboarding, to visualizing and aligning goals, cultivating opportunities, and fostering for a productive transition (Figure 1). The interviews identified 3 themes and challenges that were unique to mentoring in TRS. First, TRS mentees tend to come from much more heterogeneous fields than is typical in most other fields. Second, TRS mentors and mentees have to possess expert knowledge of the Tobacco Control Act, and maintain a vigilant focus on pursuing research that is specifically relevant to tobacco regulatory policies. Third, whereas there has been increasing acceptance that the majority of doctoral-trained research scientists leave academia,¹³ many to pursue careers in the pharmaceutical industry, TRS mentors expressed ambivalence about TRS mentees pursuing careers with tobacco companies.

The senior and early career scientists interviewed articulated the same broad attributes that define an effective mentor in any field. A skilled mentor regularly encourages the mentee, helps the mentee visualize long-term goals, and provides the mentee with opportunities for professional growth and development.^{14–16} Similarly, the TRS and other scientific fields evolve through the same mentoring stages, including orienting mentees to the field, ensuring that the mentor and mentee have appropriately aligned their expectations, encouraging mentees to pursue rich and diverse opportunities to maximize their growth, and focusing on smooth transitions in the mentor-mentee relationship to ensure mentee independence.^{15,17} Because the TRS field is relatively new, career paths are highly diverse, and funding potentially less certain. Similar to other fields, effective mentoring includes preparing mentees to be adaptable to changing funding priorities. Additionally, mentors assist mentees to focus on aligning their skill, passions, and values in pursuing meaningful career paths.

More specific to TRS mentoring is the necessity of having a nuanced understanding of the field of TRS and the ability to coach mentees in analytical regulatory thinking.¹ Whereas the FDA represents one major source of funding for TRS research, its priorities exclude certain types of policy and intervention research that may potentially impact public health, such as the effects of clean indoor air laws, second-hand smoke, and tobacco cessation.

Both senior and early career scientists highlighted the diversity of career paths available to a scientist interested in TRS. Interestingly, opinions were divided among senior scientists as to the existence and importance of potential conflicts of interest as a TRS scientist. The majority of senior scientists reported not encountering conflicts of interest, whereas a few senior scientists felt strongly that conflicts of interest present challenges for TRS scientists. Additionally, senior scientists in the TCORS Training Workgroup are still grappling with the complex issues of mentees potentially pursuing careers in the tobacco industry.

Strengths and Limitations

Based on our systematic review, we were unable to locate prior studies on the opportunities and challenges of mentoring in Regulatory Science. A strength of our study is that it drew on the expertise of scientists across numerous universities, institutions, and sectors, as well as

diverse scientific backgrounds, experiences, and education levels. Additionally, we employed qualitative research methods to explore questions of TRS mentorship and career trajectories, allowing a comprehensive assessment.

Our study has several limitations. Our method of selecting participants involved contacting well-known senior scientists in the field of TRS for our first round of interviews, and subsequently contacting early career scientists based on the recommendations of senior scientists. Many of those interviewed were affiliated with a TCORS center, the NIH, or the FDA, which may have surfaced more themes related to the FDA, the NIH, or biased replies towards TCORS priorities. Our method and our small sample size of 22 participants may not have resulted in a representative sample of the larger population of TRS scientists. In addition, we chose not to quantify responses in the study to avoid implying precision in the qualitative data.¹⁸

Similarly, as with any study utilizing participant recruitment, we did not receive responses from all the early career scientists we attempted to contact. It may be that the early career scientists inclined to respond to our interview requests represented a group with distinct experiences or opinions in TRS. As is true in the constructs of qualitative research, the extraction of themes is subjective and depends upon the researchers' biases. To diminish subjectivity, 2 researchers abstracted themes from the data. We acknowledge that an interviewer may affect participants' responses in qualitative studies. However, though the interviewer was affiliated with TCORS, she was not in the same organization as any participant and was not in a supervisory role with any participant. Furthermore, anonymity of responses was provided to all participants.

Although the TRS field is emerging globally, the thought leaders and early career scientists we sampled were all based in the US. Our study aims did not explore issues related to training international mentees, international placement of mentees, or regulatory challenges in other countries; thus, the generalizability of our findings to other countries is uncertain. Further research is needed to explore global TRS mentoring issues.

IMPLICATIONS FOR TOBACCO REGULATION

Our paper adds insights into how TRS is unique among scientific disciplines due to its stated goal to inform tobacco policy and regulation. Structured, purposeful mentorship is essential to the career success of both the mentor and mentee.¹⁴ For TRS mentors, our study provides insights into strategies for guiding mentees towards career success and satisfaction.

Additionally, TRS mentees entering the field may not have the knowledge to determine the qualities they should seek in a mentor or steps they can take to maximize the effectiveness of their mentorship. Our findings may help early career scientists learn about the tools necessary for success in diverse TRS career paths, as well as about the opportunities and limitations presented by the FDA's research priorities in TRS. In turn, mentees will be equipped better to make informed decisions and take strategic actions in their TRS mentoring relationships. Longitudinal tracking of mentees will inform how the investment of mentoring impacts quality in terms of career success in TRS.

In recognition that TRS requires different, and perhaps, more comprehensive training than previously has been offered to investigators working in traditional tobacco control, the TCORS Training Workgroup established a standardized set of TRS core domains and competencies.¹ The competencies emphasize a shared knowledge base that should be demonstrated by future tobacco regulatory scientists across disciplinary backgrounds. Even while the TRS field continues to evolve to meet the FDA's needs, the TRS core curriculum establishes the foundation of a comprehensive training program that exposes TRS mentees to the broad skills and knowledge necessary for success along this career trajectory.

Drawing on our findings, members of our research team are creating a training program for mentors that is specific to the needs of TRS scientists. The training program will highlight strategies for successfully conducting TRS research, both within the FDA's current research priorities and in topics outside of the FDA's purview. We anticipate that our training product will assist senior scientists across the broad range of TRS disciplines to mentor their mentees more effectively so that the mentees may pursue diverse career opportunities in TRS with success.

Human Subjects Statement

The study was deemed exempt from human subjects review. The Boston University Medical Campus (H-34718) and Westat (OHRP IRB00000695) Institutional Review Boards both approved the research protocol.

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Appendix

Thought Leader Qualitative Interview Questions

Opening script: Thank you so much for taking the time to speak with us today. The goal of our interview is to learn more about your experience working in tobacco regulatory science (TRS), specifically in your role as a mentor to young investigators in this field. We will use the interview information to create a training module specific to mentors in TRS. Our goal is to help TRS mentors provide effective guidance to their trainees.

Name:

Institution:

Academic Rank:

1. Have you had prior mentor training? If yes, with which program?

2. Have you had past involvement with NIH training initiatives?
3. Have you mentored in TRS previously? If yes: where, for how long, and for how many mentees?
4. Are you currently serving as a TRS mentor? If yes: where, for how long, and for how many mentees?
5. What is your primary goal as a mentor in TRS?
6. What is different about working in TRS as compared to other areas of science? What, if anything, do you consider novel about the field of TRS?
7. Has your research or practice changed to be responsive to the needs of TRS and the FDA? If so, how?
8. How are people disseminating findings in order to be responsive to the needs? Additionally, how are you helping your mentees disseminate their work accordingly?
9. Are there skills that are unique to being an effective mentor for early career TRS scientists? If so, what are these skills?
10. Following up on the previous question, how do you ensure that you continue to mentor effectively (ie, stay at the “top of your game”)?
11. What challenges have you faced as a mentor in this field? How have you dealt with these challenges?
12. If you have experience in TRS mentoring, with the benefit of hindsight, what do you wish you had known when you first started mentoring TRS scientists?
13. What kind of conflicts of interest do you anticipate as a mentor in this field?
14. What specific steps have you taken to help orient a mentee to the TRS field? Have these steps evolved over time?
15. Are there any specific documents or resources that you think are essential for early career mentees to review to be responsive to the FDA funding mechanism?
16. What is the breadth of career paths you have observed or can imagine for a trainee interested in a career in TRS?
17. We will create a series of 5–10-minute Web-based videos, highlighting individuals who have pursued diverse careers in TRS. This will help give current and future trainees and TRS mentors an understanding of the breadth of TRS careers. Which professionals (3–7 years post-training) would you recommend we interview for these videos?
18. What can a mentor do to help a mentee identify collaborative opportunities and networking? What can a mentor do to help a mentee access potential jobs?
19. What would you find valuable or helpful in a mentor training program specific to TRS scientists?

Early Career Scientist Qualitative Interview Questions

Opening script: Thank you so much for taking the time to speak with us today. The goal of our interview is to learn more about your career path in tobacco regulatory science (TRS). We will use your recorded interview and those of other early career scientists as part of a training module specific to mentors and mentees in TRS. Our goal is to help TRS mentors provide effective guidance to their trainees and to share knowledge on different types of career paths in TRS.

Name:

Institution:

Academic Rank:

1. Briefly tell us about your career path to your current position.
2. How did you network to find your job?
3. What other jobs, roles, or fields did you consider?
4. Was there a specific moment or motivator that set you on this career course?
5. What is meaningful about your job?
6. Describe a setback you've had in your career and your resilience strategy.
7. What was the most effective thing your mentor did?
8. What was something you wished your mentor understood better?
9. Is there a lesson that you learned from your mentee experience that you will take into your mentoring experience?

Systematic Review

To place our findings in context we conducted a systematic review by consulting the Boston University Medical School Lead Librarian to design a search strategy to review the literature on mentoring and regulatory science. We restricted our search to English Language articles and searched on various terms for mentoring, and regulatory science and translational medical research.

To ensure that we were inclusive in our search we used the following search terms in

PubMed:

Search ((((((“Mentors”[Mesh]) OR “Mentoring”[Mesh] OR Mentor*[TIAB])) AND English[lang]) AND Regulatory Science) AND English[lang])) OR ((((((“Mentors”[Mesh]) OR “Mentoring”[Mesh] OR Mentor*[TIAB])) AND (“Translational Medical Research”[Mesh] AND English[lang])) AND English[lang])).

The search strategy returned 136 articles. The article titles and abstracts were scanned, and where appropriate the full text reviewed. The articles were excluded as noted in the flow diagram below.

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Figure 1.
Reported Effective TRS Mentorship Methods

Table 1

Sample Characteristics

Characteristic	Early Career Scientist	Senior Scientist	Total
N	12	10	22
Women (%)	9 (75%)	3 (30%)	12
Federal Drug Agency	3	1	4
National Institutes of Health	2	1	3
Academia	4	5	9
Research Organization	3	2	9

Table 2

Themes and Illustrative Quotes from Senior Scientist Interviews

Main Themes	Illustrative Quote
Describing the field of TRS	
Novel aspects of TRS	"...The single most unique issue is trying to hold the critical dimension of informing regulatory decision-making in the design, aims, and very conceptualization of research projects from the very beginning."
FDA research priorities	"It forces us to think about how practically the results of our research would be used... How would the results of this study inform what the FDA can and cannot do in terms of regulation and rule making?"
Disseminating findings	"The main output is traditional science ... But at the same time, there are these other processes that you participate in, like advising the FDA, engaging in public comment, testifying at hearings. That's when cutting to the chase and presenting in simple terms is important."
Mentorship in TRS	
Effective TRS mentorship	"The skill I think would be having good interview skills, because you have to talk with the person to find what they want rather than just telling someone what your program is. If you're going to be a mentor you take on the role of guiding someone."
TRS mentorship goals	"My broad goal for any trainee is to get them to the stage where they can be independent and successful scientists... And within TRS, the focus there would be to do research that informs regulation, but the broad goals for fellows are all the same."
TRS mentoring challenges and solutions	"...Anyone who's done anything important is not doing the same thing at the end of their career that they were at the beginning, so it's important for people to have a broad enough base to move in their careers. Having a broader, cross-disciplinary understanding positions you well to draw from different fields."
Conflicts of interest as TRS mentor	"...How do we advise mentees on a career with someone who sells tobacco products? Or products that reduce harm? I think collectively as a field we need to take this on."
Orienting mentees to TRS	"...Learn about the methodology and requirements that are needed for regulatory science to be useful. Start with some really good TRS articles, or some bad ones to debate strengths and weaknesses ... Identify topics that require rapid and rigorous research, then move to more modest grant and paper writing, and then eventually jump into the pool with the sharks..."
Early career scientists' career futures	
Career paths	"There's the path to come work here [the FDA]... there's academia, and there's also the NIH, CDC, and other federal agencies. And lastly, there are non-profits and policy groups, or even state and local health departments."
Networking	"Having the TCORS [Tobacco Centers of Regulatory Science] is a natural way to help grow the field and for more senior scientists to be aware of what's happening and potential opportunities."

Table 3

Themes and Illustrative Quotes from Early Career Scientist Interviews

Main Themes	Illustrative Quote
Career experiences	
Career paths	“What’s hard is that, myself included, people who come into tobacco control come in from very different trajectories and diverse backgrounds. There isn’t this linear trajectory and where people study tobacco and then decide to pursue their careers in it.”
Networking	“...Even during my post-doc, I tried to stay in touch and work collaboratively, which was beneficial because it was easy to show that I had kept connections here at [institution name removed] during that time.”
Alternative paths considered	“I considered early on to go into medicine, but I frankly realized I didn’t have the temperament or patience for one-on-one treating individuals. I always had the yearning to assess structural and community level impediments to health, more so than the one-on-one counseling about diet or quitting smoking...”
Career motivators	“My experiences with [names omitted] were pivotal in shaping how I saw how one could be really successful and really dedicated to this area... Without my own driving passion I wouldn’t have continued, but definitely crucial mentors were key.”
Meaningful aspects of job	“Helping to save a billion lives for the next century; few other fields can say the same thing... the impact our research has in the real world. There are very few areas where a paper is used as evidence to pass legislation. It’s empowering.”
Career setbacks and solutions	“For me, graduate school, the process of developing your own research project... lots of times there’s a lot of knocks as you’re going about it. You first come up with what you want to do, and then reality sets in and you realize, oh you can’t do that. You don’t have money or the access to resources ...I had to change dissertation topic and start from scratch twice. But yeah, resilience is absolutely it... Keeping your eye on the bigger picture is sort of the key.”
Mentoring	
Effective mentoring	“One of the biggest things is expressing confidence in my abilities and allowing me opportunities to try new things with their assistance... A good mentor gives you opportunities to do things you may yourself not know you need... Really good mentors set a really good example of dedication to their work and bringing you into it.”
Challenges with mentors	“...When I work across disciplines there’s a sharing of knowledge and a learning curve about my discipline. ... In terms of my mentors around the world, being open to qualitative methods that are evidence-based and letting go of the notion that science is only quantitative and numbers-based.”
Mentoring lessons learned	“The lesson I feel that I learned is that when you’re a mentor, you have to provide the support but also challenge the mentee. I think sometimes we just try and be helpful and positive, but it’s also important that we have the honest conversation if they’re taking the wrong turn...”