Biomedical Engineering Education (2024) 4:339–359
https://doi.org/10.1007/s43683-024-00150-w

BMES BIOMEDICAL ENGINEERING SOCIETY

RESEARCH ARTICLE

Modeling Career Paths in Biomedical Quality Engineering

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Received: 15 June 2023 / Accepted: 29 April 2024 / Published online: 17 June 2024

Abstract

Biomedical Quality Engineers (QEs) ensure that medical devices are safe, reliable, and consistent. To better understand career pathways for biomedical QEs, we (1) quantified the prevalence of QE skills in entry-level biomedical engineering (BME) job listings and (2) interviewed seven biomedical Quality Engineers with a BME bachelor's degree. We mapped participant responses to the mechanisms in Social Cognitive Career Theory and identified common career pathways for biomedical QEs. To our surprise, over 40% of entry-level BME jobs were QE positions and 70% required QE-related skills. The interview participants were unaware of careers in QE careers as undergraduates and learned about QE while entering the job market—a surprising finding given the prevalence of entry-level QE jobs. The participants had low outcome expectations for QE careers and higher outcome expectations for research and development positions; instructors should be aware that a design-focused curriculum can bias students against QE careers. BME departments should introduce QE topics and experiences to help students make informed career decisions and be competitive in the sizable biomedical QE job market.

Keywords Career paths · Undergraduate · Employment · Social cognitive career theory · Quality engineering

Introduction

Biomedical engineering students have repeatedly expressed frustration at being passed over for jobs at career fairs while feeling like a "jack-of-all-trades" but being perceived as a master of none [1, 2]. Literature shows that Quality Engineering and regulatory positions are common jobs among biomedical engineering job listings and that biomedical engineering students could leverage their broad undergraduate educations in these fields [3, 4]. Yet there is very little research studying Quality Engineering (QE) careers for recently graduated bio- and biomedical engineers (referred to as biomedical engineer or BME in this paper). We seek to remedy this discrepancy and find any gaps between undergraduate curricula and employer needs. For this study, we use job titles from the American Society for Quality to define which careers fall under the field of Quality Engineering; examples of this include auditor, quality engineer, process/manufacturing/project engineer, consultant, and more [5]. The topics of research and development (R&D) and design emerged in our participant data and therefore need to be defined for our study. The National Center for Science and Engineering Statistics (an agency within the NSF) adheres to the definitions of R&D provided by the Organisation for Economic Co-operation and Development (OECD) [6, 7]. According to the OECD, R&D is divided into three components: basic research, applied research, and experimental development. These stages can all be found in industry positions but are distinguished from production and preproduction development because, by the OECD's definition, R&D must include the creation or use of new knowledge and ideas [7]. Other forms of development encompass the larger production pipeline, of which experimental development may be only one stage or may not be a component at all. Production and pre-production development could also only be adaptations of previous products, which does not meet the novelty criteria in the definition of R&D [7].

We also must clarify how design relates to R&D because literature on biomedical engineering education often focuses

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on the design courses that prevail in BME curricula. The OECD notes that oftentimes design and drawing work is similar to R&D work [7]. Tasks that require calculations, drawing, prototyping, etc. can be considered R&D-related. However, if the tasks are more closely focused on production, standardization, or other similar areas then they should not be considered R&D [7]. ABET defines engineering design as "the process of devising a system, component, or process to meet desired needs. It is a decision-making process (often iterative), in which the basic sciences, mathematics, and the engineering sciences are applied to convert resources optimally to meet these stated needs [8]." Comparing the two definitions, there is considerable overlap between R&D and design. We recognize that design courses may include components regarding production, manufacturing, and other aspects outside of R&D, but because design and R&D cover many similar areas and the other forms of engineering are often discussed outside the realm of design, we will consider the terms interchangeable in this study.

Theoretical Framework

We use the Lent et al. (1994) framework of Social Cognitive Career Theory (SCCT) as the basis of our study [9]. SCCT has been widely used for nearly three decades in STEM and engineering education with a variety of students and professionals to explain how career and academic-related interests develop, how choices in those areas are made, and how career outcomes are achieved [10, 11] (Fig. 1). SCCT been expanded in the last 10 years to include two additional, closely related models that report robust findings [12]. One of these models focuses on academic/career satisfaction, called the SCCT satisfaction or well-being model [13, 14]. The SCCT satisfaction model has been used to explain diverse engineering students' satisfaction with their major, their intentions to persist, and women engineers' job satisfaction [15, 16]. The second closely related model focuses on career self-management across the career lifespan, from the job search processes to retirement [17–19]. All three versions of the model include similar elements.

Important points to note about SCCT are the reciprocity between specific mechanisms in the model and the feedback loop from performance attainments back to learning experience [9]. This loop allows for an understanding of one's progression through their career, rather than requiring focus on single, linear decision-making. We chose this theory as it details many possible factors that influence one's career decision-making and shows the varying relationships between these mechanisms. This gives us the opportunity to organize an individual's experiences, beliefs, and expectations. The directionality of the model also helps us examine which links are strong or weak in a participant's experiences and how we can build upon those links to make the greatest impact on a student's career decision-making.

The results of this study mainly focus on the mechanisms of outcome expectations and learning experiences. A participant's learning experiences influence their outcome expectations and self-efficacy expectations. Self-efficacy is defined as "people's judgments of their capabilities to organize and execute courses of action required to attain designated types of performances" [20]. These are not objective measurements of skills, but subjective self-assessments of what one can do with the skills they believe they possess. Outcome expectations are defined as "personal beliefs about probable response outcomes" [9]. There are different forms these expectations can take, such as monetary, social, and self-evaluative. This mechanism works in conjunction with self-efficacy expectations to determine a person's behavior.

We operationalized learning experiences to consider references to a participant's coursework, informal learning activities, extracurricular and co-curricular activities (including research and internships), job progression, role

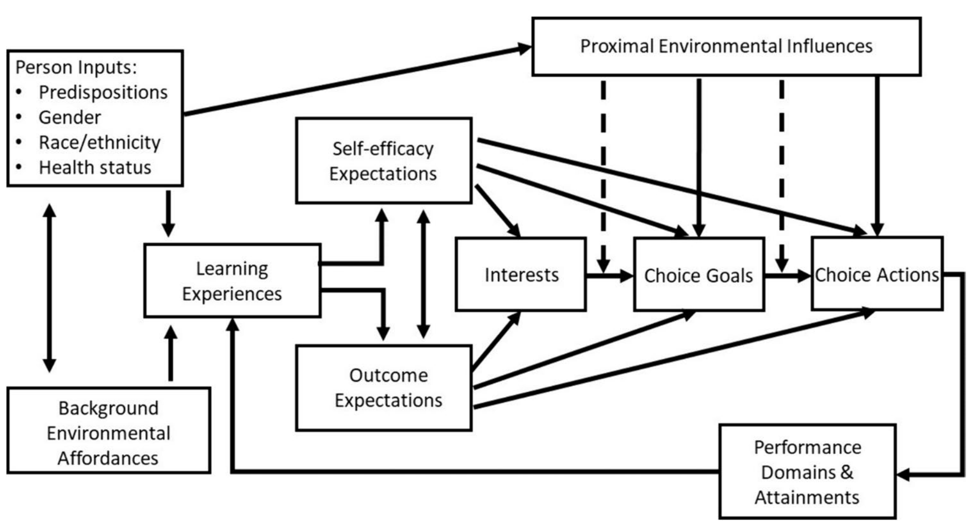

Fig. 1 Social cognitive career theory (diagram adapted from Lent, 1994 [9])

models, and experience level. We also included any references to a lack of the aforementioned concepts or a desire for them. We operationalized outcome expectations to include what a participant expected from a particular career in terms of its salary, job description, contribution to society or self-fulfillment, opportunity to learn/advance, prestige, work environment, and job security. We used these operationalized terms to inform our interview questions and data analysis in order to understand career navigation and satisfaction. We mainly considered references related to Quality Engineering, since that is the focus of the study, but from our emergent findings we also considered references related to research and development.

According to this framework, a person's learning experiences directly influence their self-efficacy beliefs and outcome expectations regarding a potential career path [9]. They will adjust their interests, goals, and actions depending on these beliefs. Therefore, understanding the learning experiences, self-efficacy beliefs, and outcome expectations of BME students can help identify the ways BME curriculum can alter students' career interests. We considered this as we reviewed the existing literature, developed our study, analyzed participant data, and drew implications from our work.

BME Programs Focus on Design

Current biomedical engineering programs focus on teaching design; this focus is reflected in the conversations surrounding BME education as well as in how the curriculum has been changing. For example, educators at the fourth BME Education Summit found design showcase events to be one of the best ways to highlight program strengths to potential employers and thereby increase student marketability [21]. Design-related courses have also become increasingly prevalent in BME curricula. In Gatchell et al.'s study of sixteen BME programs from 2004, thirteen required design courses in their curriculum. By 2013, all sixteen programs began requiring design [22]. BME curricula are increasingly emphasizing design principles.

We also see a lack of emphasis on Quality and regulatory principles in BME undergraduate education. The core curricula from Gatchell et al.'s comparison of BME programs did not include any Quality or regulatory courses in 2004 nor 2013 [22]. Layton et al. also note how university core curriculum does not explicitly teach QE skills; students must instead acquire these skills on the job or via education provided by their employer [23]. Jamison et al. repeat this exact sentiment almost 20 years later, indicating this landscape has changed very little [3]. Although little recent literature exists, we found that some universities had courses or tracks on QE principles, as early as 1995 [24]. However, we could not find evidence that this coursework has expanded into the broader BME curriculum over 25 years later. We recognize that the landscape may have changed since the time of some of these cited studies, but the paucity of literature helps motivate our current study and our goal to highlight and partially fill the knowledge gap for BME QEs. Social Cognitive Career Theory suggests that a student's learning experiences in a topic will directly affect their self-efficacy and outcome expectations related to that subject [9]. When students perceive that their programs emphasize device design but do not similarly emphasize Quality Engineering, how will their outcome expectations and self-efficacy be affected?

BME Employers Require Specialization for Design Roles

Most entry-level biomedical engineering jobs are related to Quality Engineering rather than research and development (R&D). The Bureau of Labor Statistics found that in 2020, 16% of biomedical engineering employers were in the field of medical equipment and supplies manufacturing and another 8% were in the field of navigational, measuring, electromedical, and control instruments manufacturing. That means 24% of all BME jobs are related to Quality and Manufacturing Engineering. By comparison, only 16% are in the field of research and development [25]. The skills requested by employers also lean toward QE; Jamison et al. conducted a review of 95 entry-level job postings by BME employers and found that 65 postings mention technical documentation (which includes QE-related skills) and 42 postings related to Quality. By comparison, there were only 35 postings related to design and development [3]. In a qualitative study, Layton et al. found that Quality Engineering principles are the skills industry professionals needed from new grads [23].

This slant toward QE positions is likely because biomedical engineers need more than a typical BME bachelor's degree to qualify for R&D positions. According to Farley et al., positions in design and development would require new grads to have focused coursework in electrical or mechanical engineering [26]. BMEs have noticed this trend and have expressed frustration that they are passed over for BME-related jobs in favor of other engineering majors, according to Nocera et al. [1]. Knowing what the employer wants will greatly affect a student's outcome expectations and there is currently a disconnect between employer expectations and student expectations. We hope to align these expectations by discovering exactly how much of the entry-level job market is encompassed by Quality Engineering.

BME Students are Better Prepared for Quality Engineering Roles

The broad nature of BME programs prepares students better for Quality-related careers than for R&D. When Farley et al. discussed the requirements new grads would need to enter R&D, they added that those with a typical bachelor's degree in BME would instead qualify for positions in "technical sales, clinical engineering, and technical support" [26]. Baura supports this claim in a call-to-action that notes how BME students are well-prepared for becoming biomedical Quality Engineers, as they understand interactions between living and non-living systems. Baura goes on to point out how other engineering disciplines would lack the physiology coursework necessary for medical device testing [4]. In this way, not only are BME students better prepared for QE roles over R&D roles, but they are also more equipped for QE in the medical industry than students of other disciplines.

The existing research focuses on how BME *programs* are preparing students, but there is not much literature on what *students* feel prepared to do. We seek to discover what their perceptions are regarding Quality Engineering careers. Given that programs focus on R&D, one might assume student self-efficacy and outcome expectations will likely be positive for R&D but non-existent or even negative for QE.

There is already a large body of literature on what BME programs emphasize in their coursework, what the BME job market looks like, and what educators and employers believe BME students are prepared for after completing their education [1–4, 8, 21–24, 26]. However, there is little research specific to Quality Engineering for BME students, nor research focused on careers for which BME students themselves feel prepared. All of these factors influence BME students' learning experiences, self-efficacy beliefs, and outcome expectations and thus affect the careers BME students pursue.

Research Questions

Due to the paucity of literature on these subjects, we sought to answer the following research questions:

1. What is the landscape of the BME job market relative to Quality Engineering?
2. How were Quality Engineers exposed to their current field before entering the workforce?
3. How is entry into Quality Engineering facilitated or inhibited by undergraduate learning experiences in Biomedical Engineering?
4. How did engineers perceive the field of Quality Engineering as undergraduates?

Methods

Preliminary Research

Given the lack of research regarding QE as a career option for BMEs, our team conducted an analysis of 171 job postings to quantify the relevance of Quality Engineering in BME careers. We reviewed job posts on LinkedIn and Indeed from January 2022 to May 2022, using search terms that would return entry-level BME jobs. For example, we often used the "entry-level" filter on these platforms or included it in our keywords. We also used search terms, such as "biomedical engineering," "medical devices," "bioengineering," and similar keywords. Using the methods of Jamison et al.'s job listing analysis as a guide, we developed inclusion/exclusion criteria prior to searching listings [3]. We only included entry-level positions, excluding any listing that required three or more years of experience or an M.S./Ph.D. We also required that BME graduates should be likely to apply for the position; therefore, we included listings that request BME degrees, biology degrees, health science degrees, and listings that accept any engineering discipline. We excluded listings that exclusively specified fields unrelated to biomedical engineering. We also excluded posts with insufficient information about the position. Table 1 displays a more comprehensive list of the inclusion/exclusion criteria we used to create the final list of jobs. We also developed criteria for determining whether a listing was for a role in or related to Quality Engineering. We used topics and key terms from the ASQ's Certified Quality Engineer Handbook to differentiate between QE and non-QE topics [27]. If the title of the job said "Quality Engineering" or a related role or

Table 1 Inclusion and exclusion criteria for review of job listings

Inclusion criteria	Exclusion criteria
Labeled as entry level (or requires 0–3 years of experience) and only requires a bachelor's degree	Requires 3+ years of experience and/or a master's, Ph.D., or other non-bachelor's degree (e.g., only GED or associate's degree)
Qualifications include education in bio-related engineering (e.g., biotechnology, biomedical engineering, and biomechanics), biology, health science, or related field. Posts that only say "engineering" without specification were also included	Posting exclusively requires degrees in non-biology related field (e.g., only mentions mechanical engineering, computer science, chemistry, etc.)
	Requires applicant to be based outside the U.S.A.

if over 50% of the responsibilities/qualifications listed were related to Quality Engineering, we categorized the job as a QE position. If at least two of the responsibilities or qualifications were related to QE, we classified the position as "QE-related." Figure 2 illustrates this categorization in the form of a decision tree. A detailed list of these responsibilities and qualifications can be found in Table 2.

The 171 jobs in our final list spanned 142 companies. Some of the larger companies had up to 5 jobs included in our study, but the vast majority of companies had one job post included in the study. The companies ranged from small startups to large, well-established businesses, with more small companies than large ones. We suspect this is because larger companies will use their own websites for recruiting more often than smaller companies, so they would not show up on our search platforms as often. We restricted our job search to the USA, but otherwise did not filter by location; we also included remote jobs. After reviewing all 171 job listings, we found that 42% of listings were Quality Engineering positions and 70% of jobs were related to Quality Engineering. A breakdown of these categories can be found in Fig. 3. Seeing the prevalence of QE in entry-level BME careers, we were motivated to conduct a qualitative study to uncover how well a BME undergraduate degree prepared QEs for their jobs.

Positionality

We engaged in exploration of our positionality following Secules et al. (2021) framework which includes research topic, epistemology, ontology, methodology, researcher-as-instrument, and communication [28]. We include salient aspects of this exploration in the statements below.

As an author team, we have varied formal educational experiences in the biomedical engineering education field that motivate this work; collectively we hold bachelor's, master's, and/or doctoral degrees in biomedical engineering and materials science and engineering. This work represents the first engineering education research experience for three of us, whereas one of us is well established in the field. The first and fourth authors are currently members of a biomedical engineering department as a PhD student and faculty member, respectively. The second author is an engineering education faculty member who completed a postdoctoral fellowship in biomedical engineering and the third author is a recent BS graduate who is now working in drug discovery at a biotech company. These experiences result in a collective range of understanding about the subfield of Quality Engineering as well as biomedical engineering curricula and career paths.

First author: My goal in conducting this study is to communicate my participants' experiences with the broader biomedical engineering education community in hopes of contributing to added awareness of Quality Engineering. When I earned my bachelor's degree in biomedical engineering, I was completely unaware of the field of Quality Engineering. Unsure whether to follow an industry career or continue my education, I applied both to industry positions and to graduate programs in various subjects (robotics, biomedical engineering, and mechanical engineering). I felt unsatisfied with the industry job search and the opportunities available, so I eventually decided to pursue a master's degree. These educational experiences influenced how I approached the study and how participants interacted with me. Due to my age and degree, the participants who were newer graduates connected with me as someone who understood and related to their experiences, sometimes asking me if I remembered having similar experiences or coursework as they had. I took care during the data collection to ensure I was asking follow-up questions that clarified the participants' statements rather than filling in gaps with my own experience. I asked them to elaborate or rephrase to ensure the transcript would capture their intended meaning.

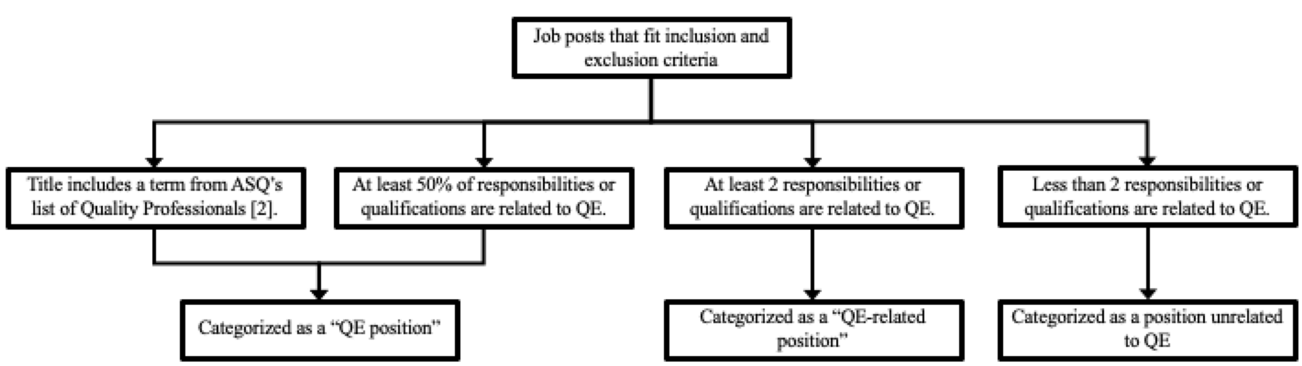

Fig. 2 Decision tree for categorizing job postings. Titles from ASQ's list of Quality Professionals include "Quality Engineer," "Manufacturing Engineer," "Quality Assurance," "Consultant," and more [5]. Example skills and responsibilities related to QE include software testing, application of Six Sigma practices, complying with FDA regulations, and auditing

Table 2 Responsibilities or qualifications related to Quality Engineering. Categorization based on the ASQ-Certified Quality Engineer Body of Knowledge [27]

Management and leadership	The quality system	Product, process, and service design	Product and process control	Continuous improvement	Quantitative methods and tools	Risk management
• Vendor validation, supplier management • Project management • Quality assurance • Quality control • Quality engineering, CQE	• Quality, quality system • Quality plan • Quality audit, regulatory review • Regulatory standards (incl. GMP, GCP, GLP) • Quality standards/requirements • Quality improvement • Document control	• Product, process, or service design • Developing standard operating procedures • Product quality • Process development • Process characterization • Change control • Process optimization • Validation/verification/qualification/compliance • Installation/operational/process qualification (IQ/OQ/PQ) • Technical/design/process specification • Failure Mode and Effect Analysis (FMEA) • Maintenance	• Product or process control • Controls process/documents • Manufacturing engineer, MES engineer • Testing, debug • Process engineer • Calibrate	• Continuous/process/performance improvement • Robust design/products • Six Sigma (and related) • Problem/issue identification • Root cause analysis • Investigate process exceptions • Flow chart • Agile (method) • Corrective action • Troubleshoot	• Quantitative methods or tools • Process capability • Performance analysis/standards/reliability/assurance • Change characterization, process monitoring • Process variability	• Risk management • Safety (standards)

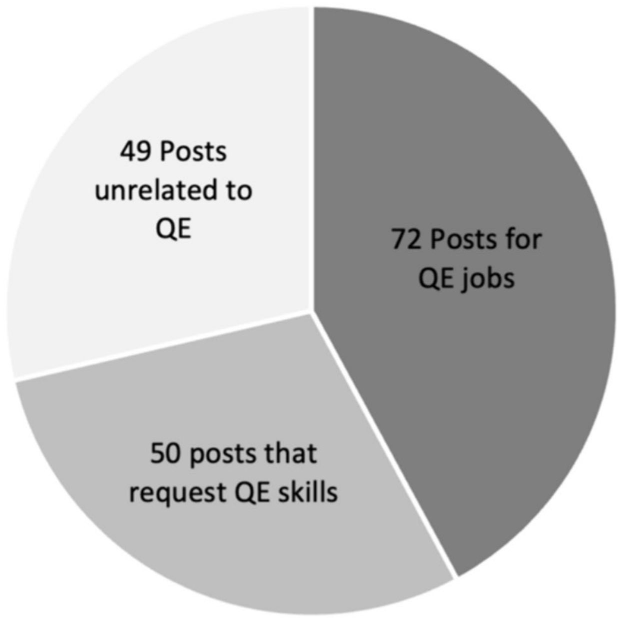

Fig. 3 Categorization of 171 job posts

Second author: My expertise in engineering education research and past experiences as a postdoctoral researcher in biomedical engineering motivated me to join this project team. I contributed theoretical and methodological knowledge gained from my experience in the field (conducting qualitative studies, teaching a graduate-level research design course, editing a journal, and serving as an NSF program officer) to mentor the team in conducting this work. My own engineering education research utilizes constructivist and critical paradigms and influenced our decision to ground this work in constructivist epistemology. I encouraged the team to communicate results in first-person, active voice language that recognizes our roles as instruments of the research.

Third author: I am a recent graduate with a bachelor's degree in bioengineering. I had a similar experience as the first author during my search for industry positions, where I struggled to refine my career expectations and match them to job postings. I became aware of Quality Engineering after graduation due to the guidance of the fourth author and studied to become an ASQ-Certified Quality Process Analyst. While I continued my job search, I joined this project, focusing on the job posting analysis because the content and results were very relevant to my own goals. Subsequently, I took an industry position within R&D, but still found numerous applications for the skills I gained from my post-graduate certification.

Fourth author: As a BME faculty member, I advise students as they navigate the entry-level BME job market. I became aware of QE late in my career through my research on automated science and was surprised by the prevalence of QE jobs and skills for entry-level engineers. I have positive views of QE and advocate for its inclusion in BME curricula. I am an ASQ-Certified Quality Engineer, and my career has benefited from formal training in QE.

Validation

We adhered to Walther, Sochacka, and Kellam's "quality in qualitative interpretive research" (Q^3) framework [29], which has been increasingly used in qualitative engineering education research (see, for example, [30]). This model describes several types of validation: theoretical, procedural, communicative, pragmatic validation, as well as process reliability. The model frames these indications of trustworthiness in terms of two distinct stages of research, which they call "making the data" and "handling the data" [29]. We mapped our work to the Q^3 model and indicated alignment in Table 3.

Making the Data

After the Institutional Review Board determined our study to be exempt (IRB protocol # 21850), we recruited seven participants via a combination of LinkedIn, email, and snowball sampling [31]. Qualitative research sample sizes vary depending on the type of study; a sample size of three to ten participants is appropriate for an exploratory, in-depth study such as this one [32–34]. The post/email we shared contained the study details as well as examples of QE job titles so participants could self-assess whether they work in Quality Engineering. We determined these example titles using the job title list from the American Society for Quality [5]. In our selection criteria, we required participants to be current Quality Engineers within the medical industry (devices, pharmaceuticals, consulting, etc.) with a bachelor's degree in biomedical engineering or a related field. Participation was voluntary and we provided each participant with compensation in the form of a $50 Amazon gift card.

We assigned numbers to protect participant identities and removed any identifiable data for publication. Participants' career experiences ranged from being in their first job post-bachelor's to having held various positions in the medical industry since completion of their bachelor's degree. Some participants have held internships, externships, or have had further education following their B.S., such as a master's degree, Ph.D., or formal certifications. A summary of these participants' career paths can be found in Table 4.

We conducted one 45–60 min interview with each participant using Zoom videoconferencing software and a semi-structured interview guide. We utilized the critical incident technique, focusing on participants' curricular and co-curricular activities during their time as undergraduates [35], and used follow-up prompts as needed either to clarify

Table 3 Validation techniques used in this study.

Step taken in the study	Corresponding validation techniques
Created participant inclusion criteria with which participants self-identified, including descriptions of career experiences	Theoretical validation; pragmatic validation
Utilized the same semi-structured, critical incident technique-based interview guide grounded in SCCT for each interview	Procedural, theoretical, and communicative validation; process reliability
Used professional transcription and NVivo software	Process reliability; procedural validation
Created a priori codes from SCCT with operationalizations of each code	Theoretical and communicative validation
Engaged in memoing	Procedural, theoretical, and communicative validation; process reliability
Used low-inference descriptors in analysis and reporting findings	Communicative validation
Determined nuances in codes and reviewed for consistency	Procedural and communicative validation; process reliability
Debriefed among research team to discuss interpretations	Pragmatic, communicative, and theoretical validation; process reliability
Highlighted quotes from different participants in publishing findings	Communicative, theoretical, and pragmatic validation

their answers, or relate their experiences to SCCT. We also asked questions regarding their experiences related to Quality Engineering, such as whether they had any exposure to QE before their first Quality Engineering position, what skills they found necessary for their job as a Quality Engineer, as well as where they acquired those skills. Example questions from the semi-structured interview guide can be found in Table 5. This data collection method yielded a rich data corpus of 108 pages of transcript text.

Handling the Data

We had the recordings professionally transcribed by Premium Business Services. We used NVivo software for interview coding and analyzed the data in three phases, depicted in Fig. 4. During the first phase, we used the SCCT framework as a priori codes, where each mechanism corresponded to its own code (e.g., Background and Self-Efficacy Expectations). We operationalized these codes according to what would likely be seen in the interview transcripts. We also used memos while coding to note patterns between participants and to update the list of operationalized code [36]. As we coded the transcripts, we used direct quotes from the interviews as low-inference descriptors to stay true to the participants' meaning.

During the second phase, we looked at the similarities and differences between participant responses within each code to determine nuances. We noticed that learning experiences and outcome expectations were the most salient, so we reviewed their coding to ensure consistency and then focused on those codes during this stage. Here, we no longer considered any repeated thoughts or topics within single interviews but looked for salience of themes across interviews. We debriefed to discuss any recurring themes and negotiate differing interpretations.

Finally, in the third phase of analysis, we sub-coded the learning experiences and outcome expectations with emergent themes we discovered in phase two. Under learning experiences, we added sub-codes for "lack of learning experiences" and "desired learning experiences" to encompass

Table 4 Summary of participant backgrounds and careers

Participant number	Gender	Institution type	Education (including in progress)	Career stage (cut-off at 5 years)	General career path	Happy in current career?
1	F	Public	B.S.	Early	QE	Y
2	F	Public	B.S.	Early	QE then new QE position	N
3	F	Public	B.S.	Early	QE	N
4	M	Public	M.S.	Early	QE	Y
5	F	Private	Ph.D.	Later	R&D then new R&D position then QE	Y
6	M	Public	B.S., CQE	Later	R&D and QE, then R&D position, then QE, then new QE position, another QE position, then current QE position	Y
7	F	Public	M.S.	Later	Business, then QE, then new QE position, then R&D, then new R&D position, then QE	Y

Table 5 Sample questions from semi-structured interview guide

Interview topic	Sample questions
Leading to college	• Can you tell me about where you grew up and things you did in high school? • How did you become interested in engineering?
Current job	• Can you tell me about your current job, including duties and responsibilities? • What did you expect your day-to-day work to be like in your current position? How prepared did you feel for your current position?
College experiences	• When you started college, what kind of career did you expect to have following completion of your degree? • Which careers did you feel your biomedical engineering curriculum expected students to enter? Tell me about what differences you think might exist between your current career and those careers.
Career preparedness	• What resources did you feel were helpful in preparing you for your job? • What resources do you wish you had as an undergraduate that you feel would have prepared you better for this position?
Exposure to Quality Engineering	• Did you take any courses focused on Quality Engineering or related skills? • Did your college offer any courses, extracurricular activities, or talks about Quality Engineering or similar topics? • Did you participate in any internships or co-ops in Quality Engineering?

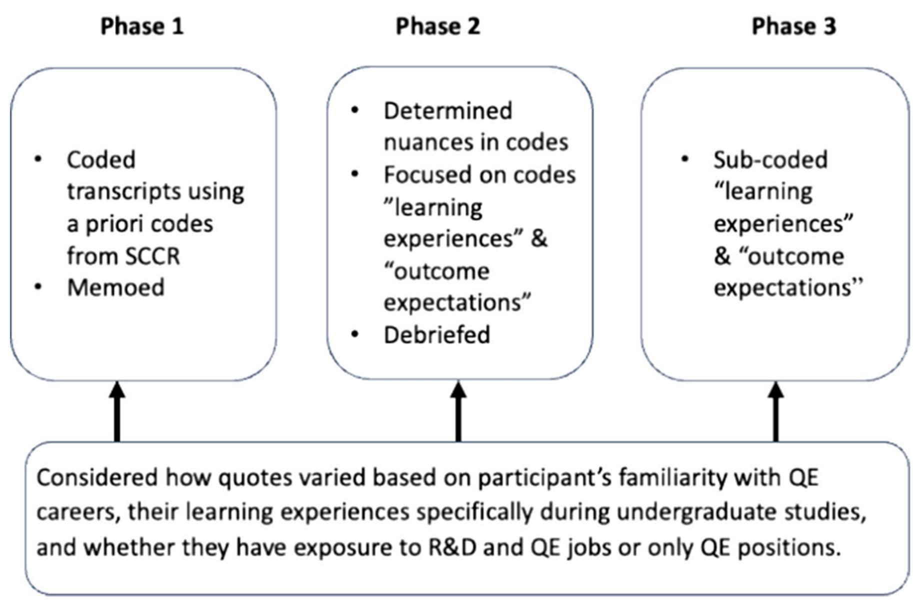

Fig. 4 Three phases of handing the data

participants talking about learning experiences they didn't have in their undergraduate and those they wish they had that could have helped their career. Under outcome expectations, we sub-coded references of participant expectations related to R&D and QE. During all three stages of analysis, we considered how quotes varied based on (1) the participant's familiarity with QE careers, (2) their learning experiences specifically during undergrad, and (3) whether they have exposure to R&D and QE jobs or only QE positions.

In publishing the findings, we include low-inference descriptors in the form of participants' verbatim quotes and were careful to use quotes from different participants.

Results

Our preliminary research served to answer our first research question: what is the landscape of the BME job market relative to Quality Engineering? We learned that Quality Engineering roles make up 42% of entry-level BME positions and 70% of BME jobs require QE-related skills. This suggests that undergraduate BME programs should have a focus on Quality Engineering. Our interest in discovering how programs prepare students for QE positions motivated the qualitative portion of our study. We used the results of our interviews to answer our other three research questions.

Across interview participants, the overarching theme that emerged was the lack of awareness of careers in Quality Engineering as BME undergraduates. Following analysis of the interviews, we also noticed that having experiences in QE and R&D gave participants the most information to determine the best career path for themselves. Results of the interview analysis followed the sub-coding specified in the methods; the two main codes were learning experiences and outcome expectations, although we also considered the other codes as we analyzed each transcript. As is the custom in presenting qualitative research, we have selected representative quotes from a variety of participants that illustrate each theme.

Theme 1: Biomedical QEs Reported a Lack of Undergraduate QE Learning Experiences

Most participants discussed their lack of QE-related learning experiences as undergraduates. Some participants were aware of the field of Quality Engineering through co-curricular activities or their family. Participant 6 said "My dad is an engineer, so I knew of Quality, just as a function." However, most QEs did not become aware of the QE field and necessary QE skills from their undergraduate coursework.

For example, as an undergraduate, Participant 3 learned about the skills needed for their eventual QE job through older students, not through the formal curriculum. When asked what they expected their job to be like and how prepared they felt for it, they said:

> So, I knew from talking to. . . other graduates and. . . people who were older than me. . . that [my job] wasn't going to be exactly [BME]. I knew that a lot of the skills that I learned in [BME] weren't going to directly translate to Quality Engineering. [Participant 3]

Unfortunately, this participant learned from older students that their formal undergraduate education would not provide skills relevant to the field of Quality Engineering. Without QE-related learning experiences, students would struggle to have any outcome expectations and self-efficacy expectations for QE careers, nonetheless positive expectations. Participant 1 echoes this sentiment by describing topics they were unfamiliar with when they began their job. They explain:

> And I remember them talking about that specifically when I first started. And I was like, "what's a submission? Like why are they planning what to put in it?" . . .they collect their clinical data and then they have to register their manufacturers and make sure they're maintaining good quality practices. And that's when things kind of start to come together. But, yeah, all the time at the beginning, I had no idea what's going on. [Participant 1]

We asked another participant what careers their undergraduate program prepared students for post-graduation. They responded:

> So, the three main tracks that I saw was [1.] medicine – so being a doctor. There was [2.] sales of medical devices, so leveraging some of the business marketing program to take your engineering background and be a good salesperson for a medical device company, which is critical because you understand your audience a lot better.
>
> And then just [3.] engineering R&D type thing. . . [University] was very research focused, and so that was kind of the ideas, you know. Doctors and engineers, you're doing your research, your development in product, that kind of stuff. And then for those that didn't fit that mold, there's this other side of things too, in the sales and the communication side of it. And so that was kind of what I understood. [Participant 6]

Participant 6 remarked that their undergraduate program prepared students for medicine, sales, and R&D. Concerningly, their current field of Quality Engineering was for "those that didn't fit that mold." Early career Quality Engineers may switch to R&D because of this belief that Quality and production Engineering are for students who do not align with any of the outcome expectations shared by their peers or program.

Participant 6 also makes the poignant statement, "Nobody talks about Quality in undergrad," which was a recurring comment from participants. Some participants knew about QE from older students or family members, but only one participant said QE was mentioned in a course (though it was not the primary topic of the course). Again, a perceived lack of learning experiences already sets Quality Engineering as a less desirable career option for students.

This finding helps answer our second research question: how were QEs exposed to their current field before entering the workforce? We originally hoped to discover specific skills or lessons they learned in their undergraduate curriculum but instead found that they were not truly exposed to QE as undergraduates.

Theme 2: Biomedical QEs Desired Undergraduate QE Learning Experiences

The perceived lack of QE learning experiences raises the question, "What learning experiences would future QEs find helpful in their careers?" We asked participants what resources they wish they had as undergraduates to prepare them for their future position in Quality Engineering. We expected participants to respond with specific certifications or standards they wish they had been taught, like the participant who answered:

> If I knew I was going to get into Quality Engineering, I think most broadly applicable would probably be project management because I think that applies in

> some way, shape, or form to any industry that you go into that's rigorous in terms of engineering or falls into regulated environment. That would, I think definitely, first and foremost, be helpful.
> After that, I think. . . standards and just kind of understanding the history behind standards, what standards are available, how to search them, and how to implement standards. [Participant 4]

However, the most common response to this question surprised us. One participant said:

> ... by the time I was a senior, I kind of knew what it [Quality Engineering] was. But I think as like a sophomore, junior, or even a freshman going into career fair and then people say, "what are you interested in?" and my answer was, "I don't know. What are you offering?"
> It would be helpful to have kind of an earlier explanation of "what does it mean to be a Quality intern or Quality Engineer?" and having that knowledge a little bit earlier to help at career fairs, to help target what I wanted to apply for internships and stuff like that. It was a lot of guesswork and just honestly like networking my way to knowing what I was talking about. So, I think earlier on, it's helpful to have an idea of what exactly it means so that you kind of know what to target. [Participant 3]

This participant discussed how an early introduction to QE-related careers would have helped them navigate career fairs. An introduction to Quality Engineering could serve as a learning experience that can affect a student's goals and actions during and after their undergraduate education.

Participant 5 shared a similar sentiment, saying

> As an undergrad, I think, or even in grad school, I'd say probably just like a summary of [federal regulations, ISO standards, etc.], just maybe like a quick class or even just like a PDF guide of kind of "what are design controls?", "what is design verification?", just like a high level of knowing where to get started. Because I feel like I sort of had it on my radar that it [Quality Engineering] was out there but had never really dug through anything in any amount of detail. But I didn't know what I didn't know, almost. So, once you start diving into it, there's a ton of information that you can find and dig into it. But I just didn't really even ever think to go looking for it, I guess, because I thought I knew how to work in a lab. [Participant 5]

Again, the participant felt a basic introduction to QE would have been helpful because they didn't understand what they needed to know to be successful in a QE-related career. Knowing about QE could have pushed them to learn more about the field and change their goals and actions.

In the case of Participant 6, having better QE-related coursework would have saved them time and prevented them from having to teach themselves QE skills. They say:

> [B]asically every company in the world has some sort of remediation going on because their procedures and documents are not quite to the current standards. And so, if you come in armed with that knowledge, you know how to speak the language already, so you can pick apart what's there and suggest improvements, and you're going to set the company up for a much better success. So, I had to learn that on my own, dive into more of that as part of the CQE certification and everything. [Participant 6]

Having that knowledge would have allowed Participant 6 to provide more value to their company earlier in their career. Another participant described a course they took in undergrad as an example of where this type of information would fit in a BME curriculum. They responded to our question by saying:

> I know as freshmen, most likely you have no idea what's going on anyway, and you're just getting used to college in general. Maybe even if that's something that the sophomores do, like have a course like that, and maybe you could have guest speakers come in and talk about their experiences. I think they did that in [introductory course on BME topics] as well, like they had industry people come in. But that might be very useful in terms of getting people familiar with what people do in this industry, specifically. [Participant 1]

This quote illustrates a recurring theme of participants wishing they had more explanation of post-graduate careers or any introduction to Quality Engineering. Even a small introduction to QE could have an outsized effect; looking at the SCCT framework, positive learning experiences related to QE during college could improve or even change a student's outcome expectations for industry careers post-grad in Quality Engineering. Without positive learning experiences, students are less likely to envision and seek out positions in Quality Engineering.

In response to our third research question, "how is entry into Quality Engineering facilitated or inhibited by undergraduate learning experiences in biomedical engineering?" we learned that participants felt unaware of and therefore unprepared for QE careers. While career fairs and connections helped provide these introductions to the field, participants did not report many examples of receiving QE-related training from their curricula. This can be seen in the data from both Themes 1 and 2.

Theme 3: Engineers with Only QE-Related Career Experience Often had Negative Outcome Expectations for QE

Our interviews found that outcome expectations changed given different learning experiences. Some participants had career experience only in QE positions, whereas others had both R&D and QE experience. Outcome expectations for Quality Engineering were usually negative when participants had experience only in one field. For example, when discussing their early career experiences in R&D engineering, a participant said:

> So, I was used to working in the Quality system. And every team that I was on for all those projects, I always had a Quality Engineer that would be a separate signature on everything I generated. But I was never signing for that role at either of those places. It was more like I was butting heads with Quality all the time because they were raining on my parade for what I wanted to do. [Participant 5]

Working with Quality Engineers without any experience as a Quality Engineer gave this participant a negative view of Quality Engineers; QEs hindered the participant's progress at work. This was a common sentiment among our participants, as seen with Participant 6, who said, "When I started working in R&D, of course, I was very aware of [Quality Engineers] because, at the time, they were the ones holding me up. And it's that stigma that Quality always says no." Here we see another participant with the expectation that Quality Engineers prevent innovation and "always say no" to improvements or changes to product designs. This view that Quality Engineers act as gatekeepers to progress makes QE a less desirable career outcome for our participants. Participant 6 elaborated on this concept by comparing QE to other fields, explaining, "I always thought QE was in the way and saying no, no, no, no, no. So, there's that definite stigma of design versus Quality." The result of these views is that after entering the workforce, engineers became disinterested in QE careers.

Even participants who acknowledged the importance of QE still desired jobs in R&D. Participant 2 discussed how working in QE was useful for learning downstream manufacturing procedures but then added that this knowledge could and would be used while working in R&D. They definitively did not want to stay in QE, saying "I don't expect to stay in Quality for very long" [Participant 2]. This participant viewed QE experience as a steppingstone to R&D. As mentioned previously, new BME grads require more than a bachelor's degree to qualify for design and development roles [5]. Perhaps some participants felt their experience in QE provided the credentials they needed to move into R&D roles.

Theme 4: Engineers with Both QE and R&D Career Experience had Positive Outcome Expectations for QE

One of our most interesting findings is how outcome expectations changed depending on whether a participant had career experience in only QE or in both QE and R&D. Only participants with experience in both areas held positive views of Quality because these participants could understand the role of QE in a product's life cycle and compare their experiences working in both environments. Participant 6, who talked about how "Quality always says no" when they were in R&D, now says of their job in QE:

> I'd rather put up the fight and say, "we need an extra two months on this project because we need to ensure that it's done correctly." I don't mind doing it. I don't mind being a squeaky wheel and causing possible conflict within the company and stuff. I've seen bosses fight for it, and I, myself, want to model my actions after that because it means that much to me personally that the patients receive the best care possible. [Participant 6]

Learning experiences from previous jobs increased interest and changed outcome expectations related to QE. Participant 7 originally left the QE field for jobs in R&D because their outcome expectation was that working in R&D would allow them to be more involved in saving lives. However, they felt drawn back to the QE field after their R&D experience, stating, "Quality never leaves you. It's really ingrained in us." Having QE and R&D experience allowed Participants 6 and 7 to make better judgments about careers and go where they felt like they can make a difference.

Other participants shared positive experiences from their careers in QE. Participant 2 expressed how much easier it is to get jobs as Quality Engineers and how much more stability there is. They shared experiences from when product lines were canceled in their company: entire R&D teams may be cut, but QE teams could often join other projects with the same role. This participant learned that since companies hire R&D engineers for specific projects, R&D engineers have much more volatility in their job security compared to QEs. Participant 4 explained how they planned to continue in the QE field because being on the cutting edge and creating new processes required strong Quality and regulatory skills. They said that to work on the forefront of medical technology, you "have to know what [regulation] exists, how it differs, and be able to kind of express that and see what the gaps are so that people following next have a framework to leverage" [Participant 4]. Their learning experiences changed their outcome expectations for QE; this participant had said they definitely would have accepted an R&D position after graduating if they were offered one, but now they think QE is necessary in order to work on new technologies. Their desire to be on the cutting edge has not changed, but their view of cutting-edge careers now includes Quality Engineering.

Participant 5 offered a direct comparison between working in R&D and QE. Discussing their shift from R&D to QE, they said:

> I transitioned from an R&D role to the Quality group. [I thought] it would be a lot more about reviewing all the documentation coming out of R&D, maintaining the procedures, all of that; it would be more of a documentation role. And I really don't miss the hands-on lab work as much as I expected.
> I think there was a level of stress associated with it that I wasn't as cognizant of until I didn't have it anymore because it was always like working on a project team. . . the timeline is really set in stone. They want to get on the market as fast as they can, obviously. And so, the project manager and the project team has the whole schedule put together and they'll say, "Okay, here are the requirements. We need to test the device. When can we have the test results?" And you have to try and plan it out. . .
> And so, I feel like working in that environment had a lot more unknowns that made it more stressful to balance commitments and give good estimates of timing and things to people on the team. Whereas now, in this role, I know how long it takes me to write a certain document. . . My work is not necessarily more predictable, because things always pop up that are unexpected, but there's a lot less of that physical uncertainty associated with it. [Participant 5]

This participant did not expect to enjoy a QE position, but in the end found QE to be less stressful than R&D and have less-demanding timelines. While their expectation that QE would entail a lot of documentation was correct, they decided that the uncertainty accompanying device design was not a good fit. Mapping this to the SCCT framework, we see that learning experiences with both QE and R&D created positive outcome expectations for QE careers and a desire to remain in a QE position. The change in their outcome expectations shifted the participants' interests, goals, and actions toward QE. As we will discuss later, these findings suggest that BME departments should introduce QE to undergraduate students along with R&D so that students have positive learning experiences and accurate outcome expectations for both fields.

The data in Themes 3 and 4 help us to answer our fourth research question: "how did engineers perceive the field of Quality Engineering as undergraduates?" Participants report having negative or non-existent perceptions of QE through their undergraduate experiences. Either they had not heard of QE as undergraduates and therefore never formed outcome expectations for the field until they entered the workforce or they felt QE was a career people entered if they couldn't obtain their desired position. While some participants reported positive outcome expectations regarding QE at the time of our interview, it seemed like their outcome expectations were developed in the workforce rather than from their undergraduate education.

Unanticipated Finding: Participants Made Unprompted Comparisons Between QE and R&D Careers

Our study was designed to investigate outcome expectations surrounding Quality Engineering, so we were surprised when so many participants brought up career goals in R&D. Most participants felt that R&D was better, more prestigious, or the desired outcome for BMEs. One explanation for the interest in R&D was that participants felt more prepared for R&D careers as undergraduates. For example, Participant 4 stated they would have chosen a design role after graduation had they been offered one because it was the focus of many of their undergraduate classes. Participant 7 originally believed working in R&D was more oriented toward saving lives, whereas QE was meant to help companies avoid lawsuits. Participant 7 returned to Quality Engineering, however, as they found QE to have become "ingrained" in them.

Participant 2's undergraduate learning experiences made them feel like R&D was the best option for an engineering degree and that other industry positions (e.g., QE) were not as good. They mention the existence of a stereotype that R&D was better than QE. When asked about the origins of the stereotype, they replied:

> . . . I think a lot of it has to do with like elitism and thinking that you're better than that. You don't want to go through engineering undergrad at [University] and then only end up as a Quality Engineer or only end up as like a manufacturing engineer. You want to be one of those people that are working on the development of new things. [Participant 2]

Viewing R&D as the stereotypic engineering job shaped this participant's career outcome expectations; this participant planned to leave QE after accruing enough experience to get an R&D position.

Participant 6 shared a similar sentiment to Participant 2, saying, "When I was an undergrad, I always thought I was going to be the R&D guy, like in the lab, making, developing something and stuff." This participant explicitly stated that during undergrad, their outcome expectations pointed toward R&D. However, after having learning experiences in both QE and R&D, they felt that there aren't "true" R&D

positions in industry except for in small companies. They explained, “And coincidentally, unless you work for a very small company, true R&D doesn’t really exist in the corporate world. So, you become more of a project manager even though it’s an R&D title” [Participant 6]. After cycling between QE and R&D roles, the participant found that they were happiest in QE positions.

SCCT-Based Models of Participant Career Pathways

The results of our job posting analysis and interviews with QE engineers are contradictory. Our job post analysis showed that QE jobs represent 42% of the entry-level BME workforce; however, all the biomedical QE’s we interviewed lacked awareness of QE when they entered the job market. How is it that so many biomedical engineers end up in QE? We used the Social Cognitive Career Theory (SCCT) framework to trace the career pathways of the QEs we interviewed. We found that proximal and environmental influences—not career goals or actions—led most biomedical engineers to QE roles. The disparate perceptions of R&D and QE roles also factor heavily into the career paths of BMEs.

From Biomedical Engineering Undergraduate to QE

All of the engineers we interviewed reported that their undergraduate training lacked any learning experiences in QE. Instead, their degree programs focused heavily on design, ideation, and other skills associated with careers in R&D. Thus, our participants entered the job market feeling like they only had R&D learning experiences, which led to positive self-efficacy only in R&D and an expectation that BMEs should work in R&D. The goal of many BME undergraduates is to find an R&D position in the medical product industry and so they apply for multiple R&D positions (Fig. 3).

While many BMEs apply for R&D jobs, few obtain them. Literature shows that BME R&D jobs typically required previous work experience (over 3 years in a similar position) or an advanced degree (M.S. or Ph.D.) [26]. Most of the true “entry level” jobs (less than 3 years of experience and no advanced degree) were in QE so participants seeking an R&D job were forced to accept a QE position instead [4]. Thus, the proximal influences of the biomedical engineering job market—and not the participants’ career goals—drove their entry into Quality (Fig. 5).

Some of our participants applied to R&D jobs in startup companies after finishing their undergraduate degrees (Fig. 5). Medical product startups generally offer lower pay and less job security compared to large, established companies [37–39]; however, two of our seven participants (Participants 2 and 4) were able to secure jobs in these smaller companies without industry experience or advanced degrees. Participant 2 says, “But, yeah, I mean, I definitely wanted to be in R&D engineering. That’s why it felt pretty nice being in that role in the startup roles.”

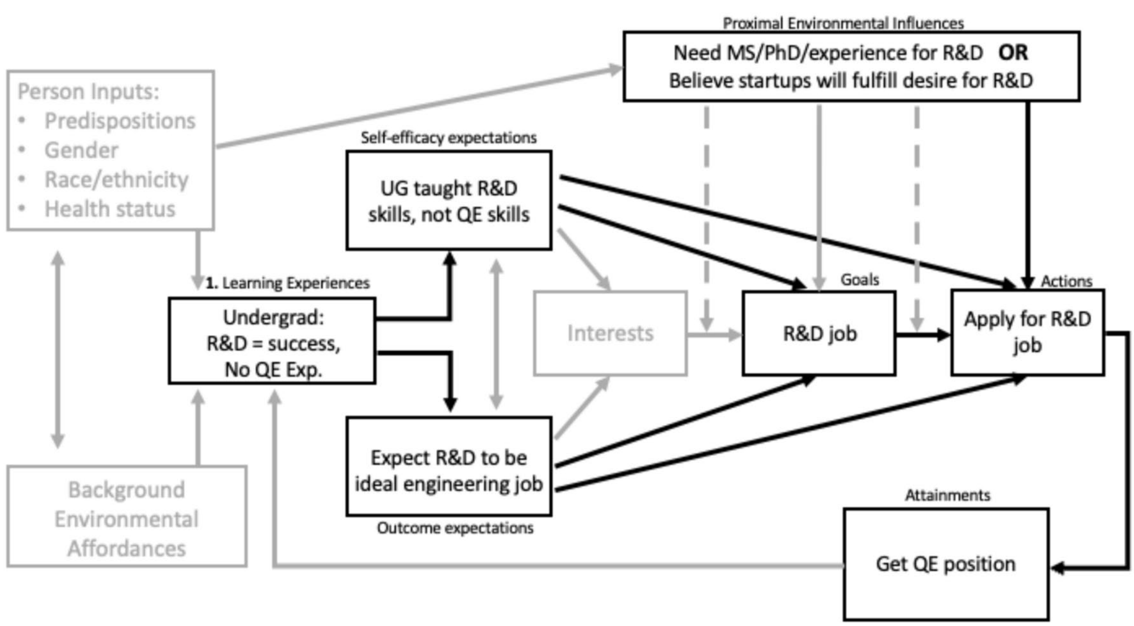

Fig. 5 SCCT model for undergraduate (UG) students who are unaware of QE before entering the workforce. QEs we interviewed initially wanted R&D jobs, but some lacked the required education or experience. These proximal factors led them to accept an entry-level job in QE

Interestingly, a so-called "R&D" job at a startup can quickly transform into a QE role as the company prepares to launch a product. Participants reported that much of their work involved production, regulatory affairs, testing, quality assurance, and other Quality roles, in part because startups lack a separate cadre of QEs to perform this work. One engineer we interviewed began their career at a startup but moved to a similar role in the QE department of a large company with increased pay and job security.

Remaining in QE Without Experiencing R&D

Participants 1 and 4 chose to remain in their original QE roles (Fig. 6). These participants found fulfillment in their jobs and reported learning experiences that revealed the importance of QE. Their career goals aligned better with a cross-functional role in Quality than a purely design role in R&D. For example, Participant 1 prioritized the customer-facing nature of many positions in QE, saying, "it's not super repetitive, like I'm doing a different thing every day and I'm working with different groups of people, whereas a lot of those roles [i.e., graduate school, research] are very internal facing. You know you're doing a lot of the same work. I liked the fact that it was a client facing role that I was going to be in." Participant 4 found they could still bring products to market in a QE role. These participants changed their career goals to want a Quality Engineering position, which they easily attained in their present role.

From QE to R&D

A QE job was not the original career goal for any of the biomedical engineers we interviewed, in part because they were unaware of QE careers until they started their job search. Proximal influences such as a competitive job market for R&D positions and the nature of work at startups forced the job seekers into a QE role, providing their first learning experiences in Quality. Here, the career paths of the QEs diverge. For two of the QEs (Participants 2 and 3), their time in Quality did not change their original outcome expectations that R&D is the ideal job in biomedical engineering (Fig. 7). They formed these expectations early during their undergraduate training and since their curriculum reportedly emphasized design but did not cover Quality, their expectations were reinforced. As QEs, they viewed their position as a stopover—a way to gain the experience necessary to secure an R&D position. They intended to apply to R&D jobs in the same or another company. For example, Participant 3 says, "I actually think I want to go into research and development for my next role, because I do kind of miss some of the, like, more technical aspects of working in BME and I do kind of miss being on more of that cutting edge." These participants believed their industry experience as a QE would alter the proximal influences of the job market and allow them to secure an R&D position.

Interestingly, none of the entry-level QEs reported dissatisfaction with their jobs. They viewed Quality as essential and spoke of their partnership with R&D to launch and support products. The desire to leave Quality seems driven by

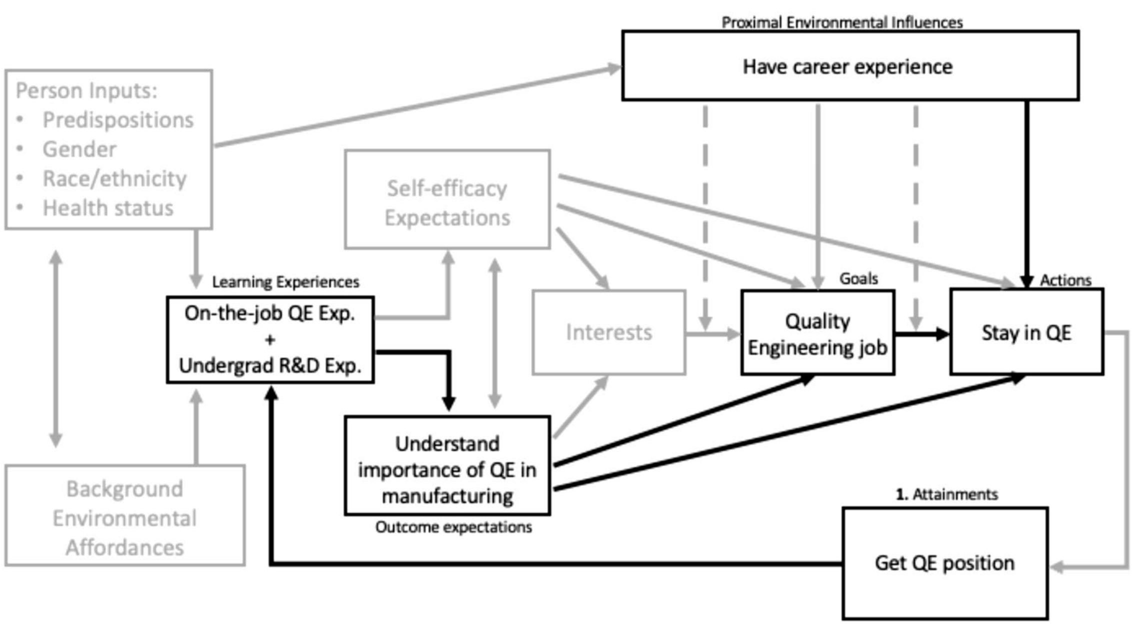

Fig. 6 SCCT model for QEs who lacked career experience in R&D but felt fulfilled in their Quality Engineering roles. These engineers chose to stay in their positions despite initially preferring a career in R&D

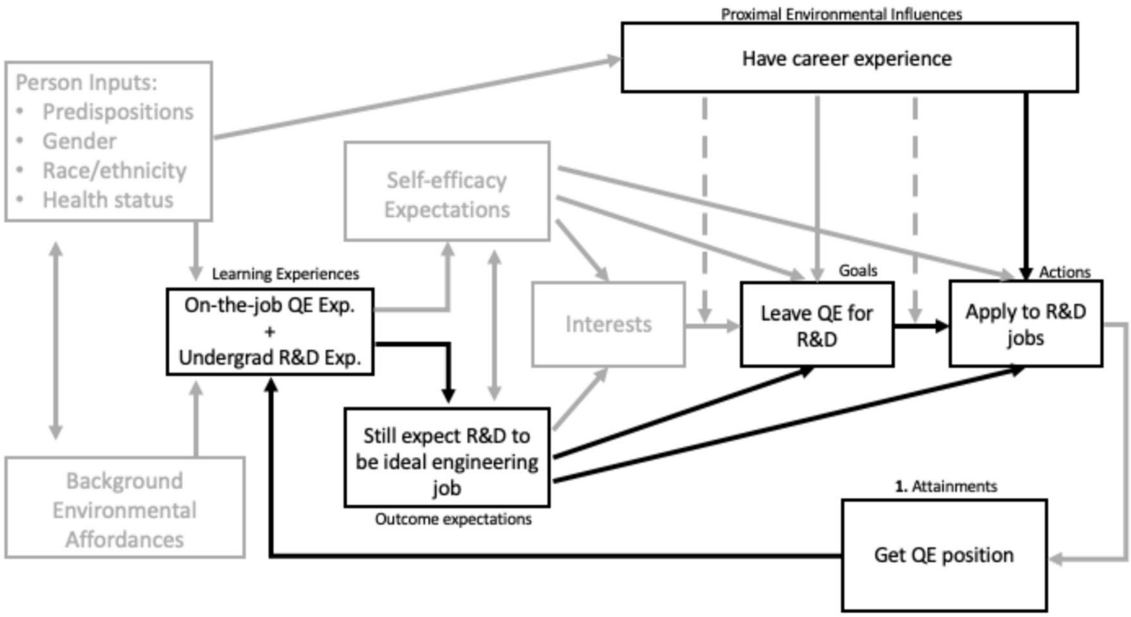

Fig. 7 SCCT model for QEs who lacked career experience in R&D and planned to leave their current Quality Engineering roles. These engineers had positive views of QE but felt R&D would be more impactful or more prestigious. They believed they now had the career experience they previously lacked in order to attain R&D roles

the participants' original outcome expectations and career goals (i.e., R&D). We wonder if these engineers were not giving their QE jobs a "fair chance" because their lack of QE learning experiences as undergraduates biased them against Quality.

From Undergraduate Directly to R&D

Although BME undergraduates appear to prioritize R&D positions, they are excluded from R&D jobs by proximal environmental factors, such as a lack of work experience or advanced degrees. However, three of the participants were current Quality Engineers who had previously held an R&D position. These participants (Participants 5, 6, and 7) secured an R&D position early in their careers either because they had advanced training or had connections to people in industry (Fig. 8).

How did these R&D engineers end up in Quality roles? Again, proximal environmental factors caused the transition: contracts ended, the engineers wished to relocate for personal reasons, or they did not enjoy working at their current company. The engineers' second job searches did not yield a similar R&D position, so they ended up in a QE position that did not align with their original goals (Fig. 9). Yet again, it appears that proximal factors—and not primary career goals—led our participants into QE.

Since these engineers entered QE by circumstance rather than direct action, it seems likely that they would want to leave QE for another R&D position that aligned with their original career goals. To the contrary, the QEs with previous R&D experience were content to remain in QE (Fig. 10). Participants 5 and 6 felt their QE position was more enjoyable, more impactful, and less stressful than their R&D roles. In particular, Participant 5 mentioned the steady schedule of QE work as opposed to the deadline-driven R&D projects, saying:

> I feel like working in that environment [R&D] had a lot more unknowns that made it like more stressful to kind of balance commitments and give like good estimates of timing and things to people on the team. Whereas now, in this role [QE], I know how long it takes me to write a certain document. [Participant 5]

Participant 6 repeatedly described a feeling of belonging and helping patients in QE, such as when they said "But, you know, I've seen bosses fight for it [safe products], and I, myself, want to model my actions after that because it means that much to me personally that the patients receive the best care possible."

We believe it was the learning experiences in both R&D and QE that allowed our participants to make a meaningful assessment of the two career paths and in some cases revise their career goals. We can see this clearly in Participant 7, who held a QE position, left for an R&D position, and subsequently returned to QE. When this participant only had experience in QE, they felt that only an R&D role would allow them to more directly save lives—a sentiment shared by other participants. The participant moved into an R&D

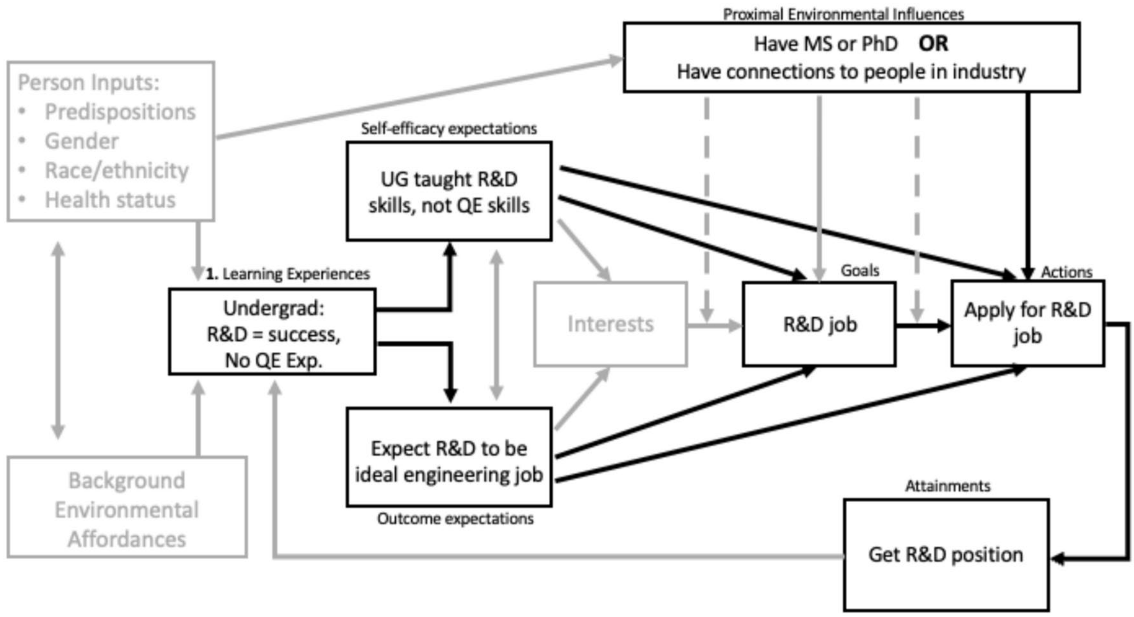

Fig. 8 SCCT model for engineers who had the required education or experience to attain an R&D role early into their career, as was their goal

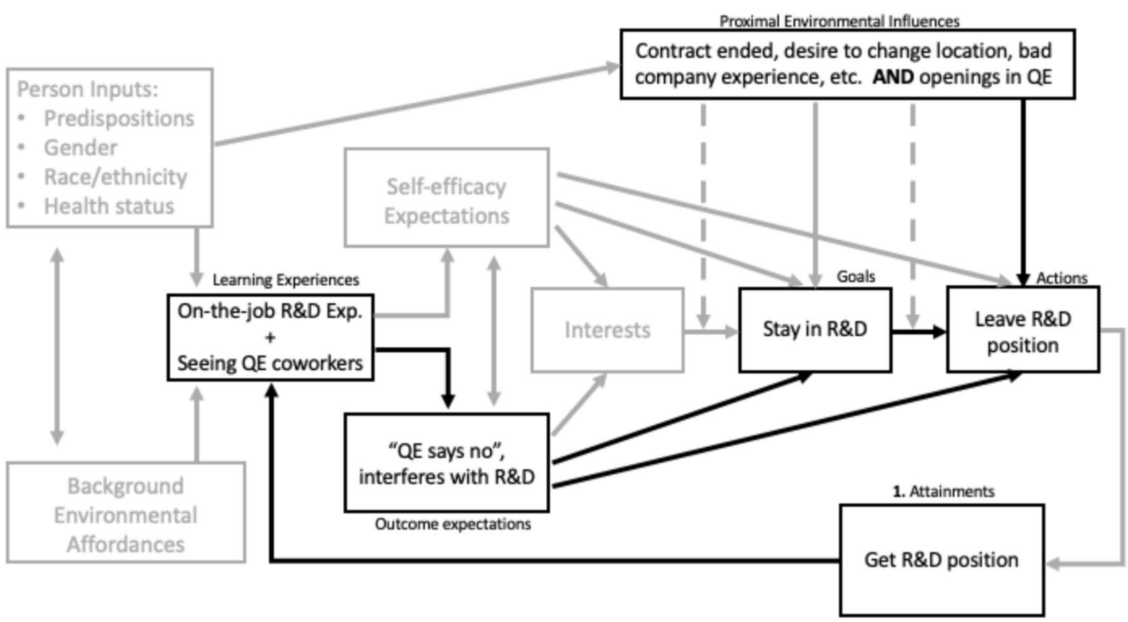

Fig. 9 SCCT model for R&D engineers who had negative views of Quality Engineering but, due to proximal influences, had to move into QE roles

role but then felt that QE had become a part of them and wanted to return. This is the participant that said, "Quality never leaves you. It's really ingrained in us" [Participant 7]. At the time of our interview with them, they were back in a QE position and were content with their role. Only the learning experiences in both QE and R&D were able to convince this engineer to revise their career goals and move back to QE.

Discussion

Undergraduate education should provide learning experiences that support career decisions. A common finding across our participants was that QE learning experiences were a prerequisite for developing interest in QE careers. Without meaningful exposure to QE, the participants heavily

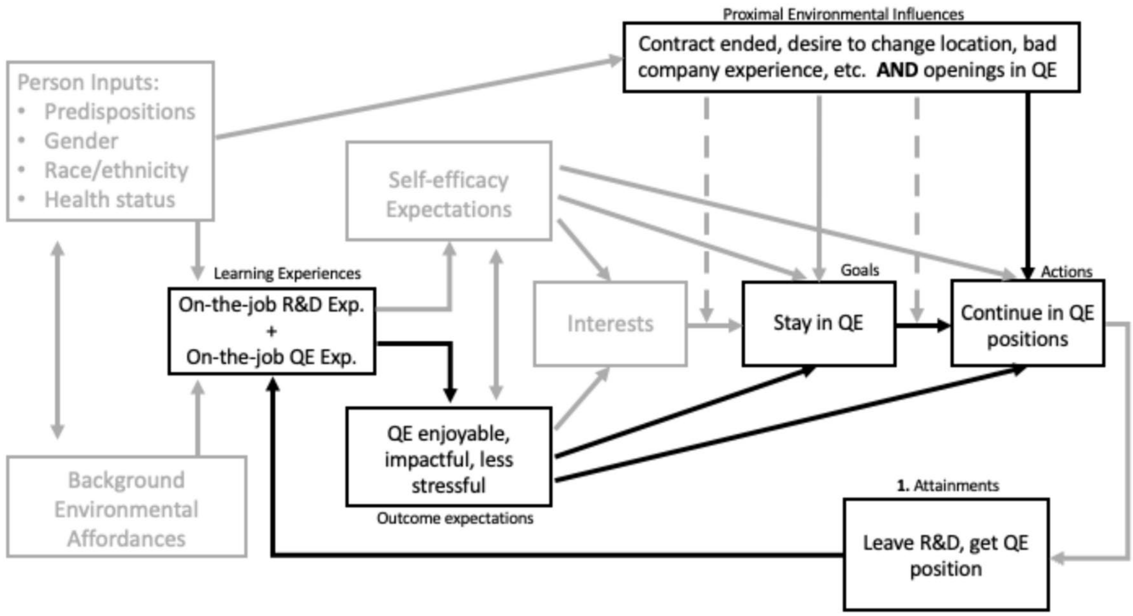

Fig. 10 SCCT model for QEs who had both QE and R&D career experience. Despite initially having negative views of QE, the engineers changed their outcome expectations of QE and R&D due to their learning experiences and chose to stay in their QE roles

favored R&D careers, with many viewing R&D as a defining feature of a biomedical engineering career. We cannot expect undergraduates to make QE their career goal if they are unaware of the field.

Simply raising awareness of QE might not be enough, as demonstrated by current QEs who enjoy their job but still desire a job in R&D. As discussed above, something about their undergraduate experiences biased them in favor of R&D, and we question the undergraduate emphasis of design as the defining feature of an engineer. Not all engineers design products or even processes. Regulation, monitoring, auditing, safety, reliability, and other foundations of QE are not given the same attention as design, prototyping, and innovation. Capstone design courses highlight the disparity between design and Quality. Design courses incorporate some QE fundamentals with lectures and assignments on, say, regulatory and safety issues. But at the final design fairs where students showcase their work, the prototype is the center of attention. We worry the continued emphasis on design cements R&D jobs as the career of choice in biomedical engineering.

Undergraduate engineering programs should develop marketable skills so students and the public can capitalize on their investments in higher education. While market forces should not entirely drive BME curricula, BME programs must acknowledge that up to 42% of all entry-level BME jobs are Quality-focused. Quality should be presented as a common and fulfilling career path for biomedical engineers, not as an alternative for graduates who lack the proximal environmental influences to enter R&D.

Undergraduate programs that introduce BMEs to Quality early will advantage students on the job market. These QE-aware students will be able to have informed conversations with companies and recruiters. Adding QE content or welcoming QEs as guest speakers is a first step toward a more comprehensive BME curriculum. We also recommend designing curricular or co-curricular activities that emulate industry by having R&D and QE teams work together on products. Internships, rotations, and industry immersion programs should balance R&D and QE roles to give students a better view of the BME career landscape.

On a positive note, the paucity of QE learning experiences in many BME programs creates low-hanging fruit for improving the marketability and career outcomes of graduates. BME students on the job market often find themselves with broad skillsets in various areas while they feel employers are only looking for specialized new hires [1, 2, 26]. Introducing Quality Engineering into BME curriculum could help solve this "jack-of-all-trades" dilemma BME students face.

Limitations and Future Research

The main limitation we found with our study is the parameters we set for participant recruitment. We originally planned to only learn about the experiences of Quality Engineers, but the interplay between QE and R&D suggest that interviewing R&D engineers would be insightful as future work.

Through this study, we were able to understand the career trajectories of those who only have experience in Quality Engineering or those who had experience in R&D and then QE. Future studies will investigate engineers who only have R&D experience and those who began in QE and moved into R&D. We also did not specifically select participants based on what career they wanted when they were undergraduates. Therefore, this study does not include the perspectives of biomedical engineers who knew of and wanted QE careers as students (although based on our conversations with current QEs, we believe few students began their education with an interest in or knowledge of the field). By selecting participants with these backgrounds, we can learn where the engineers learned of QE and how that impacted their career trajectories. Through developing and conducting this study, we also discovered a potentially incorrect assumption that participants would have a unified definition of "Quality Engineering." We realized this too late to adapt our study and therefore we included the definitions we used for our study design in the introduction. However, we expect that using future studies to ask students and engineers to define the careers discussed in this study can provide much insight into their outcome expectations and goals. A follow-up study would give a comprehensive view of industry career arcs that BME undergraduates may follow. We also recommend studying the cause of the bias between R&D and Quality Engineering. While our study uncovered the existence of this dichotomy, we still do not know if the bias comes from peers, departments, the media, or other sources.

The generalizability of results is typically used to evaluate the rigor and reproducibility of a study [40]. However, qualitative research is typically more focused on discovering in-depth and meaningful results that are not expected to be generalizable. People often expect statistical-probabilistic generalizability of quantitative research [41]. We recognize that our research cannot be generalized in this way because we cannot make the same underlying assumptions in our qualitative research; our data are subjective, our participant population is not representative of the whole, and our aim is not to create generalizable data but, instead, meaningful and detailed data. We do not consider this to be a weakness of our study, as it can still be transferrable in other ways and the results can and should be applied to other situations.

Similarities between the study and the reader's experience could create naturalistic generalizability, where the research resonates with the reader's own lived experiences. This can allow researchers and readers to explore different responses to the study without losing validity [41, 42]. Additionally, a study can be transferable either by applying the results to a situation that is congruent to that of the study methods or by understanding that the results can be applied to different settings based on the experiences of the readers [41, 43]. We expect the results of our studies to have both naturalistic generalizability and transferability through our use of rich description that consists of direct quotes from participants. The study also has some extent of analytical generalizability [41]. We think our applied SCCT diagrams can be used in other studies of career decision-making even in different contexts and with different populations.

Conclusion

This study identified gaps between BME curricula, undergraduate career expectations, and the entry-level BME job market. Undergraduate students need to be made aware of Quality Engineering and the plethora of positions in the QE field for which they are uniquely qualified. Learning experiences that balance QE and R&D are required for students to navigate their early careers in BME. While students' outcome expectations will vary, they cannot develop interest in a field without awareness or learning experiences. Developing coursework to overcome these barriers could lead to better career placement, job satisfaction, and job retention among graduates of BME bachelor's programs.

Acknowledgements The authors would like to thank the participants in this study for sharing their undergraduate and career experiences.

Author Contributions DES led the author team in conducting the research study and writing the manuscript. DES, PAJ, and JPM contributed to the study conception and design. DES performed interview data collection and analysis, with feedback from PAJ and JPM throughout. AL collected job post data and then both AL and DES analyzed the data, with feedback from PAJ. DES wrote the first draft of the manuscript and all authors commented on previous versions of the manuscript. All authors have read and approved the final manuscript.

Funding Funding was provided by the University of Illinois Urbana-Champaign and the University of Michigan.

Data Availability Due to the small sample size and in-depth nature of these interviews, participants could potentially be identifiable in the full dataset. Therefore, the datasets generated and/or analyzed in the study are not publicly available.

Code Availability Not applicable.

Declarations

Conflict of interest The authors declare that they have no competing interests.

Ethical Approval The University of Illinois Institutional Review Board approved this study as exempt under IRB 21850.

Consent to Participate Informed consent was obtained from all individual participants included in this study.

Consent for Publication Informed consent was obtained from all individual participants whose quotes were used in this study.

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