Data Analysis Methods for Qualitative Research: Managing the Challenges of Coding, Interrater Reliability, and Thematic Analysis

Michael J. Belotto PhD
Biomedical Research Alliance of New York, mbelotto@brany.com

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Abstract
The purpose of this article is to provide an overview of some of the principles of data analysis used in qualitative research such as coding, interrater reliability, and thematic analysis. I focused on the challenges that I experienced as a first-time qualitative researcher during the course of my dissertation, in the hope that how I addressed those difficulties will better prepare other investigators planning endeavors into this area of research. One of the first challenges I encountered was the dearth of information regarding the details of qualitative data analysis. While my text books explained the general philosophies of the interpretive tradition and its theoretical groundings, I found few published studies where authors actually explained the details pertaining to exactly how they arrived at their findings. Some authors even confirmed my own experience that few published studies described processes such as coding and methods to evaluate interrater reliability. Herein, I share the sources of information that I did find and the methods that I used to address these challenges. I also discuss issues of trustworthiness and how matters of objectivity and reliability can be addressed within the naturalistic paradigm.

Keywords
Qualitative Research Data Analysis, Coding, Interrater Reliability, Thematic Analysis

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Data Analysis Methods for Qualitative Research: Managing the Challenges of Coding, Interrater Reliability, and Thematic Analysis

Michael J. Belotto
Biomedical Research Alliance of New York, New Hyde Park, New York, USA

The purpose of this article is to provide an overview of some of the principles of data analysis used in qualitative research such as coding, interrater reliability, and thematic analysis. I focused on the challenges that I experienced as a first-time qualitative researcher during the course of my dissertation, in the hope that how I addressed those difficulties will better prepare other investigators planning endeavors into this area of research. One of the first challenges I encountered was the dearth of information regarding the details of qualitative data analysis. While my text books explained the general philosophies of the interpretive tradition and its theoretical groundings, I found few published studies where authors actually explained the details pertaining to exactly how they arrived at their findings. Some authors even confirmed my own experience that few published studies described processes such as coding and methods to evaluate interrater reliability. Herein, I share the sources of information that I did find and the methods that I used to address these challenges. I also discuss issues of trustworthiness and how matters of objectivity and reliability can be addressed within the naturalistic paradigm. Keywords: Qualitative Research Data Analysis, Coding, Interrater Reliability, Thematic Analysis

Introduction

The purpose of this commentary is to help students and new researchers navigate the course of qualitative data analysis, in particular, areas that are not often explained in publications of qualitative research studies, such as coding, interrater reliability, and thematic analysis (Campbell, Quincy, Osserman, & Pederson, 2013). In order to convey some of the challenges I faced as a first-time qualitative researcher, it is necessary to explain some of the details of my research. In trying to decide on the topic of my dissertation to complete a degree in public health, I thought about the difficulties I faced in my previous profession: a paramedic in the New York City 9-1-1 system. During my 12-year career in Emergency Medical Services (EMS), it seemed that many of the people I met were planning to pursue careers in other health professions, focusing on medical school, physician’s assistant, or nursing, or other public safety careers such as police officer or firefighter. This impressed upon me the notion that EMS was viewed as a transient career. Therefore, I chose to focus my dissertation on the issue of career longevity in the EMS profession. In particular, I examined if individuals came to this vocation with preconceived notions, and if so, whether preemployment expectations were aligned or misaligned with postemployment experiences. I further examined how alignment or misalignment of expectations and experiences contributed to job satisfaction and the intention to stay or leave the field.

Rapid turnover of emergency medical technicians (EMTs) and paramedics was a phenomenon I also personally experienced during my tenure as a director of a hospital-based EMS department. The importance of this problem was supported in the literature by projections...
for an aging U.S. population (U.S. Census Bureau, 2014), expected increases in age-related medical emergencies, driving greater demand for EMS professionals (U.S. Department of Labor, Bureau of Labor Statistics, 2014), and EMS agencies’ reported problems with both recruitment and retention of staff (Freeman, Slifkin, & Patterson, 2009). While my literature review yielded various studies of burnout and turnover in professionals such as emergency room physicians, nurses, and social workers, job satisfaction and employment longevity in the field of EMS was not well studied (Alexander, Weiss, Braude, Ernst, & Fullerton-Gleason, 2009; Perkins, DeTienne, Fitzgerald, Hill, & Harwell, 2009; U.S. Department of Transportation, National Highway Traffic Safety Administration, 2008, 2011). In fact, the review of the literature revealed a dearth of studies pertaining to EMS in general (Huot, 2013). Therefore, I chose a qualitative, phenomenological design for the method of inquiry for my study.

I chose the qualitative approach because it is appropriate in the early stages of research, when the important variables relevant to a particular subject of inquiry may not yet be known (Creswell, 2009). An advantage of the interpretive paradigm is it allows the researcher to understand a phenomenon through a process of exploration of initial suspicions and development of preliminary theories (Trochim & Donnelly, 2008). In my own phenomenological research (Belotto, 2017), I found that the semi-structured interview allowed me to ensure that I elicited the same core information from each participant, while also providing me with the flexibility to probe more deeply into the rich descriptions of experiences that participants shared. This enabled me as the researcher, rather than leading, to follow the participants, as they guided me to the relevant factors associated with career longevity in the EMS profession.

Given this context of the purpose and methodology of my research, herein are the specific challenges I faced and how I addressed them. I begin with a discussion of the development of my interview questions for an area of research that was young and for which no questionnaires existed. I further explain how I addressed the validity of my interview questions. I proceed to describe how I developed a system to code the interview transcripts. My process of assessing interrater reliability is also explained. Finally, I discuss how I synthesized the data into an organization of themes to interpret the findings of the research.

Content Validity

The lack of a current, validated questionnaire for a study such as mine presented a number of challenges. First, this required that I create interview questions that would ensure that I obtained the information necessary to address my research questions. Using the methods explained by Lawshe (1975), I became familiar with the procedures to establish the content validity of my core interview.

I assembled a panel with expertise in areas relevant to my research, including human resources, research ethics, qualitative research, and the EMS profession. Panel members assessed the effectiveness of the interview questions to address the research questions (see Appendix A). A 4-point Likert scale (no relevance, low relevance, moderate relevance, and strong relevance) was used rather than an odd number of choices, so that neutral comments were avoided (Lynn, 1986). Taking into account the number of panel members, the formula provided by Lawshe yielded a content validity ratio threshold, at which the degree of concurrence of the panel would not be considered to have occurred by chance, at an alpha level of .05. Therefore, questions yielding scores below the threshold were eliminated, thus increasing the overall content validity index of the core interview instrument. Finding 11 individuals with varied and relevant expertise to my study who were both qualified and willing to take the time to participate on the panel, developing and collecting the surveys, aggregating
and analyzing the data, creating the tables to display the data, interpreting and writing the results, and finally, making the necessary revisions to the interview questions added approximately two months to the project.

Quality Assurance of the Data

After IRB approval of the study, the first participant’s interview was conducted, recorded, and transcribed. In contrast to quantitative studies, the data analysis process began immediately upon the enrollment of the first participant and was continuous. This process of simultaneously recruiting participants, conducting interviews, and analyzing the data was challenging. For example, excessive time spent on data analysis resulted in recruitment and enrollment lags, which in turn resulted in a disruption to the scheduling of interviews and the stream of recordings sent for transcription, thus ultimately limiting transcripts available for analysis. Constant attentiveness was required to keep all aspects of the study flowing steadily.

I started the analysis process in keeping with what Ulin, Robinson, and Tolley (2005) described as, immersing one’s self in the data. This meant continually reading the transcripts to familiarize myself with the content. I assessed the quality of the data, whether responses were ambiguous or contradictory and whether I was getting the information I needed to answer my research questions. I also scrutinized my interview technique for bias, whether questions were asked in a neutral manner, unexpected findings had emerged, or opportunities to probe more deeply into responses were missed. For example, one participant provided a rich description of how he progressed to various positions in the EMS profession, such as becoming an educator and flight medic. This had resulted in a lengthy career of over 20 years. In reviewing the transcript; however, I realized that I had not obtained all the information I needed. Upon following up with this individual and probing more deeply into his thoughts about the profession in general, he revealed that he did not think that his career was typical and stated that he felt that for most of the workforce, EMS was a transient profession. Regularly reviewing the quality of my data, becoming more familiar with the content, and scrutinizing my interview technique all led to revisions and continual refinements of the interview process.

Data Analysis

Coding

In the review of each participant’s transcript, the “meaning units,” the words and sentences that conveyed similar meanings, were identified and labeled with codes (Graneheim & Lundman, 2004). The coding process allowed for the interpretation of large segments of text and portions of information in new ways. Assessing how these meaning units were linked led to the identification of themes. As I reviewed my data, I struggled to attach codes to various sections of text that represented those meaning units, as there seemed to be endless choices of words to characterize the experiences that participants described.

As the endless choices of characterizations were resulting in the creation of a very large number of codes, I returned to the literature to find more information about coding qualitative data. After finding and familiarizing myself with the Saldaña (2009) code book resource, I decided to use a method of “structural coding,” whereby, I labeled passages with terms that were related to the research questions. For example, since my study explored the relationship between the alignment of preemployment career expectations and postemployment experiences, job satisfaction, and the intention to leave the EMS profession, I used labels for codes such as expectations, aligned experience, misaligned experience, satisfaction, and intent.
to leave. This method greatly reduced the number of codes and provided a context to create categories of codes or code families that were related to my research questions.

For some experiences, I used a secondary label that referred to a family of challenges of the profession such as, the physical challenges of the job, working with the pain of spinal injuries, or the psychological challenges of coping with illness and deaths of patients. Finally, I utilized a “descriptive method” of coding to create a label that conveyed the essence of what I was hearing. For example, when a paramedic stated that he had not anticipated the burden of physical injuries that ultimately led to a decision to leave the field, a primary theme of the study; this was coded as “intent to leave - physical injury concern.” This approach addressed some of the challenges resulting from the open-ended questioning that is used in qualitative research, where participants may provide lengthy and complex responses, digress, or discuss multiple themes, all of which can greatly add to the difficulty of coding, and potentially reduce interrater reliability (Campbell et al., 2013).

While computer assisted qualitative data analysis software (CAQDAS) programs have become popular for processing large amounts of qualitative data, trying to learn the principles of coding and qualitative data analysis, while also becoming competent at navigating the functions of CAQDAS proved to be extremely difficult. Therefore, since CAQDAS was not an option for me, I decided to manually code my data. Rather than utilizing the old tried and true method of using numerous different colored pencils to outline sections of text, I developed a somewhat more technological variation of that approach. Using Microsoft WORD functionality, I highlighted sections of text and using the tracked changes and new comment functions, I added my codes in the margins of the transcripts.

As I analyzed each study participant’s interview, I also developed a codebook (see Appendix B). The codebook listed all the codes used for each participant’s transcript; thereby, documenting exactly how every single passage of text was evaluated. The codebook continually grew as subsequent participants discussed new topics, requiring additional codes.

**Interrater Reliability**

To assess my analysis of the data, I utilized the tool of interrater reliability. To establish trust and confidence in the findings of the research, rigor was necessary to confirm the consistency of the study methods (Thomas & Magilvy, 2011). I employed the method of triangulation, whereby, I sought peer debriefing on my interpretations (Denzin, as cited in Guba, 1981). The enrollment of 10 participants in my study resulted in approximately 200 pages of transcribed interviews. Due to this substantial amount of data, in keeping with the recommendations in the literature, I evaluated interrater reliability by analyzing a sample of texts (Barbour, 2001; Campbell et al., 2013; Hallgren, 2012; Kurasaki, 2000; Marques & McCall, 2005).

Influenced by the methods of Hruschka et al. (2004), I conducted three rounds of reliability checks. After review of the first two participants’ transcripts, I had generated 126 codes. I then shared the transcripts with two independent researchers. A meeting was held whereupon the feedback indicated that the coding scheme would have to be modified, as it was just not practical due to the large number of codes. It was at this point that I discovered the Saldana (2009) coding methods and implemented the coding process previously described.

Finding independent researchers who were both knowledgeable and willing to dedicate themselves to coding lengthy transcripts was extremely difficult. Due to the time constraints of the two independent researchers, a single independent coder was used for the second round of reliability checks. The use of one or more independent coders is supported in the literature by multiple authors (Barbour, 2001; Campbell et al., 2013; Creswell, 2009). After the independent researcher coded the transcript of the first participant using the improved coding
method, we compared how we interpreted each segment of text and calculated our level of concordance. Using the methods of Campbell et al. (2013), we calculated an initial discriminant capability of 72%. The discriminant capability of the coding scheme is a measure of the level of intercoder reliability. We then used the method of negotiated agreement to reconcile the remaining differences and recorded how many were reconciled and how many disagreements prevailed. We also maintained a record of how reconciliation was achieved (i.e., if the independent coder deferred to me or I to her). We repeated this process for a third round of reliability checks which yielded similar results.

**Development of Themes**

Upon completion of the coding of all 10 transcripts, I proceeded to the next step in my approach to the analysis of the data. This required that I develop a method to analyze the overall content of the data. At first, trying to fathom the meaning of 200 pages of words was overwhelming, and I could not find in my text books nor in any of the published studies how to manage this task. I constructed a content analysis table to identify which codes were used for each participant. The content analysis table was essentially a template of the codebook; however, at this stage, it was used to analyze aggregate data.

When the template was used for individual participants during the coding process, the comment number generated in the transcript by the tracked changes function in Microsoft Word was placed in the box with the corresponding code. In this way, by viewing the code book, I could go to the exact passage in the transcript to verify where that code was used. When the template was used to analyze overall content, the subject identifying number was placed in the box with the corresponding code. For example, if subject number one said they went into the profession thinking it was a stepping stone to other careers, then the number one was placed in the “yes” box for preconceived notions, for the code “transient career perception.” I then repeated this process for each subject’s responses.

Utilizing the content analysis table in this way, I was able to cluster items of data that were related. Since I coded the data with labels that were related to my research questions, the patterns that emerged led to the identification of categories. I then examined the patterns that had been placed together for the emergence of overarching themes (Percy, Kostere, & Kostere, 2015). If an additional second level of a pattern emerged, I categorized it as a secondary theme. For example, the psychological challenges of coping with illness and deaths of patients emerged as a primary theme, while participants also indicated that this was an expected challenge of the profession. However, some participants added that coping with the grief of family members who were suffering the losses of their loved ones was also particularly challenging. This was considered to be a secondary theme pertaining to the psychological challenges of the occupation. Since these decisions were subjective, I also used direct participant quotes to support the rationale for each theme. The aggregate analysis table enabled me to identify and distinguish the trends of various participant experiences. Handling and sorting the data in this way greatly facilitated the identification of emerging primary and secondary themes as illustrated in Table 1.

I then interpreted the data with regard to how those emerging themes addressed my research questions and whether initial suspicions were supported. I also questioned whether individual experiences that appeared to be disconfirming cases actually contested my initial beliefs. For example, while two participants did express apprehension about physical injuries, they did not indicate that this was a source of job dissatisfaction or that this was associated with the intention to leave the profession. Upon further examination, it became clear that these participants were paramedic students who were the youngest individuals in the study and did not yet have the years of experiences similar to the seasoned paramedics. When the essence of
their sentiments was actually compared to the notions of the veteran paramedics at similar time points in their careers, it became apparent that these descriptions were not disconfirming cases. Rather, when comparable career time points were assessed, the notions of the students were actually consistent with how the veterans had felt when they were first entering the profession. The exploration of experiences that appeared to be contradictory to the emerging themes served to further enhance the credibility of the findings of the research (Booth, Carrol, Llott, Low, & Cooper, 2013).

Table 1

| Categories               | Primary Themes                        | Secondary Themes                                      |
|--------------------------|---------------------------------------|-------------------------------------------------------|
| Vocational Influence     | Altruism                              |                                                       |
| Career Longevity Perception | Transient Profession                |                                                       |
| EMT to Paramedic         | Professional Growth                   | Self-Efficacy & Excitement                            |
| Challenges of the Profession | Physical Challenges                 | Physical Injury                                       |
|                          |                                       | Increased Physical Challenges with Advancing Age     |
|                          |                                       | Alternative Occupational Opportunities               |
|                          |                                       | Grief of Family Members                               |
|                          | Psychological Challenges             |                                                       |
|                          | Illness and Death of Patients        |                                                       |
| Importance of Relationships | Negative Relationships with          | Acceptance of Negative Relationships                 |
|                          | Partners / Colleagues                | Camaraderie                                           |
|                          | Dissatisfaction                      |                                                       |

Conclusion

During the course of completing my dissertation, many issues emerged as a result of conducting a qualitative research study. I observed that few authors of published qualitative studies provided a “how to” manual describing the details of their analyses. In keeping with the goal of this commentary, to help new researchers to navigate the path of qualitative data analysis, herein is my summary of the major obstacles I faced and the most helpful resources that I found to overcome these challenges.

A number of textbooks were helpful in describing the philosophical groundings of the interpretive tradition (Creswell, 2009; Trochim & Donnelly, 2008; Ulin, Robinson, & Tolley 2005). As a new qualitative researcher, this information was extremely meaningful to me as it edified me with regard to core values of the naturalistic paradigm. As I lived through the dissertation experience for approximately two years, I developed a greater appreciation for qualitative research principles and the importance of qualitative exploratory research.

For example, I had read about concepts such as spending time in the field to develop a rapport with participants to establish trust (Dooley, 2007). While I appreciated the concept, as
I continued my journey as a qualitative researcher, I began to actually experience this phenomenon, in particular with paramedic students. As I continued to listen to participants’ poignant descriptions of their experiences and feelings about topics such as how they dealt with death, the suffering of family members, and working with the agonizing pain of what were often career ending spinal injuries, I came to understand their extraordinary commitment to “my” research. I believe my presence at classes and descriptions of my own career created a rapport for participants to volunteer their time and to commit to sharing their personal feelings. As these stakeholders embraced the research topic’s relevance to their own careers, I believe at that point it became “our” research.

Guidance on specific issues, such as establishing the content validity of my interview questions was found in an article published by Lawshe (1975). This author provided all the necessary information, including how to calculate the content validity index of my interview and how to interpret the result. I found the most comprehensive resource on coding to be the coding manual by Saldaña (2009). This work of over 200 pages is filled with explanations of what codes are and their functions, different types of coding methods, and sample texts with examples of how they were coded.

I found two studies that actually discussed coding schemes and how interrater reliability was assessed in detail. The fact that researchers rarely discuss coding reliability was confirmed by Campbell, Quincy, Osserman, and Pederson (2013) in their overview of coding schemes and interrater reliability. During the conduct of HIV research at the Centers for Disease Control and Prevention (CDC), Hruschka et al. (2004) discuss how they used different coding processes for different types of studies. These authors provided details of how they created codebooks, and how they dealt with factors impacting interrater reliability, such as long interviews with a greater number of codes. The assessment of the trustworthiness of research findings is discussed in articles by Guba (1981), Thomas and Magilvy (2011), and Whittemore, Chase, and Mandle (2001). These authors provide explanations of topics such as credibility, dependability, and confirmability of research results.

One of the recurring themes I found in the literature of qualitative research was that there is not just one best way to do it (Campbell et al., 2013). Finding the most efficient method will be determined by the type of study, the researcher, and available resources If available resources to conduct the trial are limited or if there are time restrictions pertaining to completing the study, I would advise new researchers to consider curtailing the number of research questions. In my experience, having to analyze the data with regard to four research questions did add significantly to the amount of time and work required to complete the study. While the literature does support having more than one research question (Creswell, 2009; Miles & Huberman, 1994; Simon, 2011), I would advise new researchers to be prepared, as this does add length to the interview and increases the amount of time required for additional coding and analysis.

To complete my first attempt at qualitative research, I used aspects of various documented processes and developed my own methods that were relevant to my research and my situation. My challenges were shaped by my own context, my findings in the literature, my time deadlines to complete a dissertation, and my limitations as a first-time qualitative researcher. I hope that this analysis and the sources I have provided will assist future researchers and students to come.
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## Appendix A: Core Interview Questions

| Research Questions                                                                 | Interview Questions                                                                 |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| **Research Question 1**                                                            | 1. Let’s start off by talking about what you expected from the EMS vocation.         |
| What are the preconceived notions of EMTs and paramedics prior to entering the     | 2. What was the most important influence for entering this profession?                |
| vocation and their notions of the vocation after facing the realities of the job?  | 3. How did your early experiences compare to what you expected?                      |
|                                                                                  | 4. What about your experiences now? Is your experience of the job now how you      |
|                                                                                  | thought it would be after working in the field for (# of years participant has    |
|                                                                                  | been working)?                                                                       |
|                                                                                  | 5. If alignment between expectations and experiences is different now than how you  |
|                                                                                  | felt early in your career, what changed?                                             |
| **Research Question 2**                                                            | 6. Did the alignment or misalignment between your expectations and experiences affect |
| How does alignment or misalignment between preemployment and postemployment       | you?                                                                                 |
| perceptions of the vocation affect EMTs and paramedics?                           | 7. When you first started working in the field, how did you feel about your career  |
|                                                                                  | choice?                                                                              |
|                                                                                  | 8. What about now? How do you feel about your career choice now?                     |
| **Research Question 3**                                                            | 9. What was the most important thing that made you feel satisfied about your job?   |
| How does alignment or misalignment between the notions of the vocation prior to    | 10. What was the most important thing that made you feel dissatisfied with your job?|
| and following entry into the profession contribute to job satisfaction or          | 11. How did the relationship between your expectations and experiences affect how   |
| dissatisfaction?                                                                  | you felt about EMS work?                                                             |
|                                                                                  | 12. Has how you felt about the job changed over time?                                 |
|                                                                                  | 13. If your job satisfaction has changed over time, what was the most important     |
|                                                                                  | issue affecting your change in satisfaction?                                         |
| **Research Question 4**                                                            | 14. Do you plan to work as an EMT/paramedic in the field until retirement?           |
| How does job satisfaction or dissatisfaction contribute to the intent to stay in or  | 15. Are you planning to leave the EMS profession?                                    |
| leave the profession?                                                             | 16. For those planning to leave the profession: What is the most important factor   |
|                                                                                  | affecting your decision to leave the profession?                                     |
|                                                                                  | 17. For those planning to stay in the profession: What is the most important issue  |
|                                                                                  | affecting your decision to stay in the profession?                                   |
### Appendix B: Code Book

| Phenomenon of Interest                                                                 | (Expectations) | Notions | Experience/Alignment | Experiences | Satisfaction/Dissatisfaction | Intent to Leave |
|----------------------------------------------------------------------------------------|----------------|---------|----------------------|-------------|-------------------------------|-----------------|
|                                                                                       | Preconceived Notions |         |                      |             |                               |                 |
|                                                                                       | Formed prior to entering profession | Formed after entering profession | When no preconceived notion |             |                               |                 |
|                                                                                       | YES | NO | YES | NO | YES | NO | Please add “S” or “D” to phrase # |                 |
| Career Perception – Transient Career                                                  |                 |         |                      |             |                               |                 |
| Career Perception - Path to Other Profession (Health, Public Safety)                   |                 |         |                      |             |                               |                 |
| Career Perception - Fieldwork - Longevity / Retirement in EMS                         |                 |         |                      |             |                               |                 |
| (this means working on the ambulance)                                                  |                 |         |                      |             |                               |                 |
| Career Perception – Longevity / Retirement in EMS                                     |                 |         |                      |             |                               |                 |
| (this means EMS position other than fieldwork on ambulance, such as: supervisor,       |                 |         |                      |             |                               |                 |
| dispatcher, educator)                                                                  |                 |         |                      |             |                               |                 |
| Challenges – Physical Challenges                                                      |                 |         |                      |             |                               |                 |
| Challenges – Psychological Challenges                                                 |                 |         |                      |             |                               |                 |
| Challenges – Psychological Challenges – Patient Deaths                                 |                 |         |                      |             |                               |                 |
| Challenges – Psychological Challenges - Family Member Grief                            |                 |         |                      |             |                               |                 |
| Vocational Influence - Altruism                                                       |                 |         |                      |             |                               |                 |
| Vocational Influence – family member in health field                                   |                 |         |                      |             |                               |                 |
| Personality – Diversity of Practice – enjoy different types of calls                   |                 |         |                      |             |                               |                 |
| Personality – Diversity of Partners – enjoy working with different partners            |                 |         |                      |             |                               |                 |
| Personality – enjoy adrenaline rush                                                    |                 |         |                      |             |                               |                 |
| Professional Growth                                                                   |                 |         |                      |             |                               |                 |
| Professional Growth - EMT to Paramedic – increased capability – autonomy               |                 |         |                      |             |                               |                 |
| Relationships – Partners (positive, negative) – camaraderie with colleagues            |                 |         |                      |             |                               |                 |
| Relationships – with Other Health Professionals                                        |                 |         |                      |             |                               |                 |
Author Note

I currently serve as a member of the Biomedical Research Alliance of New York (BRANY) IRB, responsible for the review of research protocols. I also serve as a research compliance auditor, responsible for reviews of investigators’ sites, to ensure the conduct of research is in compliance with federal regulations and ethical guidelines. Correspondence regarding this article can be addressed directly to: mbelotto@brany.com.

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