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User-Centered Design Strategies for Clinical Brain-Computer Interface Assistive Technology Devices

Geraldine Light
Walden University

Walden University

College of Management and Technology

This is to certify that the doctoral study by

Geraldine Light

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

Review Committee
Dr. Steven Case, Committee Chairperson, Information Technology Faculty
Dr. Gary Griffith, Committee Member, Information Technology Faculty
Dr. Michael Orsega, University Reviewer, Information Technology Faculty

Chief Academic Officer
Eric Riedel, Ph.D.

Walden University
2019

Abstract

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Technology Devices

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MSIT, Walden University, 2017

MSIDT, Walden University, 2011

BS, San Francisco State University, 1983

Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Abstract

Although in the past 50 years significant advances based on research of brain–computer interface (BCI) technology have occurred, there is a scarcity of BCI assistive technology devices at the consumer level. This multiple case study explored user-centered clinical BCI device design strategies used by computer scientists designing BCI assistive technologies to meet patient-centered outcomes. The population for the study encompassed computer scientists experienced with clinical BCI assistive technology design located in the midwestern, northeastern, and southern regions of the United States, as well as western Europe. The multi-motive information systems continuance model was the conceptual framework for the study. Interview data were collected from 7 computer scientists and 28 archival documents. Guided by the concepts of user-centered design and patient-centered outcomes, thematic analysis was used to identify codes and themes related to computer science and the design of BCI assistive technology devices. Notable themes included customization of clinical BCI devices, consideration of patient/caregiver interaction, collective data management, and evolving technology. Implications for social change based on the findings from this research include focus on meeting individualized patient-centered outcomes; enhancing collaboration between researchers, caregivers, and patients in BCI device development; and reducing the possibility of abandonment or disuse of clinical BCI assistive technology devices.

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Dedication

       I want to dedicate this study to my loving husband, David, who was always there with a positive word, encouragement, and a big hug. Thank you, David, without your constant love and support completing this degree would not have been possible. I dedicate this doctoral study to my Mom and Dad, my son David, my brothers, and all my family and friends whose love and support was always nearby when it was needed most.

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Section 1: Foundation of the Study

Background of the Problem

Technology supported assistive devices for individuals with disabilities acknowledged in a published report by Russell, Hendershot, LeClere, and Howie (1997) were limited in scope. As predicted in that report, advances in assistive technology now offer both restorative and rehabilitative devices to improve quality of life, even for individuals with rare disorders (Carver, Ganus, Ivery, Plummer, and Eubank, 2015). Brain–Computer Interface (BCI) assistive technology that Vidal (1970) identified in the 1970s holds the promise of providing restorative functionality for individuals with rare disorders; however, as Rupp (2014) concluded, that promise has not been fully realized.

The significance of employing user-centered design strategies to meet expected patient-centered outcomes is exemplified by the proportion of assistive technology device abandonment or disuse that Scherer and Federici (2015) cited as being 30% or higher for a period of the past 30 years. Effective clinical BCI assistive technology devices hinge on designs that incorporate ergonomic features and aspects of signal processing to meet expected patient-centered outcomes. Ergonomic features are related to physical aspects of the device, and these features influence aspects of signal processing (Kathner et al. 2017; Lacko et al. 2017). Computer scientists have a critical role in the design process of coordinating complex ergonomic features and signal processing to meet patient-centered outcomes (Chu, 2015). Clinical BCI devices designed to meet the expectations of individuals with rare disorders and reduce the risk of disuse require the collaborative efforts of experts such as bioengineers and computer scientists.

Problem Statement

As assistive technologies emerge, computer scientists designing assistive technologies often lack design strategies (Nijboer, 2015). The rate of disuse or abandonment of assistive technologies was cited by Scherer and Federici (2015) as being approximately 30% for a period of the past 30 years. The general information technology problem is computer scientists designing assistive technologies often lack design strategies. The specific information technology problem is computer scientists designing BCI assistive technologies lack user-centered clinical BCI device design strategies to meet patient-centered outcomes.

Purpose Statement

The purpose of this qualitative multiple case study was to explore the user-centered clinical BCI device design strategies used by computer scientists designing BCI assistive technologies to meet patient-centered outcomes. The target population consisted of computer scientists engaged in the design of clinical BCI assistive technology devices for individuals with disabilities. The population for this study encompassed computer scientists experienced with clinical BCI assistive technology design located in the Midwest, Northeast, and Southern regions of the United States, and Western Europe. This population was appropriate because research conducted by Klein (2016) indicated a gap between the expectations of potential users of BCI devices and the design of BCI devices. This study may contribute to social change by increasing awareness of patient-centered outcomes in decision making during the design process, such that clinical BCI

assistive technology device designers might better meet the needs of patients to improve their quality of life.

Nature of the Study

The nature of the study describes and justifies the selection of the study methodology and design. Wohlin and Aurum (2015) suggested that to decide which methodology and design are best to guide the research study requires identification of the research problem. Methodology choices for a research study include quantitative, qualitative, and mixed-methods methodologies. As Gergen, Josselson and Freeman (2015) posited qualitative research is not concerned with testing theories but is more concerned with understanding societal concerns. For this study, I used a qualitative methodology to explore what are user centered clinical BCI device design strategies used by computer scientists designing BCI assistive technologies that might influence patient outcomes was appropriate. McKusker and Gunaydin (2014) specified that quantitative researchers are concerned with testing a hypothesis to determine the relationship between independent and dependent variables, or identify trends, and might involve the collection of numeric data for statistical analysis. I did not intend to identify trends in the field of BCI technology related to design strategies or collect numeric data for statistical analysis therefore a quantitative study was not appropriate. McKusker and Gunaydin (2014) also highlighted how a mixed-methods approach requiring the collection of both quantitative and qualitative data might provide a better understanding of the research problem. A mixed-methods approach was not appropriate for this study because it would have required conducting a quantitative study, which was not what this study required to gain

an understanding of what are user centered clinical BCI device design strategies used by computer scientists designing clinical BCI assistive technologies.

Once I decided to use a qualitative methodology the next step was selecting an appropriate research design. Wohlin and Aurum (2015) suggested that in selecting a design, researchers must appropriately investigate their research question(s), collection, and data analysis. Possible qualitative methodology designs include narrative, phenomenological, ethnographic, and case studies. Bruce, Beuthin, Shields, Molzahn, and Schick-Mararoff (2016) described a narrative study as validating stories told by individuals as sources of empirical knowledge. Because the purpose of this study was to explore what are user centered clinical BCI device design strategies used by computer scientists designing BCI assistive technologies and not to collect stories a narrative study was not appropriate. VanScoy (2015) described phenomenological research design as a method to determine what an experience means to the individual who lived and can describe the experience. Because I did not focus on the experiences of computer scientists designing BCI assistive technologies a phenomenological study was not suitable. Baskerville and Myers (2015) specified that the ethnographer observes and participates in the situation but does not seek to influence conditions. I did not to participate in the BCI device design process and therefore an ethnographic study design was not fitting for this study. Ketokivi and Choi (2014) described case study designs as appropriate for answering research questions through intensive exploration for the creation of knowledge. A qualitative methodology case study design was best suited to investigating the research question of what are user-centered clinical BCI device design strategies used

by computer scientists designing BCI assistive technologies to meet patient-centered outcomes.

Research Question

The purpose of this study was to explore the user-centered clinical BCI device design strategies used by computer scientists to design BCI assistive technology devices. Augmenting the description of the purpose of the study with an analytical *what are* provides a way to form a research question(s) for a case study (Wohlin & Aurum, 2015). Asking what the user centered clinical BCI device design strategies used by computer scientists to design BCI assistive technology devices are affords the opportunity to better understand frameworks established for BCI technology development. The overarching research question for the study was:

What are user-centered clinical BCI device design strategies used by computer scientists designing BCI assistive technologies to meet patient-centered outcomes?

Interview Questions

Each interview question must contribute knowledge to the research question. Creating an interview protocol that includes participation confirmation questions, interview questions, and possible follow-up questions (See Appendix A) might ensure consistency for the interview process with all participants. Yin (2014) suggested that interviews that are frequently used for case study research may take the form of a guided conversation but will follow a line of inquiry. For this case study I relied on an interview protocol that assisted in managing technical aspects and adhered to the intended line of inquiry.

Conceptual Framework

A conceptual framework for a qualitative study provides an organized approach to understand the nature of the phenomenon being studied. Green (2014) discussed how a conceptual framework links concepts from various theories to inform the research and make the research findings meaningful and generalizable. The conceptual model that I used for this study was the multi-motive information systems continuance model (MISC) that Lowry, Gaskin and Moody (2014) proposed regarding the influence of intrinsic motivation on the user related to the use of information systems. Given the expectations of patients for assistive technology BCI devices being a primary design concern, the MISC theory explains and predicts the discrete cognitive processes through which systems fulfill a range of motives and expectations and how this fulfillment leads to continuance intentions.

The MISC model contributes to understanding how a system-design goal is essential in finding an appropriate balance between user needs, system functionality, and development feasibility. Kubler et al. (2014) suggested the MISC model might also account for design constructs that have the potential to contribute to system use such as design aesthetics, perceived ease of use, and design-expectations fit. Lowry et al. (2014) posited the theory of intrinsic motivation versus extrinsic motivation of users related to information systems, with intrinsic motivation such as satisfaction, continuance intentions, and perceived performance being strong predictors of user outcomes. Because the intrinsic motivation of the user might be a design factor, the application of the MISC model was well suited to this exploration of what user-centered clinical BCI device

design strategies are used by computer scientists designing BCI assistive technologies to meet patient-centered outcomes.

Definition of Terms

Amyotrophic lateral sclerosis. A degenerative motor neuron disease that is commonly referred to as ALS that affects patients and limits their life span to from 2 to 4 years (Arthur et al., 2016).

Brain computer interface. A brain computer interface allows communication without movement by measuring central nervous system (CNS) activity and converting it into output thereby enabling the ongoing interactions between the CNS and its external or internal environment (Brunner et al., 2015).

Brain computer interface device. A brain computer interface device incorporates electronic signals from the brain into novel communication and control devices (Chu, 2015).

Brain computer interface technology. Brain computer interface technology is used to establish direct communication to control an external computer device through brain activity (Ienca & Haselager, 2016).

Event related potential. Event related potential (ERP) are electric potentials emanated from the brain related to internal or external events (Jin et al., 2015).

Electroencephalograph. A technique involving electric field sensors placed on the scalp to capture signals from the brain (Thompson et al., 2014).

Hedonic-Motivation System Adoption Model. Model for the design of systems that satisfy pleasure, fun, or enjoyment desire of the user (Lowry et al., 2014).

Neuroprosthetic devices. A device that supplements neural deficits or enhances neural activities through neural control of a prosthetic (Barfield & Williams, 2017).

Patient centered outcomes. Outcomes or goals that a target group identifies as being valuable (Kubler et al., 2014).

Utilitarian-motivation systems. Systems designed to satisfy the desire of the user for a practical use of the device (Lowry et al., 2014)

Assumptions, Limitations, and Delimitations

Assumptions

Completing a research study often necessitates making assumptions. Twining, Heller, Nussbaum, and Tsai (2017) posited that assumptions might represent the subjective influence of the researcher needed to conduct the research but given consideration by being reflexive. For this study, one of the assumptions I made was regarding the complexity of the design process for BCI devices that are intended for assistive technology use. I assumed this because the design of this type of BCI device must satisfy the requirements of the potential patients and is carried out as a collaboration between computer scientists, neuroscientists, and other specialists in the field of BCI technology. A second assumption I made was that disuse and abandonment might reflect patient-centered outcomes not being met. I similarly assumed that actions and intentions of computer scientists designing clinical BCI assistive technologies are driven by a cognitive desire to provide technology to improve the quality of life for potential patients.

Limitations

As part of a qualitative research study limitations must be considered and identified by the researcher. Twining et al. (2017) advised that limitations are often related to the measurement of the variables, an inadequate number of participants, errors in measurement, or errors in data collection. Additionally, Hemkens, Contopoulos-Ioannidis, and Ioannidis (2016) suggested that reporting limitations of a study is prudent because it provides other researchers with information to consider if planning to replicate or conduct a similar study, plus it provides a perspective to the extent the findings of the study can be generalized. Limitation of this case study might be related to the selection of participants for the study because the populations are likely to be from similar groups. What I discovered regarding these participants might not be the same for other dissimilar groups. Therefore, additional studies would be required to be able to generalize the results to other groups.

Delimitations

Delimitations or boundaries of the study must also be considered in qualitative research. Brusse, Kach, and Wagner (2016) discussed boundary conditions within the context of a study related to who, where, when, and the values of the researcher that might influence the generalizability of the findings. Although the field of BCI technology covers a broad range of applications, this study was limited to exploration of the user-centered clinical BCI device design strategies used by computer scientists to design BCI assistive technology devices for potential patients, such as those Guger et al. (2017) discussed with locked in syndrome (LIS) or complete locked in syndrome (CLIS) such as

resulting from amyotrophic lateral sclerosis (ALS). For this study I focused on the computer scientists participating in the development of these devices, rather than all the specialists involved.

Significance of the Study

The purpose of conducting a case study was to gain an understanding of the topic for the study. Yin (2014) suggested that an important component of a case study is the reporting phase because it provides an opportunity to share the methodology and findings from a study with others. In sharing my study information, it is possible to contribute to informed technology practice and social change.

I considered multiple aspects of clinical BCI assistive technology device design including but not limited to computer scientists, other subject experts, research institutions, commercial organizations, caregivers, and individuals with certain rare disorders in my research. Currently, the development of clinical BCI assistive technology devices is often focused on technical aspects such as signal processing. Additionally, use of clinical BCI assistive technology devices is often limited to research environments. The results from this study may assist computer scientists in filling the gap between technology aspects and patient-centered outcomes when designing BCI devices. With the outcome of filling that gap being a reduction in disuse or abandonment of clinical BCI assistive technology devices by fulfilling the expectation of improving quality of life for individuals with rare disorders.

Contribution to Information Technology Practice

My goal for this study was to assist computer scientists as decision makers in the design and development of assistive technology BCI devices to become more aware of how to incorporate user-centered design strategies in the development of clinical BCI devices. As part of this study I exemplified a potential contribution to the improvement of IT practice for positive social change by highlighting the importance for IT professionals to be knowledgeable in the specifics of both BCI technology and user-centered requirements. As Bowsher et al. (2016) reported the goal of the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) is to provide guidance and recommendations for premarket devices that have the potential to translate innovative knowledge into clinically beneficial devices. Conducting this study, I investigated consideration of patient-centered outcomes for BCI assistive technology devices. The significance of computer scientists as decision makers in the design process having an in-depth understanding of patient-centered outcomes is the likelihood they will employ user-centered clinical BCI device design practices.

Implications for Social Change

The potential of using BCI technologies to improve the quality of life as assistive technologies for patients with disabilities is a promising albeit a developing domain. As Bowsher et al. (2016) highlighted, an important aspect of this domain must be the consideration of patient-centered outcomes that will improve quality of life as part of the design process of user-centered clinical BCI devices. The potential number of ALS patients that Arthur et al. (2016) approximated to be close to 400,000 by the year 2040

represent just one group of patients with a cognitive disability whose quality of life might

be impacted by using a BCI assistive technology device. As part of this study I explored

the user-centered clinical BCI device design strategies used by computer scientists to

design BCI assistive technology devices. The information I obtained as I conducted my

study was beneficial and exemplified that social change may occur by ensuring a balance

between user needs, system functionality, and development feasibility taken together

could improve the quality of life for patients with disabilities by using BCI devices.

A Review of the Professional and Academic Literature

A review of the professional or academic literature as part of a research study

serves to support the research methodology based on the research problem being

investigated. Achimugu, Selamat, Ibrahim, and Mahrin (2014) proposed that a systematic

literature review that gathers existing evidence to formulate a research question by

collecting, reporting, analyzing, and synthesizing data from studies included in the review

helps focus on an empirical question. Furthermore, Winchester and Salji (2016)

suggested key stages of writing a literature review should include topic selection,

keyword and search term identification, information sources identification, reading list

collection, and note-taking. In this section, I provided a summary of the literature

investigation methods used in addition to an overview and discussion of relevant research

literature.

The primary focus of this study was the user-centered clinical BCI device design

strategies used by computer scientists to design BCI assistive technology devices to meet

patient-centered outcomes. The scope of the literature research included assistive

technologies, BCI technologies, associated theories. The strategy for the literature search was to research relevant databases for peer reviewed journals and articles, using key search words and terms that included acronyms and derivative forms. For example, I searched for the term *Brain–Computer Interface* and similar terms such as *human-computer interface* that Posard and Rinderhnecht (2015) used for their research. I used the Walden University Library, University of Pennsylvania and other education research libraries, relevant books, peer-reviewed search engines, professional articles and journals, websites, and publications of professional organizations. Recurrently, I used the following search sites: Google Scholar, EBSCOHost Academic Search Complete, National Institutes of Health, ProQuest Central, IEEE Explore, IEEE Computer Society Digital Library, and ACM Digital Library. To expand my reference sources, I used articles included in the reference list of articles I located. I created a digital notebook with categories pertinent to my research terms and saved digital copies of reference articles.

I started by using the research terms assistive technologies and BCI technologies to locate appropriate articles published since 2014 or newer that provided current information. As Winchester and Salji (2016) highlighted, the importance in conducting a literature review is that the information summarized demonstrates current knowledge in the topic area. Over time my search expanded to include categories of BCI technical aspects such as signal acquisition, BCI commercial and clinical devices, BCI devices for intended disabilities such as LIS and CLIS, ethics and legal issues related to BCI use, social change related to assistive technologies, and theories related to motivation such as hedonic-motivation and utilitarian-motivation, in addition to patient-centered outcomes.

The inclusion of these categories expanded the timeframe of my search to include seminal articles relevant to my study and broadened the base information available to use as the foundation for my qualitative multiple case study.

I collected, categorized, and reviewed approximately 247 articles. I filtered down my article selection by omitting unnecessary references to 156 relevant articles with 134 being peer-reviewed and 139 published since 2014 to represent values of 85.9 % peer-reviewed and 89.1 % published since 2014, required for this study. The literature review section of the proposal consisted of 93 articles with 80 being peer-reviewed and 80 being published since 2014 to represent the value of 86 % required for this study.

Types of literature reviews include argumentative, historical, methodological, theoretical, and integrative. Torraco (2016) suggested an integrative literature review is an appropriate choice when reviewing the representative literature regarding new emerging topics in an integrated way because that allows for the generation of new frameworks or perspectives. For this study, an integrative literature review that evaluated, critiqued, analyzed, and synthesized the collected literature on the topic and met the same standards for research of rigor, clarity, and replication was appropriate. For this study of BCI technology that is an emerging technology the use of an integrative literature review was both appropriate and may bring forward new perspectives on the topic of design of BCI devices by computer scientists. To conduct the integrative literature review for this study I began with an introduction of the topic, organized my finding to fit the body of literature, and concluded with a recapitulation of the findings as well as implications for future research.

One aspect of my research focused on the topic of assistive technology devices. My search of the literature yielded results from the report Russell et al. (1997) prepared that introduced the aspect of devices used for restorative and rehabilitative purposes. I considered the report of Russell et al. (1997) a seminal work regarding assistive technologies that subsequently led to more recent research such as the one Carver et al. (2015) conducted regarding individuals with disabilities. As part of my research on assistive technologies, I included devices for commercial and clinical use, devices for rare disorders, and recreational devices used for rehabilitative purposes.

Simultaneously, I researched BCI technology focused on clinical BCI restorative assistive technology devices designed for rare disorders. I identified the research of Vidal from the 1970s as seminal information for the topic of BCI devices. I also researched studies that used alternate terms for BCI such as human-computer interfaces and human-machine interfaces that encompassed the same concept of using an interface technology to establish direct communication to control an external computer device through brain activity, such as Ienca and Haselager (2016) described. I researched core aspects of clinical BCI assistive technologies that included signal processing, research limitations, challenges, and future development.

I presented from the literature challenges associated with clinical BCI assistive technology devices related to patient-centered outcomes. I included in my research the development of the MISC model and the key concepts used as a basis for the MISC model. Additionally, I examined concepts of user-centered design as strategies to meet patient-centered outcomes.

Literature Review Introduction

The specific problem addressed in this study was how BCI computer scientists design user-centered clinical BCI assistive technology devices to meet patient-centered outcomes. The purpose of this qualitative multiple case study was to investigate how BCI computer scientists use strategies during device design processes to meet patient centered outcomes. I drew upon the perspective of the MISC model that Lowry et al. (2014) proposed regarding the influence of intrinsic motivation of the user related to the use of information systems to gain an understanding of how the expectations of patients for clinical BCI devices might be a primary design concern. Because the MISC explains and predicts the discrete cognitive processes through which systems fulfill a range of motives and expectations and how this fulfillment leads to continuance intentions it was an appropriate model when considering patient centered outcomes. The main conceptual significance of this study was the application of the MISC model that Lowry et al. (2014) proposed to understand user expectations and continuance of use from a BCI device design perspective. I focused on user-centered design, patient-centered outcomes, the MISC model, BCI device technology, and the disuse or abandonment of assistive technology devices in completing the literature review for this study.

Assistive Technology

Assistive technologies supported by IT systems currently span a broad and varied range of possibilities. An exact date might not be available for the very first use of a computer based assistive technology. However, the report Russell et al. (1997) published in the *Advance Data from Vital and Health Statistics,* now renamed the *National Health*

Statistics Report, included computer devices in the category of vision devices. The report

indicated that advances in technology related to materials, microelectronics, and

microcomputers influenced patient use by making assistive devices lighter, less

expensive, and easier to use. Moving forward 7 years, LoPresti, Mihailidis, and Kirsch

(2004) presented an evaluation of assistive technology for cognition (ATC) interventions

used to support activities that require cognitive skills such as reasoning, monitoring

specific behaviors, reinforcing intrinsic abilities, or providing extrinsic support. As the

development of various types of assistive technologies continued, Scherer and Federici

(2015) posited how identifying user-centered requirements that could be matched with a

technology became significant. From their research, Scherer and Federici (2015) posited

a model to assist in determining how various influences would impact an individual's use

of an assistive technology by considering the environmental factors for use, the personal

and psychological characteristics of the user, and the desirable features and functions of

the technology. Recent work by Jeunet, Jahanpour, and Lotte (2016) highlighted user

motivation related to continuous use of the technology as a reason for user training to

encourage skill acquisition and thus promote user motivation. Therefore, it may prove to

be prudent to incorporate measurements into the design process of an assistive

technology to determine if it meets expected patient centered outcomes.

  A current inventory of assistive technologies spans disciplines that cover

individuals with both medical and physical disabilities and includes numerous

technologies. For example, since the report Russell et al. (1997) provided, as well as

prompted by the influence of an ever-increasing aging population, Bhowmick and

Hazaruka (2017) cited how state-of-the-art assistive technologies for the visually

impaired and blind individuals have gained prominence from different domains for

research. These fields of research investigate how visually impaired and blind individuals

who experience physical, social, and other barriers to accessibility and independence

might be supported by assistive technologies such as equipment, devices, services,

systems, processes, and modifications to improve their quality of life (Bhowmick &

Hazaruka, 2017). Assistive technologies for the visually impaired and blind include

glasses, lenses, a non-surgical device to allow blind people to see using their tongue,

visual information conveyed by an auditory device, mobile navigational devices, Braille

e-book readers, and obstacle detection using a smartphone. One important facet of

assistive technology for the visually impaired and blind that Bhowmick and Hazaruka

(2017) focused on was mobility needed for activities of daily living, which is also a

consideration for individuals with other disabilities. Adults with major disabilities such as

multiple sclerosis, stroke, and spinal cord injuries that may impact physical activity and

exercise that Lai, Young, Bickel, Motl, and Rimmer (2017) studied were found to use

assistive technologies such as active video games. Additionally, children with cerebral

palsy a disability that results in limited mobility are afforded the promise of upright,

functional gait by step-initiated, multichannel neuromuscular electrical stimulation

technology (Rose, Cahill-Rowley, & Butler, 2017). As predicted by Russell et al. (1997)

advances in technology have supported the creation of a wide range of assistive

technologies for all generations.

Population Needing Assistive Technology

Identifying those individuals who might benefit from the use of an assistive

technology is a first step in identifying patient centered outcomes. Recently research by

Carver et al. (2015) provided information from a 2012 report that cited the number of

individuals with some type of ambulatory disability to be approximately 37.6 million.

This number represents individuals who lack the ability to move their body within or

between environments or the ability to manipulate objects, with the majority requiring

some type of assistive technology. In 2010 the census conducted by the U. S. Census

Bureau reported that approximately 19% of the population, some 56.7 million people had

some type of disability (U. S. Census Bureau, 2016). In the foreword of the first World

Report on Disability, Stephen Hawking highlighted how computer scientists were

responsible for the assistive technologies that supported his ability to communicate and

have a career as an astrophysicist. The report went on to provide details regarding how

approximately 15% of the world population has some type of disability and a

recommendation to provide information and communication technology products,

systems, and services to individuals with disabilities (World Health Organization, 2011).

As part of that recommendation the benefits for the use of assistive technologies included

increasing independence, improved participation, and reduction of care costs.

Assistive Technology Classification and Research

Research, design, and development of assistive technologies is likely to start

based on the need of a category of disability. Classification of assistive technologies is

often based on the World Health Organization's International Classification of

Functioning, Disability, and Health guidelines (Perfect, Jaiswal, & Davies, 2017).

Additionally, the National Institutes for Health provides information on types of assistive

technologies, and the ability to search for studies related to assistive technology (National

Institutes of Health, 2017). Together, these two bodies provide researchers investigating

assistive technologies with data regarding restorative and rehabilitative assistive

technologies (Sivan et al., 2016). Thus, the domain of IT has and will most likely

continue to contribute to the advancement of various assistive technologies to improve

quality of life such as clinical BCI assistive technology devices.

Assistive Technologies for Rare Disorders

One classification of disorders that might benefit from clinical BCI assistive

technology devices would be rare neurological disorders. The National Institute for

Neurological Disorders and Stoke currently oversees research, funding, and the

dissemination of information for an extensive list of conditions classified as rare

disorders that includes Spinal Cord Injury and ALS (National Institute of Neurologic

Disorders and Stroke, 2016). Kondziella (2017) presented a historical literary

perspective regarding the possible consequences of some types of rare disorders that

result in tetraplegia, anarthria, and impaired eye movements referred to as the (LIS) and

the (CLIS) with oculomotor impairment. Individuals with disorders of consciousness

such as coma, unresponsive wakefulness state, and minimal consciousness depending on

the condition exhibit limited or no cognitive and motor functions (Guger et al., 2017).

Comparing individuals with some of these types of rare disorders, individuals with LIS

and CLIS often exhibit healthy cognitive functions but show little or no motor response and thus may benefit from clinical BCI assistive technology devices.

Brain Computer Interface Technology

History of BCI Technology

The term Brain–Computer Interface (BCI) in one of several terms that refer to the pairing of electroencephalographic (EEG) devices with the deciphering and processing power of a computer. BCI is characterized as a two-way communication path between sensors fitted to a brain and a signal feedback processing computer to map, augment, or repair cognitive or sensory-motor functions (Krucoff, Rahimpour, Slutzky, Edgerton, & Turner, 2016). Other terms sometimes used include neural-control interface, direct neural interface, and brain-machine interface however, in the 1970s Vidal (1973) used the expression BCI to describe the success of signal processing algorithms related to neurological augmentation as a possible solution for neurological impairments. Soon after Vidal (1977) demonstrated the control of a graphical computer screen object by EEG signals for the first time. In 1989, in response to the challenge of moving objects using biosignals that Vidal proffered in 1973, the first control of a robot using electro-oculogram signals met that challenge (Bozinovska, 2014). Subsequently, Jeunet et al. (2016) described how BCI bioengineering research has continued since then and has focused on using bidirectional signaling to leverage brain neuroplasticity. Bidirectional signaling allows the brain to respond to computer signals to establish neurological communication to augment or replace the standard pathways affected by neurological disabilities. Additionally, Miranda et al. (2015) highlighted how organizations such as the

Defense Advanced Research Projects Agency have funded and supported BCI research to provide advances such as restoring neural and behavioral health for the nation's warfighters. Thus, researchers have continued their efforts toward improving the quality of life for individuals with sensory-motor disabilities by meeting the 1973 challenge of Vidal to use biosignals for communication or to move objects.

Technical Aspects of BCI

It is important to understand the basics of BCI technology such as signal processing before discussing BCI devices and assistive technologies. Ortiz-Rosario and Adell (2013) focused on the significance of BCI technology related to signal processing and highlighted three main components as: signal acquisition, signal processing, and effector device. Modes for signal acquisition may include but are not limited to EEG, electro-oculogram, electrocorticography, and local field potentials, with noninvasive EEG as a preferred method because of the aspects of reduced risk and ease of use (Ortiz-Rosario & Adell, 2013). Signal processing is achieved by methods that include autoregression, wavelets, Fourier transform, and Laplacian filters associated with effector devices including robotic arms, wheelchairs, cursors, and spellers.

Signal acquisition. Non-invasive EEG headsets often preferred for BCI signal acquisition detect voltage differences between locations on the human cranium. Chu (2015) discussed both the evolution and functional aspects of brainwave headsets to detect electrophysiological brain activity that ensures identifying brain signal frequency bands correctly. There are six typical bands or ranges of brain waves each of which can be correlated to the brain condition for the individual; for example, brain waves in the

frequency of 8 to 12 Hz likely symbolize being awake in a calm, eyes closed relaxed mood (Chu, 2015). Although various models of brainwave headsets exist, Jin et al. (2015) described the noninvasive P300-based BCI as one of the most promising ERP brainwave headsets. The P300-based BCI device detects an EEG event that occurs 200 to 500 milliseconds (ms) after a visual, auditory, or somatosensory stimulus, which makes it reliable and easy to identify (Jin et al., 2015). When repeatedly stimulated with a target Jin et al. (2015) demonstrated that the P300 signal is increased, and an individual can select a deviant stimulus through mismatch negativity odd-ball ERP. Signal acquisition technology methodologies continues to evolve as the technology develops.

Signal processing. Signal processing, the second component of BCI device technology, relies on algorithms to improve the detected brainwave signals. The signal processing component consists of two steps: feature extraction and feature translation or classification (Ortiz-Rosario & Adell, 2013). To accomplish these steps, Chu (2015) suggested three main categories of algorithms for processing brainwaves including band-power feature extraction, common spatial patterns analysis, and statistical source separation. In discussing limitations related to signal processing Moritz et al. (2016) highlighted how brain signals could change over periods of time so that from a machine learning perspective, brain signal processing becomes a nonstationary learning task that must adapt mapping inputs with outputs on a continual basis. Recently, Chu (2015) posited that virtual reality might offer a newer approach to signal processing as an alternative to using imprecise algorithms. Currently a majority of research organizations use noninvasive P300-based BCI devices.

Effector devices. The third component of BCI signal processing previously identified is the effector device, which provides the desired outcome when using a BCI device. Movement and communication are two of the primary types of effector devices associated with BCI technology (Miranda et al., 2015). Although much BCI research has been focused on effector devices as assistive technologies, Miranda et al. (2015) noted that there has also been an interest in noninvasive BCI technology for healthy individuals wanting to use neural signals to explore virtual environments or engage with avatars. Based on the BNCI Horizon report, Hansen (2015) suggested that dry noninvasive BCI devices for uses such as meditation and entertainment will transition from research to commercial markets in the future. Additionally, Pinegger, Hiebel, Wriessnegger, and Muller-Putz (2017) presented information regarding a P300 ERP device developed based on user-centered design for composing music. However, as Bowsher et al. (2016) reported, the goal of many government agencies such as the CDRH is to provide support for the development for devices that have potential as clinically beneficial devices. As the field of BCI devices develops, it is possible that devices intended for clinical use will also offer alternate functions such as meditation or entertainment for individuals needing assistive technology.

Clinical Aspects of BCI Technology

The primary uses of BCI devices are for movement and communication, usually as an assistive technology to augment or repair cognitive or sensory-motor functions. Features required for clinical BCI devices to perform as an assistive technology include obtaining direct measures of brain activity (brainwaves), providing feedback to the user,

operating online, and relying on intentional control by the user (Brunner et al., 2015). As

mentioned previously it is possible to correlate brain condition with brainwave bands,

which Chu (2015) highlighted would allow specific brainwave bands to be concentrated

on as part of the functionality of assistive technology. Dependent BCI devices such as

spelling programs monitor the brain for ERPs to extrapolate the desired outcome and are

inadequate for individuals with neuromuscular disabilities, compared with independent

BCI devices that look for an evoked potential from EEG signals and are an advantage for

individuals with disabilities such as ALS or other rare disorders (Thompson et al., 2014).

Thus, the disability is often the predictor of the type of device that is required.

There are both invasive/implantable and noninvasive clinical BCI assistive

technology devices. The use of implantable devices as one aspect for clinical BCI

assistive technology has appeared in research related to the detection and treatment of

epilepsy (Klein, 2016). Other research with ALS patients and implantable devices is

limited. Vansteensel et al. (2016) indicated that benefits of an implantable device for a

patient with late-stage ALS might include more convenient home use, better decoding of

signals due to reduced background noise during signal acquisition, independent and

private conversations that are not reliant on eye trackers, and improved decoding.

Currently, research continues into the use of implantable BCI devices. However,

noninvasive devices are more often selected for use as assistive technologies.

One individual preference for noninvasive clinical BCI assistive technology EEG

type devices is between wet and dry electrodes. Huggins, Moinuddin, Chiodo, and Wren

(2015) reported that individuals demonstrated a slightly greater acceptance for dry

electrodes over gel electrodes. Peters et al. (2015) concurred that even though wet gel electrodes might offer improved signal acquisition, most users worried about the mess and inconvenience associated with their use. Currently, many clinical BCI EEG devices are noninvasive, use dry or gel electrodes, and are based on the P300 ERP, and as Guger et al. (2017) and Hansen (2015) highlighted, are often the device type of choice when working with individuals with LIS or CLIS. Most clinical BCI assistive technology devices are available only to individuals involved in research. Therefore, options for use may be limited to the type of research being conducted, and not an exact match of the desired features or functions wanted by the individual.

Challenges of Clinical BCI Technology

As with any new technology, there may be associated challenges and risks when developing new clinical devices, however with clinical BCI assistive technology devices perhaps the greatest challenge is preventing the risk of disuse or abandonment of the device. Kosmyna, Tarpin-Bernard, and Rivet (2015) provided insights into techniques such as co-learning for BCI devices, focused on improving performance and increasing usability. Other challenges include cost, access or availability, training, and potential risks. Because the majority of clinical BCI technology development is still being researched, there are a limited number of companies to purchase a device from, and they are expensive (McCrimmon et al., 2017). One possibility for individuals with disabilities such as LIS or CLIS is to enter a research program being conducted at a nearby BCI research lab. Doing so offers the opportunity to use a BCI device but also requires the individual to have a caregiver to travel to the BCI lab with them. Furthermore, the

individual is not in his/her home environment and use of the BCI device stops when they leave the lab.

Training is required for the use of a clinical BCI assistive technology device. To ensure reliability, dependability, and accuracy of signal acquisition, training is required for the device user, caregiver, and any communication partner (Peters et al., 2015). In comparing BCI devices with different approaches such as transient evoked potentials, steady-state evoked potentials, and motor imagery, Guger et al. (2017) found that both transient evoked potential and steady-state evoked potential devices typically took less training and offered greater accuracy than motor imagery devices, suggesting that they might be more beneficial for individuals with limits on time for training. Motor imagery devices require users to imagine a left hand or right-hand movement to produce an event-related potential in a given frequency range. Kubler et al. (2014) reported study results that highlighted challenges individuals encountered in learning how to use clinical BCI devices in a research setting and their extended concern for learning how to use the device in their home environment. For individuals with LIS or CLIS, reducing challenges such as device setup time and required training through improved device design to ensure accurate signal acquisition might influence the use of a clinical BCI device.

Potential risks associated with the use of clinical BCI assistive technologies in general include ethical, legal, and security challenges. As Hansen (2015) discussed, some of these risks might become more significant as clinical BCI devices move from research to commercial use, such as those related to the intentions for the use of the device. For example, the design of a device for wheelchair control will most likely be different than a

device for use as a video game, when privacy and enhancement are considered. As part of

a discussion on brain-to-brain interfacing, Trimper, Wolpe, and Rommelfanger (2014)

cited the example of a BCI device integrated suit with the ability to grasp a ball and drop

the ball on a target and questioned possible ethical concerns related to that level of

coercive control or loss of autonomy. The potential for a BCI devices to compromise the

authority of the user is an important consideration in the design.

In the development of a clinical BCI device, consideration is also needed for legal

aspects. Gooding, Arstein-Kerslake, and Flynn (2015) discussed the need to explore the

law and the use of assistive technologies in the field of neuroscience such as BCI devices

that may provide novel methods for decision making based on understanding, assessing,

and communicating wishes and preferences. Additionally, Barfield and Williams (2017)

posited that because neuroprosthetic devices might be used to enhance or compromise

brain abilities in addition to alleviating damage to the brain from disease or injury, new

laws and civil protections might be needed to protect intellectual property.

Given the expectations of individuals with LIS or CLIS, as well as caregivers,

plus the cost and effort that goes into the development of clinical BCI assistive

technology devices, perhaps the greatest challenge is preventing the risk of disuse or

abandonment of the device. Andresen, Fried-Oken, Peters, and Patrick (2016) suggested

that one of the issues related to patient acceptance and possible disuse was the emphasis

by developers on the performance of the technology versus the performance of the user

with the technology. Kathner et al. (2017) concluded that only two out of six participants

testing devices intended for home use were able to achieve satisfactory control of the BCI

device. Possible obstacles Kathner et al. identified were insufficient control of the electrode pins, the slower response of the BCI device to other assistive technology devices, and difficulty combining data from training runs, along with additional obstacles related to physical aspects of the device. Additionally, Peters, Mooney, Oken, and Fried-Oken (2016) indicated that overall participants were only somewhat satisfied with the tested BCI device related to ease of use, comfort, and workload. Scherer and Federici (2015) suggested a range of outcomes from optimal to abandonment related to assistive technologies. Keeping that range in mind and reviewing the studies reported as well as others, helps clarify possible causes of disuse or abandonment of a clinical BCI device.

Future of Clinical BCI Assistive Technology Device Design

In the 1970s Vidal used the term BCI to describe signal processing algorithms related to neurological augmentation and challenged others to develop the use of biosignals to move objects. Since then, many BCI devices have been developed to meet that challenge and other new applications not imagined by Vidal. However, most of that development has occurred in research labs and has yet to successfully transfer to clinical BCI assistive technology devices for home use. In this literature review, several aspects might be the focus of clinical BCI assistive technology device design going forward to develop a successful home device. Reflecting on the three main components of signal acquisition, signal processing, and effector device, Ortiz-Rosario and Adell (2013) posited that it is possible to consider design aspects of each. Therefore, there is the potential to incorporate unique user-centered design strategies in each of these components.

Signal Acquisition

As discussed above, the advancement of signal acquisition methodologies is likely to improve BCI device technology. Although Vansteensel et al. (2016) indicated significant benefits of implantable devices especially related to signal acquisition, responses from the 2010 Asilomar Survey that Nijboer, Clausen, Allison, and Haselager (2013) conducted showed that most BCI researchers felt the risks for invasive BCI might outweigh the benefits and were largely still unknown. Also, as Peters et al. (2015) discussed signal acquisition might improve with the use of gel electrodes, the preference for most individuals using the device and their caregivers was for dry electrodes that offered greater convenience and less mess. Likely reflecting a consensus of many other researchers regarding these two physical design considerations, the current trend has been to design noninvasive, dry electrode, P300 based clinical BCI devices.

Signal Processing

Signal processing that consists of two steps, feature extraction and feature translation, is another component of BCI device technology considered in the device design process. There are many domains, such as bioengineering, engaged in the development of clinical BCI devices. However, feature translation and classification are specific aspects of signal processing that fall within the computer science domain. Chu (2015) presented a summary of brain signal processing algorithms to interpret brain signals and proposed the creation of a standardized brain signal databank. Improving noise reduction, overcoming attenuation, and discriminating physiological interferences due to differences such as wet or dry electrodes requires digitally processing algorithms

(Chu, 2015). Iacoviello, Petracca, Spezialetti, and Placidi (2015) demonstrated that signal extraction might be affected by emotional states and thus require the use of mathematical tools for effective translation. Chu posited that creating a standardized brain signal database would promote greater collaboration between software and neuroscience committed to device development and might offer means for privacy protection. The standardized database would accumulate brain wave data, brain wave diagrams, processing and searching algorithms associated with the brain wave, and interpreted meanings (Chu, 2015). Additionally, Chu suggested that other aspects of creating a standardized brain wave database might include big data analysis and cloud computing. Creation of a standardized brain wave database may offer support for the collective efforts among the different domains to optimize brain signal data.

Another aspect of signal processing is related to the neurologic condition of the individual. Moritz et al. (2016) discussed the need for computational neuroscience such as machine learning that would address the closed-loop interactions of neural devices needed for physiological adaptions to ensure meeting end-user outcomes. Recently, Moritz et al. presented a discussion that highlighted the possible changes to neural mechanisms as the brain adapts to controlling a BCI device. Additionally, Hohmann et al. (2018) reported that shifts of wave frequency out of the normal expected range might occur with LIS or CLIS patients, such as those with ALS. To accommodate this category of ongoing changes, or type of nonstationary learning tasks, Moritz et al. suggested co-adaptive BCI devices that use machine learning to adapt mapping inputs with outputs to simultaneously and cooperatively achieve patient-centered outcomes. For individuals

relying on clinical BCI assistive technology devices, fine-tuning communication of signal processing might assist in overcoming some of the possible obstacles associated with not meeting patient-centered outcomes.

Effector Devices

Effector devices, another component of BCI technologies, are key in providing movement and communication for individuals with conditions such as LIS or CLIS. The design efforts regarding effector devices include many of the advances in technology related to materials for making assistive devices lighter, less expensive, and easier to use (Russell et al., 1997). Keates (2017) highlighted that although there are many new or retrofited assistive technology devices, many of them do not make it out of the research laboratory because they present major accessibility challenges for users. Additionally, Lacko et al. (2017) suggested the need for more ergonomically designed devices to provide better anatomical fit and supporting what Kathner et al. (2017) posited regarding obstacles for users related to physical aspects of a device the might lead to disuse or abandonment. Looking toward the future multi-sensor BCI devices as described in the study conducted by Kucukyildiz, Ocak, Karakaya, and Sayli (2017), provided a glimpse of what might be possible to offer movement for individuals with certain disabilities using BCI technologies. In considering current and future clinical BCI assistive technology device design, aspects of signal acquisition, signal processing, and effector devices need to be considered by all domains involved and perhaps most especially by computer scientists to ensure patient outcomes.

Theories

Qualitative studies frequently use a conceptual framework to provide an

organized approach for understanding the nature of the phenomenon that is being studied.

Using a conceptual framework allows linking concepts from various theories to inform

the research and supports meaningful and generalizable research results (Green, 2014).

For this study, the conceptual model used was the multi-motive information systems

continuance model (MISC) that Lowry et al. (2014) proposed regarding the use of an

information system based on the influence of intrinsic motivation on the user. The MISC

model Lowry et al. (2014) proposed that key design constructs of a system need to meet

the expectations of the user based on individual intrinsic and extrinsic motivation that

may affect outcome variables differently. This suggests that user-centered design should

incorporate both aspects motivation.

Multi-motive Information Systems Continuance Model (MISC)

The MISC model is based on other theories and models regarding motivation,

expectation, system design, outcomes, and system use. Lowry et al. (2014) explored

motivation from earlier models and theories of both intrinsic and extrinsic motivation to

expand research that might better generalize conflicting motives related to user

satisfaction, evaluation of system performance, and continuance intentions. Looking at

motivation concepts Lowry et al. (2014) identified different types of intrinsic motivation

such as hedonic and intrinsic and recognized the need to separate intrinsic motivation

fulfillment from extrinsic motivation fulfillment. Thus, the study addressed hedonic

motivation such as joy, intrinsic motivation such as learning, and extrinsic motivation

such as usefulness related to design constructs, as well as expectations with the

understanding that motivation is an antecedent to expectation.

The depth and breathe of research into the connection between technology and

motivation is extensive. Previous research Lowry et al. (2014) explored included the

expectation-disconfirmation theory (EDT) Bhattacherjee and Premkumar model. In this

context, Bhattacherjee and Premkumar (2004) stated that disconfirmation refers to a

deviation from the initial expectation that may be above or below that expectation. The

model Bhattacherjee and Premkumar (2004) proposed is based on the EDT work of

Oliver and previous Technology Acceptance Model (TAM) information. Oliver (1980)

explored the concept that antecedents such as motivation and disconfirmed expectations

that might lead to user dissatisfaction are additive and have a lasting influence on the

user. The TAM that Davis, Bagozzi, and Warshaw (1989) developed identified perceived

usefulness and perceived ease-of-use as two factors that might influence the use of

technology by an individual. This finding is relevant to user-centered design of BCI

devices due to the issue of device abandonment.

Technology Acceptance Model

The TAM, subsequent TAM 2, and unified theory of acceptance and use of

technology (UTAUT) model were also considered as possible concepts to use for the

conceptual framework of this study. Although these models do consider perceived

usefulness and perceived ease-of-use as possible influences on an individual's use of

technology, they do not consider other factors that might influence use. For example,

Alalwan, Dwivedi, Rana, and Williams (2016) cited the popularity and acceptability of

using the rational TAM model to predict user intention and acceptance of technology, but also noted that for their study the TAM needed to be extended to allow perceived risk to be considered. The study Saghafi, Moghaddam, and Aslani (2016) conducted made use of TAM as a base model but again needed to extend the TAM to include other factors such as technical support, subjective norming, and perceived risk in the study. Another study Choi and Kim (2016) conducted made use of the TAM as the base model but also extended the study to consider perceived enjoyment and perceived self-expressiveness. Searching for examples of studies that have employed the TAM, TAM 2, or UTAUT as a base model returns numerous results, likewise searching for examples of research studies that have employed an extended TAM, TAM2, or UTAUT model returns many results. For example, a search of the University of Pennsylvania Library system for research studies published in the past 12 months based on the TAM and only one additional factor such as perceived risk returned 17 studies. Therefore, for this study recognizing the TAM as a model that underpins the MISC and contributes to my conceptual framework was reasonable, but not prudent to consider as the primary conceptual model.

Expectation-disconfirmation Theory (EDT)

Individuals whose expectations of an assistive technology are not met may lead to the disuse or abandonment of the device. The EDT Bhattacherjee and Premkumar model that Lowry et al. (2014) explored might also be considered for the conceptual framework of this study. Bhattacherjee and Lin (2015) highlighted the distinction between IT acceptance related to first-time use and TAM, UTAUT, and the innovation diffusion theory, compared with IT continuance related to long-term or sustained use. Based on the

ongoing development of the expectation-confirmation model (ECM) and with perceived

usefulness and perceived ease of use considered prominent beliefs that shape usage,

Bhattacherjee and Lin (2015) posited that reasoned action, experiential response, and

habitual response might also influence continuance behavior. Therefore, the

incorporation of user-centered design alone to refine the technology may be insufficient

to ensure behavioral changes needed to mitigate disuse or abandonment of the device.

ECM related to Caregivers and Medical Personnel

One aspect of assistive technology that might influence expected patient-centered

outcomes is related to caregivers and medical personnel engagement. Recent work

conducted by Magoulas (2017) explored the relationship between the continued use of an

electronic health record (EHR) system and perceptions of a physician based on (ECM).

Factors Magoulas (2017) considered that might influence the continuance intention of a

physician for using an EHR system included satisfaction, perceived ease of use,

perceived usefulness, and institutional trust. Perceptions of caregivers and medical

personnel treating patients with rare disorders such as LIS and CLIS may unduly

influence the perceptions of the patients themselves regarding expected outcomes. From a

recent study Iranmanesh, Zailani, and Nikbin (2017) posited that continuance intention

on the part of the caregivers influenced willingness to use new medical technology. Thus,

inclusion of caregiver perceptions during the design process is warranted.

The value of caregiver input may improve adoption strategies by research

therapists. As Rupp (2014) concluded from a study of patients with spinal cord injuries

that caregivers and medical personnel frequently encountered limitations in the

application of clinical BCI devices. Limitations were due to hardware or technology factors, and medical or personal factors related such as respiratory problems, medications, autonomic dysreflexia, stress, depression, pain, and inability to control the device, which affected perceived usefulness and ease of use by caregivers and medical personnel. Given the conclusions, Iranmanesh et al. (2107) arrived at regarding willingness to use a new medical technology and the conclusions Rupp (2014) highlighted, caregivers and medical personnel may influence the continuance intention related to clinical BCI assistive technology device usage. Although it is likely that the disuse and abandonment of an assistive technology is based on the perceptions of the disabled individual, caregivers and medical personnel may influence those perceptions.

Trust is another factor inherent in the interaction between individuals with rare disorders, caregivers, medical personnel and the application of clinical BCI devices. As Klein et al. (2016) discussed researchers and clinicians may see the advancement of clinical BCI device features as appealing, but if the features are not aligned with the desires and interests of the user, they may not support continuance intention. Magoulas (2017) discussed the need for physicians to trust the EHR system related to satisfaction, usefulness, and ease of use. For individuals who are experiencing loss of movement and communication which as Klein et al. (2016) cited are compelled to trust caregivers and medical personnel, their perspective regarding satisfaction, perceived usefulness, and ease of use of the individual must be recognized. In addition to considering the expectations and perceptions of disabled individuals, considering the expectations and perceptions of caregivers and medical personnel in the design phase is prudent.

ECM related to Individuals that Require Assistive Technologies

Models such as ECM may be especially valuable in circumstances such as LIS

and CLIS. Bhattacherjee and Lin (2015) espoused that individual behavior is planned

based on conscious, reasoned intentions. Contrasting that concept is the thought that

satisfaction based on experience might be a more prominent antecedent to continuance

behavior, and that habits might weaken intentions and thus influence continuance

behavior. The new research Bhattacherjee and Lin (2015) conducted addressed the

deficiency of the TAM and UTAUT models of excluding affect or emotion by using

satisfaction as an emotive aspect of continuance behavior. Although the ECM described

here does provide an emotive aspect, the MISC provides a more comprehensive approach

to motivation and expectations of individuals related to continuance behaviors and

therefore was better for consideration as the primary conceptual model.

Task-technology Fit (TTF)

Concerns regarding technology and aspects of fit are also central as related to

assistive technologies and individuals with rare disorders. Another concept that Lowry et

al. (2014) investigated in developing the MISC was task-technology fit (TTF). A primary

aspect of TTF that Goodhue and Thompson (1995) posited was the relationship between

IT and individual performance supported by the concepts of user attitudes as predictors of

utilization and TTF as an indicator of performance. Research conducted by Vuckovic,

Wallace, and Allan (2015) concluded that BCI technology could provide techniques for

individuals with tetraplegic disorders to complete selected tasks. More recently Wu and

Chen (2017) discussed continuance intention related to perceived usefulness and attitude

for individuals participating in Massive Open Online Courses (MOOCs). Supporting the original work of Goodhue and Thompson (1995), the study Wu and Chen (2017) conducted identified attitude as one of the most critical mediators of continuance intention. This study of continuance intention related to users of a MOOC system provides a slightly different perspective from studies of continuance intention related to a work-related system because the use of the system is at the discretion of the user versus a requirement such as for employment.

Continuous intention related to the use of an assistive technology for individuals with rare disorders is based on the perception that it might improve their quality of life. Research rooted in TAM that Teo and Zhou (2014) conducted also concluded that attitude and perceived usefulness had a significant influence on continuance intention to use technology. Additional research based on TTF conducted by Zhang, Jiang, Ordonez de Pablos, Lytras, and Sun (2017) concluded that user attitudes and perception of satisfaction influenced effective outcomes. Related to the MISC Lowry et al. (2014) acknowledged that the TTF most likely did influence disconfirmation but used the term design-expectations fit (DEF) that focused on the fit of the technology to the task. Lowry et al. (2014) posited that positive disconfirmation would occur with increase DEF. Thus, although the TTF establishes a relationship between attitudes and use the MISC extends that concept in identifying the relationship between the design of the technology with motivation and expectations or attitudes.

Communication and Movement Concepts

Other possible models related to the use of BCI assistive technology devices focus on communication and movement. For example, the concept of presence for individuals with LIS or CLIS may be a determining factor in the use of a BCI assistive technology device because of the possibility of communication it affords. Early theoretical concepts proposed by Shiffrin and Schneider (1977) on Automatic/Control Processing and Attention theory, framed concepts Kubler, Kotchoubey, Kaiser, Wolpaw, and Birbaumer (2001) posited. The research of Kubler et al. (2001) proposed the use of Brain–Computer Interfaces to provide a muscle-independent channel communication to overcome LIS induced communication challenges. Subsequently, the research of Kubler et al. (2001) provided support for research Baykara et al. (2016), Halder, Kathner, and Kubler (2016), and Jin, Zhang, Daly, Wang, and Cichocki (2017) conducted. Studies such as these focused on the relationship of clinical BCI device use with communication, motivation, and patient outcomes.

Clinical BCI devices have also been used as assistive technologies to afford movement for individuals with certain disabilities. Research based on motor theory Birbaumer (2005) conducted using BCI devices although not successful in overcoming paralysis did demonstrate the possibility of restoring movement. Further research based on the work of Birbaumer (2005) conducted by Pasqualotto et al. (2015) demonstrated the successful use of BCI devices for individuals with residual control of some muscle groups in overcoming certain physical disabilities. One aspect of the research conducted by Pasqualotto et al. (2015) included investigating the influence of cognitive load related

to clinical BCI device use and highlighted that cognitive load reflected that the brain could only attend to so many things at one time.

Cognitive Load Concept

The limited capacity of the brain to assimilate data is not restricted to only sensory data but may also be affected by BCI input. Research conducted by Bauer and Gharabaghi (2015) identified cognitive load related to the use of a BCI assistive technology device as an influence on the frequency band that a classification algorithm could use to determine performance, which was different than that for a BCI device as a restorative device. Research by Kathner, Wriessnegger, Muller-Putz, Kubler, and Halder (2014) reported that healthy individuals using P300 BCI devices and exposed to heavy mental workload and fatigue, satisfactory accuracies with tasks were still possible. Additionally, Huggins, Alcaide-Aquirre, and Hill (2017) investigated mental workload related to the ability of an individual using a clinical BCI assistive technology device to differentiate between the effort required for certain tasks. For this study recognizing the cognitive workload theory as support for the MISC that contributes to my conceptual framework was practical.

User-Centered Design, Patient-Centered Outcomes and MISC

One aspect when designing almost any technology that must be taken into consideration is ensuring expected user outcomes are satisfied. The extent to which that Lowry et al. (2014) considered the user significant is reflected in the DEF concept as related to disconfirmation and continuance intentions. For individuals requiring assistive technologies especially those with rare disorders such as LIS or CLIS using DEF to

influence the highest possible disconfirmation is likely to contribute to their quality of life. One aspect for consideration when using the DEF might include what Limerick, Coyle, and Moore (2014) discussed related to agency that is the experience of controlling one's own body within the external environment and the influence of human-computer interaction. Based on the conceptual framework of user-centered design Witteman et al. (2017) highlighted the need to involve users in the development of patient decision making aids. The research Witteman et al. (2017) conducted was based on research Frank, Basch, and Selby (2014) conducted to investigate how the perspectives of researchers or clinicians that are based on their experiences and training might place them at a disadvantage for representing the patient perspective. Frank et al. (2014) highlighted the need for including the perspective of the patient but also highlighted that the rigor of the research must not be compromised. Thus, this framework seems inherent to the purpose of this study to explore the user-centered clinical BCI device design strategies used by computer scientists to design BCI assistive technology devices that are beneficial and exemplify social change by ensuring a balance is found between user needs, system functionality, development feasibility.

Engagement is often a fundamental element of effective behavioral change. Forsythe, Heckert, Margolis, and Frank (2017) discussed the importance of meaningful patient engagement based on the conceptual model of patient-centered outcomes research. Other research conducted by Lazarou, Nikolopoulos, Petrantonakis, Kompatsiaris, and Tsolaki (2018) demonstrated that the use of other technologies such as virtual reality combined with clinical BCI assistive technology might encourage feelings

of enjoyment and thus promote a better quality of life experience. Additionally,

Jayadevappa, Cook, and Chhatre (2017) cited the need to identify minimal important

difference and minimal clinical important difference changes related to health-related

quality of life patient-centered outcomes in addition to identifying only technical aspects.

Similar research Schicktanz, Amelung, and Rieger (2015) conducted highlighted the need

for clinical success to be measured by both the efficiency of the technology and the

degree to which patient-centered outcomes are met. As Lee (2016) highlighted a better

perspective of a BCI device might be that of a sensor, not an actor designed to support

users by making intelligent adaptions. From a legal perspective Steinert, Bublitz, Jox, and

Friedrich (2018) highlighted the significance of relating freedom of thought with bodily

actions supported by BCI devices. During the design and development of clinical BCI

assistive technology devices each of these aspects require consideration.

The fulfilment of stakeholder expectations is often related to research design

outcomes. Forsythe et al. (2017) included in their discussion what the impact might be on

not only patients and researchers but on other relevant stakeholders such as clinicians,

health systems, and industries of research design outcomes. For all stakeholders, one

aspect of research design outcomes might include awareness of the rate of disuse or

abandonment of assistive technologies that Scherer and Federici (2015) cited as being

approximately 30% for a period of the past 30 years. Therefore, the concept of patient-

centered outcomes was relevant to this study.

The significance of disuse or abandonment of any assistive technology device

encompasses several stakeholders, with the patient being the primary stakeholder. As

Dorrington, Wilkinson, Tasker, and Walters (2016) highlighted from the onset of the

development process the commit of resources just in terms of subject matter experts

needed to develop assistive technology devices is substantial. This perspective can be

easily substantiated by doing a search for research regarding the development of clinical

assistive technology devices and examining the list of multiple authors for many of the

endeavors. Also, related to development are the constraints of time and budget imposed

on the organization involved in the development process, which in some cases prevents

engaging end users in the process (Dorrington, Wilkinson, Tasker, & Walters, 2016).

Finally, Dorrington et al. (2016) discussed the gap between research and the commercial

availability of clinical electromyography standalone switches as assistive technology

devices for individuals with rare disorders such as Muscular Dystrophy or Cerebral Palsy.

The gap discussed earlier in this paper between research and the commercial availability

of clinical BCI assistive technology devices and the gap as Dorrington et al. (2017)

discussed might both reflect the need for greater emphasis on user-centered design.

Doing so acknowledges how minimal clinical important differences related to health-

related quality of life patient-centered outcomes are significant.

For this study to explore what user-centered clinical BCI device design strategies

are used by computer scientists designing BCI assistive technologies to meet patient-

centered outcomes using the MISC seems appropriate. Quoting from *The Premature

Burial* by Edgar Allen Poe, researchers Johansson, Soekadar, and Clausen (2017)

highlighted how the hopes of individuals with LIS or CLIS might be raised by the

possibility of using BCI devices to breach their imposed confinement. Adding to the

discussion of BCI devices and expected patient-centered outcomes, Lorenz, Pascual, Blankertz, and Vidaurre (2014) posited the need for a holistic approach to assessing the user experience with the device. Returning some level of independence to improve the quality of life for individuals with rare disorders such as LIS or CLIS based on the user perhaps is the most important requirement computer scientists should consider in the design process. Dorrington et al. (2017) highlighted how listening to the voice of the user with a rare disorder nuances in personal choices and motivation are more understandable. Thus, placing users at the center of the design process and encircling that process with technology, materials, costs, and other requirements might assist in meeting patient-centered outcomes.

The quantitative evaluation of responses by individuals to an assistive technology is likely to be an important method for ensuring successful designs. One aspect for future design and development Thompson et al. (2014) suggested as needed was the inclusion of performance measurements of both technical and end-user behavior. Recently Shaw, Ellis, and Ziegler (2018) proposed the Technology Integration Model (TIM) to address continued technology use beyond initial adoption. The TIM proposed by Shaw et al. (2018) identified features significant to support continuance intention such as ease of use and perceived usefulness but also identified factors such as intrinsic and extrinsic motivation as significant. As Kubler et al. (2014) suggested the MISC model based on DEF might account for design constructs and contribute to design aesthetics and perceived ease of use based on motivational factors. Therefore, the MISC model

contributes to understanding how an appropriate balance between user needs, system functionality, and development feasibility is possible.

Literature Review Summary

Assistive technologies for individuals with rare disorders afflicted with LIS and CLIS offer the potential for enabling movement and communication to significantly enrich their quality of life. However, there remains a gap between commercial clinical BCI assistive technology devices and those used in research environments. An important contributor to this gap might be disuse or abandonment of the BCI device because patient-centered outcomes are not being met due to a lack of user-centered device design strategies by computer scientists. For the literature review, I focused on aspects of assistive technology, BCI technology, and information regarding the conceptual framework for this study.

Transition and Summary

In this section, I provided an overview of my intended study that includes the problem statement, purpose statement, research question, a synopsis of the selected conceptual framework, and a literature review of the study topic and conceptual framework. Clinical BCI assistive technology devices that have the potential to improve the quality of life for individuals with rare disorders although in research since the 1970s have not reached the stage of development making them openly and reasonably available for these individuals. The complexity of technical aspects such as signal processing and meeting patient-centered outcomes are aspects of user-centered design that must be considered by computer scientists engaged in clinical BCI assistive technology device

development. Influences on the design process I identified included signal acquisition, signal feature extraction and signal feature translation, effector devices, plus the physiology, motivation, and expectations of the individual clinical BCI device user.

I outlined a plan for conducting the study in section two. I provided information regarding my role as the researcher, proposed population, aspects of my intended research methodology and design, data collection, organization, plus analysis, and considerations for dependability, credibility, transferability, confirmability, and data saturation related to my study.

In section three I provided an overview of the study results and conclusions, implications for social change, applications for professional practice as related to the intended population, recommendations for further study, and my reflections.

Section 2: The Project

Purpose Statement

The purpose of this qualitative multiple case study was to explore the user-centered clinical BCI device design strategies used by computer scientists designing BCI assistive technologies to meet patient-centered outcomes. The target population consisted of computer scientists engaged in the design of clinical BCI assistive technology devices for individuals with disabilities. The population for this study encompassed computer scientists experienced with clinical BCI assistive technology design located in the Midwest, Northeast, and Southern regions of the United States, and Eastern Europe. This population was appropriate because research conducted by Klein (2016) indicated a gap between expectations of potential users of BCI devices and the design of BCI devices. This study may affect social change by increasing awareness of patient-centered outcomes in decision making during the design process, such that clinical BCI technology designers might better meet the needs of patients to improve their quality of life.

Role of the Researcher

For this qualitative case study, my role as the researcher was considered in the study design process. Berger (2015) posited that the role of the researcher is as an instrument for data collection where the assembly of the facts on the problem is subjective and more vulnerable to the biases of the investigator than in quantitative studies. For this study, my objective was to collect and analyze data from the eligible participants based on the multiple case study design established for this research study.

My goal was to explore the user-centered clinical BCI device design strategies used by computer scientists to design BCI assistive technology devices for potential patients. I have not worked in that domain now or previously, and I do not have or ever have had a relationship with any of the eligible participants, which helped mitigate potential bias. Identifying relationships between the researcher and study context is important for aspects of data collection. For example, as Fusch and Ness (2015) highlighted novice researchers might assume they are not using a personal lens and then incorrectly assume they have no bias related to data collection. Novice researchers might not realize aspects of data collection such as when they reach data saturation (Fusch & Ness, 2017). Thus, the degree of success of the researcher depends on challenging transparency regarding their predispositions and the context that develops over the course of the investigation.

An aspect of the role of the researcher is to ensure that there is an ethical protocol. Vitak, Shilton and Ashtorab (2016) discussed how a lack on the part of a researcher of both technical and ethical issues related to data collection might result in scrutiny. It is important to ensure that principles of the Belmont report are met, and criticism of the ethical research practices used. For this study, I followed the guidelines established by the Walden University Institutional Review Board, and best practices such as Yin (2014) suggested for case study research. Additionally, I followed the ethical principles as provided by the Belmont report.

The task of remaining an unbiased observer is impossible. However, keeping a log of personal impressions, expectations, and assumptions helps to lessen those biases

that might otherwise slip into the scientific argument distorting what would otherwise be a report on facts and insights into solutions. Vitak et al. (2016) highlighted protecting data subjects by using deidentification as a technique to mitigate bias. Using the technique of deidentification supports my responsibility in the role of moving from a novice with a biased and uncertain curiosity about user-centered clinical BCI device design strategies to a more scholarly balanced understanding of the larger problem and perhaps some insights into solutions.

For this study I conducted interviews with eligible participants to explore the user-centered clinical BCI device design strategies used by computer scientists to design BCI assistive technology devices. Yin (2014) cited interviews as one of the possible six sources evidence commonly used for a case study. Interviews allow the focus to be on targeted case study topics and may offer both explanations as well as insightful personal views (Yin, 2014). Conducting interviews as part of a multiple case study, while being mindful to prevent bias and following ethical principles, was an appropriate technique for this study. I used the following aspects in my study to reduce personal bias and mitigate personal lens errors: (a) an interview protocol, (b) member checks, (c) deidentification of subjects, (d) reaching data saturation, and not working in the same domain as the participants.

Participants

For this qualitative multiple case study, identifying participants able to provide rich descriptions of the phenomenon was important. The participants for this multiple case study were BCI computer scientists from a variety of organizations who employ

user-centered design strategies in the development of clinical BCI devices as assistive

technologies to meet patient-centered outcomes. One possible source of participants was

computer scientists that were conducting research for global organizations such as those

that partner with the ALS Association (The ALS Association, 2018). I contacted possible

participants through other publicly available sources and requested they consider

participating in the study I was conducting regarding clinical BCI assistive technology

device research once I had IRB approval. The criteria for participant eligibility included

being over the age of 18 and having a minimum of 2 years of experience in the

development of clinical BCI devices design strategies as an assistive technology for

patients with rare disorders. Upon receipt of a returned email that included the consent of

the participant I followed up to schedule a day and time for the interview.

For any research study both the quantity and the quality of the data are important.

Ngulube (2015) recommended treating eligible participants with respect and having

interesting, relevant, and ethical research questions to influence the quality of the

interview dialogue. Malterud, Siersma, and Gaussora (2016) proposed the concept of

information power that relates aspects of participant eligibility with purposeful sampling

and sample size. Malterud et al. (2016) postulated that information power is dependent on

the aim of the study, established theory, sample specificity, quality of dialogue, and,

analysis strategy. Because one of the eligibility criteria for this study was specific for

computer scientists with experience in clinical BCI device development, the sample size

needed may be affected by that specificity.

To generate initial access to participants, I used an informational email to the membership of global organizations involved in this type of device development. As Hoyland et al. (2015) described gaining access to eligible participants working at the research site of interest might require interaction with a gatekeeper. In addition to identifying eligible participants, the gatekeeper might help or hinder the research depending upon how the validity and value of the study is viewed (Hoyland et al., 2015). To ensure participation, I established an ethical working relationship with gatekeepers and participants. Collins and Cooper (2014) suggested that understanding the researcher's role, ensuring data collection is overt, and reviewing data and participation protocols for the study demonstrate the emotional intelligence of the researcher that may be beneficial in ensuring participation. Baskarada (2014) suggested that gaining access to participants and clarifying for the organization the disclosure of data early in the process, identities limitations. Although Internet access was a requirement, no specific location was required, and there was no gender eligibility requirement because gender was not relevant to the study. Eligible participants were sent an informational email and consent form. Those participants that responded with their consent by email were then contacted by phone to schedule the interview and vet any questions regarding participation.

The consent email and initial phone call served as part of the standard access process for this study. Hoyland et al. (2015) suggested building a researcher connection with the participants to establish transparency for the study and facilitating the interview process. Therefore, the consent form email provided an informational letter regarding the reason for the study and a request to return the consent form before the initial interview.

The goal of the participant interviews was to collect information to assist in the exploration of the primary research question regarding user-centered clinical BCI device design strategies used by computer scientists to meet patient-centered outcomes. As Hyett, Kenny, and Dickson-Swift (2014) discussed, recruitment and building a relationship to support participation may positively influence data collection and the study findings. Additionally, Malterud et al. (2016) cited the significance of strong and clear communication between the researcher and participant to influence the quality of dialogue. Thus, the researcher must be mindful of the role of the interviewer to listen, adhere to the participant-researcher relationship, and follow ethical protocol.

Research Method and Design

For a novice researcher the selection of a research method and design might seem a complex process. To ensure high quality research Martensson, Fors, Wallin, and Zander (2015) proposed a model that defined research as a conscious action to gain new knowledge regarding one or more questions, in relation to a certain context(s), building on existing knowledge, and following a precise technique for conducting the research. Selection of a qualitative research method and a multiple case study design guided the identification of the precise techniques needed to support conducting high quality research for this study.

Method

Based on the identification of a research problem and construction of a research question it was possible to select an appropriate research method from three established choices of a qualitative, quantitative, or mixed method. Yazan (2015) proposed that the

goal of using a qualitative research method is to gain a better or more detailed

understanding of a phenomenon or experience by answering questions of how, what, or

why. Baskarada (2014) posited that qualitative research is not based on numerical data

but takes an inquisitive approach to the research question to collect data from diverse

sources. Additionally, Vohra (2014) highlighted that qualitative research includes a range

of data collection and analysis techniques using purposeful sampling to collect textual

data. For this study, my goal was to explore *what* user-centered clinical BCI device

design strategies are used by computer scientists designing BCI assistive technologies to

meet patient-centered outcomes, so a qualitative research method was appropriate.

Quantitative research methods differ in approach and design methods from

qualitative research methods. McKusker and Gunaydin (2014) proposed that the goal in

using quantitative research methods is to measure something, such as the percentage of

people within a community with a given medical condition, to answer a research question

with a numerical value or quantifiable amount. Malterud et al. (2016) highlighted that

because of the measurement aspect quantitative research sample size is often determined

by power calculations to demonstrate the magnitude of an intervention. Additionally,

Kozleski (2017) described a limitation of quantitative research related to the aspect of

data collection using surveys that participants respond *to* versus qualitative research that

allows participants to respond *with* the research team allows for new discoveries. Thus,

quantitative research methods are most appropriate for the investigation of variables

through experimentation or correlation using a given sample to generalize the results to a

larger population. Because my goal was not to collect data from experimentation with

variables to generalize to a larger population but was to explore what user-centered clinical BCI device design strategies are used by computer scientists designing BCI assistive technologies a quantitative research method was not appropriate.

Mixed methods research integrates both quantitative and qualitative research methods so that both hard data such as numerical values and soft data such as textual impressions contribute to the study. Vohra (2014) suggested that because mixed-methods designs use triangulation techniques using mixed-methods research might provide more useful results. However, McKusker and Gunaydin (2014) posted that conducting mixed methods research requires designing a study to carry out two studies simultaneously and is best suited when one method will not provide a complete understanding of the topic by providing cross analysis and extension of the theory. Because a qualitative research method would adequately answer the research question, that was not the situation for this study. Additionally, Ketokivi and Choi (2014) suggested one perspective for looking at quantitative versus qualitative studies was the difference between computational reasoning and cognitive reasoning. Thus, for this study a qualitative research method that considers logic in practice was best, versus a quantitative method that considers reconstructed logic and follows a linear path or a mixed methods research approach that requires a quantitative study.

Research Design

The research designs I considered for this qualitative study inlcuded case study, ethnographic, narrative, and phenomenological designs; however, only a multiple case study design supports the exploration and description of the topic, which was why it was

best suited for this research. Cronin (2014) stated that in case study research, the focus is on providing a description of a specific phenomenon from individual or multiple cases and the researcher can conduct a systematic investigation of everything in that situation. Mills, Durepo, and Wiebe (2010) provided a discussion of a multiple or collective case study design that provided a deeper understanding of the phenomena than a single case study. By carefully selecting the cases, a mix of information from various and different cases helps provide greater generalizability than a single case study (Mills, Durepo, & Wiebe, 2010). As Yin (2014) described, the power of conducting a multiple case study is analogous to replicating an experiment to ensure robustness of the findings. For this study, the participants for each case were computer scientists with 2 or more years of experience developing clinical BCI devices for different organizations. Therefore, a multiple case study was appropriate to explore what user-centered clinical BCI device design strategies are used by computer scientists designing BCI assistive technologies to meet patient-centered outcomes as a qualitative research method design.

Another option for a qualitative research study is an ethnographic study design. Percy, Kostere, and Kostere (2015) suggested a long-term investigation of a culture-sharing group to investigate beliefs and behaviors would be supported by ethnographic study design. Kozleski (2017) described the significance of ethnographic research to gain an understanding of what is happening, that is what social action takes place in a particular setting. One aspect of ethnographic research that Fusch and Ness (2015) highlighted as significant was data saturation due to lengthy timelines to complete the study and multitude of data collection methods. This study was not focused on shared

cultural knowledge of beliefs and behaviors but on exploring what design strategies are used by computer scientists for clinical BCI devices. Therefore, the ethnographic study design was not appropriate for my study.

A narrative study offers another study design for qualitative research. As Tong, Raynor and Aslani (2014) stated, if the intent of the study was to gather information through the telling of stories then a narrative study would be appropriate. Malterud et al. (2016) posited that the aspect of information power relates to narratives as well because too small a sample size might not yield diverse enough information and too large a sample size might cause the identification of themes or patterns to be difficult. Additionally, Hyett et al. (2014) described how the researcher and participant relationship is significant in provoking narratives, vignettes, and thick descriptions for analysis. Because the intent of this study was not to gather stories but to explore what design strategies BCI computer scientists use a narrative design was not appropriate.

Phenomenological study design may involve data collection from interviews like a case study. However, as Koopman (2015) highlighted for a phenomenological study the researcher is concerned with understanding responses or behaviors of a group related to a phenomenon and data collection might not gather from other available sources. Fusch and Ness (2015) described how reaching data saturation for a phenomenological study requires creating an *epoche* to block biases and assumptions to focus on the experience. Additionally, Morse (2015a) posited that research into complex phenomena often involves conducting unstructured interviews with a small number of participants but the interviews are longer and repeated thus the researcher spends a significant amount of

time with each participant. This study involved data collection from interviews and from other sources to provide triangulation, but I was not concerned with understanding a specific phenomenon. Therefore, a phenomenological study was not appropriate.

Data saturation is one aspect or criterion for consideration in the design of a qualitative case study. Fusch and Ness (2015) indicated that data saturation is not universal but study dependent and not about sample size. Malterud et al. (2016) posited that to reach data saturation the researcher may use the constant comparative method to add information until properties of categories and relationships are comprehensively saturated. Additionally, Wohlin and Aurum (2015) suggested data saturation supports data analysis as an iterative process of collecting, coding, and categorizing data to lead to emergent patterns and relationships. For this study, the goal for data saturation was to collect data that was rich in quality, thick in quantity and ensured by continued inquiry until no additional data emerges.

Population and Sampling

The population for the study includes computer scientists involved in the design and development of clinical BCI assistive technology devices that have experience balancing user expectations and design best practices. Yin (2014) highlighted the number of case replications both literal and theoretical desired for the study is significant but not formulaic. Zainal (2017) suggested that for an exploratory case study that seeks to explore a point of research interest that the objective setting of the research might be as important than a large sample size. Additionally, Robinson (2014) posited that if the goal of the study is to gain a better understanding of a framework the study requires a

nonrandom technique to select individuals from a sampling universe willing to participate from information rich cases. Because the theory of this multiple case study was straightforward and does not require excessive degrees of certainty a sample size of four or six literal replications was appropriate.

The study objective was to explore what design strategies are used by computer scientists for clinical BCI devices by using data from documents and interviews with participants with specific knowledge of that process. Malterud et al. (2016) discussed how the identification of participants with as much information as possible that meets study needs and the quality of the dialogue supports the information power model. Kozleski (2017) highlighted how research study questions influence population selection to ensure perspectives and experiences to reflect data collection requirements. Additionally, Fusch and Ness (2015) noted that research questions structured and asked of multiple participants should lead to data saturation. Thus, eligible participants recruited through homogenous purposeful sampling will have at least two years of experience working in the field of clinical BCI devices as an assistive technology.

Because this study was to explore what design strategies are used by computer scientists for clinical BCI devices as an assistive technology purposeful sampling was appropriate. Robinson (2014) described purposeful sampling as based on the objective of the study and identifying participants with selected characteristics to understand the significance of the specific study topic. Other sampling considerations include sample size, the sample universe to specify inclusion or exclusion for participation, sample sourcing that avoids bias, and ethical concerns pertaining to informed consent (Robinson,

2014). Case studies do not use statistical generalization to generalize to a population but instead use analytical generalization to generalize to theories, so the requirements for sample size are unique (Baskarada, 2014). Additionally, Yin (2014) suggested in using a critical multiple case study design to determine if theoretical propositions are valid by answering *what* questions that the sample size is not as important as obtaining rich, in-depth information. For this case study, the number of participants interviewed to obtain thick and rich data might be four to six. However, reaching data saturation will be a determinant for the number of participants needed to establish reliability and validity.

The availability of the participants will determine if conducting the interviews are possible either face-to-face or through a virtual application. Arsel (2017) posited that both face-to-face or virtually supported interviews allow observation of social cues, which might prompt additional questions or convey another meaning of their response. For this study, the first interview will use semi-structured interview questions with follow up interviews questions to ensure the collection of all relevant information.

Ethical Research

Using established guidelines to ensure this study conducts research in an ethical manner was prudent. Conducting ethical research based on the principles of the Belmont Report that include moral actions, equal participants, participant benefit, and justice Knepp (2014) suggested as necessary for the study to represent the unbiased work of the researcher and to protect participants from harm. This study limited to interviews exploring strategies used by computer scientists designing clinical BCI assistive technology devices infers little potential exposure of the participants beyond

conversational norms, except for identity that was covered by measures to protect confidentiality. Yin (2014) furthered the discussion regarding ethical standards to ensure researchers conducting case studies did not use the study to substantiate a preconceived position or to advocate for a particular orientation on the topic. Knepp (2104) highlighted that meeting ethical requirements to safeguard participants and protect their confidentiality is supported by providing the participants with a consent form to review and sign before participating in the study. The consent form was comprised of information regarding the sponsoring institution, the purpose of the study, the possible risks, the voluntary nature of the study, freedom to withdrawal from the study, and contact information.

Providing participants with the consent form to review, sign, and return at the onset of the study promotes open communication with the participants and an understanding that the study will abide by the rules and guidelines of the Belmont Report and the academic institution requirements for the study. Detailed in the consent form were simple instructions for withdrawing from the study. Participants are offered the opportunity to withdrawal from the study at any time for any reason during the study up until the final study document was in the approval for publication process without consequence. The instructions include multiple convenient methods of communicating with the researcher that include email, phone, and text messaging should a participant wish to withdrawal from the study at any time up until the final study document was in the approval for publication process. Additionally, the consent form advised participants that withdrawal may be carried out by the research participant advocate of Walden

University. All potential participants are informed there was no compensation or incentive associated with being in the study, except for the altruistic benefit of participating in a study that might contribute to the body of knowledge associated with BCI devices for individuals with rare disabilities.

For this study, the fact I do not work in the domain of assistive technology or BCI device technology supported mitigation of my possible personal bias. As Liedtka (2015) discussed the researcher for the study has an ethical obligation to mitigate personal bias. Recognizing attitudes toward the research questions and identifying assumptions based on personal experience with the subject helps mitigate personal bias. Additionally, in conducting a case study using interviews to validate that the qualitative inquiry has scientific rigor the researcher should create an interview protocol (Sarma, 2015). Once the Walden University IRB approved the study and issued approval number 09-06-18-0272148 that will expire on September 5th, 2019 all potential participants were sent an invitation letter via email with an explanation of the study. If a response was returned expressing interest in participating in the study a consent form was sent to that the potential participant to complete and return prior to engaging in the study. As Yin (2014) described protecting human subjects goes beyond the research design and technical considerations but also considers aspects of special care and sensitivity. Thus, the invitation letter also includes information for the participant for withdrawing from the study at any point, and confirmation that there are no incentives for participation.

In addition to aspects of initial contact, communication, and interviews, ethical consideration was needed for data collection handling and management. Yin (2014)

discussed the importance of maintaining a chain of evidence to increase the reliability of information from the case study. Creating a protocol for conducting data collection that covers data collection procedures, data collection questions, and management of the collected data establishes a chain of evidence and provides rigor for the study (Tong & Dew, 2016). Furthermore, Malterud et al. (2016) cited that during data analysis as themes and topics emerge from the data, another review and analysis of the collected data might be required. Data collected from initial interviews and any follow-up interviews will be stored securely on a password protected external hard drive kept in a locked drawer for five years after study completion. Once that five-year period expires, all information including data and anything regarding participants will be destroyed. In recording or working with data to ensure participant privacy and confidentiality, identities will be anonymized by being referenced as Participant 1, Participant 2, etc. in the narrative. The table matching identities with anonymous participant deidentification numbers will also be stored on the external hard drive secured in a locked drawer.

Data Collection

Instruments

For this multiple case study, to explore what are user-centered clinical BCI device design strategies used by computer scientists designing BCI assistive technologies to meet patient-centered outcomes interviews was an appropriate data collection method. Yin (2014) cited that when conducting qualitative case study interviews are often the main method for collecting data. Study interviews with member checking and participant feedback enhance reliability and validity (Awad, 2014). Data collected from face-to-face,

audio, or video supported interviews augmented with archival data provides triangulation that adds depth to the data analysis (Fusch & Ness, 2015). For this study, I will use a semi-structured interview protocol after obtaining participant signed informed consent and confirming the date, time, and location for each interview.

Audio recording devices and applications used for all interviews were pre-tested and listed in the appendices, specifications, and access to the audio technology will be sent in advance of the scheduled interview, and before starting the interview a technology check will be conducted. Twining et al. (2017) highlighted the importance of identifying and describing all data collection instruments such as questionnaires or any devices. Doing so supports setting an interview environment to allow what Arsel (2017) posited regarding additional questions that might be prompted by the observation of social cues provided by both face-to-face, phone or virtually supported interviews. Before asking interview questions, the researcher will review with the participant information regarding the purpose of the study, the procedure for withdrawing from the study, confirmation that no incentives are provided, and plans for distribution of study findings. Both phone and video interviews will be recorded using video and transcribed following the interview. Non-interview data related to assistive technology device usage was available from government sources such as the National Institute of Neurologic Disorders and Stroke (2016). Using government, healthcare, and BCI technology interest groups non-interview data collection was possible.

In qualitative research, because textual values are used versus a quantitative study that uses numerical values and statistics, other methods are required to establish

reliability and validity are needed. Ngulube (2015) offered insights into the reliability of the coding system related to the context of the research procedures. Kozleski (2017) detailed aspects of external, internal, face, catalytic, and social validity related to qualitative research, for example how analytic software offers techniques for cross-checking and triangulation. Additionally, Morse (2015b) cited that using a peer reviewed interview process to verify the eligibility of the interviewee and confirm prerequisite knowledge, skills, and experience reduces bias and adds internal validity. Additionally, Twining et al. (2017) discussed how data triangulation, member checking, and triangulation might help identify assumptions and decisions of the researcher related to data interpretation. This multiple case study provides methodological triangulation such as member checking, gatekeeper verified participant eligibility, interview recordings, and analytical software for coding, that all provide reliability and validity.

Data Collection Technique

Data collection for the study would commence with contacting potential participants and obtaining signed informed consents forms, then confirming the date, time, location for the interviews. Yin (2014) recommended that preparing to collect data the researcher should have the desired skills and values needed for research possible training for conducting the case study, and an interview protocol. My intended steps for the data collection process starting with IRB approval follow:

1. Obtain IRB approval

2. Contact potential participants through email.

3. Respond to interest inquiries from potential participants by providing information about the study, informed consent, and requesting contact information for best email address and best phone number.

4. Upon receipt of informed consent follow up with phone call to introduce myself, clarify any questions, and schedule date and time for interview.

5. Prior to interview send email to confirm date and time and reiterate interview process, confidentiality, consent to participate, right to answer or choose not to answer any question, and right to withdrawal.

6. Ensure mechanisms for data security are in place, a password protected external hard drive, locked drawer in my home office.

7. Conduct interviews starting with introductions, review of interview protocol, member checking, and overview of the topic.

8. Record audio from both phone or Skype enabled interviews.

9. Thank participants and conclude the interview.

At the beginning of each interview, time was taken to review participant rights including the right to withdrawal at any time and reiterate that the interview was being recorded. Arsel (2017) highlighted that a semi-standardized interview affords an inductive, emergent, and iterative technique for collecting data. Following the interviews, the recorded files were transcribed and annotated with a summary sent to participants for review and followed by member checking interviews. Awad (2014) suggested member checking to enhance credibility and trustworthiness of the data, and verification. The first

interview with each participant concluded with a review of their contact information and the member checking process.

Qualitative multiple case study data collection provides advantages and presents disadvantages to be considered when conducting research. Arsel (2017) discussed the performative and constructivist nature of interviews as a data collection technique for a case study as an advantage, but additionally cited the theoretical baggage the researcher might bring to the interview as a disadvantage. Twining et al. (2017) highlighted that using an iterative interview technique for data collection is an advantage and indicated that a disadvantage might be taking the response of the participant at face value. Additionally, Fusch and Ness (2015) discussed as an advantage that recognition of data saturation is reached when no new themes emerge, but also cited the possibility of a participant with specialized knowledge who introduces the *shaman effect* intentionally or inadvertently as a disadvantage.

Although interviews from multiple cases and triangulation of data with archival documents provides reliability and validity of the data collection process, member checking was also appropriate for this study. Fusch and Ness (2015) described four types of triangulation possible that include methodological, investigator, theoretical, and data triangulation. Twining et al. (2017) described participant or member checking as a process for participants to review and provide comments on transcripts and emerging findings. Further Twining et al. (2017) suggested that one of the aspects of purposeful sampling was including participants with knowledge and experience within the established sampling universe that might be able to assist in the analysis and

interpretation process. For this study, purposeful population sampling provided eligible participants capable of member checking. After the initial interviews was transcribed, the data was coded, and emergent themes identified, I sent each participant a summary of the interview information with a request to review and provide comments and details for follow up interview back to me by a specified date.

Data Organization Techniques

Once the interview data, notes, and archival data were transcribed, I used computer-based tools to assist in the coding and categorizing process. Baskarada (2014) suggested using an axial coding method to refine themes data based on relevance to the study and completed iteratively. Axial coding is the process of looking for emerging themes or categories and examining associated coded data that elucidate the theme or category (Grossoehme, 2014). I used spreadsheets, databases, and other digital methods to catalogue and organize the collected data, my logs, and my reflections. Twining et al. (2017) suggested that reviewing and analyzing the data during collection ensures the quality of the data and determines whether additional data collection is needed. Further computer assisted data analysis was possible, such as the use of nVivo 12 for qualitative research to ensure no insights into the data have been overlooked (QSR International Pty Ltd, 2017). All data was stored during the study and will be for five years after the completion of the study on a password protected external hard drive, locked in a drawer in my home office.

Data Analysis Technique

This qualitative case study was based on the theoretical propositions previously described that shaped the research question, study methodology and study design all of which should be reflected in the study results. To explore what user-centered clinical BCI device design strategies are used by computer scientists designing BCI assistive technologies to meet patient-centered outcomes purposeful sampling will be used. Robinson (2014) suggested purposeful sampling is useful when the researcher requires participants that are well-informed regarding the topic being studied. To ensure this study identified participants that had experience and knowledge that would enable them to provide substantive information regarding clinical BCI device design strategies purposeful sampling was appropriate. Twining et al. (2017) described data triangulation as using data from different participants, settings, or times. Participants in the study were from different organizations and I used iterative hand coding of the semi-structured interview data following the interviews as the recommended approach to provide triangulation. Morse (2015b) described how developing a detailed coding system at the beginning of the study regarding an unknown phenomenon would require guessing at what codes to use that might compromise the study. Fusch and Ness (2015) highlighted the aspect of triangulation and data saturation as being that data triangulation is required to reach data saturation.

Data triangulation that brings in other external data provides different perspectives on the topic and contributes to study validity. Data related to assistive technology such as that from the National Institute of Neurologic Disorders and Stroke

(2016) plus other data from healthcare and BCI technology interest groups provided non-interview data for triangulation. The combination of hand coding phrases and computer assisted coding helped ensure the best identification of emerging themes and categories from both the interview data and external data.

This qualitative multiple case study also used methodological triangulation. Hussein (2015) described how methodological triangulation provides internal consistency through crosschecking as a form of *within* methodological triangulation for a qualitative case study. Additionally, Joslin and Muller (2016) discussed *within* methodological triangulation as the use of two data collection procedures within the same design approach. For this study, member checking provided *within* methodological triangulation and as Awad (2014) highlighted enhanced credibility and trustworthiness of the data. As part of the data collection process at the end of the first interview, the contact information for the participant and instructions for follow up interview sessions was confirmed.

Much the same as creating an interview protocol, it was prudent to determine a logical and sequential process for data analysis. Twining et al. (2017) posited that the credibility of qualitative research is dependent on the logical consistency of the data analysis with the theoretical reference, research question, and data collection techniques. O'Brien, Harris, Beckworth, Reed, and Cook (2014) highlighted the significance of appropriate data analysis processes to ensure findings are explicit and transparent. Additionally, McKusker and Gunaydin (2014) discussed the rigor needed in using qualitative data analysis that is based on textual information to ensure a deep understanding of the study topic is provided. For the interviews, my questions focused on

what user-centered clinical BCI device design strategies are used by computer scientists designing BCI assistive technologies to meet patient-centered outcomes. Therefore, my data analysis was conducted to be consistent with that focus.

Using a method for the collection and analysis of data was valuable to ensure the integrity of the data. To formalize the data analysis process for this study, I used the recommendations that Yin (2014) provided regarding protecting human subjects and that Twining et al. (2017) provided about ensuring that the analysis includes the theoretical stance of the study. Additionally, I used recommendations that Braun and Clarke (2014) provided regarding creating a framework based on the data and the conceptual framework and that Wohlin and Aurum (2015) provided regarding data collection instruments and data analysis were used. The following outlines my data analysis process:

1. No identifiable participant information will be used for data analysis for this study, instead confidentiality was provided by assigning each participant with an identification alias such as Participant 1, Participant 2, and so forth,

2. Create log of data collection (Date, time, place, identification codes, method such as video, audio, and observations),

3. Transcribe recorded data using speech to text application, review and edit,

4. Include non-verbal expressions,

5. Include data from archival sources,

7. Code both by both hand and using qualitative data analysis software (QDAS),

8. Code sort blocks of text,

9. Index codes,

10. Use inductive approach to group data looking for relationships,

11. Create framework based on data and conceptual framework,

12. Write descriptive content analysis from responses in categories.

Thematic analysis focused on key themes that correlate to topics in the literature review. Braun and Clarke (2014) highlighted identifying patterns from the dataset related to the research question and research context to ensure deliberate, reflective, and thorough thematic analysis takes place. For this study, the research context included the literature review, the conceptual framework, and possibly any new studies.

One aspect of thematic analysis involved making distinctions between key themes and themes that might be of interest but not related to the conceptual framework of this study. Koopman (2015) explained the relationship when encoding qualitative information and developing codes to label the data assists in the thematic analysis. For this study developing possible codes prior to beginning thematic analysis offered a set of codes to start with that were modified as the study progressed. Having this set of codes in place might also supported what Woods, Paulus, and Atkins (2015) discussed regarding the need for critical and reflective awareness to prevent qualitative data analysis software (QDAS) from influencing qualitative research practices. Additionally, Crowe, Inder, and Porter (2015) suggested thematic analysis that provides an interpretation of participants meaning supports correlating study data with themes present in the conceptual framework. Each of these point to the need for the researcher to, as Yin (2014) suggested having an analytic strategy. The analytic strategy for this study included thematic

analysis using both hand coding and QDAS coding to develop a coding schema to summarize the themes, patterns, and topics found in the data.

During the process of data analysis, I continued to monitor the literature for new information and review the results of member checks in relationship to the key themes. Yin (2014) recommended that data analysis of all evidence, recognizing plausible rival interpretations, addressing the most significant aspect of the case, and demonstrating current awareness and discourse on the topic as needed to ensure high-quality data analysis. In addition to monitoring the literature and member checking, I reviewed and coded the data focused on identifying key themes as prescribed by my conceptual framework. No other themes emerged as I reviewed other conceptual models evaluated but not used for this study.

Consent forms that include participation guidelines such as the right to withdrawal and all data collected for the study will be secured for a period of five years after completion of the study and then destroyed. Saunders, Kitzinger, and Kitzinger (2015) discussed the opportunity to maximize informed consent by providing participants with information regarding the study data handling procedures. Buchanan and Hvizdak (2009) highlighted changes in handling data ethically due to changes in technology and the use of online tools and applications that would include audio and video files. Additionally, Saunders et al. (2015) discussed with how the use of online tools, as well as audio and video resources, present opportunities for researchers to share data. However, the issue of maintaining confidentiality must be weighed against the benefit of data

sharing. Therefore, all secured collected data will be destroyed after a period of five years.

Reliability and Validity

Qualitative research that uses textual values differs from quantitative research that uses numbers and statistical methods. Morse (2015b) discussed measures needed for qualitative research such as those used for quantitative research to demonstrate reliability, validity, generalizability that evidence of study rigor. Elo et al. (2014) used the terms dependability, credibility, transferability, and conformability, and authenticity related to the trustworthiness of the qualitative content analysis. Additionally, Wilson (2014) discussed four types of triangulation that include data, theoretical, investigator, and methodological that might be useful to provide accuracy and confirmability for qualitative research. For this study, I used data and methodological triangulation and reflexive journaling to establish study rigor.

For qualitative research, dependability refers to the reliability of the data. Elo et al. (2014) posited that dependability is comparable with the concept of quantitative research reliability. Ngulube (2015) traced dependability back to the methodological assumptions and approaches stemming from the research question. Establishing a chain of evidence as part of the study methodology by keeping a log of data handling activities supports dependability. Leung (2015) suggested several approaches that provide reliability for qualitative research including refutational analysis, constant data comparison, and comprehensive data use. Additionally, Elo et al. (2014) posited member checks as one method for constant data comparison. For this qualitative multiple case

study, member checks as a method of constant data comparison were used to provide dependability.

Credibility refers to whether from the perspective of the researcher, the participants, or readers of the study there is truthfulness. Cope (2014) discussed methods such as debriefing, member checking, triangulation, and reflective journaling to ensure data dependability, credibility, and accuracy is supported by the interpretation of the researcher. By recognizing that the researcher might have personal experiences or perspectives that could result in methodological bias, credibility reflects how clearly the research presents the perspective of the participants. For this study preventing methodological bias was supported by the fact I have no personal experience in the design of BCI devices as assistive technologies. Stewart and Gapp (2017) discussed credibility related to research rigor and trustworthiness in the context of crystallization. With crystallization resulting from immersion, intuition, and creativity that a research applies through reflection, consideration, thought, and reflexivity (Stewart & Gapp, 2017). Data triangulation Stewart and Gapp (2017) suggested contributes to crystallization by providing other sources of data that supports a more complete, holistic, and authentic study through the intertwining of writing, method, and analysis. Additionally, Twining et al. (2017) suggested qualitative research trustworthiness can be verified by having data and the data analysis systematic and transparent. For this study, member checks and data triangulation provided the opportunity to have my interpretation of the data to be verified.

Transferability in qualitative research is analogous to generalizability in quantitative research. Cope (2014) described how in qualitative studies transferability is achieved when a researcher provides appropriate information on the participants and the content of the research so that the findings can be assessed on applicability to other settings. However, Morse (2015b) suggested that transferability might only be relevant if the purpose of the study was to provide generalizations on the phenomenon. For this research, the phenomenon being studied was the user-centered clinical BCI device design strategies used by computer scientists to design BCI assistive technology devices to meet patient outcomes. Yilmaz (2013) posited that case studies do not use statistical generalization based on populations, but instead use analytical generalization to generalize to theories. Transferability of the study results might support other computer scientists designing user-centered clinical BCI assistive technology devices and thus contribute to ensuring a balance was found between user needs, system functionality, development feasibility. I used theoretical triangulation, auditing and documentation to account for transferability of the study findings to the reader and future research.

A qualitative multiple case study that is not based on quantifying information requires methodologies to ensure study rigor is provided through dependability, credibility, transferability, and confirmability. Confirmability in qualitative research is achieved when consistency, applicability, and truthfulness are ensured by exemplifying that findings were drawn from the data based on interpretations that accurately reflect the views of participants and not influenced by researcher bias (Tong & Dew, 2016). Understanding what the strategies are that computer scientists use for the design of BCI

assistive technology devices from the research participants was one of the goals of this qualitative research. Forero et al. (2018) cited that through reflexive journaling it is possible that perspectives of the researcher that introduce bias and thus influence confirmability might be reduced. Developing a rigorous qualitative semi-structure interview guide as a data collection tool Kallio, Pietla, Johnson, and Kangasniemi (2016) posited as enhancing the trustworthiness of the research. For this study I used semi-structured interview questions, reflective journaling, and a chain of evidence to establish confirmability.

Understanding and establishing when data saturation is reached is essential for qualitative research. Fusch and Ness (2015) asked the question *Are We There Yet?* when they discussed data saturation to draw attention to the quantitative aspect of data saturation such as how many interviews are needed to reach saturation. However, it is not just the number of interviews needed to reach data saturation, reliability and validity markers must also be satisfied. Malterud et al. (2016) proposed the concept of information power to guide sample size related to data saturation but also meet criteria related to the aim of the study, sample specificity, established theory, the quality of the dialogue, and analysis strategy. This study, in which I explored what strategies are used by computer scientists for the design of BCI assistive technology devices, had sample specificity based on the eligibility of the participants and using semi-structured interview questions promotes dialogue quality. Twining et al. (2017) added that along with the data saturation criteria of the number of participants that once no new concepts were raised in the collected data that theoretical or conceptual saturation could be considered met.

Participant eligibility, semi-structures interviews, member checks, and methodological triangulation were the methods used to achieve data saturation for this study.

Transition and Summary

In section two, I outlined a plan for conducting the study. I provided information regarding my role as the researcher, proposed population, aspects of my intended research methodology and design, data collection, organization, plus analysis, and considerations for dependability, credibility, transferability, confirmability, and data saturation related to my study. This section also includes references to related files located in the Appendix section such as the Consent Form, Interview Protocol and Interview Questions for this study.

In section three I provided an overview of the study, study findings, applications for professional practice and implications for social change, recommendations for further study, and my reflections.

Section 3: Application to Professional Practice and Implications for Change

Overview of Study

The purpose of this qualitative multiple case study was to explore the user-centered clinical BCI device design strategies used by computer scientists designing BCI assistive technologies to meet patient-centered outcomes. I collected data from organizations experienced with clinical BCI assistive technology design located in the Midwest, Northeast, and Southern regions of the United States, and Western Europe, interviewing and conducting member checking sessions with seven computer scientists and collecting 28 documents. The participants I interviewed were members of research teams within organizations working as computer scientists developing BCI technologies. All participants had between 2 to 25 years of experience with the average being 14 years as a computer scientist working on clinical BCI technology.

I categorized participants into two groups: those conducting invasive BCI research and those using noninvasive approaches. The gender breakdown was approximately 50/50 thus eliminating gender bias. Four of the participants had experience as the primary investigator for a research study of BCI technology, and the experience of three participants was as associate research scientists on the investigating team. Conclusions from my data analysis resulted in four strategies for employing user-centered design each with modifications based on context. I organized themes by major theme and sub-themes associated with the major theme. Reference counts are based on attributions to theme key words. A reference may be specific to one theme or incorporate two or more themes in the same reference.

Presentation of the Findings

The research question that served as the basis for my interviews was the

following: What are user-centered clinical BCI device design strategies used by computer

scientists designing BCI assistive technologies to meet patient-centered outcomes?

While participants varied in consensus regarding the timeline, each concurred that

user-centered design strategies are a pivotal aspect in meeting patient-centered outcomes

and subsequently reducing the risk of abandonment of a clinical BCI assistive technology

device. All participants indicated that to a large extent many of the investigations

regarding BCI device assistive technologies frequently took place in clinical research

facilities as experimental activities and less frequently in individual home environments.

Focus on Customization

Focus on customization of clinical BCI devices was one of the prominent themes.

The focus on customization related to design strategies included consideration of

ergonomic features as well as signal processing aspects that are needed to work

cooperatively to meet patient-centered outcomes. One intricacy associated with

ergonomic design is often related to individual motivation to use the device based on the

restorative capability of the device to overcome communication or movement disabilities.

Integrated into ergonomic design aspects, were signal processing complexities related to

signal acquisition, signal processing, or effector device features either individually or

together. Although device development takes the coordinated efforts of a team of experts

from various domains, the design of the device from a technical aspect requires

governance by computer scientists for all aspects to work effectively.

Six of seven participants agreed that customization of the BCI device as related to user-centered design was being important, and 12 documents indicated support for that theme (see Table 1 for theme and sub-theme metrics). Five of the seven participants indicated that customization of features is frequently driven at the highest level based on the requirements of the rare disorder. For example, BCI devices for communication used by individuals with ALS versus devices for movement used by individuals with spinal cord injury. Although both design types involve signal acquisition and signal processing, the effector devices are different and accordingly patient-centered outcomes are different.

Table 1

Themes of Focus on Customization with Supporting Metrics

Major Theme	Participant		Documents	
	Count	References	Count	References
Focus on Customization	6	13	12	26
Sub-themes				
Ergonomics	6	11	7	32
Signal processing	7	10	10	53
Effector devices	7	7	3	18

One of the primary considerations regarding designs for communication BCI devices governed by experts from various domains such as bioengineers is whether the basic design of the device is invasive or noninvasive. Invasive designs as described by two participants require the technical components for signal acquisition to be surgically implanted within the skull of the individual by neuro-surgeons. Noninvasive designs described by other participants require connecting the technical components to the individual by positioning either wet or dry electrodes affixed to a skull cap or framework.

For either invasive or noninvasive designs, all seven participants considered optimizing signal processing a priority to ensure effective BCI functioning.

Five of the seven participants indicated that there is a preference for the use of noninvasive BCI devices. Additionally, four of the seven participants indicated there is a preference for dry versus wet electrodes. Of the various dry electrode noninvasive models used to self-regulate cortical potentials, the P300 was discussed by most participants with only one participant referencing the mu-rhythm sensorimotor or steady-state visual evoked potential models. Three participants highlighted the trade-off between wet and dry electrodes, with wet electrode devices being uncomfortable and messy but offering greater signal accuracy versus dry cap devices compromising signal accuracy for less mess and better comfort. Various ergonomic styles for P300 systems are used to analyze and provide a means for patients to self-regulate their intentions with most using the International 10-20 electrode locations on the scalp.

Four of the seven participants indicated how the physical placement of the electrodes that is critical to signal acquisition might require a significant amount of time to set up. Five of the seven participants indicated that set-up might be especially time-consuming with patients who require specific body positioning, those who may have lesions on their scalp, and those requiring life support systems such as artificial respiration. The net impact of the amount of time needed to place the electrode system correctly, being the actual time afforded for investigating the use of the system focused on the technology, which often leads to marginalizing investigating whether the expectations of the patient are met. Six of seven participants indicated the fundamental

purpose of experimental investigation was to see if the technology worked. Five of the participants also addressed aspects of the environment where clinical BCI device research is conducted, with one specific aspect being the role of the patient's caregiver involved with the physical set-up as relevant regardless of whether it was a research laboratory or home.

Three participants described a model for a typical BCI system as a sensor to acquire neural activity, a decoder for converting signals, and a voluntarily controlled effector device. Three participants indicated that calibration of the BCI device system was required during signal acquisition and highlighted ergonomic issues such as wet versus dry cap models previously discussed. Other participants cited that signal processing or decoding was also subject to anomalies when a patient becomes fatigued or falls asleep, experiences a mood change, seems to stop participating, becomes distracted due to an environmental event such as caregiver interaction, or experiences changes in neuroplasticity due to the rare disorder.

A description of how signal processing or decoding takes place based on signal extraction, signal translation, and classification is available in the literature. Six of seven participants indicated that customization of these complex aspects of signal processing might be best addressed using machine learning, which would be included as part of a user-centered design. One participant suggested that user-centered design might be used less in signal processing and more likely to be used in signal acquisition and effector devices. While one participant indicated that incorporating learning methods that would

allow patients to modulate their brain signals especially related to signal translation might be an aspect to include in user-centered design.

Effector devices are another facet of ergonomic design related to clinical BCI technology. An effector device sometimes referred to as the selection enhancement device translates outputs into meaningful communication such as word prediction using a BCI speller or object avoidance used by a BCI wheelchair (Thompson et al., 2014). Five of seven participants and five documents referenced how improvements in technology have brought about improved usability for specific patients such as those with ALS. One participant explained how design innovation improved eye tracking systems that were expensive and inaccurate, reducing the cost factor by a power of 10 and significantly improving accuracy. Four of the seven participants indicated that ergonomic design supports the physical means for signal acquisition and effector devices to function. Both design constructs require computer scientists to establish communication between the brain of the patient and the devices to function effectively.

Ergonomic aspects are a foundational consideration in the design of a clinical BCI device. However, ergonomic aspects are probably most significant as related to aspects of customization integrated with signal processing. In the literature, Ortiz-Rosario and Adell (2013) focused that signal processing is comprised of three main components: signal acquisition, signal processing, and effector device. Ienca and Haselager (2016) described how each of these components is required to create a system that allows direct communication between the brain of an individual with a computer and an external device. Four participants indicated that the P300 model BCI device is one of the most

reliable for detecting EEG events that occur 200 to 500 ms following visual, auditory, or somatosensory stimuli. As Jin et al. (2015) described, individual modifications when using the P300, such as increasing the signal strength, often improves selectivity when using a mismatch negativity odd-ball ERP, which subsequently might improve customization. Customization of ergonomic aspects that relate human factors with the technology is key to user-centered design.

Other aspects related to customization that still rely on ergonomics but that can also be considered independently are signal processing aspects. Signal processing aspects are likely to rely on what Chu (2015) suggested for processing brainwaves using algorithms such as band-power feature extraction, spatial patterns analysis, and statistical source separation.

With expected patient-centered outcomes relying on optimal signal processing, techniques such as band filtering that recognizes brain waves associated with emotions and allows them to be filtered from the EEG data set are useful (Atkinson & Campos, 2016). As Martel el al. (2014) highlighted machine learning and adaptive signal processing techniques might provide ways to identify vigilance decrement such as when a patient falls asleep during a BCI experience and thus improve signal acquisition. Spatial pattern analysis provides techniques to facilitate detection of movement-related cortical potentials and reduce the amount of signal delay (Yao et al., 2017). While statistical source separation techniques offer a way to filter undesired signals or artifacts caused by physiological sources or other non-physiological sources such as technical issues (Minguillon, Lopez-Gordo, & Pelayo, 2017). Changes in neuroplasticity likely to occur

over time especially as a result of a rare disorder such as ALS might benefit from machine learning to identify baseline changes as another aspect of customization.

There are numerous ways in which the relationship between technology and the individual user can be considered. The MISC model that Lowry et al. (2014) provided, which is built on the foundational work regarding motivation and technology use by Bhattacherjee and Premkumar (2004), Oliver (1980), Davis, Bagozzi, and Warshaw (1989), highlights the concept of intrinsic motivation related to technology use. Exemplifying the MISC model and the influence of intrinsic motivation on meeting patient-centered outcomes are the risks associated with invasive designs such as Klein (2016) and Vansteenel et al. (2016) described. Although risks associated with invasive designs are considered greater than those associated with noninvasive designs, two out of seven participants indicated that individuals with ALS are willing to tolerate the risks of invasive BCI devices in order to communicate.

Also exemplifying intrinsic motivation related to BCI device use was the example one participant shared of an individual who declined use of a BCI device because of the way she, the individual, would look. Thus, intrinsic motivation related to BCI device use is likely to extend beyond just the desire to communicate but also account for matching the technology to an individual. As the ATC of LoPresti et al. (2004) suggested cognitive skills such as reasoning might monitor specific behaviors and reinforce intrinsic behaviors. Additionally, Jeunet et al. (2016) suggested that continuous technology use might require training to encourage skill acquisition and enhance motivation. With Scherer and Federici (2015) concluding that assistive technology is likely influenced by

environmental factors, psychological factors, and desirable features and functions of the device. Therefore, the MISC model of Lowry et al. (2014) that considers intrinsic motivation such as satisfaction, continuance intentions, and perceived performance as a predictor of user outcomes supports the incorporation of user-centered design strategies in the development of clinical BCI devices.

There are many aspects related to the customization of clinical BCI devices, and two aspects that are frequently identified are ergonomic and signal processing technology. The consensus of all seven participants was technology will continue to innovate and integrate new materials, new architectures, and new techniques such as machine learning into future more customizable clinical BCI devices. The significance of customizing a BCI device for individuals with rare disorders might be best considered when answering the question "Will they use it?" proffered by one of the participants. The extent of assistive technology device abandonment or disuse is well documented as are many of the causes, one of which is intrinsic motivation. The MISC model recognizes the influence of intrinsic motivation related to the use of technology and meeting patient-centered outcomes. Therefore, computer scientists that employ user-centered design strategies to design clinical BCI devices might consider that the goal for many individuals with disorders such as ALS is the development of a BCI device such as that used by Stephen Hawking that was decidedly customizable.

Focus on Patient/Caregiver System

Another theme that six of seven participants specified as important was consideration of the imposed patient/caregiver relationship due to certain rare disorders.

The design of many clinical BCI devices is intended for individuals with rare disorders such as ALS or spinal cord injury that have reached the stages of LIS or CLIS. Both conditions mandate that these individuals must rely on family members or professional caregivers to continually assist them with daily activities. This continual interaction between the patient and the caregiver often develops into an empathetic level of communication such that the caregiver seems able to reflect the wishes and thoughts of the patient. Five documents provided information regarding the patient-caregiver relationship. Therefore, for a clinical BCI device to meet patient-centered outcomes, it must holistically be able to satisfy both patient and mediated caregiver expectations until a completely autonomous clinical BCI device is designed and developed.

Each of the seven participants referred to patient-caregiver interactions that occurred during the time the BCI device was either being setup or in use. Five of seven participants indicated the need for establishing relationships to inform caregivers of the operational aspects of the BCI device, and to support communication between the participant, the caregiver, and the patient (See Table 2). Five of the documents indicated how in some situations, caregivers essentially become BCI system assistants, able to interface with setting up the equipment by acting as an agent accommodating the patient, based on their understood communication. Additionally, three of five participants indicted the significance of caregiver involvement with BCI device use because they know the routines of the patient, which includes daily functions and how they influence the physical and mental state of the patient. One document shared how a research event could not be conducted because the caregiver for the patient was absent. While as another

example, one participant shared how a shift in time due to daylight savings time impacted

the patient's ability to concentrate because the timing of a daily function was different.

Three participants indicated that in dialoguing with caregivers, their expectations focused

on viable clinical BCI device for use in home environments. For example, one participant

indicated a caregiver's goal for using a BCI device would include allowing for two-way

communication such as letting the patient know the caregiver was on their way if

suddenly needed by the patient.

Table 2

Themes of Focus on Patient/Caregiver System with Supporting Metrics

	Participant		Documents	
Major Themes	Count	References	Count	References
Focus on Patient/Caregiver System	6	27	5	38
Sub-themes				
Caregiver	6	14	5	24
Researcher	5	15	4	15

One variable that plays into the patient-caregiver relationship is the location of the

patient either at home or at long-term care facility where the caregiver may not have the

same level of relationship with the patient, therefore, interactions will be different. Three

participants indicated that this difference in the relationship might influence the use of a

BCI device because of the level of emotional investment with the patient, which might

lead to reluctance to deal with the ergonomic aspects such as wet electrodes and cap

placement. One participant indicated that even the act of turning the BCI device on or off

that is not under the control of the patient, might also be based more on whether the event

was successful and met the expectations of the caregiver not as much as meeting the

expectations of the patient. Two documents indicated that caregiver influence might determine whether the use of a clinical BCI device would be considered a burden or a benefit, especially given the workload responsibilities that many caregivers must assume.

Although patient-caregiver relationships might be considered unique symbiotic arrangements based on empathetic and unspoken communication, the intrinsic motivation of the patient might be different than the motivation of the caregiver, which might be more extrinsic. Beaudry and Pinsonneault (2010) as well as (Marangunic & Granic (2015) cited how emotion and motivation play a role in technology use and acceptance. The patient caregiver relationship related to clinical BCI device use as discussed by participants is likely to encompass a range of emotions for both individuals and elicit different motivation-based expectations.

The environmental setting such as a research laboratory, hospital, or home often determines what patient caregiver relationship is established. Magoulas (2017) highlighted how especially in a medical setting the perception of ease of use that institutional caregivers experience might influence satisfaction and continuance intention. As Iranmanesh et al. (2017) posited willingness to use technology by medical personnel was often predicated on continuance intention based on ease of use. Additionally, Rupp (2014) concluded from a study of patients with spinal cord injuries and medical personnel as caregivers using clinical BCI devices that factors such as respiratory conditions, medications, stress, pain, and the inability to control the device all influenced continuance intention. Therefore, meeting the expectations for the use of a clinical BCI

device is not solely based on the patient but also relies on meeting the expectations of the caregiver and a shared trusting relationship.

Trust between individuals with rare disorders such as LIS and CLIS and their caregivers is essential but not always based on the same type of relationship. As Klein et al. (2016) pointed out, researchers and medical personnel may base their opinion regarding the use of clinical BCI devices as related to their intentions, possibly different than those of the individual. Additionally, Blankertz et al. (2016) highlighted there is a stratification of BCI uses cases for BCI technology that include tools for research, tools to improve devices, interfaces, and infrastructures, as well as methods to enhance or facilitate human actions by healthy individuals with a computer. In discussing stratification of BCI use cases, Blankertz et al. (2016) considered the study of Scholler et al. (2012) conducted to detect changes in brain signals based on the quality of the video the individual using a BCI device was watching. Going forward machine learning techniques that allow signal processing to detect levels of satisfaction from the patient might offer ways to make sure patient caregiver expectations coincide.

In the case of BCI device use for individuals with rare disorders such as ALS that require caregiver support, meeting patient-centered outcomes might extend beyond the individual. In discussing meeting patient-centered outcomes, Lowry et al. (2014) highlighted how technology use is related to intrinsic motivation based on satisfaction, continuance intentions, and perceived performance that would be a strong predictor of patient-centered outcomes. At the same time, the MISC model that Lowry et al. (2014) provided is applicable related to the use of the technology by the caregiver because it

does consider extrinsic motivation such as perceived ease of use that might a predictor of caregiver expected outcomes. Therefore, the MISC model supports the unique relationship between patient and caregiver each with their own emotions and expectations based on individual aspects of motivation.

Given the patient-caregiver relationship and because motivations are likely to be different, meeting expectations are likely to be different based on these features. The MISC model of Lowry et al. (2014) is based on the work of Bhattacherjee and Lin (2015) that highlighted how reasoned action, experiential response, habitual response, perceived usefulness and perceived ease of use all contributed to the ECM of IT continuance. For example, perceived ease of use for the patient might include having the BCI device positioned correctly, while for the caregiver perceived ease of use likely includes positioning the patient, positioning other equipment, placing the correct amount of gel if being used on the electrodes, placing the device correctly and comfortably in position, and checking the calibration.

Patients, caregivers, and patient caregiver relationships are likely to influence continuance intention as prescribed by the MISC model meeting expectations based on both intrinsic and extrinsic motivation. Abandonment or disuse of a clinical BCI device by individuals with rare disorders may not be limited to the individual alone. Although some techniques to gauge the quality of an individual user's experience with a device are forthcoming, meeting expectations are still profoundly tied to meeting caregiver expectations. Therefore, computer scientists designing clinical BCI devices might do well to consider caregiver expectations as part of their user-centered design approach.

Focus on Collective Data Management

A third theme that emerged that participants indicated as significant was the nature of clinical BCI design or development and collective data management. Besides the limitation of shared information that might provide insights into how user-centered design assisted in meeting patient-centered outcomes during clinical trials, currently there does not exist a central repository of clinical BCI device information that includes signal processing data. A consequence of a lack of centralized data management might be the inability to establish metrics and or standards regarding BCI device development.

Five participants highlighted how information obtained from research involving patients in clinical trials was prohibited from being shared due to government regulations. All seven participants referred to work of researchers or research groups investigating clinical BCI devices. However, participants were not able to offer a centralized location for BCI research data (See Table 3). Five of seven participants indicated the National Institute for Health (NIH) availability for some research information and one participant indicated the BCI society as a research information source. Twelve documents indicated that a factor complicating data collection from studies of clinical BCI devices with patients was advancement of the rare disorder, as exemplified by one study in which 12 of 27 patients left the study due to rapid disease progression or death, supporting information of four participants that indicated such circumstances occurred as part of their own professional experience.

Table 3

Themes of Focus on Collective Data Management with Supporting Metrics

	Participant		Documents	
Major Theme	Count	References	Count	References
Focus on Collective Data Management	6	27	5	38
Sub-themes				
Patient	6	14	5	24
Technology	5	15	4	15

Five participants discussed how because currently clinical BCI research most

frequently is conducted in a research facility, individuals with rare disorders might not

know of this assistive technology availability or may not be able to participate due to the

distance to the research center. How the brain and the technology work is generally the

question, the researcher is trying to answer, and not as one participant indicated getting

the answer to the question "What do you want to get out of your BCI" from the patient,

which suggests why that type of data is scarce. Another participant indicated that lack of

collected data occurred because "data falls to the floor" because it is a different kind of

data and not part of the research focus.

Collection and management of BCI device data based on patient expectations and

signal processing data are both significant. As Chu (2015) suggested the collection of

brain signal processing algorithms and creating a standardized brain wave databank

would provide archival and current data that might prove valuable to other researchers.

One aspect of a standardized brain wave databank that might be beneficial would be

providing information to other researchers regarding signal processing such Iacoviello et

al. (2015) described related to emotional states and which mathematical algorithms might

be best for signal translation. Additionally, as Moritz et al. (2016) and Hohmann et al. (2018) suggested shifts of wave frequency may occur with neural devices based on neural mechanisms. Both suggested machine learning as a method to accommodate such changes as related to non-stationary learning tasks. Thus, a collective databank with a collection of signal processing algorithms might help reduce research time.

Data collection regarding effector devices might also prove beneficial. In the literature Keates (2017), Lacko et al. (2017), and Kathner et al. (2017) each suggested advances needed for assistive technology to ensure devices did not succumb to abandonment or disuse because they did meet patient-centered based on the MISC model. Interest in collecting data regarding effector devices might come from designers looking at non-clinical BCI devices. Miranda et al. (2015) noted interest in noninvasive BCI devices for healthy individuals and exploring virtual reality, Hansen (2015) identified how commercial markets might use BCI devices for meditation, and Pinegger et al. (2017) acknowledged how user-centered design might support the development of a BCI device for composing music. Collecting data regarding effector devices from other researchers such as highlighted previously might lead to user-centered designs for clinical BCI devices that would support restorative communication or movement needs but also provide other ways to improve the quality of life for individuals with rare disorders.

Limitations imposed on computer scientists by the lack of collective data availability might influence how user-centered design strategies especially related to TTF also are shared. The MISC model Lowry et al. (2014) posited considered TTF that Goodhue and Thompson (1995) proposed, which in the case of BCI devices would likely

consider differentiating between tasks for communication versus tasks for movement, keeping in mind that Lowry et al. (2014) used the term DEF is encompass the aspect of design-related technology and task fit. Data collection and data management related to clinical BCI devices connect with the MISC model of Lowry et al. (2014) by offering an opportunity for researchers and designers to share information and possibly more effectively employ user-centered design strategies based on available information regarding strategies already investigated. Collecting data related on various aspects of clinical BCI devices such as design aesthetics, perceived ease of use, and design-expectation fit might contribute to what Kubler et al. (2014) identified as design constructs supported by the MISC model. User-centered designs that could eliminate already tested aspects or include already proven successful design aspects could contribute to meeting patient expectations and therefore reduce device abandonment or disuse.

Focus on Evolving Technology

The concluding theme was the relationship between evolving technology and clinical technology this theme represents the idea that as technology evolves and improves it will influence device ergonomics, signal processing, and effector devices in a positive manner. The significance of technology evolution is two-fold as it may provide a solution to a current challenge and it also provides an occasion to consider future design possibilities. With clinical BCI device development still mainly in the experimental phase, limitations on making changes or adjustments are reduced compared with adjusting commercial or mass-produced devices that could be costlier and therefore less

like to occur. Likewise, incorporating newer technology as a result of known challenges or anticipated improvements on a continual basis will bring the device closer to meeting goals of BCI designers and expectations of BCI users.

Five of seven of the participants indicated that researchers, especially in the early phases of BCI research, saw the need to experiment to determine if BCI devices could be used to communicate with patients with rare disorders, rather than to design a device based on patient-centered outcomes. The consensus of the participants indicated that research was focused on did the technology work for communication or movement versus meeting expectations of the individuals (See Table 4). Three out of five participants indicated how recently some investigations had included measures of patient satisfaction including working with therapists, focusing on whole person dimensions, and including patients in the development of prototypes, signifying a shift in the intention of researchers from furthering science and technology related to BCI devices to meeting patient-centered outcomes.

Table 4

Themes of Focus on Evolving Technology with Supporting Metrics

Major Theme	Participant		Document	
	Count	References	Count	References
Focus on evolving technology	5	43	8	37
Sub-themes				
Patient	5	17	3	7
Technology	6	12	5	18
Devices	6	14	3	19

Three participants indicated that in addition to researchers taking advantage of evolving technology, users of clinical BCI devices might also participate in updating the

current design. As three participants explained how some members of the target audience

for studies of rare disorders and individuals using BCI devices are involved in

communities that allow them to participate in blogs and post videos recordings of their

daily life. All seven participants indicated that as with any assistive technology a key

concept was to improve the quality of life of the patient, and four of five participants

indicated that there is a disconnect between the research and the user. Using social media

technology would allow researchers to get closer to the individual users and their

caregivers, and three participants indicated that employing user-centered design could

promote researchers having a better understanding of the impact a rare disorder had on an

individual and their quality of life. Recognizing social media technology as an evolving

technology supporting individuals with rare disorders two participants also indicated it as

a way for information regarding clinical BCI studies to be distributed within

communities. The benefit of dissemination of BCI device research studies would be

realized by researchers who would have a larger patient base to draw from and by

individuals with rare disorders learning of the types of resources different studies have

available.

Another aspect of evolving technology related to BCI development includes

effector devices as three participants indicated offering examples such as improved eye

tracking systems and spellers. Additionally, four participants described ergonomic

improvements needed related to the speed of the device, the physical aspects of the

device such as wet or dry electrodes, portability of the device, and the autonomous nature

of the device. One participant explained issues related to the speed of the device and

keystroke savings based on errors using predictive software. Explaining how some BCI keyboards use a fixed number of flashes before to selecting a letter and how if the score between two letters is close the higher scoring letter is selected although that might not be the correct choice. The advent of machine learning and virtual reality technologies five of seven indicated as having a significant influence on the development of techniques for signal processing in the future, information that was supported by five of documents.

There exist today technologies that much like BCI technology have matured and improved over time. In the literature, Chu (2015) posited that virtual reality might provide improved techniques for signal processing, and Lazarou et al. (2018), Miranda et al. (2015), and Moritz (2016) each supported the idea of using an evolving technology such as virtual reality integrated into clinical BCI devices. As Forsythe et al. (2017) discussed based on the conceptual model of patient-centered outcomes, a fundamental element to effective behavior change is engagement. An example of this idea of engagement supported by combining these technologies is the work of Lazarou et al. (2018) that demonstrated the use of other technologies such as virtual reality when combined with BCI technology that might result in feelings of enjoyment that in turn might promote a better quality of life experience. While Miranda et al. (2015) highlighted the use by healthy individuals of noninvasive BCI technologies to engage with avatars or explore virtual environments, and Hansen (2015) suggested the possible use of noninvasive BCI devices for meditation or entertainment might assist in transitioning BCI devices from research to commercial availability. Thus, virtual reality as one

example of an evolving technology related to BCI technology might provide greater enjoyment for both healthy individuals and those with rare disorders.

Another evolving technology is machine learning. Aspects of machine learning integrated with clinical BCI devices were provided by Moritz et al. (2016), Ramadan and Vasilakos (2017) and Mahmud, Cecchetto, Maschietto, Thewes and Vassanelli (2017) with each group suggesting potential benefits of combining the two technologies. As Ramadan and Vasilakos (2017) described, there are many phases a BCI system goes through that include preprocessing, feature extraction, signal classifications, and device control that require integration based on hardware and software. One aspect of a BCI system and phases Mahmud et al. (2017) investigated was high-resolution neuronal probes, neuronal signal acquisition, and automated methods for intelligent signal analysis that included noise characterization and artifact removal. Artifact removal as described by Mahmud et al. (2017) must be broken into slow artifact removal that is difficult to remove due to being close in frequency to desired evoked response frequency, and fast artifact removal produced when intracortical microsimulations occur related to an evoked response that is tedious to remove due to shape and variations in frequency. Additionally, Mahmud et al. (2017) suggested that storage required for experimental data that was converted from analog to digital signals from approximately 50 hours of research would utilize 1 TB storage space and indicated that only machine learning pattern recognition algorithms could process this much data appropriately. Aspects of machine learning are likely to contribute to customization of BCI devices by accommodating differences in individual requirements of functionality.

Often cited in the literature was the experimental nature of current clinical BCI device research and what might be called a disconnect between individuals with rare disorders and researchers. Although focused the ethical aspects of BCI research Sullivan and Illes (2018) highlighted the lack of ethical language in both neural engineering journals and biomedical engineering journals and thus suggested the need to ensure that technology did not eclipse human benefit. At the same time Vansteensel, Kristo, Aarnoutse and Ramsey, (2017) highlighted how BCIs are primarily a research application and not found in daily life at home, work, or medical environments. Collecting and analyzing responses from BCI researchers worldwide Vansteensel et al. (2017) reported that one of the obstacles identified by the respondents, approximately a third of which were computer scientists, was potential patients not being aware of available BCI tools. Social media, an evolving technology, Smailhodzic, Hooijsma, Boonstra and Langley (2016) indicated was frequently used by patients to locate information to complement what not be might available from their healthcare professional, to bridge the gap between their condition, their everyday life, and traditional healthcare, to join communities for social support. Thus, social media might provide one method to connect potential users with researchers.

Although using evolving technologies and predicting ways it might on improve user-centered design is not yet a complete reality due to the still experimental status of BCI development and the fact the technologies themselves are evolving, it may assist in placing greater focus on meeting patient-centered outcomes and increase continuance intention. Using clinical BCI devices is a discretionary choice by an individual based on

intrinsic motivation with associated ongoing use based on continence intention as a result of meeting expected outcomes. The MISC model of Lowry et al. (2014) relates to both aspects for use but is also broad enough to include the extrinsic motivation of caregivers. One facet of the MISC model is DEF that Lowry et al. (2014) described as correlating increased DEF leading to positive disconfirmation, or use of the technology will be promoted if it is designed based on meeting the motivation, expectations, and attitudes of the individuals who will use it.

Applications to Professional Practice

The perceived lack of user-centered design strategies used by computer scientists in the development of clinical BCI assistive technology devices to meet patient-centered outcomes was the specific IT problem that served as the basis for this research. Provided by the participants in this research study were strategies that computer scientists and experts from other domains involved in BCI assistive technology development could employ to meet patient-centered outcomes better. The participants' thoughts on user-centered design spanned user personal aspects to highly technical aspects, representing various strategies to meet expected patient-centered outcomes. Coming from research, the participants stated they referenced the work of other researchers to influence best practices in the absence of established standards. Based on collected data the four themes identified are customization, patient/caregiver system, collective data management, and integration of evolving technologies into BCI device development. The results offer computer scientists and experts from other domains ways for inclusion in their practice.

Research teams that normally include experts in computer sciences and other domains in the field of clinical BCI assistive technology devices can adapt the results to establish metrics for such devices. Were a centralized database created for technology and patient results, metrics derived from the collected data should be included. Having metrics would provide guidelines for all involved with the development of a clinical BCI device focused on meeting patient-centered outcomes. Individual users of a BCI device are reliant on care-givers to participate in device use. Metrics should provide patients and both home and institutional caregivers opportunities to inform researchers of personal and technical expectations.

Metrics would establish guidelines based on the themes found in this investigation that research teams, patients, and care-givers could follow. The research team should determine metrics that are inclusive of patient and caregiver needs and expectations. Likewise, the metrics should support patients and caregivers in understanding the objectives of the research team. Bridging the gap between what is possible with the technology and what is possible to meet a personal expectation requires two-way communication that metrics could facilitate. These results are not limited to research teams, patients, and caregivers; other entities will also find them useful.

Healthcare organizations and healthcare professionals will also find these results useful. Healthcare is the usual starting point in the progressive journey individuals with rare disorders travel. Aligning and providing healthcare organization and professionals that may in the future be involved in daily care giving of LIS or CLIS patients with information puts them in a better position to serve as a link between research and

potential patients who can benefit from the technology. This also benefits research in expanding the base from which participants can be drawn.

Metrics coming from a centralized database if established and criteria from existing research would supplement the information needed by researchers to explore user-centered design strategies that would include caregivers and incorporating evolving technologies. During the interviews, all the participants discussed patients and many discussed caregivers or evolving technologies, as related to considerations they as a researcher had for user-centered design. Acknowledgment of the significance of these design strategies is present, and progress is being made in moving in that direction. Fundamentally, clinical BCI device development is immature and still developing with a needed focus on the technology. Identifying the significance of meeting patient-centered outcomes at this stage in the research ensures that the patient's experience is equitable with a successful technology outcome.

Implications for Social Change

My original perspective regarding social change focused on employing user-centered design that would support meeting patient-centered outcomes, reduce the likelihood of abandonment or disuse, and improve the quality of life for individuals needing to use clinical BCI devices. My fundamental perspective being that user-centered design strategies employed by computer scientists were pivotal in meeting patient-centered outcomes. I now have confidence that there is a broader group that includes researchers, technical and medical experts, and those engaged as caregivers for

individuals who are likely to benefit from the research, findings, and recommendations regarding user-centered design for clinical BCI devices.

Integrating user-centered design strategies for clinical BCI device development is perhaps best accomplished by the collective work of researchers, designers, developers, scientists, caregivers, and the individuals who will find a need for this type of assistive technology. Identifying patient-centered outcomes to be met as the basis for employing user-centered design strategies shifts the focus of design and development from impersonal to personal. Clinical BCI device users will benefit from the shift in proving if the technology is useful to proving if the technology is capable of improving quality of life. Greater acceptance and increased continual use of clinical BCI devices will bolster the efforts of collaborating teams, encourage design strategies that consider the user, and the likelihood of abandonment or disuse of the devices will be reduced.

As the focus of clinical BCI devices evolves, it offers the opportunity for the patient-centered outcomes to be a significant influencer in the design process. When BCI devices are designed to meet the expectations of an individual user in mind, it increases the possibility for the use of the device. There probably exists a belief regarding the scope of what clinical BCI devices are able to provide for individuals with ALS or other rare disorders due to the prominence of Stephen Hawking and the technology at his disposal. That belief might be best modified by considering Hawking as a model for assistive technologies and encouraging computer scientists to user-centered design strategies for individuals with rare disorders in much the same way computer scientists did to create the algorithms and the technologies used to create the assistive technology devices for

Hawking that supported his quality of life in being able to live and function as a renowned theoretical physicist.

Recommendations for Action

The computer scientists from the case organizations participating in this study although not always familiar with the term user-centered design understood what it referred to and how it was significant in practice. They were mixed with some considering it the essence of their work and others considering it to be more ancillary to the technical aspects, although that is not to say they considered it unimportant but just not a primary focus. The participants were also mixed concerning types of technology being engaged such as invasive and noninvasive. Given the scope of clinical BCI devices being explored for use as restorative assistive technologies for rare disorders and the potential of the devices, it is vital for case organizations to continue the work they are already engaged with.

Going beyond the case organizations to include other organizations conducting clinical BCI device research the creation of a collective database as a repository for technical, patient, and caregiver data is one recommendation for action. The database should be protected and require credentials for accessing some data, but also provide open access for some content. Healthcare professionals aware of such a database could direct patients there allowing them to gain information about their condition, daily life, expectations, and possible research studies to participate in or other resources. Efforts to create a BCI database and BCI society were addressed in the BNCI Horizon 2020 report

(Brunner et al., 2015). Visiting the BNCI Horizon 2020 website the framework is there, what is needed is participation by all involved with BCI research.

Recommendations for Further Study

My recommendations for further research stem from information I gained from conducting the interviews, from the literature, and from the limitations associated with this research. Conducting a qualitative study there is a potential for bias and preconceived thinking because it is subjective in nature and therefore may result in research limitations. My first recommendation is to conduct additional qualitative studies with other case organizations to compare and contrast results for a larger number of cases. To address the limitation related to the generalizability of the qualitative study results, I recommend conducting a quantitative study to better determine the generalizability of the results.

This research focused on computer scientists as unique in the team of experts developing clinical BCI assistive technology devices. I would recommend conducting the same research with other expert groups in the development team to learn how user-centered design strategies play a role in their processes. I believe there is a role for patients and caregivers of patients with rare disorders to participate in the design process, which might be best uncovered by conducting research as well.

During several of the interviews, the gap between what researchers wanted to determine and what patients or their caregivers might want was highlighted. What was also highlighted was that this was necessarily intentional but necessary due to the nature of the research. Framed by what one participant shared regarding how research teams are comprised of experts in their domains, but they are not experts in what the daily life of a

patient with ALS is, I would recommend a study to investigate ways of bridging that gap, so researchers, patients, and caregivers are coalesced in finding ways to meet expected patient-centered outcomes.

Reflections

As an IT professional working as a network administrator or implementing educational resources my perspective has always been that the purpose of technology should be to improve the quality of life for the individual whether for professional or personal use. I was familiar with TAM and other technology user related theories from supporting users in professional organizations where technology use was required not optional. I also have had the gratifying experience of providing educational resources in remote areas of Africa and watching teachers, staff, and students experience offline Internet resources such as Great Books of the World for the first time. Conducting interviews for this study and listening to researchers so dedicated to their work was a humbling event. After being meticulous not to be biased in framing the interview questions I had to redouble my efforts not to be biased in analyzing my collected data. I stand by my conviction that user-centered design is necessary to meet patient-centered outcomes, but now also recognize this is not singularly the work of computer scientists or the team of research experts. It is work that involves individuals with rare disorders and their caregivers partnering with the research team that includes computer scientists. It is a design process built on communication between all individuals and a better understanding of intrinsic and extrinsic motivations for designing, building, and using clinical BCI devices.

Summary and Study Conclusions

Designing clinical BCI devices requires advanced technology and is a complex process. The initial design is often based on the requirements for a rare disorder, such as spellers for patients with ALS to use for communication. From there design elements focus on ergonomics such as invasive or noninvasive, wet or dry electrodes, and then signal processing comprised of signal acquisition, signal translation and classification, and effector devices. The success of the design is measured by whether it can be used effectively as in the case a patient with CLIS imposed by ALS. To the researcher, success is determined by the technology working, but for the patient success means did it satisfy their intrinsic motivation for using the device. The success of the technology is not the objective of the patient; the objective of the patient is communicating as an individual to express their thoughts in perhaps the only way available to them. Computer scientists employing user-centered design go beyond developing effective technology, recognizing the technology will be abandoned if it does not satisfy the user, and work with the patient as a partner in creating devices to improve their quality of life.

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Appendix A: Interview Protocol and Questions

Study Topic: User-centered design strategies used by computer scientists for

clinical BCI assistive technology devices to meet patient centered outcomes.

Sources of data collection:

____Interviews (face to face of web based)   ____Organization Records

____Multimedia Data   ____Documents

Interview Protocol

Date and Time		
Location		
Participant ID		
Preparation	Technology check and recording reminder for participant.	
Introduction	Thank participant for meeting and provide my information.	
Purpose	Review purpose of the study: To explore user-centered design strategies used by computer scientists for clinical BCI assistive technology devices to meet patient centered outcomes.	
Participation	Participation in the study, both in interview responses and with any documentation or other sources shared with me, will support my study in partial fulfillment of the degree of Doctor of Information Technology from Walden University. The information gathered during the study might add to academic and professional bodies of knowledge regarding design strategies for clinical BCI assistive technology devices. There is no compensation of any sort associated with participation.	
Discuss Ethics	To maintain ethical standards and respect right to privacy, request permission to record the audio and video of this conversation and keep notes on this entire session. Once audio and video recording start introduce session using Participant (ID) and reconfirm permission to record and take notes on session. Confirm starting to record audio and video.	
Start Recording	Check devices.	
Begin Conversation	State my name, Participant (ID) and date.	

	Have Participant (ID) confirm being provided with background information on this study including the purpose, reason for participation, benefits of participation, and approval for recording and taking notes during this session.
Review Confidentiality	Remind each participant: ~ Free to decline to answer any question or stop participating at any time; this is a completely voluntary session. ~ Free to decline to answer any individual questions or decline to provide any information are not comfortable providing. ~ All information provide will be treated as strictly confidential and will not be disclosed to anyone, including employer. ~ Request avoid using organizational or individual names or any indicators that could be used to identify organization(s) or individual(s) in responses. ~ Names or comments that are mentioned in the interview will be removed from the transcripts and will not be included in the final report. ~ Request not discussing participation with anyone until the study concludes. ~ Any information provided in any form in the session will only be used for the purpose of this study, which will be presented in composite form with data from other participants in a doctoral study that may be published. ~ No responses will be presented in individual form. ~ Research records will be kept in an encrypted and password-protected format, locked in a safe for five years, after which time they will be destroyed. ~ Only I will have access to this data during that five-year period.
Confirmation	Ask if any questions before continuing.
Interview	Semistructured interview about understanding participant(s) thoughts on the topic and questions. Questions outlined for which open and honest thoughts are appreciated. May ask for more thoughts or explanations on portions of your responses. Providing as much information on thoughts and perspective is greatly appreciated.
Semi-structured Interview Questions	~ Current role and how long in similar roles? ~ Worked in any other roles over during career in the design of clinical BCI assistive technology devices?

Structured Interview Questions	~ What user-centered design strategies have you used for clinical BCI assistive technology devices? ~ What strategies have worked well for the incorporation user-centered design? ~ What, if any, challenges have you encountered regarding user-centered design? ~ How do strategies you use touch on user-centered design? ~ What aspects of used-centered design do you consider related to meeting patient centered outcomes? ~ What additional information regarding clinical BCI device design strategies would you like to share?
Possible Follow-Up Questions	~ What dictates or determines a user-centered design strategy? ~ What do you believe constitutes ensuring patient centered outcomes are met? ~ What if your initial strategies fail? ~ What alternate strategies might you employ? ~ How long did you work in a *previous role* as mentioned?
Collect Secondary Data	Conclude the interview portion of the meeting. Request any documents, multimedia presentations, or other information participant has agreed to provide.
Conclusion	Thank participant and to ensure interpreted responses are accurate discuss scheduling a follow-up interview and preferred method of communication for rescheduling? Thank participant again.