Capturing Muscular Dystrophy Patient Outcomes in the Electronic Health Record

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Capturing Muscular Dystrophy Patient Outcomes in the Electronic Health Record

Systems Change Project
Submitted in Partial Fulfillment
of the Requirements for the Degree of
Doctor of Nursing Practice

St. Catherine University
St. Paul, MN

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May, 2015
ST. CATHERINE UNIVERSITY
ST. PAUL, MINNESOTA

This is to certify that I have examined this
Doctor of Nursing Practice systems change project
written by

Kim Berlene Marben

and have found that it is complete and satisfactory in all respects,
and that any and all revisions required by
the final examining committee have been made.

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DEPARTMENT OF NURSING
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Thank you to each of my classmates in Cohort 6. We have journeyed together, experienced loss, and strive for a better world.
Dedication

Thank you to my parents, Robert and Betty Havens. You’ve been a role model for me, not just in the way you raised me, but in the way you live your own life. I’ve learned so much from you. Like what it means to be truly giving and caring, how important it is to be fair, how to believe in myself and in my ideals.

To my children, Courtney and Sean, I could not be more proud of the adults you have become. You have supported me along my academic journey and have been my rock. Thanks for your supporting my dream.
Executive Summary

In healthcare, creating value by improving quality while containing cost continues to challenge patients, providers, payers, politicians, and the public. Embedding clinical practice guidelines into the electronic health record has been suggested to standardize best practice and improve patient satisfaction and outcomes. Limited published studies have demonstrated whether clinical practice guidelines embedded into the EHR improve outcomes for persons with muscular dystrophy. Sixty muscular dystrophy patients participated in this quantitative study by completing three psychosocial patient-reported outcome measure surveys exploring quality of life, patient activation, and depression risk screening. This research explored the feasibility of collecting this patient data during routine scheduled clinic appointments. Participant’s responded to three process evaluation questions; length of time, relative ease to complete, and location when completed. Data analysis using SPSS summarized demographics; survey scores, and correlations between time, ease, and location. Collection of patient-reported outcomes data was found to take approximately ten minutes, relatively easy to complete, and survey scores were available to the healthcare team at the time of the neuromuscular specialty clinic visit. The electronic health record was modified to accommodate data entry and retrievability. While this study successfully demonstrated initial exploration of capturing psychosocial outcomes within the electronic health record, additional health related measures selected from the muscular dystrophy clinical practice guidelines still need to be implemented.
**Table of Contents**

Title Page........................................................................................................................................... 1
Copyright Page........................................................................................................................................ 3
Acknowledgments............................................................................................................................... 4
Dedication............................................................................................................................................... 5
Executive Summary............................................................................................................................ 6
Table of Contents............................................................................................................................... 7
List of Tables......................................................................................................................................... 10
List of Figures....................................................................................................................................... 11
Chapter 1............................................................................................................................................... 12
  Background and Significance........................................................................................................... 13
  Situations and Opportunities Leading to this Systems Change Project........................................ 16
  Congruence to the Organizations’ Strategic Plan......................................................................... 17
  Systems Change and Social Justice............................................................................................... 18
  Research Purpose............................................................................................................................. 19
  Research Question............................................................................................................................ 19
Chapter 2............................................................................................................................................... 20
  Theoretical Framework.................................................................................................................... 20
  Theoretical Models Description....................................................................................................... 20
  Application of Theory into Practice............................................................................................... 23
  Review of the Literature.................................................................................................................. 23
  Outcome Measures, Lack of Data Integration into EHRs.............................................................. 24
  Understanding Technology and Outcomes..................................................................................... 26
<table>
<thead>
<tr>
<th>Chapter 3</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>36</td>
</tr>
<tr>
<td>Sampling Strategy</td>
<td>38</td>
</tr>
<tr>
<td>Ethical Considerations</td>
<td>39</td>
</tr>
<tr>
<td>Data Collection</td>
<td>41</td>
</tr>
<tr>
<td>Findings</td>
<td>44</td>
</tr>
<tr>
<td>Summary</td>
<td>44</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter 4</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td>45</td>
</tr>
<tr>
<td>Study Findings and Discussion of Feasibility</td>
<td>46</td>
</tr>
<tr>
<td>Process Evaluation by Subject’s</td>
<td>48</td>
</tr>
<tr>
<td>Team Member Program Evaluation</td>
<td>51</td>
</tr>
<tr>
<td>Correlation between Survey Questions</td>
<td>56</td>
</tr>
<tr>
<td>Summary</td>
<td>57</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter 5</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discussion of Findings, Recommendations, and Conclusions</td>
<td>59</td>
</tr>
<tr>
<td>Findings</td>
<td>59</td>
</tr>
<tr>
<td>Section</td>
<td>Page</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>Project Strengths and Limitations</td>
<td>61</td>
</tr>
<tr>
<td>Discussion Recommendations to the Neuromuscular Clinic</td>
<td>62</td>
</tr>
<tr>
<td>Project Dissemination</td>
<td>63</td>
</tr>
<tr>
<td>Evaluation Plan</td>
<td>65</td>
</tr>
<tr>
<td>Recommendations for Further Research</td>
<td>66</td>
</tr>
<tr>
<td>Role and Value of the DNP</td>
<td>67</td>
</tr>
<tr>
<td>Summary</td>
<td>62</td>
</tr>
<tr>
<td>References</td>
<td>68</td>
</tr>
<tr>
<td>Appendix</td>
<td>78</td>
</tr>
<tr>
<td>Logic Model</td>
<td>78</td>
</tr>
<tr>
<td>IRB Application Approval</td>
<td>79</td>
</tr>
<tr>
<td>Information Sheet for Research</td>
<td>80</td>
</tr>
<tr>
<td>Questionnaire</td>
<td>82</td>
</tr>
</tbody>
</table>
List of Tables

Table 1. Comparison Between Participant and Team Member Responses on Process Evaluation Question

Table 2. Patient Health Questionnaire (PHQ) Scores for Depression Risk
List of Figures

Figure 1. Participant Gender.................................................................................................................46

Figure 2. Length of Time (minutes) Reported to Complete PROM Surveys.....................48

Figure 3. Patient Reported Outcome Measures (PROM) Survey Completion Location……..49

Figure 4. Ease of Completing Patient Reported Outcome Measure (PROM) surveys.......51

Figure 5. Patient Activation Level by Gender..................................................................................54

Figure 6. WHOQOL-BREF Scores by Participants.................................................................55
Chapter 1

Patient information is critical to nurses as a partner in health care delivery and coordination. Having access to vast amounts of information at the point of care assures patient safety with the delivery of the right care, at the right time, and to the right individual (IOM, 2001). Clinical outcome measures guide practitioners in assessing and documenting essential data points, allowing optimal care delivery. When clinical outcome measures are not available at the point of care, particularly in the case of individuals with chronic conditions, services are jeopardized. Adequate outcome data allows team members to compare individual patient’s responses as well as population characteristics over time.

Targeting interventions known to improve care and minimize complications have the potential to influence the natural history of a disease. Muscular dystrophy (MD) is an example of a chronic disease whose progression can be slowed when diagnosis is made early and plans of care are coordinated. Generally, treatments are focused on the physical needs, over psychosocial needs (Bushby, et al., 2010; Wagner, Lechtzin, & Judge, 2007). Practice guidelines for the care of patients with MD are less likely to be practiced when they are not embedded in the electronic health record (EHR). Another problem is that health information entered into the EHR is difficult to access in a usable manner.

When a nurse care coordinator incorporates best practices, recommendations focus on physical needs while psychosocial concerns are too often ignored. Patients engaged in care-decisions are more likely to have higher quality of life and less likely to experience secondary conditions, such as depression (Deen, Lu, Rothstein, Santana, & Gold, 2011; National Institute of Mental Health, n.d.). The psychosocial indicators were the focus of this initial project.
Background and Significance

Coordination of clinical care is a crucial component in the management of chronic diseases, such as MD. Coordinated care is best provided in a multidisciplinary care setting in which the individual and family can access the expertise of an interdisciplinary team following clinical practice guidelines (Bushby et al., 2009). When clinical practice guidelines are systematically developed, practitioners and patients are assisted in making best practice recommendations and decisions about appropriate health care for specific conditions (DiCenso, Guyatt, & Ciliska, 2005; Spurney et al., 2014). Guidelines developed for the MD population, when embedded in the EHR, provide structure for coordination of care by making key pieces of information available in order to better meet the needs of these individuals.

Muscular dystrophy is a progressive degenerative disease affecting more than one million Americans (Muscular Dystrophy Association, 2012). Symptoms range from mild muscle weakness to complete paralysis. The age of onset varies from birth to adulthood. Depending on the type of MD, life expectancy aligns with the average population; or in the case of Duchenne Muscular Dystrophy, tragically, early adulthood. In addition to functional decline, secondary conditions add to the complexity of care. Individuals with a neuromuscular condition are more likely to also have a diagnosis of depression or other mental health issues (Bushby, et al., 2009).

Nationally severe depression affects 6.9% adults, 9.1% youth, and 2.7% children at the cost of $1,591/year for adults and $1,931/year for children (National Institute of Mental Health, n.d.). Prevalence of depression in patients with a disability is a staggering 25-44% (Hendriksen, Poysky, Schrans, Schouten, Aldenkamp, & Vles, 2009; McDermott et al., 2005; Pinto-Meza, Serrano-Blanco, Penarrubia, Blanco, & Haro, 2005). Patients living with a disability and a comorbidity of depression are at an economic disadvantage. For someone with a disability, s/he is
more likely not to work, work part-time, or earn about $16,000 less per year than someone without a disability (CDC, 2013; ICSI, 2013).

Many therapies and interventions have led to improvements in function, quality of life, health, and longevity for persons with MD (Bray, Bundy, Ryan, North, & Burns, 2011; Holloway, et al., 2008; McDonald, et al., 2013). Despite gains in MD care, deficits remain, especially in the area of care coordination and use of clinical guidelines. Recommendations reported in the literature guiding the trajectory of care for patients with MD were facilitated by the Centers for Disease Control and Prevention (CDC) (Bushby et al., 2009). The CDC funds the Muscular Dystrophy Surveillance Tracking and Research Network (MD STARnet). This is the only research program collecting population data on people with MD and is limited to only a few select states, not including Minnesota. Technology tools are still too underdeveloped to provide the infrastructure needed to support care coordination based on clinical guidelines and fully utilize the EHR for easy retrievability of outcome data.

Incorporating outcome data into the EHR creates the foundation for improving care coordination through data mining. Data mining is a term that describes the ability to extract large volumes of data from various sources for the purpose of discovering meaning and generating knowledge (Williams, 2011). Linking the EHR with clinical guidelines to inform providers about the outcomes of care for patients with MD takes a committed team. Organizations need to prioritize development of the EHR to accommodate these guidelines and the data for outcome measurement.

Historically, most organizations have defined patient outcomes using data gathered to meet regulatory requirements. Typically, patients are not regarded as a credible source of evidence and their perceptions are not collected. Failing to include the ‘patient’s voice’ when
assessing various aspects of care limits a holistic understanding of an organization’s service delivery. Patient-Reported Outcome Measures (PROM) are meant to address this issue and are used to improve the value of care by getting information directly from patients about their functional health and well-being (IHI, 2015; Velentgas, Dreyer, & Nourjah, 2013).

The use of PROM in the United States has lagged, compared to practice internationally. Knowing what is important to the patient, from the patient’s perspective, is integral to adherence with care recommendations. PROMs are growing as a measurement of performance change in response to the pressures to improve outcomes in both quality and cost (Velentgas, Dreyer, & Nourjah, 2013). Far from being just the latest health care fad, using PROMs help health care providers and, ultimately, patients make informed decisions and achieve a high-quality, high-value health system. Porter and Lee (2013) challenge the healthcare system to “[maximize] value for patients by achieving the best outcomes at the lowest costs” (p. 3). Organizations successfully implementing PROMs incorporate the patient voice into the clinical decision-making process.

To coordinate, collaborate, and deliver care management, the nurse care coordinator requires access to real time data. Lack of organized and consolidated information limits efficiencies and the effectiveness of case identification, case formulations, and the practice of care coordination (Bushby et al., 2009). When health data is not accessible or organized in a user-friendly view, safety issues, disparities or inconsistencies in care delivery result. Furthermore, repetitive tests and procedures add to the cost of health care, burdening the nation’s care delivery system. (Bakken, Cimino, & Hripesak, 2004; McGonigle, & Mastrian, 2009). Finally, in addition to all the consequences mentioned above, there are tremendous personal, social, psychological, financial, and professional costs endured by patients, families, providers,
and health care systems when health data is in silos and not readily accessible to the clinician for care decision support (Kohn, Corrigan, & Donaldson, 1999).

**Situations and Opportunities Leading to this Systems Change Project**

The organization where this systems change project (SCP) was conducted is a mid-western, predominately pediatric healthcare system providing specialty inpatient and outpatient care to individuals with childhood onset physical and cognitive disabilities. The population served includes children, teens, and adults. This organization includes a hospital and eight ambulatory clinics located throughout the state. Two of the ambulatory clinics offer coordinated specialty care to individuals with MD focusing on either pediatric or adult models of care.

Important to this SCP is the electronic health record (EHR) implemented, March 2012, requiring forms used in the paper record be translated to an electronic version. Despite the system and documentation templates intended to facilitate multidisciplinary care, this has not happened, and nurses are the primary users. In addition, the usefulness of the medical record has not been maximized and does not include clinical practice guidelines necessary for goal planning, standardization of the data to be collected for reporting, and rarely display trended points across time. Volumes of data are collected and entered into the EHR but are often difficult to retrieve. With a nurse coordinator leading the data collection, organizing data in a retrievable way is critical to provider access and data supported decision making.

Within the neuromuscular clinic and organization utilized for this project, limitations and deficiencies existed in the usability of health data for patient care delivery. The question, “How can health data be used to support care coordinator clinical decision-making and ultimately improve patient outcomes?” remains unanswered. Implementing technology tools for capturing patient-focused information is in early development. Many clinic team members wonder whether
a framework could be developed that would allow better use of patient reported measures with
the ultimate goal of improving health outcomes.

**Congruence to the Organizations’ Strategic Plan**

The organization where this SCP was conducted was committed to the implementation of
outcome measurement and data reporting. The 2014 action plans supported pilot project
proposals within specialty clinics. In order to gather the PROM data, the workflow needed to be
developed for collecting PROM data, creating standardization for entry into the EHR, and
capturing data to generate reports. There was commitment for data mining to measure patient
outcomes, in particular for PROM.

This systems change project (SCP) focused on the collections of PROM that supports the
mission and organizational priorities at this specialty healthcare organization. Access to
coordinated specialty care for persons with a progressive neuromuscular disease aligns with the
Triple Aim of the Accountable Care Act; improving patient experience, cost of care, and quality.
Finding solutions to improve the patient experience and contain costs are expected (IOM, 2013).
The mission of this specialty care organization is to help improve patient’s health, achieve
greater well-being, and enjoy life.

This SCP was implemented as a result of a need identified within the informatics
initiative supported in the organization’s 2014 Annual Plan. Specifically, the lack of practice
guidelines within the EHR, inconsistent practice, and loosely defined outcome measures are
areas for improvement. Organizationally there are steps that needed to be followed for approval
from all interested parties. These included the following stakeholder’s involvement:

1. Neuromuscular multidisciplinary team

2. Outpatient nursing informatics team
3. Outpatient managers

4. Informatics multidisciplinary Steering committee

The steps for project implementation followed the organizations’ policies and procedures outlined for all informatics projects. A clearly prepared statement of the project along with project goals and outcomes was developed. This project was approved as an organizational priority. Projects are approved if there is patient safety, outcomes, or financial benefit. Good communication was critical with the key stakeholders and decision-makers throughout this project.

**Systems Change and Social Justice**

Aligning care with social justice can offer efficient, outcome-oriented and cost-effective care to vulnerable, high-risk patients whose ability to seek care is complex. Adherence to treatment recommendations is complicated by a progressive neuromuscular condition. Poverty and social, psychological and political factors are compromised by market concerns. There is often tension between market justice and social justice. Market justice focuses on self-interest and personal effort. Social justice focuses on shared responsibility. Approaches to manage these opposing factors require a balancing act. According to Donley (2010), “attention to the mission of health care, rather than its margin, will be one outcome,” (p. 37) to support social justice in program planning.

This SCP applies social justice principles by removing barriers that keep people vulnerable, and by gathering valuable information to understand a patient’s ability to manage care while advancing well-being. Engaging patient’s in development of the care plan is a step closer towards improving individual and ultimately population health (Donley, 2010). The United States Conference of Catholic Bishops (2009) states, “In particular, the person with
mental or physical disabilities, regardless of the cause or severity, must be treated as a unique person of incomparable worth, with the same right to life and to adequate health care as all other persons.” (p. 11-12). Complex care coordination including the patient’s voice is an effective strategy to improve benefits of care.

Research Purpose

The purpose of this SCP was to establish a process to collect patient reported outcome measures for entry into the EHR and determine feasibility of data retrieval for outcome data reporting. Limited reporting on this topic has been published and this project has the potential to address a number of unmet needs. At the conclusion of this project, the following objectives will be met:

- Collaborate with the neuromuscular team to identify the psychosocial patient outcomes measures collected during annual clinic visits,
- Establish the process for collecting these patient surveys,
- Create the process for entering the data into the EHR,
- Retrieve PROM data from the EHR for reporting.

This project focuses on exploring and testing a process for collecting specific psychosocial aspects of health information from patients that is intended to be incorporated into the electronic health record and will be available for report generation.

Research Question

The following research question guided the plan of study, “What is the feasibility of implementing and evaluating a process for systematically assessing psychosocial outcomes for patients with muscular dystrophy and then integrating them into the electronic health record for report retrieval?”
Chapter 2

This chapter presents the theoretical framework guiding this systems change project (SCP) and outlines a review of literature, which includes research exploring outcome measures as a component of nurse coordinated care guidelines. Care coordination, technology, and outcome measures are described, as well as the benefit and challenges of the electronic health record (EHR) for data retrieval and outcome reporting. Finally, the rationale for the value and timeliness of this SCP is made evident in the project plan and return-on-investment calculations.

Theoretical Framework

A thorough review of nursing and social science literature describing theoretical models or frameworks was conducted as the foundation for integration of multidisciplinary, evidence-based MD clinical guidelines and outcome measurement into the EHR. Evidence-based care guidelines have been identified to improve patient safety, effectiveness, efficiency, and cost of care. With the integration of guidelines embedded into an electronic health record, multidisciplinary care has the potential to standardize practice and improve communication in the team. The ability to demonstrate these improvements is dependent on access to meaningful data. The Theory of Goal Attainment and Diffusion of Innovations were identified as theoretical frameworks supporting this work. The aim of this review was to describe these theories in terms of the underpinnings of nursing knowledge, ways of knowing, practice application, and applicability to the integration of evidence-based guidelines through data gathering into practice.

Theoretical Models Description

The Theory of Goal Attainment was developed from the work of Imogene King. King acknowledged “the problems and prospect of knowledge development in nursing” (Parker & Smith, 2010, p. 148) within her framework and theory. The problems identified were the lack of
a professional nursing language, theoretical nursing phenomena, and limited concept
development (Parker & Smith, 2010). King considered concept development as a continuous
process guiding the development of the interacting systems framework.

The interacting systems framework was used to develop King’s *Theory of Goal
Attainment*. The personal, interpersonal, and social systems interact resulting in a transaction
occurring to address nursing as a process of human interaction (Masters, 2012). The framework
focuses on whole rather than isolated parts. King defines four major metaparadigm concepts that
include person, environment, health, and nursing. These describe nursing as a process of human
interaction between nurse and client as communication to set goals, explore action, and use data
for evaluation.

The model of *Diffusion of Innovations* has transformed the way human beings
communicate and adopt new ideas. Everett Rogers work originated in agriculture and was
derived from his education in sociology and statistics. Roger’s research and work became widely
accepted in communication and technology. Rogers related his communications research to
practical health problems, including hygiene, family planning, cancer prevention, and substance
abuse (Rogers, 2002). Critical to the success of integrating new ideas into practice is introducing
a ‘change agent’ to establish relationships with stakeholders (White, 2011).

Four main elements influence the spread of a new idea: the innovation, communication
channels, time, and a social system. These elements work in conjunction with one another.
Diffusion is the process by which an innovation is communicated over time among the members
of a social system with process central to the theory (Rogers, 2003). Wright, Gagliardi, Fraser, &
Quan (2011) successfully evaluated an evidence-based model to apply *Diffusion of Innovations*
in health service organizations for standardizing surgical interventions.
Rogers created a model to demonstrate that adopters of any new innovation or idea can be categorized as innovators (2.5%), early adopters (13.5%), early majority (34%), late majority (34%) and laggards (16%), based on the mathematically based bell-shaped curve. These categories provide a common language for innovation researchers (Rogers, 2002). Each adopter's willingness and ability to adopt an innovation depends on their awareness, interest, evaluation, trial, and adoption. (Rogers, 2002; Rogers, 2003)

Diffusion of an innovation occurs through a five-step decision-making process, through communication over a period of time among a team. The stages are knowledge or awareness, implementation; and confirmation or adoption by the individual, organization, or larger social systems. Throughout the diffusion process not all individuals exert an equal amount of influence over all individuals. Opinion leaders are influential in spreading, either positive or negative, information about an innovation and have the most influence during the evaluation stage of the innovation-decision process and with late adopters (Rogers, 2003).

These two theories were clear, complex and consistent; interconnected models, and applicable to nursing; as well as business, technology, and health care. Both theories are complex with many interrelated concepts and components. The Theory of Goal Attainment was found to guide nurse and patient communication; support standardize language for informatics integration; focus on individual, community, and global concerns for health; and supported the nurse as the care coordinator. The Diffusion of Innovations model guides the diffusion of new ideas for individuals and society. The change agent is critical as the champion that could be filled by the advanced practice nurse; applicable to the health care team or the individual patient’s adoption to goal attainment; and consistent with the integration of informatics into health care.
Research, peer reviewed articles, and books published by these theorists were applied into practice and very accessible. Many articles and books have been written to refine these concepts and demonstrate their strength (Masters, 2012; Parker & Smith, 2010; White, 2011). Finally, both theories were found to be clinically significant, practical, and applicable.

**Application of Theory into Practice**

The application of the *Theory of Goal Attainment* and the model for *Diffusion of Innovations* to embedding patient-centered outcome data in the EHR will contribute to a successful nurse-led project. Awareness of a team member’s level of adoption is an important consideration throughout this project. The nurse leader, as change agent, is responsive to both positive strides and unforeseen barriers to project implementation. The leader keeps the team focused on the outcome of successful systems integration.

Major concepts in King’s *Theory of Goal Attainment* and Roger’s *Diffusion of Innovations* model promote connecting health issues between individuals, health care communities, and society. Integrating outcome data, as building blocks, recommended from evidence-based clinical guideline into the EHR supports communication between the healthcare team and the patient (Masters, 2012). These theories were found to meet the criteria for well-developed concepts, terminology, consistency, and applicability within EHR development and therefore, support this SCP to integrate patient-reported outcome measures into the EHR (Chinn & Kramer, 2011).

**Review of the Literature**

A literature search was undertaken to support the integration of outcome data from evidence-based clinical guidelines into the EHR. CINAHL, PubMed, and Medline databases of original, peer-reviewed studies, practice guidelines, and meta-analyses from 2008-2014 were
searched. Key search terms used were evidence-based practice guidelines, effectiveness of practice guidelines, patient goals setting, and outcomes measures.

After an exhaustive search, limited books, journal publications, reference lists, and systematic review were identified as appropriate to support this project. Several published qualitative and quantitative studies were discovered to support clinical guidelines embedded in an EHR’s improves chronic conditions (Caldwell, Katz, & Pascarella, 2011; Pantoja, & Britton, 2011) such as diabetes (Albu, et al., 2013; Crosson, Ohman-Strickland, Cohen, Clark, & Crabtree, 2012); heart failure (Dykes et al., 2005); gastro-esophageal reflux disease (Player et al., 2010); obesity (Savinon, Taylor, Canty-Mitchell, & Blood-Siegfried, 2012); and hypertension (Shelley et al., 2011). However, no studies linking embedded clinical guidelines to improved outcomes have been published for persons living with MD at this time. More specifically, there were no published studies on psychosocial outcomes for patients living with MD.

The following is a review of related topics for integration of outcomes measures into the EHR to answer the research question. Selection of outcome measures is an initial first step when implementing clinical practice guidelines. Once outcome measures are determined, then decisions must be made about how to collect, access, and utilize them. Tools in the EHR, such as clinical alerts, assist the nurse care coordinator to gather consistent, reliable data that improves reporting capabilities. How these tools improve care is still being investigated.

**Outcome Measures, Lack of Data Integration into EHRs**

The *Outcome Measures Hierarchy* is a framework for identifying and categorizing population outcome measures. The outcomes for any medical condition can be organized in a three-tiered hierarchy. Collection of multiple outcome data representing each of these tiers for any specialty population is defined as a success (Porter, 2011). Selection of outcomes
measurement data according to these tiers has been used to prioritize recommendations from clinical practice guidelines according to this framework. The following is a description of each of the three tiers used to select outcome data.

Survival and degree of health or recovery achieved is the focus of Tier 1. The health status of patients achieved or retained focuses on survival as the overriding outcome of importance to be measured, over various time periods and conditions. In patients with a life limiting condition, such as Duchenne muscular dystrophy, maximizing the duration of survival may not be the most important outcome, especially when comparing quality of life at the expense of medically intensive interventions. “Achieving high value for patients must become the overarching goal of health care delivery, with value defined as the health outcomes achieved per dollar spent” (Porter, 2011, p. 1). The degrees of health or recovery achieved or retained at the peak or steady state, which normally includes dimensions such as freedom from disease and relevant aspects of functional status. Patient reported outcome surveys using quality of life questionnaires is an example of data collected in this Tier.

Outcome measures related to the recovery process or complications are data collected in Tier 2. The recovery process and time to return to normal activities are quantified. According to Porter (2011), disutility of care or treatment process in terms of discomfort, retreatment, short-term complications, and errors, along with secondary consequences are barriers to recovery. Side effects to medications, unplanned hospitalizations, or readmission following discharge are examples of Tier 2 data collected.

Sustainability of health is the outcomes measured in Tier 3. Quantifying recurrence of the original disease or longer-term complications are measured. Additionally, this measurement includes capturing new health problems created by consequences of treatment or secondary
conditions (Porter, 2011). The screening for depression risk is an example of a patient reported
outcome in this Tier. “The failure to prioritize value improvement in health care delivered and to
measure value has slowed innovation, led to ill-advised cost containment, and encouraged
micromanagement of physicians’ practices, which imposes substantial costs of its own” (Porter,
2011, p. 5).

Rigorous, disciplined measurement and improvement of value is the best way to drive
system progress. Value should always be defined around the patient. In a well-functioning health
care system, value is measured by the outcomes achieved. Care for a medically complex
condition usually involves multiple specialties and numerous interventions. Failure to prioritize
improvement in health care delivery and value-based care has slowed innovation and misdirected
4).

**Understanding Technology and Outcomes**

Evidence-based guideline integration into the EHR is a practice in its infancy. Electronic
health records are still being implemented with the aim of achieving Meaningful Use
requirements. Meaningful Use was established as an incentive program for electronic health
record development by health care organizations and providers within the American Recovery
and Reinvestment Act of 2009. Meaningful Use is defined as a certified electronic health record
designed to improve quality, safety, efficiency, and reduce health disparities by engaging
patients and families through improved care coordination while maintaining privacy and security
of patient health information (Federal Advisory Committees, 2015). Healthcare organizations are
at various stages in the application of informatics to improve patient outcomes. This literature
review reflects inconsistencies for implementation of evidence-based guidelines within the EHR to improve patient outcomes (Caldwell, Katz, & Pascarella, 2011; Pantoja, & Britton, 2011).

A wide range of EHR implementation exists within clinical practice. Some organizations continue to rely on paper records, while others have fully integrated multiple aspects of the electronic record. Various stages of EHR implementation were discovered in this literature review. Studies compared practice groups using paper or electronic records (Crosson, Ohman-Strickland, Cohen, Clark, & Crabtree, 2012; Player et al., 2010; Savinon, Taylor, Canty-Mitchell, & Blood-Siegfried, 2012). Other studies demonstrated how the EHR has been used for gathering outcome data (Cherry, Ford, & Peterson, 2011; Parente, & McCullough, 2009). Additionally, studies described EHRs before and after implementation of clinical decision support (Dykes et al., 2005; Shelley et al., 2011). Each of these studies provided a picture of the inconsistencies and various stages of implementation to reveal a realistic picture of healthcare organization EHR adoption across the country.

**Comparison of Outcomes in Paper and Electronic Records**

Studies comparing improved patient outcomes between paper and electronic records report inconsistencies. In a study conducted by Player et al. (2010) improvements diagnosing gastro-esophageal reflux disease (GERD), medication intervention, and identification of atypical symptoms using the EHR in a randomized control trial compared with paper record were significant (p< .01) but not for treatment intervention (p=.32). Prompts in the EHR had a positive effect for establishing a diagnosis and prescribing medication. There were variations from the recommended guidelines for medications prescribed for GERD. This study supports the EHR as preferable to a paper record but limitations for following guidelines existed.
Savinon, Taylor, Canty-Mitchell, and Blood-Siegfried (2012) demonstrated improved adherence to childhood overweight and obesity guidelines following EHR customization compared with paper record. These researchers reported descriptive statistics in terms of frequency and percent of difference between EHR and paper but did not perform statistical significance. They suggested improvements for recognition and diagnosis for improving interventions and outcomes of childhood obesity. This conclusion is difficult to confirm without statistical tests reported.

In contrast Crosson, Ohman-Strickland, Cohen, Clark, and Crabtree (2012) reported paper records over the EHR improved evidence-base diabetes care significant (p=.01) when comparing outcomes of chronic care. These researchers compared practice groups that had not implemented an EHR with those that had. Limitations of this study were the comparison of practices within a single group by comparing early adopter implementers. None of these studies were longitudinal so it would be difficult to determine sustainability in practice.

**Comparison of EHR Benefits and Challenges**

Improving the quality of care and outcomes is an important benefit for implementation of an EHR. Two studies explored benefits and challenges of EHRs. Parente and McCullough (2009) compared quality indicators for infection and postoperative pulmonary emboli outcomes comparing electronic record with nursing notes and imaging reports. Statistical significance was not reported for the effect of the EHR on patient safety. While this was a large Medicare patient population study over four years, the significance level was not specifically reported and is a concerning limitation.

A qualitative study describing the experiences of staff, residents, and family in a long-term care facility identified quality, documentation, access, and financial themes (Cherry, Ford,
& Peterson, 2011). The researchers reported improved documentation and accessible information by staff. Families did not agree with staff on engagement with the patient, reporting the electronic record as a barrier to the relationship. Other inconclusive findings were improved quality and financial return-on-investment for an EHR. Rigor was established within the qualitative analysis of the interviews. Overall the information suggested more positive responses than disadvantages. Even with limitations in these two studies support for improved care with an EHR is evident.

**Decision Alerts in EHRs to Outcomes**

Standardization of EHRs varies among healthcare organizations. Advanced EHRs include decision reminders and alerts for critical clinical information to parallel evidence based guidelines. Two studies compared EHRs before and after implementation of these alert reminders (Dykes et al., 2005; Shelley et al., 2011). Dykes et al. (2005) found that clinician adherence to heart failure but not stroke guidelines for EHR automated pathways was significant for self-management (p=.000) and education (p=.000); but medical intervention was not significant. These researchers suspected problems with the stroke patient findings were a nonequivalent control group made up of pre-intervention and untreated post-intervention patients.

A longitudinal study compared the impact of the EHR with and without alerts for adherence to hypertension guidelines (Shelley et al., 2011). All measures were significant for blood pressure (p=.05) and process measures (p=.01). In these two studies EHRs with alert reminders were found to improve patient outcomes with embedded clinical guidelines.
Synthesis

There is supportive evidence in this review of the literature for the benefits of EHRs with embedded clinical guidelines to improve patient outcomes, but overall the findings are inconclusive. It is possible that chronic conditions are better managed with support of an EHR with guideline alert reminders (Dykes et al., 2005; Shelley et al., 2011). In these studies hypertension and heart failure self-management were in better control with improved outcomes. Other positive results were EHR embedded improved documentation and information access (Cherry, Ford, & Peterson, 2011), implementation of infection and postoperative pulmonary emboli quality indicators (Parente & McCullough, 2009), guidelines for diagnosis and identification for atypical symptoms for gastro-esophageal reflux disease (Player et al., 2010), and improved screening and identification of childhood obesity (Savinon, Taylor, Canty-Mitchell, & Blood-Siegfried, 2012). Alternatively when comparing paper and EHR records it is difficult to determine if organizations early in transition (Crosson, Ohman-Strickland, Cohen, Clark, & Crabtree, 2012) are less experienced so have not yet experienced benefits of EHR embedded guidelines for improving outcomes (Players et al., 2010).

Clinical guidelines embedded within the EHR have been shown to improve health outcomes for persons living with chronic illness. With organizations at various stages of EHR implementation and development there is reason to believe pursuing improved patient outcomes within an EHR has merit. An exhaustive literature search did not find any studies implementing the MD clinical guidelines within the EHR. Muscular dystrophy care guidelines embedded into an EHR could support the nurse coordinator in communication with the patient and care team for planning patient-focused goals and improve outcomes. Additional studies will be needed to test
an EHR framework with clinical guidelines to improve multidisciplinary access to patient health information and as a means for data mining to examine and improve patient outcomes.

Overall the findings of a systematic review by Holroyd-Leduc, Lorenzetti, Straus, Sykes, and Quan (2011) were relatively weak and observational. The authors also acknowledge limitations in the systematic review by including published articles in English, inconsistent terminology between types of clinical practices and geographical locations. A robust review of the literature was evident in the studies included; excluding important studies is low. Overall the findings from this systematic review are that the EHR has structural and process benefits. On the other hand, the impact on clinical outcomes is less clear. Holroyd-Leduc, Lorenzetti, Straus, Sykes, and Quan (2011) recognized the need for more rigorous research to evaluate the impact of the EHR on patient outcomes and recommend further studies using randomized control trials.

A critical review of the literature revealed support for the EHR as tools to assist healthcare providers implement clinical guidelines. By combining the scientific analysis of current studies along with the Holroyd-Leduc et al. (2011) systematic review, gaps in knowledge are identified. An exhaustive literature search did not find any studies implementing the MD clinical guidelines or collecting MD outcome measures within the EHR.

Little has been reported in the literature about clinical outcome measures for patients with MD. Even less has been reported about integrating MD clinical guidelines and outcome measures into the EHR. Selection of the outcome measures using a model such as, Porter’s *Outcome Measures Hierarchy* as a framework for identifying and categorizing population outcome measures has broad implications for stratifying and prioritizing data relevance.

Application of the MD care guidelines into practice with retrieval of outcome measure from the EHR needs to be shared with multidisciplinary clinics caring for patients with MD to
experience the benefits. A project to integrate evidence based guidelines for patients with MD into practice and create the process for collecting outcome measures within the EHR is needed. From this review of the literature, support for a project to demonstrate improved patient care, quality, and outcomes by integrating MD care guidelines within the EHR exists.

**Project Plan**

Development of a logic model provided an organizing framework for this SCP (Appendix A). Articulating the problem statement based on assumptions and influencing factors guided goal development. Planning this SCP around considerations for resources, activities, outputs, and project outcomes were used for creating a realistic timeline. Fortunately the systems were in place to progress, meeting all deadlines.

The site mentor was committed to the success of this SCP and communicated support to the clinic team and organization’s leadership. This site mentor was also the clinic manager of the research site and nurse leader collaborating with the outpatient informatics team. She was supportive, accessible, and provided timely feedback with regularly scheduled progress meetings. An initial challenge was with IRB approval for student research through two different organizational entities. Once the site mentor facilitated the submission of a letter of support to the IRB, the project was approved.

Specific to this SCP the site mentor agreed to inclusion of clinic patients for enrollment into the study during scheduled clinic visits. She provided the physical space and time necessary to consent patients and completion of the PROM surveys and evaluation questions. Minimal resources were associated with this SCP. Costs underwritten by the organization to complete this study included staff time (administrative, nursing, and support), salaries, paper, and copying/printing costs. Additional costs incurred in this SCP were the hours required for the
an analyst to custom build the framework to format data entry within the EHR and the methodology used for data reporting. As an organizational goal, this time was planned within the information systems department budget.

**Return-on-Investment (ROI)**

Costs associated with a SCP are viewed in terms of the return-on-investment (ROI), considering direct and indirect cost along with the perceived benefits. The economic impact of providing coordinated care to collect PROM data within the EHR in terms of quality and value are unknown. This SCP attempts to quantify the ROI. While the costs of this project are minimal, the potential for patient benefits are great.

Health care delivery and payment are shifting toward models focused on providing greater value to guide the work for more complex and focused health care organizations (Combes, 2014). As health care providers and insurers increasingly assume risk for clinical care delivery tied to financial success, the focus will be on providing care that optimizes outcomes and efficiency. This SCP could lead to positive results by improving the patient experience, outcomes, and overall health of a segmented population while reducing per capita cost.

Patients living with a disability and a co-morbidity of depression are at an economic disadvantage. Someone with a disability is more likely not to work, work part-time, and earn about $16,000 less per year that someone without a disability (CDC, 2013; ICSI, 2012). Planning a program to identify patients at risk for depression seen in a neuromuscular clinic should include a cost benefit analysis for determining the financial burden and benefits of the program to the individual, organization, and society.

Any new project should be evaluated for feasibility and scalability in program planning. Organizational and stakeholder support is critical to success of a new project. This project was
deemed appropriate for implementation within this organization and has information technology support for integrating the results of psychosocial surveys into the EHR. The clinical team is vested in the success to shift from provider-directed care to an engaged, patient-centered and shared decision-making approach (Green, Perrin, Polen, Leo, Hibbard, & Tusler, 2009; Hibbard, Mahoney, Stock, & Tusler, 2007). The budget for staff time and information systems support has been approved.

Porter and Lee (2013) challenge health care leaders and policy makers to adjust the paradigm from a supply and demand focus to “maximizing value for patients by achieving the best outcomes at the lowest costs” (p. 3). Applying economic principles Schafermeyer (2000) states, “buyers exert a market force on prices by the amount of goods and services they demand and suppliers exert a market force based on their ability and willingness to supply products for consumption” (p. 44). This SCP applied economic principles to demonstrate value.

Patients find value when multi-specialty providers’ combined efforts to integrate the plan of care. Porter (2011) states, “The benefits of any one intervention for ultimate outcomes will depend on the effectiveness of other interventions throughout the care cycle” (p. 2). Care activities are interdependent and value for patients is often revealed only over time and is manifested in longer-term outcomes such as sustainable recovery, need for ongoing interventions, or occurrences of treatment-induced illnesses. When care focuses on maintaining function and maximizing independence are the goals, efforts to improve quality of life are the outcome. The only way to accurately measure value is to track patient outcomes and cost long-term. Measuring, reporting, and comparing outcomes are perhaps the most important steps toward rapidly improving outcomes and making good choices about managing costs.
This SCP was piloted within the MD clinic, with an organizational plan of implementing a sustainable process that can be modified for other patient populations and specialties. Implementation of psychosocial patient surveys to a targeted, single population was a pilot project within one clinic. This was deemed not be burdensome for the organization, as the survey scores have been integrated in the EHR and are available for all providers and other specialty clinics to use. The cost for expanding survey data collection is minimal since programming the EHR has been completed. Both feasibility and scalability for this SCP have been considered and organization support has been provided.
Chapter 3

A review of the study design and methodology used in this Systems Change Project is described below. Considerations for subject selection with inclusion and exclusion criteria, data collection, and protection of human subjects are discussed in terms of risks and benefits. Finally, the study process for guiding data analysis is summarized.

Method

The purpose of this project was to determine the feasibility of implementing and evaluating a process of gathering psychosocial data using three validated survey instruments and integrating this information into the EHR for MD patients, for use as population outcome measures. A standardized psychosocial outcomes data collection and reporting system using standardized, validated surveys was lacking. This project focused on piloting a process for collecting this clinic information from patients that was incorporated into the EHR and available for report generation.

This study was a quantitative research design including both descriptive and comparative methods for data analysis. Quantitative methodology was used to collect patient reported outcome measures by the care coordinator, as researcher. This data was scored and then entered into a database and the total score entered into the patients EHR. The process questions were entered into the study database only. A pilot study of 60 patients was used to demonstrate a successful implementation of the project. Initially, the study team anticipated equal representation by gender, although not an expectation of the study. In some types of muscular dystrophy, more males than females are affected.

Patients seen in a neuromuscular clinic were invited to complete a series of psychosocial survey instruments. The organization has all patients sign an annual Consent to Treat. One of the
questions asks about inclusion in research studies. If a patient indicates s/he is not interested in participation they are not approached about ongoing studies.

At clinic registration, patients scheduled in the neuromuscular clinic were introduced to the study and invited to participate by study personnel. Once they agree to participate, an IRB-approved *Information Sheet for Research* was provided. Following informed consent, patients were asked to complete three psychosocial survey instruments and three process evaluation questions on paper.

Data collected at enrollment from the medical record included age, gender, and neuromuscular diagnosis once completing the consent process. Study team members were available to support the completion of these surveys if the patient was unable to complete the surveys because of physical weakness. The survey instruments completed in this SCP included the Patient Health Questionnaire (PHQ) depression screen, World Health Organization Quality of Life (WHOQOL-BREF), and Patient Activation Measures (PAM). These surveys were selected by the neuromuscular team and had been implemented with other patient populations in the organization. Finally, subjects completed three process evaluation questions to answer the question of feasibility.

The survey instruments were scored and this data was entered into the study database. The total score along with the item responses were entered into the patient’s record as standard of care. As part of the consent process these patients knew the survey’s responses would become part of their medical record. The process questions were entered into the study database only.

The project team evaluated the program as the project progressed. The team members evaluated the pros and cons of the method used to completing the survey instruments, factors that
benefit or hinder the process of collecting data, revisions made to process during the project implementation, and ways the data potentially improves care.

**Sampling Strategy**

The study population was a convenience sample of patients with a diagnosis of muscular dystrophy presenting for care at a specialty healthcare organization in the neuromuscular clinic. The neuromuscular team sees approximately 400 patients annually in the clinic. It was anticipated that with about 60 patients enrolled in the study, the team would be able to answer this study question. It was estimated that gender would include equal numbers of male and female, 30 males and 30 females, although more males are diagnosed with gender specific neuromuscular conditions. Inclusion and exclusion criteria were used to screen patients that were invited to participate in this project.

**Inclusion:**

- Patients with a genetically confirmed neuromuscular diagnosis
- Age 18 and older

**Exclusion:**

- Patients that have declined to participate in research
- Patients who do not have a genetically confirmed neuromuscular diagnosis
- Patients younger than 18 years
- Patients were identified from the medical record with a neuromuscular condition using diagnosis codes. The nurse coordinator, as the researcher, reviewed patients scheduled for upcoming clinic appointments. The annual *Consent to Treat* form was reviewed for each potential patient and confirmed willingness to be approach about research opportunities. If the
patient met the inclusion criteria and was willing to be approached about research involvement s/he was added to the study list.

At the next scheduled appointment in the neuromuscular clinic, these patients were invited to participate in a research study involving a series of psychosocial survey instruments and process evaluation questions. If the patient agreed to study participation they were provided with a study-specific consent form. Study personnel were available for the consent process and to answer any questions posed by participants. Subjects were assured his or her participation in the study was completely voluntary, and that declining would not affect their relationship with clinicians and services rendered.

**Ethical Considerations**

The Institutional Review Board (IRB) for this research site and the student’s academic institution IRBs approved this study prior to enlisting subjects (Appendix B). Researchers involved with this study had completed human subjects training and understood the ethical elements essential to conducting research involving vulnerable populations. Confidentiality was maintained related to patient information and as described in the informed consent (Appendix C). Some of this data, collected as PROM, became part of the electronic health record as standard of care. Subjects were informed as part of the consenting process. Specifically, the total score from the PHQ, WHOQOL-BREF, and PAM became data as part of the electronic health record and were considered standard of care.

All patient information remained confidential in terms of the data collected for this study. Collection of this patient information was considered low risk and no harm or adverse events occurred. Data for this study was kept in a locked cabinet or electronically password protected accessible by only the researcher, study coordinators, and study staff.
The researcher maintained a database of study participants. Each subject was assigned a study identification number. A study identification number cross-references patient’s in the study database only – names and medical record numbers were not included in the database. Only the researcher and study personnel had access to the code sheet linking the patients’ identities with the study ID number. The study database was maintained under hospital security precautions for protected health information, entered into the secured research database, and within the patient medical record.

**Risk and Benefits.** The risk for participation in this project was minimal. The survey instruments are validated tools selected as standard of care and entered into the EHR that was secured by the healthcare organization. This project was designed to provide understanding of the feasibility for collecting this information based on participate feedback. Patient’s information used in the project was confidential and any copies of surveys were locked in the PI’s file drawers or password protected in the organizations computer. A study number and specific names known only to the researcher identified individual patients.

The direct benefits for participation were minimal and still unknown. By completing the survey questionnaires patients learned about activation and levels of engagement with the knowledge and skills for managing health and health care from the Patient Activation Measure (PAM). Patients with scores at-risk for depression on the Patient Health Questionnaire (PHQ) were referred to mental health services. As these surveys are incorporated into care more benefits may be identified.

An indirect benefit to completing these surveys were patients had an opportunity to provide feedback on the process to be implemented in the clinic. Specifically, participants were asked to provide feedback on length of time, difficulty, and location when all questions had been
answered by collecting this survey information during a routine clinic visit. Eventually once the clinical guidelines are completely integrated in to the EHR, it is expected there will be a positive impact on quality care for the patients.

Standardizing the outcome data for patient populations was considered to be a benefit to the neuromuscular population and the organization. With the minimal risk to patients for participation in providing feedback for responding to survey instruments and the potential benefits to including this information in the electronic health record and standardizing the outcome data for this population the benefits were greater than the risks. The results of this pilot study will be used in the future for designing processes for collecting data to be incorporated in the EHR. This project was the first step to integrating muscular dystrophy guidelines through the collection of psychosocial outcome measures to improve patient care.

**Data Collection**

Data for this study was collected on paper and kept in a locked cabinet accessible to only the researcher, study coordinators, and study staff. Next the item responses on the survey instruments were scored and this data was entered in a secure organization research database. The original PROM survey forms were sent to the medical record department for scanning into the patient’s medical record after the total score was entered in the EHR.

Once the study has concluded, the copies of data forms will be destroyed according the shredding policy of the organization. The database will be disabled according to organizational policy. The PROM data entered into the patient’s medical record will be maintained as standard of care for the life of the EHR.
Questions were formulated to guide the development of this project for implementing and evaluating a process for integration and data gathering of psychosocial outcomes in the electronic health record for muscular dystrophy patients (Appendix D). This includes:

1. What are feasible data collection methods to acquire psychosocial data for entry into the EHR?
2. What are factors that benefit or hinder the collection of psychosocial outcome measures by the healthcare team?
3. In what ways might the data collected be used to improve care?

Both the study participants and the team members completed two questions to determine feasibility and answer these program evaluation questions. These questions included length of time to complete PROM surveys and ease of completing these surveys. The study participants completed a third question indicating the location within the clinic when the surveys were completed; i.e. waiting room, exam room prior to provider visit.

**Instruments Used.** Subjects completed three PROM survey instruments. The surveys were the Patient Health Questionnaire depression risk screen (PHQ-2 or PHQ-9), World Health Organization Quality of Life (WHOQOL-BREF), and Patient Activation Measures (PAM). These instruments have all been validated and are considered standard of care. Three additional process evaluation questions were asked; and included level of difficulty/ease in a Likert Scale, length of time to complete, and location in the clinic when completed the survey.

The WHOQOL-BREF is a 26-item survey derived from the WHOQOL-100. It produces scores in four domains related to quality of life: physical health, psychological, social relationships and environment. It also includes an overall quality of life and general health score. WHOQOL-BREF domain scores demonstrated good discriminant validity, content validity,
internal consistency, and test–retest reliability with a Cronbach’s alpha of .89 or greater (The WHOQOL Group, 1998). The WHOQOL-BREF is useful in studies that require a brief assessment of quality of life. In addition, health professionals administer it for assessment and evaluation of treatment efficacy using the WHOQOL-BREF (Skevington, Lotfy, O’Connell, & WHOQOL Group, 2004).

The PHQ-9 is a widely accepted, standardized depression-risk screening tool that is completed by the patient. This nine question tool is scored on a scale of 0 to 27 based on the scale of Not at All (0), Several Days (1), More Than Half the Days (2), or Nearly Every Day (3) for responses to the questions over the last 2 weeks. The tool has been shown to be valid and reliable with a Cronbach alpha of .86 or greater (Kroenke, Spitzer, & Williams, 2001). Using this patient self-report tool engages the patient in his or her own progress, in addition, to providing an assessment of current status and a means for measuring outcomes (Kroenke, Spitzer, Williams, 2003; Pinto-Meza, Serrano-Blanco, Penarrubia, Blanco, & Haro, 2005).

The PAM is a 13-item self-administered survey. Each question offers a choice between five possible responses ranging from disagree strongly to agree strongly and not applicable. Based on responses, an activation score ranging from 0 to 100 is converted into one of four levels of activation. Patient activation is defined as the knowledge, skills, confidence, and behaviors needed for self-managing health (Hibbard, Stockard, Mahoney, & Tusler, 2004). The activation level indicates the degree to which individuals take an active role in managing his or her health and health care. According to studies conducted by Hibbard and colleagues, the PAM has strong psychometric properties and has been shown to be valid and reliable with a Cronbach’s alpha of .86 (Hibbard, Mahoney, Stockyard, & Tusler, 2005). An individual with a higher PAM score is more likely to understand that his or her active involvement is critical to the
state of his or her health and considered to be more in charge of his or her health. Scores on the PAM and levels of activation have been found to predict a range of behaviors, and a four-point difference in PAM scores has been identified as a meaningful difference in terms of maintaining specific health promoting behaviors.

Findings

The data was analyzed using descriptive statistics in Software Package for the Social Sciences (SPSS) by the principle investigator with access to consultation from a statistician and research administration support. Analysis of the data included descriptive statistics for mean, median, and percent. The subjective statements about perception of completing the questionnaires by patients and team members were collected and summarized. The study team completed a program evaluation during regularly scheduled committee meetings to analyze the success of this project by integration of patient psychosocial data into the EHR. Total scores from each of the PROM surveys are considered baseline outcome data for future comparison and were entered into the EHR available for report generation.

Summary

The method for data collection and analysis followed a descriptive, quantitative study design to determine feasibility of this SCP. The sampling strategy, ethical considerations, participant demographics, and survey data was described. Subjects were asked to complete three psychosocial survey questionnaires followed by three process evaluation questions; including three survey questions about ease of completion, lengths of time to complete, and location at the time they finished the questionnaires. These were asked in addition to the three PROM surveys for the purpose of program evaluation to determine feasibility of this project. Once the data were analyzed the findings were used to evaluate the patient experience and provide information to the
neuromuscular team about the sustainability of this process for collecting and embedding psychosocial information into the EHR.
Chapter 4

The following section summarizes demographic information, an analysis of the program evaluation survey results, and PROM questionnaire scores. In addition, it includes a comparison from the patient experience with completing psychosocial surveys and the teams evaluation of collecting survey data based on the research question, “What is the feasibility of implementing and evaluating a process for integration and data gathering of psychosocial outcomes in the electronic health record for muscular dystrophy patients?”

Demographics

Sixty patients agreed to enroll in this study and signed an informed consent. Study participants included forty-two males (70%) and eighteen females (30%). Gender differences were not unanticipated; in general, more males than females are diagnosed with muscular dystrophy (see Figure 1).

Figure 1

*Participant Gender*
The population of patients receiving services at the neuromuscular clinic tends to mimic general disease distribution and therefore a seventy percent rate of male participation was not unexpected.

The age range for these research participants extended from eighteen to seventy-nine years. The mean was thirty-nine with a standard deviation (SD) of 18.89 years. All study participants met inclusion criteria with a genetically confirmed neuromuscular diagnosis. Of these participants, forty-four (73.3%) were diagnosed with muscular dystrophy and sixteen (26.7%) with other neuromuscular conditions.

The majority of patients who were approached to participate in this study were agreeable, however, five eligible patients refused to participate. Because the team did not want patients to feel pressured or seemingly coerced into participation, minimal effort was made to account for reasons leading to refusal. Study representatives speculated that patients did not participate because of feeling rushed or simply not wanting to spend time completing surveys, summarized from statements recorded when patients declined participation. Patients were supported with these decisions and a refusal rate of eight percent is not unreasonable.

**Study Findings and Discussion of Feasibility**

Descriptive analyses including frequencies of categorical variables, along with mean and standard deviation for continuous variables, were analyzed to address the question of feasibility. Statistical Package for Social Sciences (SPSS), Version 21.0, was used for statistical analysis of the subject’s survey process. Feasibility was determined by having team members complete the three PROM questionnaires as well as answering process evaluation questions prior to the enrollment of subjects. Following this activity, enrolled subjects completed the same surveys in order to compare results. Additional data was collected to measure subject responses in regard to
the length of time it took to complete surveys, easy of completion and the location where data was collected. The participants completed the question about location at the time PROM surveys were completed to determine if scores were available in the EHR for the medical provider. The following is a review of both the subject and team member results.

**Process Evaluation by Subject’s**

All sixty subjects used a paper and pencil format to complete a total of forty-eight questions in the three separate surveys utilized in this project. While subjects were asked if they needed physical assistance with survey completion, all declined this invitation. The average completion time was 10.65 minutes (SD 5.4 minutes) with a range of 3 – 30 minutes. The majority of subjects completed all questionnaires within a range of 5 – 15 minutes (see Figure 2). Seventy percent of these participants completed these surveys in ten minutes or less, with only two participants spending greater than twenty minutes.

Figure 2

*Length of Time (minutes) Reported to Complete PROM Surveys*
The researcher was interested in knowing if clinic location made any difference in how questionnaire data was collected. The information is important because it addresses questions regarding clinic flow, feasibility of completing questionnaires prior to the medical provider entering the exam room, and accessibility of data at the point-of-care. Subjects completed questionnaires either in the waiting room or in the exam room. Fourteen participants (24%) completed questionnaires while still in the waiting room, while the majority of the participants, specifically forty-six (76%) completed questionnaires once invited into the clinic exam room (Figure 3).

Figure 3

*Patient Reported Outcome Measures (PROM) Survey Completion Location*

The decision on whether to ask subjects to complete surveys prior to, rather than following rooming was based on when the patient arrived to the clinic, how quickly he or she was roomed and whether any comfort cares were provided prior to questionnaire administration. These variables impact the time planned for completing surveys. On average the team determined patients would need approximately 10 minutes to complete the three surveys. The goal is to have
the surveys scored and entered in the EHR to be available for the healthcare team prior to seeing
the patient.

While it was not intentional to compare the feasibility of questionnaire completion in the
waiting room versus exam room, it is worth noting the association between location, time to
complete and the age of the subjects. When considering the relationship between age of subjects
(18 – 79 year) and time to complete these questionnaires, the Person’s correlation is $r = -0.78$.
This means there is very little effect between age and time to complete these surveys.

When comparing data about those who complete surveys in the waiting room verses
exam room, there was no significance between time of completion and diagnosis, gender, or age
as demonstrated using ANOVA calculation ($p = 0.371$). If decisions are made about where a
patient is asked to provide data based on certain preconceived notions, data does not support this
conclusion.

One of the barriers when engaging patients to complete a questionnaire is the
instrument’s perceived difficulty. Staff may hesitate to ask a patient perceived to be
intellectually, physically, or cognitively impaired to participate in data collection. In this project,
subjects were asked how difficult they felt it was to complete this collection of surveys on a scale
ranging from one to 10. A score of one was very easy and 10 indicated that a subject found the
surveys very difficult to complete. On average, the subjects scored a difficulty measure of 2.57
(SD 1.70). These subjects reported a range of difficulty from 1 – 8; none reported a difficulty
score of nine or ten (Figure 4).
Ease of Completing Patient Reported Outcome Measure (PROM) surveys

The majority of patients felt question items on these surveys were fairly easy to complete, with 75% of subjects rating the level of ease ranging from one to three. By combining the lowest levels of this spectrum, a full 57% of subjects rated its ease as either a one or two. As a result, the findings suggested these questionnaires are fairly easy to complete.

Team Member Program Evaluation

The researcher was interested in understanding whether there was an identified difference between how the study team perceived variables surrounding survey completion as compared to subject data. Team members completed each questionnaire and evaluation questions in the same manner as research participants. In order to better understand the challenges of gathering outcome measures, it was important to allow study members to experience the survey process firsthand and contrast their experience with the study sample. The researcher was specifically interested in the following variables: time and ease of completion, as well as difficulty.
Seven team members completed each of the PROM questionnaires and then evaluated the process for easy of completion and time to complete. In addition, each individual was asked to indicate how much time it took to finish all of the surveys. The team’s responses confirmed that of the study participants. As a whole, the questionnaires were rated easy to complete, with an average score of 1.6 (a score of one is an easy rating, while ten is difficult). This compares to the subjects score for completion as 2.57 level of ease. In terms of length of time to complete surveys, the team member average was 5.4 minutes with a range of 5-6 minutes, while the subjects needed an average of 10.65 minutes. A comparison of the participant’s and team member’s responses is contrasted as represented in Table 1.

Table 1

Comparison between Participant & Team Member Responses on Process Evaluation Questions

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</tbody>
</table>

The findings described above are important and address preconceived notions and barriers to system change. Prior to this project, the researcher speculated that measuring patient reported outcomes would take much longer than anticipated. Time is of the essence in a busy neuromuscular office and many staff questioned the burden of adding tasks that might impact clinic flow. Because the clinic lacked data to respond to these concerns, findings support this project and helped the team move forward and justify proposed changes. The team members, with the support of the community member, felt these surveys were a reasonable expectation for this patient population.
In addition to feedback from the team members on length of time and ease of survey completion, other comments included an observation of question repetition between the three survey instruments and some unclear language. Since these are validated tools, each of the questionnaires must be administered following survey instructions and wording of questions cannot be changed. Based on feedback from the study team, and most importantly, the community member, the team recommended these survey questionnaires as important information to collect as patient reported outcome measures. This recommendation considered the potential burden to ask subjects to complete a significant number of combined questions resulting from the administration of the three different PROM survey questionnaires.

**Questionnaire Responses**

In addition to demonstrating the feasibility of gathering patient outcomes, the researcher was also interested in how clinical data was stored within the electronic health record. Patient reported outcome measures (PROM) offer important data to providers when delivering care. This study provided information data about quality of life, engagement in healthcare decision-making, and depression risk to providers as baseline data for this population of patients. What does the data say about patients with neuromuscular diseases? Do the findings of this research correspond with national databases? Now that patient reported outcome measures are known, what are the implications for practice? Analyses of these survey results are described below.

The Patient Activation Measures (PAM) questionnaire is an indicator of an individual’s level of activation or ability to engage in healthcare decision-making. This is important because the more engaged the persons is the more likely he or she is to manage health care decisions, while a lower level of engagement may indicate the person is unable to direct his or her care. A PAM rating ranges from Level one to four, with a score of one indicating that an individual
CAPTURING OUTCOME DATA IN THE EHR

requires a high level of assistance and Level four meaning the individual is very engaged to independently direct his or her own health care. The combined result from the subject’s reported level of activation on the PAM reflects a normal distribution curve. In this study population, six subjects received a level one PAM score (10%), eleven subjects (18%) were level two, thirty-two subjects (54%) were level three, and eleven subjects (18%) were level four. In each of the levels, there were more males than females, except level 2 where none were female, as seen in Figure 5.

Figure 5

*Patient Activation Level by Gender*

Almost 70% of study subjects reported managing his or her own health care, as well as making independent health care decisions, as demonstrated by scoring either a level three or level four on the PAM. On the other hand, about 30% of subjects report needing assistance with skills to make their own healthcare decisions or managing the plan of care, as demonstrated by scoring as either level one or level two.

The WHOQOL-BREF was administered to identify the subject’s quality of life. An individual can score up to 100 on this scale, indicates high quality of life. A score greater than 75 is considered high quality of life. The total score for the sixty subjects completing the quality of
life questionnaire ranged from sixty-one up to ninety-eight. A relatively high score of eighty-two was the average for these subjects, indicating a very high quality of life (Figure 6).

Figure 6

**WHOQOL-BREF Scores by Participants**

The Patient Health Questionnaire (PHQ) was administered to determine a subject’s risk for indicators of depression. Scoring zero on the PHQ indicates that no indicators of depression are self-reported by subjects over the past two weeks. Of the sixty subjects in this study, forty-six (76.7%) did not report depression risk indicators on the PHQ. Fourteen (23.3%) of the subjects completing the PHQ reported responses on the PHQ that indicated possible depression risk as seen in Table 2. Twenty-four percent depression risk is higher than the average population and aligns with reported depression in individuals with a disability.
Table 2

*Patient Health Questionnaire (PHQ) Scores for Depression Risk*

<table>
<thead>
<tr>
<th>Type of PHQ Survey</th>
<th>PHQ-2 (No Risk)</th>
<th>PHQ-9 (Depression risk)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male number (%)</td>
<td>34 (56.7)</td>
<td>8 (15)</td>
<td>42</td>
</tr>
<tr>
<td>Female number (%)</td>
<td>12 (20)</td>
<td>6 (8.3)</td>
<td>18</td>
</tr>
<tr>
<td>Total</td>
<td>46 (76.7%)</td>
<td>14 (23.3%)</td>
<td>60</td>
</tr>
</tbody>
</table>

**Correlation between Survey Questionnaires**

A review of subject’s PROM questionnaire scores and any relationships between quality of life, activation, and depression risk was of interest to the SCP team. A comparison between subject’s responses between the WHOQOL-BREF score and the PAM score were conducted. There was not linear relationship between quality of life and engagement in healthcare decision-making (p = 0.123). Therefore, quality of life is unrelated to a patient’s skills and abilities to manage healthcare decisions when comparing QOL and PAM scores.

Of the patients completing the PHQ depression risk screen, fourteen patients scored at risk for depression. This is approximately twenty-four percent of these subjects reporting indicators at risk for depression. When comparing this subset of patients with quality of life and engagement in healthcare management, the average QOL was a mean of 78.8 (SD 8.34). Although, for subjects with depression risk the QOL score was close to three points lower than the total pool of subjects. The Pearson correlation was 0.568 (p = 0.034). There is indication of a relationship between depression risk and a lower quality of life, but not very strong.

The study team was interested in depression risk in relationship to subject’s quality of life (QOL) and ability to manage health care decisions. Fourteen subjects (23.3%) reported indicators
of depression risk. Possible depression rates for subjects in this study are higher than the national average, but in alignment with person living with disability. The team wondered, “Would depression risk be a barrier to quality of life and level of activation?” Logically, it could be assumed that depression has an impact on QOL and ability to manage his or her health care. A one-way analysis of variance (ANOVA) was calculated comparing the WHOQOL and PAM for the fourteen subjects at-risk for depression. Significance was considered if the P-values were less than 0.05 for these subjects. Collecting these outcome measures are valuable to clinical practice and the way the health care team makes care plan recommendations. Treating depression would be necessary to remove barriers and create an environment for engaging in health care decision-making.

**Summary**

Patients are willing to respond on PROM surveys and complete these questionnaires prior to a specialty clinic visit if invited by the provider and the burden is low. The key stakeholders were involved, and were included in the formulation of the research question and selection of PROM surveys for data collection in this quantitative study evaluating feasibility. When comparing both the team’s experience and the patient’s experience, these three PROM questionnaires were reported to be easy to complete within approximately ten minutes. The WHOQOL, PAM, and PHQ survey questionnaires were selected since other clinic teams in the organization were already using them. They were collected in a research database but had not been integrated into practice or embedded into the EHR until this project. Implementing the framework for entry into the EHR was a natural next step. The EHR now has the data entry fields to enter and store the total survey scores and ability to review specific questionnaire item responses. This project demonstrated the feasibility of improving patient data quality and
outcomes measurements by beginning the process of integrating the psychosocial components of the MD care guidelines within the EHR.

As previously stated, when health data is not accessible or organized in a user-friendly view, safety issues, disparities, or inconsistencies in care delivery result. The results from this project evaluation support the need to use these databases for comparing with different diagnosis groups in the future. Clinical guidelines embedded within the EHR have been shown to improve health outcomes and costs for persons living with chronic illness. Consistent collection of clinical and psychosocial data for reporting outcome measures based on evidence-based guidelines for chronic conditions is needed. While an exhaustive literature search did not find any studies implementing the MD clinical guidelines or collecting outcome measures within the EHR, the results from this pilot study demonstrated a successful framework for further development. Expanding the collection of PROM data to the additional eight hundred pediatric and adult neuromuscular patients at an annual clinic visit has been initiated.

The workflow process and electronic health record framework are now developed to expand from PROM data to physiologic measures, such as functional abilities and pulmonary function. The muscular dystrophy clinical practice guidelines provide the evidence-base recommendations for selection of these physiologic measures. Longitudinal data will become available for future comparison.
Chapter 5

This systems change project was initiated to determine the feasibility of establishing and evaluating a process for obtaining data essential to evidence based care guidelines for muscular dystrophy. The following section provides discussion of study findings, an overview of recommendations, a dissemination plan, and suggestions for future research.

Discussion of Findings, Recommendations, and Conclusions

Findings

This systems change project answered the following research question: “What is the feasibility of implementing and evaluating a process for systematically assessing psychosocial outcomes for patients with muscular dystrophy and then integrating them into the electronic health record for report retrieval?” The first finding discussed will address feasibility as described above. Other finding discussed will be organizational support, electronic health record data retrieval, and evaluation of data mining.

Feasibility. Study findings suggest that it is possible to systematically collect outcome measures at the point of care. Data collection, as described from a patient’s perspective is easy, does not take much time, and is acceptable as an activity that can be completed prior to meeting with the provider. This project demonstrates that it is possible to collect patient outcome data so staff can retrieve data in real time and use pertinent information to support clinical decision-making. There must also be infrastructure in place that allows data to be entered in the EHR for efficient access and retrieval throughout the clinic visit.

This project established a process for collecting patient surveys. It is important to utilize survey instruments with patient populations that are shown to be valid, reliable, and acceptable. In addition, organizations must select survey instruments that are used consistently so processes can be standardized throughout each department. Another finding related to feasibility is the
simple fact that if patient outcomes are measured, such as risk for depression, interventions and services must be in place in order, to assess severity and need for immediate care or referral.

**Organizational Support.** Another key finding of this project speaks to the importance of obtaining organizational and stakeholder support when attempting to create system change. By identifying a point person who assumed project leadership, the change process was greatly enhanced. In addition, because this project required collaborative effort, building a highly invested team was a priority in order to achieve successful project outcomes.

**Electronic Health Record and Data Retrieval.** In order for collected patient data to be useful to care providers, it must be accessible and easily retrieved in comprehensive reports; and when appropriate, have the capacity to trend data over time. A major finding of this study speaks to the importance of creating an informatics infrastructure that allows data to be useful in informing practice decisions. Technology is constantly changing. Creating an evaluation mechanism allows health care providers to be responsive and proactively recommend process modifications to align with EHR system’s needs.

**Evaluation and Data Mining.** Nursing informatics provides standardized language to evaluate data, both on an individual and population basis. The ability to evaluate patient outcomes from a variety of perspectives is the essential to quality assurance. Using an epidemiological perspective allows organizations, the neuromuscular community and others to better understand disease patterns, trends, interventions, and practice deficits.

This project was a first step to implementing a nurse lead process for collection of PROM data into the EHR based on clinical practice guidelines. Lack of organized and consolidated information limits efficiencies and the effectiveness of diagnosing and recommending interventions (Bushby et al., 2009). A sustainable process must be established and maintained for
longitudinal reporting to occur. When data is relatively easy and quick to collect, entered in the EHR and retrievable, providers have the information necessary for patients to benefit.

**Project Strengths and Limitations**

Many positive factors contributed to the successful completion of this SCP. The neuromuscular team was supportive of this project. As described in Roger’s *Diffusion of Innovation* model, a champion is necessary to lead the project by using a variety of strategies to improve awareness, interest, and communication (Rogers, 2013; White, 2011). The researcher was the champion in this case. The project team’s readiness and willingness to support change was apparent.

Another strength was the fact that the site mentor was also the research sites’ clinic manager. She was committed to the success of the project and agreed to allow patients to participate in the study during clinic appointments. One of her management roles was to be a representative on the outpatient nursing informatics team. She was influential in gaining support for the work needed to be successful in completing this project.

Critical to the success of this project was organizational support described in the Strategic Plan to implement outcome measures. This provided access to organizational resources, such as an informaticist and time needed for creation of the data fields within the EHR and system testing. In addition, patients cared for in the neuromuscular clinic were eager to participate in this study and willing to disclose very personal information.

A final strength of this SCP was the ability to demonstrate feasibility of collecting patient-reported outcomes and to do so with ease, efficiency, and low burden. The study team was able to pilot a data collection process and with informatics support, embed this into the
EHR. If it not been for an infrastructure already in place, this project would not have been as meaningful or comprehensive.

Limitations of this study include the methodology, sampling, and lack of generalizability of findings. Although this was a quantitative methodology, there was no control group, thus the findings are not generalizable. Had there been a comparison group, different instruments might have been administered, impacting results as measured by time of completion, ease, and acceptability. A larger sample size was used in this study in an attempt to minimize the effect of a single sample group. The totals scores for each questionnaire was stored in the EHR, which patients understood prior to signing consent. Efforts to minimize subject’s perception of burden and survey fatigue must be considered. It is important to note, five patients refused to participate in this study and although the reasons were not solicited, comments were recorded. Themes included lack of time and no interest.

**Discussion Recommendations to the Neuromuscular Clinic**

As a result of completing this project, recommendations have been made to the neuromuscular multispecialty team. The following recommendations include:

- Use standardized instruments to collect patient-reported outcome measures
- Complete survey’s prior to provider entering the clinic room
- Train staff distributing survey’s using a script and on the process for requesting patients to complete the surveys
- Apply new technologies for survey completion; i.e. iPad, patient portal, e-Health
- Review individual and population data at program meeting and establish quality improvement process model for missing data
• Reduce the number of survey questions to continually minimize burden; i.e. evaluate the PAM-6 and a single QOL question using a visual analogue scale

• Expand data collection to physiologic and functional measures

**Project Dissemination**

This Systems Change Project (SCP) evolved as a result of the challenges described above, and a request from the neuromuscular team to integrate psychosocial outcomes measures into the practice, embed them in the EHR, and create a means for data reporting. The team reported that data consistency and retrieval for reporting is now an efficient processes and patient reported measures are now automated. Successes from this project need to be shared with both internal and external audiences.

Developing the systems to access outcome data in the EHR is critical to demonstrating adherence to, and effectiveness of, recommendations from clinical practice guidelines. Reports of successful programs integrating clinical practice guidelines in the EHR are lacking in the literature. Publishing this study would provide other organizations a model to use clinical practice guidelines to select outcome measures, understand the importance of patient voice in establishing the plan of care, and applying informatics principles to data entry and retrieval in the EHR.

Several organizational teams have been introduced to this project and the enhancements incorporated into the EHR. Both the Spina Bifida and Cerebral Palsy Program Development Teams have invited this student to share the work from this project. They have begun collecting PROM data in those clinics. One team in the organization has been collecting PROM data for research purposes only, but not using them to inform clinical care. With the data fields built into the EHR, they are in the position to integrate patient voice into the care.
Further, prior to the completion of this project, inconsistencies and repetitiveness in the documentation of health data and challenges of retrieval from the EHR were identified as dissatisfying by the team. The neuromuscular team now voices support for the process created by assessing the feasibility of gathering PROM, entering data into the EHR, and evaluating outcomes as related to this pilot project. The EHR was customized to provide standardized fields for data entry and allowed for data mining. Sharing the success of this project has created the means for data mining in the EHR and outcome reporting which has a lasting benefit to the organization.

The neuromuscular team has agreed that the next steps in this process include using additional clinical practice guidelines to direct medical interventions and requests that these standards be embedded into the EHR. Specifically, the team would like to see physiologic and functional data collected in the same manner that psychosocial measures were assessed. Sharing this information with other Muscular Dystrophy clinics nationally could generate interest in developing a shared multi-site clinical registry.

The organization made the decision to replace the current EHR and over the next year clinical teams will be asked to participate in this conversion process. The neuromuscular team is well positioned to replicate the work from this project and expand the types of outcome data that will be included in this informatics build. This project supported an organizational objective for collecting outcome data and data mining. This project has demonstrated a successful process for other specialty teams requesting organizational support for their projects.

Although this research project began as a means to collect outcome data during the clinic visit, there have been important unanticipated consequences. For example, when a patient is identified as ‘at risk’ for depression it is evident that a formalized intervention plan be in place.
In addition, communication channels for referral and follow-up must be established. With advances in technology, a patient portal might be considered to be the next step in providing a means to collect data electronically from home prior to the clinic visit. It is apparent this project cannot be thought of in terms of a final product or outcome, but rather a process that has offered significant benefit.

**Evaluation Plan**

The evaluation process may occur formally as well as informally. Informal evaluation feedback has already taken place and it surrounds patients refusing to complete surveys. As additional patients are invited to complete survey questionnaires, complaints about intrusive questions have been shared and individual survey question items are unanswered. This has prompted the team members to reevaluate how patients are asked to participate in completing PROM surveys. The subjects in this study were well informed about the purpose of the survey questionnaires and how they benefit. Providing more information about how these survey results will be used and why it is important will be necessary.

The neuromuscular team should also continually consider the burden on patients to collect PROM data. Survey fatigue is a risk. The team should review the literature for reliable and valid instruments asking fewer questions. For example, one might wonder about the following question, “Could a visual analog scale ask about quality of life with one question and reflect a patient’s quality of life similar to the twenty-six-item WHOQOL-BREF?” The length of time and methods to collect patient information should be considered in the evaluation to improve patient satisfaction. Reducing the number of overall survey questions asked may also address the concern of duplicate questions across the three instruments.
A formal evaluation plan should be developed to monitor consistency of data collection and accuracy of entry into the EHR. Sustainability will be challenged as patients return for the next annual clinic visit. Establishing a workflow process alerting the clinical team to invite patients to complete annual surveys will be needed. Equally important is consideration for improved outcomes and knowing what interventions have made a difference. The team will continue to report PROM scores at monthly meetings. Refinements will be incorporated within the current committee structure and collaborative decision-making for implementing these changes.

**Recommendations for Further Research**

This pilot study demonstrated that patients are willing to complete patient reported outcome measures using carefully selected questionnaires on paper prior to an annual clinic visit. Moving forward, other methods for collecting patient reported data must be considered. Initially, this clinical team was hoping to offer use of iPad technology for patients to complete these surveys. Other electronic survey methods should be studied using a similar evaluation process as this SCP. Patient portals or an electronic patient chart could be accessed in the weeks before the clinic visit so these questionnaires would be completed prior to the appointment and assessable to the team in preparation for the clinic appointment.

This study was with adult patients seen in the neuromuscular clinic. By initiating collection of patient reported measures at diagnosis beginning in childhood, there is now a mechanism to observe patterns over the lifespan of each patient and the group as a whole. A study of these patterns could inform the natural history of disease progression and its relationship to quality of life, patient engagement, and psychosocial secondary conditions. Other possible studies of interest would be the relationship between the patient-reported measures with clinical
interventions from the practice guidelines and patient education. Porter (2011) suggested that improving outcomes in one tier of the *Outcome Measures Hierarchy* have a positive effect in other tiers. The focus of this study was not to compare these changes following interventions. Future studies could and should report on these effects.

The responses in these PROM surveys and compared with the patient experience need to be explored. Studies have demonstrated implementation of strategies to improve patient activation, as demonstrated by changes in the PAM level resulting in better health outcomes and reduced health care usage. As this organization engages patients as active partners in developing the plan of care, studies need to be conducted to confirm these reports in a population of patients living with a disability. Studies are also needed to compare outcomes of early depression risk identification with the strategies to impact remission and reduce costly care. Each of the PROM surveys offers a wealth of research opportunities, especially for patients living with chronic disabilities. There is a gap in the literature surrounding care for individuals with complex, chronic disabilities and additional studies are warranted.

**Role and Value of the DNP**

First and foremost, this SCP highlights the value of the Doctor of Nursing Practice (DNP) role in systematically reviewing a patient care issue and presenting this issue to key stakeholders in a way that is relevant to current practice. The DNP is not only rooted in nursing care, but in the ability to work with multiple disciplines to implement system change. The DNP is skilled in not only being knowledgeable about evidence-based practice, but also how to apply evidence to unique situations. In this case, the situation was evaluating the practice of implementing psychosocial PROM in the EHR and making recommendations for change. The DNP bridges the gap between knowledge and practice in a practical application. This project is an example of
using evidence from the literature, from expert opinion, and from data to inform future practice. The DNP is a lead change agent.

**Summary**

Coordination of care using clinical practice guidelines for neuromuscular patient populations is still in its early stages of development in specialty care. Improved psychosocial outcomes have shown to positively impact quality of care and lead to decreasing secondary conditions, such as depression. Nurses will be challenged to embrace collection of PROM data, while at the same time, preserve the importance of the clinical experience.

This project demonstrates how a nurse researcher can apply theory to frame a practice issue and lead organizational change. By organizing and leading an interdisciplinary team, practice can be enhance and support quality of care. This SCP effectively implemented a process to improve collection of patient outcomes for entry in the EHR and becomes retrievable for reporting.
References


Muscular Dystrophy Association (MDA). *Fact sheet [brochure].*


Appendix A – Logic Model

Muscular Dystrophy (MD) Psychosocial Patient Reported Outcome Measures (PROM) Embedded in the EHR Logic Model

Problem Statement: Psychosocial patient reported measures are inconsistently implemented and outcome data unavailable that need to be embedded in the electronic health record (EHR) for measuring patient outcomes

Goal: Neuromuscular patient outcome data collects at the annual specialty clinic visit will be retrieved from the electronic health record and available for analysis from the data warehouse

Assumptions/Influencing factors: 1) Evidence-based clinical guidelines for MD improves patient engagement, outcomes, and data analysis 2) Coordinated care improves patient satisfaction 3) Patient data in the EHR is retrievable for reporting from a data warehouse 4) Organizational support for implementing psychosocial PROM surveys will benefit from consistent data that is retrievable
Appendix B
IRB Application Approval

Expedited Review Approved by Chair - IRB ID: 237
3 messages

Fri, Jun 6, 2014 at 12:23 PM

To: Kim Marben
From: John Schmitt, IRB Chair
Subject: Protocol #237
Date: 06/06/2014

On behalf of the IRB, I have reviewed your response to stipulations for application #237: Capturing Muscular Dystrophy Patient Outcomes in the Electronic Health Record. You have addressed all edits and clarifications as requested. As a result, the project has been approved as revised

If you have any questions, feel free to contact me or email via the Mentor messaging system. Also, please note that all research projects are subject to continuing review and approval. You must notify our IRB of any research changes that will affect the risk to your subjects. You should not initiate these changes until you receive written IRB approval. Also, you should report any adverse events to the IRB. Please use the reference number listed above in any contact with the IRB.

This approval is effective for one year from this date, 06/06/2014. If the research will continue beyond one year, you must submit a request for IRB renewal before the expiration date. When the project is complete, please submit a project completion form. These documents are available in the St. Catherine University Mentor IRB site.

We appreciate your attention to the appropriate treatment of research subjects. Thank you for working cooperatively with the IRB; best wishes in your research!

Sincerely,

John Schmitt, PhD
Chair, Institutional Review Board
jsschmitt@stkate.edu
APPENDIX C

INFORMATION SHEET FOR RESEARCH
Capturing Muscular Dystrophy Patient Outcomes in the Electronic Health Record

You are invited to be in a research study where we will be collecting information about our patients in an effort to provide better care. The purpose of this study is to create the model for collecting outcome data from the electronic health record. We will be analyzing the results to see if this effort improves our patient’s outcomes. You were selected as a possible participant because you are a patient in the Gillette Lifetime Neuromuscular Clinic. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by: Kim Marben, MSN, RN, nursing supervisor, Gillette Lifetime Specialty Healthcare and St. Catherine’s University doctor of nursing practice student.

Procedures:

If you agree to be in this study, we would ask you to do the following things:
We will ask you to select the method you would like to use to complete the three questionnaire surveys; paper, iPad, or 1:1 interview and answer three additional questions about your experience completing these three surveys. We anticipate that your time to participate in this research to answer three additional evaluation questions will take about five minutes or less. We also would like your permission to access your medical record to gather information about your age, gender, diagnosis, and scores from the three questionnaires.

Risks and Benefits:
The only risk is confidentiality of the data. Measures are in place to protect your confidentiality. There are no direct benefits to participation. However, this research may help patient care in the future.

Confidentiality:
The responses to the questionnaires are considered a part of your medical record and will be available to your medical team. In any sort of report we might publish, we will not include any information that will make it possible to identify a subject. Research records will be stored securely and accessible to only the study staff.

Voluntary Nature of the Study:

Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with Gillette Children’s Specialty Healthcare. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.
Contacts and Questions:

The researcher(s) conducting this study is (are): Kim Marben. You may ask any questions you have now. If you have questions later, you are encouraged to contact her at Gillette Children’s Specialty Healthcare, 651-229-3878 or kmarben@gillettechildrens.com. The student’s faculty advisor at St. Catherine’s University is Roberta Hunt, Ph.D. and can be contacted at 651-690-6851 or email rjhunt@stkate.edu.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), contact Patient Representative of the Quality Improvement Resources Department at Gillette Children’s Specialty Healthcare, 200 East University Avenue, St. Paul MN 55101, Telephone 651-229-1706 or 1-800 719-4040 (toll free) or e-mail qualityrep@gillettechildrens.com.

You may also send feedback by going to: https://www.gillettechildrens.org/contact-us/ and completing the feedback form.

You will be given a copy of this information to keep for your records.

Statement of Consent:
You are making a decision whether or not to participate. Your signature indicates that you have read this information and your questions have been answered. Even after signing this form please know that you may withdraw from the study.

I consent to participate in this study.

Signature of Participant ___________________________ Date _____________

Signature of Researcher ___________________________ Date _____________
APPENDIX D

Questionnaire

Data Collection

Subject Instruments and questions:

1. World Health Organization Quality of Life (WHOQOL – BREF) - attached
2. Patient Health Questionnaire – 2 plus (PHQ2+) - attached
3. Patient Health Questionnaire – 9 (PHQ-9) - attached
4. Patient Activation Measure (PAM) – attached

Additional questions:

1. On a Likert scale of 1-10 how easy or difficult was this to complete?
   1 _____ 2 _____ 3 _____ 4 _____ 5 _____ 6 _____ 7 _____ 8 _____ 9 _____ 10
   Easy
   Difficult

2. How long did it take you to complete this questionnaire? _____ minutes

3. Location when you completed the questionnaire? (check appropriate location)
   _____ Waiting room; _____ clinic room; _____ after appointment

Additional information collected:

1. Subject invitation log (patient name, MR#, date of clinic visit):
   a. Number of patients consented: ________
   b. Number of patients completing on paper: ______
   c. Number of patients completing on iPad: ______
   d. Number of patients completing using other method (1:1 interview): ______;
      method(s) __________________________
   e. Number of patients completing all 3 questionnaires: ________
   f. Number of patients completing and baseline measurements:
      _____ WHOQOL-BREF; ___average score; ___ range
      _____ PHQ-2; response: ____ # No; ____ #Yes (If yes, proceed to PHQ-9)
      _____ PHQ-9; response: _____ <10 score; _____ 10 or greater score
      _____ PAM; response: ____ Level 1; ____ Level 2; ____ Level 3; ____ Level 4
   g. If did not complete all 3 questionnaires, reason “in the patient’s own words
      without prompting” Response: _________________________________
   h. Number of patients declining to participate: ______
i. Reason declining “in the patient’s own words without prompting” Response: ______________________________________

2. Medical Record Review
   a. Gender: _____ male; _____ female; other __________________
   b. Age (years): _____
   c. Diagnosis: type of neuromuscular disease ______________________

Study Team Evaluation:

1. Discuss the pros and cons of methods used to collect psychosocial data.
   a. What were pros of using paper?
   b. What were cons of using paper?
   c. What were pros of using iPad?
   d. What were cons of using iPad?
   e. What other methods were used; i.e. 1:1 interview?
   f. What were pros of this other; i.e. 1:1 interview method?
   g. What were cons of this other; i.e. 1:1 interview method?
   h. What other methods can you think of that could be used to collect this information?

2. What are factors that benefitted or hindered the collection of psychosocial outcome measures?
   i. How easy or difficult was it to enter questionnaire information into the EHR?
      i. Brainstorm responses by the outcomes measure team
      ii. Use a Likert Scale at each meeting to trend responses over time.

      1 _____ 2 _____ 3 _____ 4 _____ 5 _____ 6 _____ 7 _____ 8 _____ 9 _____ 10

      Easy                                              Difficult

   j. How easy or difficult was it to retrieve questionnaire information from the EHR?
      i. Brainstorm responses by the outcomes measure team
      ii. Use a Likert Scale at each meeting to trend responses over time.

      1 _____ 2 _____ 3 _____ 4 _____ 5 _____ 6 _____ 7 _____ 8 _____ 9 _____ 10

      Easy                                              Difficult

   k. Why do you think not all questionnaires were completed?
      i. Brainstorm responses by the outcomes measure team

3. What revisions were made to improve the process during implementation?

What ways might the psychosocial outcome measures be used to improve care?