

2018

Nurse's Role Within the Informed Consent Process: A Systematic Review of the Literature

Maria Faison
Walden University

Follow this and additional works at: <https://scholarworks.waldenu.edu/dissertations>

 Part of the [Nursing Commons](#)

This Dissertation is brought to you for free and open access by the Walden Dissertations and Doctoral Studies Collection at ScholarWorks. It has been accepted for inclusion in Walden Dissertations and Doctoral Studies by an authorized administrator of ScholarWorks. For more information, please contact ScholarWorks@waldenu.edu.

Walden University

College of Health Sciences

This is to certify that the doctoral study by

Maria Faison

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

Review Committee

Dr. Barbara Niedz, Committee Chairperson, Nursing Faculty

Dr. Mary Martin, Committee Member, Nursing Faculty

Dr. Patricia Schweickert, University Reviewer, Nursing Faculty

Chief Academic Officer

Eric Riedel, Ph.D.

Walden University

2018

Abstract

Nurse's Role Within the Informed Consent Process: A Systematic Review of the
Literature

by

Maria Cristina Faison

MSN, Walden University, 2013

BSN, University of the Incarnate Word, 2007

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

Walden University

August 2018

Abstract

Each year, over 50 million surgical and nonsurgical inpatient procedures are performed and yet, shared decision making between patients and health care providers is not achieved. Obtaining patients' informed consent is part of a nurse's daily routine during admissions and before a procedure. The purpose of this project was to evaluate evidence to answer the practice-focused question regarding support for a policy change to implement a nurse-driven informed consent protocol. The systematic literature review was conducted using the adapted literature review by Souza, Silva, and Carvalho, which consisted of 6 levels for evaluating evidence. A total of 15 articles were graded using the updated Johns Hopkins nursing evidence-based practice model. Evidence from the literature review showed that nurses had several roles in the informed consent process: advocate, communicator, and witness. A modified Real Time Delphi 2 round survey was used to measure an expert panel's reaction to the systematic review and to evaluate a nurse-driven informed consent protocol. The results showed consensus from the expert panel ($n=16$; 81% agreement) for implementing a nurse-driven informed consent protocol, with Cronbach's Alpha, $\alpha = .70$ for internal consistency and reliability, and Fisher's exact test yielded $p = 1.0$, showing no differences between staff nurses and managers in advocating for a policy change. Implications for positive social change include improving a nursing process, and impacting patient outcomes, and encouraging collaborative decision-making in health care.

Nurse's Role Within the Informed Consent Process: A Systematic Review of the
Literature

by

Maria Cristina Faison

MSN, Walden University, 2013

BSN, University of the Incarnate Word, 2007

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

Walden University

August 2018

Dedication

I dedicate this paper to all the nurses of the Armed Forces who I have worked side-by-side with both in times of war and during peacetime. Your courage and dedication to our nation and soldiers keep me motivated in improving patient outcomes.

In Loving Memory of

Romeo T. Cendana

1945 – 2013

You will always be in my heart.

Acknowledgments

I would like to acknowledge my husband, Shawn Faison, for his unending encouragement while I pursued this degree. I would also like to thank my preceptor, Kathleen Smith for her astute guidance and editing expertise. Thank you both for your valuable support and assistance throughout this process.

Table of Contents

List of Tables	iv
List of Figures	v
Section 1: Introduction.....	1
Introduction.....	1
Nurse Involvement.....	1
Problem Statement	2
Purpose.....	3
Nature of the Doctoral Project	4
Significance to Practice.....	4
Summary	5
Section 2: Background and Context	7
Introduction.....	7
Concepts, Models, and Theories	7
Six Stages of Systematic Literature Review	7
Relevance to Nursing Practice	8
Existing Scholarship	9
Local Background and Context	10
Informed Consent Process and Nurse’s Role.....	10
Informed Consent Process and Training.....	10
Advocate	14
Communicator.....	16

Witness.....	17
Role of the DNP Student.....	18
Summary.....	19
Section 3: Collection and Analysis of Evidence.....	20
Introduction.....	20
Practice-Focused Question.....	20
Sources of Evidence.....	21
Published Outcomes and Research.....	21
Evidence Generated for the Doctoral Project.....	21
Analysis and Synthesis.....	23
Summary.....	23
Section 4: Findings and Recommendations.....	25
Introduction.....	25
Summary Findings.....	27
Implications.....	32
Recommendations.....	33
Strengths and Limitations.....	34
Section 5: Dissemination Plan.....	36
Dissemination Plan.....	36
Analysis of Self.....	36
Summary.....	37
References.....	38

Appendix A: Literature Summary With Level of Evidence	44
Appendix B: Permission from John Hopkins	48
Appendix C: Survey Questions.....	49
Appendix D: Draft Policy/Protocol	52
Appendix E: Power Point Presentation for SMEs	55

List of Tables

Table 1 *Hierarchy of Evidence* 10

Table 2 *Demographic and Characteristic of Expert Panel* 30

Table 3 *Reliability Statistics – Cronbach’s Alpha* 31

Table 4 *Staff and Managers Willing to Implement Nurse-Driven Informed Consent Protocol*..... 32

List of Figures

Figure 1. Inclusion Process..... 27

Figure 2. John Hopkins Nursing Evidence-Based Rating Scale 28

Section 1: Introduction

Introduction

Each year, over 50 million surgical and nonsurgical inpatient procedures are performed and yet, shared decision making between patients and health care providers is not achieved (CDC/NCHS National Hospital Discharge Survey, 2010). For these patients, the foundation of a respectful relationship between provider and patient is the informed consent process. Before any surgical or nonsurgical procedure, obtaining informed consent is an ethical and legal obligation in medicine. Nurses are accustomed to the principles and implementation of the informed consent process as it is part of their daily routine; and yet the informed consent is often involved in scrutiny both in the United States and around the world (Spatz, Krumholz, & Moulton, 2016).

Informed consent is a process and not merely about obtaining a signature from the patient. The military is not immune to litigation given the number of patients seen daily in any treatment facility (Faram, 2016). They, like their civilian counterpart, are searching and investing in ways to improve the informed consent process such as electronic forms (Gallegos, 2014). But improving must also consist of implementing policy and offering continued education. Currently, practice assumes that nurses have little significance in the informed consent process.

Nurse Involvement

Nurses have many roles in the informed consent process. In 2015, the ANA Code of Ethics for Nurses (American Nurses Association, 2015) released updated provisions with interpretive statements. The provision particularly related to informed consent is

Section 1.4, The Right to Self-Determination. This provision stressed that nurses should support patients throughout the decision-making and treatment process (Section 1.4, Paragraph 1) and that nurses have an obligation to know and understand the moral and legal rights of patients (Section 1.4, Paragraph 2).

The ultimate responsibility of informed consent falls to the physician, where they must inform the patient of the (a) risks, (b) benefits, and (c) alternatives of a proposed treatment or surgery (Menendez, 2013). Nevertheless, it is a great opportunity for nurses to drive this practice change; but, many nurses do not fully understand the legal and ethical guidelines of the informed consent process. Rock and Hoebeke (2014) found that the nurse's role in the informed consent process is not consistent which could put them at risk for liability claims and risk to their licensure. A clear definition and practice is needed to protect nurses during the informed consent process as well as offering continuous ethics training to include the informed consent process.

Problem Statement

Health care organizations are required to have an informed consent policy and procedure to be compliant with Centers for Medicare and Medicaid Services (CMS), state and case law, as well as Joint Commission standards. The problem statement for this project is that since the informed consent process is governed by local policy, the nurse's role is not clearly defined in the process therefore, policy change is needed to support a nurse-driven informed consent protocol. In local practice, nurses often begin the informed consent process by preparing the forms and/or witnessing the patient's signature. Ethical considerations often arise when nurses do not fully understand their

role and they expose themselves and the hospital to liability by attempting to answer patient's questions or practicing outside their scope (Rock & Hoebeke, 2014).

Doctoral projects such as this can influence, improve, and expand nursing practice and policy by providing accurate and up-to-date insight into the nurse's role in the informed consent process. According to Ham-Baloyi and Jordan (2016), reviews are vital to the clinical and academic nursing community. This systematic literature review will help nurses by providing quality and usability of literature.

Purpose

Nurses are very involved with the informed consent process. However, there is a practice gap in many organizations, because the nurse's role is not clearly defined. The purpose of the DNP project is to evaluate the literature for relevant evidence to support a policy change and provide the educational needs of nurses within the informed consent process. The basis for this systematic review was formed by the following research question:

Can evidence be found to support the implementation of a nurse-driven informed consent protocol?

Nurses with a DNP degree are in the position to improve patient outcomes, mitigate risks, and reduce cost (Zaccagnini & White, 2011). The AACN Essentials of Doctoral Education for Advanced Nursing Practice state nursing requires both practice experts and nurse scientists for patient care. Aligning this DNP project to these elements and competencies can lead to generating evidence through critically appraising existing

literature and other evidence to determine and implement the best evidence for practice (American Association of Colleges of Nursing, 2006).

Nature of the Doctoral Project

The goal of this systematic review was to organize findings related to the nurse's role in the informed consent with the intention to influence a policy change and effect a positive social change in nursing practice. A modified RT Delphi technique was used to measure an expert panel's reaction to the systematic review and to generate consensus to implement a nurse-driven informed consent protocol.

The reaction and answers from the expert panel will rely on the organization and analysis of the evidence. This will be established using Souza, Silva, and Carvalho (2010) six stages of the literature review process. This will be examined in more detail in Section 3.

Significance to Practice

The DNP graduate's clinical scholarship is to apply knowledge in a solution of a problem (Terry, 2015). Appraising existing literature, applying relevant findings to developing practice guidelines, designing and implementing processes to evaluate practice outcomes, and methodologies are activities of evidence-based practice that a doctoral practitioner can assume. This project can influence health care decisions and improve patient outcomes (Dearholt & Dang, 2017).

Conducting a systematic review is significant to this project and to nursing because currently, the nurse's role in the informed consent process is not clearly defined. By developing policies or protocols, nurses can be empowered in their role in the

informed consent process. It is important that nurses understand their role in the informed consent process. Having clear guidance and training is part of how we manage our patients. It sets the tone for providing the best nursing care through scientific evidence (Terry, 2015).

Summary

Arnold et al. (2008) stated that the Institute of Medicine (IOM) has challenged the American healthcare system to be more patient-centered and evidence-based. Nurses should possess the knowledge, skills, and attitudes (KSAs) to continuously improve the quality and safety within the unit in which they work (The Core Competencies Needed for Health Care Professionals, Chapter 3, 2003). The informed consent process falls within the six competencies defined by IOM: patient-centered care, teamwork and collaboration, evidence-based practice (EBP), quality improvement (QI), safety, and informatics. Despite the fact that nurses are often involved in the informed consent process, they are not driving the informed consent practice. Nurses blindly ask patients to “sign-here” on the consent form without understanding the legal and ethical implications putting their license at risk. A policy change is needed to define the nurse’s role.

A systematic review will allow for the compilation of this information and can easily lend itself to the direct role nurses have on the informed consent process. Data in the form of peer reviewed published work and articles, will be gathered by inclusion and exclusion criteria, and then analyzed using the John Hopkins nursing evidence-based practice model (Dearholt & Dang, 2017). The following section will contain concept

model, relevance to nursing practice, background information, and my role as a DNP student.

Section 2: Background and Context

Introduction

Obtaining an informed consent is a process and often, the role of nurses is to obtain and/or witness a patient giving a signed informed consent (Sim, 2008).

Researchers have found that nurses often have many different roles in the informed consent process and yet, policy does not define these roles. The practice-focused question was: Can evidence be found to support the implementation of a nurse-driven informed consent protocol? In this section, the following will be reviewed: (a) the Souza et al. (2010) six stages of project literature review, (b) relevance to nursing practice, (c) evidence on the relevance of the problem, and (d) my role with the DNP project regarding informed consent process.

Concepts, Models, and Theories

Six Stages of Systematic Literature Review

The conceptual framework for this project is the adapted literature review by Souza et al. (2010). Using different data sources can often lead to errors and bias but having a systematic and rigorous approach such as this framework can reduce this. The following is the process for preparing a literature review:

1. Preparing the guiding question
2. Searching or sampling the literature
3. Data collection
4. Critical analysis of the studies included
5. Discussion of results

6. Presentation of the systematic review

Nursing has done an excellent job in increasing its' evidence-based initiatives, so much so, that various types of reviews are needed (integrative reviews, systematic reviews, meta-analyses, and qualitative reviews. Rodgers and Knafl (2000) stated that an integrative review summarizes past empirical or theoretical literature to give a more comprehensive understanding of a healthcare problem. Systematic reviews can build nursing science, formulate research questions, and propose the need for future research and policy initiatives (Souza et al., 2010; Whittemore & Knafl, 2005).

This methodology allows combining experimental and non-experimental research which can play a greater role in evidence-based nursing practice. Despite similarities between the different reviews (meta-analyses, systematic reviews, qualitative reviews, and integrative reviews), they differ in sampling, purpose, and type of analysis. The goal of this systematic review is to review evidence or the lack of, by searching through combined data of theoretical and empirical literature. The varied sampling frame of the systematic review could potentially result in a concept, theory, or health care problem important to nursing (Cooper, 1982; Souza et al., 2010; Whittemore & Knafl, 2005).

Relevance to Nursing Practice

Implementing an effective informed consent process has been challenging for the healthcare industry especially since there are governing bodies and organizations that influence the informed consent process such as: (a) federal law and state statutes, (b) the Joint Commission Patient Safety Goals, and (c) American Hospital Association (AHA) The Patient Care Partnership. And while these legal authorities and accrediting agencies

require specific contents in the informed consent (risks and benefits) that providers or advanced practice nurses must adhere to, nurses are also guided by the Code of Ethics (ANA, 2015).

Researchers have defined the nurse's role as advocate, witness, or communicator while supporting training needs of nurses within the informed consent process. As much time as nurses spend with informed consents, they are not driving the informed consent practice. Cook (2016) conducted a literature review evaluating informed consent and nursing role which included 23 articles for analysis. Cook concluded that the 23 articles lacked data to support nurses as part of the informed consent process. Cook also called for further research and study to develop evidence-based approach to the nurse's role in informed consent. Nurses have a big impact on the informed consent process and they are in prime position to implement a practice change.

Existing Scholarship

The literature review yielded 23 peer-reviewed articles published between 2005 and 2017; and Google Scholar found an additional six articles for a total of 29 articles. Once exclusions were applied, a total of 15 articles were used for grading. The quality of literature was graded based on the updated Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) model (Dearholt & Dang, 2017). Articles that met the search criteria were weighed against each of the levels and categorized. Table 1 shows the hierarchy of evidence reviewed. The literature review matrix (Appendix A) was used for summarizing and organizing the articles in the discussion of the DNP project.

Table 1

Hierarchy of Evidence

Level	Description	Articles in Evidence
I	Experimental Study	0
II	Quasi-experimental Study	0
III	Nonexperimental Study	5
IV	Expert opinion (Systematic Review, clinical practice guidelines)	1
V	Opinion (clinical expertise, personal experience)	9

From “The Johns Hopkins Nursing Evidence-Based Practice Rating Scale”
(https://www.hopkinsmedicine.org/evidence-based-practice/ijhn_2017_ebp.html)
Reprinted with permission.

Local Background and Context

Informed Consent Process and Nurse’s Role

Participating in the informed consent process is part of a nurse’s daily task, and the role of the nurse can differ throughout the process: advocate, communicator, or witness (Susilo et al., 2013). Nurses can play the role separately or in combination depending on the situation. It is therefore, important for organizations to offer ongoing ethics training with informed consent. The following sections will reflect on how nurse-driven practice and training can improve the informed consent process.

Informed Consent Process and Training

Nurses should be aware of two forms of patient consent: (a) general or implied consent and (b) informed consent. General consent, which most nurses are familiar with,

is the patient's permission to be touched (i.e. taking their vital signs or performing routine nursing procedures). In 2005, Aveyard examined how nurses obtained consent for routine nursing procedures. Six focus groups of six to 12 nurses ($n=50$) were used in this qualitative study. Aveyard found three major themes from the data analysis: (a) the use of information prior to nursing care, (b) the patient who refuses nursing care, and (c) the patient who is unable to consent to nursing care procedures. The author found that some nurses carried out procedures after minimal or no explanation, despite patient's refusal to care, and failing to administer care in the best interest of the patient. In all three themes, Aveyard found nurses' lack of commitment to the informed consent process as a call to develop guidelines and provide training.

Agnew and Jorgensen (2010) wanted to examine the OR consenting process. A qualitative study was conducted using telephone interviews with 18 patients who either completed their informed consent two to four weeks prior to surgery or those who were consented on the day of surgery. The data were analyzed using a general inductive approach derived from grounded theory. Three themes were found as a result: (a) patient perception, (b) too little or too much information, and (c) providing clarity. The authors found that communication with their physician was deemed more important by the patients instead of the length of time they spent consulting; however, they also found that physicians did not individualize information based on patient's specific needs (Agnew & Jorgensen, 2010). They suggested that since perioperative nurses spent the most time with the patient during the surgery process, they should lead the consenting process and ensure that patients are provided enough information to make shared decision-making.

They also recommend that a policy be implemented that includes specific informed consent process training.

Fairfax, Christmas, Norton, and Jacobs (2012) explained that health care providers did not follow a standard informed consent process. In this qualitative study, critical care nurses (RN), resident physicians (RES), advanced practitioners (AP), and attending physicians (ATT) were surveyed to determine variations in the consent process. The response rate was 134 of 610 participants (22%) with 51% RN ($n=68$), 17% RES ($n=23$), 7% AP ($n=9$), and 25% ATT ($n=34$). Fairfax et al. (2012) found that 34% physicians (ATT) and 27% residents (RES) did not have informed consent discussions with 50% or more of their patients. This showed that more effort must be made with implementing evidence-based standards with the informed consent process to protect patients and health care providers.

The theme of training and policy resonated with Tabak and Zvi (2008). In this scholarly paper, the authors examined how nurses were faced with a minor and their participation in the informed consent process. A 15-year-old who was able to have a doctor-patient relationship was denied this by his strictly religious Jewish family. The boy was not able to consent on the course of treatment. Emancipation rules differ within each State, country, and laws. Within Israeli law, the parents are the child's representatives and they partner with the medical staff in the informed consent process. Nonetheless, a doctor-patient relationship is built on trust and mutual understanding which was hindered when the parents did not include the child in the decision-making process. Often times, nurses can be vital in these situations by acting as a mediator,

coordinator, and advocate. Tabak and Zvi recommend that for nurses to become comfortable in these situations, a training program should be available to help them learn and develop skills in obtaining informed consent, as well as applying protocols that will provide solutions to difficult situations such as this.

Aside from the need for providing training and implementing policy, organizations need to revamp their informed consent process. Patient engagement and shared decision-making can only happen if patients can understand the informed consent. Lorenzen, Melby, and Earles (2008) worked on enhancing the informed consent process by using the principles of health literacy at an Iowa Health System network of facilities located in two states. The pilot test began with completely revamping the consent document and health care providers completing a computer-based learning module focusing on informed consent as a process. Nurses were specifically trained in the teach-back process to evaluate patient understanding. Once the teams agreed on content and design of consent document, implementation began in an ambulatory surgery facility. Lorenzen et al. (2008) wanted to (a) increase the number of patients to read the consent form before signing it and (b) increase documenting patient knowledge of anticipated procedure. The results compared the ambulatory nursing staff members survey tool between patients ($n=41$) who received the original consent form; and Campus 1 patients ($n=35$) and Campus 2 patients ($n=53$) who received the new consent form. Lorenzen et al. (2008) found that the data did support the anticipated results: Campus 1 (77% patients) and Campus 2 (91% patients) read the consent compared to the original consent; and adding the teach-back portion provided the nurses with an assessment tool for

measuring patients' understanding of their procedures. This pilot was successfully adopted by the health system.

Advocate

A patient's understanding can be hindered by age, medication, or the disease process; therefore, nurses should always assess their patients during the informed consent process. The Population Reference Bureau (Mather, 2016) reported that by 2060, the aging population of the United States will double to over 98 million (ages 65 and older). This population poses a significant challenge for the medical community – increases in nursing home care, a rise in Alzheimer's disease, and increases in obesity rates. With increased hospitalization, it is even more important for nurses to assess decision making capacity and their ability to give informed consent.

Vaartio-Rajalin and Leino-Kilpi (2011) found this especially important with oncology patients. They defined advocacy as an iterative process whereby nurses are constantly analyzing, counseling, and responding to patients' care and self-determination preferences. The patient's understanding and consent during the treatment phase can dramatically change once they begin treatment. A literature review was conducted by Vaartio-Rajalin and Leino-Kilpi on nurses' advocacy activities: analyzing, counseling, and responding. Deductive analysis on 42 articles was used to compare description of oncology nurses' advocacy activities to activities previously identified by Vaartio (2008) and Vaartio, Leino-Kilpi, Suominen, and Puukka (2008). Vaartio-Rajalin and Leino-Kilpi (2011) found that oncology nurses played an important role in educating patients and families within the informed consent process; and that a structured instrument for

measuring the information needs of patients with cancer during different phases of the illness is needed.

This was also observed by Gladfelter (2006) and Grace and McLaughlin (2005) who opined that nurses are advocates of patient education and patient safety. Gladfelter believed that the more information a patient received about their plastic surgery the more realistic their expectations would be for the procedure. Gladfelter suggested that a web-based educational tool would improve patients' decision-making. Gladfelter also noted that the nurse's role of advocate is ensuring that patients understand and comprehend the informed consent process, this allows for quality care and support for the informed consent process.

Grace and McLaughlin (2005) described how nurses can deal with ethical issues within the informed consent process. In this article, a veteran nurse starting in a new facility assessed that her maternity patient did not fully understand the procedure for her breeched baby. Although the physician discussed the procedure with the patient and the consent form was signed; the nurse began to suspect that the patient did not fully understand the complications associated with the procedure. Despite voicing concerns to the physician, it was ignored and the baby went into distress calling for an emergency C-section. According to the Code, nurses are obliged to be patient advocates but often times, nurse's concerns are not taken seriously. Nurses should be able to raise concerns at the institutional level or by peer review while also being provided by ongoing ethics training within the informed consent process.

The role of witness is also conveyed in the article by Clifford (2013). In this expert opinion paper, Clifford reviewed the two types of patient consent: (a) general consent which for example, involves permission to obtain vital signs and (b) informed consent. Perianesthesia nurses know that they are often the witness to the informed consent. Similar to other articles, Clifford emphasized that nurse can advocate for patients by continually assessing, educating, and communicating on behalf of patients.

Advocating for patients can also involve family members. Mahon (2010) addressed this issue involving geriatric patients. There will be many times when a nurse must determine not only the patient's capacity to consent but also who should decide for the patient if they are not able to consent. For these reasons, informed consent training and clear policy is needed.

Communicator

The nurse is the hub of communication achieved through assessing, gathering, and interpreting information between the health care team, family members, and patients. Developing effective communication skills is vital especially during the informed consent process (Gladfelter, 2006). In Axson, Giordano, Hermann, and Ulrich (2017), 20 full-time baccalaureate prepared registered nurses were surveyed to understand what they knew about the informed consent process. The qualitative descriptive study used a semi-structured interview approach and found three nursing roles in the informed consent process: (a) the nurse as communicator, (b) the nurse as advocate, and (c) the clerical role of the nurse. Axson et al. (2017) found that nearly half ($n=9$) did not agree that the nurses had a defined role in the informed consent process despite the numerous daily encounters

across different clinical settings. The participants revealed to the researchers that nurses often participated in the informed consent process by addressing their patient's needs and "did so without clearly delineated guidelines regarding the nursing role as it pertains to informed consent" (Axson et al., 2017, p. 6). For nurses to be effective and proficient in the ethical challenges nurses face within the informed consent process, they need to be provided with ongoing ethics educational training so they can meet the needs of their patients and families.

Moore (2016) found that nurses faced challenges when educating patients about induced labor since many women were already influenced by their physician and because most clinician offices employ non-nursing staff. In this analysis, the author found that nurses faced challenges to providing high-quality, effective models of maternity care especially within three concepts: (a) shared decision-making, (b) informed consent, and (c) women's use of evidence within the context of maternity care. The informed consent process is an appropriate opportunity to include women in the informed, shared decision-making models of maternity care and nurses have an opportunity to improve the process through adequate communication tools.

Witness

While it is the provider/clinician's responsibility to initiate and discuss the risks and benefits of the informed consent with the patient, the nurse is often expected to witness the patient's signature on the form. The role of advocate and communicator is essential before the patient gives consent; this is when a nurse can assess the patient for concerns or questions, as well as his/her capacity to understand the risks and benefits.

Often nurses are faced with complicated situations such as those patients with different cultural or religious beliefs (Nasrabadi & Shali, 2017). In Marrone (2016), a nurse was faced with witnessing a patient's consent who was of Saudi decent. The physician explained the risks and benefits of the scheduled coronary artery bypass surgery but when it came to sign the consent, the patient allowed her husband and her father to sign for her. The legal interpretation of the witness is that he or she observed that it was the patient who signed the consent form (Marrone, 2016). This can be concerning for many nurses. Marrone (2016) suggested that health care organizations should develop, implement, and evaluate goals and standard operating procedures that will protect all stakeholders while responding to diverse needs of patients and families during the informed consent process.

Role of the DNP Student

My motivation for this DNP project grew out of my experience with working with electronic health initiatives as a program manager and clinical informaticist. As more and more organizations are implementing electronic health records and applications, paper-based processes such as informed consents can be improved and provide data on patient engagement, patient outcomes, and the nurse's added value to care.

The healthcare system is changing through technology, new policies, new healthcare delivery systems (i.e. PCMH, Patient Centered Medical Home), and quality improvement. Defining roles, having measurable data, and providing evidence-based practice for informed consent can improve patient outcomes and encourage shared-decision making.

Summary

The informed consent process needs an overhaul. The Joint Commission has reported 48 sentinel events involving informed consents since 2010 and in 2017, surveyors identified compliance issues related to informed consent in over 500 hospitals (Improving the Informed Consent Process in the Hospital Setting, 2017). Health care organizations can improve their informed consent process by revamping their policy and improving training for nurses' emerging role in informed consent process.

Nurses are not legally responsible for obtaining the informed consent unless they are an APRN such a Nurse Practitioner or a Nurse Anesthetist. Typically, their role is to collect or witness the signature of the patient. But ethically, the nurse's role is to be the patient's advocate. It is within this role that nurses can determine whether patients have received sufficient information to make an informed decision. The next section will highlight the sources of evidence gathered, the steps taken, and the analysis procedure for the practice-focused question.

Section 3: Collection and Analysis of Evidence

Introduction

The purpose of this project was to conduct a systematic literature review to find evidence that will influence policy change for the nurse's role in the informed consent process. Nurses have an opportunity to facilitate practice change but nurses need organizational support through policy and guidelines to define their role in the informed consent process.

The nurse's role in the informed consent process has been examined by the nursing profession around the world. There is no question as to who is responsible for obtaining consent – it is the provider's responsibility. But nurses are faced with situations which can disrupt the process like clashes between a teenage patient and his parents, a legally competent developmentally-delayed adult who does not fully understand the risks, or a Muslim woman who cannot speak for herself. The nurse's role in the informed consent process is complex; one that has many considerations of ethics, law, and facility policy. A standard of practice can help nurses work according to the ANA Ethics Code and advocate for their patient.

Practice-Focused Question

The nurse has many roles in the informed consent process: communicator, advocate, and clerk as noted by Axson et al. (2017). Yet, if nurses are asked about their role, there is a lot of confusion. There is no question that many, if not all, nurses will face ethical questions related to informed consent and as a healthcare provider, patient safety and understanding is part of their responsibility. Nevertheless, there is little support for

nurses to adopt a practice guideline for their role in in the informed consent process. Can evidence be found to support the implementation of a nurse-driven informed consent protocol?

Sources of Evidence

Published Outcomes and Research

A systematic literature review was used for this DNP project as the primary source of evidence. Whitemore and Knafl (2005) found that reviews included a combination of diverse methodologies that are relevant to evidence-based nursing. The Walden University library was used to identify potential articles for current evidence using: MEDLINE (Medical literature), CINAHL (Cumulative Index to Nursing and Allied Health Literature), CINAHL Plus with Full Text, MEDLINE with full text, and PsycINFO (Psychological Information).

The search terms were identified by scanning background literature and included the following key words: *nurse* and *informed consent*. The search was narrowed using Boolean searches: *nurse*, *informed consent*, and *patient understanding*. Exclusions were applied to narrow the results: articles not written in English, articles that did not have a direct correlation between nurses and informed consent, and articles not related to surgical/procedural consents.

Evidence Generated for the Doctoral Project

Participants. A panel of experts was used to reinforce the validity of the literature and to determine if it they would support the implementation of a nurse-driven informed consent protocol. Panel eligibility criteria included: (a) a position title that has

direct provider-patient relationship, (b) position title that can influence policy, or (c) nurses who function in a patient care setting, where informed consent processes are part of their day-to-day experience. The 20 expert panelists came from four different nursing disciplines: (a) nurses from administrative areas with policy-making authority, (b) certified registered nurse anesthetists (CRNAs), (c) nurses in unit management managerial positions, and (d) nurses in staff nurse positions who are involved in informed consent processes regularly. Steps were taken to avoid liability and maintain participant's anonymity.

Procedures. A modified RT Delphi method was used to gather the panels' expert judgement and to generate consensus. The Delphi method was developed by RAND Corporation and has been used across many disciplines (Gordon & Pease, 2006). Although an effective method in planning, decision-making and policy research, it has been criticized for its lengthy process. In 2004, Defense Advanced Research Projects Agency (DARPA) improved the process and allowed consensus to be in real-time: RT Delphi. The modified RT Delphi included two rounds of surveys: (a) six questions for Round I and (b) 10 questions for Round II (Appendix C). Face and Content validity was established by securing a review of the data collection instruments from a chief nursing officer who was interested in the systematic review.

An e-mail invitation was sent to 20 nurses from various treatment facilities throughout the United States that included a brief introduction and a request to participate. Once the panel had been identified, a follow-up email included the power point presentation (Appendix E) that highlighted the practice-focused question, the

results of the literature search, the significance to nursing practice and a draft nurse-driven protocol (Appendix D); as well as the instructions to access the survey. Surveys were generated via Survey Monkey. Panel members were given one week to review and complete the survey for each round.

Protections. A Walden University's IRB Form A (preliminary review form) was completed and approved with the Number 04-06-18-0312046. All data collected via Survey Monkey were summarized in a de-identified way to maintain participant's anonymity. All results and findings were held confidential.

Analysis and Synthesis

The modified RT Delphi consisted of two rounds of survey questions. The initial round included six questions while the second round included 10 questions. IBM SPSS was used to perform descriptive statistics, Cronbach's Alpha, and Fisher's exact test. This analysis should influence the need to update a policy supporting the nurse-driven informed consent protocol (Appendix D).

Summary

Nurses, nurse practitioners, or other advanced practice nurses who must treat or provide a procedure to a patient is required to obtain an informed consent. In most cases, it is the physician's responsibility to obtain consent, but nurses are often involved in the process either as a witness to the patient's signature or as a communicator between the patient and health team. I explored the various nurse roles implicit within the informed consent process, as well as the informed consent process itself. The success of this project necessitates collaboration with the subject matter experts and their participation with the

survey. A central theme was derived from the analysis and possibly encouraged further DNP projects, research and/or policy development. Section 4 contains findings from the expert panel survey and recommendations for improving the nurse's role within the informed consent process.

Section 4: Findings and Recommendations

Introduction

Nurses are very involved with the informed consent process. The literature addressed the many roles of nurses within the informed consent process: advocate, witness, communicator (Axson et al., 2017), and the different ethical situations that can occur. Many times, nurses initiate the process without fully understanding the risk or legal implication to their licensure (Rock & Hoebeke, 2014). However, there is a practice gap in many organizations, because the nurse's role is not clearly defined. The purpose of the DNP project was to evaluate the literature and use the results of the systematic literature review to support the implementation of a policy change and meet the training needs of nurses in the informed consent process. The literature review found few quantitative, experimental studies regarding the nurse's role in the informed consent process. The adapted literature review by Souza et al. (2010) was used to determine the articles for review (Figure 1) while the John Hokins Nursing Evidence-Based rating scale (Figure 2) was used to analyze the included articles.

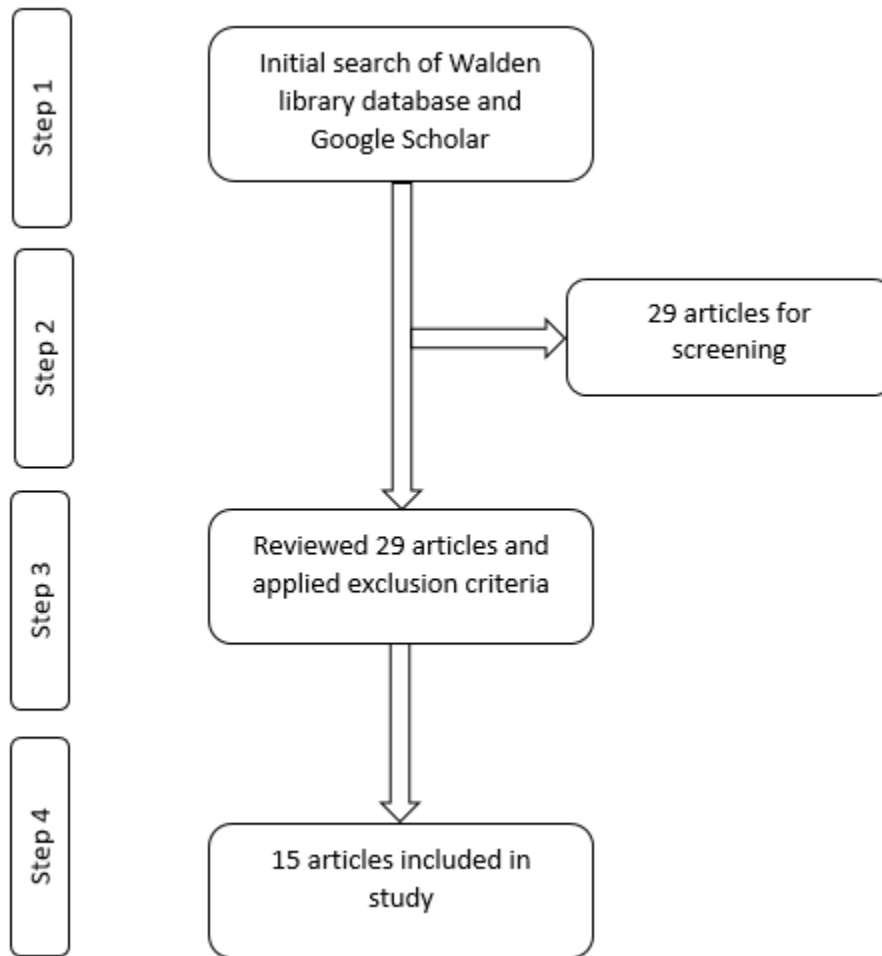


Figure 1. Inclusion Process for Literature Review.

STRENGTH of the Evidence		
Level I		Experimental study/randomized controlled trial (RCT) or meta analysis of RCT
Level II		Quasi-experimental study
Level III		Non-experimental study, qualitative study, or meta-synthesis.
Level IV		Opinion of nationally recognized experts based on research evidence or expert consensus panel (systematic review, clinical practice guidelines)
Level V		Opinion of individual expert based on non-research evidence. (Includes case studies; literature review; organizational experience e.g., quality improvement and financial data; clinical expertise, or personal experience)

QUALITY of the Evidence		
A High	Research	consistent results with sufficient sample size, adequate control, and definitive conclusions; consistent recommendations based on extensive literature review that includes thoughtful reference to scientific evidence.
	Summative reviews	well-defined, reproducible search strategies; consistent results with sufficient numbers of well defined studies; criteria-based evaluation of overall scientific strength and quality of included studies; definitive conclusions.
	Organizational	well-defined methods using a rigorous approach; consistent results with sufficient sample size; use of reliable and valid measures
	Expert Opinion	expertise is clearly evident
B Good	Research	reasonably consistent results, sufficient sample size, some control, with fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence
	Summative reviews	reasonably thorough and appropriate search; reasonably consistent results with sufficient numbers of well defined studies; evaluation of strengths and limitations of included studies; fairly definitive conclusions.
	Organizational	Well-defined methods; reasonably consistent results with sufficient numbers; use of reliable and valid measures; reasonably consistent recommendations
	Expert Opinion	expertise appears to be credible.
C Low quality or major flaws	Research	little evidence with inconsistent results, insufficient sample size, conclusions cannot be drawn
	Summative reviews	undefined, poorly defined, or limited search strategies; insufficient evidence with inconsistent results; conclusions cannot be drawn
	Organizational	Undefined, or poorly defined methods; insufficient sample size; inconsistent results; undefined, poorly defined or measures that lack adequate reliability or validity
	Expert Opinion	expertise is not discernable or is dubious.

*A study rated an A would be of high quality, whereas, a study rated a C would have major flaws that raise serious questions about the believability of the findings and should be automatically eliminated from consideration.

Figure 2. John Hopkins Nursing Evidence-Based Rating Scale. Reprinted with permission from “The Johns Hopkins Nursing Evidence-Based Practice Rating Scale” (https://www.hopkinsmedicine.org/evidence-based-practice/ijhn_2017_ebp.html)

Summary Findings

There were no Level I and Level II articles of the 15 articles analyzed. There were however, five Level III articles, one Level IV article, and nine Level V articles that were analyzed. Of the 15 articles, three subthemes were identified: (a) witness, (b) advocate, and (c) communicator; while five particular articles emphasized the need for implementing or changing policy and offering ongoing ethics training to nurses regarding their role with informed consent.

Agnew and Jorgensen (2012) offered the recommendation to policy makers and nurse managers that perioperative nurses should have specific training and have a developed structured process so they can continue to advocate for their patients prior to

surgery. Policy and training can improve the patient's understanding of what is included in the informed consent while allowing the perioperative nurse time with each patient.

Marrone (2016) focused not only policy and training but also on research, education, and practice development with regards to informed consent. Marrone suggested that health care organizations work together and in accordance with applicable laws and accreditation standards so that these facilities can be responsive to the diverse needs of patients. Health care organizations should implement appropriate goals, policies, and management accountability with the informed consent process whereby services can ensure cultural, patient-centered decision-making (Marrone, 2016).

Hospitals should not only consider the cultural differences of patients but should also focus on the organization's culture (Grace & McLaughlin, 2005). Susilo, Scherpbier, Tanto, Yuhanti, and Ekawati (2013) recommended that hospital policy and culture should be changed so nurses can better understand their role within the informed consent process so perceptions won't influence clinical knowledge and education in legal and ethical perspectives with informed consent.

Finally, Tabak and Zvi (2008) recommended that nurses be included in local ethics committees and nursing-policy-making bodies so that appropriate decision-making protocols be developed to ensure nurses can respond to different ethical situations and continue to advocate for patients during the informed consent process.

The 15 articles from the systematic literature review were presented to a panel of experts as a way to influence their thinking and revise a policy supporting a nurse-driven informed consent protocol. Nurses play key roles in the informed consent process.

However, they do not drive the informed consent practice, and policies are not consistent with the ANA Code of Ethics.

The IBM Statistics 24 software was used to perform a descriptive statistic for discrete measures of demographics and characteristics of the expert panel (Table 2). There were 16 study participants of 20 invited who completed the survey resulting in an 80% response rate. The expert panel members were mostly female (56.3%), with half having 5-10 years (50%) and the other half having greater than 10 years of nursing experience (50%), and half currently working as clinical/staff nurses (50%).

Table 2

Demographic and Characteristic of Expert Panel

	Percent
Gender	
Male	43.8
Female	56.3
Years of Experience as a Nurse	
1-3	
3-5	
5-10	50.0
>10	50.0
Education	
Associates	6.3
Bachelors	31.3
Masters	31.3
Masters not in Nursing	6.3
Doctorate	18.8
Doctorate not in Nursing	6.3
Nursing Job/Role	
Clinical/Staff	50.0
Nurse Educator	18.8
Advanced Practice Nurse (CRNA, NP, CNS, etc.)	6.3
Clinical Nurse Leader (Head Nurse, Nurse Manager)	12.5
Nursing Leadership (Middle Level Management, CNO)	12.5

The IBM Statistics 24 software was also used to conduct Cronbach's Alpha to establish internal consistency reliability among the survey questions pertaining to the

draft nurse-driven informed consent protocol ($N = 4$). The survey used a 5-point Likert scale, where 5 = *strongly agree* and 1 = *strongly disagree*. Reliability measures are shown in Table 3. Cronbach's alpha showed the questionnaire reached high internal consistency, $\alpha = .70$. Cronbach's (1951) rule-of-thumb is that alpha should reach 0.70 for an instrument to have an acceptable level of self-consistency.

Table 3

Reliability Statistics – Cronbach's Alpha

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.703	.726	4

Note: The responses to the survey are on a 5-point scale, where 5 = Strongly Agree and 1 = Strongly Disagree.

The intent of the project was to influence the expert panel to implement a policy change for a nurse-driven informed consent protocol based on the literature review for the defined nurse's role in the informed consent process. A Fisher Exact test ($p = 1.0$) was then performed and found both staff and management nurses would equally advocate for the policy change (Table 4), as 13 of the respondents approved of the draft policy and three did not, an 81% support rate. This reinforced what was found in the literature that: (a) nurses play a major role in the informed consent process and (b) a change to policy/protocols is needed.

It is likely that additional Delphi rounds might have resulted in consensus with 100% of the panel approving the draft policy, as the literature found was compelling

enough to convince most members of the panel. This notwithstanding, interviews were conducted with the three dissenters to determine barriers. This qualitative data surfaced four themes: (a) concern about legal consequences of a nurse-driven informed consent, (b) despite the literature presented, the perception is that informed consent is the physician's responsibility, (c) given all of the staff nurses' current responsibilities, there is no time for more active nurse involvement, and (d) fear of reprisal when the nurse's advice as communicator and advocate goes contrary to the advice of the surgeon.

Table 4

Staff and Managers Willing to Implement Nurse-Driven Informed Consent

*Protocol***Error! Bookmark not defined.**

Position	Implement Nurse-Driven Informed Consent Protocol		
	Yes	No	Total
Staff	7	2	9
Manager	6	1	7
Total	13	3	16

Fisher's exact two-tailed test $p=1.0$ ($p>.05$).

Implications

The results of this project have great implications for the nursing community. The literature review showed how involved nurses are within the informed consent process; yet, the practice lacks any nurse involvement at the DNP practice setting. Nurses can act as an advocate, communicator, witness, or facilitator in the informed consent process.

Currently, local policy drives how nurses participate regardless of the fact that nurses often do more than witness a signature.

The nursing community should take a closer look at their local informed consent policy and implement changes that will coincide with the ANA Code of Ethics to support nursing practice. This is a great opportunity to drive change and expand training for the nurse's role in the informed consent process. This is especially true for the novice nurses. Of the three panel members who did not agree with advocating for a nurse-driven informed consent protocol, two clinical/staff nurses did not think they could influence policy or any practice change due to their lack of seniority. The editor-in-chief for American Nurse Today, Gelinias (2018) has said that for change to be successful, nurses need new skills and new levels of understanding. To empower all nurses, education and training should be ongoing to include the informed consent process

There was one manager who also did not agree with advocating for a nurse-driven informed consent protocol. This panel member, although in a leadership position, did not work in a clinical area so is unfamiliar with the current, local informed consent policy. If time permitted, more conversation would probably have influenced this expert.

Recommendations

An initial recommendation would be to conduct research studies so that the role of the nurse in the informed consent process be supported by data and theory. The nurse's role in the informed consent process is not just limited to witnessing the patient's signature. They also advocate, communicate, and provide patient support (i.e., clarify, explain, answer questions) throughout the process.

Though the literature review was adequate to convince the majority of the expert panel (13 of 16 expert panel members, 81.25%), more evidence is needed to persuade the three who dissented. Studies of informed consent are mostly conducted in acute care settings such as peri-operative specialty areas or in clinical trials research. More studies are needed in different care settings and not only for operative procedures. Informed consents are also required for feeding tube or central line placement. Further discussion is needed to break down barriers and stereotypes with informed consents (i.e. it is the physician's responsibility). Bonsall (2015) wrote that informed consent is a way of nursing, so nurses should find ways to improve the process.

Another recommendation would be for nursing leaders to implement a nurse-driven informed consent protocol similar to the draft example in Appendix D. Studies have shown that nurse driven protocols have improved patient outcomes (Grap et al., 2003), contained cost (Bair, Ivascu, Nittis, & Howells, 2005), increased nursing job satisfaction (Beck & Johnson, 2008), and increased retention rates in many hospitals. For a nurse-driven informed consent process to be successful, support from corporate is crucial. Luckily, there are numerous articles that nurses can reference to help implement a protocol.

Strengths and Limitations

The strength of this project was the realization that the systematic literature review found evidence that nurses play many roles in the informed consent process. The challenge now is developing evidence-based practice on the nurse's role in the process and to implement ongoing training for nurses. Future research on the informed consent

process should include more Level IV and Level V studies and should address barriers to an expanded nurse's role in the informed consent process. A limitation of the project was that I had a limited number of Delphi rounds. With more discussion and conversation (and perhaps additional opportunities that were "face to face" rather than virtual), the three dissenters might have changed their mind about supporting the policy after their perceived barriers were addressed. Another limitation to this project is selection bias. Despite following a guided inclusion criteria process, having one literature reviewer increased the likelihood of selection bias. A minimum of two independent reviewers would decrease this limitation.

Section 5: Dissemination Plan

Dissemination Plan

There is a practice gap with the informed consent process despite the major role nurses play in the process. Local policies do not define the nurse's role which is inconsistent with the changes made to the ANA Code of Ethics. The systematic literature review discovered that the nurse's role differed throughout the process and that more training is needed for the practice. Encouraging nurse leaders to implement a nurse-driven protocol can improve the practice of informed consent process. This can easily be done, by me after graduation - I would like to have several poster presentations at different nursing conferences (i.e. ANIA or HIMSS) and assist with actually facilitating a nurse-driven informed consent protocol and training plan.

Analysis of Self

This literature review provided me with the opportunity to learn in great depth what is and what a systematic literature review isn't. The intent was to complete a full systematic review but finding appropriate articles proved to be lacking. Although, this process was immensely valuable, as it increased my skills in the selection and exclusion criteria. Another process that proved to be valuable was producing the surveys and producing a draft policy/protocol,

As I continue in my career as a Nurse Informaticist, I have come to recognize that there are still many practice gaps in nursing, especially as organizations are implementing health information technology (e.g. mobile apps, new electronic health records). There are many opportunities for new DNP practitioners to improve nursing practice and

implement training needs for nurses so they can deliver quality care to our complex population.

Summary

Discovering evidence for the different nursing roles in the informed consent process is significant to nursing practice. The gap between policy and practice needs to be decreased; and this can be done by supporting nurse-driven protocols. Nurse leaders must also be made aware that nurses need ongoing ethical training to include the informed consent process. This is especially true as our patients become more complex and more culturally diverse. Awareness and education can protect nurses and improve patient satisfaction with informed consent.

References

- Agnew, J., & Jorgensen, D. (2012). Informed consent: A study of the OR consenting process in New Zealand. *AORN Journal*, 95(6), 763-770.
- Arnold, S., Decker, C., Ahmad, H., Olabiyi, O., Mundluru, S., Reid, K., . . . Spertus, J. (2008). Converting the informed consent from a perfunctory process to an evidence-based foundation for patient decision-making. *Cardiovascular Quality and Outcomes*, 1, 21-28.
- Aveyard, H. (2005). Informed consent prior to nursing care procedures. *Nursing Ethics*, 12(1), 19-29.
- Axson, S., Giordano, N., Hermann, R., & Ulrich, C. (2017). Evaluating nurse understanding and participation in the informed consent process. *Nursing Ethics*.
- Bair, H., Ivascu, F., Nittis, P., & Howells, G. (2005). Nurse driven protocol for head injured patients on warfarin. *Journal of Trauma Nursing*, 12(4), 120-126.
- Beck, L., & Johnson, C. (2008). Implementation of a nurse-driven sedation protocol in the ICU. *Dynamics*, 19(4), 25-28.
- Bonsall, Lisa (2015). Informed Consent: An Ethical Way of Nursing. Retrieved on May 16, 2018 from [https://www.nursingcenter.com/ncblog/may-2015-\(1\)/informed-consent-an-ethical-way-of-nursing](https://www.nursingcenter.com/ncblog/may-2015-(1)/informed-consent-an-ethical-way-of-nursing).
- CDC/NCHS National Hospital Discharge Survey. (2010). Retrieved September 20, 2017, from Centers for Disease Control and Prevention, National Center for Health Statistics (NCHS) Ambulatory and Hospital Care Statistics Branch:

http://www.cdc.gov/nchs/data/nhds/4procedures/2010pro4_numberprocedureage.pdf

Clifford, T. (2013). Informed Consent - Role of the Perianesthesia Nurse. *Journal of PeriAnesthesia Nursing*, 28(6), 413-414.

Code of Ethics for Nurses with Interpretive Statements. (2015). Silver Spring: Nursesbooks.org.

Cook, W. (2016). "Sign Here;" Nursing Value and the Process of Informed Consent. *Plastic Surgical Nursing*, 34(1), 29-33.

Cooper, H. (1982). Scientific Guidelines for Conducting Integrative Research Reviews. *Review of Educational Research*, 52(2), 291.

Cronbach, L. (1951). Coefficient alpha and the internal structure of tests. *Psychometrika*, 16, 297-334.

Dearholt, S., & Dang, D. (2017). *Johns Hopkins Nursing Evidence-Based Practice*. Indianapolis: Sigma Theta Tau International.

Fairfax, L., Christmas, B., Norton, J., & Jacobs, D. (2012). Breakdown of the Consent Process at a Quaternary Medical Center: Our Full Disclosure. *The American Surgeon*, 78, 855-863.

Faram, M. (2016, December 20). Navy reports decline in medical malpractice. Retrieved from <https://www.navytimes.com/navy-times/news/your-navy/2016/12/20/navy-reports-decline-in-medical-malpractice/>

Gallegos, M. (2014, April 18). Consent form goes electronic at BAMC. Retrieved from <https://bamc.amedd.army.mil/articles/2014/bamc-electronic-consent-form.asp>

- Gelinas, Lillee (2018). Sparking change in Nursing [Editorial]. *American Nurse today*, 13(5), 4.
- Gladfelter, J. (2006). Managing Patient Expectations. *Plastic Surgeon Nursing*, 26(2), 73-76.
- Gordon, T., & Pease, A. (2006). RT Delphi: an effort, “round-less” almost real time Delphi method. *Technology Forecasting and Social Change*, 73(4), 321-333.
- Grace, P., & McLaughlin, M. (2005). When Consent Isn’t Informed Enough. *American Journal of Nursing*, 105(4), 79-84.
- Grap, M., Strickland, D., Tormey, L., Keane, K., Lubin, S., Emerson, J., . . . Sessler, C. (2003). Collaborative practice: development, implementation, and evaluation of a weaning protocol for patients receiving mechanical ventilation. *American Journal of Critical Care*, 12, 454-460.
- Ham-Baloyi, W., & Jordan, P. (2016). Systematic review as a research method in post-graduate nursing education. *Health SA Gesondheid*, 21, 120-128.
- Improving the Informed Consent Process in the Hospital Setting. (2017). Retrieved July 16, 2017, from Joint Commission:
https://www.jointcommission.org/informed_consent_process_training.aspx
- Liu, Y., Aunguroch, Y., & Yunibhand, J. (2016). Job satisfaction in nursing: a concept analysis study. *International Nursing Review*, 63(1), 84-91.
- Lorenzen, B., Melby, C., & Earles, B. (2008). Using Principles of Health Literacy to Enhance the Informed Consent Process. *AORN Journal*, 88(1), 23-29.

- Mahon, M. (2010). Advanced Care Decision Making: Asking the Right People the Right Questions. *Journal of Psychosocial Nursing & Mental Health Services*, 48(7), 13-19.
- Marrone, M. (2016). Informed Consent Examined within the Context of Culturally Congruent Care: An Interprofessional Perspective. *Journal of Transcultural Nursing*, 27(4), 342-348.
- Mather, M. (2016, January). Fact Sheet: Aging in the United States. Retrieved February 5, 2018, from <http://www.prb.org/Publications/Medica-Guides/2016/aging-unitedstates-fact-sheets.aspx>
- Menendez, J. (2013). Informed Consent. *JONA Healthcare Law, Ethics, and Regulation*, 15(4), 140-144.
- Moore, J. (2016). Women's Voices in Maternity Care: The Triad of Shared Decision Making, Informed Consent, and Evidence-Based Practice. *Journal of Perinatal Neonatal Nursing*, 30(3), 218-223.
- Nasrabadi, A., & Shali, M. (2017). Informed Consent: A Complex Process in Iran's Nursing Practice. *Journal of Korean Academy of Nursing Administration*, 23(3), 223-228.
- Rock, M., & Hoebeke, R. (2014). Informed Consent: Who's Duty to Inform? *MEDSURG Nursing*, 23(3), 189-191.
- Rodgers, B., & Knafl, K. (2000). *Concept development in nursing: foundations, techniques, and applications*. Philadelphia: Saunders.

- Sim, J. (2008). Your role in informed consent: Part 1. Dimensions of Critical Care Nursing, 27(2), 70-73.
- Souza, M., Silva, M., & Carvalho, R. (2010). Integrative review: what is it? How to do it? Einstein (Sao Paulo), 8(1), 102-106.
- Spatz, E., Krumholz, H., & Moulton, B. (2016). The New Era of Informed Consent. JAMA, 15(19), 2063-2064.
- Susilo, A., Van Dalen, J., Scherpbier, A., Tanto, S., Yuhanti, P., & Ekawati, N. (2013). Nurses' Role in Informed Consent in a Hierarchical and Communal Context. Nursing Ethics, 20(4), 413-425.
- Tabak, N., & Zvi, M. (2008). When Parents Refuse a Sick Teenager the Right to Give Informed Consent: The Nurse's Role. Australian Journal of Advanced Nursing, 25(3), 106-111.
- Terry, A. (2015). Clinical research for the doctor of nursing practice. 2nd ed. Burlington: Jones & Bartlett Publishing.
- The Core Competencies Needed for Health Care Professionals. (2003). Retrieved from Health Professions Education: A Bridge to Quality: <https://www.ncbi.nlm.nih.gov/books/NBK221519/>
- The Essentials of Doctoral Education for Advanced Nursing Practice. (2006). Retrieved January 4, 2016, from American Association of Colleges of Nursing: <http://www.aacn.nche.edu/publications/position/DNPEssentials.pdf>

- Vaartio, H. (2008). Maintenance of advocacy in everyday practice of procedural pain care. Prague: EACME Conference “Organizing Bioethics. Challenges for Western, Central and Eastern Europe.”
- Vaartio, H., Leino-Kilpi, H., Suominen, T., & Puukka, P. (2008). The content of advocacy in procedural pain care – patients’ and nurses’ perspectives. *Journal of Advanced Nursing*, 64(5), 504-513.
- Vaartio-Rajalin, H., & Leino-Kilpi, H. (2011). Nurses as Patient Advocates in Oncology Care: Activities Based on Literature. *Clinical Journal of Oncology Nursing*, 15(5), 526-532.
- Whittemore, R., & Knafl, K. (2005). The integrative review: updated methodology. *Journal of Advanced Nursing*, 52(5), 546-553.
- Zaccagnini, M., & White, K. (2011). *The Doctor of Nursing Practice Essentials*. Sudbury: Jones & Bartlett Publishing.

Appendix A: Literature Summary With Level of Evidence

Reference	Research Method	Main Findings	Level of Evidence	Key Word(s)
Agnew, J. and Jorgensen, D. (2010). Informed Consent: A Study of the OR Consenting Process in New Zealand. <i>AORN J</i> 95, pp.763-770.	Qualitative Study	Perioperative nurses are in the position of advocating and ensuring patients understand the informed consent process.	III	Informed Consent Process Training Policy
Aveyard, H. (2005). Informed Consent Prior to Nursing Care Procedures. <i>Nursing Ethics</i> , 12(1), pp. 19-29.	Qualitative Study	Consent prior to nursing care procedures is an essential but undeveloped concept, for which a new ethos is required.	III	Informed Consent Process Training
Axson, S., Giordano, N., Hermann, R., and Ulrich, C. (2017). Evaluating nurse understanding and participation in the informed consent process. <i>Nursing Ethics</i> ,	Qualitative descriptive study	Nurses believe they do not have a clear defined role in the informed consent process despite having many roles throughout the process.	III	Communicator
Clifford, T. (2013). Informed Consent – Role of the Perianesthesia Nurse. <i>Journal of PeriAnesthesia Nursing</i> , 28(6), pp.413-414.	Expert Opinion	Perianesthesia nurses have a responsibility to ascertain that the patient has a clear understanding of the proposed interventions and to advocate on behalf of patients who express any ambiguity.	V	Advocate
Fairfax, L., Christmas, B., Norton, J., and Jacobs, D. (2012). Breakdown of the Consent Process at a Quaternary Medical Center: Our Full	Qualitative Study	This study showed variation in consent practices among practitioners.	III	Informed Consent Process Training

Disclosure. The American Surgeon, 78, pp.855-863.				
Gladfelter, J. (2006). Managing Patient Expectations. Plastic Surgical Nursing, 26(2), pp.73-76.	Expert Opinion	By incrementally improving the quality of information that patients receive and by supporting the process of informed consent, mismanaged patient expectations can be reduced.	V	Advocate
Grace, P. and McLaughlin, M. (2005). When Consent Isn't Informed Enough. American Journal of Nursing, 105(4), pp.79-84	Expert Opinion	The idea that nurses are obliged to be their patients' advocates is articulated in our codes of ethics.	V	Advocate Policy
Lorenzen, B., Melby, C., and Earles, B. (2008). Using Principles of Health Literacy to Enhance the Informed Consent Process. AORN J, 88(1), pp.23-29.	Qualitative Study	Incorporating reader-friendly language and formatting makes it more likely that patients will read the document, understand it, and therefore give informed consent. Adding "teach back" into the document provides a means of evaluating patient understanding.	III	Informed Consent Process Training
Mahon, M. (2010). Advanced Care Decision Making: Asking the Right People the Right Questions. Journal of Psychosocial Nursing & Mental Health Services, 48(7), pp.13-19.	Expert Opinion	Decision making capacity, the ability to give informed consent or informed refusal, may not be accurately assessed or may not be assessed at all. Nurses are often ideally positioned to contribute to decision-making by the clinical team and with the patient.	V	Advocate
Marrone, S. (2016). Informed Consent	Expert Opinion	National health care systems must develop,	V	Witness Policy

Examined within the Context of Culturally Congruent Care: An Interprofessional Perspective. <i>Journal of Transcultural Nursing</i> , 27(4), pp.342-348.		implement, and evaluate strategic goals and standard operating procedures that protect and preserve the legal, ethical, and financial integrity of health care organizations and the national health care infrastructure in general while at the same time being responsive to the diverse needs of patients and families that may access the health care system.		
Moore, J. (2016). Women's Voices in Maternity Care: The Triad of Shared Decision Making, Informed Consent, and Evidence-Based Practice. <i>Journal of Perinatal Neonatal Nursing</i> , 30(3), pp. 218-223.	Qualitative Study	Nurses have an opportunity to provide critical information that supports maternity models of care focused on evidence-informed, shared decision making through digital communication.	III	Communicator
Nasrabadi, A. and Shali, M. (2017). Informed Consent: A Complex Process in Iran's Nursing Practice. <i>Journal of Korean Academy of Nursing Administration</i> , 23(3), pp.223-228.	Literature Review	Obtaining informed consent in the context of a nursing practice in Iran is challenging.	V	Witness
Susilo, A., Van Dalen, J., Scherpbier, A., Tanto, S., Yuhanti, P. and Ekawati, N. (2013). Nurses' Role in Informed Consent in a Hierarchical and	Qualitative Study	Nurses play many roles in informed consent and that roles are influenced by training, hospital culture and policy, patients' understanding, family	III	Advocate Policy

Communal Context. Nursing Ethics, 20(4), pp.413-425.		involvement, and cost-related issues.		
Tabak, N. and Zvi, M. (2008). When Parents Refuse a Sick Teenager the Right to Give Informed Consent: The Nurse's Role. Australian Journal of Advanced Nursing, 25(3), pp.106-111.	Scholarly Paper	Nurses need to learn and develop the skills needed in obtaining informed consent.	V	Informed Consent Process Training Policy
Vaartio-Rajalin, H. and Leino-Kilpi, H. (2011). Nurses as Patient Advocates in Oncology Care: Activities Based on Literature. Clinical Journal of Oncology Nursing, 15(5). Pp.526-532.	Literature Review	Nurses play an important role as patient advocates in cancer care. The literature reviewed for this article showed that nurses use their role to promote and safeguard the well-being and interests of their patients.	IV	Advocate

Appendix B: Permission from John Hopkins

Home » Johns Hopkins Nursing Evidence-Based...

JOHNS HOPKINS NURSING EVIDENCE-BASED PRACTICE MODEL AND TOOLS

HERE ARE YOUR JHNEBP TOOLS (AND A SURPRISE GIFT)!

Thank you for your submission. We are happy to give you permission to use the JHEBP model and tool in adherence of our legal terms mentioned noted below:

- You may not modify the model or the tools without written approval from Johns Hopkins.
- All reference to source forms should include "©The Johns Hopkins Hospital/The Johns Hopkins University."
- The tools may not be used for commercial purposes without special permission.
- If interested in commercial use or discussing changes to the tool, please email ijhn@jhmi.edu.

Click [HERE](#) to access the 2013 zipped file of the tools. These tools correspond to the 2nd edition of the book.

Click [HERE](#) to access the 2017 zipped file of the tools. These tools correspond to the 3rd edition of the book.

You can learn more about the 2017 updated model and tools [HERE](#).

Please note: If you choose to use the Johns Hopkins Nursing Evidence-Based Practice Model and Tools in any other way, another form will need to be submitted.

Exclusive offer for users of our JHNEBP model and tools. Did you know we also offer an online course about the JHNEBP model? **We'd like to give you \$20 off this engaging online experience.** The course follows the EBP process from beginning to end and provides guidance to the learner on how to proceed, using the tools that are part of the Johns Hopkins Nursing EBP model. Click [HERE](#) to take online course. Use coupon code **JHNEBPTOOLS** at check out.

Appendix C: Survey Questions

Dear Expert,

This survey seeks your opinion on the implementation of an Informed Consent Policy whereby the nurse's role is defined. As you are aware, practice vary. We hope that by collecting your opinion it will help move towards consensus between managers and policy-makers.

This survey should take less than 15 minutes and can be completed on a smartphone or tablet.

Thank you for taking the time to complete this survey.

Maria Faison, MSN, RN
DNP Student
Walden University

Round I

Survey Questions:

- 1) What is your gender?
 - a. Male
 - b. Female
- 2) What is your highest level of education?
 - a. Associate's
 - b. Bachelor's
 - c. Master's
 - d. Master's not in nursing
 - e. Doctorate
 - f. Doctorate not in nursing
- 3) Years of Experience in Nursing
 - a. 1-3
 - b. 3-5
 - c. 5-10
 - d. >10
- 4) What is your primary role in nursing?
 - a. Clinical/staff nurse (Med-Surg, ICU, Recovery, etc.)
 - b. Nurse Educator
 - c. Advanced practice nurse (NP, CNS, CRNA, etc.)
 - d. Clinical Nurse Leader (Head Nurse, Nurse Manager)
 - e. Nursing Leadership (Patient Care Director, Middle Level Management, Chief Nursing Officer)

- 5) Do you influence policy at your organization?
 - a. Yes
 - b. No
 - c. NA
- 6) Are you familiar with the informed consent policy at your organization?
 - a. Yes
 - b. No
 - c. NA

Round II

The following survey items pertain to the nurse-driven informed consent protocol:

1. Staff incidents involving informed consents are a concern
 1. Strongly Disagree
 2. Disagree
 3. Neutral
 4. Agree
 5. Strongly Agree
2. Nurses understand the legal and ethical indication of informed consents
 1. Strongly Disagree
 2. Disagree
 3. Neutral
 4. Agree
 5. Strongly Agree
3. Nurse-driven protocols improve patient outcomes
 1. Strongly Disagree
 2. Disagree
 3. Neutral
 4. Agree
 5. Strongly Agree
4. Nurses should document patient's understanding of informed consent
 1. Strongly Disagree
 2. Disagree
 3. Neutral
 4. Agree
 5. Strongly Agree
5. Policy or Protocol should define nurse's role
 1. Strongly Disagree
 2. Disagree
 3. Neutral

4. Agree
5. Strongly Agree
6. Nurses should receive ongoing ethical training to include the informed consent process
 1. Strongly Disagree
 2. Disagree
 3. Neutral
 4. Agree
 5. Strongly Agree
7. Nurses should document patient's understanding of informed consent
 1. Strongly Disagree
 2. Disagree
 3. Neutral
 4. Agree
 5. Strongly Agree
8. Looking at the attached nurse-driven informed consent protocol - would this protocol increase nurse and patient satisfaction with the informed consent process?
 1. Strongly Disagree
 2. Disagree
 3. Neutral
 4. Agree
 5. Strongly Agree
9. Looking at the attached nurse-driven informed consent protocol - would such a protocol make the informed consent process more effective?
 1. Strongly Disagree
 2. Disagree
 3. Neutral
 4. Agree
 5. Strongly Agree
10. Would you advocate for a nurse-driven informed consent protocol at your facility?
 1. Strongly Disagree
 2. Disagree
 3. Neutral
 4. Agree
 5. Strongly Agree

This concludes the survey. Thank you for your participation. If you want the results of the survey, please provide your email.

Appendix D: Draft Policy/Protocol

INFORMED CONSENT PROTOCOL	NURSE-DRIVEN INFORMED CONSENT PROTOCOL	Policy 1.1
---------------------------------	---	------------

PURPOSE

This protocol is to support the Registered Nurse (RN) facilitation of the informed consent process for patients undergoing procedures.

- ❖ The responsibility for final verification of the patient's informed consent remains with the medical practitioner responsible for the procedure.
- ❖ RNs facilitating informed consent do so with the authorization of the registered medical practitioner responsible for the patient's procedure as defined in the Informed Consent Form.
- ❖ Authorization to participate in informed consent applies only within the RNs normal work area for named procedures, which have been designated by Doctor.

OBJECTIVE

To ensure that patients are provided with information and the opportunity to discuss their planned procedure in preparation for completion of the informed consent process.

EXCLUSIONS

RNs complete their assessment as to a patient's competence to consent. RN consent is not appropriate for:

- * Children aged 15 years or younger
- * Adults without the capacity to retain or recall the information given to them
- * Adults who do not agree for a RN to obtain their consent

For these patients, the full consent process must be completed by the registered medical practitioner responsible for the procedure.

STANDARDS TO BE MET

ACTION	RATIONALE
<p>RNs may participate in obtaining informed consent as per Informed Consent Form held within each relevant department:</p>	<p>To ensure RNs obtain consent on procedures that they have been designated to undertake, within the clinical service they are employed - by the registered medical practitioner undertaking the procedure.</p>
<p>RNs demonstrate competency to participate in obtaining informed consent:</p> <ul style="list-style-type: none"> • The RN must have been employed within the clinical service for a minimum of 6 months, completed orientation training and competency assessment related to the informed consent process. • This includes: <ul style="list-style-type: none"> • Knowledge of the procedure and risks / potential complications. 	<ul style="list-style-type: none"> • To ensure that RNs demonstrate knowledge of procedures before consent is obtained from patients. • To ensure RN is working within scope of practice when obtaining consent from patients. • To demonstrate competence in the facilitated consent process.
<p>Consent process meets organizational standards:</p> <ul style="list-style-type: none"> • Ensure that if required, the patient and family have access to interpretation service. • Complete a nursing assessment, including comprehensive information about the patient's medication, medical and surgical history. • Ensure all information is recorded in the relevant care pathway where available. • Check treatment and consent forms match the referral. Documentation for proposed treatment / procedure. 	<ul style="list-style-type: none"> • To ensure patient understands the proposed procedure, potential risks and their options. • To assess if patient does not have any contraindications that will place them at risk to undergo the procedure. • To ensure consent process is completed. • To ensure patient signs the correct consent form for the correct procedure.

<ul style="list-style-type: none"> • Ensure the patient has received the information booklets relevant to their intended procedure. • Ensure that all information documents have been reviewed with the patient and completed accurately for a patient's procedure. • This includes information around the use of moderate (conscious) sedation. • Discuss the risks and complications as well as potential consequences of these complications as outlined within patient information booklets. • When the patient has signed Consent Form, countersign that you have verified the patient understands the procedure, and potential risks and options. • Document completion of Informed Consent Form in appropriate electronic health system. 	<ul style="list-style-type: none"> • To meet informed consent standards. • To meet data analysis standards.
<p>Any identified patient concerns are escalated to the registered medical practitioner who verifies consent with the patient prior to commencing the procedure.</p>	<p>To ensure patient concerns are addressed by the registered medical practitioner.</p>

Appendix E: Power Point Presentation for SMEs

Nurse's Role within the Informed Consent Process: A Systematic Review of the Literature

BY: MARIA FAISON, MSN, RN
DNP STUDENT
WALDEN UNIVERSITY

Nature of the project

- Patient autonomy and shared decision-making have been a focal point in today's healthcare standard especially when more than 50 million surgical and nonsurgical inpatient procedures are performed each year.
- As nurses, the informed consent is part of everyday routine – during admissions or before a procedure.
- The purpose of this doctoral project is to evaluate evidence to support a policy change for the implementation of a nurse-driven informed consent protocol whereby the nurse's role is defined.

Practice focused question

Can evidence be found to support the implementation of a nurse-driven informed consent protocol?



- The ultimate responsibility of informed consent falls to the physician, where they must inform the patient of the (a) risks, (b) benefits, and (c) alternatives of a proposed treatment or surgery (Mendez, 2013).
- Nevertheless, it is a great opportunity for nurses to drive this practice change; but many nurses do not fully understand the legal and ethical guidelines of the informed consent process.
- The goal of this integrative review is to organize findings related to the nurses' role within the informed consent with the intention to influence policy and effect a positive social change in nursing practice.

Significance to
practice

Methodology

- The systematic literature review was conducted using the adapted literature review by Souza, Silva, and Carvalho (2010) which consisted of 6 levels for evaluating the evidence.
- And graded using the updated Johns Hopkins Nursing Evidence-Based Practice Model.
- A modified RT Delphi technique will be used to measure an expert panel's reaction to the systematic review and to generate consensus to implement a nurse-driven informed consent protocol.
- Descriptive Statistics, Cronbach's Alpha, and Fisher Exact Chi test in SPSS will be used for the findings.

Results

The review yielded 23 peer-reviewed articles published between 2005-2017 and Google Scholar found an additional 6 articles for a total of 29 articles. Once exclusions were applied - a total of 15 articles were used for grading. The quality of literature was graded based on the updated Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) model (Dearholt & Dang, 2017). Articles that met the search criteria were weighed against each of the levels and categorized.

Informed Consent Process and Training

Informed consent process and training: 4 articles

Participating in the informed consent process is part of a nurse's daily task, and the role of the nurse can differ throughout the process: advocate, communicator, or witness (Susilo, Van Dalen, Scherpbier, Tanto, Yuhanti, and Ekawati, 2013). Nurses can play the role separately or in combination depending on the situation. It is therefore, important for organizations to offer ongoing ethics training with informed consent.

Nurse's Role

Advocate (6 articles): With increased hospitalization, it is even more important for nurses to assess decision making capacity and their ability to give informed consent.

Communicator (2 articles): The nurse is the hub of communication, assessing, gathering, and interpreting information between the health care team, family members, and patients.

Witness (3 articles): The legal interpretation of the witness is that he or she observed that it was the patient who signed the consent form (Marrone, 2016).

Recommendations

- Conduct evidence-based studies so that the role of the nurse in the informed consent process be supported by data and theory.
- Nursing leaders to implement a nurse-driven informed consent protocol and ongoing informed consent training.



References

Marrone, S. (2016). Informed Consent Examined within the Context of Culturally Congruent Care: An Interprofessional Perspective. *Journal of Transcultural Nursing*, 27(4), pp.342-348.

Menendez, J. (2013). Informed Consent. *JONA's Healthcare Law, Ethics, and Regulation*, 15(4), pp.140-144.

Newhouse, R., Dearholt, S., Poe, S., Pugh, L., and White, K. (2015). *The Johns Hopkins Nursing Evidence-based Practice Rating Scale*. Baltimore, MD

Susilo, A., Van Dalen, J., Scherpbier, A., Tanto, S., Yuhanti, P. and Ekawati, N. (2013). Nurses' Role in Informed Consent in a Hierarchical and Communal Context. *Nursing Ethics*, 20(4), pp.413-425.

