

EXAMINATION OF THE INFORMED CONSENT PROCESS AS EXPERIENCED  
BY PATIENTS WHO UNDERWENT A DE NOVO TRANSJUGULAR  
INTRAHEPATIC PORTOSYSTEMIC SHUNT, CHEMOEMBOLIZATION OR  
RADIOEMBOLIZATION PROCEDURE

Marsha A. Hughes-Gay

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Doctoral Committee

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Claire Draucker, PhD, RN, FAAN, Chair

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Anne Belcher, PhD, RN

May 22, 2019

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Carol Shieh, DNSc, MPH, RNC-OB, FAAN

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Josette Jones, PhD, RN

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Marsha A. Hughes-Gay

## DEDICATION

This work is dedicated to my husband David and my children Jessica and Jasmine. You have only known a wife or mother that has been in school. Your support, understanding, and encouragement have meant the world to me.

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Marsha A. Hughes-Gay

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RADIOEMBOLIZATION PROCEDURE

The purpose of this study is to examine the informed consent (IC) procedure as it was experienced by patients who had undergone a de novo transjugular intrahepatic portosystemic shunt (TIPS), chemoembolization (TACE), or radioembolization (TARE) procedure in an Interventional Radiology (IR) Department. The three main study aims and a fourth exploratory aim are as follows: (1) Describe how patients who underwent a de novo TIPS, TACE, or TARE procedure in an IR Department described the IC procedure; (2) Describe what information patients who underwent a de novo TIPS, TACE, or TARE procedure in an IR Department recalled being told during the IC procedure; (3) Describe the satisfaction of patients who underwent a de novo TIPS, TACE, or TARE procedure in an IR Department with the IC procedure; and (4) Explore how the IC experiences of patients who underwent a de novo TIPS, TACE, or TARE procedure in an IR Department differed according to their levels of health literacy. Using a qualitative descriptive design, participants were recruited from an IR department that performed these procedures. A total of 14 participants were interviewed about their IC experiences and the Newest Vital Sign (NVS) Health Literacy assessment was administered. The participants described the IC procedure by discussing the staff they encountered, their feelings during the visit, the support persons who accompanied them, and the decisions they made about the procedure. The participants recalled being told

about how their procedure would be performed, the care they would need, and the benefits and risks of the procedure. Most were satisfied with the information received during the IC procedure and found the information consistent with how they experienced the procedure. A few participants would have liked more visual materials, additional details about the procedure, simpler language, or more explanation of the medical terminology. No apparent differences in the IC experience could be attributed to health literacy. These findings suggest that persons' experiences during the IC process are multi-faceted and affected by their emotions and concerns and the nature of their encounters with their healthcare providers.

Claire Draucker, PhD, RN, FAAN, Chair



## TABLE OF CONTENTS

List of Tables .....	xi
List of Figures .....	xii
List of Abbreviations .....	xiii
Chapter One-Introduction and Nature of the Study .....	1
Background and Description of the Problem.....	1
The Role of Nurses in Informed Consent Processes.....	3
Study Purpose .....	3
Theoretical Basis of Study .....	5
Core Control Unit .....	6
Illness Representations, Content and Structure .....	6
Procedures, Action Plans, and Appraisals .....	8
The Self-System of Executive Tools and Function .....	8
CSM and the Informed Consent Process .....	9
Definitions and Key Terms.....	11
Significance and Contribution .....	12
Assumptions and Philosophical Perspective.....	12
Summary .....	13
Chapter Two-Literature Review .....	14
Introduction.....	14
Informed Consent Process for Medical Procedures.....	14
Patient Experiences of IC for Medical Procedures .....	15
Amount of Information Received.....	15
How Information is Provided.....	16
Quality of Information Provided.....	17
When Information is Provided.....	17
Nature of Communication with HCPs .....	18
Disclosure of Risks and Benefits .....	19
Loss of a Sense of Control and Autonomy .....	20
Summary .....	20
Enhanced Procedures for the IC Process .....	20
Technology-Enhanced IC Procedures.....	21
Supplemental Written Information .....	24
Illustrations .....	25
Extended Time for Informed Consent Process .....	25
Summary.....	25
Health Literacy and IC.....	26
Assessment of Health Literacy Skills .....	28
Rapid Estimate of Adult Literacy in Medicine (REALM) .....	28
Test of Functional Health Literacy of Adults (TOFHLA).....	29
Newest Vital Sign (NVS).....	29
Comparison of Health Literacy Screening Tools.....	30
Health Literacy and Informed Consent Procedures .....	30
Summary .....	31
IR Procedures.....	31

Transjugular Intrahepatic Portosystemic Shunt (TIPS) .....	32
Risks Associated with the TIPS Procedure.....	34
Chemoembolization (TACE) and Radioembolization (TARE).....	36
Risks Associated with the Procedures .....	37
Summary.....	38
Chapter Three-Research Study .....	39
Introduction.....	39
Research Purpose and Aims.....	39
Research Design.....	40
Population .....	41
Sampling and Setting .....	42
Inclusion and Exclusion Criteria.....	43
Sample Size.....	44
Recruitment.....	44
Data Collection .....	45
The Newest Vital Sign Tool .....	47
Compensation .....	49
Data Management .....	49
Data Analysis .....	49
Evaluative Framework.....	52
Application.....	54
Chapter Four-Results .....	55
Introduction.....	55
Sample .....	55
Description of Interviews.....	56
Findings.....	57
Participant Exemplars .....	68
Summary of Findings.....	73
Chapter Five-Discussion.....	75
Summary of Findings .....	75
Findings and Prior Literature .....	75
Limitations .....	79
Suggestions for Future Research .....	81
Clinical and Practical Applications.....	83
Summary.....	85
Appendices.....	86
Appendix A Study Introduction Letter to Potential Participants .....	86
Appendix B Informed Consent for Study .....	87
Appendix C Health Summary Form .....	91
Appendix D Demographic Form .....	93
Appendix E Newest Vital Sign Assessment Tool.....	94
Appendix F Study Participant Demographics.....	96
Appendix G Comparison of Possibly Limited Literacy and Almost Always Adequate Literacy Groups .....	97
References.....	99
Curriculum Vitae	

## LIST OF TABLES

Table G-1: Participants Use of the Internet to Find Information on Procedure in Appendix G.....	97
Table G-2: Participants Use of Questions During the IC Process in Appendix G .....	97
Table G-3: Participant Satisfaction with the IC Process in Appendix G.....	97
Table G-4: Participant Recall of Risks Discussed During the IC Process in Appendix G.....	97
Table G-5: Participant Recall of Benefits Discussed During the IC Process in Appendix G.....	98

## LIST OF FIGURES

Figure 1: Early view of the Common Sense Model.....	7
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## LIST OF ABBREVIATIONS

ANA	American Nurses Association
AMA	American Medical Association
CSM	Common Sense Model of Self-Regulation
Gy	Gray
HCP	Healthcare Provider
IC	Informed Consent
IR	Interventional Radiology
MD	Medical Doctor
NAAL	National Assessment of Adult Literacy
NP	Nurse Practitioner
NVS	Newest Vital Sign
PA	Physician's Assistant
REALM	Rapid Estimate of Adult Literacy in Medicine
RN	Registered Nurse
TACE	Trans-arterial chemoembolization
TARE	Trans-arterial radioembolization
TIPS	Transjugular intrahepatic portosystemic shunt
TOFHLA	Test of Functional Health Literacy of Adults

## CHAPTER ONE-INTRODUCTION AND NATURE OF THE STUDY

### **Background and Description of the Problem**

Patients who are scheduled for diagnostic tests and procedures often engage with health care professionals to complete an informed consent (IC) procedure. Healthcare providers (HCPs) provide information about the test or procedure, the reasons for the test or procedure, and its risks and benefits. After the provider has given the information and the patient has had the opportunity to consider the information and ask questions, an IC document is typically signed.

Skidmore-Roth and Pagana (2010) describe informed consent as follows:

Permission obtained from a patient to perform a specific test or procedure. Informed consent is required before most invasive procedures are performed and before a patient is admitted to a research study. The document used must be written in a language understood by the patient and be dated and signed by the patient and at least one witness. Signed consent should be obtained by the person performing the procedure. Included in the document are clear, rational statements that describe the procedure or test. Also required is a statement that care will not be withheld if the patient does not consent. Informed consent is voluntary. By law, informed consent must be obtained more than a given number of days or hours before certain procedures, including therapeutic abortion and sterilization, and must always be obtained when the patient is fully competent. An individual must be of a certain legal age to give consent; laws vary from state to state. (p. 96)

IC procedures are based on ethical principles related to autonomy and self-determination. Physicians and nurses have an ethical duty to ensure that patients understand and participate in their care. The American Medical Association (AMA), in their Code of Ethics, states, “The patient’s right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice” (American Medical Association, 2012, opinion 8.08). The American Nurses Association’s (ANA) Code of Ethics states that patients have the moral and legal right to

determine their treatment, or to refuse treatment, based on the information provided to them. This information should be provided in way that can be understood. The ANA Code of Ethics, section 1.4, (2015) also states that the nurse has a responsibility to understand the moral and legal rights of patients with regard to their care:

Patients have the moral and legal right to determine what will be done with and to their own person; to be given accurate, complete and understandable information in a manner that facilitates an informed decision; and to be assisted with weighing the benefits, burdens, and available options in their treatment, including the choice of no treatment. (p. 19)

Further, the ANA Code of Ethics informs nurses that their primary commitment is to their patients, which includes having honest conversations regarding their treatment options (American Nurses Association, 2015, codes 2.1, 6.2).

IC is based on the assumption that patients understand and consider information presented to them and feel free to make decisions about all tests and procedures. Yet research suggests this is not always the case, and, despite experiencing IC procedures, patients often do feel fully informed about procedures they undergo (Falagas, Korbila, Giannopoulou, Kondilis, & Peppas, 2009). Among family practice physicians, patient dissatisfaction with IC procedures is the seventh leading cause of litigation (Roberts, 2003).

One factor that might influence patients' experiences of IC procedures, especially the extent to which they fully understand the information, is health literacy. Health literacy is defined by Ratzan and Parker (2000) as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (page iv). The Institute of Medicine estimates that 36% of adults in the US - about 90 million people - and 59% of the elderly

have limited health literacy (Institute of Medicine, 2004). Limited health literacy could have adverse implications of IC processes, especially for complex tests and procedures.

### **The Role of Nurses in Informed Consent Processes**

In the role as patient advocate, the Registered Nurse has legal, ethical and moral obligations to ensure the patient has the information necessary to make informed decisions related to their care. Nurses often provide patients with health information in verbal, written, and visual formats and need to ensure that patients are able to navigate the multiple forms needed for IC and follow the directions on the forms provided (IOM, 2004). Nurses should also confirm that patients fully understand the rationale, benefits and risks, and expected outcomes of tests and procedures because if patients misunderstand this information, this would lead to an uninformed choice (IOM, 2004, Tariman, Chochrane, Doorenbos, & Schepp, 2012).

### **Study Purpose**

Nurses and other healthcare professionals need an in-depth understanding of how patients experience the IC process especially for complex and invasive procedures in order to ensure that these processes meet their informational needs and thus allow them to fully participate in their healthcare. Much of the research on IC procedures is focused on the measurement of indices of patient understanding and knowledge of the test or procedure for which they are consenting, and little is known about how patients experience IC procedures, including their perspectives on the healthcare encounters in which the IC procedures are embedded. In addition, it is unclear how health literacy might influence their experiences. To examine how patients experience the IC process, persons who have undergone de novo transjugular intrahepatic portosystemic shunt



(TIPS), chemoembolization (TACE), or radioembolization (TARE) procedure will be interviewed about their experiences. These three procedures (defined below) were chosen as the focus of this study because the procedures are similar in that they are all invasive, associated with significant risks, and require a pre-procedure visit in which the procedure is described and consent is obtained.

The purpose of this study is to examine the IC procedure as it was experienced by patients who underwent a de novo TIPS, TACE, or TARE procedure in an Interventional Radiology (IR) Department. The specific aims are as follows:

1. Describe how patients who underwent a de novo TIPS, TACE, or TARE procedure in an IR Department describe the IC procedure;
2. Describe what information patients who underwent a TACE, TARE, or de novo TIPS procedure in an IR Department recalled being told during the IC procedure;
3. Describe the satisfaction of patients who underwent a de novo TIPS, TACE, or TARE procedure in an IR Department with the IC procedure.

In addition, the following exploratory aim was addressed:

4. Explore how the IC experiences of patients who underwent a de novo TIPS, TACE, or TARE procedure in an IR Department differed according to their levels of health literacy.

A Qualitative Descriptive (QD) study as described by Sandelowski (2000) was conducted to address the study aims. This research method was chosen as the investigator sought to obtain rich data based on the study participants' own words regarding the IC procedure rather than data derived from pre-determined variables as would be obtained in a quantitative study (Neergaard, et al., 2009; Sandelowski, 2000). This method allowed

patients to freely discuss what was most important to them during the IC procedure (Merriam, 2009; Streubert-Speziale & Carpenter, 2003). An exploratory component of the study was to examine how patients of varying health literacy levels experienced the IC process.

### **Theoretical Basis of Study**

The model guiding the study is the Common Sense Model of Self-Regulation of Health and Illness (CSM) (Diefenbach & Leventhal, 1996; Leventhal, Brissette, & Leventhal, 2003). The CSM is a theoretical framework that explains how patients in a wide range of settings recognize and respond to a health threat. The CSM considers patients to be problem solvers who formulate and carry out action plans to address health threats by using a variety of cognitive, behavioral and perceptual processes (Diefenbach & Leventhal, 1996; Leventhal et al., 2014; Leventhal, Phillips, & Burns, 2016). The model was first proposed in the early 1970's and has continued to evolve through the addition of more complex structures to show how cognitive and emotional systems are activated and action plans are developed (Diefenbach & Leventhal, 1996; Leventhal, 1970, Leventhal et al., 2014). The basic CSM model appears below in Figure 1.

According to the CSM, health threats can arise from internal or external stimuli. Internal stimuli include any deviation from one's normal state including bodily changes resulting from an illness. External stimuli arise in the environment and could include the illness of another or information received from a HCP or community. These stimuli initiate interacting perceptual, behavioral and cognitive responses. The structure of the CSM is comprised of four parts: 1) the core control unit; 2) an illness representation, content and structure; 3) procedures, action plans and appraisals (the output side of the

model); and 4) the self-system of executive function and tools (Diefenbach & Leventhal, 1996; Leventhal et. al, 2014; Leventhal, Brissette, & Leventhal, 2003).

### **Core Control Unit**

The core control unit of the CSM is a feedback loop that permits self-regulation based on the representation of a health threat, action plans that could control the threat, and the consequences of the action plans. Early studies using the CSM model revealed that patients used cognitive processes to control the threat and emotional processes to control their emotional responses to the threat. An early study of smoking cessation, for example, found that patients needed both fear-inducing messages (emotional process) and an action plan (cognitive process) to result in action against the threat (Leventhal, Watts, & Pagano, 1967).

### **Illness Representations, Content and Structure**

The CSM includes five domains of illness representation that are based on patients' perceptual and procedural knowledge and are described as common-sense ideas (Leventhal et al., 2014). The five domains are identity, timeline, consequence, cause, and control. The following figure illustrates these domains and the affective behaviors with which they are associated. The feedback pathway demonstrates how the domains integrate with cognitive and physical behaviors which may lead to a representation of illness, a cue to action, and the development of an action plan. Continuous feedback may then maintain or change the representation of illness. Depending on the type of feedback (e.g. signs and symptoms, perceived threats), action plans may change or be abandoned all together.

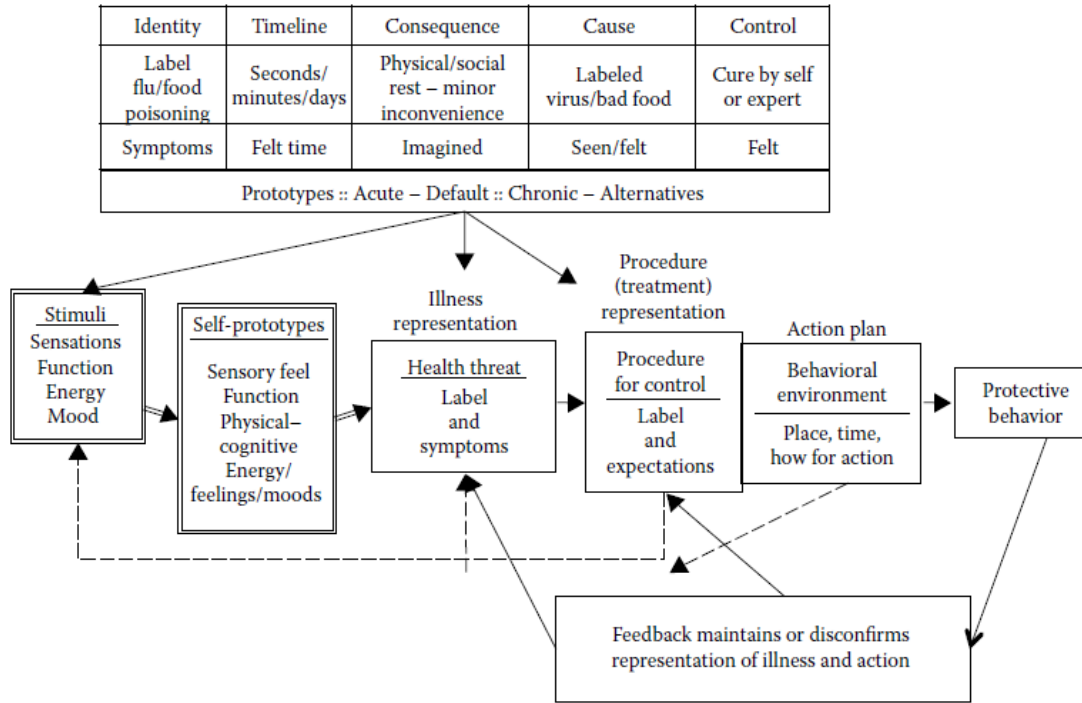


Figure 1: Early View of the Common Sense Model. From “Modeling Health and Illness Behavior. The Approach of the Commonsense Model” by Leventhal, Bodnar-Deren, Breland, Hash-Converse, Phillips, Leventhal, & Cameron, in Baum, Revenson, & Singer (Eds.), *Handbook of Health Psychology* (2<sup>nd</sup> Edition, p. 16), 2014, New York, United States: Taylor and Francis Group LLC Books. Copyright [2010] by Taylor and Francis Group. Reprinted with permission.

**Identity domain.** Patients label their symptoms for a particular illness (health threat) based on the known signs and symptoms (the stimuli) of the illness as well as their past experiences and those of others. Once the symptoms are perceived and labeled, the feedback system is activated and the patients’ cognitive and emotional responses to the label are initiated (Leventhal et al., 2014).

**Timeline domain.** Patients formulate a timeline for the health threat based on their beliefs about how an illness should progress. Patients may, for example, determine the illness is self-limiting and, if it does not subside, may determine an action plan is needed. Illnesses perceived as acute may call for immediate action plans, whereas as

illnesses perceived as chronic may call for action plans that are less urgent (Leventhal et al., 2014).

**Consequence domain.** Patients determine the anticipated consequences of the health threat or particular treatments based on their own experiences or those of others. The consequences may be financial, emotional, or physical. This domain informs the feedback system which may influence the patient's choice of treatment (Leventhal et al., 2014).

**Cause domain.** Patients determine the cause of their symptoms, which could be an external agent, their own behaviors, and their internal susceptibilities. The cause of a health threat may inform the action plan with regards to the current treatment or future prevention of the threat (Leventhal et al., 2014).

**Control domain.** The patient determines the treatment for the health threat based on whether there is a cure for or a way to control the condition. Patients determine if they or a HCP will control the condition (Leventhal et al., 2014).

### **Procedures, Action Plans, and Appraisals**

In the CSM, an intervention for a defined health threat is labeled a procedure. Procedures can be for short- and long-term outcomes and can range from taking an over-the-counter medication to a complex medical intervention. Procedures are implemented by action plans and are based on illness representations (Leventhal et al., 2014).

### **The Self-System of Executive Tools and Function**

The above three systems operate in the context of executive functioning. Executive functioning includes monitoring system outputs, holding information in memories, and thoughts and behaviors (Leventhal et al., 2014). The CSM stipulates that

each person has a prototype of the self and access to subjective cues of their physical self that activate their illness representations, which in turn determine their choice of treatments for a particular health threat (Leventhal et al., 2014). The continuous feedback system provides the patient with information based on past experiences, emotional responses, and new information.

### **CSM and the Informed Consent Process**

The CSM provides a foundation for the current study as it identifies a number of theoretical structures that are highly relevant to the IC process. For example, the core control unit, defined in the theory as the feedback loop that permits self-regulation of health and illness, serves as the context in which the IC process occurs. The theory would suggest that prior to IR procedures, patients would have established an illness representation for the liver disease that necessitates the procedures and determined the threat of the disease. They would have labeled their symptoms (identity domain), formulated a timeline (timeline domain), determined the anticipated consequences of the illness and the IR procedure (consequence domain), determined the etiology of their symptoms (cause domain), and determined if the control of the treatment lies with them or their HCP (control domain).

Information provided to patients during the IC process related to any of these domains can influence their decision regarding the procedure. For example, if patients' symptoms are described as life-threatening (identity domain) and acute (timeline domain), they may be more inclined to consent to the IR procedure (action plan) regardless of the risks of the procedure (consequences). Because many participants in this study had severe liver impairment (identity domain) and the consequences of not

having the IR procedure were dire (consequence domain), these factors were likely salient in IC discussions. Conversely, if participants had been asymptomatic or had minimal symptoms, the urgency for IR procedures indicated by the HCP might not have been consistent with their perception of the health threat (Leventhal et al., 2014), and they may have been more reluctant to consent to the procedure.

The consequence domain of the illness representation is particularly relevant to the IC procedure. The consequences, which would be the risks and benefits of having or declining a de novo TIPS, TACE, or TARE procedure, are central concerns in providing IC. IC processes, including the opportunity to ask questions, should assist patients in determining the likely outcomes of an action plan of having or rejecting the procedure or seeking alternative options. For example, participants in this study may have decided that the risks and discomforts associated with the IR procedure would be offset by elimination of the need for frequent paracentesis.

The *if-then* scenario that underlies patients' action plans are likely to be at play during the IC process. Patients are tasked to decide *if* they have a procedure, *then* what outcomes will occur. For an IR procedure, the results could be relief of symptoms, better quality of life, or the slowing of the progression of the liver disease or could include be one of the risks associated with the procedure. Conversely, decline of an IR procedure could result in avoidance of the risks of the procedure but could result in decline or death (Leventhal Brissette, & Leventhal, 2003). The CSM, therefore, will help provide a theoretical elucidation of the participants' descriptions of the IC process for the de novo TIPS, TACE, or TARE procedures. The findings will be considered in the context of these theoretical constructs.

## Definitions and Key Terms

*Chemoembolization (TACE):* The delivery of chemotherapy drugs directly to a tumor site, usually in the liver, directly by catheter through an artery. This allows for higher doses of medication to be delivered to the tumor and disrupts the blood supply to the tumor (Morena-Luna et al., 2013).

*Health Literacy:* The reading skills, numeracy skills, and comprehension level needed to use health information and make decisions about one's healthcare (Speros, 2005).

*Informed Consent:* The exchange of information between a HCP and patient regarding a procedure. The information includes a description of the procedure and its associated risks and benefits (Skidmore-Roth & Pagana, 2010).

*Informed Consent Document:* A written document describing a procedure and its associated risks and benefits signed by patients giving healthcare providers permission to perform the procedure (Skidmore-Roth & Pagana, 2010).

*Interventional Radiologist:* A physician with specialized training in minimally invasive procedures using imaging guidance to diagnose and treat diseases (Society of Interventional Radiology, 2006).

*Radioembolization (TARE):* A procedure using a catheter that allows directed placement of yttrium-90 microspheres via the hepatic artery to emit internal radiation to the tumor site. This disrupts the blood flow to the tumor and limits damage to the surrounding normal tissues (Salem et al., 2010).

*Transjugular Intrahepatic Porto Systemic Shunt (TIPS):* A minimally invasive procedure in which vascular access is obtained via the jugular vein in the patient's neck



and small catheters are used to reach the liver. Pressures within the vasculature of the liver are obtained and, using contrast (x-ray dye), images are obtained. A tract is created in the liver using balloons and stents connecting the hepatic and portal veins resulting in hepatic decompression (Boyer, 2003; Boyer & Haskal, 2005; Boyer & Haskal, 2009).

### **Significance and Contribution**

The legal and ethical requirements of the IC procedure are paramount in the provision of patient-centered care. If patients are to actively participate and direct their care, the IC procedure experience should be conducted in a way that allows patients to make informed decisions regarding tests and procedures. This study will provide a rich description of how an IC procedure for an IR procedure is experienced within the context of a healthcare encounter and explore how this experience might differ for patients with varying health literacy levels. The study will thus provide foundational information for initiatives aimed at improving IC process to improve patient satisfaction and safety. For example, information obtained in this study may help HCPs develop communication techniques that could improve the IC experience for patients or reexamine procedures that patients may find to be problematic.

### **Assumptions and Philosophical Perspective**

The study has the following assumptions:

1. The HCP should provide information during the IC procedure in a satisfactory and meaningful way to patients.
2. HCPs are legally and morally obligated to support patient self-determination.
3. The IC procedure is experienced subjectively.
4. Patients narratives will provide rich data regarding their IC procedures.

## **Summary**

The IC procedure is an interaction between HCPs and patients with regard to an impending medical procedure. Information is provided to patients about the procedure, and they are given the opportunity to ask questions so that they can make a fully informed choice about undergoing the procedure. In some instances, the information provided to the patient can be complex as is the case of TIPS, TACE, or TARE procedures conducted in IR Departments. As indicated by the CSM, the HCP and patient both have integral roles in the decision to undergo a procedure. This chapter identified the need to explore the IC procedure from patients' perspectives in their own words. The purpose of this study is to examine the IC procedure as it was experienced by patients who underwent a de novo TIPS, TACE, or TARE procedure in an IR Department. Results from this study may assist in the development of strategies to improve IC experience for patients undergoing complex and risky procedures.

## CHAPTER TWO-LITERATURE REVIEW

### **Introduction**

Patients are asked to provide IC for complex medical procedures, including high risk IR procedures, such as a de novo TIPS, TACE, or TARE (Skidmore-Roth & Pagana, 2010). In the IC process, HCPs deliver medical information about procedures to patients, and patients then consent to the procedures by signing a formal document (Skidmore-Roth & Pagana, 2010; AMA, 2006). Yet research shows patients may sign IC documents for procedures based on information that they do not fully understand including the risks and benefits of the procedures (Falagas et al., 2009; Roberts, 2003). Health literacy might be one factor that influences the process of IC (IOM, 2004). Despite the importance of IC in the care of patients undergoing complex procedures, little is known about how patients experience the process of IC. The purpose of this study is to examine the IC procedure as it was experienced by patients who underwent a de novo TIPS, TACE, or TARE procedure in an IR Department. This chapter will address the following topics: IC process for medical procedures, patient experiences with IC for medical procedures, enhanced procedures for the IC process, health literacy and IC, measurement of health literacy, assessment of health literacy skills, health literacy and IC procedures, and IR procedures.

### **Informed Consent Process for Medical Procedures**

The purpose of IC for medical procedures is to provide patients with essential information about procedures, including benefits and risks, so patients can make informed decisions regarding the procedures. Patients may receive information about upcoming procedures from the referring physicians or from the facilities in which the

procedures will be performed (Davies et al., 2004; Mayberry & Mayberry, 2001). Information required for IC may be given to patients at different time points. Patients scheduled for some procedures may receive information days or weeks in advance and therefore have the opportunity to discuss treatment options and seek opinions from family members, friends, and other HCPs (Fisher, Johnstone, & Williamson, 2011; Lin, Kan, & Chen, 2012; Lin, Pang, & Chen, 2012). In other cases, patients may be asked to provide IC immediately before undergoing urgent or emergent procedures and may have little time to fully consider the decision. Hospitalized patients are often asked to provide IC for procedures within minutes before they are delivered (Proctor, Price, Minhas, Gumber, & Christie, 1999; Kay & Siriwardena, 2001). In some cases, HCPs provide treatment without consent from patients or their legally authorized representatives if the patients cannot provide IC and it is deemed that a reasonable patient would agree to the procedure if able to do so (Easton, Graber, Monnahan, & Hughes, 2007).

### **Patient Experiences of IC for Medical Procedures**

Some researchers have investigated how patients experience the process of IC for medical procedures. Studies have examined the views and experiences of patients who have undergone an IC process related to the amount of information received during the process, how the information was provided, the quality of information, when in relationship to the procedure the information was provided, how relationships with HCPs affected the IC process, communication of risks and benefits, and how the IC process affects patients' sense of control and autonomy.

### **Amount of Information Received**

Research has been conducted on patients' perceptions about the amount of information that is provided to them during IC procedures. Some patients report being provided too much information, which they believe adversely affects their ability to make an informed choice about a procedure (Fisher, Johnstone, & Williamson, 2011). In a study by Agnew and Jorgensen (2012), for example, 10 of 18 patients reported that they had received too much information prior to their scheduled surgical procedure. Conversely, some patients report receiving too little information. In the Agnew and Jorgensen (2012) study, the other eight patients claimed that they were not given enough information to make an informed decision. Fisher, Johnstone, and Williamson (2011) reported that six of twelve patients in their study who underwent electroconvulsive therapy indicated they had not received enough information about the therapy, including details about the possible side effects. In several studies, the amount of information desired by patients varied significantly (Daniels & Vogel, 2012; Degerliyurt, Gunsolley, & Laskin, 2010; Fisher, Johnstone, & Williamson, 2011) and was affected by their prior knowledge of the procedure (Fisher, Johnstone, & Williamson, 2011).

### **How Information is Provided**

Information regarding procedures can be provided to patients in a variety of ways. The information can be provided verbally by a HCP, described in pamphlets or documents that describe specific procedures, or embedded in the IC document. Some research has examined patient preferences regarding how information is delivered. For example, 62% of patients in a study by Daniels and Vogel (2012) wanted access to information about osteopathy treatments on the internet or via email but also wanted verbal information about the treatments from the HCP. The information they wanted

from the HCP included the possibility of having to undress (79% of participants), possibility of pain caused by the exam (86%), low grade risks (89%), and rare but severe risks (68%). In a study of patients undergoing IR procedures, their understanding of and satisfaction with the procedure increased when verbal information was provided in addition to written information (Davies et al., 2004).

### **Quality of Information Provided**

Several studies have examined the written information given to patients prior to a procedure and found that the quality of information and patients' understanding of the material varies widely (Daniels & Vogel, 2012; Mayberry & Mayberry, 2001; Williams et al., 2009). Miller, Abrams, Earles, Phillips, and McCleary (2011) compared a health literacy-based consent process to a standard practice in several facilities. They reported that over 70% of respondents in both groups believed the physician explained their surgery adequately and listened to their questions. The researchers concluded that physician-patient communication contributes to patients' perceptions that they have been fully informed regarding their procedures.

### **When Information is Provided**

Several studies have revealed that the timing of the delivery of information to patients undergoing procedures affects their experiences of IC. Information can be provided when patients are referred for a procedure, which allows them time to review the information (Daniels & Vogel, 2012; Degerliyurt, Gunsolley, & Laskin, 2010). During hospitalizations, patients may be asked to provide their written or verbal consent just prior to routine care treatments by HCPs (Mahjoub & Rutledge, 2011) or just prior to procedures that are urgent in nature (Proctor, Price, Minhas, Gumber, & Christie, 1999;

Kay & Siriwardena, 2001), and this can hinder the IC process. In a study of IC procedures conducted with patients requiring urgent abdominal surgery, for example, only 22% could recall having been told about the side effects or potential complications related to the surgery (Kay & Siriwardena, 2001). A study by Proctor, Price, Minhas, Gumber, and Christie (1999) compared recall when IC was obtained from 48-72 hours prior to an endoscopic procedure to recall when IC was obtained immediately before the procedure in order to assess if retrograde amnesia due to the use of medications used in the procedure affected patient recall of the information provided to them. These researchers reported there was no significant difference in patient recall at the different time periods and concluded that IC procedures were appropriate any time prior to sedation.

### **Nature of Communication with HCPs**

Several studies have focused on the role of the nature of the communication between patients and HCPs during the IC process. This research revealed that good communication between HCPs and patients is most important to patients during IC procedures (Agnew & Jorgensen, 2012; Daniels & Vogel, 2012; Fisher, Johnstone, & Williamson, 2011; Martindale, Chambers, & Thompson, 2009). The provision of tailored information by HCPs based on the unique needs of patients, for example, has been shown to enhance the IC process (Miller, Abrams, Earles, Phillips, & McCleary, 2011). Some research indicates that communication between patients and HCPs during the IC process is often inadequate or that patients and HCPs perceive aspects of the IC process differently. Mahjoub and Rutledge (2011) found significant differences in how patients and HCPs perceived communication of risks associated with procedures. For example,

for certain nursing procedures, the nurses reported giving more information than patients believed they had received. Information provided to patients may be given without the opportunity for patients to discuss alternatives to the procedures or in ways that are not tailored to their needs. In the study by Agnew and Jorgensen (2012), for example, some patients stated that they felt demeaned by physicians who described procedures in extremely simplistic language.

### **Disclosure of Risks and Benefits**

The disclosure of risks and benefits is an essential element of the IC process (Bulen, 2003). The risks that are disclosed to patients during the IC procedure depend on the likelihood of the occurrence of the risks or on the individual practices of HCPs. Studies that have examined the type and amount of risks revealed during IC processes indicate a wide variability in practices of HCPs in regards to risk disclosure (Agnew & Jorgensen, 2012; Mayberry & Mayberry, 2001; Rahman, Clamp & Hutchinson, 2011). A study by Mayberry and Mayberry (2001), for example, revealed that only 4% of patients wished to be informed of a risk with a 1 in 10,000 chance of occurrence from a gastroscopy while 27% of solicitors (i.e. attorneys) specializing in negligence cases wanted that same risk listed on patient information documents (i.e., IC documents). In an informative review, Cardinal, Gunderman, and Tarver (2010) discussed the problems associated with the IC procedures for radiological exams in routine care and for patients with special considerations like pregnant women and children. The authors reported that HCPs may not capture the full benefit-to-risk ratio of exams or procedures administered to patients that expose them to ionizing radiation because patients may then decline diagnostic or therapeutic procedures.



### **Loss of a Sense of Control and Autonomy**

Research has shown that patients can experience a loss of a sense of control, self-efficacy, and autonomy during the IC process (Bulen, 2003; Fisher, Johnstone, & Williamson, 2011). Some studies revealed that patients may perceive a lack of choice due to the severity of their medical condition (Waller & Repko, 2008; Agnew & Jorgensen, 2012) or not be aware of alternatives to procedures that might be available to them (Cook, Marshall, Damato & Salmon, 2010). Bulen (2003) recommends that to promote self-efficacy and autonomy, the IC process should be an interactive process between the patient and the HCP with the viewpoint and concerns of the patient at the center of discussion.

### **Summary**

Several research studies have documented the perceptions of patients with regard to the amount, type, timing and delivery of information during the IC process for medical procedures. The studies suggest that the amount and type of information desired by patients varies widely, but there is little research that identifies what patient characteristics or types of procedures account for this variation. Research does indicate, however, that good communication with providers is associated with patient satisfaction with consent procedures. While some studies have focused on patients undergoing radiology procedures, there is lack of information on the perceptions of patients who have undergone a de novo TIPS, TACE, or TARE procedure.

### **Enhanced Procedures for the IC Process**

In addition to the signing of an IC document, a variety of procedures have been developed to enhance the IC process. These procedures include the use of technology-enhanced IC processes, the inclusion of supplemental written materials, the inclusion of illustrations in written materials, and extending the time of the IC discussions. The procedures have evolved in tandem with advancements in technology and an increased awareness of the shortcomings of relying solely on the IC document to present information.

### **Technology-Enhanced IC Procedures**

Studies have been conducted to determine the efficacy of using technology-enhanced procedures to deliver information during the IC process. As media and technology have evolved, these studies have transitioned from the use of video tapes to compact discs-read only memory (CD-ROMs) and digital video disks (DVDs) to the use of iPad® technology and computer-based interactive software. In several studies, patients were asked to view a brief video that provided information about their scheduled procedure and/or treatment and their knowledge of the material was then assessed (Batuyong, Jowett, Wickramasinghe, & Beischer, 2014; Cowan et al.; Luck, Pearson, Maddern, & Hewett, 1999; Olver, Whitford, Denson, Peterson, & Olver, 2009; Rossi, Guttman, MacLennan, & Lubowitz, 2005; Tait, Voepel-Lewis, Chetcuti, Brennan-Martinez, & Levine, 2014). In a study on IC for cancer treatments, for example, Olver et al. (2009) used a CD-ROM that contained text, graphics, videos and internet links regarding the nature and risks of the treatments. One group of patients was given the CD-ROM and another was provided with standard written materials. Comparison of information recall between the two groups indicated there was no significant difference in

the recall of the number of drugs included in the treatment, the length of the treatment, or the treatment goal. Two studies examined the efficacy of procedures utilizing computer technology. Tait, Voepel-Lewis, Chetcut, Brennan-Martinez, and Levine (2014) used an iPad® interactive program, and Batuyong, Jowett, Wickramasinghe, and Beischer (2014) utilized interactive computer software comprised of high quality 2D and 3D graphics. Participants in both studies answered questions during and after viewing the presentations regarding their scheduled procedure, and both studies reported significantly higher recall of information received by the computerized interactive programs compared to information provided by standard written materials. These results are congruent with those reported in the meta-analysis of IC intervention studies by Schenker, Fernandez, Sudore, and Schillinger (2011). The meta-analysis included 15 studies that evaluated the use audiovisual IC procedures and revealed that 11 studies demonstrated improvement in patient comprehension. These authors reported that in 8 out of 10 high quality studies, patients who watched video media had higher information scores than patients who received standard IC procedures.

A study by Hall et al. (2012) examined the impact iMedConsent™, a computer-based consent program adopted in the Veterans Administration (VA) health system, on patient comprehension. The iMedConsent™ system allows a HCP to tailor the information presented to the patient while also providing the required information on the IC forms. During the IC process, the HCP is able to choose a patient's scheduled procedure from a pre-loaded list and provide that information to the patient. The system provides standardized information regarding risks, benefits and alternatives to each procedure along with pictures and pre- and post- procedure instructions. The IC form can

be tailored to specific patients while including required information. All signatures are obtained via signature pad and the information is uploaded into the patient's electronic medical record. The researchers administered a questionnaire before and after the IC procedure to patients who had completed a surgical iMedConsent™. They reported that patient comprehension on procedure-specific risks and benefits improved from 50% to 60% but there was no improvement in the comprehension of alternatives to the procedure. The researchers acknowledged that even with improvement in the post-IC process scores, there was a generally low level of comprehension of the material presented. Hall et al. (2012) also examined patient decision-making with the use of iMedConsent™. The pre-IC process questionnaire indicated that 29% of patients wanted their physician to be the primary decision maker, but when patients completed the post-iMedConsent™ questionnaire, only 3% of patients wanted their physician in that role. The researchers concluded that the iMedConsent™ process may empower patients to make their own healthcare decisions. However, the Hall et al. (2012) study also revealed that prior to the iMedConsent™ procedure, 85% of the patients indicated they wanted to know as many details as possible, but this number dropped to 25% after the IC process using iMedConsent™. Additionally, while none of the participants indicated they wished to know as few details as possible prior to the iMedConsent™ procedure, 36% indicated they wished to know as few details as possible after the IC process using iMedConsent™. The researchers concluded that HCPs need to carefully consider the amount of information they provide to patients. This conclusion is supported by the finding of Agnew and Jorgensen (2012) that the amount of information that patients desire is variable.

## **Supplemental Written Information**

Studies have been conducted on the use of supplemental written materials during the IC process. Smith et al. (2012) conducted a study in which 121 trauma patients undergoing a surgical procedure were randomized to receive structured verbal IC communication or structured verbal communication with supplementary written materials. Patients' recall of risks presented during the IC process was then assessed post-operatively (mean of 3.2 days later). Patients provided with written materials in addition to the standardized verbal information recalled risks with a mean score of 64% whereas patients provided with standardized verbal information only recalled risks with a mean score of 41%. Several studies also revealed that the use of supplemental written information detailing risks associated with procedures during the IC process resulted in better patient recall of those risks post-procedure (Armstrong et al., 1997; Inglis & Farnill, 1993; Makdessian et al., 2004).

In contrast, Brown, Massoud and Bance (2003) conducted a randomized controlled trial in which no differences were revealed between groups that received a handout and those that did not. Other studies (Courtney, 1997; Inglis & Farnill, 1993) found limited enhanced recall in patients who received supplemental written information. Inglis and Farnill (1993), for example, reported that patients receiving detailed information recalled only two of six risks of anesthesia. Courtney (1997) reported that patients who received a booklet prior to a procedure regarding anesthesia had better recall on only two of the six knowledge questions after the IC process than patients not

receiving a booklet. In addition, there were no differences in recall between the groups after the procedure.

### **Illustrations**

The inclusion of illustrations in written materials to convey risks associated with surgical procedures during the IC process seems to result in better patient recall of those risks. Langdon et al. (2002) studied patients scheduled for hip arthroplasty, and Chan et al. (2002) studied patients scheduled for thyroidectomy and parathyroidectomy. In both of these randomized controlled studies, groups that received illustrated information recalled the information better than those that did not.

### **Extended Time for Informed Consent Process**

Studies have examined the value of extending the amount of time typically used for the IC process by adding formal instruction or education with a HCP in addition to standard consent procedures. These sessions allow time for questions and discussion. A study by Dodd and Mood (1981) revealed that an intervention group receiving such sessions recalled more of the drugs used for chemotherapy (78%) than a control group (34%). The intervention group also recalled more side effects (52% versus 36%) and indications for chemotherapy (86% versus 64%) than the control group. In contrast, Lapid et al. (2003) reported that extended sessions did not improve recall in patients receiving Electro-convulsive Therapy.

### **Summary**

Some studies of enhanced IC procedures have shown improvements in IC outcomes with regard to patient understanding and recall of the material presented. However, there are also studies that have reported no difference between intervention

groups who received enhanced procedures and control groups who did not. Moreover, in some studies patients' understanding of procedures and recall of information remained low overall regardless of whether enhanced procedures were used. While multiple studies have been conducted about factors that influence the IC process, few have obtained in-depth patient narratives to better understand their perceptions of these procedures using their own words.

### **Health Literacy and IC**

Because adequate IC processes depend on the patient fully understanding the risks and benefits of procedures, health literacy might be a salient factor in the IC process. Although health literacy is defined in a variety of ways, a common definition follows: "The degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions" (Ratzan & Parker, 2000). The IC process may be compromised for the approximately 90 million Americans who have inadequate health literacy skills (US Department of Education, 2006).

A concept analysis by Speros (2005) revealed that health literacy includes several attributes: reading skills, numeracy skills, comprehension, and the capacity to use health information to successfully function in the role of patient. In addition, Speros stressed that being exposed to the language of health care is needed for health literacy (Speros, 2005).

The catalyst for many studies on health literacy was the IOM report (2004) titled *A Prescription to End Confusion*. Health literacy research has been conducted in various patient populations in community and acute settings, and researchers have concluded that

low health literacy contributes to poor health outcomes including less use of preventative health services, less knowledge of one's medical condition, increased hospitalizations, and low self-reported health status (Institute of Medicine [IOM] 2004). In a systematic review of 96 studies on health literacy, for example, Berkman, Sheridan, Donohue, Halpern, and Crotty (2011) reported that low or marginal health literacy was associated with poor health outcomes, inappropriate use of health services, and decreased uptake of routine mammography and influenza vaccine. The reviewers also reported that health literacy can at least partially explain some racial disparities in health outcomes. Due to these outcomes, low health literacy is estimated to contribute to healthcare costs of 73 billion dollars a year in the U.S. (Hawkins, Kantayya & Sharkey-Asner, 2010).

Factors that affect the health literacy of individuals include ethnicity, socio-economic status, low educational attainment, low general literacy, and older age (Institute of Medicine [IOM], 2004). However, experts stress that even those patients with high levels of education require health information that is free of medical jargon and tailored to their individual needs (Benson & Forman, 2002; Institute of Medicine [IOM], 2004; Paasche-Orlow & Wolf, 2007).

In 2003, the US Department of Education conducted the National Assessment of Adult Literacy (NAAL) study. The findings revealed that 12% of participants had below basic health literacy skills (e.g., skills needed to perform simple and concrete literacy activities), 22% had basic skills (e.g., skills needed to perform simple and everyday literacy activities), 53% had intermediate skills (e.g., skills needed to perform moderately challenging literacy activities), and 12% had proficient skills (e.g., skills needed to perform complex and challenging literacy activities, ability to synthesize information).



Persons over age 65 scored lower on health literacy even when education was controlled. People with low educational attainment and socio-economic status and those who spoke a language other than English prior to starting school had lower health literacy scores than other groups (US Department of Education, 2006).

### **Assessment of Health Literacy Skills**

Given the importance of the role of health literacy in health outcomes and the requirements of accrediting agencies to address health literacy, tools have been developed to assess health literacy in clinical and community settings. Tools commonly used to assess health literacy levels include the Rapid Estimate of Adult Literacy in Medicine (REALM), the Test of Functional Health Literacy of Adults (TOFHLA), and the Newest Vital Sign (NVS) (Murphy, Davis, Long, Jackson, & Decker, 1993; Pfizer, n.d.).

#### **Rapid Estimate of Adult Literacy in Medicine (REALM)**

The Rapid Estimate of Adult Literacy in Medicine (REALM) is an assessment tool that consists of 66 words to be read out loud by the patient. The person administering the test marks the words that are correctly pronounced by the reader. Scores for correct pronunciation are associated with a grade reading level as follows: 0-18 =  $\leq$  3<sup>rd</sup> grade reading level; 19-44 = 4<sup>th</sup>-6<sup>th</sup> grade reading level; 45-60 = 7<sup>th</sup>-8<sup>th</sup> grade reading level; and 61-66 =  $\geq$  9<sup>th</sup> grade reading level. Yet because the REALM test does not assess comprehension, a reader may be able to pronounce a word and not understand its meaning (Murphy, Davis, Long, Jackson, & Decker, 1993). Collins et al. (2012) reviewed several health literacy assessment tools, including the REALM, in a systematic analysis. They reported that the REALM tool has been extensively tested and is still widely used to assess health literacy. Some researchers have indicated that because the

REALM does not assess essential components of health literacy (i.e. comprehension of printed information, numeracy, finding health information), it should be used to screen patients for their inability to read and correctly pronounce medical terms but cannot accurately assess health literacy (Dumenci et al., 2013).

### **Test of Functional Health Literacy of Adults (TOFHLA)**

The Test of Functional Health Literacy of Adults (TOFHLA) addresses comprehension and numeracy skills, both of which are considered important components of functional health literacy. The TOFHLA consists of two parts. The first part is a written assessment in which words are missing from a sentence and the reader is asked to choose words to fill in these blanks. While the words are similar, there is only one that is grammatically correct. The second part of the tool consists of numeracy questions that assess the ability to interpret medication labels/instructions and decipher instructions on appointment times. The long version is 67 items and takes on average about 22 minutes to administer, although a short version with 36 items has been developed. The TOFHLA scores indicate three levels of functional health literacy: Inadequate, Marginal, and Adequate (Parker, Baker, Williams, and Nurss, 1995). The TOFHLA is widely used in clinical practice and is considered the standard by which other health literacy assessment tools are validated (Dumenci et al., 2013).

### **Newest Vital Sign (NVS)**

The NVS is a rapid assessment tool to assess health literacy. Using a nutritional label for ice cream, the person administering the test asks the patient six questions regarding information on the label. Scores are based on the number of correct answers and results are placed into one of three categories. A score of 0-1 suggests high likelihood

of limited literacy, a score of 2-3 indicates likelihood of limited literacy, and a score 4-6 indicates likelihood of adequate literacy. The questions require the patient to use numeracy and reading skills (prose literacy) as well as scan the label for relevant information (document literacy). The tool can be administered in about three minutes. The NVS has been compared to the TOFHLA and, in the English Version, was reported to be more sensitive than the TOFHLA for those with marginal functional health literacy. The NVS is considered a valid tool for the assessment of functional health literacy. Pfizer has made the NVS available on its website and provides a toolkit, instructions, and printable documents at no charge for HCPs (Pfizer, n.d.; Weiss et al., 2005).

### **Comparison of Health Literacy Screening Tools**

No single health literacy screening tool can account for all socioeconomic and cultural differences in populations to provide a highly accurate score. In their analysis of several health literacy screening tools, Collins et al. (2012) concluded that though several have been validated, additional work needs to be done to develop health literacy assessment tools: “At this time we are in need of a screening tool that can be used across different socioeconomic and cultural lines. Current health literacy screening tools demonstrate different properties depending on the context of use” (p. 606).

### **Health Literacy and Informed Consent Procedures**

Because the IC process requires the patient to exchange information with the HCP in order to make a decision regarding their treatment and care, low health literacy would seemingly impact a patient’s ability to understand the information being presented and make informed decisions. The Joint Commission requires that written information for patients to be in language they can understand and that HCPs talk with patients and

provide them with information that is culturally relevant and easy to understand (The Joint Commission, 2007, 2010).

A few studies have been conducted on the impact of health literacy levels and the IC process. Donovan-Kicken, Mackert, Guinn, Tollison, and Breckenridge (2012) reported that that patients find that many medical terms and phrases, even when plain language is used, are difficult to understand. Using the REALM tool, researchers used a verbal IC process and recorded the amount of time it took for the patient to sign the consent form. Those who took 6 seconds or less to sign the document scored higher on the REALM (Sharp et al., 2013). In a study of 435 subjects recruited from the Improving Medication Adherence Through Graphically Enhanced Intervention in Coronary Heart Disease (IMAGE-CHD) study (Kripalani, Bengtzen, Henderson, & Jacobson, 2008), researchers reported that higher health literacy, as measured by the REALM, was associated with increased comprehension of the IC document.

### **Summary**

Health literacy may be important to the IC process as it is critical to the comprehension of information presented and foundational to decision-making. Several assessment tools are available to assess health literacy but no tool captures all of the nuances of health literacy. While a few studies have examined how health literacy scores effect IC outcomes, no studies have examined how differing levels of health literacy might affect persons' experiences in providing IC.

### **IR Procedures**

To study patients' perceptions of the IC process, three procedures were chosen for this research: de novo TIPS, TACE, and TARE. These procedures were chosen because

they are moderately complex procedures with risks that can be serious and life-threatening (Boyer, 2003), thereby rendering the IC process for these procedures particularly important. In addition, unless performed emergently these procedures require a pre-procedure clinic visit in which benefits and risks are discussed with the patient. These visits allow patients time to process the information and discuss it with others in order to make a decision about whether or not to have the procedure. Moreover, due to the complexity of these procedures, health literacy may be an important factor in patients' experiences with the IC process. To provide an understanding of the context of the study, the three procedures are described below.

### **Transjugular Intrahepatic Portosystemic Shunt (TIPS)**

After being conducted on canines (Rösch, Hanafee, Snow, Barenfus, & Gray, 1971), the TIPS procedure was first performed on humans in the early 1980s. An Interventional Radiologist performs the procedure. Patients are placed in the supine position on the procedure table. Support personnel in the room include nurses with specialized training in sedation and advanced cardiac life support and radiology technologists or technicians. Once the patient is properly draped, the nurse may administer pain and conscious sedation medications. In some instances, patients may have their procedure under a general anesthesia. The Interventional Radiologist numbs the area near the jugular vein in the patient's neck, obtains access, and uses small flexible catheters to reach the liver. Contrast medium is injected and images are viewed and recorded using fluoroscopy and cineradiography. The Interventional Radiologist can obtain hepatic venous pressure gradients and map the vascular system of the liver. A tract is then created in the hepatic parenchyma using a balloon, and a stent that connects

the hepatic and portal veins and the hepatic system is decompressed (Boyer, 2003; Boyer & Haskal, 2005).

The TIPS procedure is performed for several indications that involve portal hypertension including bleeding varices (e.g., esophageal and gastric), a bridge to liver transplant, Budd-Chari Syndrome, extrahepatic portal vein thrombosis, relief of ascites, and several other hepatic conditions that contribute to portal hypertension (Columbato, 2007; Boyer & Haskal, 2005; Boyer & Haskal, 2009). The TIPS procedure can be used as a preventive measure, primary treatment, or treatment for some conditions in which medical management has failed (Boyer & Haskal 2005).

Patients referred to an Interventional Radiologist for a TIPS procedure for the treatment of portal hypertension are assessed for risk including co-morbidities. Hepatic scores on the Child-Pugh or the Model for End Stage Liver Disease (MELD) indicate risk (Boyer & Haskal, 2005; Parvinian et al., 2013). Conditions that are contraindicated for a TIPS procedures include congestive heart failure, multiple hepatic cysts, uncontrolled systemic infection or sepsis, severe pulmonary hypertension, and unrelieved biliary obstruction and as primary prevention of variceal bleeding (Boyer & Haskal, 2005).

The creation of the tract within the liver that connects the hepatic and portal veins provides decompression of the portal circulation and thus relieves portal hypertension. As it can often be accomplished under sedation, the risks associated with a general anesthesia are reduced. The minimally invasive technique of accessing the liver via the jugular vein in the neck reduces the risks associated with insertion site bleeding. Because the Interventional Radiologist accesses a vein, there is no need for heavy pressure at the site of insertion as is required when an artery is used for circulatory system access, as is

the case during a cardiac catheterization. Risks associated with open abdominal surgical procedures (e.g. large incisions and deep vein thrombosis) are reduced (Boyer & Haskal, 2005; Columbato, 2007)

**Risks Associated with the TIPS Procedure.** Several risks are associated with a TIPS procedure. Boyer and Haskal (2005) state, “Creation of a TIPS ranks among the more complex procedures performed by interventional radiologists, and it is important that each physician monitor their success and complication rates” (p. 397). Stents can migrate into other areas within and outside of the liver (Boyer & Haskal, 2005). In a case study (Rumi, 1999), a TIPS stent was found in the pulmonary artery of a patient who had undergone liver transplantation. Other risks and/or complications associated with TIPS procedure include bleeding, infection, hepatic encephalopathy, de novo or recurrent ascites, shunt occlusion, stenosis, thrombosis, sepsis, hemolysis, congestive heart failure, and liver capsule puncture (Haskal & Boyer, 2005; Boyer, 2003).

Subclinical hepatic encephalopathy (HE) occurs in patients with cirrhosis and may predict the development of post-TIPS overt hepatic encephalopathy (Nardelli et al., 2016). The signs and symptoms of HE are delineated using the West Haven classification system. Grade one HE includes mild confusion, shortened attention, and slowing of mental tasks performance. Grade two HE includes lethargy, deficits in mental task ability, and intermittent disorientation. Grade three HE includes disorientation, confusion, somnolence, and the inability to perform mental tasks. Grade 4 HE patients are in a comatose state and unresponsive to stimuli (Casadaban et al., 2015).

In a study by Casadaban et al. (2015) of 191 subjects who underwent a TIPS procedure, 91 (48%) had prior HE. Of those subjects, 39 (43%) developed HE post-

TIPS. In a study of 82 cirrhotic subjects, Nardelli et al. (2016) aimed to use covert HE pre-TIPS as a risk factor for overt HE post-TIPS. Of the 82 subjects, 35 (43%) developed overt HE post-TIPS with 77% of those subjects having been affected by covert HE prior to their TIPS. The researchers indicated covert HE may be predictive of overt HE after TIPS.

Older age is a significant predictor of 90-day mortality. Parvinian et al. (2013) reported 52% of patients over the age of 55 had died within 90 days post-TIPS procedure in their retrospective review at a single academic university-affiliated hospital. Patients undergoing TIPS are also exposed to ionizing radiation in doses that have been determined to be associated with skin injuries due to the higher fluoroscopy time. In a review of 135 cases, the mean fluoroscopy time was 38.7 minutes with a mean number of images at 231. Injury of the skin from radiation can be observed at a dose of 2 Gy. Of the 135 patient cases, 53 were exposed to a radiation dose of > 2 Gy. Radiation adverse effects can range from redness to skin ulceration. Given that TIPS patients may require additional procedures, the cumulative dose of radiation can increase with subsequent treatments (Miller et al., 2003, part 1; Miller et al., 2003, part 2).

**Summary.** The TIPS procedure is a complex medical procedure that has demonstrated success in the treatment of conditions in which portal hypertension is a clinical component or complication. While this minimally invasive procedure has benefits to the patients deemed appropriate for the procedure, it carries significant risks that can range from mild to severe, including early mortality. These risks can occur at the time of the procedure or during the post-procedure period and patients require monitoring for these complications.



### **Chemoembolization (TACE) and Radioembolization (TARE)**

TACE and TARE are treatments for hepatocellular carcinoma (HCC). In 2017, it is estimated there will be more than 40,000 newly diagnosed cases of HCC in the United States (National Cancer Institute, 2017). In the United States, only 5% of patients with HCC are considered appropriate for hepatic resection surgery (El-Serag, 2017). Liver transplantation is an option but is limited due to organ availability. Patients with unresectable HCC with nodules in a single lobe and without portal vein thrombosis or liver decompensation (El-Serag, 2017) are may be considered for TACE or TARE. Patients are staged using a variety of tools such as Child-Pugh Score that assigns points based on level of encephalopathy, ascites, bilirubin, albumin, and prothrombin. The Barcelona Clinic Liver Cancer Staging is a standard for evaluating prognosis and treatment (El-Serag, 2017).

TACE and doxorubicin-eluting beads transarterial chemoembolization (DEB-TACE) are treatments that obstruct the flow of blood in the hepatic artery that supplies blood to a liver tumor and deliver chemotherapeutic drugs. These procedures allow for higher intra-tumor drug delivery (Huang, Zhou, Wang, Cheng, & Ma, 2013). TACE is considered a first line treatment for unresectable HCC in patients whose liver function is preserved (Malagari et al., 2008). DEB-TACE accounts for about half of the HCC chemoembolization (Johnson, 2017).

An Interventional Radiologist, a physician with specialized training in minimally invasive procedures under imaging guidance, performs these procedures (Society of Interventional Radiology, 2006). For TACE and TARE procedures, patients are placed on

a table in the supine position in the IR room. Access to the hepatic circulatory system is obtained via the femoral artery, and the patient access site is thoroughly scrubbed and draped accordingly. For those patients in which conscious sedation is used, nurses provide pain and sedation medications. These nurses have received training in advanced liver support and conscious sedation. They monitor the patient's vital signs, pain, and well-being throughout the procedure. Patients may also have these procedures under a general anesthesia. In those instances, an anesthesiologist is responsible for anesthesia care. A contrast medium is injected and fluoroscopy and cineradiography are used to visualize the vasculature of the treatment area. Using small flexible catheters and guiding wires, an Interventional Radiologist guides the agent to the tumor site within the liver. The TARE procedure is similar but microspheres containing either Yttrium-90 or ethiodized oil labeled with iodine or rhenium are delivered to the site (Edeline, Gilabert, Garin, GBourcher, & Raoul, 2015; Malagari et al., 2008). The use of TARE has increased in recent years (Johnson, 2017).

A meta-analysis by Zhang, Li, Ji, Zhao, and Lu (2015) indicated that patients receiving TARE had a greater survival rate than those receiving TACE (Zhang, Li, Ji, Zhao, & Lu, 2015). In 2016, Facciorusso, Serviddio, and Muscatiello published a meta-analysis comparing TACE to TARE and found that TACE was more effective in delaying tumor progression (Facciorusso, Serviddio, & Muscatiello (2016). Those patients treated with TARE had shorter hospital stays, better laboratory results, and fewer complications when compared to those receiving TACE (Zhang et al.). More randomized controlled trials are needed to compare the efficacy of the two treatments.

**Risks Associated with the Procedures.** Risks associated with TARE include extra-hepatic uptake of the microspheres into other organs such as the gallbladder. Radioembolization-induced liver disease (REILD) has been described as a risk factor in these patients (Edeline et al. 2015). A study by Kennedy et al. (2009) revealed the instance of REILD in a group of 515 patients was only 4%. Excessive radiation to the lungs can result in pulmonary fibrosis (Edeline et al., 2015). Other risks can include post embolization syndrome (PES), which includes symptoms such as fatigue, abdominal pain, nausea/vomiting, diarrhea, fever, and weight loss (Huang et al., 2013; Salem et al.,

### **Summary**

Studies have been conducted on factors that influence the IC experience for patients undergoing medical procedures or treatments, such as the mode, timing, and amount of information presented, but the results of these studies have been mixed. Researchers have also explored methods to improve standard consent procedures by adding print materials and illustrations, using technology-enhanced delivery platforms, and extending interactions between HCPs obtaining consent and patients. Some of these enhancements have resulted in improvements in patient knowledge and satisfaction, but in many studies indices of patient knowledge about the procedures remained low. Few studies have explored the experience of providing IC from the perspectives of patients undergoing complex medical procedures associated with significant risks. Moreover, the role health literacy might play in patient perceptions of their IC experiences is unknown. In order to improve the effectiveness and acceptability of IC procedures, more information is needed about how patients themselves experience IC procedures.

## CHAPTER THREE-RESEARCH STUDY

### **Introduction**

This chapter describes the research design and methods used to meet the study aims. The following topics are addressed: research purpose and aims, research design, population, sampling and setting, inclusion and exclusion criteria, sample size, and recruitment.

### **Research Purpose and Aims**

The purpose of this study is to examine the IC procedure as it was experienced by patients who underwent a de novo TIPS, TACE, or TARE procedure in an IR Department. The specific aims were as follows:

1. Describe how patients who underwent a de novo TIPS, TACE, or TARE procedure in an IR Department describe the IC procedure.
2. Describe what information patients who underwent a de novo TIPS, TACE, or TARE procedure in an IR Department recalled being told during the IC procedure.
3. Describe the satisfaction of patients who underwent a de novo TIPS, TACE, or TARE procedure in an IR Department with the IC procedure.
4. Explore how the IC experiences of patients who underwent a de novo TIPS, TACE, or TARE procedure in an IR Department differ according to their levels of health literacy.

### **Research Design**

This study used a qualitative design as the aim was to understand the IC process from the participants' perspectives. The design allowed the investigator to discover what was most important to patients who underwent a de novo TIPS, TACE, or TARE procedure by allowing them to freely discuss their consent experiences (Merriam, 2009; Streubert-Speziale & Carpenter, 2003). More specifically, a QD approach (Merriam, 2009) was used to provide a straightforward summary of the participants' narratives about their consent experiences.

The goal of QD research is to provide a rich and pragmatic description of a specific phenomenon of interest. Researchers using QD stay "closer to the data" (Neergard, Olesen, Andersen & Sondergaard, 2009, p. 53) than do researchers using other qualitative methods. QD is the qualitative method least encumbered by theoretical frameworks as no pre-selected variables are used to constrain the collection of data (Neergard, et al., 2009; Sandelowski, 2000). Sandelowski (2000) suggests this method may be "less sexy" (p. 334) than other qualitative methods but can provide pragmatic information to guide practice.

QD differs from other methods in a variety of ways. While Grounded Theory is an inductive and cyclical method with the goal of development a theory, QD produces low-interpretive frameworks or typologies (Hood, 2012). QD is also distinct from Phenomenology as the latter is used to interpret the latent meanings of the experiences of participants (Merriam, 2009; Neergard et al., 2009), whereas QD provides a practical surface description of a phenomenon.

The procedures used in QD studies vary but share some commonalities. Sampling is typically purposeful with a goal of maximum variation (Neergard et al., 2009). Data

may be collected from individual participants or focus groups (Sandelowski, 2000, p. 338). Questions used for data collection are open-ended and may be minimally to moderately-structured. Data collection is not limited to interviews but may also include artifacts and extant documents. Data include the “who, what, where, and why” (Sandelowski, 2000, p. 338) of the phenomenon of interest. Data collection and analysis may occur simultaneously. Data are presented in a variety of ways that fit the context of the study and are often analyzed with standard content analysis procedures (Sandelowski, 2000) that uncover patterns in the data (Neergaard et al., 2009; Sandelowski, 2000).

QD was the most applicable method for this study as the investigator aimed to provide a straightforward and pragmatic description of how patients experience IC prior to undergoing a de novo TIPS, TACE, or TARE procedure rather than to develop theory or provide an interpretive rendering of the data. The study included purposive sampling, individual semi-structured interviews, and content analysis of the interview transcripts.

### **Population**

The population for this study included patients who had undergone one of the three IR procedures within the three prior months. The three procedures were chosen for three reasons. First, unless urgent in nature, they require a pre-procedural visit with an Interventional Radiologist. For all three of the procedures, patients receive information about the procedures during this visit. This gives them time to consider the information they are given; discuss the information with family, friends, and providers; and seek out additional information regarding the procedure from other sources. This was consistent with the study aims because the investigator was interested in understanding consent processes that include time for consideration and deliberation. In contrast, for most other

IR procedures, patients present to the IR Department the day of procedure, receive information about the procedure, sign the consent, and then undergo the procedure immediately. Second, the three procedures are associated with notable risks. The investigator was particularly interested in how patients understand or interpret such risks when they are explained to them during the consent process. Patients undergoing more routine and less risky procedures would likely have substantively different consent experiences. Third, the procedures are moderately complex and thus the information provided to the patient during the IC procedure could be complicated. Thus the three procedures are similar in that they involve a pre-procedure visit, have significant risks, and are complex.

### **Sampling and Setting**

Purposive sampling was used in this study. The sample included patients who had one of the procedures described above performed by a member of the Indiana Radiology Partners (IRP) practice group and had not had a revision of their procedure. These procedures are performed by Interventional Radiologists at Eskenazi Health (formerly Wishard Hospital), Indiana University (IU) Health University Hospital, and IU Health Methodist Hospital, all of which are located in Indianapolis, Indiana. The IRP provide IR services to several IU Health affiliated hospitals in central Indiana as well as to Eskenazi Health. The 14 Interventional Radiologists in the IRP also hold academic appointments with the IU School of Medicine, Department of Radiology and Imaging Science, ranging from Volunteer Clinical Assistant Professor to Professor in rank. The department provides direct clinical care to patients, participates in clinical research, and offers physician fellowships in IR.

The three hospitals listed are all tertiary care centers providing advanced and specialized care to the Indianapolis, Indiana metropolitan area. The hospitals also provide care for residents of several counties that surround Indianapolis including Hamilton, Hancock, Shelby, Johnson, Morgan, Hendricks, and Boone counties and throughout the State of Indiana. Approximately 40-50 TIPS procedures are performed annually at University Hospital and 15 are conducted at Methodist Hospital. While TACE and TARE procedures are performed at all three hospitals, the majority of these procedures, approximately 20 cases per month, are done at University Hospital.

### **Inclusion and Exclusion Criteria**

The inclusion criteria are as follows:

1. Age 18 years and older.
2. Underwent de novo TIPS, TACE, or TARE procedure in the prior three months.
3. Participated in the IC process and signed the consent form for the procedure.
4. Able to read, write, and speak English.

Exclusion criteria are as follows:

1. Family member or healthcare representative provided consent.
2. Had a revision of the TIPS procedure.
3. Had a repeated TACE or TARE procedure.
4. Documented history of dementia.

Only adults were included in the sample as the consent procedures are different for children and adults. While the procedures are performed in the pediatric population for the same indication as adults (Czauderna et al, 2006 ; Hawkins, Kukreja, Geller, Schatzman, & Ristagno, 2013; Huffman, 1994; Maloglowkin, Stanley, Steele, & Ortega,



2000), pediatric patients provide assent for procedures and parents or guardians provide legal consent. In order to reduce limited recall of the IC procedure, participants were interviewed within three months of their procedure. Those patients who had TIPS revisions, or repeated TACE or TARE, were excluded since they would have experienced an additional IC procedure and may have had markedly different experiences due to their prior exposure to the information and the procedure.

### **Sample Size**

The size for QD studies is not specified a priori, rather participants are enrolled until content saturation has been achieved. Sandelowski (1995) indicates that while the sample size in QD studies may be as low as 10, the final sample size for any study depends on the complexity of the research question and the homogeneity of the sample. Because all participants had their procedure in the same radiology department and experienced a similar IC process, the sample was homogeneous in that regard. However, due to the exploratory aim related to health literacy, the sample was to be divided into three groups (high likelihood (50% or more) of limited literacy, possibility of limited literacy, and almost always adequate literacy), and a sample size of 21 participants was planned. Seven participants per group were anticipated to be sufficient to investigate the influence of health literacy on the participants' experiences with the IC process.

### **Recruitment**

The IR Department software was used to search for patients who had a de novo TIPS, TACE, or TARE procedure in the prior three months. Once a list of patients who meet the timeframe criteria was generated by the Interventional Radiologist who was a sub-investigator on the study, the investigator reviewed the information to confirm that

potential participants met basic inclusion criteria. The Interventional Radiologist holds the academic rank of Professor of Radiology and Surgery with the IU School of Medicine. The IU School of Medicine is a covered entity for the purpose of the IU Office of Research Administration and thus he had access to the patient information and could provide a list of these patients to the investigator.

A letter introducing the study, written by the Interventional Radiologist, was mailed to the potential subjects (Appendix A). The investigator then contacted patients who met criteria by phone and offered them the opportunity to participate in the study. During this initial call, a brief description of the study was provided and potential participants' questions were answered.

For those who agreed to participate, a copy of the IC document (Appendix B), the Indiana University Authorization for Release of Health Information for Research form (commonly called the HIPAA form at IU), and the audiotape consent was sent to them via their preference of email, fax, or U.S. Mail so they could review the study consent form in depth and discuss it with family and friends if they so choose. Five days after the consent was sent to potential participants, the investigator called them to ask if they would still be interested in participating.

### **Data Collection**

When the potential participants agreed to participate in the study, an interview was scheduled. If a potential participant did not wish to meet face-to-face, the investigator offered the participant the opportunity to participate via video chat or by phone. All interviews, with the exception of one that was conducted in a private room in a public library, were conducted over the phone.

Prior to the interviews, the investigator reviewed the IC document (Appendix B) and answered any questions the participants had regarding the study. The participants were asked to sign the IC document (Appendix B), the Authorization for Release of Information form, and the audiotape consent form. If the interview was to be conducted by phone, the participant was asked to fax, email, or mail the signed consents and the IU Authorization for the Release of Health Information for Research form to the investigator prior to the interview. All participants interviewed by phone returned their documents via a pre-stamped and addressed envelope to the investigator. A copy of all documents was provided to the participants.

Prior to the interviews, information about the participants' diagnoses and conditions, pre-procedure clinic visit dates, procedure dates, dates of signature on the IC, and post-procedure adverse events were obtained from the medical record in the IR Department and entered on the Health Summary Form (Appendix C). Demographic and medical information (Appendix D) was used to fully describe the study sample.

After the required documents were signed, the investigator conducted the interview. The participants were asked to complete a brief demographic sheet (Appendix D) that included the following: date of birth, race/ethnic group, gender, and highest level of education. A semi-structured interview guide was developed with questions designed to answer the study aims, although it was used flexibly so that participants could fully describe those aspects of the IC experiences that were most important to them.

The following opening statement was used: You had a procedure in the Interventional Radiology Department at \_\_\_\_\_ (University, Methodist, of Eskenazi [Wishard]) Hospital on (date). I'd like to discuss the appointment you had before the

procedure when you spoke with the (physician, PA, or NP) about the procedure and what that experience was like. I'll be asking you several questions about that appointment and I'd like for you to think back to that meeting with the (physician, PA, NP). Any details that you can provide to me about that appointment, even if they seem small or not very important, can be very helpful to me. You can choose to not answer a question if you are not comfortable doing so.

The following questions were included in the interview guide:

1. Tell me about the experience you had when you met with the (physician, NP, PA) to discuss the (chemoembolization, radioembolization, or TIPS) procedure.
2. Who came with you to that appointment?
3. Who spoke to you about the procedure? (Physician, Nurse Practitioner, Physician Assistant, multiple people)
4. What kind of information were you given during that appointment?
5. Describe how you felt when (Physician, Nurse Practitioner, Physician Assistant) described the procedure to you.
6. What types of questions did you (or family/friend) ask during the appointment?
7. Tell me about any written information that was given to you.
8. Did you search for information from other sources (i.e. internet, friends, etc.)?
9. Now that you've had the procedure, describe how satisfied you were with the information that was provided to you.
10. Can you think of anything that might have been more helpful to you during the informed consent procedure?

### **The Newest Vital Sign Tool**

Following the interview, the NVS (Pfizer Health Literacy Toolkit, n.d.) was administered (Appendix E). The NVS is an assessment tool for health literacy that has been validated against the Test of Functional Health Literacy of Adults (TOFHLA) tool. The TOFHLA has been widely used since it was developed in the mid-1990's (Weiss et al, 2005). The NVS uses the nutritional label for ice cream and requires the participant to use language and numeracy skills to answer six questions. The test can be administered in approximately 4 minutes. Pfizer has provided a NVS toolkit for HCPs at no cost and provides information on the administration and evaluation of NVS scores. Scores of 4 to 6 indicate adequate health literacy, scores of 2 to 3 indicate the possibility of limited health literacy, and scores of 0 to 1 indicate limited health literacy. The format of the test is familiar to participants because a standardized nutritional label is seen on all pre-packaged foods for sale in the United States. (Parker, Baker, Williams, and Nurss, 1995; Pfizer Health Literacy Toolkit, n.d). The NVS English version has an internal consistency of Cronbach  $\alpha=0.76$  with good criterion validity ( $r=0.59$ ,  $P<0.001$ ). There is no ceiling effect in the NVS as seen in the TOFHLA, and the NVS may be more sensitive for those with marginal health literacy levels than the TOFHLA (Weiss et al., 2005).

The NVS was chosen for this study as our aim related to health literacy is exploratory and the NVS is less burdensome and perhaps less threatening than other tools. Because it can be administered in approximately three minutes while the TOFHLA can take between 18 and 22 minutes, the NVS was less likely to lead to participant fatigue following the semi-structured interview, which was the primary data collection strategy.

### **Compensation**

Participants were paid \$20.00 in the form of a gift card after completion of the interview and NVS assessment. The amount of compensation was minimal and was not viewed by the investigator as being coercive.

### **Data Management**

The interviews were transcribed by the investigator. All identifying information was removed from the transcripts, and each transcript was identified by an identification number (001, 002, etc.). The transcripts were kept in electronic form in a Box Health Data Account (BHDA) on a computer that had password protection. Hard copies of transcripts were kept in a locked file cabinet.

### **Data Analysis**

The data were analyzed with standard content analytic procedures using the following the following steps (Miles, Huberman, & Saldaña, 2014):

**Step One: Review of Transcripts.** The investigator read all of the transcripts several times to fully understand the experiences of the participants. The investigator's general impressions of the interviews were described in memos. A brief case description was written for each participant.

**Step Two: Extraction of Text Units.** The investigator highlighted all text units (e.g., sentences, phrases, words) related to the IC procedure.

**Step Three: Coding.** The investigator then coded all text units. Saldaña (2009) defines a code as “a word or short phrase that symbolically assigns a summative, salient,

essence-capturing, and/or evocative attribute for a portion of language-based or visual data” (p. 2). The investigator’s dissertation chair verified the codes.

**Step Four: Display of Data.** Codes were placed into a case-by-variable table as described by Miles, Huberman, and Saldaña (p. 224). This table was structured with cases presented on the vertical axis and variables of interest on the horizontal axis. The rows were divided into three sections: adequate, possibly limited, and limited health literacy levels as assessed by the NVS tool. The table was also divided into three main columns in order to organize the codes to answer each aim. The three main columns were labeled as follows: (1) IC Experience, (2) Information Provided, and (3) Satisfaction. Column 2 was further divided into Verbal Information and Written Information, and Column 3 was further divided into Helpful and Non-helpful aspects of the IC experience. Each code was placed in the appropriate cell by the investigator.

In order to ascertain if there were overt differences among the three IC experiences for each of the three procedures, data related to each of the three procedures were highlighted with different colors on the table and compared. No differences were noted, seemingly because the three procedures were of similar risk and complexity.

**Step Five: Categorization.** The codes in each column were categorized and summarized for each study aim. The codes in Column 1 were categorized to identify the most salient aspects of the IC experience from the participants’ perspective, the codes in Column 2 were categorized to identify the information the participants recalled being told about their procedures, and the codes in Column 3 were categorized to identify aspects of the IC procedure the participants found to be helpful or not helpful. The investigator’s dissertation chair assisted the investigator develop the categories. The final categories

were developed through discussion and consensus and verified by a review of the transcripts.

**Step Six: Narrative Summary.** Once the codes in each column had been categorized, the investigator wrote a narrative description of the categories as well as a summary of each column.

**Step 7: Analysis for Aim 4.** To explore how the IC experiences of the participants differed according to their levels of health literacy, the sample was divided into groups based on their scores on the NVS (Pfizer, n.d.). The narratives of the groups were examined for explicit references to issues that might reflect the influence of health literacy on their experiences during the IC process. Remarks were highlighted that suggested that the participants (a) did not understand, or had trouble understanding, any information presented to them, either verbally or in the consent form; (b) were given information with terms that were too technical or difficult to understand, or (c) had misinterpreted information given to them. Data display tables were developed in which such remarks were divided according to the health literacy groups. The table was then used to explore if the health literacy groups showed any manifest differences in the number or nature of such remarks.

An exploratory ad hoc examination of group differences was also conducted. Several factors discussed in the participants' narratives that might possibly be related to health literacy and that could be easily quantified or dichotomized were identified. These factors included (a) the number of risks and benefits identified by the participants, (b) whether or not the participants sought information from the internet, (c) whether or not they asked questions during the IC process, and (d) whether or not they were satisfied



with the IC process generally. To examine if the number of risks and benefits recalled differed among the two groups, a Fisher's exact test was conducted (Pagano & Gauvreau, 2018). To determine if the groups differed according to whether or not they searched the internet, asked questions during the IC process, or were satisfied with the IC process, a Fisher's Exact Test was conducted (Pagano & Gauvreau, 2018). Significance was set at 0.05.

### **Evaluative Framework**

The evaluative framework for qualitative research as described by described by Miles, Huberman, and Saldaña (2014) was used to ensure the quality of the findings. The criteria from this framework used in this study are as follows: objectivity/confirmability, dependability/auditability, authenticity, and transferability.

**Objectivity/confirmability.** Objectivity and confirmability is the acknowledgement of the need to remain neutral from investigator bias (Miles, Huberman, & Saldaña, 2014). In order to assure objectivity and confirmability, the investigator was attune to personal biases that might affect her findings. This was particularly important as the investigator has previously worked in the IR Department at Eskenazi Hospital (formerly Wishard Hospital), was the research coordinator at the Imaging Science Division at the IU School of Medicine, and had a working relationship with many of the staff and personnel in the IR Departments where the study will be conducted. She thus recorded any thoughts or feelings regarding data that seem to be related to her past experiences and personal beliefs and reviewed these memos with her dissertation chair.

**Dependability/Auditability.** Dependability and auditability refers to the consistency and stability with which study procedures are enacted (Miles, Huberman, &

Saldaña, 2014). The investigator ensured that the procedures of the study as detailed in this proposal were consistent with the QD method and were followed regularly throughout the study process. Any deviations from the procedures as presented were discussed with the investigator's dissertation chair and in some instances with her dissertation committee. The investigator arranged regularly scheduled meetings with her dissertation committee chair to obtain feedback regarding consistency of study procedures (Miles, Huberman, & Saldaña, 2014). In addition, all original memos, transcripts, coding documents, and data displays were maintained as an audit trail and periodically reviewed by the dissertation chair.

**Credibility/Authenticity.** Credibility and authenticity is the “truth value” of the findings (Miles, Huberman, & Saldaña, 2014). In order to assure credibility and authenticity, the investigator designed a semi-structured interview guide to elicit rich and meaningful data related to the study aims. The transcripts were regularly reviewed by the investigator's dissertation committee chair to provide feedback on the investigator's interviewing techniques. The investigator was able to show how the findings were clearly and systematically drawn from the data by the use of the case-by-variable table described above (Miles, Huberman, & Saldaña, 2014).

**Transferability.** Transferability is the ability to apply study findings to other contexts or populations (Miles, Huberman, & Saldaña, 2014). The investigator described the population and context of the study fully so that users of the findings will be able to determine the applicability of the findings to their own settings. A full description of the IR settings in which the participants had their IC procedure conducted and a detailed description of the study participants is provided in all reports. For example, demographic

information regarding gender, socio-economic status, ethnicity, and age of the sample is described fully so that readers can determine if these study findings can be applied to other persons receiving IR procedures.

### **Application**

The study findings will inform HCPs on how patients experience the IC process for complex IR procedures. The results provide information about how IC procedures might be improved to ensure patients have been fully informed and satisfied with the procedures. The study will inform agencies and facilities who strive to meet The Joint Commission standards with regard patient communication as detailed in their standard (2010) entitled: Advancing Effective Communication, Cultural Competence, and Patient and Family Centered Care

## CHAPTER FOUR-RESULTS

### **Introduction**

This chapter presents the study findings. First, the outcomes of recruitment efforts and a description of the sample characteristics are provided, followed by a brief description of the interviews. The major portion of the chapter is structured according to the study aims and reveals how the participants described the IC procedure, what information they recalled from the IC procedure, and their satisfaction with the IC procedure. The results of the exploratory aim related to health literacy are also addressed.

### **Sample**

All participants were recruited from one hospital site from June 2016 through February 2018. Although the study protocol initially included only persons undergoing de novo TIPS procedures, persons undergoing TARE and TACE procedures were added to bolster enrollment following a protocol review by the Simon Cancer Center Scientific Review Committee. These procedures are of comparable risk and complexity to the TIPS procedure.

Eighty-three persons had one of the three IR procedures during the recruitment period, met study criteria, and were sent a letter inviting them to participate in the study. When contacted by the investigator, 46 (55.4%) agreed to review the IC document and consider participation, and 17 (36.9%) of those persons agreed to participate. Many of the persons contacted declined to participate for a variety of reasons: they were in extended care facilities, very ill, incarcerated, or deceased. In some cases, potential participants' phones had been disconnected or they could not be reached with available contact information. Two of these persons who agreed to participate did not respond to multiple

follow-up attempts to schedule interviews and were considered screen failures.

Interviews were therefore conducted with 15 persons. One of these persons had had a TIPS revision between the time he agreed to review the study consent document and when he returned it to the researcher. The investigator was unaware of the revision at the time of the interview but withdrew the person's data once this became known as he no longer met study criteria. The final sample included 14 participants, which represented 16.8% of those eligible.

The demographic characteristics of the sample can be seen in Table 1 (Appendix F). Of the 14 participants, eight (57.1%) were male and six (42.8%) were female. They ranged in age from 38 to 73 years of age with a mean age of 58 years. Eleven (78.5%) identified as White, 2 (14.3%) as White and Native American, 1 (7.1%) as Black, and 1 (7%) as Hispanic. Seven had a high school diploma, 3 had some college, 2 had less than a high school diploma, 1 had a bachelor's degree, and 1 did not disclose educational level.

Twelve subjects underwent a de novo TIPS procedure due to portal hypertension caused by cirrhosis of the liver. Two subjects underwent a TARE procedure due to hepatocellular carcinoma (HCC). All but one participant had a regularly scheduled visit prior to the procedure in which they provided consent. One participant had an emergent procedure in the hospital and thus provided consent immediately prior to the procedure.

### **Description of Interviews**

Thirteen interviews were conducted over the phone, and one was conducted in person in a private room of a public library close to the participant's home. The semi-structured interviews ranged in length from approximately seven minutes to just over thirty minutes.

All the participants were alert and oriented and answered all of the interview questions and completed the health literacy assessment. All could recall the pre-procedure clinic visit to the Interventional Radiologist during which their procedure was discussed and they provided consent. Many were able to recall specific details about the visit, including interactions with several HCPs and ancillary staff, who accompanied the participants to the visit, and testing that was also completed at the visit. In response to questions about the IC process, participants often discussed their ill health more generally, the procedures they had experienced, and their overall health outcomes. Because this information provided a context for the questions about the IC process, participants were welcomed to discuss these experiences. However, when they were redirected to discuss their IC experiences more specifically, all were able to focus on this topic. No participants became upset or distressed when answering interview questions. All completed the entire interview, although some participants were more verbose than others. Two interviews were interrupted; one due to dropped cell coverage and the other due to an urgent situation for the interviewer. These interviews resumed within less than 15 minutes after the delays.

### **Findings**

The findings are first discussed according to each of the three main study aims. For each main aim, the key topics discussed by the participants are identified and described. Examples and verbatim quotes from the participant transcripts are provided to support the findings presented. Following the discussion of each aim, an extended quote from one participant that exemplifies several aspects of the findings about that aim are presented. Next, two case studies are provided based on the experiences of two

participants who provided rich detail about their somewhat contrasting IC experiences. Finally, the findings related to the exploratory aim related to health literacy are discussed.

**Aim One: Describe how patients who underwent a de novo TIPS, TACE, or TARE procedure in an IR Department describe the IC procedure**

The initial interview question was open-ended and asked subjects to describe the IC procedure. This question was purposely broad so that the investigator could determine which characteristics of the IC procedure the participants were most likely to remark on before the interview moved on to more structured questions. This strategy is based on the assumption that participants' remarks to such opening questions reveal particularly salient or memorable aspects of an experience. In response to the initial interview question, most participants discussed the quality of their interactions with providers during the IC visit, the emotions they experienced during the visit, support persons present at the visit, and the decision to have the procedure.

**Quality of interactions with providers.** Many of the participants, when asked about the IC process generally, commented about the quality of their interactions with the staff obtaining IC and the IR physician who would perform the procedure. Some participants first described the interactions they had with support staff in the clinic prior to meeting the physician. The participants recalled that these staff members obtained their vital signs and obtained basic health information. The participants also recounted how a nurse practitioner or physician's assistant obtained their medical history and explained their planned procedure. The participants generally remarked that these interactions were amiable. A 58-year-old man who underwent a TARE procedure stated,

“And he [physician’s assistant] was very informative. He was pretty good. It was just pleasant, that I remember.”

During the IC visit, the participants also interacted with the IR physician who would perform the procedure, and many discussed this interaction in some detail. Several remarked about the IR physician’s extensive expertise in performing the procedure, his national reputation, his high success rate, and how highly he came recommended by the participants’ primary care physicians or liver specialists. Some discussed his demeanor during the interaction, remarking that he seemed “very sure of himself,” although several indicated that they wanted an IR physician who was highly self-confident. A 61-year-old woman who underwent a de novo TIPS procedure stated, “I felt relieved that everything he’d done, he’d done for years. And it wasn’t like his first rodeo, you know.”

**Emotions experienced during the visit.** In describing the IC visit, many participants focused on the feelings that the visit provoked. Several indicated that they felt frightened when the IR provider described the de novo TIPS, TACE, or TARE procedure. A 73-year-old woman who underwent a de novo TIPS procedure stated, “I was scared as I could be. I’m pretty tough, but I was.” Some worried about undergoing the procedure generally, while others had concerns about specific risks such as infection and bleeding. A 47-year-old man who underwent a de novo TIPS procedure became concerned when the provider stated, “ ‘Obviously, we’re slitting your jugular vein, the last thing we want you to do is have high blood pressure and bleed out on us.’ ” A few participants did not feel afraid at the time of the IC visit but became fearful when they went home and considered the information they were given about their procedures. A 59-



year-old woman who underwent a de novo TIPS procedure stated, “I wasn’t scared at first. It was when I got home and started thinking about it.”

Some participants indicated they had no fear or concerns when the IR procedure was described to them. Because many had been ill for some time and had endured years of medical testing, they had become accustomed to invasive procedures. Even the possibility of death did not concern a few of them. A 47-year-old man who underwent a de novo TIPS procedure stated, “I have no fear really when it comes to things like that. If I’m going to die, I’m going to die.” Others were not fearful or worried because they had faith the procedure would go well. A 61-year-old woman stated, “And I just said to him [IR physician], I’m not gonna die on the table. Cause God’s not ready for me to die yet. You know, he’s not done with me yet.”

**Support persons present during the visit.** When describing the IC visit, many participants indicated they brought someone with them who could provide support. The participants indicated that it was important to have someone accompany them to this appointment to help them remember information provided, ask questions, give emotional support, and provide practical assistance, such as driving them to and from the clinic. The support persons included friends, significant others, spouses, and other family members. During the IC procedure, however, only a few of the support persons asked questions regarding the IR procedure to be performed. A 58-year-old man who underwent a de novo TIPS procedure stated, “I took my wife. We’re currently separated, but we still get along really well. I took her along with me just so I’d have somebody with me.”

The participant who had an emergency de novo TIPS procedure in the hospital did not have a support person present when he provided IC. This participant, a 49-year-

old man, stated, “There was nobody at the hospital . . . so I had nobody to turn to. I had to get on the phone to call my wife and daughter.”

**Decision to have procedure.** When asked to describe the IC procedure, many participants focused on their decision about whether to have the IR procedure that had been recommended to them. After hearing the risks and benefits, they determined that the procedure was the best choice for their current health status and could potentially improve their quality of or extend their lives. A 59-year-old woman who underwent a de novo TIPS stated, “But the more and more I was having to go and get drained, I just felt it [TIPS] was a better option for me cause it was wearing me down.” A 49-year-old man who underwent a de novo TIPS procedure stated, “At this point I was, my personal opinion, if it was available to us finally, it was the only smart option we had left.” A few participants had decided before the IC process that they would have the IR procedure done. A 60-year-old man who underwent a de novo TIPS procedure stated, “I needed this procedure done. Before I even got a chance to talk to Dr. X, I wanted to do it.” A 73-year-old woman who underwent a de novo TIPS procedure discussed the choice of having the procedure with her family and stated, “It was a decision that the girls [her daughters] and I made before I got there [to the IC visit].”

**Summary.** Most of the participants, when describing the IC procedure, talked about the staff they encountered, the feelings they experienced during the visit, the people who came to the IC visit with them, and the decisions they made about having the procedure. A 58-year-old man who underwent a de novo TIPS procedure covered several of these topics succinctly:

I mean, I thought it [the IC procedure] was okay. I mean, it’s all kinda scary to me no matter what. Just because of, what they’re doing . . . I

mean they're going in main arteries and what have you. It's just kinda scary stuff. You just don't know, you know. Okay, what could happen? And the bad part about it is, you don't know what questions to ask either, because you don't know enough about it. At least I didn't know enough about it. But I mean, as far as the meeting, it was pleasant. They were very informative. They told me everything that, at least I could think of, as far as questions go.

**Aim Two: Describe what information patients who underwent a de novo TIPS, TACE, or TARE procedure in an IR Department recalled being told during the IC procedure.**

When the participants were asked what information they recalled being told during the IC procedure, they focused on being told about how the procedures were performed, the care that would be required, and the risks and benefits of the procedures. Some of the information was provided to them as a routine part of the IC visit and some information was provided to them in response to questions they asked. Most of the information was provided verbally by the IR physician or staff member, but some participants were given written information such as hand-written drawings or pamphlets or booklets describing the procedure. Although the sections below focus on information given to the participants during the IC visit, they had often received some information about the procedures from their HCPs before the visit. A few had also received information from family or friends familiar with the procedure or from internet sites.

**How the procedures were to be performed.** Most participants recalled being given information about technical aspects of the procedure. A 61-year-old woman who underwent a de novo TIPS procedure stated, "Dr. X came in and talked to me again and totally explained how the procedure would work. How they would do the procedure itself." Several were told how the liver would be accessed via "arteries" in the groin or

neck. Some who underwent a de novo TIPS procedure were informed that a stent would be placed in their liver and the liver would be accessed through the jugular vein. Those who underwent a TARE procedure were told about the Y-90 device.

**Care needed for the procedures.** Some participants recalled being told about the care they would receive before, during, and following the procedure. A 38-year-old woman who had a de novo TIPS procedure stated she was told “everything involved as far as nursing, people that would be in the operating room, as far as like anesthesiologists and students and things like that ....” Some participants asked and were given details about how long they would be in the hospital or would be “down” after their procedures. A 58-year-old man who underwent a de novo TIPS procedure stated, “As a matter of fact, I don’t think I had any other questions other than how long am I going to be down.” Some also asked about and were provided instructions of post-procedure restrictions on their activities, such as the length of time after the procedure that they should not lift heavy objects. A few recounted being given information about what to do if complications arose after discharge. For example, a 65-year-old woman who had a de novo TIPS procedure was told to go to the emergency room if she experienced pain.

**Benefits of the procedures.** Many of the participants recalled being told the benefits of the procedure. These benefits included decreasing the need for frequent paracentesis, increasing the chance of getting on the liver transplant list, stopping intestinal bleeding, and extending life. A 47-year-old man who underwent a de novo TIPS procedure stated, “It was gonna allow me to get the blood flowing from my liver and below back into the heart and moving better.”

**Risks of the procedures.** All participants recounted being informed about risks associated with the procedure. The participants most often recounted being told the risk of bleeding. Some had been told they could develop blood clots during or after their procedure or could possibly “bleed out.” A 65-year-old woman who had a de novo TIPS procedure stated, “There was always a possibility of extra bleeding cause you go into the liver.” A few participants recalled being told about risks related to post-procedure encephalopathy including confusion and the potential for hallucinations. A 38-year-old woman who underwent a de novo TIPS procedure stated, “Having the blood flow back might make me a little confused for a while. And if it continued, I might need to go on medication. If not, that was great.” Although less frequently mentioned, some participants recalled being told of the risks of incision opening and infection.

Almost half of the participants said they were told during the IC process that there was risk of dying during the procedure. Some were given specific mortality rates. A 66-year-old-man who had a de novo TIPS procedure stated, “Yes, I had a chance of dying. But it was like two or five percent.”

After being told about the risks, some participants concluded they were minor whereas others concluded they were serious. A 60-year-old man who had a de novo TIPS procedure was unable to recall any specific risks but had determined that he did not need to be worried about them. He stated, “I mean, it wasn’t nothing major.” On the other hand, a 57-year-old man who had a de novo TIPS procedure stated, “He [the physician] did say there was a fair amount of risk to the procedure itself.” A few recalled being told they were at a lower risk for potential complications because their health status was good.

**Summary:** Most of the participants recalled being told about how their procedure would be performed, the care they would need, and the benefits and risks of the procedure. A 61-year-old woman who underwent a de novo TIPS procedure described receiving information during the IC process:

Dr. X came in and talked to me again. And totally explained exactly how the procedure would work. How they would do the procedure itself. What it [the stent] had to go through and go down and to be able to put the shunt in my liver. And he did specify that there is a chance of death with any surgery. . . I asked him to explain to me and to draw, actually draw a diagram kind of thing exactly how the procedure's gonna go. And they showed me.

**Aim Three: Describe the satisfaction of patients who underwent a de novo TIPS, TACE, or TARE procedure in an Interventional Radiology Department with the IC procedure.**

When asked if they were satisfied with the IC procedure, all but a few said they were satisfied. Many of the participants responded to this question, however, with comments about their satisfaction or dissatisfaction with the IR procedure, the outcomes of the procedures or with their current health status. When asked to consider the IC procedure specifically, they were able to do so and identified several sources of satisfaction or dissatisfaction.

**Satisfaction with IC process.** In regards to the IC process, most participants were satisfied. They were pleased with the quality of information they received, the amount of time staff spent giving information on their procedures during the clinic visit, and congruency between the information provided and their actual experience with the procedure.

Most participants felt they were given ample and accurate information about the procedure they were to undergo. The information provided a feeling of “safety” and these participants felt they knew “exactly” what was going to happen to them during their procedure. A 59-year-old woman who had a de novo TIPS procedure stated, “Well, he [the physician] explained it [the procedure] thoroughly so I understood it. He did a very good job explaining it to me.”

Some participants appreciated the amount of time taken during the pre-procedure visit to explain the procedure. Several said they were able to ask questions and received the information they needed about their procedure. A 73-year-old woman who had a de novo TIPS procedure stated, “After he [physician] got done with his thing, he had to tell me both sides. He gave me a long enough time. He just didn’t hurry me up and hurry me out.”

Some participants were pleased that the information they received during the IC process was congruent with what actually happened during the IR procedures. They felt prepared for the procedure and did not experience any surprises. A 62-year-old woman who had a de novo TIPS procedure stated, “I was very satisfied. They told me exactly what was going to be done and what the outcomes should be. It’s [liver stent] working, it’s doing what it’s supposed to be doing.”

**Dissatisfaction with the IC process.** A few participants, however, expressed dissatisfaction with the IC process. These participants were unhappy because they had to wait a long time for their IC appointment, were not shown anatomical models/diagrams to help them understand the procedure, and did not have all their questions answered to their satisfaction.

One participant was perturbed about the wait time for his pre-procedure visit. A 47-year-old man who had a de novo TIPS procedure stated, “He [IR physician] didn’t even make it into the room until 5:15 or 5:20. Kinda ticked me off considering I sat there for an hour and twenty, fifteen minutes or whatever.” This participant was also dissatisfied with the visit for a number of other reasons. For example, he complained that the diagrams of his procedure were hand-drawn rather than professionally printed. He stated, “I mean I would think with what he [the IR physician] considered basically a hundred-thousand-dollar surgery, it wouldn’t be him hand drawing a liver on a scratch piece of paper.”

Another participant, a 66-year-old man, expressed dissatisfaction with the answers received from the HCPs in response to his questions during the IC process about how the procedure would be done. This participant sought additional information about the procedure on the internet and from a friend who was a physician. Another participant, a 58-year-old man who had a TARE procedure, would have appreciated the opportunity to discuss additional treatment options during the IC process. He stated he wished the IR physician “would give me other options besides Y90. That’d be helpful. I mean, you don’t do it every day.” A couple of participants mentioned that they did not understand some terms used during the IC process. A 66-year-old man who underwent a de novo TIPS procedure stated, “...[They should use] plain language, I don’t understand the medical terms and all that.”

A few of the other participants complained about other aspects of their experiences with the procedure but not related to the IC process. These complaints included poor communication with the waiting family and friends post-procedure, being



cared for by unfamiliar providers following the procedure, and a variety of issues related to post-procedure care such as being moved to multiple rooms and conflicts with roommates.

**Summary:** Most participants were satisfied with the IC process because they obtained the information they needed and the information they received matched their actual experiences with the procedure. A typical response to the IC process was offered by a 60-year-old man who had a de novo TIPS procedure: “I mean they pretty much explained it to me. It was explained to me just right. They couldn’t have done a better job.” The few participants who were dissatisfied would have liked professional diagrams, more information, and explanations in simple language.

### **Participant Exemplars**

In order to provide a more in-depth description of the overall IC process from the participant perspective, two participants’ experiences are described in some detail. The participants used for these exemplars are referred to as Participant A and Participant B. These participants were chosen as exemplar cases because they provided particularly robust descriptions of their overall IC experience and because they had experiences that differed considerably from each other.

**Participant A.** Participant A was a 65-year-old woman who underwent a de novo TIPS procedure for a diagnosis of cirrhosis of the liver. She had been informed by her liver specialist that she would go into liver failure within a couple of years. Her goals for the procedure were to get onto the liver transplant list and to improve her health enough to have gastric sleeve surgery for weight loss. The liver specialist had spoken to her on

several occasions about the TIPS procedure, and she felt as if she understood the need for the procedure.

When she met the IR physician to discuss the de novo TIPS procedure during the IC visit, he mainly reinforced the information given to her by the liver specialist.

Participant A said the information she received from the liver specialist and the information she received from the IR physician and the staff were consistent. During the IC visit, she asked questions related to her length of stay in the hospital, how her pain would be controlled, and if there would be any activity restrictions after the procedure. Participant A was told the major risks associated with a TIPS procedure, especially the risk of bleeding and the possibility that she might develop blood clots. Participant A's sister came with Participant A to the IC appointment, and while her sister did not ask any questions, she did take some notes during the discussions.

Overall Participant A was satisfied with the IC process for the de novo TIPS procedure. She did not feel rushed during the IC procedure appointment, and the IR physician and his assistant took ample time to answer all of her questions to her satisfaction. However Participant A would have liked some of the medical terms, like "jugular," explained to her and felt she would have benefitted from seeing pictures of how the procedure is performed.

Participant A did seek additional information about the procedure from other sources. She spoke about the procedure with an acquaintance whose relative underwent a de novo TIPS procedure. Moreover she looked for information on the internet, but said she believed that it "drives some doctors crazy" when patients obtain information in this way.

Participant A's decision to have the de novo TIPS procedure was straightforward; while she was concerned with the risks, the possibility that she could get on the liver transplant list outweighed any concerns she had about the safety of the procedure. Although her desire for a liver transplant was the main factor driving her choice to have the de novo TIPS procedure, her decision was also influenced by the trust she had in her liver specialist, who recommended the IR physician. Additionally, she was reassured about having the procedure by the self-assured nature of the IR physician.

Patient A did experience complications after her procedure and was required to stay in the hospital for a few days. However, she indicated she was nonetheless satisfied with the information she received during the IC process. She suggested that if other patients did not have the amount of information she did prior to the IC process, they may need more information regarding medical terms and how the procedure was done than she received during her pre-procedure visit.

**Participant B.** Participant B is a 47-year-old man who had a de novo TIPS procedure. He was referred by his liver specialist to the IR physician for a de novo TIPS procedure consultation due to the portal hypertension caused by the cirrhosis.

Participant B's experience with the IC process was not as positive as that of Participant A. He is the participant mentioned above who had to wait nearly one and a half hours past the scheduled appointment time for the IC visit. This was the first thing that he mentioned when asked to describe the IC process, and this delay seemed to set the tone for the visit.

When asked about his experience with the IC process, Participant B focused many of his remarks on the IR physician. Participant B mentioned that the physician was

“honest” and “factual” in his delivery of the information about the TIPS procedure and described the risks and benefits and how procedure would be performed. Participant B, however, complained that the physician seemed “in a hurry” and drew a diagram by hand to show how the stent would travel through the liver, whereas Participant B would have expected a more polished visual given the expense of the surgery. He remarked several times that he found the physician’s very self-assured demeanor to be off-putting, but indicated that the physician’s confidence and experience were reassuring, such that Participant B had no fear about having the procedure.

Participant B recalled being told the risks and benefits of his procedure. The physician told him he was a “great candidate” for the procedure, which would get the blood flowing from his liver to his heart. He stated, “He [the physician] told me if I quit drinking I may never have to have a liver transplant.” In regards to risks, Participant B remarked that the physician told him that “one or two percent of the people in my situation die in the first sixty days.” Participant B recalled that he was told about the risks of anesthesia, bleeding, and blood clots. Participant B indicated that he decided “right then” [during the IC visit] to have the procedure.

Participant B revealed that his girlfriend accompanied him to the IC visit and asked one or two questions. The couple was sent home with several pages of information about the TIPS procedure. After the IC visit, Participant B’s girlfriend sought additional information on the internet, which the couple found to be very consistent with information provided to them by the physician.

In regards to satisfaction with the IC process, Participant B was generally satisfied with the amount of information he was given, but, as stated above, he would have wanted

an “extremely well drawn out diagram” and a process that was “more professional.” He stressed that although he was not fearful because his risks were low, he surmised other people might be “pretty darned worried” and might appreciate the opportunity to speak with a patient who had had a de novo TIPS procedure or having a video tape to view at home.

Participant B’s procedure went well but he listed a series of complaints about his post-procedure experiences. He was dissatisfied with the lack of communication with waiting family members, delay in being transferred to a room, and a long wait in being given something to eat. Nonetheless when summing up the IC process, he stated, “It seemed straightforward to me... The actual consent form I’m sure was drawn up by doctors and lawyers alike.”

**Aim Four: Explore how the IC experiences of patients who underwent a de novo TIPS, TACE, or TARE procedure in an IR Department differ according to their levels of health literacy**

The purpose of this exploratory aim was to examine if there were any differences in how participants experienced the IC process based on their health literacy level. As stated above, the investigator administered the NVS (<https://www.pfizer.com/helath/Literacy/public-policy-researchers/nvs-toolkit>) assessment for health literacy just prior to their interview. According to the developers of this assessment, a score of 0-1 indicates a “high likelihood of limited literacy,” a score of 2-3 indicates “the possibility of limited literacy,” and a score of 4-6 indicates “almost always indicates adequate literacy.” None of the participants scored in the 0-1 category, 8 participants scored between 2-3, and 6

scored between 4-6. The participants were placed into two groups based on these scores (“possibility of limited literacy” and “almost always indicates adequate literacy”). Only a few participants in either group made remarks indicating that they had trouble understanding information presented to them during the IC process, were given information with terms that were too technical or difficult to understand, or had misinterpreted information given to them. Moreover, no manifest differences were detected between the groups in the number or nature of these remarks. For example, the group that scored in the range of “possibility of limited health literacy” was not more likely to comment that they struggled to understand information presented to them than the group that scored in the range of “almost always indicates adequate literacy.” Moreover, as seen in Tables 2-4 (Appendix G), the groups did not differ significantly on the number of risks and benefits identified by the participants (Table 5, Table 6), whether or not the participants sought information from the internet, whether or not they asked questions during the IC process, and whether or not they were satisfied with the IC process generally. Overall, therefore, the role of health literacy did not seem to discernibly influence the participants’ narratives related to their IC experience.

### **Summary of Findings**

The participants provided adequate information to address each study aim and most could clearly recall the IC process. When describing the process, the participants focused on their interactions with staff and the IR physician, the feelings that arose during the process, the support they received from family and friends who accompanied them, and how they made the decision to have the procedure. The main benefits of the procedures that the participants recalled being told about during the IC process were the

extension of their life expectancy and the freedom from parenthesis. The main risk of the procedures that the participants recalled being told about during the IC process was bleeding. They were also told there was some risk of death, although some were reassured that this risk was small because of their overall health status. Some participants were quite frightened about having the procedures, whereas others were confident that it would turn out well. All were convinced that their procedure was necessary given their health status, and none debated extensively about whether to have the procedures done or not. Most of the participants were satisfied with the IC procedure overall, although a few would have liked some medical terms being explained and the procedure being diagrammed more adequately. Health literacy did not seem to have a major influence on how the participants experienced the IC process.

## CHAPTER FIVE-DISCUSSION

The purpose of this study is to examine the IC procedure as it was experienced by patients who underwent a de novo TIPS, TACE, or TARE procedure in an IR Department. This chapter will summarize the study findings and discuss several major findings as they relate to existing literature on the IC process, outline the study limitations, provide suggestions for future research, and discuss clinical implications.

### **Summary of Findings**

The study findings provide a description of how patients undergoing a complex IR experienced the IC procedure based on their own words. When asked to describe the IC procedure, the participants focused on their interactions with their providers, the emotions the participants experienced during the IC visit, the support persons present during the visit, and their decision to have the procedure. They recalled being informed about how their procedure was to be performed; the care they would need before, during, and after the procedure; and some of the benefits and risks to the procedure. Most were satisfied with the IC process although a few mentioned some sources of dissatisfaction. The health literacy level of the participants did not seem to influence the responses of the participants to the IC process. Several of the major findings resonated with the findings of prior studies.

### **Findings and Prior Literature**

One key finding in the current study was that interactions with the providers during the IC visit were important to participants. Unlike the on-going relationships they had with their routine health care providers, the IC visit was a brief encounter focused specifically on the procedure. While most research focuses on patient-provider



relationships in on-going care, a few studies have examined the nature of these relationships in single encounters. Keating et al. (2002), for example, examined the relationship between trust in physicians and problems experiencing during an office visit (e.g., physician not giving patients enough time to explain the reason for their visit, physician not providing understandable answers to questions) and found that lower trust in the physician was associated with each problem. Several participants in our study indicated the IC process was acceptable not because of good rapport with the provider but because they had trust in the IR physician due to his renowned expertise, which was often more important than his “bedside manner.” Just as our participants were seemingly reassured when told how their procedure would improve their life-threatening symptoms, a phenomenological study of patient perceptions of general practice consultations (Anden, Andersson, & Rudebeck, 2005) revealed that patients most wanted a cure, symptom relief, or an understanding or confirmation of “what they had.” Therefore, our findings and these findings related to one-time consultations suggest that the promise of successful outcomes rather than interpersonal considerations may be most important during these visits.

Other studies have also addressed our finding that even participants who recounted similar risks varied in terms of how serious they perceived these risks to be. This may have been because some of our participants perceived their risks to be low because they were told they were in the top percent of “good candidates” based on their overall health status at the time of the procedure. Indeed Zipkin et al. (2014), based on a systematic review, concluded that risks should be presented to patients based on their individual risk level instead of risks to the population as a whole. Yet we found some of

our participants nonetheless seemed to downplay the risks of the procedure, which was similar to a finding in a study by Lloyd (2001). In this study, participants tended to underestimate their own risks when compared to others, a phenomenon Lloyd terms optimism bias. He argued that risk information given to patients is often not used in decision-making regarding treatments and may be less important than how persons perceive their own risks or than other factors or concerns.

Only a few participants in our study were dissatisfied with the amount of information they received during the IC process. Prior studies suggest that satisfaction with the amount of information received may be due to individual factors. For example, Rood et al. (2015) discussed how patients dealing with threatening information use one of two coping styles: monitoring (seeking threatening information) and blunting (avoiding threatening information). In a sample of patients with hematological malignancies, the authors found these coping styles were related to the need for information, information satisfaction, and involvement in treatment decision-making in complex ways. Thus, the need for information and satisfaction with information provided is likely based on a variety of factors, some of which are unique to the patient.

A few of our participants did indicate that would have liked better diagrams to explain the procedure and the use of simpler terminology. The success of using visual materials to explain complex procedures has been discussed in the literature. In a study of patients undergoing a TACE and TIPS procedure and a Inferior Vena Cava (IVC) filter placement, the researchers developed educational DVDs for patients to view (Koh, Degerstedt, Addicott, & Schenning, 2018). The use of the DVDs resulted in better understanding of the procedures when compared to verbal explanations alone.

Additionally, those participants who viewed the DVDs before speaking with the IR physician received lower doses of sedation during their procedure and reported higher intraprocedural comfort levels (Koh, Degerstedt, Addicott, & Schenning, 2018).

While several of our findings resonate with prior literature, the study will make a unique contribution as it is one of the only studies that has queried persons about their perspectives on the IC process for a complex IR procedure. This approach revealed some nuances to understanding the patient experience that had not been dealt with in-depth in prior literature. For example, while prior literature suggested that “good” patient-provider communication contributes to satisfaction with the IC process (Agnew & Jorgesen, 2012; Daniels & Vogel, 2012; Fisher, Johnstone, & Williamson, 2011), our findings suggest that the assuredness of the provider may be more important than a supportive communication style. Similarly while prior literature has focused on patient satisfaction with the amount and type of information presented about procedure risks, our findings suggest that satisfaction with the IC process may be as influenced by extraneous factors surrounding the visit such as wait times (Agnew & Jorgensen, 2012; Mayberry & Mayberry, 2001; Rahman, Clamp, & Hutchinson, 2011). Our study is also one of the only that addresses in-depth the feelings and emotions patients experience during the IC visit and the important role of the support persons who accompany them to this visit.

Our findings are consistent with some components of the CSM (Leventhal, Brissette, & Leventhal, 2003; Leventhal et al., 2014; Leventhal, Phillips, & Burns, 2016). For example, several of the domains of illness representation in the model were evident in our findings. In regards to the identity domain, participants perceived signs and symptoms of their illness to be life-threatening and life-altering. Because their liver

disease was typically advanced, most did not debate about whether or not to have the procedure because not having the procedure did not seem like a real option. In regards to the timeline domain, while the participants' diseases were chronic, the need for the procedure was acute, and therefore there was a sense of urgency in decision-making. All consented to the procedure at the time of the encounter with the IR physician, and none took the document home to think about the decision. In regards to the consequence domain, some participants believed the procedure would improve their quality of life by decreasing or eliminating the need for frequent paracentesis or managing their esophageal varices. Other participants believed that the procedure would save or prolong their lives or provide a bridge to transplantation. In regards to the domain of control, the participants placed their confidence in the skills of IR physician who was a renowned expert on the procedures (Leventhal et al., 2014). The feedback loop is thus clearly reflected in the study findings; the participants judged a severe threat to their health status and elected to have their procedures despite the risks as the benefits of the procedure were essential to their survival.

### **Limitations**

The targeted sample size for this study was approximately 20 to 30 participants, which is typical for QD studies (Kim, Sefcik, & Bradway, 2016). However, the final sample size was 14 because recruitment proved particularly challenging. The recruitment challenges were primarily related to the serious nature of the illness that was being treated by the procedures. Many potential participants who were contacted stated they were too ill to participate, some had been placed into extended care facilities, several had died, and a few were incarcerated. However, the data provided by the 14 participants

proved to be adequate to address the primary study aims. Although the smaller sample provided rich information related to the participants' experiences with the IC process, a larger sample would have captured more variation in descriptions of IC experiences and thus more robust findings.

The sample also lacked ethnic diversity. Thirteen of the participants were white, two had some Native American ancestry, and one was Black/African American. Because so few minority persons participated in the study, no claims can be made about how ethnicity might have influenced the participants' experiences of the IC process. Participants from racial and/or ethnic minorities, for example, may have different perspectives with regard to the quality of their interactions with HCPs or with their satisfaction with the IC process.

Focusing only on three similar IR procedures also limited claims that can be made about the IC process more generally. In particular, the finding that the participants did not tend to debate whether or not to have the procedures based on the information given to them during the IC process probably reflects the seriousness of their illnesses and that the procedures were necessary to extend their lives. The decision-making process would likely be different for elective procedures or for situations in which there were other equally promising options for treatment. Moreover, only those persons who agreed to have the procedures were included in the sample so it is unclear how the IC process differed for those who refused the procedure. Including a variety of types of procedures and sampling participants who engaged in the IC process but declined a procedure would have likely provided a broader view of the IC process and possibly yielded different findings with regards to the study aims.

Although enrollment was open at three hospital sites, all subjects were recruited from one hospital, which is well-known for performing TIPS, TARE, and TACE procedures. Additionally, only one IR physician performed all of the procedures for the participants. This provider is nationally recognized in the performance of the all three procedures and performs the majority of them at this hospital. The IC process may have varied for persons who had the procedures done at different sites by a different IR physician. However, while the participant responses to the IC process might be specific to the physician's stature and personal style of interaction, or to IC procedures that are standard at the site, the findings nonetheless suggest important factors that matter to persons undergoing procedures needed to extend their lives.

The measurement of health literacy using the NVS (Pfizer, n.d.) also posed a limitation. Researchers agree that no single tool can adequately assess the subjective and objective aspects of health literacy (Altin, Finke, Kautz-Freimuth, & Stock, 2014). In particular, the NVS (Pfizer, n.d.) has been critiqued because the scoring categories (i.e., high likelihood of limited literacy, likelihood of limited literacy, likelihood of adequate literacy) lack precision, and calls have been made for additional studies on the reliability and validity of the tool (Pfizer, n.d.) (Mancusco, 2009). Therefore, the health literacy scores obtained from the NVS (Pfizer, n.d.) for our participants may not have been adequate to uncover the influence of health literacy on the experience of providing IC.

### **Suggestions for Future Research**

To further research in the IC process experience, researchers should recruit participants from a variety of sites. Studies conducted at tertiary medical centers that regularly perform TIPS, TARE, and TACE procedures with diverse racial and ethnic

populations could provide robust participant narratives from varying cultural viewpoints. Moreover, researchers may wish to compare the narratives of participants who have undergone a medically necessary procedure to those participants who have had truly elective procedures such as cosmetic surgeries. Additional insight could be gained if participants perceived an actual choice between one treatment or another for their condition, such as having the option of taking a medication in lieu of having a surgical procedure.

Recruiting subjects who have interacted with a variety IR physicians at a variety of different sites would help determine what findings are provider- or site-specific. Differences in how healthcare delivery systems conduct IC processes likely contribute to the patient experiences in either negative or positive ways.

While our findings provide a description of how persons experience the IC process, what information they remember being told about their procedures, and their general satisfaction, we recognize that agreement to undergo a procedure that involves considerable risk is not a point-in-time event but rather a dynamic process of engagement that is influenced by a host of contextual factors. Future researchers should explore how persons decide to have healthcare procedures by conducting longitudinal studies that can contextualize consent as one aspect of patient engagement that evolves over time and that is influenced by a number of factors. Such factors might include input from their primary care or specialty providers, personal factors such beliefs and attitudes about their illness, influence of support persons, and the changing nature of their illness.

## **Clinical and Practical Applications**

Nurses and HCPs may use the results of this study to better understand the patient experience during the IC process and to consider best practices related to IC. For example, while a positive “bedside manner” is always a best practice, patients might be as interested in provider comportment that suggests self-assurance and self-confidence. They may feel that provider confidence outweighs interpersonal warmth in one-time IC encounters as they are most concerned about having their fears and concerns about the procedure alleviated. The IC process thus might include information about the provider’s expertise and success rates.

Our findings indicate that patients might benefit from being told of their personal risk due to their current health status rather than being merely informed of what risks are associated with the procedure more generally. Moreover, a few participants mentioned that some information presented to them included jargon that was hard to understand, which reinforces that providers should present information in straightforward terms and confirm that patients understand the information and interpret it in a way that is accurate. Some participants requested providers use supplement verbal information with visual materials such as pictures and/or models when describing procedures that are complex in nature. Providers may consider developing DVDs or other technology-enhanced programs to describe complex radiological procedures such as those that were the focus of this study.

Because our findings revealed that the participants experienced a variety of emotions during the IC process, providers should include time to allow patients to express their feelings and discuss any concerns about the procedure they may have.



Providers may need to encourage patients to talk about their feelings and concerns as patients may consider the IC visit only a time for them to prepare for the procedure.

Providers should also consider involving the support persons who accompany the patient to the IC visit in discussions. Some of the support persons who accompanied our participants asked questions, but many remained quiet. Support persons who are actively engaged in the process could clarify information provided to the patients, ensure that the patients understand the information being presented to them, and express the support persons' own concerns and worries.

Some of our participants had decided to have their procedures before the IC process and before they formally learned about the benefits and risks. Providers should ask patients about their decision-making process and query about what information was instrumental in their decisions. This would help ascertain what factors influenced patient's decisions to have the procedure and provide an opportunity to clear up any misinformation.

Our findings suggest that while it is important for providers to inform their patients about the procedure itself, it is also important to address pragmatic issues such as how long they are slated to stay in the hospital, when they may return to work, what will be required for follow-up care, and what changes they might expect to their quality of life. To be fully informed about a procedure, patients need to know how they will be cared for before, during and after the procedure, especially if they have had few procedures or surgeries in the past.

While participants' satisfaction with the IC process was closely tied to the amount and quality of information given them, providers should consider that satisfaction with

the IC process is also influenced by circumstances surrounding the visit, such as wait times and interactions with support staff that occur before the IC encounter begins. For example, if persons are kept waiting for the appointment in which they consent to the procedure, their irritation could affect how they hear and process information about the procedure they will undergo. Providers should thus take care to start IC appointments on time and afford patients and their support persons ample time to absorb, process, and ask questions about information they receive.

### **Summary**

This study demonstrates that persons' experiences during the IC process are multi-faceted and complex. Many aspects of the IC visit were important to the participants including their interactions with providers, especially the IR physician. Most recalled being told about similar risks to the procedures during the visit, but interpreted their own risk in a variety of ways. The majority were satisfied with the IC process, although a few wished to have the information explained in a simpler or more visual way. Our findings related to our exploratory aim did not suggest the health literacy influenced the participants' experiences of IC in any obvious ways. The findings should be considered in light of the study limitations including a small, homogeneous sample of patients who all had their procedures performed at one site by one IR physician. Future studies on this phenomenon should examine the IC process for a variety types of procedures, at several sites, and with a more diverse population. Providers engaged in the IC process should remember that while the IC process is an exchange of information, it is also an interaction affected by emotions and concerns that should be addressed at the encounter.

## APPENDIX A

### STUDY INTRODUCTION LETTER TO POTENTIAL PARTICIPANTS

This IRB approved form letter was sent to potential study participants on IU Health Radiology Department letterhead.

Dear \_\_\_\_\_:

You recently underwent a procedure at (Eskenazi, IU Methodist, or IU University) hospital in the Interventional Radiology Department. I am writing to let you know that a research study is being conducted that may be of interest to you. It is possible that you may be eligible to participate in this study; however, only the investigators of the study can determine if you meet the requirements to participate.

The study is being conducted by an Indiana University School of Nursing (IUSON) faculty member, Dr. Claire Draucker, and Marsha Hughes-Gay, RN, an IUSON doctoral student. The study is examining the experience of patients who participated in an informed consent discussion. If you meet the criteria for participation, you will provide some basic medical information, complete an interview, and complete a six question health literacy form.

Ms. Marsha Hughes-Gay will contact you by phone to see if you are interested in participating. Please be aware that your participation is voluntary and there are no consequences to you if you choose not to participate.

Thank you for your consideration of this study.

Sincerely,

Matthew S Johnson, MD FSIR  
Professor of Radiology and Surgery  
Director, Interventional Oncology  
Director, Clinical Research, Department of Radiology  
Indiana University School of Medicine  
Indiana University Health University Hospital  
550 North University Boulevard  
Indianapolis, Indiana 46202-5253

## APPENDIX B

### INFORMED CONSENT FOR STUDY

# INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FORM

## **Examination of the Informed Consent Process as Experienced by Patients Who Have Undergone a Chemoembolization, Radioembolization or Transjugular Intrahepatic Portosystemic Shunt (TIPS) Procedure**

You are invited to participate in a research study of the experiences of patients who have participated in an informed consent (IC) process for a chemoembolization, radioembolization or transjugular intrahepatic portosystemic shunt (TIPS) procedure. Chemoembolization and radioembolization are used to treat cancerous tumors. A TIPS procedure reduces the pressure of blood flowing through the liver. You were selected as a possible subject because you provided IC for one of these procedures in the past three months in the Interventional Radiology Department at Indiana University Health University Hospital, Indiana University Health Methodist Hospital, or Eskenazi Health. Please read this form and ask any questions you may have before agreeing to be in the study.

### **STUDY PURPOSE**

The purpose of this study is to describe the experiences of patients providing informed consent to undergo a chemoembolization, radioembolization or de novo TIPS procedure. Additionally, the study will examine differences of the patient experience based on varying degrees of health literacy.

The study is being conducted by Marsha Hughes-Gay, RN, a doctoral candidate from Indiana University School of Nursing, under the supervision of her advisor, Claire Burke Draucker, PhD, RN, FAAN, of the Indiana University School of Nursing.

### **NUMBER OF PEOPLE TAKING PART IN THE STUDY**

If you agree to participate, you will be one of 21 subjects who will be participating in this research.

### **PROCEDURES FOR THE STUDY**

If you agree to be in the study, you will do the following things:

- 1) Complete a demographic document collecting basic information about you including your (a) name, (b) date of birth, (c) race/ethnic group, and (d) highest level of education.
- 2) Complete an assessment of your health literacy levels using the Newest Vital Sign tool. This tool provides a nutritional label and asks between four and six questions about the label. This assessment takes approximately six minutes to complete.
- 3) Provide information about your health history and medical conditions.
- 4) Participate in an interview consisting of questions pertaining to your experience during the IC process for

your procedure. This interview will last approximately one hour. The interview may be face-to-face, by telephone, or by electronic methods such as FaceTime®, Skype®, or other video chat capabilities. Face to-face interviews may be conducted in your home or other mutually agreed area that would allow for privacy (e.g. library study room, community center meeting room).

5) Have your interview audio recorded.

### **RISKS OF TAKING PART IN THE STUDY**

While on the study, the risks are:

- You may experience frustration while completing the health literacy assessment using the Newest Vital Sign tool.
- You may experience feelings of anger or embarrassment when recalling the events of the IC process.
- You may worry about repercussions by healthcare providers in the Interventional Radiology Department.
- The potential loss of confidentiality.
- There may be risks we do not know about.

Efforts will be made to minimize these potential risks. The investigator will assist you with the Newest Vital Signs tool and you are allowed to take as much time as you need to answer the questions. The purpose of this research is to better understand your experience during the IC process so there are no wrong or right answers during the interview portion of the study. Participation in this study will not affect your care. Your individual identity will not be disclosed to the staff in the Interventional Radiology Department. No identifiable information about your interview or survey responses will be shared with care providers. All study documents are kept on a secured server and paper forms are kept in locked cabinets in locked offices in an office area that has limited access.

### **BENEFITS OF TAKING PART IN THE STUDY**

There is no direct benefit to participating in this study.

### **ALTERNATIVES TO TAKING PART IN THE STUDY**

Instead of being in the study, you may choose to not participate

### **CONFIDENTIALITY**

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published and databases in which results may be stored. The audio recordings and the transcript of the recording will be stored on a secure server that requires a password. These will be stored for a period of seven years as required by Indiana State law

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, a transcription service, the Indiana University Institutional Review Board or its designees, the Indiana University School of Nursing, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) who may need to access your research records.

## **COSTS**

Taking part in this study may lead to added costs to you in the form of transportation to the interview site if not conducted in your home. If the interview is conducted by telephone or other electronic means (such as Skype® or Facetime®) your phone and data plan may charge you for additional minutes or data usage.

## **PAYMENT**

You will receive payment for taking part in this study. The payment is a twenty-dollar (\$20) Wal-Mart gift card.

Payments is made when the demographic form, health history summary, assessment of health literacy using the

Newest Vital Sign, and interview is completed. There is no gift card payment for partial completion of the study

## **FINANCIAL INTEREST DISCLOSURE**

The costs associated with this study may be partially or fully paid for by a grant provided to Marsha Hughes-Gay, MSN, MPH, RN as part of a dissertation program.

## **CONTACTS FOR QUESTIONS OR PROBLEMS**

For questions about the study contact the researcher, Marsha Hughes-Gay, RN at (office number/mobile number) or Dr. Claire Draucker, RN, at (office number). If you cannot reach the researcher during regular business hours (i.e., 8 a.m. to 5 p.m.), please call the IU Human Subjects Office at 317-278-3458. After business hours, please call Marsha Hughes-Gay at (mobile number)

In the event of an emergency, you may contact Marsha Hughes-Gay, RN at (mobile number).

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or offer input, contact the IU Human Subjects Office at 317-278-3458 or 800-696-2949.

## **VOLUNTARY NATURE OF THIS STUDY**

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Indiana University Health, Eskenazi Health, or the Indiana University School of Nursing.

Your participation may be terminated by the investigator without regard to your consent in the following circumstances: If you cannot complete the Newest Vital Sign assessment or participate in the interview independently

## **SUBJECT'S CONSENT**

In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

**Subject's Printed Name:** \_\_\_\_\_

**Subject's Signature** \_\_\_\_\_ **: Date:** \_\_\_\_\_  
(must be dated by the subject)

**Printed Name of Person Obtaining Consent:** \_\_\_\_\_

**Signature of Person Obtaining Consent:** \_\_\_\_\_ **Date:** \_\_\_\_\_

May 2, 2017 v07/2015 3

**Protocol 1605909865 IRB Approve**

APPENDIX C

HEALTH SUMMARY FORM

Patient Name: \_\_\_\_\_ MRN \_\_\_\_\_

Patient's insurance coverage (circle one): Private Medicaid Medicare None/self-pay  
Other: \_\_\_\_\_

Medical reason for the IR procedure: \_\_\_\_\_

Date of : Pre-Procedure IR clinic visit: \_\_\_\_\_

Did the potential subject sign the Procedure consent?  Yes  No-signed by  
someone else (Stop)

**IF THE POTENTIAL SUBJECT DID NOT SIGN THE CONSENT  
FOR THE PROCEDURE—DO NOT PROCEED—SCREEN FAIL**

Date Informed Consent signed: \_\_\_\_\_

Informed consent process by: \_\_\_\_\_ MD PA RN-NP

Date of IR procedure: \_\_\_\_\_

Facility: University Hospital Methodist Hospital Eskenazi Hospital

IR procedure performed by: \_\_\_\_\_

Date of 1 month IR follow up (if appl): \_\_\_\_\_

If a TIPS procedure (pre procedure if calculated) (if calculated) MELD score: \_\_\_\_\_  
Child-Pugh score: \_\_\_\_\_

A review of the medical hx at the time of pre-procedure appointment, the patient had/has  
the following conditions:

- |   |  |                                       |                                    |
|---|--|---------------------------------------|------------------------------------|
| <input type="checkbox"/> Anemia             | <input type="checkbox"/> Angina / chest pain | <input type="checkbox"/> CAD          | <input type="checkbox"/> CHF       |
| <input type="checkbox"/> COPD               | <input type="checkbox"/> CVA                 | <input type="checkbox"/> Diabetes     | <input type="checkbox"/> Cirrhosis |
| <input type="checkbox"/> Hepatitis B        | <input type="checkbox"/> Hepatitis C         | <input type="checkbox"/> Hypertension |                                    |
| <input type="checkbox"/> Cancer, type _____ |  |                                       |                                    |

- Neurological disorder:  Alzheimer's  Parkinson's  Huntington's  
 Other \_\_\_\_\_

Other hx: \_\_\_\_\_



Has the patient had the following in the last 2 months:

- Chemotherapy
- Dialysis—type\_\_\_\_\_
- Radiation treatment

Is the patient on the liver transplant list at the time of the Pre-procedure clinic visit?

- Yes    No

At the time of IR procedure was the patient on oxygen therapy?    Yes    No

In the 48 hours post procedure procedure, did the patient experience any adverse events or complications?

If so, list (include tx's provided):

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APPENDIX D

DEMOGRAPHIC FORM

Subject Demographic Form

Name: \_\_\_\_\_

Date of Birth: \_\_\_\_\_ Gender:  Male  Female

Race/Ethnic Group:

- Asian
- Caucasian / White
- Black / African American
- Hawaiian / Other Pacific Islander
- Native American / Alaska Native / First Nation
- Other, please describe: \_\_\_\_\_

Are you:

- Hispanic or Latino
- Not Hispanic or Latino

What is your highest level of education?

- Less than high school (K-8<sup>th</sup> grade)
- High school, did not graduate
- High school diploma / GED
- Some College—did not graduate
- Bachelor's degree
- Master's Degree
- Doctoral degree

APPENDIX E

NEWEST VITAL SIGN ASSESSMENT TOOL

<b>Nutrition Facts</b>			
Serving Size		½ cup	
Servings per container		4	
Amount per serving			
Calories	250	Fat Cal	120
			%DV
<b>Total Fat</b>	13g	20%	
Sat Fat	9g	40%	
<b>Cholesterol</b>	28mg	12%	
<b>Sodium</b>	55mg	2%	
<b>Total Carbohydrate</b>	30g	12%	
Dietary Fiber	2g		
Sugars	23g		
<b>Protein</b>	4g	8%	

\*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

**Ingredients:** Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

This label is provided to the participant. The scoring sheet is completed by the person administering the assessment (next page). Interpretation is provided below the scoring sheet



APPENDIX F

STUDY PARTICIPANT DEMOGRAPHICS

Total Participants N=14

	Number of Participants	Percentage of Participants
<b>Gender</b>		
Male	8	57.1
Female	6	42.8
<b>Race-(self identified)</b>		
White/Caucasian	11	78.5
Black/African American	1	7.1
White/Caucasian & Native American	2	14.3
<b>Ethnicity</b>		
Hispanic	1	7
Non-Hispanic	13	92.8
<b>Age in years</b>		
≤ 50	3	21.4
≥ 50	11	78.5
<b>Highest level of education</b>		
< High School Diploma	2	14
High School Diploma	7	50
Some college/vocational	3	21.4
Bachelor's Degree	1	7
Not disclosed	1	7
<b>NVS Health Literacy Score</b>		
0-1	0 (zero)	0 (zero)
2-3	8	57.1
4-6	6	42.8

APPENDIX G

COMPARISON OF POSSIBLY LIMITED LITERACY AND ALMOST ALWAYS ADEQUATE LITERACY GROUPS

<b>Table G-1 Participant use of the internet to find information on procedures</b>		
<b>Group</b>	<b>Sought information on internet</b>	<b>Did not seek information from internet</b>
Possibly limited literacy	3	5
Almost always adequate literacy	4	2
Fisher's Test p-value	0.5921 not significant	

<b>Table G-2 Participants use of questions during IC process</b>		
<b>Group</b>	<b>Asked questions during IC process</b>	<b>Did not ask questions during IC process</b>
Possibly limited literacy	4	4
Almost always adequate literacy	4	2
Fisher's Test p-value	0.6270 not significant	

<b>Table G-3 Participant satisfaction with IC process</b>		
<b>Group</b>	<b>Satisfied with IC process</b>	<b>Not satisfied with IC process</b>
Possibly limited literacy	7	1
Almost always adequate literacy	4	1
Fisher's Test p-value	0.9999 not significant	

\*one subject did not specify satisfaction.

<b>Table G-4 Participant recall of risks discussed during IC process</b>		
<b>Group</b>	<b>Total Number of recalled risks</b>	<b>Test of proportion = 0.50 p-value</b>
Possibly limited literacy	10 (41.67%)	0.4142
Almost always adequate literacy	14 (58.33%)	

<b>Table G-5 Participant recall of benefits discussed during IC process</b>		
<b>Group</b>	<b>Total Number of recalled benefits</b>	<b>Test of proportion = 0.50 p-value</b>
Possibly limited literacy	9 (64.29%)	0.2850
Almost always adequate literacy	5 (35.71%)	

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**Curriculum Vitae**  
**Marsha A. Hughes-Gay**

**License**

State of Indiana  
Registered Nurse

**Education**

MSN: 2009  
Community Health Major  
Indiana University  
IUPUI

MPH: 2009  
Behavioral Health Science Major  
Indiana University  
IUPUI

BSN: 1997  
Indiana University  
IU Kokomo

ASN: 1994  
Indiana University  
IU Kokomo

**Professional Experience**

Indiana University  
Clinical Assistant Professor, School of Nursing—Bloomington campus: August  
2016—Present  
Teaching in the Traditional BSN program

Clinical Assistant Professor, School of Nursing—Columbus campus: August  
2011—July 2016  
Teaching in traditional BSN and ASN to BSN programs.

Clinical Research Nurse, School of Medicine: November 2005 – Present  
Experience in a variety of disciplines: Neurology, Gastroenterology/

Hepatology, Interventional Radiology, and Radiology (modalities: CT, MRI,  
ultrasound)

Teaching assistant, School of Nursing: 2009-2010

MedFocus

Case Manager in Global Product Safety Department

Placed at Eli Lilly Corporate Center in Indianapolis, Indiana: April 2005 to October 2005. Contractor position

Indiana University

Clinical Research Nurse, School of Medicine: October 2001 to April 2005

Health and Hospital Corporation

Wishard Hospital (now Eskenazi Health)

Indianapolis, Indiana

Staff Nurse—Interventional Radiology / Cardiac Catheterization Lab: June 1998-October 2001

Marion County Health Department

Indianapolis, Indiana

Public Health Nurse—Community Based Care: June 1997-May 1998

Resource Pool / Agency

RN Specialties, Inc.—various months—Medical Surgical and Cardiac Units in Indianapolis.

Community Hospital, Indianapolis—Cardiac Cath Lab

Riverview Hospital

Noblesville, Indiana

Staff nurse / Charge nurse Medical Surgical; Pediatrics; ICU/CCU: May 1994 to June 1997.

Phlebotomist / Lab Technician: September 1989 to May 1994

Anesthesia Respiratory Technology, Inc. (ARTEC)

Noblesville, Indiana

Customer Service / Accounting: June 1984 to April 1988

**Certifications**

American Heart Association

Basic Life Support (BLS) Provider

American Society of Clinical Pathologists (ASCP)

(PBT), ASCP

**Committees**

Indiana University

Institutional Review Board for Bloomington (IRB-IUB) and alternate for IUPUI Boards 1,2,3, and 4.—Current Member

Indiana University School of Nursing (Core Campus)  
Science of Nursing Division—Current member  
Faculty Council—Past member  
Traditional BSN Curriculum—Past member  
Admission Progression Graduation (APG) alternate-Past member

Indiana University School of Nursing (Bloomington Campus)  
Course Leader H356 and H371

Indiana University School of Nursing (Columbus Campus)  
Course leader: R375, H371, & H356  
Synergy Faculty Group  
Faculty Awards Committee—Past member

National, State, & Community Representation  
Leader of 4H Club, Brown County Indiana  
EI-AHEC Research Committee—2012-2016  
EI-AHEC Clinical Rotations Committee—2014-2016  
Schneck Medical Center EBP Group member-Past member  
Chair of the Regional Medical Institutional Review Board-resigned in July 2016

### **Coordinator**

IU School of Nursing—Columbus, Indiana Campus until July 2016:  
BSN Program Coordinator for Traditional and Accelerated tracks  
Preceptor Training Coordinator  
BSN Clinical Rotation Coordinator  
Clinical Homes Model Coordinator and Principal Investigator

### **Service**

New Faculty Mentor at IUPUC  
IUPUC Honors Student Mentor: 2015-2016

### **Membership**

National League for Nursing  
Sigma Theta Tau—Alpha Chapter  
Academy of Communication in Healthcare

### **Continuing Education**

American Association of Colleges of Nursing

Baccalaureate Education Conference, November, 2018  
New Orleans, LA

Elsevier Faculty Development Conference  
January, 2014  
Las Vegas, NV

Indiana University Quarterly Research Coordinator Meetings  
Indianapolis, Indiana.

Indiana University National Center of Excellence in Women's Health Conference  
Monthly Series

Association for Community Health Improvement (ACHI)  
Spring Training for Health Champions  
Phoenix, AZ March 2006

Society of Interventional Radiology (SIR) 30<sup>th</sup> Annual Scientific  
Assembly in New Orleans, LA—April 2005. In conjunction with ARNA  
meeting.

Genetech, Inc., Investigator Symposium on Thrombolytics  
(GIST). Beverly Hills, CA—October 2004.

Society of Interventional Radiology (SIR) 28<sup>th</sup> Annual Scientific Assembly in Salt  
Lake City, UT—April 2003. In conjunction with 21<sup>st</sup> Annual Meeting of ARNA.

Genetech, Inc., Investigator Symposium on Thrombolytics (GIST).  
Scottsdale, AZ—November 2002.

Society of Cardiovascular and Interventional Radiology (SCVIR) 27<sup>th</sup> Annual  
Scientific Assembly in Baltimore, MD—April 2002. In conjunction with 20<sup>th</sup>  
annual meeting with ARNA.

Bard Corporation Intra-Aortic Balloon Pump Operation and Monitor Training  
1996 and 2000.

## **Publications & Presentations**

Judge, D.S., Murray, B., **Hughes-Gay, M.**, & Robinson, D. (2016). Building  
Bridges: collaboration between community college and university.  
Teaching and Learning in Nursing, 11(2), 58-61  
Doi: 10.1016/j.teln.2015.12.001

Judge, D., **Hughes-Gay, M.**, Robinson, D., & Todd, J. (2015). *Building Bridges:  
collaboration between community college and university.*

(Presented at the 14<sup>th</sup> Annual International Nursing Association for Clinical Simulation and Learning (INACSL) in Atlanta, GA

**Hughes-Gay, M.** (2005, April). *How to make research a more rewarding experience in your department.* (Presented at American Radiological Nurses Association (ARNA) in New Orleans, LA)

Rovane, R., Daniels, D.M., **Hughes-Gay, M.** & Nyhuis, A. *Analysis of non-fatal dogbites in children in a Midwestern city.* Accepted abstract / poster to American Public Health Association Meeting Washington, DC, 2007.

\*Seminar on Research Coordinator Roles and Responsibilities  
W.L. Gore & Associates  
Responsible for all content, 6 hours  
Phoenix, AZ April 2009

Research Coordinator Education Program  
Speaker: Management of Adverse Events and Serious Adverse Events; PI Responsibilities.  
Indiana University—multiple presentations

## **Research Experience**

Indiana University School of Nursing—Dissertation Study

“Examination of the Informed Consent Process as Experienced by Patients Who Have Undergone A Transjugular Intrahepatic Portosystemic Shunt (TIPS) Procedure”, Claire Draucker, PhD, RN Committee Chair / Principal Investigator. Marsha Hughes-Gay, MSN, MPH, RN—Doctoral Student

Indiana University School of Nursing—Principal Investigator

“Clinical Homes Model—A pilot study”, Marsha Hughes-Gay, MSN, MPH, RN

Indiana University School of Medicine—Research Coordinator / sub investigator:

“Creatine Safety, Tolerability, and Efficacy in Huntington’s Disease”, Liz Zauber, M.D., University of Rochester.

“A Safety and Efficacy Study of Dimebon in Patients with Huntington’s Disease”, Joanne Wojcieszek, M.D., Pfizer.

“Efficacy and Safety of AFQ056 when combined with increased doses of L dopa in Parkinson’s Disease patients with moderate to severe L dopa induced dyskinesia”, Joanne Wojcieszek, M.D., Novartis.

“A Phase 2, Randomized Multicenter, Placebo-Controlled, Double-Blind, Parallel-Group Study to evaluate the Efficacy, Safety, and Population Pharmacokinetics of Once-Daily Oral E5501 Tablets Used Up to 7 Days in Subjects with Chronic Liver Diseases and Thrombocytopenia Prior to elective Surgical or Diagnostic Procedures”, Paul Kwo, M.D., Eisai Ltd.

“A Phase II, Multi-Center, Randomized, Open-Label, Active Control, Dose Ranging Study of Interferon-Alfa-2b Given via Continuous Subcutaneous Infusion in Subjects with Hepatitis C Virus Genotype 1 Infection; COPE-HCV Clinical Study

Continuous Infusion delivery via the Medtronic Paradigm® Infusion System Clinical Evaluation for Chronic HCV”, Paul Kwo, M.D., Duke Clinical Research and Medtronic.

“Safety and Efficacy of the Extracorporeal Liver Assist Device (ELAD) in Patients with Fulminant Hepatic Failure (FHF), VTI-202 protocol”, Paul Kwo, M.D. Vital Therapies.

“Efficacy and Safety of the Extracorporeal Liver Assist Device (ELAD) in Subjects with Acute on Chronic Hepatitis (AOCH), VTI-206 protocol”, Paul Kwo, M.D. Vital Therapies

“A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Study to Investigate the Safety and Efficacy of CP-690,550 in Subjects with Moderate to Severe Crohn’s Disease”, Michael Chiorean, M.D., Pfizer.

“A blinded, randomized, placebo-controlled, study to evaluate the safety, tolerability, pharmacokinetics, and antiviral activity of multiple doses of ABT-333 alone and in combination with pegylated interferon (pegIFN) and Ribavirin (RBV) in subjects with Genotype 1 chronic hepatitis C virus (HCV) infection”, Paul Kwo, M.D., Abbott Laboratories.

“Randomized, Phase 2 Trial of Atorvastatin, Raftilose Synergyl, and Sulindac Among Patients at Increased Risk for Sporadic Colorectal Neoplasia”, Michael Chiorean, M.D., CPN-Mayo Rochester.

“A Multi-Center, Investigator-Blinded, Randomized, 12 Month, Parallel Group, Non-Inferiority Study to Compare the Efficacy of 1.6 to 2.4 Asacol® Therapy QD Versus Divided Dose (BID) in the Maintenance of Remission of Ulcerative Colitis”, Michael Chiorean, M.D., Procter and Gamble Company.

“A Phase 1b Randomized, Placebo-Controlled Clinical Trial to Study the Safety and Efficacy of MK-7009 in Hepatitis C Infected Patients”, Paul Kwo, M.D. Merck & Co., Inc.

“A Phase II Open Label Study of MK-7009 Administered Concomitantly with Pegylated Interferon Alfa-2a and Ribavirin to Patients with Chronic Hepatitis C Infection After participation in other MK-7009 clinical Trials”, Paul Kwo, M.D. Merck & Co., Inc.

“A Phase III Randomized Trial of Cryoablation vs Radiation for the Palliation of Painful Bone Metastases”. Gordon McLennan, M.D., NIH, NCI with Endocare.

“Outcome Trial Evaluating the Efficacy and Safety of Norditroponin® in Adult Patients on Chronic Haemodialysis: A Randomized, Double-blind, Parallel Group, Placebo Controlled, Multi-center Trial, Phase 3 (OPPORTUNITY) ID NN1630-1453. Sharon Karp, M.D., Novo Nordisk

“A Multicenter, Randomized, Double Blind, Placebo Controlled, parallel Group Trial to Evaluate the Efficacy and Safety of E2007 in Patients with Painful Diabetic Neuropathy”, John Kincaid, M.D., Eisai.

“Effect of thyroid hormone concentration on performance of sensorimotor task”, Genzyme

“A Phase I Study to Assess the Safety and Pharmacokinetics of Telaprevir (VX950) in Subjects with Moderate and Severe Degrees of Hepatic Impairment”, Paul Kwo, M.D., Vertex Pharmaceuticals, Inc.

“A randomized, controlled trial of catheter related infection event rates using antibiotic-impregnated catheters vs conventional catheters in pediatric cardiovascular surgery patients”, Elaine Cox, M.D., Cook Critical Care.

“Rex Medical-Option\* Vena Cava Filter IDE Study”, Matthew S. Johnson, M.D., Rex Medical, LLP.

“A Phase III, Open-Label Study of Tenecteplase for Restoration of Function in Dysfunctional Hemodialysis Catheters”, Gordon McLennan, M.D., Genentech, Inc.

“The Wingspan™ Stent System and Gateway™ Balloon Catheter, A Humanitarian Use Device”, Juan Tejada, M.D. \*\*IRB Regulatory\*\*

“Neuroform™ Microdelivery Stent System: A Humanitarian Use Device”, Juan Tejada, M.D., \*\*IRB Regulatory\*\*

“A Phase III, Multi-Center Open-Label Study to Evaluate Safety and Efficacy of MultiHance® at the Dose of 0.10 mmol/kg in Magnetic Resonance Imaging of the Central Nervous System in Pediatric Patients”, Annette Douglas-Akinwande, M.D., Bracco Diagnostics, Inc.

“Patient Centered Care: Increasing Access to Test Results”, Annette J. Johnson, M.D., (NIH Funded).

“Functional Assessment of the Pancreas in Normal Volunteers and in Patients with Chronic Pancreatitis with Secretin Enhanced MRCP”, M. Fatih Akisik, M.D., Repligen Corp.

“Monitoring Hepatitis and Cirrhosis by (23) Na MRS/MRI”, Navin Bansal, PhD (NIH Funded).

“Prospective Evaluation of Hepatic Tumors After Chemoembolization Using High Field MRI with Gadobenate Dimenglumine (MultiHance®)”, M. Fatih Akisik, M.D., Grant from Bracco Diagnostics, Inc.

“A Humanitarian Device Exemption Use Protocol of TheraSphere® for the Treatment of Unresectable Hepatocellular Carcinoma”, Gordon McLennan, M.D., \*\*IRB Regulatory\*\*

“PREDICT=Patients with Renal Impairment and Diabetes Undergoing Computed Tomography”, Tariq Hameed, M.D., Bracco Diagnostics, Inc.

“INVEST: Investigational Vertebroplasty Efficacy and Safety Trial, A Controlled Trial of percutaneous Vertebroplasty”, NIH multi center trial, Mayo Clinic, Rochester, MN (NIH passthrough)

“Whole-body MRI in the evaluation of pediatric malignancies”, American College of Imaging Network, (ACRIN).

“A non randomized, Prospective study of IVC filter retrieval out to 12 weeks without interim filter manipulation utilizing the Gunther Tulip Vena Cava Filter”, Jan Namyslowski, M.D., Cook.

“Clinical Investigation of Lung CAD”, Sean Teague, M.D., Philips Medical Systems.

“Cardiovascular Outcomes in Renal Atherosclerotic Lesions”, Thomas Casciani, M.D., Medical College of Ohio—NIH passthrough.

“Central Nervous System Correlates of Gastric Electrical Stimulation in Patients with Gastroparesis”, Thomas Nowak, M.D.

“Phase I trial with Plasmin to evaluate safety and to select the doses for phase II in patients with hemodialysis graft occlusion”, Bayer Corporation.

“Carotid Revascularization Endarterectomy vs Stent Trial (CREST)”, Juan Tejada, M.D., The CREST Center-Guidant.



“Clinical Comparison of Split-Cath and Hemosplit tunneled hemodialysis catheters”, Matthew S. Johnson, M.D.

“Beta Radiation for Treatment of Arterial-Venous Outflow (BRAVO)”, Novoste Corporation.

“Safety of TPA dwell for restoration of function of dialysis catheters”, Gordon McLennan, M.D.

“Radiology Report Quality: A randomized controlled trial of point and click structured reporting versus conventional dictation”, Annette Johnson, M.D.

“Multi center clinical study to determine the effectiveness and safety of HEDA in the screening of women for breast cancer”, Z-Tech.

“Time to Hemostasis After Traction Removal of Tunneled Cuffed Central Venous Catheters”, Michael Stecker, M.D.

“Cutting Edge, Cutting Balloon Hemodialysis Access Management Trial”, Boston Scientific.

“Cook Gunther Tulip™ Vena Cava Mreye™ Filter Retrievability Study”, Cook, Inc.

“Wallgraft® Endoprosthesis and the Unistep™ PLUS Delivery System for Complex Iliac Stenosis and occlusion, Matthew S. Johnson, M.D., Boston Scientific.

“Wallgraft® Endoprosthesis and the Unistep™ PLUS Delivery System for Peripheral Aneurysm and Trauma”, Matthew S. Johnson, M.D., Boston Scientific.

“Investigational Device Evaluation of the GORE TIPS Endoprosthesis (VIATORR) in De nov TIPS and TIPS Revisions”, W. L Gore and Associates.

“A Prospective, Multi center Evaluation of an IMPRA/Bard ePFTE Encapsulated Carbon Lined Nitinol Endoluminal Device for AV Access graft Applications”, Gordon McLennan, M.D., IMPRA Inc.

“Effect of Doxycycline on Osteoarthritis Progression”, NIH Multi center trial.

“Radiographic Progression of Knee Osteoarthritis”, Multipurpose Arthritis and Musculoskeletal Disease Center, NIH Multicenter trial.

“A Multicenter, Non Randomized Clinical Study of the ITI Renal Stent for the Treatment of Renovascular Hypertension”, Intra Therapeutics, Inc.

Indiana University School of Nursing—Graduate Student / co-investigator:

“Cooked Creek Community Assessment”, Indiana University School of Nursing MSN Community Health Nurse Project, 2005/2006.

“Asthma Friendly Schools Initiative (AFSI)—Student Project, Indiana University School of Medicine—Department of Public Health, MPH project, 2009.