EMPOWERING PATIENTS THROUGH HEALTH LITERACY IN THE INFORMED CONSENT PROCESS

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ABSTRACT

Empowering Patients Through Health Literacy
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Doctor of Medical Humanities Dissertation by

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Medical terminology can be difficult to understand to individuals who do not normally have a background in science or healthcare. It is a language that describes the parts of the body, diagnosis and medical procedures. Health literacy is an important term to be discussed now and in the future. The general population struggles with understanding health literature, prescriptions given by the physician, the actual medications and instructions given by the pharmacist and reading an informed consent form.

Health literacy and the Informed Consent process is an important approach to the practice of medicine. It is important because of the opportunities it can provide to professional staff and patients. The United States has a complex system of healthcare which includes complexity in the understanding of the words that are used in healthcare. There are barriers to effective health communication. There is low or marginal literacy, jargon, stress and increased complexity of self care, cultural and individual learning styles. There are people who have problems with quantitative data such as understanding prescription drug dosages and number of day's a medication should be taken.

This dissertation examines the thoughts of clinical research professionals with using health literacy in the informed consent process. The author examines this issue within the context of the historically complex of clinical research, literary works and scientific studies.

The results of an original human participants research study are presented that investigate clinical research professional's opinion about health literacy. A questionnaire is used to survey a small group of clinical research professionals who conduct clinical research studies. The questionnaire explores the area of promoting health literacy to apply practical solution to improve patient/provider communication especially in the Informed Consent process. This will result in a more comprehensive and humanistic paradigm for the informed consent process. I will argue that health literacy may be the key to empower patients in the Informed consent process.

IN MEMORY OF MOM

CONTENTS

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I thank you Lord, my savior, my friend for nudging me in ways to complete this important assignment.

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To my clinical research colleagues and friends, thank you for believing in me and for your support.

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To the younger generations to come, remember the verse:
"I press toward the goal for the prize of the upward call of God in Christ Jesus."
Philippians 3:14

INTRODUCTION

Background and Motivations for Research

According to Bonne Lorenzen, RN, MSN health care today exposes consumers to a significant amount of critical information ranging from prescription bottle labels to insurance forms and from dietary guides to procedural consents.[1] The complexity of the information prevents a significant number of patients from fully comprehending, understanding and processing the information in a way that can be usable.

Health literacy presently defined by Healthy People 2010 is the degree to which individuals have the capacity to obtain, process, and understand health information and services needed to make appropriate health decisions.[2] The 2003 national Assessment of Adult Literacy by the National Center for Education Statistics showed that 36% of adults have basic or below basic health literacy.[3] According to the national assessment of Adult Literacy Survey (NAALs) basic would be considered having the basic set of skill needed to read, understand, and act on basic health information.[4]Some people will not understand what health professionals are talking about. According to Osborne, literacy matters in

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[1] Bonne Lorenzen, Constance E. Melby, Barb Earles, "Using Principles of Health Literacy to Enhance the Informed Consent Process," *ACORN Journal*, 88, no. 1 (July 2008): 23.

[2] Ibid., 23.

[3] Ibid.

[4] Sheida White, "Key Concepts and Features of the 2003 National Assessment of Adult Literacy." National Center for Education Statistics. December 2005: 3. Retrieved August 6, 2006 from http://nces.ed.gov/NAAL/index.

health care because life-threatening or potentially harmful mistakes may happen when people cannot read or understand written information.[5]

Unfortunately, many of the people who need medical information the most, such as senior citizens and urban emergency department patients, are the least likely to understand and act on healthcare information.[6]

The ability to make a decision to participate in clinical trials is based on a combination of skills, including patients having an understanding of research and science, patients being able to seek out and evaluate health information, and providers giving messages that are appropriate for the populations served. Moreover, literacy in one domain can assist in the development of skill in another domain and can compensate for competency deficiencies in another domain. Health literacy is important for understanding and revealed inaccuracies and misconceptions of information necessary for an individual to understand the clinical research process (e.g., study designs, risk and benefits, and how to contact study protections such as investigators and Institutional Review Board). Clear understandings of the science and its purpose are imperative for informed consent.[7]

I also believe that a lot of young people between the ages of 18 – 25 may not be able to understand and act on healthcare information. The reason I say this is because

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[5] Helen Osborne, Health Literacy from A to Z: Practical Ways to communicate your health message, Sudbury, MA; (Jones and Bartlett Publishers, Inc., 2005), 8.

[6] Richard Feifer, "How a Few Simple Words Improve Patients' Health," *Managed Care Quarterly* 11, no. 2 (2003): 30.

[7] Kiameesha R. Evans, M. Jane Lewis, Shawna V. Hudson, "The Role of Health Literacy on African American and Hispanic/Latino Perspectives on Cancer Clinical Trials," *Journal Cancer Education* 27 (2012): 304.

this age group has mainly relied on their parents to take care of the details of their lives which include healthcare.

The growing interest in children's involvement in decisions about their health care and in the child's rights and responsibilities compound these challenges. Many legal issues and ethical dilemmas revolve around the parent's duty to act in their child's best interest while protecting them from harm and also recognize children's varying ability to participate in their own healthcare decisions.[8] This society is moving very quickly and this age group in my opinion doesn't take the time to understand their health and the ramifications of not understanding what goes on with healthcare. A young person's level of resilience can depend on how they feel about themselves, their interpretation of events, and opportunities to make choices.[9] The health professional is the expert in medical knowledge but it must be remembered that parents have superior knowledge about their child and their child's best interest, which is often based on family values.[10]

I have worked 14 years in the area of clinical research as a CRA(Clinical Research Associate).and have found it to be a fascinating area to work. I have been exposed to the following therapeutic areas: Consumer Products, Monoclonal Antibodies, Allergy, Dementia, Alzheimer Disease, Dermatology, Gastroenterology, Podiatry, HIV, Wound Care, Diabetes, Ostomy, and Oncology. The importance of the CRA role in clinical research cannot be over-emphasized. CRAs are on the front line and play a major role in study conduct and quality. Bad studies are not usually the fault of the site

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[8] Liz Gormley-Fleming and Anne Campbell, "Factors involved in young people's decisions about their health care," *Nursing Children and Young People* 23, no. 9, (November 2011): 19.

[9] Ibid., 21.

[10] Ibid.

personnel; they result from poor planning and study design, and from improper selection, preparation and training of the study site. A CRA may not be involved in planning and study design, but the last three are usually CRA responsibilities. Few people on the drug development team have as much direct impact on study quality and timeliness as the CRA.[11]

The CRA is the main defense against data errors during clinical trials, which cost millions of dollars to correct. In addition, based on the annual sales of an average performing drug, the cost for each day's delay in getting the drug approved is more than a million dollars. The CRA has a major impact on the timely completion of trials, assuring that company development timelines are realistic and are met or exceeded. It's not hard to understand the value of a good CRA in terms of program quality and cost.[12].

I had has the privilege to work with key opinion leaders across the United States and abroad many European countries. I have always been interested in the consent process and wondered if patients really understood what they were signing. Informed consent is very important in general health care in the physician's office, pharmaceutical/medical device clinical trials and in the hospital setting.

Informed consent is one of the main safeguards for the protection of human subjects in research. The decision of whether or not to participate in a study is not an easy one because there is the hope of help and the desire to please the physician, as well as apprehension and fear of the unknown.[13] Informed Consent is defined by the ICH

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[11] Karen E. Wooden and John C. Schneider, *The CRA's Guide to Monitoring Clinical Research* (Boston: Thomson CenterWatch, 2003), 21.

[12]Ibid., 21.

[13] Wooden and Schneider, *The CRA's Guide to Monitoring Clinical Research*, 64.

Guidelines for Good Practice as: "A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.[14]

Medical Humanities is a great example of influencing the patient/physician relationship. Likewise, a parallel may exist with health literacy in the informed consent process. Health literacy may bridge the gap of distrust between the medical world and patients (or subjects). The focal point of this dissertation examines the issue of Health Literacy among a group of clinical research professionals. I will argue that health literacy may be the key to empower patients in the Informed Consent process.

In Chapter one I begin with a discussion about the history of literacy and health literacy and empowerment. This chapter discusses the widening interest and awareness. It gives definitions of what health literacy means and why it is critical to empowerment. It also gives a definition of literacy.

Chapter two discusses the history of the Informed Consent Form Process in Clinical Research. Historical facts are brought to life through the Nuremberg trials and Tuskegee Institute Study and readability of the consent form. A landmark decision regarding physician disclosure was also discussed.

Chapter three begins with a discussion about social and economic factors and health literacy. Also, health literacy and the informed consent process, health literacy and the health care professional, health literacy tools and health literacy challenges.

Chapter four shows the results from the questionnaire survey that was answered

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[14] Wooden and Schneider, *The CRA's Guide to Monitoring Clinical Research*, 64.

by clinical research personnel. Their responses from the questionnaire survey indicate that there is perceived value incorporating health literacy in the Informed Consent process. The Data results in this chapter support the research present in the previous chapters.

. Chapter five is my conclusions to this dissertation.

Chapter 1

LITERACY AND HEALTH LITERACY

Human beings have over the ages developed a series of media to express or represent features of the social and natural world or to translate one medium into another through culturally acceptable analogues: drum beats experienced as if spoken words, Asian contour graphics or Western notations representing musical performance, hand gestures carrying cognitive meaning, and cartography representing spatial relationships. Writing is just one of these culturally developed forms. It is true that it is currently an extremely widespread and highly valued medium, but seen in comparative perspective it is no more transparent or obvious than any other communication technology. Nor can we assume that the elusive relationships between writing and what it represents. Is it really visible speech?[15]

One common model of literacy is the type well known in recent centuries of Western history: phonetically based alphabetic writing, tied to the concept of a linear text, often with the connotations of something validated through high culture and, at the same time, rightfully open to mass use. But there are other writing systems too. These include to follow one standard typology, pictographic, ideographic and phonetic (syllabic or alphabetic) forms; manuscript as well as print; and a number of different materials: stone, clay, papyrus, parchment, paper, computer screen.

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[15]Ruth Finnegan, "Literacy," In *Encyclopedia of Social and Cultural Anthropology* (London: Routledge, 2009), 1. http://search.credoreference.com/content/entry/routencsca/literacy/0.

These varied forms are not just merely precursors of the alphabetic achievements of Western civilization but represent differing ways in which human beings have developed technologies which expand human control over time and space, and built these into their cultural institutions.[16]

The recent Western paradigm of literacy is of a symmetric process, with reading and writing naturally going together. But they can also be split or, at the least, differentially developed. Historians have, for example, analyzed signature literacy-people sometimes signed their names on, say, marriage registers, but did not necessarily read or write otherwise. Indeed it is sometimes to the advantage of rulers to encourage their subjects to read but not to master more active writing skills. Literacy turns out to be not so much one undifferentiated thing as a cluster of skills which people deploy differentially, more, or less, fully, and in a series of different ways, depending both on their own individual situations and the culture within which they live.

It is important to distinguish health literacy from literacy in general. Literacy is a word question that deceptively suggests simplicity instead opens up a world of complexity. It is surprising how often the literature discusses research, conceptual frameworks, and approaches to teaching literacy (which is often characterized as reading and / or written) without explicitly defining what is meant by these terms.[17] The belief that individuals with extensive needs for support cannot acquire literacy sills often results

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[16] Finnegan, "Literacy," 1.

[17] Elizabeth B. Keefe and Susan R. Copeland, "What Is Literacy? The Power of a Definition," *Research & Practice for Persons with Severe Disabilities* 36, no. 3-4 (2011): 92.

in a lack of opportunity to learn these skills and therefore becomes a self-fulfilling prophecy.[18]

The United Nations Educational, Scientific and Cultural Organization (UNESCO) established the Experimental World Literacy Program in 1966 and characterized literacy as being a fundamental human right.[19] Despite the fact there is general agreement that literacy is a human right, there is no general agreement about the definition of literacy. This is not a new issue to educators.[20]

According to the UNESCO during its history in English, the word 'literate' mostly meant to be 'familiar with literature' or in general terms 'well educated, learned'. While maintaining its broader meaning of being knowledgeable or educated in a particular area, during the late nineteenth century it has also come to refer to the abilities to read and write text. In recent years four understandings of literacy have appeared from the debate of the notion: 1) Literacy as an autonomous set of skills; 2) literacy as applied, practiced and situated; 3) literacy as a learning process; and 4) literacy as text. The focus is furthermore broadening so that literacy is not only referring to individual transformation, but also to contextual and societal transformation in terms of lining health literacy to economic growth and socio-cultural and political change.[21] Literacy is relevant in everyday life.

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[18] Keefe and Copeland, "What Is Literacy? The Power of a Definition," 92.
[19] Ibid., 92
[20] Ibid., 93
[21] Kristine Sorensen, Stephan Van den Broucke, James Fullam, Gerardine Doyle, Jurgen Pelikan, Zofia Slonska and Helmut Brand, for (HLS-EU) consortium Health Literacy Project European, Health literacy and public health: " A systematic review and integration of definitions and models," *Biomed Central Public Health* 12:80, (2012): 1.

Literacy is as much a process as an outcome and requires constant attention and upgrading. The key is to reach a level of fluency at which one can achieve working knowledge of the particular language (or skill), enough to function at a level conductive to achieving health goals. Knowledge, information, and media forms are context-specific, and context dictates what skills and skill levels are required to access health resources. For example, technical jargon may be appropriate in academic discourse provided it allows for a more precise explanation of certain concepts. However, when directed at nontechnical consumers or those outside of a particular research or practice culture, technical language may need to undergo a translation process in order to convey a message properly. Whereas a scientist may be interested in acetylsalicylic acid, a patient requiring pain relief knows this substance only as Aspirin or ASA.[22]

What Is Health Literacy

As with Literacy the same development can be traced in the realm of health literacy. Health literacy as defined by Healthy People 2010 is the degree to which individuals have the capacity to obtain, process, and understand health information and services needed to make appropriate health decisions.[23] Although other definitions of health literacy exist (Appendix 4), this definition is selected for use within the context of this dissertation because it allows discussing concepts essential to understanding health

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[22] Cameron Norman, "ehealth Literacy: Esssential Skills for Consumer Health in a Networked World," *Journal of Medical Internet Research* 8, no. 2 (April-June 2006): 6.

[23] US Department of Health and Human Services, *Healthy people 2010: Understanding and improving health*, 2nd ed., (Washington, DC: US Government Printing Office, 2000), Section 11, 20.

literacy concepts in the Informed Consent process. The informed consent process relies on patients/subjects to understand a written document or something that is said and make the appropriate decision for them.

Health literacy is a term introduced in the 1970s and of increasing importance in public health and healthcare. It is one of the most pressing issues in our health care system today.

For some time most emphasis was given to health literacy as the ability to handle words and numbers in a medical context, and in recent years the concept is broadening to also understanding health literacy as involving the simultaneous use of a more complex and interconnected set of abilities, such as reading and acting upon written health information, communicating needs to health professionals, and understanding health instructions. American studies in the 1990s linked literacy to health, showing an association between low literacy and decreased medication adherence, knowledge of disease and self-care management skills. Consumers rely on health information that is written to sustain and maintain our health and the health of our families. The written word needs to be understood by everyone so that mistakes cannot be made. Health care today exposes consumers to a significant amount of critical information, ranging from prescription bottle labels to insurance forms and from dietary guides to procedural consent.[24] Earlier studies had shown measurable and meaningful benefits to the health of nations from educational interventions. This led health researchers in the United States to

[24]Lorenzen, "Using Principles of health Literacy to Enhance the Informed Consent Process," 23.

investigate the link between reading skill and a range of health-related outcomes, including health knowledge, medication adherence, and hospitalization rates.[25]

In 1999 the American Medical Association convened an ad hoc committee to look at the problem of health literacy. The committee recommended four areas for future research: 1) health literacy screening, 2) improving communication with low-literacy patients, 3) costs and outcomes of poor health literacy patients, and 4) causal pathways of low poor health literacy influences health.[26]

The World Health Organization defines health literacy as follows: Health literacy represents the cognitive and social skills which determine the motivation and ability of individuals to gain access to understand and use information in ways which promote and maintain good. Health literacy means more than being able to read pamphlets and successfully make appointments. It involves helping people to develop confidence to act on that knowledge through personal forms of communication and through community based educational outreach.[27] Health literacy involves improving verbal communication. This can be accomplished by speaking slowly, simplifying language and avoiding medical jargon.

According to Shiva Sadeghi, many patients stated that providers frequently used medical jargon in their communication and that this impeded their understanding of their disease and treatment options. Difficulty in understanding medical terms was associated

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[25]Sheida White, "Key Concepts and Features of the 2003 National Assessment of Adult Literacy," 3.

[26]Alexa McCray, "Promoting Health Literacy," *Journal of the American Informatics Association* 12, no. 2 (March/April 2005): 152.

[27] Daniel C. Mullins et al., "Health disparities: A barrier to high-quality care," *American Journal Health System Pharmacy* 62 (September 15, 2005): 1879.

with insufficient literacy skills or unfamiliarity with the specific medical condition they are suffering from. Some of the feedback from her patients said the following, "what makes it difficult for me to understand is medical terminology. There are long words I have no idea. As I said, I have got, like a grade 5, maybe grade 4 now understanding of words and …you just…if I can't make out the word, I skip over it and I lose the whole concept." Another patient referred to the difficulty in understanding Latin words and elaborated "well…I mean, initially when I got diagnosed they kept calling it…in my case they kept calling it tracheobronchomegaly and I didn't know what that was, and there was very little information on that particular name on the Internet at the time." [28]

In a literacy and health literacy study that was conducted in Dominicans with Diabetes by Judith Aponte, states to advance the literature on Dominicans with diabetes, and health literacy and general literacy different types of research should be conducted. Future research considerations should include the following: identifying the Hispanic subgroups in their sample to identify and provide data on specific Hispanic subgroups; inclusion of Dominicans in their sample; using Spanish tools in evaluating health literacy and general literacy in Hispanics who are monolingual (Spanish only); and comparing them to those who are bilingual (English and Spanish); examining health literacy and general literacy and the impact they have on diabetes knowledge and self management among Dominicans or different Hispanic subgroups; examining the implications health literacy and general literacy have on diabetes-related complications among different Hispanic subgroups; comparing the rates of diabetes in U.S. Dominicans to those living

[28] Shiva Sadeghi, Dina Brooks and Roger S. Goldstein, "Patients' and providers' perceptions of the impact of health literacy on communication in pulmonary rehabilitation," *Chronic Respiratory Disease* 10, no. 2 (2012): 69

in the Dominican Republic; and examining the relationship between health literacy and general literacy among different Hispanic subgroups with diabetes.[29]

The use of "chunks and checks" could provide the patient with only two or three concepts at a time and check for understanding of information through the "teach back." The "teach back" technique is asking the patient to repeat in their own words. An example would be to say "Tell me what you will do and show me how you will do it…" The participants should be sitting throughout the discussion.[30]

Health literacy is modifying written language by using common words, using active voice, writing simple instructions for the patient to take home and numbering the steps to be taken. The instructions would be read and reviewed with the patient and underline or circle key points and use picture and diagrams to supplement written information.[31]

Health literacy creates a shame-free environment by involving all staff in the effort to simplify and clarify written and oral language. A look at forms, intake procedure, telephone contacts, signage, and one on one interactions are reviewed. There should be a gentle offer to help with paperwork and reassure patients that many people have difficulty with health care information and that you(as a health care professional) can help. A new system should be set up to review medication, treatment instructions, and appointment confirmation before the patient leaves the office or institution.

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[29] Judith Aponte, "Literature Review: General Literacy and Health Literacy in Dominicans with Diabetes," *Hispanic Health Care International*, 11, no. 4 (2013): 171.

[30] Joanne G. Schwartzberg, "Low Health Literacy: What Do Your Patients Really Understand?" *Nursing Economics*, 20, no. 3 (May-June 2002): 147.

[31] Ibid., 147.

Conducting follow-up calls to check for understanding and compliance, offering reassurance and reminders.[32]

Health literacy is using available resources so that family members can act as surrogate readers and reinforce health care information at home. The patient should be asked if they would like to invite a family member or friend to accompany him/her to the counseling and planning portion of the visit. There should be consideration when appropriate for specific situations, referral to literacy programs, health educators, home health services, and volunteers.[33] It could be a hard task to accomplish when asking for change in health behaviors that may be culturally sensitive.[34]

An example of a cultural sensitive program is an Asian grocery store based cancer education program based in San Diego County, California. The objectives of this program were to (1) assist health care providers, educators, promoters, and policymakers in recognizing the multiple ethnic subgroups that exist under the Pan Asian population and (2) understand that similarities and differences in health exist within ethnic subgroups of the population. Data were collected and analyzed from a convenience sample of 1202 Asian-American women in San Diego county, California, regarding their breast cancer knowledge, attitudes, and screening behaviors before and after participation in the brief educational intervention. The authors found statistically significant variations in breast cancer knowledge, attitudes, and screening behaviors among ethnic subgroups. These findings reiterate the importance of identifying cultural differences that can affect

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[32] Schwartzberg, "Low Health Literacy: What Do Your Patients Really Understand?," 147.

[33] Ibid., 147.

[34] Mullins, "Health disparities: A barrier to high-quallity care," 1879.

health literacy and create inequalities in health and health care among minority subgroup populations.[35] Improving health literacy in a population involves more than the transmission of health information; it involves community participation in health interventions, a hard task to accomplish when asking for change in health behaviors that may be culturally sensitive.[36]

According to a study that was authored by Felecia Wood, an assistant professor at the University of Alabama, she focused on a free clinic in rural Alabama and attempted to assess the health literacy of patients seeking care. The study, published in the spring issue of the Rural Nurse Association's Online Journal of Rural Nursing and Healthcare asked patients age 18 and older to take a health literacy test in fall 2003. The research found that 49% (28 out of 57 patients) would be unable "to read most patient education materials…and would benefit from low-literacy and audiovisual education strategies." Wood says a takeaway from the study is that providers shouldn't hand patients a pamphlet and automatically expect them to understand the material.[37]

Most current health education and promotion materials are communicated in printed form, usually written at the 10th grade level or above. People with limited health literacy find these materials of very little use. As a result, there is a large segment of the population that is unable to access the full benefits of health information and services.

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[35] Mullins, "Health disparities: A barrier to high-quallity care," 1879-1880.
[36] Ibid., 1880.
[37] J. Mantone, "Reading, writing and relating. Providers – and urban- urged to pay more attention to health literacy," *Modern Healthcare* 35, no. 32 (August 8, 2005): 2.

Closing this gap is critical to reduce health disparities and provide fairness and equity[38]. Nurses can be a benefit in promoting health literacy. There are several ways nurses can promote improved health literacy which would be the following: serve as a patient advocate by enhancing the woman's autonomy and assisting her in voicing her values. Reinforce risks and benefits and assure understanding of informed consent. Anticipate that the patient will not tell you that she cannot read. Use "living room language" that the patient can understand. Utilize pictures and stories to illustrate important points. Repeat instructions. Limit the amount of information given. Confirm understanding of information by using "teach-back" or "show me" approaches. Demonstrate respect, care and sensitivity for all patients.[39]

Using community businesses as a venue for distribution and dissemination of health related information is becoming very popular in helping people become more health literate. Such information might include health information, fact sheets, product information pamphlets, and notification of clinical trials, health fairs, and health screenings.[40] Implicit in most definitions is the notion that health literacy, much like any other type of literacy, goes well beyond mere numeracy and grade-level reading ability. Rather, it is contextual and includes sociocultural elements. Health literacy transcends provider-patient communication to include peer, family, and community communication

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[38] Marilynn R. Wood, Chris A. Kettinger, Mira Lessick, "Knowledge Is Power, How Nurses Can Promote Health Literacy," *Nursing for Women's Health* April/May 2007: 183.

[39] Ibid., 184.

[40] Barbara H. Johnson et al., "Health literacy of an Urban Business Community," *Journal of Health Care for the Poor and Underserved* 23, no. 1, (February 2012): 245.

channels.[41] Examples of health literacy are as follows: By improving people's access to health information and their capacity to use it effectively, health literacy is critical to empowerment.[42] Also, Health literacy is defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health and services needed to make appropriate health decisions."[43]

Health literacy is an important aspect of life on a daily basis. According to health professionals what occurs in the hospital room and doctor's office is an all too common event: Patients do not always fully understand their diagnosis or treatment. As a result, they may not follow through or do so correctly with their home care programs with medications or preventive care.[44] Unfortunately, this is a true statement. I encountered a having a conversation with a young adult about some symptoms they were having and she finally went to their physician office to have some test done. The physician gave them a diagnosis but the patient was still in the dark because she didn't understand the medical jargon and didn't ask enough questions to really understand what was going on with her body.

There is a National Action Plan to improve Health Literacy. It is to engage organizations, professionals, policymakers, communities, individuals, and families in a

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[41] Jeffrey Huber, "Top Down versus Bottom Up: The Social Construction of the Health Literacy Movement," *The Library Quarterly: Information, community, Policy* 82, no. 4, (October 2012): 430.

[42] Don Nutbeam, "Health Literacy as a public health goal: a challenge for contemporary health education and communication strategies into the 21st century," *Health Promotion International* 15, no. 3 (2006): 264.

[43] Carolyn Crane Cutilli, "Health Literacy," *Orthopedic Nursing*, 24, no. 3, (May/June 2005): 227.

[44] Michelle Vanderhoff, "Patient Education and Health Literacy," *PT Magazine* (September 2005): 42.

linked, multisector effort to improve health literacy. The plan is based on the principles that (1) everyone has the right to health information that helps them make informed decisions and (2) health services should be delivered in ways that are understandable and beneficial to health, longevity, and quality of life.

According to a report written by the Institute of Medicine, low health literacy of patients can stem from any of several factors including: native language, socioeconomic status, gender, race, and ethnicity. Influences of mass media, advertising, marketing, and the plethora of health information sources available electronically, listening and speaking skills, ability to read and do math, cognitive delays, memory problems or psychological disorders (ex. Depression), and others.[45]

The American Medical Association (AMA) in the 1990's undertook a view of the literature relating to the effects of health literacy. The AMA Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs reviewed 216 published articles and conferred with researchers in the area to reach consensus on a linkage between health literacy and patient health.[46] This committee defined health literacy as constellation skills, including the ability to perform basic reading and numerical tasks required to function in the health care environment. Patients with adequate health literacy can read, understand, and act on health care information. The sentence of that definition is the one commonly used today. The AMA report went on to acknowledge the disparity between the skills needed to be health literate and the literacy skill of many Americans and the

[45] Vanderhoff, "Patient Education and Health Literacy," 42.
[46] Ibid., 42.

need for improved communication between patients and health care providers.[47] People will not usually admit to having problems understanding their health professional but it happens every day. I have known some people to not be able to read. Which is a problem because but they can't really help themselves or their family.

The term health literacy was first used in 1974 in a paper calling for minimum health education standards for all grade school levels in the USA. However, few references to health literacy can be found in the literature until 1992. Physicians affiliated with Emory University and UCLA conducted the seminal work on health literacy in a 2-yr study funded by the Robert Wood Johnson Foundation in 1992. The study was designed to determine participant's ability to successfully complete basic reading and numeracy tasks required to function adequately in health care setting.[48] However, health literacy involves skills in listening, speaking, arithmetic, problem solving and decision making, which are influenced by society and cultural.

Health literacy is very dependent on being functionally literate with written information. There have been many studies to examine the general literacy in the United States. A major literacy study was conducted by the National Assessment of Adult Literacy Survey (NAALs) in 1992 and 2003. In the 1992 study, functional literacy was measure across three skill areas: prose (both expository and narrative), document (short forms or graphically displayed information), and quantitative (graphs/charts or numerical display). Tasks in each skill area were rated in one of five levels-from simple (Level 1)

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[47] Barbara F. Schloman, "Health Literacy: A Key Ingredient for Managing Personal Health," *Online Journal of Issues in Nursing* 9, no. 1-2 (May 31, 2004): 1.

[48] Carolyn Speros, "Health Literacy: concept analysis," *Journal of Advanced Nursing* 50, no. 6 (2005): 635.

to complex (Level 5). Health literacy refers to the basic set of skills needed to read, understand, and act on basic health information. The average reading level in the United States is at the eighth and ninth grade level.[49] Literacy skills are a stronger predictor of an individual's health status than age, income, employment status, education level, or racial/ethnic group. An increasing body of evidence indicates that low health literacy may be an underlying factor in high use of some health care services as well as influencing health outcomes. The relatively hidden issue is estimated to cost the U.S. health care system up to $73 billion annually for risk and poor health outcomes.[50]

The summary of the NAALs is as follows: at the lowest level of literacy skill termed NAALS level 1, individuals can only perform basic tasks such as signing their name or finding a work or fact in a short written article. Forty to forty-four million adults at NAALS level 1 are often considered functionally illiterate , can fill in the blanks on a job application forms, and complete a deposit slip that lists two checks.[51]

Individuals in NAALS level 2, which consists of 50 million adults, have somewhat more advanced skills but are still substantially limited in their ability to read and understand text. They are considered marginally literate, given a wage and tax statement that comes with a pay check, identify the gross pay for this year to date and locate an intersection on a street map.[52] In contrast, people at NAALs levels 3(61 million adults), 4 and 5(34-40 million adults respectively) have sufficient literacy skills to permit

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[49] National Center for Education Statistics. National Assessment of Adult Literacy (NAAL). December 2005. Retrieved August 6, 2006 from http://nces.ed.gov?NAAL/index.

[50] "Literacy Facts-Did you know?," Retrieved August 6, 2006 from http://uuhsc.utah.edu/pated/authors/literacy.html.

[51] Cutilli, "Health Literacy," 228.

[52] Ibid.,228.

full functioning in society. Those at NAALS level 5, the most advanced literacy level, have well developed literacy skills that enable them to perform complex tasks, such as writing lengthy documents and extracting data from tables and graphs. This information clearly shows that most adults are not at the higher proficiency. This translates to adults not really understanding what is going on with their health care. It shows the need for increased literacy. This study did not take in account any non-English speaking adult. This was just English speaking adults. The numbers could be increased by bringing in this information.

However, it is not enough for people to just have information but also have access to healthcare. Which at this time is being worked on with the Affordable Health Law that has been passed? The word empowerment has been used recently. The World health Organization (WHO) definition moves health professionals beyond providing information to also empowerment.[53]

Health Literacy and Patient Empowerment

In the health behavior literature, two concepts have assumed dominating role-patient empowerment and health literacy. Both have been advanced as important determinants of a range of health –related behaviors and the outcomes of patient communication and public health efforts. However, the two are often conflated in studies, and studies of one regularly either ignore or assume the other. Health literacy

[53] Virginia Mika et al., "The ABC's of Health Literacy," *Family Community Health* 28, no. 4 (2005): 353.

and patient empowerment are distinct concepts but closely interwoven and must be considered in conjunction to understand individual health behavior and the impact on it of communications.[54]

Patient empowerment assumed a prominent place in visions of optimal health following the Ottawa Charter of 1986, which proposed that health promotion is the process of enabling people to increase control over, and to improve, their health. For some, this vision takes on a relational (e.g. doctor-patient) dimension-emphasizing the need for more egalitarian structures and a more equitable distribution of power between practitioners and patients. Others take a more individualistic view, focusing more on informed choice, or on patient experience of feelings of power, control, or greater self-esteem.[55]

The appeal of patient empowerment rests on three different traditions of thinking. It is advanced first on ethical grounds, particularly as a way increasing personal autonomy in patients' involvement in decision making related to their health. A second reason for the growing interest in patient empowerment has been the view that citizens should participate in and take responsibility for their health care in order to control healthcare costs. Third, and perhaps most importantly, patient empowerment is advocated as improving health outcomes.[56]

Empowerment can be defined as a process by which people gain mastery over their lives. Studies of empowerment in different disciplines are based on the proposition

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[54] Peter J. Schulz and Kent Nakamoto, "Health literacy and patient empowerment in health communication: The importance of separating conjoined twins," *Patient Education and Counseling* 90 (2013) :4

[55] Ibid., 4.

[56] Ibid.

that to improve the quality of their lives both in the workplace and at home, people should be able and motivated to bring about changes, not only in their personal behavior, but also in their social situations and the organizations that influence their lives. As such, empowerment is a relational construct (e.g. in the doctor-patient consultation) associated with the concepts of power, equity, and control of situations, and thus implies a capacity to solve problems and get a fair share of resources. The concept refers to both the state of being empowered and the process of becoming so.[57]

When empowerment is discussed in relation to health behavior, health care or the health system, we speak of patient empowerment, despite the fact that persons who are not at the moment patients are also included when for instance disease prevention or the position of individuals vis-à-vis the health system are treated. Generally, patient empowerment is conceived as the patient's participation as an autonomous actor taking increased responsibility for and a more active role in decision making regarding his or her health.[58]

The authors adapted the following set of measures that identify constructs inherent in empowerment:

- Meaningfulness (or relevance) refers to the value of the activities, judged in relation to the individual's own ideal of life. Meaningfulness is about the individual experiencing the feeling that what he or she does is meaningful and worth investing energy in. If the patient does not consider his/her activities as being relevant for his own quality-of-life, this will result in resignation, apathy or

[57] Schulz and Nakamoto, "Health literacy and patient empowerment in health communication: The importance of separating conjoined twins," 5.

[58] Ibid., 5.

disengagement. On the other hand, higher levels of relevance are believed to result in commitment and involvement.

- Self-efficacy (or competence) is a key cognitive component of social cognitive theory. Self efficacy is the belief in one's capabilities to produce desired results by one's actions. Without efficacy, people have little incentive to act. Referring to the degree to which a person can perform terms of task activities skillfully when he or she tries, the concept has been widely investigated in social psychology, in motivational theories as well as in cognitive theories which conceptualize self-efficacy in terms of expectancies and perceptions of control.[59]
- Impact mean that the accomplishment of a task is perceived to make a difference in the scheme of things. The more impact individuals believe they have, the more internal motivation they should feel.
- Self-determination (or choice) refers to a decision that is characterized by autonomous initiation and is self-determined. It presupposes a distinction between an intentional behavior where people want to act in a way that would yield certain outcomes and a kind of behavior that is pressured and coerced by intra-psychic or environmental forces.[60]

What is central to this operationalization is that the components all highlight the subjective experience of empowerment and its force as a motivation for action. This

[59] Schulz and Nakamoto, "Health literacy and patient empowerment in health communication: The importance of separating conjoined twins," 5.

[60] Ibid., 6.

distinguishes empowerment from literacy, which focuses on knowledge and abilities to use it.[61]

[61] Schulz and Nakamoto, "Health literacy and patient empowerment in health communication: The importance of separating conjoined twins," 6.

Chapter 2

HISTORY OF THE INFORMED CONSENT FORM

"Unless you've studied medicine, you don't know what you're signing. It was Greek to me. No one ever really explained anything to me. They handed me the papers and gave me a lot of time to look them over. I just asked a few questions, then went ahead and signed it. That was probably a stupid thing to do, but I had suffered with this IBS for so long."

Frank, subject in an Irritable Bowel Syndrome trial[62]

Informed consent is more than just a signature on a form; it is a process of information exchange that may include, in addition to reading and signing the informed consent document, subject recruitment materials, verbal instructions, question/answer sessions and measures of subject understanding. Institutional review Boards (IRBs), clinical investigators, and research sponsors all share responsibility for ensuring that the informed consent process is adequate. Thus, rather than an endpoint, the consent document should be the basis for a meaningful exchange between the investigator and the subject.[63]

The clinical investigator is responsible for ensuring that informed consent is obtained from each research subject before that subject participates in the research study. FDA does not require the investigator to personally conduct the consent interview. The investigator remains ultimately responsible, even when delegating the task of obtaining

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[62] Kenneth Getz, *The Gift of Participation* (Bar Harbor, ME: Jerian Publishing, 2007), 119.

[63] *FDA Good Clinical Practice, 2008 Reference Guide*, Book 1B (April 1, 2008 – March 31, 2009): 42.

informed consent to another individual knowledgeable about the research. The consent process begins when a potential research subject is initially contacted. Although an investigator may not recruit subjects to participate in a research study before the IRB reviews and approves the study, an investigator may query potential subjects to determine if an adequate number of potentially eligible subjects is available[64]. The consent form is a very important part of clinical research. It must be reviewed and signed prior to any procedures are conducted on patients. Many studies have been cited by the FDA because the study was begun without a consent form signed and dated.

The Nuremberg Code of 1937

The Nuremberg trials against Nazi physicians and researchers accused of inhumane medical experimentation was a signal moment in the development of the doctrine of informed consent.[65] Those twenty-four physicians were convicted of committing atrocities in Germany after World War II. For hundreds of years, children were typically recruited for scientific studies. They were easy to recruit precisely because they were vulnerable. This practice reached its ugliest point in Europe in the late 1930s, when children diagnosed with various defects were sometimes sacrificed because they were deemed too costly for the government to care for.[66]

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[64] *FDA Good Clinical Practice, 2008 Reference Guide*, 42.

[65] George J. Annas, Michael Grodin, eds., *The Nazi Doctors and the Nuremberg Code: Human rights on Human Experimentation* (New York: Oxford University Press, 1995).

[66] Getz, *The Gift of Participation*, 167.

At the beginning of World War II, Germany was the most scientifically and technologically advanced country in the world and even had a proposed code of research ethics. In the field of medicine, the Nazi government supported midwifery, homeopathy and nutrition programs as well as research into ecology, public health, human genetics, cancer, radiation and asbestos. They were the first to ban smoking in public buildings. Women were denied tobacco ration coupons because of concern about the effect of nicotine on the fetus. German physicians stressed the importance of preventive medicine rather than curative medicine.[67]

The Nazi party, however, exploited people's trust in the medical community and public health by performing unethical experiments and atrocities on populations they discriminated against. The German Air Force, for example, was concerned about the survival of pilots at extremely high altitudes. One question they wanted the answer to was: What was the maximum safe altitude for bailing out of a damaged aircraft? To answer this question, researchers designed a series of experiments involving internees at the Dachau concentration camp. In one series of experiments, researchers placed the victims in vacuum chambers that could duplicate the low air pressure and anoxia (lack of oxygen) at altitudes as high as 65,000 feet (about two to three times the maximum altitude that aircraft were flying). Approximately 200 internees at Dachau were used in these experiments, and about 40% died as a result. Some deaths were caused by extended anoxia; others were attributable to lungs rupturing from the low pressures in the chamber.[68]

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[67] Getz, *The Gift of Participation*, 167-168.
[68] Ibid., 168.

Experiments involving battlefield medicine included treatment of gunshot wounds, burns, traumatic amputations and chemical and biological agent exposures. In these experiments, the wound was first inflicted upon the victim (by gunshot, stabbing, amputation or other traumatic method) and then treated using various techniques. For example, in a study of sulfanilamide at the Ravensbrueck camp, Polish women were shot and slashed on the legs. The resulting wounds were stuffed with glass, dirt and various bacteria cultures, and sewn shut. The infected wounds were then treated with experimental anti-infective agents.[69]

Nazi experiments on treating exposure to chemical-warfare agents were ongoing throughout the war years. Concentration camp internees were forced to drink poisoned water and to breathe noxious gases. Some were shot with cyanide-tipped bullets or given cyanide capsules. It was not uncommon for one out of every four internees in these studies to die as a result of their involvement in the experiments.[70]

Representatives of the British, French, Soviet and United State governments established the International Military tribunal in Nuremberg, Germany, in 1945, after the initial Nuremberg Trial of Nazi leaders, a series of supplemental trials was held. The trial, officially known as United States v. Karl Brandt et al., and commonly referred to as "The Nazi Doctors Trial," was held from December 9, 1946, to July 19, 1947. As the title indicates, the judges and prosecutors in this court trial were all from the United States. The 23 defendants (including 20 physicians) - all members of the Nazi Party-

[69] Getz, *The Gift of Participation*, 169.
[70] Ibid., 169.

were charged with murder, torture and other atrocities committed in the name of medical science.[71]

When the final judgment in the Nazi Doctors Trial was delivered on July 19, 1947, 15 of the 23 defendants were found guilty. Seven were sentenced to death. Four American judges presiding issued a ten point code that described basic principles of ethical behavior in the conduct of human experimentation. This ten-point code is known as the Nuremberg Code. The Code is an "ethical standard" and reflects the modern thinking that:

- Informed consent should be obtained without coercion.
- The experiment should be useful and necessary.
- Human experiments should be based on previous experiments with animals.
- Physical and mental suffering should be avoided.
- Death and disability should not be expected outcomes of an experiment.
- The degree of risk to be taken should not exceed the humanitarian importance of solving the problem.
- Human subjects should be protected against even remote possibilities of harm.
- Only qualified scientists should conduct medical research.
- Human subjects should be fee to end an experiment at any time.
- The scientist in charge must be prepared to end an experiment at any stage.[72]

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[71] Getz, *The Gift of Participation*, 169.
[72] Ibid., 170

Declaration of Helsinki

In 1953, the World Medical Association began drafting a document that became known as the Declaration of Helsinki. This statement of ethical principles, first issued in 1964, defined rules for "therapeutic" and "non-therapeutic" research. It repeated the Nuremberg Code requirement for consent for non-therapeutic research, but it did allow for enrolling certain patients in therapeutic research without consent. The Declaration of Helsinki also allowed legal guardians to grant permission to enroll subjects in research, both therapeutic and non-therapeutic and recommended written consent-an issue not addressed in the Nuremberg Code. In addition, the Declaration of Helsinki requires review and prior approval of a protocol by an IRB.[73] The following are the thirty-five items in the Declaration of Helsinki.

A. INTRODUCTION

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs.

2. Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.

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[73]Getz, *The Gift of Participation*, 170.

3. It is the duty of the physician to promote and safeguard the health of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfillment of this duty.

4. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."

5. Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in medical research should be provided appropriate access to participation in research.

6. In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.

7. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best current interventions must be evaluated continual through research for their safety, effectiveness, efficiency, accessibility and quality.

8. In medical practice and in medical research, most interventions involve risks and burdens.

9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations

are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.

10. Physicians should consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

11. It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity right to self-determination, privacy, and confidentiality of personal information of research subjects.

12. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

13. Appropriate caution must be exercised in the conduct of medical research that may harm the environment.

14. The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol

should include information regarding funding, sponsors, institutional affiliations, and other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for post study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.

15. The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins. This committee must be independent of the researcher, the sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No change to the protocol may be made without consideration and approval by the committee.

16. Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervisor a competent and appropriately qualified physician or other health care professional. The

responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.

17. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive t the health needs and priorities of this population or community and if there a reasonable likelihood that this population or community stands to benefit from the results of the research.

18. Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.

19. Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.

20. Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.

21. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects.

22. Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.

23. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of the personal information and minimize the impact of the study on their physical, mental and social integrity.

24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and discomfort may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in written. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse.

There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.

26. When seeking informed consent for participation in a research study the physician should be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent should be sought by an appropriately qualified individual who is completely independent of this relationship.

27. For a potential research subject who is incompetent, the physician must seek informed consent form the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with competent persons, and the research entails only minimal risk and minimal burden.

28. When a potential research subject who is deemed incompetent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.

29. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a

necessary characteristic of the research population. In such circumstances the physician should seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by research ethics committee. Consent to remain in the research should be obtained as soon as possible from the subject or a legally authorized representative.

30. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of the research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

31. The physician may combine medical research with medical care only to the extent that the research is justified by its potential preventive, diagnostic

or therapeutic value and if the physician has good reason believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

32. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:

The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.

33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.

34. The physician must fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never interfere with the patient-physician relationship.

35. In the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent form the patient or a legally authorized representative, may

> use an unproven intervention if in the physician's judgment it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, this intervention should be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information should be recorded and, where appropriate, made publicly available.[74]

The Belmont Report

Ethical principles and guidelines for the protection of human subjects of research (known as the Belmont Report), was published April 18, 1979. The Belmont Report established boundaries between practice and research. In practice, clinicians administer drugs or treatment to benefit patients. According to the Belmont Report, research and practice may be carried out together when research is designed to test safety and efficacy of therapy. However, if there is any element of research in a practice, then that activity should undergo review. Therefore, it is necessary to have a division between practice and research.[75]

The Belmont Report also established the three basic ethical principles of research: Beneficence, Autonomy, and Justice. Beneficence means doing no harm. Autonomy requires respect for persons and emphasizes the voluntary nature of participation in research. Patients have the right to choose whether they want to take part in a research

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[74] World Medical Association, Inc., "Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects," (June 1964): 1-8, http://www.wma.net/en/30pblications/10policies/b3/index.html.

[75] Valerie Hatton "Informed Consent Its History, Purpose, and Process," *SoCRA Source* 59 (February 2009): 35.

study. Justice means that researchers will not just conduct the study on an indigent population or vulnerable population. Anyone can participate in research.[76]

In 1991, the federal policy for the protection of human subjects, to be regulated by the FDA, was published in the Code of Federal Regulations. This policy established the principle of informed consent. It required investigators to give potential research participants ample time to read the informed consent form and consider whether to participate in the study and minimize the possibility of coercion or undue influence during the informed consent process.[77]

The policy also prohibited the use of exculpatory language, whether oral or written, through which the research participant is made to waive or appear to waive any of the research participant's legal rights, or language that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. The policy required the informed consent form to be written in a manner that is understandable to potential research participants.[78]

Tuskegee Study

While the United States, Great Britain, France, and Russia were condemning the physicians of the Nuremberg trials, American scientists and physicians did not talk about what was going on here in the United States. Long after the Nuremberg Code was

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[76] Valerie Hatton "Informed Consent Its History, Purpose, and Process," *SoCRA Source* 59 (February 2009): 35.

[77] Ibid., 35.

[78] Ibid.

announced and informed consent laws were being issued and rewritten, human research subject protection was far from guaranteed.

The treatment for syphilis at the turn of the twentieth century was, at best, crude and involved the use of "heavy metal" (mercury and arsenic) compounds. These were poisons, highly toxic to humans, and had to be administered for a year or more. Severe reactions, even death, were not uncommon from the treatment and some evidence suggested that treated patients lived shorter lives than the untreated.[79]

An agency of the U.S. Public health Service (PHS), which was to become the Centers for Disease Control and Prevention (CDC), designed a study to demonstrate the need for establishing syphilis treatment programs by investigating the effects of untreated disease. This evolved from a genuine concern about minority health problems. The PHS was a key force in promoting rural medical care. Macon County, Alabama, was selected as the site for the project because previous epidemiological studies had shown an extremely high rate of disease. To secure the cooperation of the black subjects, the participation of black physicians was seen as essential. The Tuskegee Institute and its John A. Andrew Hospital were used because of their position of trust in the local community. A local nurse who had trained at the Tuskegee Institute was hired to be the on-site representative. The project was scheduled to end after assessing what health effects had occurred.[80] This project still has an effect on modern day research and medical practices. The nurse that was assigned to this project was an African American named Eunice Rivers Laurie. There have been many writings about

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[79] Cynthia Dunn and Gary Chadwick, *Protecting Study Volunteers in Research*, 2nd ed. (CenterWatch, 2002), 20.

[80] Ibid., 21.

her approach and significance. Although Nurse Rivers played other roles in the study, her most defining was convincing family members to allow post-mortem studies. In an author interview conducted by James H. Jones, Nurse Rivers admits that after witnessing the first couple of autopsies she was left feeling uneasy. Her statement was, "I wasn't sold on autopsy, so I had a problem selling it to other people."[81] In order to uphold her status as a nurse who was able to follow a doctor's order, Rivers overcame this uneasiness quickly. During the first twenty years of the Tuskegee Study, Nurse Rivers was able to bring 144 out of the 145 men who died to autopsy.[82] There is no doubt that the success of Rivers directly stems from her approach. Unlike the cold and formal health officials and male doctors, Nurse Rivers was very aware of the people that she was dealing with, allowing her to predict their reactions to many things such as word choice. Words like autopsy, along with other medical terminology, would only cast doubt, causing the family to recoil in distrust. Rivers was careful to explain that the doctors would perform something similar to a surgery in order to find out why the man died. Even this caused a small amount of fear, which Rivers explained by saying, "They (family of the deceased) didn't want somebody thinking that the body had been opened up."[83] Often times Nurse Rivers would need to describe, in detail, how the process worked to assure the family that all of the cuts would be out of view when the subject was dressed and laying in the coffin. Due to all of this concern, Rivers made it clear to the physician that, "if you mess up that body, you won't get another."[84]

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[81] James Jones, *Bad Blood* (New York, NY: The Free Press, 1993), 151.
[82] Ibid., 152-153.
[83] Ibid.
[84] Ibid., 153.

Nurse Rivers truly served as the mediator between the professionals and the subjects. It is clear that without Nurse Rivers, or someone of similar status and social ties, the Tuskegee Study would not have had the longevity that it did. It was her job to monitor as many of the men as she could, and she spent much of her time and energy doing this. One participant of the study remembered such things as, "Nurse Rivers would come by and check on us between times we see the doctors. Yes, sir, she sure would. Come in and visit with us and talk to us and ask us how we dong…it was very nice."[85] There is a movie that speaks to the Tuskegee Study and Nurse Rivers, it is entitled "Miss Evers'Boys" (1997). This body of work was produced for the HBO cable network and explored the social and ethical issues at the heart of the Tuskegee study. Although the movie is framed as a series of flashbacks during the 1971 congressional hearings about the experiment, the film employs the viewpoint of Nurse Eunice Rivers who knew of the study's true nature. The film won three Emmy Awards including top acting honors for actress Alfre Woodard.

In the beginning, there was no intent to deny anyone treatment on a long-term basis, however, it did evolve into something completely different. The study called for 200 to 300 syphilitic black males, aged 25 and older, to be enrolled. They were to be given complete physical examinations, a thorough medical history and then followed for six to eight months. During that time, they would not be treated. This study demonstrates that competent and well-intentioned researchers may run into problems if

[85]James Jones, *Bad Blood* (New York, NY: The Free Press, 1993), 156.

they do not identify and examine the ethical assumptions and consequences of their actions.[86]

In October 1932, subjects were sought and encouraged to participate in the study with offers of free examinations and medical care. The men were not informed about their disease or the fact that the research would not benefit them. Non-therapeutic spinal taps, which were conducted in May 1933, were supposed to end the experiment; but a second phase, or follow-on study started in late 1933. This phase introduced new procedures to strengthen scientific validity and to gain more information. A control group of 200 black men and autopsies of deceased subjects were added to the study. Like the original subjects and according to the conventions of the day, the members of the control group were not informed about the purpose of the study, but were told that "government doctors" were examing people for "bad blood."[87]

Each year, new physicians were sent on a special assignment to Alabama to conduct the "roundups" and medical examinations. The study procedures became so routine that the study continued without any exploration or understanding of the potential ramifications of the project. Many of the itinerant physicians later filled positions of authority in the PHS and /CDC.[88]

In 1943, penicillin was accepted as the curative treatment for syphilis. However, during World War II, to keep the syphilis study subjects from receiving treatment, it was arranged with the local draft board to exempt them from the military. By 1951, penicillin was widely available as the treatment for syphilis, but it continued to be

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[86] Dunn and Chadwick, *Protecting Study Volunteers in Research*, 21.
[87] Ibid., 21.
[88] Ibid.

withheld from the study subjects.[89] In order to understand the controversy of untreated syphilis is a sexually transmitted disease, which passes to others through contact with a syphilis sore and prenatally through a syphilitic mother. The disease has three main stages in which different manifestations can occur, if not treated. On average, 21 days after infection the first stage begins. In this stage, a sore called a chancre is common. Typically small in appearance, there can be one or more sores with little or no pain. They usually last three to six weeks and will heal without treatment. However, if not treated the disease moves into the secondary stage.[90]

During this stage, the typical manifestation of the disease is a rash that appears on the body in many different areas. Often times the rash does not itch or will be so faint in color that goes un-noticed. These rashes also typically can be mistaken for other sicknesses, leading to a misdiagnosis. If the person does not receive treatment, the disease will move into the latent phase.[91]

At this point, there are many different effects the disease can have on a person. While some people can go years without any signs of the negative effects, others can experience life-altering complications such as damage to the internal organs. These organs include the brain, nerves, eyes, heart, blood vessels, liver, bones, and joints. Other signs and symptoms of the late stage of syphilis can include difficulty

[89]Dunn and Chadwick, *Protecting Study Volunteers in Research*, 21

[90] Department of Health and Human Services, "Syphilis- CDC Fact Sheet," *Center for Disease Control and Prevention*, January 29 2014: 2.

[91] Ibid., 2.

coordinating muscle movements, paralysis, gradual blindness, and dementia. In some cases, these effects can lead to premature death of the host.[92]

Actually, the availability of penicillin was used by the study investigators as justification for continuing the study because it made the protocol a "never-again" scientific opportunity. Neither the ethical issues nor the fact that the supposedly untreated subjects had received some minimal treatment was addressed. Announcement of the Nuremberg code and its requirement for informed consent and avoidance of harm had no impact on the study. Publication of the Declaration of Helsinki in 1964, with its extensive set of ethical requirements, had no effect on the study.[93]

After obtaining copies of letters and other study-related documents in 1972, the Associated Press assigned an investigative reporter, Jean Heller, to uncover the story. Her best source of information was the CDC itself. The study had never been hidden. Several articles had been published and CDC officials discussed it candidly. Her story was published in the New York Times and the Washington Star on July 25, 1972.[94]

The public reaction to the Syphilis Study was strong, James B. Allen, a U.S. Senator from Alabama, denounced the study as appalling, "a disgrace to the American concept of justice and humanity." The fact that the PHS had conducted the study was particularly distressing because instead of protecting citizens, it had used them for research. Some people thought that the study was racist. Others believed that social class was the critical issue, i.e., that poor people, regardless of race, was the ones at risk

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[92] Department of Health and Human Services, "Syphilis- CDC Fact Sheet," 2.
[93] Dunn and Chadwick, *Protecting Study Volunteers in Research*, 22.
[94] Ibid., 22.

because, at that time, they made up a disproportionate share of subjects in most medical experiments.[95]

An article that appeared in the Atlanta Constitution on July 27, 1972, stated, "Sometimes, with the best of intentions, scientists and public officials and others involved in working for the benefit of us all, forget that people are people. They concentrate so totally on plans and programs, experiments, statistics-on abstractions-that people become objects, symbols on paper, and figures in a mathematical formula or impersonal "subjects" in a scientific study." Many saw a need to protect people from experiments and scientists who ignored human values."[96]

In reaction to the revelations about the Syphilis Study and other research "scandals," several bills to regulate research were introduced in Congress. During February and March 1973, Senator Edward Kennedy held hearings on experimentation with human subjects. In March 1973, the Syphilis Study was stopped, and treatment was given as needed. In April 1973, the CDC informed the survivors that the government would pay all of their medical expenses for the rest of their lives. In 1975, the government extended treatment to the wives who had contracted syphilis and to their children who had been born with congenital syphilis. This money continues to be paid to these citizens today. In a formal White House ceremony in 1997, President Clinton apologized to study subjects and their families and called for renewed emphasis on research ethics.[97]

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[95] Dunn and Chadwick, *Protecting Study Volunteers in Research*, 22.
[96] Ibid., 22.
[97] Ibid.

In 1974, Congress passed the National research Act. The Act required regulations for the protection of human subjects that included requirements for informed consent and review of research by institutional review boards (IRBs). This Act also created the National Commission for the Protection of human Subjects of Biomedical and Behavioral Research. In 1979, the National Commission published the "Belmont Report," which is the corner stone statement of ethical principles upon which the federal regulations for the protection of subjects are based.[98]

In 1981, The DHHS and the FDA published convergent regulations that were based on the Belmont Principles. These mandated a role on the IRB for persons with broad backgrounds and members who could represent community attitudes. Informed consent was required for participants, and specific elements of information were required. After 10 years of negotiation and coordination, 17 federal departments and agencies agreed to adopt the basic human subject protections. These were published in 1991 and are referred to as the "Common Rule." Thus, essentially all federally sponsored research is now covered by a common set of regulations that has its origins in the National Research Act and the Syphilis Study.[99]

HeLa Cells

The more recent revelations about circumstances surrounding HeLa cells rekindled angst and anger in the African American community in relation to clandestine

[98] Dunn and Chadwick, *Protecting Study Volunteers in Research*, 22.
[99] Ibid., 22.

human subject research. Without permission, recompense, or acknowledgement, the human tissue of one individual was used in medical experimentation over many decades to global effect, spawning countless medical discoveries, and generating untold corporate profits. Meanwhile, neither the donor nor her family knew of the human tissue contribution, or the uses to which it was put: "and, who's the lady they took the cells out of, and she didn't even know it? Henrietta Lacks. They took cells and have been using them for how many years. She didn't know it, nor did her family. And they are just now finding out, while for decades medicine made a lot of money. I'm not opposed to helping people, but you have got to get my permission to use what I have donated. You can't be sneaking around with it."[100]

What the popular book entitled the Immortal Life of Henrietta Lacks by Rebecca Slot and new coverage about what was done made it widely known that the unwitting donor was an African American woman, Henrietta Lacks, whose children have lived in poverty, dealing with chronic illnesses and lacking health insurance, while her cells have generated corporate profits over six decades.[101] This is yet another example where understanding of what is going on and actually in this case having an informed consent would be very helpful.

Studies aren't hard to find, even for those people not actively looking to participate. Studies are regularly advertised in newspapers and on the radio and TV. They're posted on bulletin boards in community centers and physician waiting rooms.

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[100] Aaron G. Buseh et al., "Community leader's perspectives on engaging African Americans in biobanks and other human genetics initiatives," *J Community Genetic* 4, no. 4 (October 2013): 5.

[101] Buseh et al., "Community leader's perspectives on engaging African Americans in biobanks and other human genetics initiatives," 6.

Call centers now routinely contact homes soliciting volunteers. Trials are also detailed in direct-mail brochures, discussed at patient support group meetings and health fairs, and personally offered as treatment options by thousands of investigators across all 50 states. Recently in the July 2013 issue of Essence magazine there was a Work and Wealth article which gave examples of how to earn extra money over the summer. A total of eight ways to increase your income now were listed in the article. There was a question asking how far is your dollar going these days? The article answered with the following:

> Probably not as far as it used to. With sky-high gas prices becoming the norm and nearly half of American women admitting that they have more credit card debt than savings, many of us are feeling the pinch. But it doesn't have to be that way. No need to wait for your next raise. Make an extra $500 or $5,000 this month with one of these savvy strategies.

The article made mention that one could possibly make a potential of $5,000 or more for overnight studies by contributing to science. The section said the following, "for every medical breakthrough, there's a clinical study that showed scientists if the treatment would work." "Researchers depend on volunteers to test drugs and other treatments for effectiveness, and they pay big bucks in the process."

While some clinical trials require participants to have a particular illness, many solicit healthy volunteers. For example, the Parexel Clinical Research Unit at Baltimore's Harbor Hospital recently asked for healthy volunteers to participate in overnight studies that paid between $1,200 and $6,000 for a few days of their time. "Clinical trials are considered safe, but there's still some risk, so ask about the pros and

cons and side effects before participating. If you do decide to take part, the world and your wallet could benefit."[102]

Instead of placing the clinical research information in the moneymaking idea section, I think it would have been more appropriate to have it set off as a separate article which explains and define clinical research and what it entails. Then include the money making aspect which is very appropriate. There is nothing wrong about being paid to be included in a clinical study. There is nothing wrong about having an article about clinical research in a magazine that targets African American women. However, I do believe that was an opportunity to have a separate article that could be ongoing for months to educate about clinical trials. I would have liked to see more definitions given and also some reference to having to sign an informed consent before any type of testing can be done to the subject.

The article did list CISCRP as a resource to learn about clinical trials. However, I believe it would have been more effective to discuss what the organization really does. CISCRP has already gifted four U.S. cities- Boston, Indianapolis, Dallas, and Philadelphia- with an annual aware for all Clinical Research Education Day. The event takes place on "neutral turf" and brings together all key stakeholders to raise public awareness of trials while helping professionals in the clinical research enterprise look at the world through the public eyes.[103]

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[102] Tamara Holmes, "Work and Wealth, Contribute to Science," *Essence Magazine*, July 2013: 74.

[103] Deborah Borfitz, "The Recruitment Problems," *Bio – It World* 7, no. 7 (September 2008): 31.

Invitations to attend come from dozens of organizational partners, such as churches and YMCA who CISCRP supplies with educational materials. Based on exit surveys, 75 percent of consumers are more willing to participate in trials after attending the program. These are not recruitment fairs. They put human face on the people who volunteer for clinical trials while increasing public understanding of the risks and benefits of participating.[104]

Legal Aspects

Arato vs. Avedon Decision

The landmark Arato vs. Avedon decision played a large role in defining what is legally required of health care professionals in the way of making information available to patients.

No one likes to be the bearer of bad tidings. While physicians' behavior regarding disclosure of lethal conditions (especially cancer) has changed radically over the past twenty years, many physicians still understandably find it daunting to have to disclose an incurable condition to a patient. Are patients nonetheless entitled to rely on their physicians to be candid about their prospects, including limited life expectancy?[105] It may be true that no one wants to inform a patient of distressing information, in my opinion it is a necessity. I do believe that as a patient I would want to know everything

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[104] Deborah Borfitz, "The Recruitment Problems," *Bio – It World* 7, no. 7 (September 2008): 31.

[105] Alexander Morga Capron, "Duty, truth and whole human beings," *Hastings Center Report* 23, no. 4, (July/August 1993): 1.

possible about my condition, prospect and probable life expectancy. I don't want my physician to hold anything back.

On July 21, 1980, while removing Miklos Arato's nonfunctioning kidney, surgeons discovered and removed a six-inch tumor from his pancreas. After the pathologist confirmed that the tumor was cancerous, the surgeon referred Mr. Arato for an oncologic consultation but did not tell the Arato's that pancreatic cancer spreads easily and only five percent of its victims survive for five years, nor did he provide any other information on life expectancy.[106] I can't speak for the surgeon, however; it appears that he referred the patient to the oncologist for a professional opinion.

When Melvin Avedon, the oncologist, met with the Arato's he stated that Mr. Arato "was at risk for two types of recurrence…and that if he should develop such recurrence, it would mean his disease was not cured, and in fact his disease would be incurable." Dr. Avedon proposed a combination of radiation and chemotherapy that had been shown experimentally to be effective in other forms of pancreatic cancer. He said the treatment might prevent recurrence but might have no benefit at all.[107]

At this first meeting, Dr. Avedon gave Mr. Arato an 18-page questionnaire to fill out. Among the questions was: "if you are seriously ill now or in the future, do you want to be told the truth about it?" Mr. Arato circled "yes" in answer to the question. Mr. Arato also verbally asked that he be told the truth.[108] Since Mr. Arato verbally asked to be told the truth it's obvious that he could read the questionnaire.

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[106]Alexander Morga Capron, "Duty, truth and whole human beings," *Hastings Center Report* 23, no. 4, (July/August 1993): 2.

[107] Ibid., 2.

[108] Ibid.

Although Dr. Avedon and other physicians participating in Mr. Arato's treatment thought it likely that he would die of the cancer, none of them told him about his probable life expectancy. Similarly, in April 1981, when test results showed the cancer had probably recurred and Dr. Avedon believed "Mr. Arato's reasonable life expectancy would be short, measured in months,…Dr. Avedon did not tell that to Mr. Arato."[109] In my opinion, the patient had a right to know about his life expectancy.

When Mr. Arato was hospitalized late in June, Dr. Avedon told him that although he was no longer curable, "they could try to make things better so that he might have some good time ahead." Mr. Arato apparently did not want to discuss this, so Dr. Avedon went to Mrs. Arato and asked whether he should confront Mr. Arato further because of any outstanding issues that needed to be resolved, perhaps through consultations with lawyers or accountants. Mrs. Arato said that they should not give him further information. Discharged from the hospital on July 5, Mr. Arato was readmitted to the hospital on July 21 and died four day later.[110] This was a very emotional time for the Arato's; however, they still needed to have all the information that was available.
The trial court dismissed several causes of action that Mr. Arato and their children brought against Mr. Arato's physicians, but allowed the jury to consider the case on the theory that the physicians had breached their fiduciary duty fully and fairly to disclose material information. The plaintiffs claimed not only that Mr. Arato might have chosen not to undergo the time-consuming and painful treatments but also that the Aratos would have redone their wills (for tax reasons), would have disposed of his electrical contracting

[109]Capron, "Duty, truth and whole human beings," 2.
[110]Ibid.

business, and would not have entered into other transactions that required his expertise for their success.[111]

Over the plaintiffs' objections, the trial court permitted the defendants and other physicians to testify as experts to establish the standard among competent physicians regarding the disclosure of life expectancy information to patients. The jury returned a verdict for the defendants, finding that they had not been negligent in their medical management and had provided adequate information to enable Mr. Arato "to make an informed decision regarding the proposed treatment."[112]

The conventional part of the plaintiffs' appeal concerned whether the instructions to the jury adequately conveyed that in California—as in about half the states—the standard of disclosure by physicians is set by the law (what would be significant to a reasonable person in the patient's position) rather than by practices within the medical community. At defendants' request, the instructions on disclosure ended with a statement that could have been taken from the Hippocratic canon: "However, the law recognizes that the primary duty of a physician is to do what is generally best for the patient."[113]

Because the jury was told it must base the standard of care it applies to professional conduct (including disclosure) only on the opinions of the experts who testified, the court of appeal found the instructions misleading; it also concluded that the trial court had erred in allowing expert testimony on the community standards in providing life expectancy information. It reversed and ordered a new trial.[114]

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[111] Capron, "Duty, truth and whole human beings," 2.
[112] Ibid., 3.
[113] Ibid.
[114] Ibid.

Had this case involved only the effect of disclosure on Mr. Arato's decision to undergo treatment, the trial court's instructions would be just one more illustration of what critics see as the hesitancy of judges to subject the professional discretion of their medical colleagues to lay review, even when the law officially proclaims such expectations. The case also illustrates the difficulties in knowing what constitutes "the truth" under such circumstances and in deciding whether the failure to disclose one fact (life expectancy) turns what was disclosed (that a recurrence of cancer would be incurable) into a deluding half-truth.[115]

But the heart of the plaintiffs' claim goes beyond decision making about chemotherapy and radiation to the relevance of life expectancy information to Mr. Arato's general existence. On this point, the court of appeal faced a delicate task because the state's Supreme Court has handed down many landmark rulings on medical disclosure. This may explain the somewhat strained aspect of the Arato opinion, as the court labored to fit what is really a case of first impression within existing case law.[116]

The suit brought following the patient's death claimed that, had he known the short life expectancy and the small chance of successful cure, he would not have undergone the treatment, and thus he had not given fully informed consent. The suit further claimed that his ignorance of his situation prevented him from adequately ordering his affairs, resulting in his family suffering financial hardship.[117]

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[115] Capron, "Duty, truth and whole human beings," 3.
[116] Ibid., 3
[117] Linda Farber Post, *Handbook for health Care Ethics Committees* (Baltimore, MD: Johns Hopkins University Press, 2006): 304.

The Arato court found that the physicians had provided the patient with what was required to give an informed consent-sufficient information material to the treatment decision to enable the patient to make a knowledgeable choice. The unreliability of statistical morbidity data, plus the patient's apparent reluctance to learn his life expectancy, removed the physician's burden to disclose the information. Because of its emphasis on not imposing unwanted, potentially distressing information, it has been suggested that Arato represents an expansion of the therapeutic exception to the disclosure obligation.[118]

Readability of the Informed Consent

After both research participants and investigators voiced concerns that informed consent documents for clinical trials were becoming too long, complicated, and difficult to understand, the National Cancer Institute (NCI), along with the Office for Protection from Research Risks (now the Office of Human Research Protections) and the U.S. Food and Drug Administration, formed an Informed Consent Working Group to propose solutions.[119]

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[118] Linda Farber Post, *Handbook for health Care Ethics Committees* (Baltimore, MD: Johns Hopkins University Press, 2006): 304.

[119] National Cancer Institute, "Simplication of Informed Consent Documents," http://www.cancer.gov/clincaltrials/conducting/simplificaton-of-informed-consent-docs/p...(11/2/2013): 2.

The Working Group included a diverse group of experts: physicians, nurses, patient advocates, Institutional Review Board (IRB) members, ethicists, legal experts, communication experts, and representatives of the pharmaceutical industry.[120]

In 1998, the group issued its "Recommendations for the Development of Informed Consent Documents for Cancer Clinical Trials." The recommendations are used by investigators writing consent documents and by IRBs reviewing such documents. In addition, a consent form template was created that includes all of the federally required elements for the documents, including the explanation of the research procedures, related risks and possible benefits, alternatives to participation, and the rights of research participants.[121]

Informed consent documents should be understandable to the patient population at the local facility. Documents should be written at an eighth grade or lower reading level. Investigators are also encouraged to use computer software applications or other techniques that assess reading level. Technical and legal jargon should be avoided. Use of active, short sentences, personal pronouns, clear page layout with "white space" borders, and large fonts make documents easier to read. The use of simple outlines, flow charts, diagrams, study schemas, calendars, and other graphics are encouraged. Consent

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[120] National Cancer Institute, "Simplication of Informed Consent Documents," http://www.cancer.gov/clincaltrials/conducting/simplificaton-of-informed-consent-docs/p...(11/2/2013): 2.

[121] Ibid., 2

forms should use the second person because it reflects the conversation between the investigator and potential research participant.[122]

An example of technical jargon would be the medical terminology that is involved with the disease or condition that is being investigated. Let's say that someone is diagnosed with lung cancer. There are more than a dozen types of lung cancer, but about 90 percent fall into two main categories; small cell and non-small cell.[123] In discussing non-small cell lung cancer words such as squamous cell carcinomas (cancer cells that are typically found in the larger airways inside the lung) may be used. A physician may tell the patient that an Anesthesiologist (a physician who specializes in the administration of anesthesia) will be involved if surgical removal of a tumor is necessary.[124]

In diagnosing Lung Cancer there are different diagnostic tests that can be done. Computerized tomography (CT scan) also known as a computerized axial tomography (CAT) scan. Positron Emission Tomography (PET) is an imaging test similar to x-rays and CT scans however, PET scans reveal the function of cells, whereas the other tests show only cell structure.[125]

This working group created a checklist for easy to read Informed Consent Documents. In terms of the text they suggested that words should be familiar to the reader. Any scientific, medical, or legal words are defined clearly. The words and terminology are consistent throughout the document and the sentences are short, simple,

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[122] National Cancer Institute, "Simplification of Informed Consent Documents," http://www.cancer.gov/clincaltrials/conducting/simplificaton-of-informed-consent-docs/p...(11/2/2013): 6

[123] Walter Scott, M.D., *Lung Cancer- A guide to diagnosis and treatment* (Omaha, Nebraska: Addicus Books, Inc., 2000), 10.

[124] Ibid., 129.

[125] Ibid., 20-21.

and direct. The line length is limited to 30-50 characters and spaces and the paragraphs are short with one idea per paragraph. The verbs are in active voice (i.e., the subject is the doer of the act), and personal pronouns are used to increase personal identification. Each idea is clear and logically sequenced (according to audience logic) and the important points are highlighted. The study purpose is presented early in the text and the titles, subtitles, and other headers help to clarify organization of text. The headers are simple and close to the text and all underline, bold, or boxes give emphasis. The layout balances white space with words and graphics. The left margins are justified with right margins are ragged. Upper and lower case letters are used the style of print is easy to read with type size at least 12 point. Readability analysis is done to determine reading level (should be eighth grade or lower). Items that should be avoided are abbreviations and acronyms, large blocks of print and words containing more than three syllables.[126]

The graphics should be helpful in explaining the text, easy to understand and meaningful to the audience. The text and graphics should go together and appropriately located, simple and uncluttered with images reflecting cultural context. The visuals should have captions; each visual should be directly related to one message. The cues, such as circles or arrows, point out key information. The colors, when used, should be appealing to the audience and avoid graphics that won't reproduce well.[127]

The communications methods should include time to read and discuss the forms. Researchers should encourage the potential research participant to thoroughly read and re-read the consent form and supplemental materials, if provided, and to discuss the

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[126] National Cancer Institute, "Simplification of Informed Consent Documents," 13.

[127] Ibid., 13.

proposed research with others before signing the consent form. This may require a delay between the describing of the study and the signing of the consent document.[128]

It may be helpful for the researcher to ask the potential research participant short questions, after the research has been described and the consent form read, in order to assess that the potential research participant has at least a basic understanding of what the research involves. Example questions includes: tell me in your own words what this study is all about, tell me what you think will happen to you in this study, what do you expect to gain by taking part in this research, what risks might you experience by participating in the research, what are your alternatives (other choices or options to participating in this research). Videos, audiotapes, interactive computer programs, and discussions with qualified lay individuals may assist in educating the potential research participant about the clinical trial.[129]

The Chesapeake Research Review, Inc. conducted a readability project. The Chesapeake Research Review, Inc. IRB's respect for the autonomy of research participants and concerns about the factors that influence subjects' understanding of the research that they are participating in, led to the staff undertaking an extensive project to evaluate the reading level of the consent documents approved by the IRB. The fundamental reason for undertaking this initiative was: If subjects do not understand the contents of the informed consent document they may not fully comprehend the risks

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[128] National Cancer Institute, "Simplification of Informed Consent Documents," 13.

[129] Ibid., 14

associated with the research or their responsibilities. This would not only be unethical but could also compromise the safety of the subject.[130]

Chesapeake Research Review, Inc.'s IRB serves as the IRB of record for many institutions and investigators conducting biomedical and behavioral research. Like some of the other IRBs, Chesapeake IRB uses templates for informed consent forms where researchers can drop in sections related to specific projects. Most, if not all, of the information that can be standardized is included in the template.[131] The objective of the project was to use the readability scales to produce informed consent forms that potential subjects can read and understand, written as close as possible to the eighth grade reading level or lower. An eighth grade reading level is what is most commonly recommended for informed consent forms. A subcommittee was developed and they used the Flesh Reading Ease Formula. As part of this process, they took a typical informed consent form of 12 pages arbitrarily edited it down to tow pages. The readability scale went from a very high level to a very low level, primarily because the members had decreased the number of page and changed the number of syllables, increased the amount of white space, and so forth.[132]

Chesapeake IRB revised its informed consent forms from a grade level of 12 to a grade level of 7.8 by using wording that made more sense to subjects. For example, in the section describing foreseeable risks of participating in research, instead of "Acceleration of arrhythmias, induced arrhythmias (abnormal fast heart rhythms during

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[130] Felix A. Khin-Maung-Gyi and Amy Schwarzhoff, "Informed Consent Forms: Are We Writing Them for Subjects?," *SoCRA Source* November 2009: 16.

[131] Ibid., 17

[132] Ibid., 18.

the implant), and" the document included "Abnormally fast heart rhythms during the implant."[133]

Chesapeake Research Review, Inc. developed its readability project in order to help subjects participate in research on a more informed basis and to help control or eliminate misconceptions about research.[134]

Informed Consent and Patients

The informed consent process is an integral component of cancer treatment, prevention, and cancer control clinical trials. It ensures that potential trial participants are well-informed about the study purpose, methodology, risks, and benefits. The code of Federal Regulations requires information given to the subject or the representative shall be in language understandable to the subject or the representative. However, concerns have been voiced by clinical investigators, patients, consumer advocates, Institutional Review Board Representatives, and cooperative group chairpersons about the overwhelming amount of technical information that is presented to potential subjects and how best to convey that research information.[135]

Many factors impact the comprehension of informed consent information. They include formal education, method of presentation, nature of information, vocabulary levels, age, literacy skills, cultural differences in the understanding of risk information,

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[133] Khin-Maung-Gyi and Schwarzhoff, "Informed Consent Forms: Are We Writing Them for Subjects?," 8.

[134] Ibid., 8

[135] Cathy D. Meade, "Improving Understanding of the Informed Consent Process and Document," *Seminars in Oncology Nursing* 15, no. 2 (May 1999): 124.

and cognitive biases of quantitative or qualitative probability. Providing too much complex information can lead to poor understanding, miscommunication about role, expectations and study procedures, and ultimately contribute to misinformed consent.[136]

As part of basic ethical standards and U.S. federal compliance for human protection, participants who consider taking part in a research study must go through an informed consent process. The goal of this process is for potential research participants to have a comprehensive understanding of the purpose for the study, the method of data collection, and the possible risks, benefits, and alternatives before making a voluntary decision to participate. Previous studies report mixed results about how much information study participants actually can read, understand and retain after completing the consent process. Not retaining or being able to recall information from the informed consent process has potentially important ethical and legal implications and consequences for research quality and integrity. Most serious among these is that poor recall and retention may indicate that information was not fully understood and the decision to volunteer to participate in a study was not a fully informed choice. Poor recall and retention may also affect participant adherence to the study protocol or study attrition which are particularly important in longer clinical trials.[137]

Variability of recall and recognition of consent information has often been attributed to differences in process or method factors, such as interval of time between presentation of the information and evaluation consent readability and method

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[136] Cathy D. Meade, "Improving Understanding of the Informed Consent Process and Document," *Seminars in Oncology Nursing* 15, no. 2 (May 1999): 124.

[137] Joan M. Griffin et al., "Long term clinical trials: How much information do participants retain form the informed consent process?," *Contemporary Clinical Trials* 27, no. 5 (October 2006): 2.

presentation but there is little consensus across studies. In a five year¸ multi-center study showed that nearly two-thirds (64.7%) of participants knew the study's purpose. Remarkable, however, was that a sizable proportion did not (35.3%). Likewise, nearly 20% of the 1789 answering any one question did not know the name of the medication they had been taking and nearly 70% did not know the major side effect associated with the medication.[138]

Clinical trials require a commitment from participants to follow a protocol, and for this study, to consistently take a study medication over a relatively long period of time. In spite of the commitment to complete the study, these findings suggest that even the simplest and most basic information may not be understood or retained by a fraction of patients enrolled in clinical trials. The difference in the proportion of incorrect answers for study purpose (35.3%) versus the name of the study medication (20.4%) may indicate that the drug name was recalled because of the continuous repetition of taking and refilling of the trial medication during the study period, while the study purpose was not reinforced as frequently. A lack of reinforcement may also explain why only 30% of participants could correctly identify the study medication's main side effect. Also possible is that the original information on the consent form detailing possible side effects or the study question on side effects was not worded with enough precision for participants to remember accurately.[139]

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[138] Joan M. Griffin et al., "Long term clinical trials: How much information do participants retain form the informed consent process?," *Contemporary Clinical Trials* 27, no. 5 (October 2006): 6.

[139] Ibid., 7

The study has several limitations did not have data to show whether participants understood the study's basic information after consenting to participate, making it difficult to ascertain whether information was initially understood and then forgotten. While study coordinators were required to follow a standard protocol and review the information with every patient and a witness before obtaining consent, it is possible that participants did not understand the basic information about the study at the onset, and therefore could not recall the correct information upon finishing the trial. It is also possible that coordinators at some sites did not have the organizational resources, supportive research environment, or adequate time to consent patients, which resulted in variability by site. Second, over the course of the trial, the level of illness severity among participants may have increased or cognitive function may have decreased, making recall difficult, as has been shown in previous studies. Thirdly, the study only included men, and therefore, could not generalize the findings about women or examine any possible differences by gender, although gender differences in the retention of consent information have not been commonly reported. Fourth, it was assumed that those who did not answer a specific question did so because they did not know the correct answer from the multiple choices. Although subsequent analyses do not show any evidence of differences when coded differently, our approach may have led to an overestimate of the frequency of incorrect answers.[140]

In conclusion the variation across traditionally underserved and underrepresented groups underscores the potential gaps in knowledge that need to be addressed in order to

[140] Griffin et al., "Long term clinical trials: How much information do participants retain form the informed consent process?" 7.

assure each participant's ethical participation in research and to assure the methodological and pragmatic goals of recruiting and retaining diverse study participants so that results from clinical trials can be generalized to larger populations. The most effective methods to assure the understanding of key information is using simple, non-technical language on informational materials and consent forms, budgeting additional time for study team members or patient educators to review information and answer questions, repeating core concepts routinely, or formally assessing valid consent. Maintaining simple, nontechnical language, repetition, and budgeting additional time for study personnel to review information could easily be adopted and used throughout the course of a long term clinical trial to assure that information is understood and retained.[141]

[141]Griffin et al., "Long term clinical trials: How much information do participants retain form the informed consent process?" 7.

Chapter 3

SOCIAL AND ECONOMIC FACTORS AND HEALTH LITERACY

Health consumers face numerous challenges as they seek health information, including the complexity of the health systems, the rising burden of chronic disease, the need to engage as partners in their care, and the proliferation of consumer information available from numerous and diverse sources. Individuals are asked to assume new roles in seeking information, advocating for their rights and privacy, understanding responsibilities, measuring and monitoring their own health and that of their community, and making decisions about insurance and options for care. Underlying these complex demands are the varying and sometimes inadequate levels of, first, consumer knowledge and, second, skills for using and applying a wide range of health information.[142]

Epidemiologists have been able to document links between socioeconomic status and health, and links between educational attainment and health. A 1998 report from the U.S. Department of Health and Human Services offered evidence from accumulated studies that health, morbidity, and mortality are related to income and education factors. For example, life expectancy is related to family income. So too are death rates from cancer and heart disease, incidences of diabetes and hypertension, and use of health services. Similarly, death rates for chronic disease, communicable diseases, and injuries as reported in 1998 were inversely related to education: those with lower education achievement are more likely to die of a chronic disease than are those with higher

[142] Lynn Nielsen-Bohlman, Allison M. Panzer, David A. Kindig, "Health Literacy: A Prescription to End Confusion," *National Academy of Sciences* (2004): 19. Http://books.nap.edu/catalog/10883.html.

education achievement. In essence, the lower your income or educational achievement, the worse your health.[143] Every day, millions of adults must make decisions and take actions on issues that protect not only their own well-being, but also that of their family members and communities. These actions are not confined to traditional health-care settings such as doctors and dentists' offices, hospitals, and clinics. They take place in homes, at work, in schools, and in community forums across the country. Health-related activities are part of the daily life of adults, whether they are sick or well.[144]

At home, parents may have to calculate a child's weight and age to determine the correct dosage of an over-the-counter medicine. People are also expected to follow directions from health-care providers, presented verbally or in writing, during recovery from an illness or the management of a chronic disease. At work, employees may need to determine correct workstation placement or safe use of toxic chemicals. Safety warnings are posted in the community, and at work, and are discussed in newspapers and on television.

Many health-related decisions are made in the marketplace. When reading nutritional information on food labels, for example, consumers are expected to understand that calculation of sugar content must include the sugar listed on the snack food label as well as the fructose and corn syrup.[145] Adults need to meet the demands of bureaucracies and institutions to access health programs and services. For example, adults are asked to fill out insurance forms, understand their rights and responsibilities

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[143] Nielsen-Bohlman, Panzer, and Kindig, "Health Literacy: A Prescription to End Confusion," 20.

[144] Ibid., 20.

[145] Ibid., 21.

provide medical history, and provide informed consent for medical procedures. The documents required for some of these activities often contain legal and scientific terms unfamiliar to many individuals.[146] The language typically used by those working in health and medicine is filled with scientific jargon. This increases the difficulty for the average consumer. References are made to biological systems (e.g., endocrine) and anatomy (e.g., atrial valve) as well as to groupings of diseases and disorders (e.g., renal, cardiovascular, neurological, respiratory) that are not typically used in everyday conversation. Furthermore, they are scientific terms not typically taught in the K-12 school system. For example, many people do not know that they have bronchi or where they are located; yet those with asthma will be presented with the very critical information that this chronic disease involves inflammation of the bronchi and that a particular type of medicine helps. A person's ability to understand health, medical issues, and directions is related to the clarity of the communication.[147]

Health literacy is intimately linked to many issues of critical importance to the nation and to our health policies. The public health mandate of protecting the health of the nation relies on communication strategies for issues as different as obesity and bioterrorism. Health literacy is of concern to people addressing worker health and safety, product labeling, environmental health, patient rights and responsibilities, quality of care, or access to information, insurance, and services.[148]

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[146] Nielsen-Bohlman, Panzer, and Kindig, "Health Literacy: A Prescription to End Confusion," 19.

[147] Ibid., 23.

[148] Ibid., 26.

Limited health literacy is often unreported by patients, unappreciated by policy makers and health-care workers, and unappreciated by the general public. Without improvements in health literacy, the promise of many scientific advances to improve health outcomes will be diminished.[149]

Illiteracy is a critical economic problem in the United States. Two areas it affects are health and health care. Health literacy is increasingly important to help people navigate complex health systems and better manage their own health. The consequences of inadequate health literacy include poorer health status, lack of medical care knowledge, impaired comprehension of medical information, lack of knowledge about medical conditions, lack of understanding and use of preventive services, poorer compliance rates with treatment modalities, increased hospitalizations, and increased health care costs. People with low health literacy are more likely to report poor health, have an incomplete understanding of their health problems and treatment, and are at greater risk of hospitalization.[150]

Economics is defined as the allocation of scarce resources. Health-oriented activities consume a large portion of economic resources of modern societies, such as the United States, in the production and distribution of health care. Health care is not free. It represents a major commitment of resources: time, energy, skill development, raw materials, and capital, which are then unavailable for other forms of production. Health spending is predicted to outpace the overall U.S. economy by 2.5% per year, resulting in

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[149]Nielsen-Bohlman, Panzer, and Kindig, "Health Literacy: A Prescription to End Confusion," 26.

[150] Roberta Pawlak, "Economic Considerations of Health Literacy," *Nursing Economics* 23, no. 4 (July-August 2005): 173.

growth from 13.2% of GDP in 2000 to 17% in 2010. National health care expenditures in the United States are predicted to rise in excess of 43 trillion by 2012. Weiss and colleagues caution the average annual health care costs of persons with very low literacy may be four times greater than for the general population. Low literacy, an aging population, prevalence of chronic conditions, and a complicated health care system influence and magnify health disparities in the United States. Illiteracy places an additional cost burden on the U.S. health system, with complicated economic implications.[151]

Health literacy is a complicated concept that has many economic implications and requires attention in modeling and research. Age, genetics, language, race and ethnicity, education, employment, socio-economic status, and environment potentially influence health literacy. These determinants have variability within populations as well as variability between populations. Screening tools for literacy and functional health literacy (medical terminology and numerical tests) exist currently. Although useful tools, they are limited in their ability to measure the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions (health literacy). If health literacy is viewed as determinant of population health, strategies for improvement may be most efficient if targeted at the provider and payer level with the overall goal of improved informed consumers. Communication to enhance understanding and competence in implementing self-care as well as prescribed treatments must exist beyond the written word. To this end, reduction of health disparities and improved population health are theorized in the

[151] Pawlak, "Economic Considerations of Health Literacy," 174.

proposed model. Promoting health literacy as national priority is outlined in Healthy People 2010. The Institute of Medicine (2004) report on Health Literacy offers suggestions for steps addressing the concept of health literacy within a public health/public education framework. It is hoped that health literacy will improve population health, and economic efficiency in health care delivery and consumption.[152]

While working at a medical device company that specializes in wound care and ostomy I found that they were increasing the health literacy about fecal incontinence. Fecal incontinence (FI) is the involuntary passage of stool. Approximately 10% of community-living people, both men and women have FI. FI interferes with many activities of daily life including sleep, work, discussing FI with others and social activities. It can be distressing and embarrassing and lead to are part of social isolation, low self-esteem, reduced intimacy, anxiety, and depression.[153]

The terms, labels, and descriptions of FI are part of health literacy. Many people who have FI do not have a term with which to label the condition appropriately. Rather, they often confuse FI with diarrhea or defecation urgency. Reasons for the lack of a label for FI may be unfamiliarity with the word incontinence or its meaning, avoidance of thinking much about the problem, or the social taboo against discussing FI with others. Some clinicians use the term bowel leakage when discussing FI with patients. There is little information reported on communication about FI between patients and healthcare providers. Knowing which terms people use to refer to FI and describe its symptoms

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[152] Pawlak, "Economic Considerations of Health Literacy," 180.

[153] Kristina Patel, Donna Z. Bliss, and Kay Savik, "Health Literacy and Emotional Responses Related to Fecal Incontinence," *Journal WOCN* January/February 2010: 73.

assists clinicians in recognizing when a patient is attempting to discuss the condition. This knowledge might also assist the clinician to initiate questions about FI.[154]

Health literacy influences patients' care seeking and communication about health problems. Persons with FI used a variety of alternate terms to label the problems of FI that can inform clinicians to inquire about the possibility of FI during a health assessment. There is a need for improving health literacy related to FI in those who have the problem. The variety of terms by which FI is referred suggests that identifying people who have FI requires discerning inquiry and terms for FI and types of emotional responses differ between men and women and younger patients versus older patients.[155] If patients are not aware of their correct disease they cannot participate in a clinical study because of the lack of health literacy.

Health Literacy and the Informed Consent Process

Health care today exposes consumers to a significant amount of critical information, ranging from prescription bottle labels to insurance forms, and from dietary guides to procedural consents. The complexity of the information prevents a significant number of patients from fully comprehending it.[156] The barriers to informed consent include language-limited interpreters for some languages, cultural issues, and lack of medical knowledge and education which contribute to patient's inability to fully

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[154] Patel, Bliss, and Savik, "Health Literacy and Emotional Responses Related to Fecal Incontinence," 74.

[155] Ibid., 78.

[156] Lorenzen, "Using principles of Health Literacy to Enhance the Informed Consent Process," 24.

comprehend information given to them regarding their medical condition and the procedures involved.[157]

As part of a 2003 Clinical Performance Improvement Strategic Plan, Iowa health System Incorporated health literacy as a systemwide quality initiative. Iowa health system comprises 10 senior hospital affiliates in seven cities, a rural hospital network, and more than 300 primary career physicians. The Iowa health System health Literacy Collaborative in 2004 with overarching health literacy goals targeted toward improving interpersonal and written communication and creating a patient –centered environment.[158]

Teams chose to improve consent documents and processes as part of their goals to improve patient understanding through the use of plain language, teach back, and reader-friendly print materials. The catalyst for choosing consent documents as one of the first major projects was the team's concern that consent forms are complex. Fry Readability Formula analyses of representative Iowa health System affiliate consent forms demonstrated that many were written at or above the 17th grade level. Because of this, it was uncertain whether patients understood the consent form before signing it, which made it unclear whether the consent given was informed consent.[159]

Obtaining the patient's informed consent is required by the Joint Commission as stated in Standards RI.2.40, "Informed consent is obtained," and PC.6.30, "The patient

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[157] I. Koransky, "Informed consent for patients with limited health literacy moving from the conceptual to the actual." Paper presented at: The Foundation for Patient Safety, Empowerment, and Quality Health Care: Reading, Writing and Arrhythmias. June 2006, Rosemont, Il.

[158] Lorenzen, "Using principles of Health Literacy to Enhance the Informed Consent Process," 24.

[159] Ibid., 24.

receives education and training specific to the patient's abilities as appropriate to the care, treatment, and services provided by the hospital."[160]

The Office of the General Counsel of the American Medical Association contends that the essence of informed consent is not having a patient sign a written form but is a process involving communication between a patient and physician that includes verification of a patient's understanding and their authorization or agreement to undergo a specific medical intervention.[161] Congruently, health care providers have a duty to provide information in simple, clear, and plain language and to evaluate whether patients have understood the information before ending the conversation.[162]

Each affiliate had a health literacy team that participated in learning sessions and monthly conference calls to confer on a variety of health literacy interventions. The affiliate team cited here was multidisciplinary, including members who served in clinical education, risk management medical education, and adult learners and new readers in a local community college extension program.[163]

A foundation for understanding health literacy at the staff level was an important first step. Each affiliate team developed an education plan for staff, focusing on the Iowa health Literacy Collaborative goals. At this affiliate, the approach to staff education included:

- Viewing the Institute of Medicine video Health Literacy: "A Prescription to End Confusion"

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[160] Lorenzen, "Using principles of Health Literacy to Enhance the Informed Consent Process," 24.
[161] Ibid., 24.
[162] Ibid.
[163] Ibid.

- Completing a computer based learning module defining health literacy concerns and means of improving communication;
- Adding material on health literacy to a learning module on patient rights for new employee orientation and annual all staff required education; and
- Designing a health literacy program and presenting the program to physicians.

Most adults admit to not reading consent forms for reasons including that the form is too long, the format is crowded or intimidating, the font size is too small, and unexplained medical legal terms are used.[164] Beginning with the procedural/surgical consent document, an iterative process was used to develop plain language consent. The consent was developed in collaboration with health literacy teams, risk manager, health care providers, and members of the Iowa Health System Law Department, and new readers who reviewed many drafts to assist in clarifying terms and content as well as improving the design. The criteria for the new forms were as follows:

- Limit to one page, one or two sided
- Simple words;
- Short sentences;
- Minimal medical terms;
- 12 to 14 point serif fonts;
- Generous white space;
- Numbering and bullets;
- Clear headings;

[164] Lorenzen, "Using principles of Health Literacy to Enhance the Informed Consent Process," 25.

- Key use of bold text; and
- 1.5 line spacing

An expected outcome of the pilot test was an increase in the number of patients who read the consent form before signing it. A secondary, and more critical, expected outcome was documenting patient knowledge regarding the anticipated procedure, thus supporting informed consent.[165]

Baseline data were collected by ambulatory surgery nursing staff members using the survey tool for 41 patients, ages 26 to 80 years, who underwent varying procedures and were given the original consent form. During a subsequent seven-week period, the new consent form was given to 35 patient's ages 34 to 87 years scheduled for eye surgery (ie, Campus #1). Data were collected from these patients using the same survey process. The new consent form was then pilot tested on a second campus ambulatory surgery unit(i.e., Campus #2) with a group of 53 patients ages one month to 91 years scheduled for varying procedures. Their responses were monitored through the same survey process.[166]

When comparing use of the original and new consent forms, significant difference were seen in nurses' responses to the first question: "Did the patient/family read the consent?" For the original consent, 25% of patients read the form. During the pilot programs with the new consent, 77% and 91% from Campus #1 and Campus #2, respectively, read the consent. Survey comments provided by nursing staff members indicated that because of poor vision preoperatively, 57% of the patients in the first pilot

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[165] Lorenzen, "Using principles of Health Literacy to Enhance the Informed Consent Process," 25.

[166] Ibid., 25.

group asked the nurse to read the consent form to them. Because Campus #1 was composed of patients undergoing eye surgery, the poor vision may have played a part in the results; therefore, it is believed that the results from the Campus #2 pilot represent a truer comparison to the original consent group.

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In this survey, significantly more patients read the "reader-friendly" consent than the original complex consent. This supports the findings from the literature that most patients do not read the consent due to literacy issues with the document.

Overall, the project successfully employed a collaboration of one health care system and hospital representatives to embrace health literacy concepts by revising procedural/surgical consent documents. The resulting pilot projects have contributed to

[167] Lorenzen, "Using principles of Health Literacy to Enhance the Informed Consent Process," 28.

the body of evidence-based practice and to the development of best practices in the area of health literacy.[168]

Communication between health care providers and patients can be improved by using evidence-based, health-literacy concepts. This is a fertile field for additional study. There also is continued need to document the effect of teach back as a convincing method for verifying patient understanding. Use of the new consent documents provided nursing staff members with a clear opportunity to assess patients' comprehension of their procedures.[169]

The new consent documents help nursing staff members confirm patient understanding by providing an easy to read format and by requiring the patient to articulate procedural plans through the use of teach back. Implications for nursing include the verification and documentation of patient understanding and simplification of the consent completion process with regard to time and effort.[170]

Each step toward improving health literacy is a step toward improving patient knowledge and understanding of factors involving personal health care. This is ultimately linked to improving patient safety and honoring patient rights. Through the use of health literacy principles, the consent document can become a tool to encourage and evaluate informed consent. Increasing readability of the document encourages patients to read what they are signing. Most importantly, the teach-back portion provides an assessment tool for measuring patients' understanding of their procedures.

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[168] Lorenzen, "Using principles of Health Literacy to Enhance the Informed Consent Process," 28.

[169] Ibid., 28.

[170] Ibid.

Communication with medical and nursing staff is paramount in implementing a new consent document. Increasing staff member awareness of the concepts of health literacy is the starting point.[171]

Health Literacy and the Health Care Professional

Medical informed consent is essential to the physician's ability to diagnose and treat patients as well as the patient's right to accept or reject clinical evaluation, treatment, or both. Medical informed consent should be an exchange of ideas that buttresses the patient-physician relationship. The consent process should be the foundation of the fiduciary relationship between a patient and a physician. Physicians must recognize that informed medical choice is an educational process and has the potential to affect the patient-physician alliance to their mutual benefit. Physicians must give patients equality in the covenant by educating them to make informed choices. When physicians and patients take medical informed consent seriously, the patient-physician relationship becomes a true partnership with shared decision-making authority and responsibility for outcomes. Physicians need to understand informed medical consent from an ethical foundation, as codified by statutory law in many states, and from a generalized common law perspective requiring medical practice consistent with the standard of care. It is fundamental to the patient-physician relationship that each partner

[171]Lorenzen, "Using principles of Health Literacy to Enhance the Informed Consent Process," 29.

understands and accepts the degree of autonomy the patient desires in the decision making process.[172]

Nearly one quarter of Americans read at or below the fifth grade level, yet medical leaflets and other healthcare data are often written at or above the 10th grade level. The American Medical Association (AMA) Foundation estimates 90 million Americans are classified as having low health literacy. Health literacy, which is defined as the ability to read, understand and act on healthcare information, affects patients regardless of medical condition, socioeconomic class, age group, or educational level.[173]

Poor health literacy contributes to a host of healthcare problems, including increased health costs, medication errors, adverse drug events and noncompliance. According to the AMA Foundation, the cost to the healthcare system because of poor health literacy alone results in approximately $73 billion annually in unnecessary doctor visits and hospitalizations. The National Academy on an Aging Society states people with low health literacy skills are less likely to obtain preventive care and are more likely to have poor health outcomes. According to research published in the Journal of American Board Family Practice, a person's Sickness Impact Profile (SIP) is highly correlated with their reading level, even after adjusting for factors such as age, sex, ethnicity, marital status, insurance, occupation, and income.[174]

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[172] Timothy J. Paterick, "Medical Informed Consent: General Considerations for Physicians," *Mayo Clinic Proceedings* (March 2008): 313.

[173] Feifer, "How a Few Simple Words Improve Patient's Health," 29.

[174] Ibid., 29.

There are steps that can be taken to bridge the health literacy gap between healthcare providers and patients, resulting in an improved physician/patient relationship, better patient health, and reduction in healthcare costs.[175]

Healthcare providers can do their part to increase medical/health literacy. The following tips can close the gap between healthcare providers and the patients they treat. These tips have been proven effective for Medco health's Positive Approaches health management programs. The programs focus on educating members about their disease state and help them learn how to better manage their health. The easy to understand communication provided within the programs has been extremely successful in improving patient adherence to therapy regimens, with program participants reporting satisfaction rates of 95 to 100 percent.[176]

The patient's perspective is critical. Physicians, healthcare providers, and medical literature should avoid general background information and instead focus on a "need to know" basis by emphazing the desired behavior, rather than just the medical facts. Materials should focus on what to do and why, not what to know. Healthcare providers should adopt a keep it simple approach for medical and prescription information in both verbal and written form. Offer small bits of information at a time and limit the message to main objectives. The "keep it simple" approach is effective for all literacy levels, and is preferred by patients, according to the National Work Group on Literacy and Health. Print materials should include different font sizes and headings to help ensure key messages are not misunderstood or ignored. When providing a list, use

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[175] Feifer, "How a Few Simple Words Improve Patient's Health," 30.
[176] Ibid., 30

bullets. Pages should look uncluttered, with a balance of printed materials and white space. When developing printed materials for seniors, the font size should be large enough for them to easily read. Restating a message by providing a summary offers reinforcement and emphasizes the message.

In addition to providing written materials, healthcare providers should reinforce messages verbally. Ask patients if they understand their therapy regimens, and have them repeat verbal instructions to guarantee patient comprehension. Some healthcare providers offer additional verbal resources to patients, such as a 24 hour toll free number to assist them with any questions or concerns about their conditions or treatments.

People with low health literacy often have poor reading skills. They read words individually, rather than in context, and also tire during long passages or skip over unfamiliar words. One needs to approach the level of their reading materials with caution and be cognizant that people with low health literacy may miss the message's context and draw incorrect conclusions if they cannot understand what is written. Create materials that require the reader's active involvement, such as checklists and questionnaires. Reinforce key messages by providing visual aids. Although photographs, color illustrations, and cartoons can improve comprehension, they should be used strategically. The use of graphics should enhance the message, not compete with it.

The use of visual aids reinforces key messages by providing visual aids. Although photographs, color illustrations, and cartoons can improve comprehension, they should be used strategically. The use of graphics should enhance the message, not compete with it. The use of scare tactics should be avoided. Healthcare providers should focus on positive aspects of treatment. Excessive focus on the negative consequences of

a condition can worsen patient compliance. In verbal and written communications, healthcare providers should use an emotionally supportive language and tone rather than a threatening one. Messages can be written in a positive tone while maintaining a serious message. For instance, literature in a diabetes guidebook discussing the serious possibility of developing diabetic nephropathy should be followed by steps diabetics can take to prevent it. The message should be tested for effectiveness. The use of focus groups to assure content is on target, comprehensible, relevant, affective, and culturally sensitive.[177]

Health Literacy Challenges

It may not be obvious but there are challenges to a successful health literacy campaign. A traditional strategy for addressing health literacy problems has focused on developing educational programs to help increase the literacy levels of health care consumers. Schools, colleges, hospitals, clinics, and libraries are just some of the institutions that can offer educational programs to increase public health literacy levels. These programs can be offered as topical seminars, as credit or noncredit courses, and as a part of distance education programs.[178]

The US kindergarten through twelfth grade educational system offers a site for interventions to improve general literacy and health literacy. The recent IOM report on health literacy reviewed current programs and opportunities in education and found that

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[177] Feifer, "How A Few Simple Words Improve Patient's Health," 31.

[178] Ruth Parker and Gary L. Kreps, "Library outreach: overcoming health literacy challenges," *Journal of the Medical Library Association* 93, no. 4 (October 2005): 82.

there are currently significant obstacles and barriers to successful health literacy in kindergarten through twelfth grade education programs.[179]

While educational programs to help consumers improve their reading, numeracy, writing, speaking, and listening skills can improve literacy levels, these programs have some limitations, too. Consumer education programs often take a long time to improve literacy and health literacy levels, and they are not very helpful to consumers at the moment when they most need relevant information to address current health problems. In additions, more than 300 published studies indicate that most patient and health information materials far exceed the reading ability of most US adults.[180]

Educational programs can help consumers develop the functional abilities to gather relevant health information, interpret health information, engage in meaningful deliberations with their health care providers, and explain their symptoms and health experiences clearly. Moreover, educational programs must be tailored to the needs of consumers and patients to learn how to negotiate and navigate the many complexities and bureaucracies of the modern health care system; to learn essential skills for self-management of chronic conditions; and to learn how to communicate about their health needs for acute, chronic, and preventive care.[181]

Health literacy education programs must be developed to reflect the unique contexts of language and culture. To have effective communication with different ethnic

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[179]Ruth Parker and Gary L. Kreps, "Library outreach: overcoming health literacy challenges," *Journal of the Medical Library Association* 93, no. 4 (October 2005): 82.

[180] Ibid., 82

[181] Parker and Kreps, "Library outreach: overcoming health literacy challenges," 82.

groups, the program should employ language and examples that are familiar to that particular group of people.

Another major challenge faced by consumer literacy education programs is that they generally only address one of the multiple audiences affected by health literacy problems. Educational programs also need to be developed and implemented to help health care providers and caregivers cope with health literacy problems. Educational programs also need to be developed and implemented to help health care providers and caregivers cope with health literacy problems. Educational programs for doctors, nurses, and other health care providers can help train these professionals to communicate effectively with consumers who have low literacy; to seek feedback from consumers to determine how well they understand relevant health information, and to develop strategies for vividly explaining complex terms and procedures. Informal caregivers, such as family members, also need help through education to increase their understanding of relevant health information.[182]

Health literacy is a complex issue, and improvements in health literacy require a variety of approaches. Health literacy not only involves the communication skills and abilities of health care consumers to understand spoken, written and mass-mediated communication about health and health care, but it also involves the communication skills and predispositions of a broad range of health care providers and information sources and the support of the larger health care system in promoting effective health communication. Moreover, effective health communication is interactive and adaptive,

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[182] Parker and Kreps, "Library outreach: overcoming health literacy challenges," 82.

utilizing many different channels of communication and operating across a number of different contexts. To address current problems of health literacy effectively, the multiple interdependent dimensions of this complex issue have to be addressed. This means developing sophisticated multidimensional approaches and crating interdisciplinary partnerships to address the many problems associated with health literacy in the modern health care system. Ninety million Americans have difficulty understanding and acting on health information. To treat this silent epidemic, efforts are needed to strengthen skills and coping strategies for consumers and providers. Partnerships between different health information specialists, health care providers, and consumers who desperately need relevant health information can help overcome the many problems related to health literacy.[183]

An example of improving health outcomes would be form a Dr. Hixon who took the case of Mrs. P, a 38 year-old woman with moderate persistent asthma who returned to his office after an absence of several months. He did not know her well, but it seemed she had visited an emergency department several times over the past months and was completely out of the various asthma inhalers and tablets that had been prescribed for her. Their discussion was frustrating, and it was not clear to him why she had stopped taking her medications as prescribed. The more specific his questions about her medications became, the more confusing her answers were.[184]

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[183] Parker and Kreps, "Library outreach: overcoming health literacy challenges," 82.

[184] Allen L Hixon, "Functional Health Literacy: Improving Health Outcomes," *American Family Physician* 69, no. 9 (May 1, 2004): 2077.

He realized they were not communicating well, so he stepped back and probed for stressors. "How are things at home? How is your husband, how is your job, how are your kids?" All were reportedly fine. The he asked about her childhood. "Where did you grow up and attend school?' How many years of school did you complete?" She told him two years. "Did you ever have trouble with reading?" She said she had never learned. "How do you know how to take your medicines?" She told him she could read numbers, so when she saw the numeral "2," for example, she would take two pills or perhaps take one pill two times a day. In addition, she said that sometimes her kids would read for her. Suddenly, we were beginning to understand each other.[185]

He was able to simplify her medications to one combination inhaler, and I took extra time to explain how to use it properly. She repeated the message to him and to the medical student; they hugged as she left the examination room.[186]

Patient provider communication is a concern when patients and providers speak different languages. Unlike functional health illiteracy, the issues related to communication are readily apparent. Health professionals will seek an interpreter. In a study of HIV-1 transmission in Haiti, participants were required to pass an oral examination on the contents of the consent form with a passing score of 12/15 (80%) before enrollment. Fifth teen individuals were given information during a single meeting with a physician, and three (20%) passed. Thirty subsequent volunteers were given information by a counselor during three meetings, and 24 (80%) passed. The psychologist, not involved in the research, asked the questions orally in Haitian Creole on

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[185]Allen L Hixon, "Functional Health Literacy: Improving Health Outcomes," *American Family Physician* 69, no. 9 (May 1, 2004): 2077.

[186] Ibid., 2077

the same day that volunteers finished receiving information. It was concluded that research participants can comprehend a complex consent form if sufficient care is taken to provide them with information. However, the findings indicate that the standard consent process of a single meeting between investigator and volunteer might be insufficient, and that new techniques should be developed to improve the informed consent process.[187]

However, this same level of awareness of a communication gap is not seen when patients have a low health literacy level because of the hidden nature of this disability.[188] Therefore, nurses need to help raise the awareness of this problem. Nurses need to engage in a dialogue with other healthcare professionals. Staff can be directed to research articles and to measure that assess level of health literacy. These materials can form the basis of interdisciplinary conferences. Experts can be invited to address the issue.[189] Nurses must be more aware of the strong probability that clients in general and many in particular are incapable of understanding and following even the most basic health care instructions. The systems in which nurses work, must aggressively manage this problem. Nurses are the de facto health educators in most settings. Health literacy is a huge national problem that demands immediate action.

Wound ostomy continence nurses (WOCN) have supported health literacy post discharge from surgery. For ostomy patients, the timing and content of education is crucial in helping improve their health literacy and adjusting to living with an ostomy.

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[187] Daniel W. Fitzgerald et al., "Comprehension during informed consent in a less developed country," *The Lancet* 360 (October 26, 2002): 1301-02.

[188] Judith A. Erlen, "Functional Health Illiteracy," *Orthopaedic Nursing* 23, no. 2 (March/April 2004): 152.

[189] Erlen, "Functional Health Illiteracy," 152.

Clinicians should keep several points in mind, some of which they may or may not have been able to address during hospitalization. Patients are dealing with many emotions and concerns that may include cancer diagnosis, treatments, pain, concerns about body image, and recovery from major and sometimes unexpected surgery. Due to time constraints, limited resources, and short duration of stay, the only achievable skill during hospitalization may be learning how to empty the pouch. Patients are discharged with literature and product samples that may be overwhelming. Following discharge, patients try to establish their independence while dealing with other common concerns related to intimacy, returning to work, and social situations. Stoma change and peristomal skin issues or other complications may develop.[190] Throughout this process, the WOCN has a significant impact by providing self-care education and advice to patients. But where do patients go when they don't have access to a WOCN? In March of 2008, a calling service was launched by the ConvaTec Customer Interaction Center (CIC), with 18 WOCNs dedicated to providing support and information to new ostomy patients. Self management education patients should be customized to the learning and language needs of the individual. The ConvaTec WOCN calling service allowed a patient can sign up directly or via their WOCN or other healthcare professional. After signing, appropriate literature and product samples are sent to the patient. A WOCN calls the patient several days after enrollment in the program to follow-up and reinforce nurses' instructions in the hospital. Topics discussed include appropriate product usage, information on support groups and quality of life products (i.e. Closed end pouches), and any patient questions or

[190] Amy Locke, "A Resource for the WOCN to Support Health Literacy Post Discharge," *Ostomy Files*, accessed January 14, 2011, 1 http://www.o-wm.com/content/resource-wocn-support-health-literacy-post-discharge.

concerns. Since it began in 2008, the ConvaTec WOCN calling service has influenced the health literacy of close to 47,000 patients. A patient survey completed in 2009 found satisfaction with follow-up nurse phone call after discharge was 96.29% and 93.12% were satisfied with the information and support they received. The WOCN calling service helped ensure that ostomy patients get the information and support they need to return to a high quality of life.[191] The company feels that they help impact the health literacy of those that they serve.

Health Literacy Tools for the Health Care Professional

Low health literacy is widespread among U.S. patients, yet limited research has been done to assess the effects of health literacy practices designed to combat the problem, particularly among safety-net providers in primary care settings. The Association of clinicians for the Underserved conducted a survey of health care facilities across the county and then followed it up with visits to five selected sites for staff and patient interview. The study identified five health literacy practices that staff considered especially valuable for their group's patients and potentially applicable to other clinics: a team effort, beginning at the from desk; use of standardized communication tools; use of plain language, face-to face communication, pictorials, and educational materials;

[191] Locke, "A Resource for the WOCN to Support Health Literacy Post Discharge," 2.

clinicians partner with patients to achieve goals; and organizational commitment to create an environment where health is not assumed.[192]

Promising Practice 1: A team effort, beginning at the front desk

Clinicians felt that the entire care team, from reception area to checkout, should be involved. Each team member has an obligation to know if the patient is challenged by health literacy issues and to share this information, formally or informally, with other members. In that way, the care team can work collaboratively to meet the patient's needs.[193]

The front-desk and triage personnel, for example, play an important role in setting a positive tone for the visit, as these staff members are the people who patients see when entering and leaving the clinic. They assist patients with filling out paperwork and guide them to where they need to go. At times, the front-desk personnel also serve as a liaison between patients and the care team by listening to patient feedback at checkout. At one practice, patients are given clipboards so that they may take notes during their visit; any unanswered question can be addressed prior to leaving the clinic. In other clinics,

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[192] Sharon E. Barrett, Jennifer Sheen Puryear, and Kathie Westpheling, *Health literacy practices in primary care settings: examples from the field* (The Commonwealth Fund, January 2008), 5.

[193] Barrett, Puryear, and Westpheling, *Health literacy practices in primary care settings: examples from the field*, 5.

patients are given forms that encourage them to express any outstanding concerns or to compliment (or complain about) individual staff members, as appropriate.[194]

Physicians typically do not act alone in providing the health care per se. They also rely on physician assistants, nurse practitioners, medical assistants, clinical pharmacists, nursing staff, and other members of the care team to restate directions and explanations concerning treatment plans and medication dosing and to provide patient follow-up. At another center, staff frequently telephone patients, especially young mothers or elderly individuals with cognitive disabilities, shortly after a visit in order to ensure that medications and other recommendations are understood and being carried out.[195]

A patient at another center is greeted by a clinical staff assistant, who administers a Learning Assessment and a Psychosocial Screening to help clinical staff members understand the patient's level of health literacy and his or her stress level. The assistant's review of the patient's filled-out paperwork also serves in part as a literacy assessment. Immediately following the visit with the provider, a nurse meets with the patient to review the treatment plan and answer any questions. At discharge, the clinical staff assistant also checks, one last time, to determine whether there were any unanswered questions the patient may have felt uncomfortable asking the doctor or nurse.[196]

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[194] Barrett, Puryear, and Westpheling, *Health literacy practices in primary care settings: examples from the field*, 5.

[195] Ibid., 5.

[196] Ibid.

Promising Practice 2: Use of standardized communication tools

Clinicians responding to the online survey, as well as those who participated in the interview, generally have had little exposure to, and lack knowledge of, formal communication strategies. There are three formal techniques that are used, Teach Back, Ask Me 3, or Motivational Interviewing that are quite effective at improving communication.[197] Clinicians report using the Teach Back method did ensure that patients understand their treatment plan, to help them set goals for their health, and to support the patients in reaching those goals. At another clinic, clinicians are trained in and encouraged to use the Teach Back method and Motivational Interviewing, together with drawings and plain language, to communicate health information to patients. Staff has also adapted the Ask Me 3 approach to make it clinician-driven; instead of the patient being required to ask the clinician three questions, the clinician asks the questions in order to encourage dialogue and determine what the patient wants to focus on during the visit.[198]

The Health Literacy Committee at another clinic is currently in the process of implementing the Ask Me 3 strategy by encouraging patients to ask their clinical questions that will help them better understand their health and increase compliance with treatment. Meanwhile, the committee is encouraging clinicians to use the Teach Back method to verify that patients have understood their treatment plan. Among the clinicians

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[197] Barrett, Puryear, and Westpheling, *Health Literacy Practices in Primary Care Settings: Examples From the Field*, 7.

[198] Ibid., 8

responding to the online survey, as well as those participating in the interview, those who use Motivational Interviewing report that this technique is effective with their patients.[199]

Whether they use these formal techniques or not, clinicians are most familiar with the following four communication strategies:

- Health-education materials designed for patients with low reading levels
- Individualized health-education sessions for patients with low health literacy
- Giving patients the opportunity to bring a family member or friend to the appointment
- Using dedicated health literacy specialists at the health facility.

The five clinics visited did not have a dedicated health literacy specialist available onsite, but outreach workers and other staff members often assumed this role. Health facilities also employ other strategies, such as making referrals to a social worker, to assist patients with low health literacy.[200]

Promising Practice 3: Use of plain language, face-to-face communication, pictorials, and educational materials

Clinicians reported that certain common-sense approaches were quite effective at improving their communication with patients. These approaches include the use of plain language, free of medical jargon, sitting face-to-face with the patient, use of simple

[199] Barrett, Puryear, and Westpheling, *Health Literacy Practices in Primary Care Settings: Examples From the Field*, 8.

[200] Ibid., 8.

diagrams or pictograms to illustrate explanations and the use of educational materials geared to low health literacy individuals.[201]

The clinicians interviewed often spoke about repeating their directions and recommendations, just to be sure they are being heard, and frankly asking patients whether they understand their treatment plan, purpose of any medications, and the dosing of those drugs. To increase the likelihood of such comprehension, clinical staff members are trained to use everyday language and avoid jargon (or clearly define it) with their patients. At another center, providers are allowed 30 minute visits with patients. This not only offers the parties a better opportunity to build their relationships but also give patients more time to get their questions addressed.[202]

The facilities visited recognized the value of having forms and educational materials on hand that are culturally and linguistically targeted to each population group they serve and are at the appropriate literacy levels.[203]

At another center, a fourth-grade literacy level is generally applied when translating forms or devising curricula for any type of patient education. Much of that education is done in group format, which helps build peer support and widens the information's reach.[204]

Another center has developed several health-education brochures targeted to its patient population. They have revised the forms that patients are asked to complete; and the aim of these revisions were simplicity, both in language and layout. Welcome

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[201] Barrett, Puryear, and Westpheling, *Health Literacy Practices in Primary Care Settings: Examples From the Field*, 9.

[202] Ibid., 9.

[203] Ibid.

[204] Ibid.

letters, as well as letters sent to patients for billing purposes, have also been revised to use simpler language and design. All printed educational materials were reviewed by a Health Literacy Committee for literacy levels, as well as cultural and linguistic appropriateness, before being placed in display racks. Bulletin boards in the waiting rooms are also carefully placed and composed to achieve maximum visibility and impact on the patients while not overloading them with too much information.[205]

Promising Practice 4: Clinicians partner with patients to achieve goals

Some clinicians conduct goal setting with their patients and work together to achieve the goals. At the beginning of a clinical visit the medical personnel asks the patient to select one health goal from the Patient Goal Contract, which graphically displays a range of choices such as losing weight or reducing stress. The patient may also opt for a personal goal that is not on the list. Clinicians and staff partner with the patients to help them reach their goal; and once it is achieved, they help them set and endeavor to reach another one.[206]

Before patients are seen by a clinician, they not only set or reaffirm their goal with the medical assistant but also go through a review in which they tell the assistant how and when they take their medications. Patients are asked to bring all their medications to each visit for this purpose. Once the provider sees the patient, the

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[205] Barrett, Puryear, and Westpheling, *Health Literacy Practices in Primary Care Settings: Examples From the Field*, 10.

[206] Ibid., 11.

medical assistant returns to the exam room to review the treatment plan, ask the patient to state what he or she is going to do at home, and ask if any questions remain.[207]

Promising Practice 5: Organizational commitment to create an environment where health literacy is not assumed

In some health care facilities, health literacy practices were established because administrative leadership supported their integration throughout the clinic. Physicians themselves have often admitted that they were not familiar with health literacy concepts or practices until they joined a health care facility that had infused it as part of the operating philosophy, provided in service training and new employee orientation, and perhaps even participated in a research study on health literacy. At other clinics, health literacy practices began as a result of clinicians' previous involvements elsewhere in other health collaborative, perhaps, where providers used established communication techniques with their patients. Regardless of the impetus, clinicians are increasingly realizing that there is link between person health literacy and his or her health.[208]

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[207] Barrett, Puryear, and Westpheling, *Health Literacy Practices in Primary Care Settings: Examples From the Field*, 11.

[208] Ibid., 11.

Chapter 4

CLINICAL RESEARCH PROFESSIONAL PERCEPTIONS OF HEALTH LITERACY

There are currently 185 Health Literacy related clinical trials that are registered in Clinical Trials.gov which is a service of the U.S. National Web-based Institutes of Health. ClinicalTrials.gov is a resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions. The Web site is maintained by the National Library of Medicine (NLM) at the National Institutes of Health (NIH). Information on ClinicalTrials.gov is provided and updated by the sponsor or principal investigator of the clinical study. Studies are generally submitted to the Web site (that is, registered) when they begin, and the information on the site is updated throughout the study. In some cases, results of the study are submitted after the study ends. This Web site and database of clinical studies is commonly referred to as a "registry" and "results database."

ClinicalTrials.gov includes information about medical studies in human volunteers. Most of the records in ClinicalTrials.gov describe clinical trials (also called interventional studies). A clinical trial is a research study in which human volunteers are assigned to interventions (for example, a medical product, behavior, or procedure) based on a protocol (or plan) and are then evaluated for effects on biomedical or health outcomes. ClinicalTrials.gov also includes records describing observational studies and programs providing access to investigational drugs outside of clinical trials (expanded access). Studies listed in the database are conducted in all 50 States and in 185 countries.

ClinicalTrials.gov does not contain all clinical studies conducted in the United States because not all studies are required by law to be registered. However, the number of studies registered each year has increased over time as more policies and laws requiring registration have been enacted and as more sponsors and investigators voluntarily register their studies.

ClinicalTrials.gov was created as a result of the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDAMA required the U.S. Department of Health and Human Services, through NIH, to establish a registry of clinical trials information for both federally and privately funded trials conducted under investigational new drug applications (IND) to test the effectiveness of experimental drugs for serious or life-threatening diseases or conditions. NIH and the Food and Drug Administration (FDA) worked together to develop the site, which was made available to the public in February 2000.

The ClinicalTrials.gov registration requirements were expanded after Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA). Section 801 of FDAAA (FDAAA 801) requires more types of trials to be registered and additional trial registration information to be submitted. The law also requires the submission of results for certain trials. This led to the development of the ClinicalTrials.gov result database, which contains information on study participants and a summary of study outcomes, including adverse events. The results database was made

available to the public in September 2008. FDAAA 801 also established penalties for failing to register or submit the results of trials.[209]

Out of the 185 studies, there is 1 study that will be involving Health Literacy Intervention for Informed Consent of Cancer Patients considering clinical trial participation. The study hasn't begun; however, the plan is start in 2014 and end in 2015.

My work in the health care industry has provided me the interest for conducting this small study as part of my research. For the last thirty years I have worked primarily in the pharmaceutical industry at various levels of leadership in New Jersey. I have worked primarily managing clinical trials in various therapeutic areas. During this time, I have often questioned whether patients understand health literature, information given to them by clinicians and what could help that reality. I believe that the area of health literacy is a way to assist in better health care management for patients and clinicians.

Method

Sample

I solicited 16 health care professionals that work in the area of clinical research to participate in this study. This research study examined familiarity and perception with the term health literacy. All participants received IRB approved consent.[210] The participants were verbally solicited for their participation. I had previously worked with several participants and met others at clinical research industry meetings. Data on gender, age, and race was not collected.

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[209]Clinical Trials.gov, A service of the U.S. National Institutes of Health, accessed February 27, 2014, http://clinicaltrials.gov/ct2/about-site/background.

[210] A sample of the consent form is found in Appendix 1.

Two of the industry participants were Clinical Research Investigators. Six were Registered Nurses. Six were Clinical Research Associates. One was a Clinical Research Study Coordinator. One was an institutional Review Board employee. The majority of participants (n=16) perceive value in health literacy may be the key to empower patients in the Informed Consent process. Results of the survey are discussed below.

Limitations

The cohort sampled for this case study is limited in size. Therefore, the numbers are too small to say the responses are representative of the population.

Results of Survey questions

How long have you worked in the clinical research setting?

Five participants worked less than five years. Four participants worked less than ten years. Four participants worked less than twenty years and three participants worked more than twenty years.

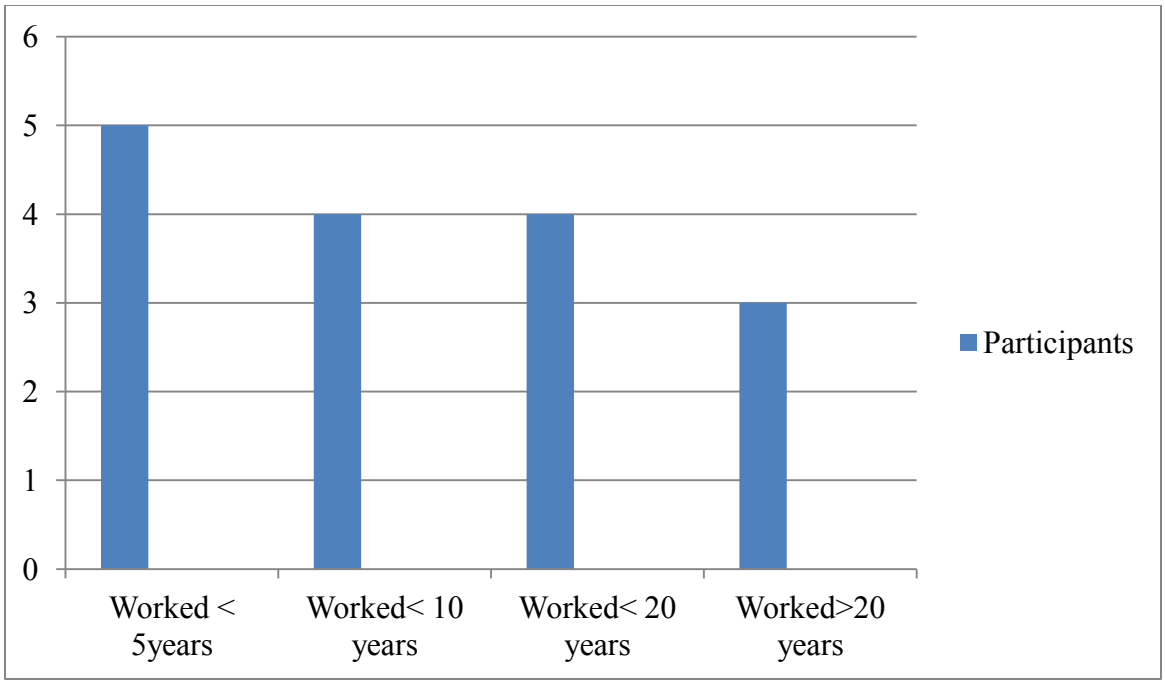
Discussion

According to an article in Daily finance,

> If you put aside the government and nonprofit organizations, the pharmaceutical sector had the dubious honor of topping all others when it came to U.S. job cuts in 2010. Outplacement company challenger, Gray & Christmas reports that, of the roughly 530, 000 jobs eliminated in this country last year, nearly 54,000 were at

pharmaceutical firms. Another 28, 000 were announced in the health care/products sector.[211]

It was good to see that people are working and are having longevity in their careers.



Why do you work in the area of clinical research?

- It has been a great opportunity to work with famous health leaders.
- I enjoy working in a fast paced environment.
- I have always worked with a physician and he started working in clinical research.
- I work in the area of wound care and was approached by a medical device company.
- I have interest in health sciences.

[211] Melly Alazraki, "Which sector lost the most jobs in 2010?" *Pharma. Daily Finance*, an AOL Money and Finance Site, (January 7, 2011): 1. http://www.dailyfinance.com...accessed 4/22/2014

- I happen to fall into this career by chance.
- It has been a good living.
- It has been a great opportunity to make a living. I have been able to advance medical science.
- As part of my job at a patient education agency.
- It has been very rewarding.
- I work in clinical research to make a difference in clinical medicine helping bring better drugs to people quicker.
- Rewarding area with ongoing changes almost on a daily basis. Continue to grow and learn. Ability to reap the rewards of the corporate world as well as continuing to interact with many people.
- Tested a major drug when first developed.
- I find the work very interesting and fast paced. I enjoy multi-tasking and meeting new people on an ongoing basis.
- To improve patient outcomes.
- There was one survey that did not answer the question.

Discussion

This question illuminates what motivates the clinical research professional to work in that field. Their responses were based upon having rewarding work, and being part of the scientific community. However, it would appear that by their answers that they would be master negotiators to accomplish their task. Key to every successful negotiation is advance planning, preparation, and patience. The Clinical research

professionals deal with various parties for different purposes at the same time; hence they require excellent negotiation skills.[212]

Are you familiar with the term "Health Literacy?"

- Ten participants are familiar with term health literacy
- Six participants were not familiar with the term health literacy.

Discussion

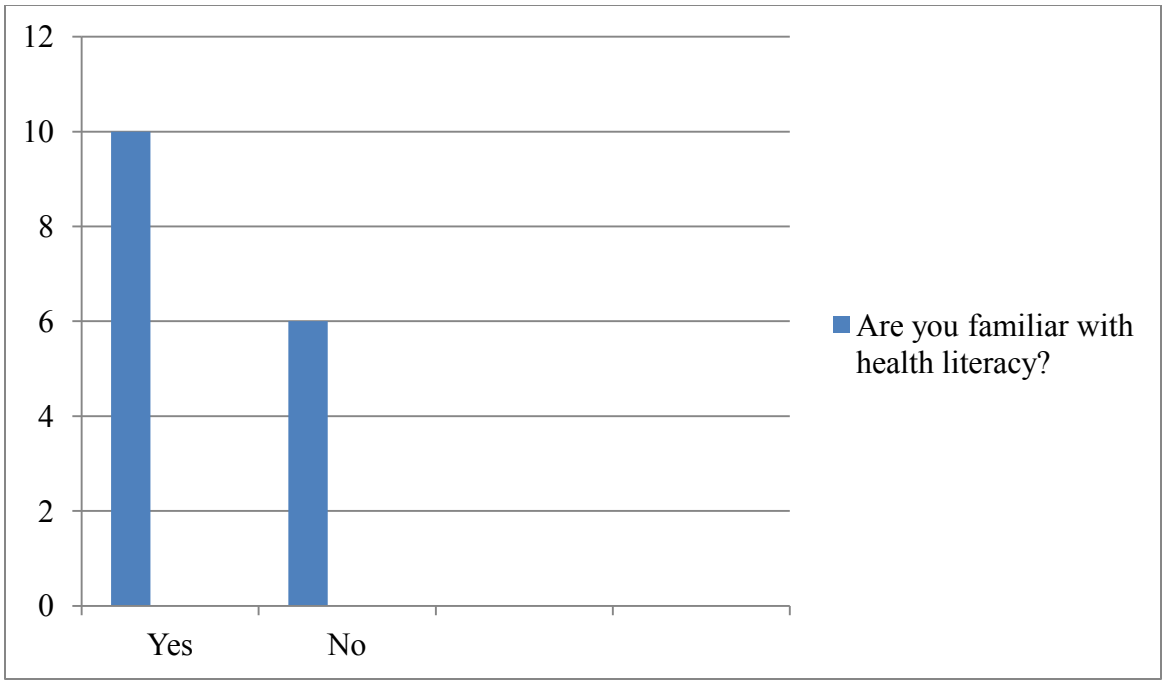
The clinical approach to health literacy offer differing conceptualizations of the relationship between knowledge and health literacy. Much of the clinical encounter is focused on obtaining information about and from the patient.[213]

This question illuminates the familiarity of the term health literacy. Health literacy is a relatively new concept, emerging in the medical and public health literature only within the last decade.[214]

[212] Sanjay Hake, "Negotiation skills for clinical research professionals," *Perspectives in Clinical Research* (July – September 2011): 105-108.

[213] Andrew Pleasant, "A tale of two health literacies: Public health and clinical approaches to health literacy," 23, no. 2 (January 25, 2008): 152.

[214] Speros, "Health literacy: concept analysis," 639.



If you are familiar with term Health Literacy, in your own words define Health Literacy.

- Ability to understand and process health information.
- The ability to understand health language.
- Understanding basic health information.
- Health Literacy is helping the everyday person understand disease states and therapies.
- Health Literacy is the ability for a person to read comprehend and act on health information.
- Having the ability to understand and process health information such as how to follow a prescription, follow medical orders and obtain treatment.
- Understanding health terms and initiatives.

- Subjects and patients understand medical jargon and make decisions based on that understanding.
- Health terms.
- The basic knowledge a person has regarding their healthcare decisions.

Discussion

The definitions are all interrelated that they include health, understanding and processing health information. As documented in the literature, there are many definitions of health literacy. These differences are due to work background, profession, and experience in the field.

What do you think is the current perception of health literacy and the Informed Consent process?

- I don't know.
- I think there is a trend to included health literacy in the Informed Consent.
- I don't think there is a perception.
- Not sure.
- It seems to be a popular topic.
- I don't think there is a current perception between health literacy and the informed consent.
- I don't think there is enough people who are aware of health literacy.
- I don't think it is thought of.
- No perception.

- The Informed Consent is still to complex.
- The average person is not aware of health literacy or what an informed consent is. IRBs do not know how to incorporate health literate information in clinical trial materials.
- By the general population I don't think they understand the process of how to move through the health care system. The informed consent process is usually a total mystery with legal terms.
- Patients should be more aware of what is involved with their drugs and health before a procedure is done.
- I don't that an individual is able to process the state information presented to them in their own terminology and level of understanding.
- I don't think it is thought of at all with the informed consent process.
- Health literacy with informed consent assures that an individual is able to process the stated information presented to them in their own terminology and level of understanding.

Discussion

There is opportunity to incorporate health literacy in the informed consent process. Health professionals will have to provide subjects/patients with clear and understandable information to help them understand their medical condition and its treatment.[215]

[215] Richard Safeer and Jann Keenan," Health Literacy: The Gap Between Physicians and Patients" *American Family Physician* 72, no. 3 (August 1, 2005): 466.

What is your perception of health literacy and the Informed Consent process?

- An assessment of the patients understanding of the informed consent repeated back and verified by those obtaining informed consent.
- I think it is a necessary element. I know that most informed consent s do not have language that is understandable.
- Everyone needs to be educated.
- I completely understand the requirements and components of the Informed Consent process having been the person responsible for composing the document. I feel as an RN I understand health literacy.
- It could be made easier for the patient and caregiver.
- Understand the words in the informed consent.
- I think it would help the Informed Consent process.
- Being knowledable about health and medical terminology.
- Plain English and be able to make decisions.
- I agree with the definition above.
- Understanding health literature.
- Understanding health words.
- Understanding health terms.

Discussion

There should be ongoing studies on health literacy and the informed consent process and the perception. There didn't seem to be a clear cut answer on perception of health literacy and the Informed Consent process.

What is your opinion of the relationship between clinical research personnel and subjects?

- It appears to be good.
- It is good.
- Good(2)
- Very good (3).
- There is very little. Most of the time clinical research personnel don't even say thank you.
- I would not characterize it as a relationship. It is a matter of viewing subjects as a number.
- It is a fine line toward to protect the subject's privacy as well as obtaining relevant data. Questionnaires don't always paint a true and complete picture of a clinical study especially when dealing with medical devices.
- Not enough information is given to patients.
- I believe the relationship is good.
- A good clinical researcher will assure that the participants are aware to the research process and study criteria, components of the study before agreeing to participate in the study.

Discussion

This question illuminates how a good relationship is important to the clinical research process. Since the clinical research personnel are coming from different

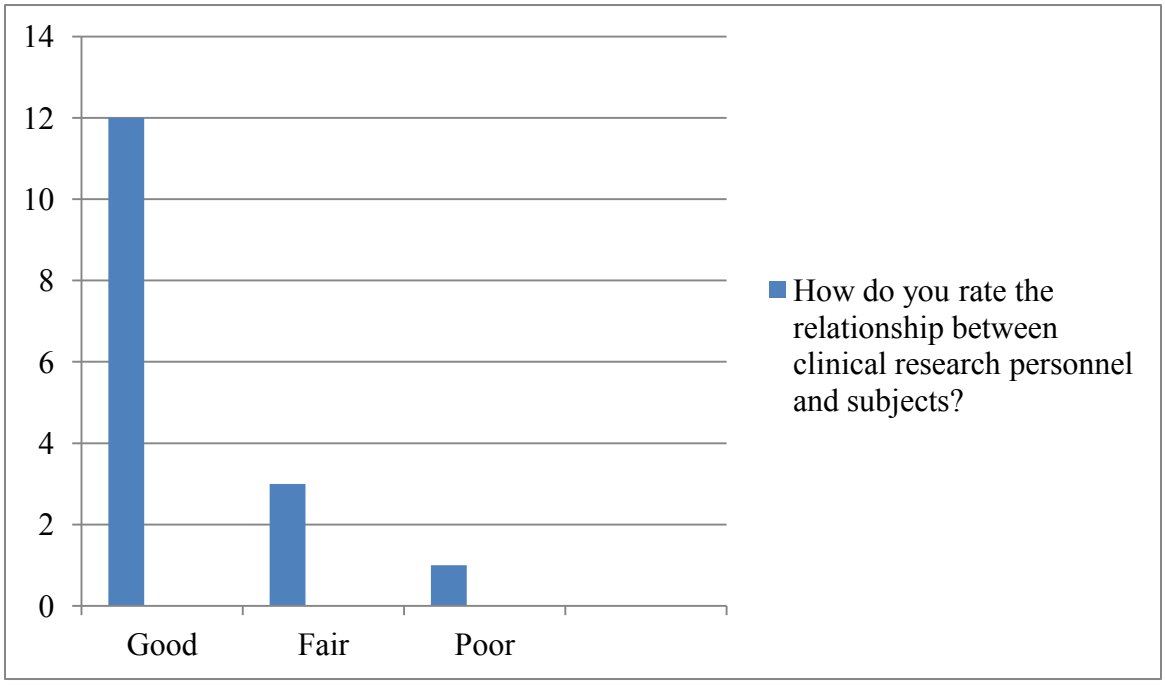
therapeutic areas, it is possible that their answers would reflect their specific clinical research setting.

How do you rate the relationship between clinical research personnel and subjects?

- Good (12)
- Fair (3)
- Poor (1)

Discussion

I expected the majority to say good. The reason is because it is important to have a good relationship with patients. Recruiting subjects can be very difficult and it requires personnel that are good at establishing and sustaining relationships.

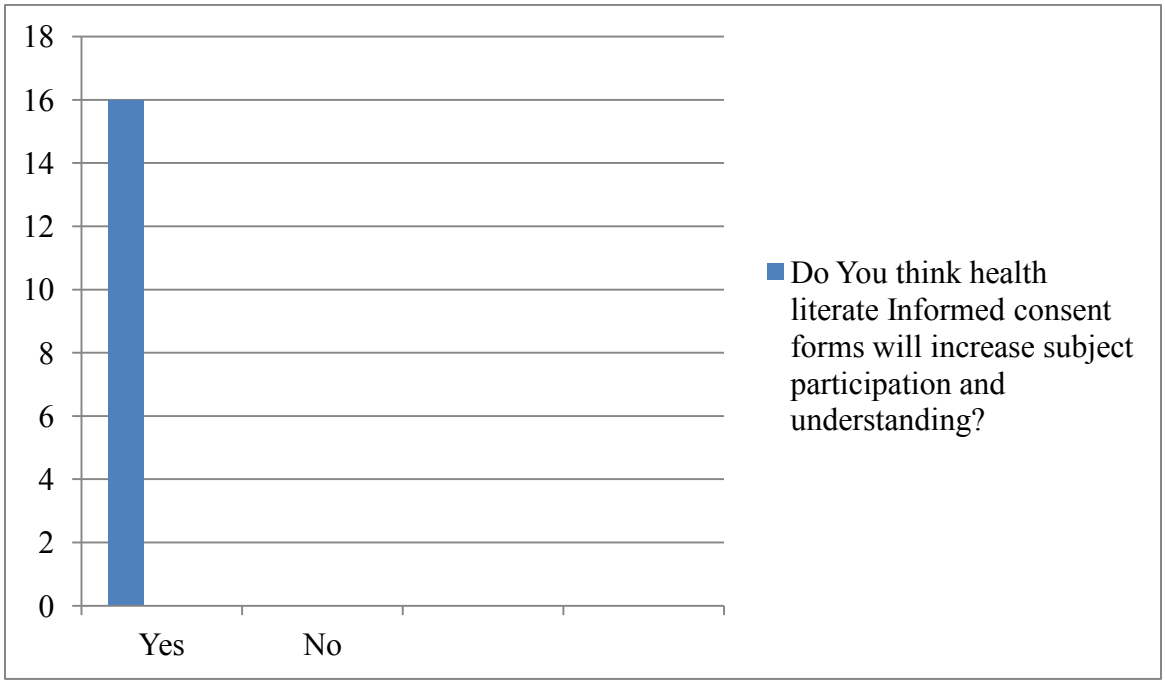


Do you think health literate Informed Consent Forms will increase subject participation and understanding?

- Yes (16)
- No (0)

Discussion

It appears from the positive number that health literacy is important to participation and understanding of the clinical trial. Health literate consent forms will be important for future studies.



If you answered yes to question 12, how will you incorporate this in your work place?

- In conducting a study the participant will be given ample time and opportunity to discuss their participation of the study.
- I will start giving a straight language definition for big words.
- Sign up boards and classes.
- Not currently employed, however, Informed Consent were written at my company were at a 5th grade level.
- We try to create informed consent and clinical trial resources that were written at a 5th grade level, using plain language, large font size and clear graphics.
- My whole team does nothing but make the Informed Consent process easier. We take today's Informed consent and put color, animation and illustration to it.
- I will make certain that I review the consent forms in the future.
- To make suggestions to Pharma personnel.

Discussion

Health literacy will become more popular as time goes by.

Are you aware of any existing health literate informed consent in your work place?

- Yes (2)
- No (14)

Discussion

I didn't expect a lot of yes; however, in the future that number will change.

If you answered yes to question 14, have they helped increased subject participation and understanding?

- They always need the addition of the research team to interpret.
- Yes.

Discussion

It was good to see a positive answer.

Do you foresee any value in health literacy for the informed consent process in clinical research?

- Yes (15)
- One participant was unsure.

Discussion

This answer is consistent with the literature of seeing value in health literacy and informed consent.

If you answered yes to question 16, would you expand upon your answer?

- Most likely it will increase the length of the document from what is usually a 6-10 page document.
- Providing participants with health literate informed consents will better prepare them for the expectations of the trial.
- Anytime you can engage the subject you make them feel part of the process.
- It is good for patients understand their health affairs.
- I can see the value; they would be less questions from patients.
- For participants, subjects would have a clearer and expanded knowledge base of the study.

- I do see value with incorporating a more health literate informed consent.
- Maybe, hopefully it will make a change.

Discussion

There is value in health literacy.

Do you feel that health literacy may be the key to empower patients in the Informed Consent process?

- Subjects generally fell powerless in my review. They always know they can stop at anytime, where lies their power.
- Yes(15)

Discussion

Having a health literate document would be better received and understood by potential subjects (patients). It's my feeling that there will be more research in the future on this topic.

I have learned that work longevity is great to have especially in this difficult financial economy. Most of the respondents were actively working and appear to enjoy what they do. I believe that work satisfaction and success is essential to introducing health literacy in the informed consent process. This was one of the reasons I asked "why do you work in the area of clinical research." Most of the respondents mentioned the scientific aspect and others the rewarding aspect of it.

I was curious to know how familiar the respondents were with the term "Health Literacy." It is a relatively new concept especially for the informed consent process. Clinical research professionals are so busy that it may be a burden to add something else to the process already. In many cases informed consent templates are used for each study and all the professional has to do is just add the new studies information. It will take effort to develop templates that are more literate.

I wanted to know if they were familiar with the term Health Literacy to come up with a definition. The answers that were received are familiar with other definitions in the literature. I should mention that the respondents did not have any knowledge that they would receive this questionnaire in advance. Most were approached at professional meetings and they agreed to participate.

Even though their definition of Health Literacy was current with the literature's definition, there wasn't enough positive thought about the perception of health literacy and the Informed Consent process. This is interesting because on one hand they know the definition but on the hand its not being used in the field. This study has shown the opportunity to increase the usage of health literacy in the informed consent process.

The question regarding their personal perception of health literacy and the informed consent process was overwhelming positive. I felt the following feedback was helpful in their answers: "I think it is a necessary element. I know that most informed consents do not have language that is understandable." This study gives a platform for others to go forward to continue the conversation and give thought to this process.

I was interested in the relationship between clinical research personnel and subjects because there is information to suggest subjects may feel like a guinea pig.

According to Morris, a successful outcome (mutually agreed relationship) is important both to the volunteers and the researchers for the successful conduct of the research. The relationship forms an essential component of their handling of a potentially anxious and embarrassing situation. Invoking and moving between multiple roles and identities is part of the process of navigation through unfamiliar social territory and active negotiation of a socially satisfactory researcher-subject relationship.[216]

When considering how these findings relate to other experimental settings, the balance of power would be expected to vary according to the nature of the research or trial and the nature of the participants. A healthy volunteer, for example, is in a different situation form a patient looking for access to a potential treatment and this is likely to affect the researcher-subject relationship. The relationship between researcher and subject is likely also to vary according to the benefits available: a simple economic transaction requires a less personal and nuanced relationship than interactions based on an uncertain benefit to a sick subject's health. Her findings suggest that the outcome of the negotiation about the relationship at the point of human contact may have consequences (both positive and negative) not only for sustaining the relationship between researchers and volunteers, but also for the scientists' ultimate research outcomes.[217]

I wanted to know about their relationships with subjects. Overall it was good and showed a trend towards keeping it that way.

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[216] Norma Morris and Brian Balmer, "Volunteer human subjects' understandings of their participation in a biomedical research experiment," *Social Science & Medicine* 62 (2006): 1006.

[217] Ibid., 1007.

It was interesting that all respondents thought that health literate informed consent forms will increase participation and understanding. However, the majority were not aware of any existing health literate informed consents in their work place. This shows an opportunity for future research in this area and also more work to be done in actual clinical trials.

This study did gain positive results for seeing any value in health literacy for the informed consent process in clinical research. According to Cathy Meade, the follow key points help improve understanding of the informed consent process and document:

- Consider principles of teaching, learning, and communication when crafting and delivering informed consent communications.
- Build alliances with patients: get in touch with patients' attitudes, knowledge, and perceptions about study participation.
- Recognize that many factors influence comprehension, especially low educational, literacy, and vocabulary levels.
- Screen literacy skill using informal (ie. facial expressions) and formal measures (ie, REALM).
- Present information according to the patient's preference, "neither too little or too much." Gauge preference by asking patients about their perception of the quality and quantity of the information being conveyed.
- Obtain patient input and feedback throughout the informed consent process.
- Include a family member or friend in the informed consent interaction.
- Enhance the reading ease of the informed consent document b using a variety of design techniques. Use advance organizers to introduce key sections.

- Simplify verbiage. Be clear and concise. Use plain language. Relate medical terminology to everyday situations from the patient's viewpoint.
- Provide time for patients to digest the information. Parcel out information according to cues received from the patient.
- Provide multiple opportunities for interaction both in the document itself and during the informed consent process.
- Summarize often. Ask the patient to speak/write about the elements in the informed consent document.
- Probe and verify understanding: ask patients to repeat what they have heard in their own words. Avoid close ended questions. Don't just ask "do you understand?'
- Assess understanding using reliable and valid measures.
- Use a combination of printed and electronic methods to reinforce the informed consent message, i.e., interactive media, internet, pictures, telephone, audiotapes, and videotapes.
- Encourage and provide take home consents/supplementary aids.
- Enhance the communication of the required elements of informed consent with "tailored messages" customized to a subject's demographics, psychographics, or behavioral characteristics.
- Evaluate your interactions. Ask yourself: What has been understood: What needs clarification? How can I improve the process?
- Improve your communication skill through continuing education training.

- Conduct systematic investigations to advance science. Ask yourself, "What areas need further research?"[218]

Health Literacy Interventions

We depend on relevant health information to promote our own health and the health of others; we need relevant health information to make the best decisions about avoiding health risks, detecting and diagnosing health problems, and seeking the best available health care services. Yet widespread problems with health literacy significantly limit effective dissemination and understanding of relevant health information in society, especially among many vulnerable populations where health literacy challenges are especially pervasive.[219]

There are many different paths for addressing health literacy problems. Each path has its own strengths and weaknesses, and it may take a combination of strategies to address the complexities of overcoming health literacy effectively. A review of interventions can help libraries develop integrated models for outreach to address health literacy challenges.[220]

A traditional strategy for addressing health literacy problems has focused on developing educational programs to help increase the literacy levels of health care consumers. Schools, colleges, hospitals, clinics, and libraries are just some of the

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[218] Meade, "Improving understanding of the Informed Consent Process and Document," 133.

[219] Parker and Kreps, "Library outreach: overcoming health literacy challenges," 81.

[220] Ibid., 82.

institutions that can offer educational programs to increase public health literacy levels. These programs can be offered as topical seminars, as credit or noncredit courses, and as a part of distance education programs.[221]

The recent IOM report on health literacy reviewed current programs and opportunities in education and found that there are currently significant obstacles and barriers to successful health literacy in kindergarten through twelfth grade education programs. Adult education programs hold opportunities for implementation of programs to improve health literacy and provide promising models. For example, MedlinePlus has been linked to the Health & Literacy Special Collection http://www.worlded.org/us/health/lincs/>, a website designed to support adult basic literacy and health literacy education. The IOM report also notes that health providers receive little training and education to develop their skills in improving health literacy.[222]

Consumer education programs often take a long time to improve literacy and health literacy levels, and they are not very helpful to consumers at the moment when they most need relevant information to address current health problems. In addition, more than 300 published studies indicate that most patient and health information materials far exceed the reading ability of most US adults.[223]

Another limitation too many consumer health literacy educational programs is that they focus solely on reading, writing, speaking, and listening skills and not on the larger set of communication strategies consumers need to get the most out of the modern

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[221] Parker and Kreps, "Library outreach: overcoming health literacy challenges," 82.

[222] Ibid., 82.

[223] Ibid.

health care system. Educational programs can help consumers develop the functional abilities to gather relevant health information, interpret health information, engage in meaningful deliberations with their health care providers, and explain their symptoms and health experiences clearly. Moreover, educational programs must be tailored to the needs of consumers and patients to learn how to negotiate and navigate the many complexities and bureaucracies of the modern health care system; to learn essential skills for self-management of chronic conditions; and to learn how to communicate about their health needs for acute, chronic, and preventive care.

Virginia Adult ESOL Health Literacy Toolkit

A good example of an educational program that provides training for functional health literacy is the Virginia Adult ESOL Health Literacy Toolkit. The toolkit was created by a hospital social worker and ESOL educator. The toolkit offers explanations, tips, materials, and links to help ESOL teachers and programs better understand and address the health literacy challenges faced by adult English language learners in U.S. healthcare.

Introduction to ESOL Health Literacy

This section defined what ESO: health literacy is and what people need to know about it. The article explains health literacy as it pertains to the unique situation of English language learners (ELLs). It proposes ways the ESOL field can help improve learner health literacy and better prepare learners for the U.S. health care system. It goes over health literacy basics for those new to health literacy in the U.S. and

interdisciplinary efforts to improve health literacy.[224] There were several cases studies that describe the experience of ELLs trying to access and navigate U.S. health care, and then prompt teachers to identify ways ESOL health lessons can empower learners in such scenarios.

Using the U.S. Health Care System

This section provided educators with explanations and resources for taking some of the confusion out of understanding U.S. health care for ESOL learners. Some useful U.S. Health Care and Public Health terms were provided for some health care, public health and social service system terms that might be pertinent for some ELLs. There was a list that contained links to low-cost health care services for uninsured or underinsured that included clinics, vision care, hearing care, dental care, mental health care, women's health, workers' compensation information, multicultural social services, family services, insurance assistance, and legal aid. There were tips for troubleshooting health insurance and explanations about state law and available resources related to avoiding and addressing medical debt.

Teaching ESOL Health Literacy

This section presented concrete content that English language learners need to know to function effectively in health care and ideas for how to approach health literacy curriculum development, lesson planning and bringing lessons to life.

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[224] Kate Singleton, "Virginia Adult ESOL Health Literacy Toolkit," Virginia Adult Learning Research Center located at Virginia Commonwealth University, 1.Accessed February 5, 2014, http://www.valrc.org/toolkit.

ESOL Health Literacy Partnership

Partnering with a health care program or organization to improve health literacy for ESOL learners can be rewarding for all involved. Health care specialist or providers know their medical specialties, however; may not be literacy experts.[225] It is a good idea for them to form a partnership to communicate their medical information in clear and simple ways.

Links for Educators

This section lists online health literacy resources, grouped by topic. Some of the topics were as follows: background information on health literacy, health care glossary, culture and health, health care access and navigation, paying for health care and healthcare partnerships.

Links for Learners

This section was helpful information about going to the doctor in the United States. There were important basic information about finding health care, communicating with the doctor or hospital, paying for health care and understanding health information (figure). There were tips for using finding a clinic, clinic services, clinic costs and making a clinic appointment. There were tips to communicating better with doctors, understand information better and remember information better. There

[225] Singleton, "Virginia Adult ESOL Health Literacy Toolkit," 1

were also tips on how to practice writing down a medical history for you and your family and practice writing information about your medication.[226]

Another variation of health literacy educational programs is strategic communication training, where health care system participants are taught to develop adaptive and culturally sensitive communication skills to overcome health literacy challenges.[227]

Another major challenge faced by consumer literacy education programs is that they generally only address one of the multiple audiences affected by health literacy problems. Educational programs also need to be developed and implemented to help health care providers and caregivers cope with health literacy problems. Educational programs for doctors, nurses, and other health care providers can help train these professionals to communicate effectively with consumers who have low literacy, to seek feedback from consumers to determine how well they understand relevant health information, and to develop strategies for vividly explaining complex terms and procedures, Informal caregivers, such as family members, also need help through education to increase their understanding of relevant health information.[228]

Health literacy is a complex issue, and improvements in health literacy require a variety of approaches. Health literacy not only involves the communication skills and abilities of health care consumers to understand spoken, written and mass-mediated communication about health and health care, but it also involves the communication

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[226] Singleton, "Virginia Adult ESOL Health Literacy Toolkit," 1

[227] Parker and Kreps, "Library outreach: overcoming health literacy challenges," 82.

[228] Ibid., 83.

skills and predispositions of a broad range of health care providers and information sources and the support of the larger health care system in promoting effective health communication. Moreover, effective health communication is interactive and adaptive, utilizing many different channels of communication and operating across a number of different contexts. Ninety million Americans have difficulty understanding and acting on health information. To treat this silent epidemic, efforts are needed to strengthen skills and coping strategies for consumers and providers. Partnerships between different health information specialists, health care providers, and consumers who desperately need relevant health information can help overcome the many problems related to health literacy.[229]

[229] Parker and Kreps, "Library outreach: overcoming health literacy challenges," 84.

Chapter 5

CONCLUSION

Conducting clinical trials and conducting tests on patients is very valuable in obtaining treatments using new or improved medications, saving lives or providing relief for symptoms. Behind every medicine and treatment are people who gave the gift of participation in clinical trials. Without people to volunteer for clinical trials, the world would be a far different place. New diseases would flourish. Well-known diseases-many of which are managed today with medication and lifestyle changes would instead cripple or disfigure. Flu epidemics would rage unchecked. Many adults and children stricken with cancer would be buried or face the end of life as opposed to fighting the disease and living longer and productive lives.[230]

The ability to make a decision to participate in clinical trials is based on a combination of skills, including patients having an understanding of research and science, patients being able to seek out and evaluate health information, and providers giving messages that are appropriate for the populations served.[231]

The consent form spells out the study procedure, how long the study will last, side effects that could happen and how much you will be paid for your participation, if anything. The form also states the reasons for various research steps, hoped for benefits and other available treatment options. Consent forms can be long, complicated and

[230] Getz, *The Gift of Participation*, 1.

[231] Evans, "The Role of Health Literacy on African American and Hispanic/Latino Perspectives on cancer clinical Trials," 304.

unfortunately poorly written. Others can be more straightforward and clearly written.[232] Informed consent is key to the patient-centered approach of modern medicine, and it relies on patients understanding the information that they are given to inform their decision.[233]

Empowering patients through health literacy in the informed consent process is an important approach to the practice of clinical trial and medicine. There is growing interest in the study of Health Literacy. The United States has a complex system of care which includes complexity in the understanding of that care. There are barriers to effective health communication. There is low or marginal literacy, jargon, stress and increased complexity of self care, cultural and individual learning styles. There are people who have problems with quantitative data such as understanding prescription drug dosages.

When a patient does not understand how to follow the instructions given by his or her doctor and other health professional's instructions to complete a task, it leads to decreased health because of a lack of adherence to prescribed forms of treatment and self care. People with poor health literacy skills are more likely to make medication errors, twice as likely to be hospitalized and have more outpatient visits per year.

Each step toward improving health literacy is a step toward improving patient knowledge and understanding of factors involving personal health care. This is

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[232] Evans, "The Role of Health Literacy on African American and Hispanic/Latino Perspectives on cancer clinical Trials," 304.

[233] Victoria Richardson, "Patient comprehension of informed consent," *The Journal of Perioperative Practice* (September 2012): 26.

ultimately linked to improving patient safety and honoring patient rights.[234] Through the use of health literacy principles, the consent document can become a tool to encourage and evaluate informed consent. Increasing readability of the document encourages patients to read what they are signing. Most importantly, the teach-back portion provides an assessment tool for measuring patients' understanding of their procedures. Communication with medical and nursing staff is paramount in implementing a new consent document. Increasing staff member awareness of the concepts of health literacy is the starting point.[235]

Through my research, I demonstrated that health literacy is valuable to the clinical research community to help patients/subjects in the Informed consent process. The survey responses of the six-teen clinical research professional proved to have value. It was interesting to know that the majority of the professionals worked in the field more than five years. There has been a lot of downsizing in the pharmaceutical industry where a lot of clinical research personnel work. According to an article in Daily Finance, "If you put aside the government and nonprofit organizations, the pharmaceutical sector had the dubious honor of topping all others when it came to U.S. job cuts in 2010. Outplacement company challenger, Gray & Christmas reports that, of the roughly 530,000 jobs eliminated in this country last year, nearly 54,000 were at pharmaceutical firms. Another 28,000 were announced in the health care/products sector."[236] In general

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[234] Lorenzen, "Using Principles of health Literacy to Enhance the Informed Consent Process," 23-29.

[235] Ibid, 29.

[236] Margit Anderson and Amy Hibberd, "Downsized? Now What? A former senior Clinical research associate explores life after downsizing," *The Monitor* (February 2012): 49.

it appears that there is continuity in personnel in the clinical research arena from the survey.

It was clear that the majority of the participants work in clinical research because they want to make a difference, interest in health sciences, very rewarding, and they can continue to grow and learn. More than half of the participants are familiar with the term health literacy and understand the definition. It is evident that they can benefit from a lot more training on health literacy and how it relates to their work.

The survey introduced these clinical researchers on how there is a need to incorporate health literacy in their Informed Consent Forms. Not only must training occur at their individual level, but also at the leadership level in their respective companies to ensure a long term commitment. This topic of health literacy will continue to be very important for a very long time.

This study of health literacy and the informed consent form is an example of Medical Humanities in action. Or in other words, it can provide the practical tools to infuse humanism into medical practice. It is definitely an interdisciplinary and inter-professional approach to the matter of medicine and the human condition. It includes art, literature, history, philosophy, anthropology, and culture. It also includes the practice of medicine, doctor-patient relationships, and local/national/global healthcare issues.

This study has laid the foundation for future research to incorporate health literacy in the informed Consent Process in clinical research and in other medical settings. Even though my study cohort is very small, in combination with the writings that have been done, health literacy should be a training opportunity for all in the medical field.

APPENDIX 1

CONSENT FORM

EMPOWERING PATIENTS THROUGH HEALTH LITERACY IN THE INFORMED CONSENT PROCESS

CONSENT FORM

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1. INTRODUCTION

You are invited to be a participant in a research study about the perceived values of Health Literacy in the Informed Consent Process. **You were selected as a possible participant because** you work in the area of clinical research. **We ask that you read this document and ask any questions you may have before agreeing to be in the study. The study is being conducted by** Gloria L. Riller, (Principal Investigator) Doctoral Candidate Drew University Caspersen School of Graduate Studies (CSGS), Medical Humanities Department. I may be contacted at 908-930-5033 or glrmonitor@yahoo.com.

2. BACKGROUND

The purpose of this study is find out the perceived opinion of health professionals on the impact of Health Literacy in the Informed Consent Process. Health literacy is becoming increasingly important measure of health understanding. There are many articles on Informed Consent which focuses on the readability of the document.

3. DURATION

The length of time you will be involved with this study is no more than a half hour and may take as little as ten minutes. Your participation will just include the survey only.

4. PROCEDURES

If you agree to be in this study, we will ask you to do the following things: There are no office visits in this study. Data for the study will be collected via a survey. All subjects will receive the same survey. If you agree to be in this study, I will ask you to do the following things: (1) review and sign the Informed Consent Form. A copy of the signed Informed Consent form will be given (or sent electronically if applicable) to you and the original will be retained by the Principal Investigator. You will then be given the survey to complete. If you feel uncomfortable answering any questions, you may stop at any time. You may also feel free to skip questions. Your participation in this study is voluntary.

5. RISKS/BENEFITS

This study has the following risks: there are no foreseeable risks to your participation in this study. If you feel uncomfortable answering any questions, you may stop at any time. You may also feel free to skip questions.

The benefits of participation are: The benefits of participation include increasing knowledge in the area of health literacy that will ultimately serve to establish and to strengthen the relationship between society and Clinical Research.

6. CONFIDENTIALITY

The records of this study will be kept confidential. To ensure the integrity of the survey you will not write your name on any of the pages. To protect your confidentiality your survey will be coded based upon your role (e.g., PI=Principal Investigator and CRA=Clinical Research associate, etc.). Records will be stored and retained in a secure and locked cabinet and in accordance with ICH guidelines. Records access will be limited to the Principal Investigator only.

7. VOLUNTARY NATURE OF THE STUDY

Your decision whether or not to participate in this research will not affect your current or future relations with Drew University. If you decide to participate in this study, you are free to withdraw from the study at any time without affecting those relationships and without penalty.

8. CONTACTS AND QUESTIONS

You will be given debriefed after completing the survey. No deception is involved

The researcher(s) conducting this study is(are) Gloria L. Riller. **You may ask any questions you have right now. If you have questions later, you may contact the researcher at glrmonitor@yahoo.com, or call at 908-930-5033.**

If you have questions or concerns regarding this study and would like to speak with someone other than the researcher(s), you may contact:

Allan C. Dawson

Assistant Professor of Anthropology

Chair Drew University IRB

36 Madison Avenue

Madison, NJ 07940

973-408-3000

9. STATEMENT OF CONSENT

The procedures of this study have been explained to me and my questions have been addressed. I understand that my participation is voluntary and that I may withdraw at any time without penalty. If I have any concerns about my experience in this study (e.g., that I was treated unfairly or felt unnecessarily threatened), I may contact the Chair of the Drew Institutional Review Board regarding my concerns.

Participant signature_____
Date_____

Appendix 2

Clinical Research Health Literacy Assessment Survey

1. **Are you an Investigator?**
   Yes No

2. **Are you a Nurse?**
   Yes No

3. **Are you Clinical Research Associate?**
   Yes No

4. **Are you a Clinical Research Study Coordinator?**
   Yes No

5. **Are you an Institutional Review Board employee?**
   Yes No

6. **How long have you worked in the clinical research setting?**
   Less than 5 years

   Less than 10 years

   Less than 20 years

   More than 20 years

7. **Why do you work in the area of clinical research?**

_____
_____
_____
_____
_____
_____
_____
_____

8. **Are you familiar with the term "Health Literacy"?**
   Yes No

8.1 If you are familiar with term Health Literacy, in your own words define Health Literacy

_____
_____
_____
_____

1. *For purposes of this research study, we are using the following definition of Health literacy as defined by Healthy People 2010. It is the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.*

8.2 What do you think is the current perception of health literacy and the Informed consent process?

_____
_____
_____
_____
_____

9. **What is your perception of health literacy and the Informed consent process?**

_____
_____
_____
_____
_____

10. **What is your opinion of the relationship between clinical research personnel and subjects?**

_____
_____
_____
_____
_____
_____

11. **How do you rate the relationship between clinical research personnel and subjects?**
    Good Fair Poor

12. **Do you think health Literate Informed Consent Forms will increase subject participation and understanding?**
    Yes No

13. **If you answered yes to question 12, how will you incorporate this in your work place?**

_____
_____
_____
_____
_____
_____

14. Are you aware of any existing health literate informed consent in your work place?

Yes No

15.. If you answered yes to question 14, have they helped increased subject participation and understanding?

_____
_____
_____
_____
_____

16.Do you foresee any value in health literacy for the informed consent process in clinical research?

Yes No

17.If you answered yes to question 16, would you expand upon your answer?

_____
_____
_____
_____
_____

18. you feel that health literacy may be the key to empower patients in the Informed Consent process?

_____
_____
_____
_____

Appendix 3

EMPOWERING PATIENTS THROUGH HEALTH LITERACY IN THE INFORMED CONSENT PROCESS

DEBRIEFING FORM

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1. PURPOSE OF THE STUDY

The study in which you just participated was designed to find out perceived value of Health Literacy in the Informed Consent Process. There have been increasing concerns that subjects/patients may not fully understand what the consent process really means and the process may need improvement

2. METHODOLOGY

In this study you were asked to answer a written survey. No deceptions were involved

3. ADDITIONAL RESOURCES

For more information on the topic of this research,

4. CONTACT INFORMATION

If you are interested in learning more about the research being conducted, or the results of the research of which you were a part, please do not hesitate to contact Gloria L. Riller, glrmonitor@yahoo.com or call 908-930-5033. Or you may contact the faculty advisor, Philip Scibilia DMH, at Drew University, Madison, NJ.

Appendix 4

Conceptual Models of Health Literacy

Reference	Dimensions	Antecedents	Consequences
1 Nutbeam (2000) (36)	-Functional health literacy -Interactive health literacy -Critical health literacy	Health promotion actions (education, social, mobilization, advocacy)	Individual benefits -Improved knowledge of risks -Compliance with prescribed actions, improved capacity to act independently on knowledge -Improved individual resilience to adversity Community/social benefits -Increased participation in population health programs -Improved capacity to influence social norms and interact with social groups. -Improved capacity to act on social and economic determinants of health. -improved community empowerment.

2 Lee et al. (2004) (47)	-Disease and self-care knowledge. -Health risk behavior -Preventive care and physician visits. -Compliance with medications.	-Social-economic status -Gender -Ethnicity -Health insurance coverage -Disease severity -Income discrepancy -Ethnic composition of the community	-Health Status -Emergency care -Hospitalization
3 Institute of Medicine (2004) (8)	-Cultural and conceptual knowledge -Listening -Speaking -Arithmetical skills -Writing skills -Reading skills	-Education, culture and language. -Communication and assessment skills of people with whom individuals interact for health -Ability of the media, the marketplace, and governmental agencies to provide health information in an appropriate manner	Health outcomes and costs
4 Zarcadoolas et al. (2005) (38)	-Fundamental literacy Science literacy -Civic literacy -Cultural literacy	-Health Status -Demographic, sociopolitical, psychosocial and cultural factors	Ability to apply information to novel situations. Ability to participate in public and private dialogues about health, medicine, scientific knowledge and cultural beliefs
5 Speros (2005) (48)	-Reading/numeracy skills	-Literacy -Health –related	-Improved self-reported health

	-Comprehension -Capacity to use health information in decision making -Successful functioning in healthcare consumer role	experience	status -Lower healthcare costs -Increased health knowledge -Shorter hospitalization Less frequent use of healthcare services
6 Baker (2006) (49)	-Health-related print literacy -Health-related oral literacy	-Health-related reading fluency -Health-related vocabulary -Familiarity with health concepts Complexity and difficulty of the printed and spoken messages in the healthcare environment	-Acquisition of new knowledge -More positive attitudes -Greater self-efficacy Positive health behaviors -Better health outcomes
7 Paashe-Orlow & Wolf (2007) (40)	-Listening -Verbal fluency -Memory span -Navigation	-Socioeconomic status Occupation -Employment status Income -Social support -Culture and language -Education -Age -Race/ethnicity Personal competences such as vision, hearing,	-Access and utilization of healthcare (influenced by patients' navigation skills, self-efficacy and perceived barriers, and by system's complexity, acute care orientation and tiered delivery model). -Patient/provider interactions (influenced patients' knowledge, beliefs

		verbal ability, memory and reasoning.	and participation in decision making, and by providers' communication skills, teaching ability, time and patient-centered care). Self care (influenced by patients' motivation, problem-solving, self-efficacy, knowledge/skills, and by support technologies, mass media, health education and resources)
8 Kickbusch & Maag (2008) (2)	-functional -Interactive -Critical	-Education system -Health-care system -Culture/home and community -Work -Politics Market	-Health outcome and costs
9 Mancuso (20) (43)	-Capacity -Comprehension Communication	-Operational competence -Interactive competence -Autonomous competence -Informational	-Healthcare costs -Knowledge of diseases and treatments -Self-management skills -Ability to care for

		competence -Contextual competence -Cultural competence	chronic conditions -Compliance -Medical or medication treatment errors -Access to and use of healthcare services. -Use of expensive services such as emergency care and inpatient admissions. Prevention and screening health-promoting behaviors Health status, defined as physician illness or perceptions of illness, disease or impairment
10 Manganello (2008) (50)	-Functional health literacy -Interactive health literacy -Critical health literacy Media literacy	-Individual traits (age, race, gender, cultural background, cognitive and physical abilities, social skills) -Media use -Peer and parent influences -Mass media, the education system and the health system	-Health behavior -Health costs -Health service use
11 Freedman et al. (2009) (35)	-Conceptual foundations	Social, environmental and	-Resolve some of society's more pressing health

	-Critical skills Civic orientation	political forces	issues -Alleviate social injustices.
12 von Wagner et al.(2009) (51)	-Ability to rely on literacy and numeracy skills when they are required to solve problems	-Epidemiological or structural determinants -individual influences -Reading and arithmetic skills -External influences	-Access and use of healthcare -Patient-provider interaction -Management of health and illness[237]

[237] Sorensen et al., *Health Literacy and Public Health: A Systematic Review and Integration of Definitions and Models*, 6-7.

APPENDIX 5

Definitions of health literacy

1. WHO (1998) The cognitive and social skills which determine the motivation and ability of individuals to gain access to understand and use information in ways which promote and maintain good health.
2. American Medical Association's (1999) The constellation of skills, including the ability to perform basic reading and numeral tasks required to function in the healthcare environment.
3. Nutbeam (2000) The personal, cognitive and social skills which determine the ability of individuals to gain access to, understand, and use information to promote and maintain good health.
4. Institute of Medicine (2004) The individuals capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions.
5. Kickbusch, Wait & Maag (2005) The ability to make sound health decision(s) in the context of everyday life-at home, in the community, at the workplace, the healthcare system, the market place and the political arena. It is a critical empowerment strategy to increase people's control over their health, their ability to seek out information and their ability to take responsibility.
6. Zarcadoolas, Pleasant & Greer (2003, 2005, 2006) The wide range of skills, and competencies that people develop to seek out, comprehend, evaluate and use health information and concepts to make informed choices, reduce health risks and increase quality of life.
7. Paasche-Orlow & Wolf (2006) An individual's possession of requisite skills for making health-related decisions, which means that health literacy must always be examined in the context of the specific tasks that need to be accomplished. The importance of a contextual appreciation of health literacy must be underscored.
8. EU (2007) The ability to read filter and understand health information in order to form sound judgments.
9. Pavlekovic (2008) The capacity to obtain, interpret and understand basic health information and services and the competence to use such information to enhance health.

10. Rootman & Gordon-Elbihbety (2008) The ability to access, understand, evaluate and communicate information as a way to promote, maintain and improve health in a variety of settings across the life course.

11. Ishikawa & Yano (2008) The knowledge, skills and abilities that pertain to interactions with the healthcare system.

12. Mancuso (2008) A process that evolves over one's lifetime and encompasses the attributes of capacity, comprehension, and communication. The attributes of health literacy are integrated within and preceded by the skills, strategies, and abilities embedded within the competencies needed to attain health literacy.

13. Australian Bureau of Statistics (2008) The knowledge and skills required to understand and use information relating to health issues such as drugs and alcohol, disease prevention and treatment, safety and accident prevention, first aid, emergencies, and staying healthy.

14. Yost et al. (2009) The degree to which individuals have the capacity to read and comprehend health-related print material, identify and interpret information presented in graphical format (charts, graphs and tables), and perform arithmetic operations in order to make appropriate health and care decisions.

15. Adams et al. (2009) The ability to understand and interpret the meaning of health information in written, spoken or digital form and how this motivates people to embrace or disregard actions relating to health.

16. Adkins et al. (2009) The ability to derive meaning from different forms of communication by using a variety of skills to accomplish health-related objectives.

17. Freedman et al. (2009) The degree to which individuals and groups can obtain process, understand, evaluate, and act upon information needed to make public health decisions that benefit the community.[238]

[238] Sorensen et al., *Health Literacy and Public Health: A Systematic Review and Integration of Definitions and Models*, 6-7.

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