Clinical Trials Informed Consent

An educational intervention to improve nurses' knowledge and communications skills

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BACKGROUND: Teach-back is an evidence-based tool recommended for use during informed consent (IC) discussions. The nurses' role in the IC process is important, particularly for patient education and advocacy.

OBJECTIVES: The aim was to initiate and evaluate an educational program for nurses to improve knowledge and communication skills used in IC for cancer clinical trials.

METHODS: An educational program was presented to nurses. Anonymous pre-, post-, and one-month postprogram surveys measured nurses' knowledge of research and the importance of and confidence using teach-back during IC discussions.

FINDINGS: Nurses had high research knowledge scores and statistically significant improvement in pre- and post-test scores of conviction and confidence using teach-back. Nurses employed essential elements of teach-back before the program but had greater recognition of elements after the program.

KEYWORDS
informed consent; cancer; nursing; patient understanding; teach-back

DIGITAL OBJECT IDENTIFIER
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CLINICAL TRIALS ARE DESIGNED TO INVESTIGATE NEW TREATMENTS and discover the safety and efficacy of novel agents or modification of an existing regimen. The National Institutes of Health (2018) reports 288,177 research studies worldwide; 64,467 are cancer-related. Informed consent (IC) is required for participation in clinical trials and is based on historically significant events and grounded in the ethical principles of respect for people, beneficence, and justice (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). Federal regulations intended to protect participants in research define the basic requirements for IC. Included in these are the following (U.S. Department of Health and Human Services Office for Human Research Protections, 1998; U.S. Food and Drug Administration, 2018):

- Disclosure that the study involves research, that participation is voluntary, and of costs associated with participation
- An explanation of the risks and benefits, how confidentiality is maintained, and who to contact for questions

A change was made to the federal Common Rule governing consent for clinical research (U.S. Department of Health and Human Services, 2017). The new rule is aimed at strengthening protection for people who volunteer to participate in research and highlights efforts to promote understanding of clinical research participation. The importance of nurse involvement in the IC process for patient education, for adherence to ethical standards, for study adherence, and to advocate for patients is recognized by the Oncology Nursing Society ([ONS], 2016) and the American Nurses Association ([ANA], 2016). One recommended core competency for oncology clinical trials nurses is to "demonstrate leadership in ensuring patient comprehension and safety during initial and ongoing IC discussions" (ONS, 2016, p. 12). However, the complexity of cancer-related clinical trials presents additional challenges to the IC process; this has resulted in abundant research addressing issues related to patient understanding of IC.

Literature Review

The electronic databases PubMed, CINAHL®, Cochrane Database, and OVID were searched for articles published from 2000–2017. Search terms were as

follows: *informed consent*, *cancer*, *patient understanding*, *interventions*, and *nursing*. Because of the nature of this project, the focus of the literature review was narrowed to cancer-related articles and studies.

Understanding of Informed Consent

In one systematic review looking at data related to understanding of IC during a 30-year period, 103 studies were reviewed; 33% were cancer-related (Nguyen Thanh et al., 2015). The authors reported that patients understood 52%–76% of some required components of IC. They found concepts such as randomization and placebo poorly understood; unfortunately, this has not changed in the past 30 years (Nguyen Thanh et al., 2015). Similarly, Nishimura et al. (2013) reported a systematic review of 54 interventions and a meta-analysis of 22 interventions in randomized, controlled trials to look at patient understanding of IC. They reported that enhanced consent forms and extended discussions were the most effective in improving patient understanding. In a previous systematic review, Flory and Emanuel (2004) found that having a research team member spend time with patients one-on-one appeared to be the most effective way of improving patient understanding.

Interventions to improve patient understanding and decision making during the IC process have had mixed results. Kao, Aranda, Krishnasamy, and Hamilton (2017) reviewed interventions to improve patient understanding in cancer-related clinical trials. These included communication skills workshops, audiovisual information, and written information. Their findings indicate that interventions may improve patient satisfaction of the IC process; however, the effect of interventions is unclear regarding understanding. Schumacher et al. (2017) reported that at least 80% of patients (N = 50) enrolling in cancer clinical trials responded incorrectly to required elements of IC (experimental nature of the trial, efficacy, potential risks), supporting evidence of continued lack of understanding of essential IC elements. Garrett et al. (2017) looked at patients with advanced cancer and assessed their knowledge about research. They found that patients could identify some study specifics but often did not understand the general purpose and procedures of clinical trials. Joffe, Cook, Cleary, Clark, and Weeks (2001b) conducted a cross-sectional survey of patients with cancer and found overall satisfaction with the IC process. They found level of education, language spoken at home, not signing the IC during the first discussion about the trial, reading the consent form prior, and the presence of a nurse during the discussion among factors that improved patient knowledge.

Health Literacy

During IC discussions with study participants, health literacy or reading level assessment is often minimal or inconsistent (Agency for Healthcare Research and Quality [AHRQ], 2015a; Montalvo

TABLE 1.
EDUCATION PROGRAM ON INFORMED CONSENT FOR CANCER CLINICAL TRIALS

TOPIC	DISCUSSION	REFERENCES
History of informed consent	■ Based on ethical principles and historic events ■ Review of 8 basic elements of informed consent ■ Required for participation ■ Responsibility of healthcare providers	National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979; U.S. Food and Drug Administration, 2018
Role of the nurse in informed consent	■ Patient education ■ Safety ■ Advocacy ■ Varies according to local practice and policy	American Nurses Association, 2016; Oncology Nursing Society, 2016
Barriers to patient understanding of informed consent	■ Language ■ Culture ■ Age ■ Health literacy ■ Assessment of health literacy	Agency for Healthcare Research and Quality, 2015a; Cohen et al., 2013; Davis et al., 2002; Hallinan et al., 2016; Lentz et al., 2016; Sudore et al., 2006
Interventions studied	■ Enhanced consent form ■ Multimedia ■ One-on-one conversation	Kao et al., 2017; Nishimura et al., 2013
Teach-back	■ What is teach-back? ■ Elements of teach-back and examples of using teach-back during informed consent	Agency for Healthcare Research and Quality, 2015b; Ha Dinh et al., 2016; Jefford & Moore, 2008; National Quality Forum, 2005
Discussion of best practice	■ Barriers found in your current practice ■ Have you tried interventions? What works?	–

& Larson, 2014). Perrenoud, Velonaki, Bodenmann, and Ramelet (2015) systematically reviewed evidence related to health literacy interventions. They suggested that improving readability and simplification of the document using audiovisual or multimedia aids may help patients with low literacy. Tamariz, Palacio, Robert, and Marcus (2013) looked at evidence that supported interventions to improve the IC process in patients with low literacy. They identified studies that suggest patients have improved understanding when they interact with study team members.

Teach-Back

Teach-back or teach-to-goal is an evidence-based method to verify patient understanding and is recommended during IC discussions (Baer, Good, & Schapira, 2011; Fidyk, Ventura, & Green, 2014; Jefford & Moore, 2008; Lentz, Kennett, Perlmutter, & Forrest, 2016; Montalvo & Larson, 2014; Sudore et al., 2006). Teach-back has been found to have positive effects in healthcare outcomes and to be effective for patients with low health literacy (Ha Dinh, Bonner, Clark, Ramsbotham, & Hines, 2016; Kripalani, Bengtzen, Henderson, & Jacobson, 2008). Kripalani et al. (2008) recommended the practice of teach-back because it is feasible and generalizable in research settings, allowing patients the opportunity for immediate feedback from researchers.

After recognizing the need to improve patient understanding of IC, AHRQ (2015b) and the National Quality Forum ([NQF], 2005) developed recommendations and guidelines that include the use of teach-back in the IC process. Two articles (Baer et al., 2011; Cohen, Jenkins, Holston, & Carlson, 2013) identified the use of teach-back in studies related to patients with cancer and recommended the use of this method with patients. Sudore et al. (2006) studied teach-to-goal during the IC process for a study related to advance directives.

TABLE 2.
SAMPLE CHARACTERISTICS (N = 26)

CHARACTERISTIC	$\bar{X}$	RANGE
Years of nursing experience		
RN or nurse practitioner	20	3–40
Clinical research nurse	6	0–17
CHARACTERISTIC		**n**
Highest level of education		
BSN		13
MSN		11
DNP		1
MPH		1

"Participants reported increased conviction and confidence using teach-back after the education program."

This study had a large, ethnically diverse sample and measured how many times authors needed to repeat information related to specific aspects of the study using the teach-to-goal method. Using this method, they found that 98% of participants, including those with literacy and language barriers, demonstrated understanding of the information presented to them.

Nurses' Role in Informed Consent

Nurses' role in IC may vary from one institution to another and is guided by local policy and practice. Evidence of improved patient understanding when a nurse was present during IC discussions was noted by Joffe et al. (2001b). Recurring themes in the literature support staff training programs in the IC process, one-on-one extended interactions during IC discussions, and the importance of having a knowledgeable person present (Jefford & Moore, 2008; Lentz et al., 2016; Nishimura et al., 2013; Nusbaum, Douglas, Estrella-Luna, Paasche-Orlow, & Damus, 2017). Studies support teach-back education programs for providers to improve IC discussion, but application in oncology nursing practice has not been thoroughly studied.

This article reports on the evaluation of an educational program to improve patient understanding of IC. The program objectives were to initiate and measure the effects of an education program for nurses aimed at improving knowledge and communication skills during IC discussions for cancer clinical trials.

Methods

Design

To evaluate the program, the design was a one-group, pre-/post-test quasiexperimental design. The program evaluation was approved by the Dana-Farber/Harvard Cancer Center and University of Massachusetts Lowell institutional review boards. IBM SPSS Statistics, version 25.0, and Microsoft Excel® were used for data analysis and graphs.

Education Program

The education program consisted of a 60-minute lecture with a Microsoft PowerPoint® presentation. The content is described in

Table 1. The program participants were encouraged to visit the AHRQ and NQF websites for more detailed information related to the use of teach-back during IC (AHRQ, 2015a, 2015b; NQF, 2005). These sites provide a comprehensive guide for using teach-back during IC. Examples of teach-back include the following:

- "It's my job to explain things clearly. To make sure I did this, please tell me, in your own words, what the risks of being in this trial are?"
- "This is important for your safety. I want to make sure you understand. Please tell me how you are going to take the study medications."

An essential element of teach-back is using nonshaming language and putting the responsibility for patient understanding on the nurse.

Sample and Setting

The sample was a convenience sample of nurses at Dana-Farber Cancer Institute. Recruitment took place via email notification using the nursing department email distribution list. Consent was implied by attendance of the program and completion of the surveys. Continuing education units were offered on completion of a program evaluation.

Procedures

Paper surveys were used to collect pre- and immediately postprogram data. The one month postprogram survey data were collected using Qualtrics, a web-based survey application. The preprogram survey collected demographic data, answer to an open-ended question, and perceived patient understanding of clinical trials using a modified version of the Quality of Informed Consent, Part B (QuIC-B) (Joffe et al., 2001a). Research knowledge was measured using the Research and Knowledge Scale (RaKS) (Powell et al., 2017), and fundamentals of teach-back were measured with the Conviction and Confidence Scale (CCS) (AHRQ, 2015b) at all time points. Permission to use RaKS and QuIC-B were obtained from the authors.

TABLE 3.
MEAN CONVICTION AND CONFIDENCE SCORES

	PRETEST (N = 26)		POST-TEST (N = 26)		1 MONTH POST-TEST (N = 22)	
QUESTION	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD
How convinced are you that it is important to use teach-back?	8.5	1.79	9.46	0.706	9.14	1.36
How confident are you in your ability to use teach-back?	7.38	1.65	8.69	1.54	8.55	1.76

Note. Scores range from 1 (not important) to 10 (very important).

IMPLICATIONS FOR PRACTICE

- Recognize the importance of patient education, and participate in up-to-date, evidence-based education programs to ensure continued learning and competency.
- Use teach-back, an evidence-based intervention, during informed consent discussions.
- Meet specific patient needs for education and validate understanding by using teach-back.

Measures

Joffe et al. (2001a) developed the QuIC for patients with cancer. It is based on the eight elements of IC required by the federal government. Content validity was reviewed by bioethicist consultants, and the survey was pilot-tested. Test–retest reliability demonstrated that the interclass correlation coefficient between two administrations was 0.77. This is the most frequently cited tool used in studies of patient understanding found in the current literature. For this project, Part B (subjective understanding) was used and modified to reflect nurses' perceived level of patient understanding. It includes 14 questions, which are measured on a five-point ordinal scale ranging from 1 (no understanding) to 5 (understands very well). The raw average for each participant was scaled on a normalized scale ranging from 0–100 (summary score = [raw average – 1] x 25).

The RaKS was developed to measure a patient's ability to understand and process information about research (research literacy). The scale has 16 true-or-false statements and was designed using evidence from literature, focus groups of former research participants, and a review of IC documents. The authors identified eight domains of research literacy that were relevant to health-related research, including "understanding of: goals of research, human subject protections, ethical research conduct, randomization and experimentation, relationship between research and treatment, confidentiality, research as a choice, and researcher responsibility" (Powell et al., 2017, p. 118). Using classic theory testing (Kuder-Richardson Formula 20 [KR-20]), the authors reported internal consistency (KR-20 = 0.81) and test–retest reliability (r = 0.84). They found preliminary internal consistency reliability and validity of this tool to assess knowledge and understanding of research by individuals. A score of 100% indicates greater knowledge and understanding of research. Although designed for patients, this tool seemed appropriate to use to measure nurses' knowledge of research.

The CCS is included in the AHRQ IC toolkit and is recommended for use in healthcare settings. Two questions are measured on a 10-point ordinal scale ranging from 1 (not important) to 10 (very important). The questions ask, "How convinced are you that it is important to use teach-back?" and "How confident are you in your ability to use teach-back?" (AHRQ, 2015b). The survey asks nurses to identify essential elements of teach-back used in practice, including the following: "use a caring tone of voice and attitude; display comfortable body language, make eye contact, and sit down; use plain language; ask the patient to explain, in their own words, what they were told;

use nonshaming open-ended questions; avoid asking questions that can be answered with a yes or no; take responsibility for making sure you were clear; explain and check again if the patient is unable to teach-back; use reader-friendly print materials to support learning; document use of and patient's response to teach-back; and include family members/caregivers if they were present" (AHRQ, 2015b, p. 2).

Results

Twenty-six nurses attended the program. The participants included 22 RNs and four nurse practitioners (see Table 2). Participants were asked, "What do you consider the most important role of a research nurse?" Participants could choose more than one response. Responses were organized into the following major categories and included patient education (n = 16), patient advocacy and navigation (n = 8), monitoring toxicity (n = 4), and confirmation of eligibility and IC (n = 2). The QuIC-B mean score was 61% (SD = 15.96).

Ratio data from scores of the RaKS were compared (preprogram, $\bar{X}$ = 91, SD = 6.19; postprogram, $\bar{X}$ = 90, SD = 6.6; one month postprogram, $\bar{X}$ = 91, SD = 5.67). Repeated-measures analysis of variance (ANOVA) of mean scores was nonsignificant, ($F[2, 42] = 0.193$, $p = 0.825$). Ratio data from scores of the CCS were compared (see Table 3). Repeated-measures ANOVA of mean scores were significant for conviction ($F[2, 42] = 7.61$, $p = 0.002$) and confidence ($F[2, 42] = 8.715$, $p < 0.001$). Participants used elements of teach-back before the program; however, they could identify elements with greater frequency after the program (see Table 4).

Discussion

Knowledgeable members of the research team (including nurses) being present during IC discussions is encouraged, but very little has been written specifically for nurses. Nurses who participated in this project were experienced, representing years in nursing and research (oncology clinical trials), and demonstrated high research knowledge scores (RaKS). They recognized the importance of their role in education and advocacy for patients entering clinical trials. Their perception of patients having low understanding of some fundamental aspects of clinical trials expands on previous findings in the literature. The low QuIC-B mean score (61%) of nurse perception of patient understanding is an important finding. Previous studies reported actual patient scores of the QuIC-B from 80%–90% (Bergenmar, Johansson, Wilking, Hatschek, & Brandberg, 2014; Ha Dinh et al., 2016; Hoffner et al., 2012; Joffe et al., 2001b; Shiono et al., 2014). This discrepancy supports the need for nurses to explore methods to improve patient understanding, whether real or perceived.

Teach-back was introduced in this program as a method that provides real-time assessment of patient understanding and is feasible to use during IC discussions. Information that is available online (AHRQ, 2015b; NQF, 2005) can be adapted for local

TABLE 4.
ELEMENTS OF TEACH-BACK USED IN PRACTICE

ELEMENT	PRETEST (N = 26) n	POST-TEST (N = 26) n	1 MONTH POST-TEST (N = 22) n
Use a caring tone of voice and attitude.	25	26	22
Display comfortable body language, make eye contact, and sit down.	26	26	22
Use plain language.	25	25	21
Ask patients to explain, in their own words, what they were told.	15	22	16
Use nonshaming, open-ended questions.	18	22	18
Avoid asking questions that can be answered with a yes or no.	11	14	17
Take responsibility for making sure you were clear.	25	22	22
Explain and check again if the patient is unable to teach back.	16	20	18
Use reader-friendly print materials to support learning.	19	21	16
Document use of and patient's response to teach-back.	10	15	20
Include family members or caregivers if they are present.	26	26	22

practice and introduced to nurses in education programs, workshops, or orientation programs. Participants in this program reported increased conviction and confidence using teach-back after the education program. Essential elements of teach-back were being used prior to the education program; however, participants had greater recognition of the elements following the program. These evaluation results underscore that nurses can better manage the IC process, addressing factors that influence patients' understanding of IC. Additional studies can confirm that using teach-back during cancer clinical trials IC discussions can verify patient understanding and outcomes.

Limitations

The project was conducted in one setting, an academic cancer center, and findings may not be generalizable. Methodological limitations included a small sample size. The RaKS was designed for patients, not healthcare providers, and is a newly developed tool with evidence of prior use only by original authors. The QuIC-B, also designed for patients, required modification to assess perceived, not subjective, patient understanding. The CCS is included in the AHRQ toolkit; however, use of this tool in other studies or projects was not found in published literature.

Conclusion

This program evaluation confirmed that teach-back is an effective method for oncology nurses to master to improve patient understanding of IC for clinical trials. Evaluation of this program suggests that nurses had high research knowledge scores and statistically significant improvement in pre- and post-program test scores of conviction and confidence using the teach-back method.

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REFERENCES

Agency for Healthcare Research and Quality. (2015a). Health literacy: Hidden barriers and practical strategies. Retrieved from http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/tool3a/index.html

Agency for Healthcare Research and Quality. (2015b). *Use the teach-back method: Tool #5.* Retrieved from https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/healthlittoolkit2_tool5.pdf

American Nurses Association. (2016). *The nurse's role in ethics and human rights: Protecting and promoting individual worth, dignity, and human rights in practice settings.* Retrieved from https://www.nursingworld.org/~4af078/globalassets/docs/ana/ethics/ethics-and-human-rights-protecting-and-promoting-final-formatted-20161130.pdf

Baer, A.R., Good, M., & Schapira, L. (2011). A new look at informed consent for cancer clinical trials. *Journal of Oncology Practice, 7,* 267–270. https://doi.org/10.1200/JOP.2011.000347

Bergenmar, M., Johansson, H., Wilking, N., Hatschek, T., & Brandberg, Y. (2014). Audio-recorded information to patients considering participation in cancer clinical trials—A randomized study. *Acta Oncologica, 53,* 1197–1204. https://doi.org/10.3109/0284186X.2014.921726

Cohen, M.Z., Jenkins, D., Holston, E.C., & Carlson, E.D. (2013). Understanding health literacy in patients receiving hematopoietic stem cell transplantation. *Oncology Nursing Forum, 40,* 508–515. https://doi.org/10.1188/13.ONF.508-515

Davis, T.C., Williams, M.V., Marin, E., Parker, R.M., & Glass, J. (2002). Health literacy and cancer communication. *CA: A Cancer Journal for Clinicians, 52,* 134–149. https://doi.org/10.3322/canjclin.52.3.134

Fidyk, L., Ventura, K., & Green, K. (2014). Teaching nurses how to teach: Strategies to enhance the quality of patient education. *Journal for Nurses in Professional Development, 30,* 248–253. https://doi.org/10.1097/NND.0000000000000074

Flory, J., & Emanuel, E. (2004). Interventions to improve research participants' understanding in informed consent for research: A systematic review. *JAMA, 292,* 1593–1601. https://doi.org/10.1001/jama.292.13.1593

Garrett, S.B., Koenig, C.J., Trupin, L., Hlubocky, F.J., Daugherty, C.K., Reinert, A., . . . Dohan, D. (2017). What advanced cancer patients with limited treatment options know about clinical research: A qualitative study. *Supportive Care in Cancer, 25,* 3235–3242. https://doi.org/10.1007/s00520-017-3734-4

Ha Dinh, T.T., Bonner, A., Clark, R., Ramsbotham, J., & Hines, S. (2016). The effectiveness of the teach-back method on adherence and self-management in health education for people with chronic disease: A systematic review. *JBI Database of Systematic Reviews and Implementation Reports, 14,* 210–247. https://doi.org/10.11124/jbisrir-2016-2296

Hallinan, Z.P., Forrest, A., Uhlenbrauch, G., Young, S., & McKinney, R., Jr. (2016). Barriers to change in the informed consent process: A systematic review of the literature. *IRB, 38*(3), 1–10.

Hoffner, B., Bauer-Wu, S., Hitchcock-Bryan, S., Powell, M., Wolanski, A., & Joffe, S. (2012). "Entering a clinical trial: Is it right for you?": A randomized study of the clinical trials video and its impact on the informed consent process. *Cancer, 118,* 1877–1883. https://doi.org/10.1002/cncr.26438

Jefford, M., & Moore, R. (2008). Improvement of informed consent and the quality of consent documents. *Lancet, 9,* 485–493. https://doi.org/10.1016/S1470-2045(08)70128-1

Joffe, S., Cook, E.F., Cleary, P.D., Clark, J.W., & Weeks, J.C. (2001a). Quality of informed consent: A new measure of understanding among research subjects. *Journal of the National Cancer Institute, 93,* 139–147. https://doi.org/10.1093/jnci/93.2.139

Joffe, S., Cook, E.F., Cleary, P.D., Clark, J.W., & Weeks, J.C. (2001b). Quality of informed consent in cancer clinical trials: A cross-sectional survey. *Lancet, 358,* 1772–1777. https://doi.org/10.1016/S0140-6736(01)06805-2

Kao, C.Y., Aranda, S., Krishnasamy, M., & Hamilton, B. (2017). Interventions to improve patient understanding of cancer clinical trial participation: A systematic review. *European Journal of Cancer Care, 26*(2), e12424. https://doi.org/10.1111/ecc.12424

Kripalani, S., Bengtzen, R., Henderson, L.E., & Jacobson, T.A. (2008). Clinical research in

low-literacy populations: Using teach-back to assess comprehension of informed consent and privacy information. *IRB, 30*(2), 13–19.

Lentz, J., Kennett, M., Perlmutter, J., & Forrest, A. (2016). Paving the way to a more effective informed consent process: Recommendations from the Clinical Trials Transformation Initiative. *Contemporary Clinical Trials, 49,* 65–69. https://doi.org/10.1016/j.cct.2016.06.005

Montalvo, W., & Larson, E. (2014). Participant comprehension of research for which they volunteer: A systematic review. *Journal of Nursing Scholarship, 46,* 423–431. https://doi.org/10.1111/jnu.12097

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *Belmont report: Ethical principles and guidelines for the protection of human subjects of research* (DHEW Publication No. [05] 78-0012). Washington, DC: U.S. Government Printing Office.

National Institutes of Health. (2018). Finding a clinical trial. Retrieved from https://www.nih.gov/health-information/nih-clinical-research-trials-you/finding-clinical-trial

National Quality Forum. (2005). Improving patient safety through informed consent for patients with limited health literacy. Retrieved from http://www.qualityforum.org/Publications/2005/09/Improving_Patient_Safety_Through_Informed_Consent_for_Patients_with_Limited_Health_Literacy.aspx

Nguyen Thanh, T., Nguyen Tien, H., Le Thi Bich, T., Nguyen Phuoc, L., Nguyen Thi Huyen, T., Kenji, H., & Juntra, K. (2015). Participants' understanding of informed consent in clinical trials over three decades: Systematic review and meta-analysis. *Bulletin of the World Health Organization, 93,* 186–198H. https://doi.org/10.2471/BLT.14.141390

Nishimura, A., Carey, J., Erwin, P.J., Tilburt, J.C., Murad, M.H., & McCormick, J.B. (2013). Improving understanding in the research informed consent process: A systematic review of 54 interventions tested in randomized control trials. *BMC Medical Ethics, 14,* 28. https://doi.org/10.1186/1472-6939-14-28

Nusbaum, L., Douglas, B., Estrella-Luna, N., Paasche-Orlow, M., & Damus, K. (2017). Survey of risks and benefits communication strategies by research nurses. *Nursing Ethics,* 969733017734410. https://doi.org/10.1177/0969733017734410

Oncology Nursing Society. (2016). *2016 oncology clinical trials nurse competencies*. Retrieved from https://www.ons.org/sites/default/files/OCTN_Competencies_FINAL.PDF

Perrenoud, B., Velonaki, V.S., Bodenmann, P., & Ramelet, A.S. (2015). The effectiveness of health literacy interventions on the informed consent process of health care users: A systematic review protocol. *JBI Database of Systematic Reviews and Implementation Reports, 13*(10), 82–94. https://doi.org/10.11124/jbisrir-2015-2304

Powell, L.R., Ojukwu, E., Person, S.D., Allison, J., Rosal, M.C., & Lemon, S.C. (2017). Psychometric development of the research and knowledge scale. *Medical Care, 55,* 117–124.

Schumacher, A., Sikov, W.M., Quesenberry, M.I., Safran, H., Khurshid, H., Mitchell, K.M., & Olszewski, A.J. (2017). Informed consent in oncology clinical trials: A Brown University Oncology Research Group prospective cross-sectional pilot study. *PLOS ONE, 12*(2), e0172957.

Shiono, Y.N., Zheng, Y.F., Kikuya, M., Kawai, M., Ishida, T., Kuriyama, S., & Ohuchi, N. (2014). Participants' understanding of a randomized controlled trial (RCT) through informed consent procedures in the RCT for breast cancer screening, J-START. *Trials, 15,* 375. https://doi.org/10.1186/1745-6215-15-375

Sudore, R.L., Landefeld, C.S., Williams, B.A., Barnes, D.E., Lindquist, K., & Schillinger, D. (2006). Use of a modified informed consent process among vulnerable patients: A descriptive study. *Journal of General Internal Medicine, 21,* 867–873.

Tamariz, L., Palacio, A., Robert, M., & Marcus, E.N. (2013). Improving the informed consent process for research subjects with low literacy: A systematic review. *Journal of General Internal Medicine, 28,* 121–126. https://doi.org/10.1007/s11606-012-2133-2

U.S. Department of Health and Human Services. (2017, January 18). Final rule enhances protections for research participants, modernizes oversight system [Press release]. Retrieved from https://www.hhs.gov/about/news/2017/01/18/final-rule-enhances-protections-research-participants-modernizes-oversight-system.html

U.S. Department of Health and Human Services Office for Human Research Protections. (1998). Informed consent checklist. Retrieved from https://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/index.html

U.S. Food and Drug Administration. (2018). Informed consent for clinical trials. Retrieved from https://www.fda.gov/ForPatients/ClinicalTrials/InformedConsent/default.htm