

READABILITY AND LANGUAGE OF INFORMED CONSENT

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Writing informed consent forms at a sixth grade reading level and making them understandable to study subjects is a challenge. Consent form language is shaped both by 1) concepts, categories and value judgments (CCVJ) as well as 2) an emerging public relations vocabulary. First, a few examples are provided because CCVJ are too easily misunderstood by prospective subjects. Second, the ways in which a public relations vocabulary shapes consent form language, including subject perceptions of research and the therapeutic misconception (in which subjects believe that they will directly benefit from medical research) are discussed.

Introduction

IRBs often require informed consent forms to be written at a sixth grade reading level. According to Rudolf Flesch's Reading Ease Score, this requires a writing style with an average sentence length of 14 words, and 139 syllables per 100 words (i.e., many short words). Writing consent forms at the sixth grade reading level may be almost impossible. (See Hochhauser, M. *Why You Can't Write a Consent Form at a Sixth-Grade Reading Level*. *DIA Forum*, 2002, 38(2), 22-25.)

Paasche-Orlow and Taylor reviewed readability standards at 114 United States medical school Websites. Using the Flesch-Kincaid readability formula in Microsoft Word, they found an average 10.6 grade for these 114 consent form templates. But as they note, this may be an underestimate because Word inexplicably scores only to grade 12. But the Fry readability scale averaged grade 13 for consent form templates, meaning that the average readability score exceeded

the stated standard by 2.8 to 6 grades. Only 8% of medical schools had templates that met their own standards!

Concepts, Categories, and Value Judgments

Consent form language of informed consent is shaped by concepts, categories, and value judgments (CCVJ), as described by Doak, Doak and Root (See Hochhauser, M. *Concepts, Categories and Value Judgments In Informed Consent Forms*. *IRB: Ethics & Human Research*, 2003, 25(5), in press.)

Concepts are easily misunderstood because they describe general ideas, abstract concepts, or references. A few examples of concept words I found in 10 informed consents are "at random," "investigational drug," "research study," and "standard medical therapy." While categories describe groups of things ("adverse reactions," "clinical study procedures," and "risks and benefits"), value judgments describe amounts or thresholds for action ("common side effects," "moderate increase," and "usual dose").

Better explanations of CCVJ should improve consent form comprehension. For example, within the context of European Directive guidelines, Berry, Knapp, and Raynor analyzed how 200 undergraduates estimated prescription drug side effects. Students always overestimated the risks; they judged that "very common" side effects would affect 65% of patients, while the actual European Union definition was "more than 10%."

Table 1 provides a few sample explanations for CCVJ frequently used in informed consent forms. For example, the concept "assigned by chance" can be explained as "assigned by a coin toss." The category "concomitant medications" can be explained as "drugs you take at the same time such as" The value judgment "common side effects" can be explained as "side effects experienced by x% of subjects."

TABLE 1
Concepts, Categories, Value Judgments (CCVJ)
and their Explanations

| | |
|------------------------------------|---|
| Concepts | Explanations |
| assigned by chance | assigned by a coin toss |
| childbearing potential | if you could get pregnant |
| current and previous health status | your health history |
| financial compensation | we will pay for/we will not pay for |
| identifiable information | your name and address |
| oral administration | swallow a pill |
| placebo | sugar pill |
| scientific presentation | a talk at a medical conference |
| screening process | test you for . . . |
| sponsor | XZY Drug Company |
| | |
| Categories | Explanations |
| abnormal laboratory tests | abnormal blood test results for . . . |
| benefits to which you are | your health plan benefits; your patient rights otherwise entitled in this state |
| | |
| concomitant medications | drugs you take at the same time such as . . . |
| foreseeable risks and discomforts | you might have these six problems . . . |
| investigational medications | experimental drugs not yet approved |
| information protection laws | laws that protect your privacy |
| most common side effects | the x most common effects you can have are. . . |
| regular blood tests | a blood test every month |
| | |
| Value Judgments | Explanations |
| common side effects | side effects experienced by x% of subjects |
| mild-to-moderate nausea | nausea without vomiting |
| long-term | more than x months |
| minimum duration | less than xx minutes/hours |
| no medical benefits | will not cure . . . |
| rapid infusion | less than x minutes |
| rare occasions | fewer than x% of subjects |
| reasonable medical costs | we will pay for . . . /we will not pay for . . . |
| reported infrequently | less than x% of subjects reported . . . |
| serious allergic reaction | a reaction so serious that you need emergency treatment/hospitalization |
| | |
| usual dose | 1 pill x times per day |
| very rarely | less than x% of subjects will experience |

Public Relations and Informed Consent

The language of informed consent is also being shaped by public relations vocabulary (See Hochhauser, M. *Is "Therapeutic Misconception" being used to recruit subjects?* ARENA Newsletter, 2003, XVI(2), 5-7.)

Brescia's 1999 article on patient (not subject!) recruiting placed patient recruiting squarely within a public relations communication perspective. She suggested that researchers:

1. Include catchy and memorable "virtual brand" name acronyms for clinical trials. [But such acronyms can be misleading by suggesting that a clinical trial is more effective has actually been shown.]
2. Include advertising campaigns to reach the audience, public relations to establish credibility and trust, and grass-roots level groups to spread the word through media-based disease awareness campaigns. [Is someone in a clinical trial a "patient" or a "subject?" Federal regulations refer to "subjects," but some clinical trial advertising refers to "patients."]
3. Conduct planning studies to discover how patients feel about their condition, the kind of language they use and are responsive to, what makes them feel better, what prompts them to take action, and so forth.

Patient perceptions of research are important aspects of this public relations approach and have been used as a subject recruiting strategy (Table 2). In their research on patient preferences, Sugarman and Kass found that 90% had very favorable/favorable attitudes about medical research; 70% thought medical research usually/always advanced medical science. Patients thought that medical experiments were riskier than medical research (70% vs. 10%), but that medical research was riskier than medical studies or clinical investigations. Patients thought that they would be better off in medical research than in medical experiments, clinical trials, or clinical investigations.

Sugarman and Kass concluded that:

- The words that researchers chose to describe research created very different meanings for patients. "Medical study" was the most positive phrase; "medical experiment" was the riskiest phrase,
- Potential subjects may not understand crucial differences between research and standard treatment, and
- Most patients seem to be motivated by self-interest (to get better treatments) and altruism (to help others and to advance science).

The graveyard of discarded therapies speaks to the value of being in the control group." Dr. Thomas Chalmers, former dean of the Mt. Sinai School of Medicine and a clinical trial specialist)

Therapeutic misconceptions about research are ethically troubling. Appelbaum et al. found many research subjects believing that research projects would medically benefit them. Despite what they are told and read in the consent form, some subjects see no conflicts between research and treatment, especially if the researcher is also their personal physician.

Therapeutic misconceptions can be used as a subject recruiting strategy. Although bioethicists are concerned about therapeutic misconception and how it might produce uninformed/misinformed consent, public relations and subject recruiting firms are actively using therapeutic misconception as a recruiting strategy. For example, Joan Bachenheimer, CEO of BBK Healthcare, said, "The millions of Americans who sign up for medical research are partners in the process and view research studies as treatment options, as do physicians." Carolyn Aldige of the Cancer Research Foundation said, "The key to getting around the barriers that surround words like experimental and investigational is education."

TABLE 2
Patient Perceptions of Research

- 90% of patients had very favorable/favorable attitudes about medical research
- 70% of patients thought medical research usually/always advanced medical science
- Patients thought medical experiments were riskier than medical research (70% vs. 10%), but that medical research was riskier than medical studies or clinical investigations
- Subjects thought they would be better off in medical research than in medical experiments, clinical trials, or clinical investigations

Dr. Robert L. Comis of the Coalition of National Cancer Cooperative Groups said, “In particular, we believe that Cancer Clinical Trials offer a frontline treatment option that you should consider while conducting your research and planning your attack with your doctor.”

Harris Interactive, which recruits subjects for clinical trials, said, “The challenge for clinical research is to persuade more people that they will not suffer as a result of participating and that they will be treated as patients and not as guinea pigs.

They should understand that they are not likely to suffer more pain or side effects from the experimental treatments than they would from standard treatments.” (See Hochhauser, M. *DTC clinical trial advertising (letter)*. *Applied Clinical trials*, 2002, 11(6), 1).

Research and treatment are not the same because of: 1) randomization, 2) study protocols that limit individualized treatment, 3) researcher ignorance of what subjects are getting in a double-blind studies, 4) control groups, and 5) rights specific to human

subjects (Table 3). To improve “informed” consent, researchers should minimize therapeutic misconceptions by telling prospective subjects how research and treatment are different:

- Research (which produces general knowledge) is different from treatment (which involves personalized patient care).
- Medical care is individualized for each patient; research is standardized for all subjects.
- Describe experimentation and randomization.
- Describe placebos (if being used).
- Describe inclusion/exclusion criteria.

TABLE 3
Why Research is Not Treatment

As a human subject in research . . .

You are a subject in research, not a patient for getting standard treatment for your disease

All subjects get standard treatment

Research produces generalizable results that might help others; it may not help you

You may get an experimental treatment or standard treatment or placebo

Your treatment will be determined based on random assignment

Research requires inclusion and exclusion and criteria for each subject

Research MDs do not know what drug you get in a double-blind study

You have human subject rights; your research information may be shared with . . .

Research is not treatment. Informed consent is required

As a patient being treated . . .

You are a patient getting standard treatment your disease

All patients get individualized treatment

Treatment is expected to help you

You will get the best available standard treatment

Your treatment will be determined based on your individual needs

Standard treatment does not have inclusion exclusion criteria to be treated

Personal MDs know what drug you are taking

You have patient rights; your patient information may be shared with . . .

Treatment is not research. Informed consent is not required

- Tell prospective subjects they are subjects in research, not patients getting a new treatment.
- Describe a subject's rights and benefits.
- Describe how research information is shared. (Research privacy rights under HIPAA are different from treatment privacy rights).

The Language of Clinical Trials

The language of clinical trials contains similar, often interchangeable, words with different meanings. For example, are participants human subjects, patients, study volunteers, or study participants? Are participants enrolled in an experiment, study, research investigation, clinical research study, research project, clinical trial, research study, or medical research trial? Do participants receive study drugs, new drugs, study medications, investigational drugs, research (investigational products), investigational (experimental) agents, new investigational drugs, or new treatments? Are participants at risk for research-related injuries or research-related illness?

Will enrollment be enhanced by choosing certain words over others? For example, should the informed consent say "research subjects in an experiment who get an experimental drug and might experience a research-related injury" or "study volunteers in a clinical study who get a new drug and might experience a research-related illness?" Who decides which words to use? (*See Hochhauser, M. Who chooses the language of clinical trials? ARENA Newsletter, 2002, XV(3), 3-4.*)

Self Study Quiz - Answer Key

(See Pg. 9)

Answers:

1. b. true (Section 46.122)
2. a. true (Section 46.117 c)
3. b. an additional element (Section 46.116 b)
4. b. for, against, and abstained (Section 46.115 [2])
5. c. three (Section 46.115 b)
6. c. eight (Section 46.116)
7. b. research subject's rights and a research-related injury (Section 46.116 [7])
8. a. true (Section 46.116 [3])
9. b. false (Section 46.116 b)
10. a. one (Section 46.114)