

Who Understands? II: A Survey of 27 Words, Phrases, or Symbols Used in Proposed Clinical Research Consent Forms

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After presentation of data from our previous study¹ of this subject, we continued to encounter terminology during IRB sessions whose meanings we questioned whether or not research study participants understood. Our board members had lengthy discussions on the meanings of many terms used in participant consent forms and on participant comprehension. Of special note is the fact that the lay press has presented articles on difficulty patients have in understanding patient consent forms.² Because of these continuing problems of understanding, we compiled and researched a new list of terms used in clinical research consent forms.

This study was conducted in the spring of 1995 using the controlled methods reported in our prior publication.¹ However, subjects were not screened to separate those with medical training. As in the first study, participants were given the two-page (front and back) questionnaire and monitored during their completing the form.

A total of 302 individuals, all who were over eighteen years of age, were interviewed. This consisted of a main group of 291 participants (118 males and 173 females) and a subgroup of 11 nonresearch nurses (10 females and 1 male). This latter group of nurses was also included in the survey, but their results were not included in the overall analysis of the lay data. In the main group there were 104 individuals who had 12 years of schooling or less and 187 individuals who had college training. For the analyses of the lay data we drew a line between those who had up to a high school education and those whose education went beyond high school.

Interviews were conducted in New Jersey, Pennsylvania, and California in churches, fire houses, offices, homes, airports, and beauty salons.

Among interviewees' occupations were probation officer, marketing coordinator, paralegal, salesperson, civil engineer, computer programmer, housewife, tax collector, scientist, teacher, interior designer, retiree, dietitian, insurance agent, chemist, business manager, writer, mailman, secretary, controller, grocery clerk, bookkeeper, realtor, neuropsychologist, policeman, builder, fireman, bank teller, clergyman, postal clerk, social worker, church organist, student, dental assistant, painter, stock broker, electrician, artist, and plumber.

Questions and resulting answers follow (key words are highlighted) in Table 1.

Discussion

Some of the data are interesting. For instance, in a standard consent form the term *Institutional Review Board* is frequently referred to. Yet only 12 percent of the overall lay population knew this term accurately. We were not surprised that the most common perception among the participants was that an Institutional Review Board is a committee that reviews your medical records to determine whether or not you should be institutionalized. We suggest that the consent form define the term as "committee that has reviewed this research project to help ensure that the rights and welfare of the participants are protected and that the study is carried out in an ethical manner."

Another term, *sponsor*, was not understood well by the lay population studied. We suggest the term be defined in the consent form, "the company that makes the test drug in this study," or other appropriate language. Similarly, we suggest the term, "study doctor," in place of the word *investigator*.

Analgesic did not score well, in spite of its frequent use in television commercials. We suggest the replacement of "pain medication" or "pain reliever."

The predominant answers given for the definition of *serum* probably stem from the radio days of Sergeant Preston and his dog, "King," who braved sleet, snow, and storm to get the "serum" delivered to save a

young child. Most of the answers were slanted toward serum as being a drug! We suggest that wherever applicable the word “blood” be substituted for serum.

Baseline visit ranks along with similar terms, such as “screening visit,” “run-in phase,” and “washout period” used in many forms we see. We suggest the terms be deleted, and in their place the form use easily identified phrases, such as “first period,” “second week,” or “final phase.”

In contrast to *concomitant* the term *concurrent* has a high level of understanding. The former is a word definitely to be avoided in lay consent forms.

The data show that educational level plays a large role in understanding. However, we also see that clinical research jargon in a consent form can be detrimental to understanding the text.

When reviewing consent forms, it appears that the lack of understanding of clinical jargon by the lay population is a natural thing. In the medical profession, we use a jargon all our own and naively think that the rest of the world also understands. Often we see the symbols, “<”, “>”, and mg used. These are symbols that are not familiar to a lay population, and should be explained in the text of the forms. Often a detailed explanation is not needed, and merely confuses the potential study participant. When describing the amount of blood to be drawn, it may be better to express the volume in teaspoons, a common household measurement. Milligrams can be expressed as a fraction of an ounce in weight or an approximate number of grains of sand to give an idea of the small quantity with which one is dealing.

Shaping and molding consent forms to a common base lay language is a difficult task. But the rewards are directly proportional to the time and thinking, and of finding common lay terms to describe a final path. In our review of over fifty terms from consent forms we found a paucity of understanding by those lay populations for whose use they are intended. We found virtually no difference in data from one area of the country to another. It is hoped that presentation of these data from two studies may help in encouraging medical writers to use more common lay terms in preparing documents for clinical research participants.

Table 1.
Terms and Percent Understanding of Various Groups

	Overall	College	High school	Nurses
If you were told you had a fracture , what would this mean to you?	95	96	93	100
What is an Institutional Review Board (IRB) ?	12	12	12	27
If you had a lesion , what does this mean?	65	73	73	73
In a drug research study who would be the sponsor ?	65	64	40	55
In a drug research study who takes the role of investigator ?	35	41	26	55
What is an analgesic ?	49	55	39	91
What does perforation mean?	66	74	50	100
What does malaise mean?	26	28	22	82
What is a carcinogen ?	69	77	53	100
What does pruritis mean?	6	7	3	55

If you had a hypersensitivity to a drug, what would this mean to you?	79	87	64	100
What is meant by transient ?	36	47	15	64
What is meant by the term reproductively abstinent ?	42	45	35	45
What is meant by the term replication ?	47	51	31	64
If you had a mean blood pressure reading, what is meant by the term mean ?	39	51	17	64
If you were to titrate your dose, what would this mean?	12	17	2	36
In a medical sense what is serum ?	16	19	11	73
In a medical sense what is a metabolite ?	5	6	2	36
If you were in a drug research study, what is a baseline visit ?	41	51	24	64
If you were using a research drug and you were asked to taper the dose, what would you do?	81	84	73	82
In a medical sense, what are sequelae ?	7	11	0	9
What is malignancy ?	79	86	67	82
What are concurrent drugs?	47	59	25	64
When speaking of drugs, what is tolerability ?	72	79	59	82
What do these symbols mean? ♂, ♀	52	66	26	82
What does regimen mean?	55	67	31	82
In a clinical research study what are concomitant drugs?	7	10	0	0

References

1. Waggoner, WC, and Mayo DM: Who Understands? A survey of 25 words or phrases used in proposed conical research forms. *IRB* 1995: 17:6-9.
2. McFarling, UL: Cancer consent forms found difficult to read. *Boston Globe*, 13 October 1994.

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