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IMPROVING THE PROCESS OF INFORMED CONSENT

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Introduction

In recent decades, there has been an unprecedented increase in our knowledge base provided by various sciences, especially molecular and genetic sciences. Much of that knowledge is being adapted for use in clinical applications at a volume and rate that makes it difficult for scientists to “keep up.” Because such information is generally very complex, communication between scientists and the public is often superficial and unidirectional, even in cases when those innovations impact on people’s health. Thus, it is no wonder that the public often does not understand these scientific discoveries and has difficulty integrating them into their world views. In response to the need for improved communication both for legal and ethical reasons, a greater emphasis has been placed on informed consent, which is the process through which researchers and participants become more knowledgeable partners in medical decision making, developing realistic expectations about the outcomes of medical interventions, and assuring participants of their rights in the context of medical research (Harvard Risk Management Foundation, 1998).

Most decision making takes place in the context of either incorrect or incomplete information. Fortunately, the consequences of most decisions have little substantial effect on daily life. On the other hand, a relatively small number of decisions--even a single decision--can have a tremendous impact. For example, as discussed below, the decision to undergo screening for BRCA1 and BRCA2 genes that detect the presence of genetic mutations associated with increased risk of breast cancer (among other types

of cancer) falls into that latter category. Thus, in the process of deciding to undergo such screening, it is crucial that women have both correct and complete information to inform their decision and that the information is communicated in a way that is comprehensible to them.

Since 1991, federal legislation known as the Common Rule has guaranteed potential participants the right to specific pieces of information to assist them in making their decision to participate in a research study. Informed consent documents have become more comprehensive because of the guidelines provided in the Common Rule. Although research participants do not need to become experts, they are entitled to understand the procedures, risks and benefits, alternative procedures, confidentiality of records, and the voluntary nature of their participation. Few would argue with the importance of providing human subjects with an explanation of their rights as participants in scientific research. However, many could find fault with the ways in which such information is communicated. The Common Rule provides guidance about what the content of an informed consent statement should be, but it does not provide assistance on how an informed consent should be organized, how specific points should be articulated, how uncertainty and complex probabilistic statements should be communicated, or, in sum, how much information is needed to make a person's consent informed. Furthermore, the Common Rule does not require that the researcher ensure (by testing) that the information has been understood by participants--beyond asking them if they did understand it--and having the consent form vetted by an institutional review board (whose membership may be very unlike the research participants).

Although all participants are guaranteed the information stated in the Common Rule, they come to the research setting with different information needs and processing skills. Informed consent is an individual process; a single--“one size fits all”--approach to informed consent is not likely to suffice. In this paper, we consider BRCA1 and BRCA2 screening as an example of a recently developed technology and examine how the “informed” portion of informed consent might be tailored to individuals while delivering all the information called for under the Common Rule. We draw on theories grounded in the social sciences to consider different ways of structuring the informed consent process and communicating information to women who have a heightened interest in genetic screening for breast cancer.

Informed Consent and Autonomy

The notion of informed consent arises from the principle of autonomy, which includes autonomy of will (self-legislation) and autonomy of action (being free from constraint by society except in instances in which others are involved). Autonomy holds that in “self-regarding actions we ought to be as free as possible to do as we wish” (Beauchamp and Childress, 1979: 59). Also contained in the principle is the idea that in evaluating the self-regarding actions of others, we ought to respect their right to make their own judgments as they respect our right to make our own. Thus, the autonomous person is one who self-determines his or her actions through a moral deliberation process that is unimpeded by any authority’s influence.

Informed consent is a way of protecting the autonomy of subjects and patients, yet it serves other functions: it promotes individual self-determination, protects subjects and patients from harm, avoids fraud and duress, encourages self-scrutiny by medical

professionals, promotes rational decisions, and involves the public in supporting autonomy as a general social value and in controlling biomedical research (Capron, 1979). The informed consent process protects the right to exercise self-determination by ensuring that individuals make those decisions that affect their lives, even though others may have more information about a given situation. In the context of medical research, the researcher certainly knows more about a given procedure and its consequences. Yet informed consent provides at least a theoretical assurance that the participant will be given all the relevant information needed to make a decision in an autonomous manner.

Although informed consent is generally taken as one theoretical construct, it is composed of both informational and consent elements (Beauchamp and Childress, 1979). If one of those elements is missing, a valid informed consent has not been given. There are two informational elements in informed consent: the disclosure and the comprehension of information. Thought on the amount of information to be disclosed has shifted over time. Beauchamp and Childress (1979) comment on three moral standards for determining the content of informed consent forms: (1) what is operative in the biomedical professions; (2) what a "reasonable person" would want to know; and (3) what an individual research participant wants to know. Allowing the biomedical professions to determine what information should be disclosed, as the first standard suggests, is increasingly less popular because it implies that the health care provider can act in the participant's best interest even when the participant is capable of comprehending the information and making an independent decision. Such a paternalistic standard relies on the values of the provider without regard for the values of the participant. Other discussions of informed consent have focused on the second

standard, although the definition of a “reasonable person” can vary considerably (Merz and Fischhoff, 1990). The third standard--what an individual participant wants to know--is of limited merit because potential participants are unlikely to know what information is needed to make an informed decision. A compromise that includes both the second and third standards guides the content of most informed consent forms: the information to be disclosed should include whatever the “reasonable person” would find relevant to the decision-making process as well as any additional information that the potential participant wants to know. Central also to the informational elements is that the disclosure be made in “language understandable to the subject” or the subject’s representative (Code of Federal Regulations Title 45 CFR Part 46.116).

Consent is also made up of two parts: that the consent be voluntary and that the person be competent to consent. The voluntary aspect of consent refers to the ability to make a choice without coercion or undue influence. Coercion occurs when an actual threat of harm or forceful manipulation is used to influence a person’s decision. Undue influence involves excessive reward or irrational persuasion to induce a person to decide something in a certain way. When either of those two factors is present in the decision, the consent, although perhaps informed, is not valid. However, simply because a person experiences pressure or influence in making a decision, it does not necessarily mean that the decision was made involuntarily. Virtually all decisions are made against a background of competing interests, obligations, wants, and needs.

Competency refers to the ability to make a rational decision. Under ideal conditions, competency would be constant over time. However, the ability to make rational decisions can vary with age, mental status, and other factors. As a result, competence

is not an element that is always fully present or absent in an individual. For example, some people may be intermittently competent, and some may be capable of simple but not complex decisions.

Important questions remain about the amount of information potential research subjects need in order to be capable of consenting. Several studies (e.g., Faden, 1977; Fellner and Marshall, 1970) have found that the majority of potential subjects do not use all of the information disclosed in informed consent forms when making a decision about participation. However, those investigators do not suggest that the subjects' decisions were uninformed or that the disclosed information was irrelevant in the decision-making process. Although many factors impede *full* comprehension, it does not necessarily follow that subjects do not experience *adequate* comprehension. When people consult medical, financial, or legal professionals for advice, they are not likely to understand fully all that is communicated to them, but what they do comprehend may be sufficient to make an informed decision. Unfortunately, few studies have actually assessed how well people comprehend the information provided in the context of recruiting research participants and eliciting informed consent.

A Theoretical Approach to Understanding Informed Consent

As individuals go through the process of informed consent, they must often process a considerable amount of information that is scientifically complex and studded with uncertainties. Efforts to structure the presentation of that information may benefit from the experience of others in presenting similarly complex issues. Although fewer empirical studies provide information about that process than one might wish, several well-established theoretical constructs provide guidance. Two such theoretical

frameworks, decision theory and risk communication theory, can be applied to the informed consent process by addressing both the content and the process of delivering complex and potentially threatening information to lay audiences.

Decision theory offers a well-tested (see, for example, Jungermann et al., 1988; Merz et al., 1993), systematic, and comprehensive framework for examining the processes that underlie decision making from the perspectives of both experts and laypersons.

Structurally, it relies on two types of decision models: (1) normative or expert models and (2) descriptive or layperson models (Bostrom et al., 1992,1994; Atman et al., 1994; Fischhoff and Quadrel, 1991). Normative models focus on the steps that experts determine are essential in decision making and draw extensively on cognitive processes. Descriptive models diagram the thought patterns that laypersons report following as they make decisions; such schemes go beyond cognitive processes to include perceptions, values, attitudes, and beliefs. Thus, normative models depict the theoretical decision-making process that people *should* follow. They are objective in that they try to capture the actions, consequences, and uncertainties that face a decision maker. Because the normative model is objective, it serves as a useful comparison for the more subjective descriptive model of the layperson's decision making. Descriptive models demonstrate how people *actually* make decisions. The discrepancies that arise between normative and descriptive models may indicate areas that can usefully be investigated to better understand decision making.

The theory of risk communication offers guidance on how to convey relevant information effectively (NRC, 1989; Fischhoff, 1989a). Risk communication focuses on the goals of improving or increasing the base of accurate information available to

decision makers and ensuring the decision makers consider themselves adequately informed (at least within the limits of available knowledge). Risk communication is not about turning the recipients of such information into experts. Rather, the goal is to provide them with sufficiently balanced information so that they can take further action or so that they will know what type of additional information to seek. The theory has been used to structure both large- and small-scale communications, from national campaigns to educate the public about hazards posed by radon to how people understand package inserts accompanying pharmaceutical products (Bostrom et al., 1994; Atman et al., 1994; Jungermann et al., 1988).

Risk communication theory holds that the content of risk messages should be geared toward a target audience, a tenet consistent with the use of lay decision models in decision theory. The communication needs to provide receivers with a basic understanding of the exposure, effects, and mitigating processes relevant to the hazardous condition or situation about which they must decide. Effective communication incorporates the target audience's existing beliefs, realizing that they are the filter through which the receiver interprets and integrates additional information. To facilitate that integration, new information should be presented within an appropriate structure and should be reinforced with textual aids (Atman et al., 1994). Although there is a temptation to simplify information, those who have worked with this theory caution that risk messages should not minimize the areas of uncertainty that exist (NRC, 1989).

Risk communication theory is meant to guide the development of an accurate and balanced summary of information that reflects the state of knowledge, the existing

uncertainty, and the disagreements about the risks under consideration. A recent report on risk communication published by the National Research Council (1996) identified the following tenets for successful risk communication:

- *Get the science right*, with high scientific standards governing the analytic methods, assumptions, measurements, and treatment of uncertainty.
- *Get the right science*, by having the analysis address the concerns of scientists, public officials, and a broad range of affected parties. Those concerns may go beyond health and safety to include economic consequences and social well-being.
- *Get the right participation*, by having participants in the process cover all the information and all the perspectives relevant to the decision.
- *Get the participation right*, so that affected parties feel adequately represented and that their participation has been able to affect the way a risk decision or problem is defined and understood.

Regardless of whether the risk affects one individual or a group of people, these guidelines promote the type of open and honest communication that is central to informing consent. For BRCA1 and BRCA2 screening, these principles underscore the need to provide complete information, which includes stating what is not known, and to communicate it in a such way that women feel empowered to make the decision for themselves.

For an area as complex and potentially misunderstood as genetic screening for breast cancer, the theories of decision making and risk communication, with their associated methods and principles, can provide guidance in the development of improved informed consent documents.

Informed Consent and Genetic Screening for Breast Cancer

When BRCA1 and BRCA2 tests became commercially available, it was apparent that they would be used in a variety of clinical contexts, not all of which would have access to genetic counselors. Thus, the American Society of Clinical Oncology (ASCO, 1996) published guidelines for pre- and posttest counseling and for informed consent documents. They articulate eleven points that should be communicated to individuals prior to DNA testing:

- information on the specific test being performed, including its accuracy;
- implications of both positive and negative test results;
- the possibility that the test result will not be informative;
- options for estimating the subject's level of risk without genetic testing;
- probability of passing the mutation on to offspring;
- fees involved in testing and counseling;
- risks of psychological distress;
- risks of insurance and employment discrimination;
- issues related to the confidentiality of resulting information; and
- options and limitations of medical surveillance and screening after testing.

This list of items indicate that a substantial amount of information needs to be provided to patients before screening, but ASCO does not offer any guidance on how such information should be communicated nor on how to assure the information was understood.

Few studies have looked at informed consent in the context of genetic screening for breast cancer. Indeed, only a handful of studies have considered what higher-risk

women know or would like to know about their genetic predisposition for breast cancer.

In a study that considered the specific informational needs of women who were considering genetic screening for BRCA1 mutations, investigators (Bernhardt et al., 1997; Geller et al., 1995) conducted a series of nine focus groups (a total of 86 women), stratifying the women by level of risk and by socioeconomic status. Women came to the groups with the knowledge that breast cancer could be inherited, but they were less likely to know that risk for the disease could be inherited from the paternal as well as the maternal side of the family. Most women knew that the probability of getting breast cancer increased with age. However, they had misperceptions about the typical age at diagnosis, believing that women typically developed breast cancer during their 30s and 40s. Women in both high- and low-risk groups tended to overestimate their risk for breast cancer, and many women found it difficult to express that risk in probabilistic terms (i.e., as a percentage).

The results of the focus groups suggest that women of different socioeconomic status have different informational needs. For example, women of lower socioeconomic status came to the study with less knowledge about breast cancer than the women with higher socioeconomic status. Women of higher socioeconomic status asked for information on the characteristics of the screening test, including accuracy, predictive value of a positive result, and significance of a negative result. Women of lower socioeconomic status believed that the genetic test would be used to diagnose breast cancer, not to predict their risk of developing it in the future. That belief persisted even after the researchers explained that the test's goal was to detect a predisposition to cancer. In general, women of lower socioeconomic status expressed more interest in

the practical aspects of testing, such as how a sample would be obtained, what pain would be associated with testing, who would perform the tests, where the test would be done, and how long it would take to get results. However, women of lower socioeconomic status were more likely than women with higher socioeconomic status to view the information generated by testing as empowering. Nevertheless, most women believed that the information generated by genetic testing would help stimulate appropriate health behaviors, such as increasing the frequency of mammograms and diet modification.

This group of researchers (Bernhardt et al., 1997; Geller et al., 1995) concluded that the disparate informational needs of women with different educational backgrounds argued for tailoring information for different groups. Moreover, because the women in the focus groups responded more enthusiastically to anecdotes and personal experiences than to facts and statistics, the authors suggested the use of stories about women who had both accepted and declined testing as a way to present relevant information. The authors indicated that the nondirective approach employed in genetic counseling might not be the most effective way to provide information. Many women wanted direction and recommendations from their health care providers; they showed a clear interest in being educated by experts who could provide “correct” information. However, despite such interest, there was no indication that the women were abrogating their decision-making role.

In the context of clinical research, scientists have an ethical obligation to deliver information that the targeted population deems important and comprehensible. But researchers may well wonder about the effect of improved information delivery systems

on participation rates. Reports from the focus groups in the study discussed above indicate that as information about the test increased, women's willingness to participate in screening decreased (Geller et al., 1995). Initially, most women were interested in being tested. But, as they heard and presumably understood more about the limitations and uncertainties associated with the test, their willingness to participate declined. To date, only one study has looked at that issue systematically. Lerman and coworkers (1997) conducted a randomized clinical trial of two information delivery systems (education only versus education plus counseling)¹ for women considering BRCA1 testing and who had first-degree relatives (i.e., sisters, mothers, or daughters) diagnosed with breast cancer. When compared with the waiting-list control condition (neither education nor counseling as a part of the experiment, but receiving education after the follow-up period was completed), the counseling and education mode produced greater increases in knowledge than the mode with education alone. However, the proportion of women in the two experimental conditions who said that they intended to get screened and the proportion providing a blood sample was the same in both groups, 52 percent.

The variation in findings described above concerning the relationship between information and willingness to be screened for BRCA1 mutations may reflect differences in methods, samples, and design, including choice of outcome measures. However, the differences may also reflect the fact that women seek or eschew screening for hereditary breast cancer for different reasons, such as distrust of the

¹Topics covered in the education intervention included: risk factors, patterns of inheritance, benefits of testing, limitations of testing, risks of testing, and limitations of options. The counseling component covered: experience with cancer in the family, anticipated impact of positive and negative results, anticipated outcomes of not being tested, coping skills, and communication of test results to others.

medical system, a desire to plan for the future, a desire to confirm or disprove suspicions, or advancement of medical science. What appears indisputable is that two small studies cannot answer complex questions about information delivery and participation rates.

Toward an Improved Process of Informed Consent

Developments in the molecular and genetic sciences continue to revolutionize the knowledge base and the tools used in the field of cellular function and dysfunction. Scientists are constructing high-resolution genetic linkage maps, determining the complete nucleotide sequence of human DNA, and developing both models and technology to explore genetic contributions to human growth, development, and disease. It appears, however, that our understanding of processes and communication systems at the cellular level has outstripped our understanding of how the scientific community communicates its findings to the different lay groups who are interested in and affected by genetic diseases and who constitute the pool of potential participants for clinical research. Although legislation and guidelines have been enacted to ensure that sufficient information is communicated to people deciding whether or not to participate in research studies, little attention has been paid to assessing the usefulness and effectiveness of the informed consent process from the users' perspective. The basic questions of how participants understand and use information in making these decisions remain unanswered.

A consistent criticism of informed consent documents has been the difficulty of understanding them; they appear to be written for a group other than the lay public (ACHRE, 1995). If informed consent documents are not understandable by their

intended audience, then they are falling short of their intended purpose. Improving the informed consent process for BRCA1/BRCA2 screening must begin with a review of informed consent documents that are currently used in the field, characterizing their content and quality. Analyzing the structure, style of presentation, complexity of vocabulary and grammar, comprehensibility, and positive and negative messages of currently used documents would provide an objective basis for evaluating their effectiveness. Deficiencies in the informed consent process can be remedied by drawing on the scientific contributions of experts in other fields, especially breast cancer, genetic screening, decision theory, and risk communication.

The process of communicating complex scientific information about BRCA1/BRCA2 screening to high-risk women is not unique to clinical research. In many instances, policymakers and interested citizens face a dilemma similar to that of potential research participants: they lack formal scientific training but must understand detailed scientific and technical analyses in order to participate effectively in the decision process. Merely “translating” a technical document into lay terms will not, however, solve the problem if the content of the document does not address the questions and concerns of the targeted population. Thus, the National Academy of Sciences’ Committee on Risk Characterization argued that the targeted population should participate in deliberating relevant issues and developing informational materials (NAS, 1996). By actively seeking input from experts in breast cancer, genetic screening, and risk communication, as well as first-degree relatives of women diagnosed with breast cancer--the people to whom such a communication is directed--informed consent documents avoid being “translations” of technical knowledge and legal regulations and are better able to address participants’ information needs.

Very few studies have included first-degree relatives, and those efforts have generally been small and have relied on limited convenience samples of women. A rigorous assessment of the informed consent process needs to be based on input from women of different ages, races, and levels of education, representing a range of subpopulations at risk for inherited breast cancer. Including the different perspectives of a range of subpopulations at risk for inherited breast cancer is crucial to “get the right participation and the participation right,” as stated in the NAS tenets on risk communication noted earlier.

Few scientists would argue with the importance of tailoring information to meet the needs of specific individuals and answering their questions. But few studies have monitored the information delivered during counseling sessions. One approach that proffers the possibility of standardizing the content of risk communication during the informed consent process is the use of computer-assisted instruction (CAI). CAI technology may reduce the variability in the quality of informed consent caused by differences in counseling capabilities across sites and time, yet it could allow participants to tailor the presentation of (nonrequired) information to meet their particular needs and preferences. CAI can be offered in conjunction with a human counselor, who would be available to answer any questions that the person might have and to provide any information requested that was not covered in the CAI format. The use of computer-based technologies may allow us to achieve both standardized content and presentation of information. In that way, the process of studying informed consent is held to the same standards of science used to develop genetic screening tools, thus, “getting the science right,” as the NAS panel put it. By drawing on the expertise of the computer, medical, and social sciences and by integrating the information needs of

first-degree relatives, we believe it may be possible to “get the right science” as well.

Finally, the issues related to informed consent are not restricted to BRCA1/BRCA2 screening for breast cancer. As more genetic tests are developed and their results are used to guide diagnostic and treatment decisions, the investment in scientific methods and technologies to improve the delivery and evaluation of information in settings involving BRCA1/BRCA2 testing may yield benefits for other research areas as well.

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