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Conceptualizing the Role of Research Literacy in Advancing Societal Health

Janet L. Brody, Ph.D.,

Oregon Research Institute; Center for Family and Adolescent Research

Jeanne Dalen, Ph.D.,

Oregon Research Institute; Center for Family and Adolescent Research

Robert D. Annett, Ph.D.,

University of New Mexico School of Medicine

David G. Scherer, Ph.D., and

University of Massachusetts, Amherst

Charles W. Turner, Ph.D.

Oregon Research Institute; Center for Family and Adolescent Research

Abstract

Purpose—To provide a conceptual formulation for “research literacy” and preliminary evidence for the utility of the construct in enhancing knowledge of and ethical participation in research.

Methods—Examined the impact of a brief educational intervention on parents’ research knowledge and their research participation decisions.

Results—Research-related knowledge was improved. Parents with greater knowledge were more comfortable with their research participation decisions. Enhanced understanding of child volition increased parents’ willingness to enroll their children in research.

Conclusion—The proposed research literacy model identifies methods to enhance population knowledge and appreciation of research, strengthening links between scientific advancement and health.

Advancements in evidence-based health care are contingent upon the successful conduct of incisive and ethical biomedical research. This research, in turn, is dependent on volunteers willing to participate in clinical trials. Yet, less than 2% of the American population participates in clinical research each year. Recruiting people to participate in biomedical research is a significant challenge to scientific and health care advancement, with 80% of all clinical studies delayed due to low enrollment (Newsweek 2009). While evidence-based health care is inherently cost-effective, this efficiency can only be sustained by facilitating the enrollment of research volunteers. Furthermore, major health disparities among population sub-groups point to the imperative of identifying strategies for greater minority participation in clinical trials (Thomas et al. 2011).

One major impediment to participation in biomedical research is the public’s naiveté about medical and social science research. Most individuals in the United States have a poor

Correspondence regarding this manuscript and requests for reprints should be submitted to the first author, Dr. Janet Brody, Center for Family and Adolescent Research, Oregon Research Institute, 707 Broadway S. E., Suite 402, Albuquerque, NM 87106; jbrody@ori.org; phone: (505) 842-8932, fax: (505) 842-5091.

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understanding of science (Miller 1998), and seventy five percent of the public reports they have little or no knowledge of clinical research or the participation process (Getz 2007). This lack of knowledge compounds the challenge to clinical researchers facing the task of ensuring that individuals enrolled in research do so in a manner consistent with the ethical imperatives of informed consent for adults and voluntary assent for children. These ethical imperatives require that individuals make a fully informed, voluntary decision and appreciate the meaning or implication of research participation (Faden, Beauchamp, & King 1986).

Over the past three decades, studies examining research participation decisions demonstrated that individuals fail to comprehend critical differences between regular treatment and research participation, a phenomenon referred to as the “therapeutic misconception” (Appelbaum, Lidz, & Grisso 2004). A recent NIH policy forum examined why the therapeutic misconception continues to be a significant challenge to informed consent despite 25 years of study (Henderson et al. 2007). This panel identified five major domains of understanding deemed necessary for an adequate comprehension of research that distinguishes health research from health care. These domains included an awareness 1) that the scientific purpose of a study is designed to produce generalizable knowledge, 2) that research participation may involve study procedures intended only to generate scientific knowledge not necessary for patient care, 3) that the interventions studied in clinical research are based on less knowledge and more uncertainty about risks and benefits to a population than occurs when a doctor offers standard interventions, 4) that interventions are based on a strict adherence to a protocol with defined treatment dose and scheduling, and 5) that clinicians as investigators presents physicians in dual roles that may confound the distinction between treatment and research. Additionally, there are a number of key contextual and ethical considerations for research participation decisions such as sources of research funding, scientific relevance of the research question, financial compensation, and potential conflicts of interest that are not well understood by the general public (Durantini & Albarracin 2009; Greco & Diniz 2008; Scherer et al. 2005).

The lack of public awareness and engagement in clinical research and persistent misunderstanding of its purpose, is the consequence of poor knowledge of basic research principles (Henderson, Churchill, Davis, Easter, Grady, & et al. 2007) and is indicative a broad-based national problem of insufficient “*research literacy*.” This paper introduces the concept of research literacy, which we define as the cognitive and social understanding of the basic purpose, process, and value of research and research participation. We contend that it represents a critical link between science and health, and that increasing research literacy in the population will lead to greater public awareness of the importance of research and augment research participation.

The conceptualization of research literacy is drawn from the more general topic area of health literacy, which is defined as “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 (WHO Commission on the Social Determinants of Health 2007).” Recent research has highlighted the broad impact of poor health literacy, which includes reduced physical and mental health outcomes, poor treatment adherence, and increases in health disparities (Journal of General Internal Medicine 2006). Barriers to teaching health literacy concepts to children have also been examined (Borzekowski 2009).

Baker (2006) developed a theoretical formulation for the relationship between individual capacities, oral literacy, and health outcomes which we have adapted for a conceptual model of research literacy. In particular, Baker’s model notes the importance of prior knowledge in

the form of vocabulary and conceptual understanding of health and health care as primary inputs to literacy. Similarly, biomedical and behavioral science research involves a highly specialized vocabulary and a set of processes and procedures based on scientific principles. There has been limited empirical consideration of individual capacities to comprehend conceptual aspects of the scientific process. Instead, informed consent research has focused on the readability of consent forms (Hochhauser 2003; Lawson & Adamson 1995; Ogloff & Otto 1991; Paasche-Orlow, Taylor, & Brancati 2003). Baker's model of health literacy explicates literacy outcomes in terms of new knowledge, positive attitudes, greater self-efficacy, and behavior change that ultimately results in improved health (Baker 2006). In our conceptual model of research literacy (Figure 1), we propose that research literacy encompasses (1) knowledge of research concepts, (2) attitudes towards research, (3) self-efficacy in the ability to weigh participation decisions, (4) increased motivation to explore research options, and (5) participation in research. Our hypothesis is that research literacy develops as an iterative process, with each component being strengthened by enhancements to any of the components. For example, increased knowledge of research concepts will improve the ability to weigh participation decisions. Greater understanding of research may also increase motivation to explore research participation options or improve attitudes that ultimately lead to decisions to participate in research. Alternatively, the experience of research participation may shift attitudes about research or contribute to a greater understanding of research concepts. Thus our circular representation is meant to convey the reciprocal influence of each component on the development of other research literacy components, which collectively enhance overall research literacy. Ultimately, we hypothesize that research literacy has a direct bearing on societal advancements in health.

To begin the process of assessing the usefulness of the research literacy framework, we conducted a preliminary assessment of the impact of a research literacy intervention on parents' understanding of research concepts and willingness to enroll their young children in research. Research participation by children involves a more complex decision-making process than for adult informed consent. Ethically, psychologically, and legally, children and adolescents are presumed to be a vulnerable population because of their inability to fully appreciate the risks and benefits associated with clinical research and to make a voluntary participation decision. Consequently, there are unique safeguards or protections in the federal regulation of research with children and adolescents (Institute of Medicine 2004). Ethical standards require that potential research participants with uncertain competence be granted a maximal level of decision-making autonomy consistent with their decision-making capacities. Therefore, United States regulations require researchers to obtain both parental permission and the assent of children age seven and older (56 Federal Register 1991; 66 Federal Register 2001). Thus, ethical research participation decisions for children differ from medical treatment decisions in that they are a corporate responsibility of the parent and child (although parents typically are not aware of this distinction).

In the present study, parents of young children were asked to consider enrolling their child in a hypothetical asthma study. One half of the parents received a brief research literacy educational intervention prior to making a research participation decision with their child. We hypothesized that the intervention would significantly increase participants' knowledge of research concepts and result in greater willingness to enroll in the research study.

Method

Procedures for this study were reviewed by a human research review committee and participants provided written informed consent/assent prior to study procedures. One hundred children between the ages of 6–12 with a prior diagnosis of asthma, and at least one parent were recruited to participate. The children received an asthma evaluation from a

pediatric asthma specialist. Following this, both the parent and child were shown a ten-minute videotaped presentation of a hypothetical pediatric asthma study presented by the asthma specialist who conducted the evaluation. For half the participants, the specialist recommended to the family that they participate in the study; the other half of the families did not receive the recommendation.

Parents were then asked to consider the hypothetical pediatric asthma study and indicate the extent to which they would be interested in enrolling their child. The hypothetical study was based on a previously completed randomized clinical trial that examined the effects of an FDA approved allergy medication on school performance. By random assignment, half of the parents then received a brief research literacy educational intervention. The concepts explained in the literacy intervention included (1) parental permission and child assent (2) distinctions between research and treatment (3) the importance of voluntary participation. In order to standardize the intervention it was presented via videotape, by the same asthma specialist who explained the research study. Parents in the other condition did not receive the intervention.

A 13-item Pediatric Research Knowledge Questionnaire was completed by all parents. The questionnaire was developed by the authors to determine parent understanding of child-research concepts and was based directly on information presented in the educational intervention. The questionnaire used a 7-point Likert scale format with responses ranging from “definitely not” to “definitely yes”. Finally, parents were directed to discuss the asthma study with their child and make a final participation decision. All children were also interviewed to determine the extent to which they understood and were interested in participating in the hypothetical pediatric asthma study.

Results

One hundred families participated in the study. Child age ranged from 6–12, with a mean age of 8.3 (sd = 1.7) years. Parent mean age was 37.0 (SD= 7.0). Males accounted for 55% of the child participants. Mothers accounted for 90% of the parents. A majority of families (64%) were Hispanic. Racial composition of participants included 73% white, 8% American Indian, 4% African American, 1% Asian, and 10% mixed/other. Educational background of the parents was broadly distributed with highest educational achievement at 32% High school, 35% with some college background, 17% achieving a Bachelors degree and 14% having a post-graduate education. Annual income for about half the sample was at \$40,000 or less. Twenty five percent reported income over \$60,000.

Internal Consistency of the Pediatric Research Knowledge Questionnaire

The Pediatric Research Knowledge Questionnaire evaluated parents' knowledge of scientific, ethical and legal issues related to the participation of children in research. The internal consistency of the items was assessed to provide evidence of construct validity. The results of coefficient Alpha analyses for the three rationally derived subscales were as follows: The Distinctions between Research and Treatment subscale included five items, Standardized Alpha = .80 (e.g. “The goals of medical care are the same as the goals of research”). The Child Assent subscale included five items with a Standardized Alpha = .73 (e.g. “It’s important for parents to know how a child feels about participating in a research study”). The Volition subscale, with three items had a Standardized Alpha = .81 (e.g. “A child’s participation in research must be voluntary”). Analyses to confirm the subscales measured single constructs were conducted using individual factor analyses for each subscale. For the Distinctions between Research and Treatment subscale, a single eigenvalue = 2.8, explained 56% of the variance. For the Assent subscale, a single eigenvalue = 2.4,

explained 48.7% of the variance. For the Volition subscale, 72.6% of the variance was explained with a single eigenvalue = 2.2.

Effect of the Research Knowledge Intervention

To examine the impact of the educational intervention on parents' knowledge of scientific, ethical and legal issues associated with child-research participation, we conducted a 2×3 analysis of variance on the parents' total research knowledge score. The independent variables were the research knowledge intervention (received or not received) and the parents' level of education (high school, associates/vocational education, college or above). Parent education level was included in the analysis to evaluate whether differences in research knowledge could be explained by differences in prior education. The research knowledge score (dependent variable) was obtained by summing the scores on the three subscales (total possible score = 91). Findings demonstrated a highly significant main effect of the research knowledge intervention on the total research knowledge score, $F(1, 86) = 31.3, p = .000$. The median score for those receiving the intervention was 86% correct ($M = 75.8, SD = 9.8$). The median for those not receiving the intervention was 72% correct ($M = 66.1, SD = 7.4$). The main effect of parent education level and the interaction effect of parent education with the research knowledge intervention were both non-significant.

Impact of Research Knowledge Score on Research Participation Decisions

To examine whether the participants' research knowledge predicted their willingness to enroll in the asthma research study, binary logistic regression was conducted using scores on the three knowledge questionnaire subscales as independent variables. The final research participation decision was the dependent measure. Results indicated that parent scores on the child volition factor significantly predicted enrollment in the study; Parents with a greater understanding of child volition in research participation decisions were more likely to enroll their child in the study ($Wald = 5.22, p = .02, OR = 1.12$).

To test the hypothesis that research knowledge increases self-efficacy in making research participation decisions, we conducted an analysis of variance on the parents' comfort with their decision based on whether they had received the educational intervention. Since younger children are perceived as more vulnerable than older children, we included child age in the analysis to determine whether a parent's comfort with the decisions would be affected by the age of their child. Overall, parents who received the research knowledge intervention ($M = 6.54, SD = 0.93$) reported being significantly more comfortable with their research participation decisions than parents who did not receive the intervention ($M = 6.00, SD = 1.30, [F(1, 93) = 5.62, p = .02]$). The interaction effect of the Knowledge Intervention x Child Age variables was also statistically significant [$F(1, 93) = 5.16, p = .025$]. A comparison of means for parents with younger children revealed that those receiving the knowledge intervention ($M = 6.6, SD = 1.0$) were significantly more comfortable with their participation decision than those not receiving the intervention ($M = 5.5, SD = 1.4, [t(50) = 3.03, p < .00]$). Comfort with the participation decision did not differ for parents of older children. Private interviews with the children indicated that virtually all parents honored their child's research participation preferences. Research participation decisions were not affected by whether the asthma specialist recommended participation to the family.

Discussion

This paper provides a conceptual formulation for research literacy and preliminary evidence for the utility of the construct in addressing issues related to research knowledge, decision-making self-efficacy, and participation in research. We argue that the general lack of

awareness, involvement in, comprehension of, and appreciation for links between research and health, can all be traced to a general problem of poor research literacy.

As a preliminary test of this hypothesis, we examined whether a brief educational intervention could improve parents' knowledge of research concepts and ethical considerations related to child research and affect research participation decisions. Our findings suggest that, regardless of the participants' prior level of educational attainment, research-related knowledge could be substantially increased with a targeted educational intervention, and, moreover, that increasing research knowledge made parents more comfortable with their research participation decisions. We also found that increasing parents' understanding of the ethical importance of child volition in research participation increased parents' willingness to enroll their assenting children in the hypothetical study.

While these preliminary data are encouraging, there are limitations to the conclusions that may be drawn with this study. We did not have a pre-test for the research knowledge questionnaire that may have identified pre-intervention differences (although parents were randomly assigned). Moreover, our educational intervention did not include information about broader contextual issues such as conflicts of interest or research funding sources. Our measure of research knowledge was similarly focused to match the intervention and did not evaluate the full range of topics that could be included in a measure of research literacy. Such an instrument does not yet exist. However, these preliminary data provide support for the utility of developing one in the future.

Most significantly, we believe these data highlight the need to improve population understanding and appreciation of biomedical and behavioral science research. The general practice within the research community is to focus on informed consent/assent documents for individual research protocols. Virtually no attention is given to explaining the larger scientific and ethical context in which research is conducted. This lack of attention contributes to ongoing problems associated with continued interest and enrollment in research studies, the therapeutic misconception, and ethical issues associated with research participation. The conceptualization of research literacy establishes a model for enhancing population knowledge and appreciation of research concepts that aid ethical participation decisions. Ultimately, improving research literacy in the population may motivate increased interest in research participation as the link between scientific advancement and health is more fully appreciated.

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Figure 1.
A model of Research Literacy