Universal Design of Research: Inclusion of Persons with Disabilities in Mainstream Biomedical Studies

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Although persons with disabilities of all kinds have as wide a range of health conditions as the general population, they are profoundly underrepresented in mainstream health research. Such underrepresentation might contribute to the health disparities in this population. We propose the concept of Universal Design of Research (UDR), which would promote routine inclusion of persons with disabilities in mainstream biomedical and psychosocial studies, without the need for adaptation or specialized design. Elements of UDR include the use of multisensory formats for recruiting participants, presenting research instruments and interventions, and data gathering from participants and should promote the inclusion of participants with a wide range of abilities, thus enhancing the generalizability of results.

BACKGROUND

Disabilities in the U.S. health care system. According to the U.S. Centers for Disease Control and Prevention, an estimated 47.5 million Americans, or 22% of the U.S. population, have a disability, defined as specific functional or sensory limitations (8). Among this group are 13.5 million people (for example, people over the age of 65, or with diabetes or cardiac disease), the percentages of persons with disabilities are even higher.

Health care professionals often equate disability with poor health, even though many persons with disabilities live long, healthy, and active lives. However, persons with disabilities are at high risk for developing poor health for a variety of reasons, including (i) susceptibility to the same chronic health conditions that affect many Americans (for example, cardiac conditions, diabetes, overweight, cancer, and arthritis); (ii) sequelae of their disabling conditions; and (iii) the lack of equal care for people with disabilities in the American health care system because of a lack of reasonable accommodations (2–6).

In spite of the fact that persons with disabilities use health care more often than does the general population, they are profoundly underrepresented in mainstream health research (research not focused on disabilities) (6). For example, 20% of individuals with diabetes describe difficulty seeing (9), and insulin pens have been widely used to inject insulin by visually impaired people since their introduction in the late 1980s. However, even though copious research exists on patient accuracy of dosing with insulin pens, such studies have routinely excluded people with visual disabilities (10).

Exclusion from health research might result from a misconception among health professionals that disabilities are of interest primarily as end points in studies, rather than as demographic characteristics of participants (2). In addition, many researchers are unfamiliar with the ways that persons with disabilities access information and perform activities of daily living. Lacking knowledge about how to design research studies in accessible formats, researchers may assume incorrectly that persons with visual impairment cannot fill out a questionnaire or those with hearing impairment cannot understand verbal instructions and therefore must be excluded.

Without studies that include persons with disabilities, clinicians lack evidence for effective treatment of this large minority group.

INTRODUCTION

More than 20 years have passed since the Americans with Disabilities Act became law (1). Among the many benefits provided by this landmark legislation was the requirement for health professionals to make reasonable accommodations to provide health care to individuals with disabilities equivalent to that provided to those without disabilities. However, evidence exists that those with disabilities are often not served well by the U.S. health care system (2–5). One reason for this disparity is that persons with disabilities are grossly underrepresented in mainstream health research (research not focused on disability) (6).

Although such individuals are a part of all geographic communities and have as wide a range of health conditions as the general population, several major publications that address the state of health care for people with disabilities in the United States note that researchers often explicitly or implicitly exclude this group (3–7). Consequently, even though many persons with disabilities have common conditions, such as diabetes, cardiac disease, or cancer, most translational studies about such diseases do not include these people. As a result, we do not know to what extent study findings may generalize to those with disabilities. In this Commentary, we propose Universal Design of Research (UDR) as a new model for including persons with disabilities in mainstream research (Fig. 1).

Fig. 1. Making biomedical studies more inclusive through UDR. Providing a magnifier to allow persons with low vision to read a questionnaire is an example of a simple adaption that can promote the participation of disabled individuals in mainstream research studies.

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They do not know whether or how research conducted in nondisabled populations applies or does not apply to persons with disabilities. For example, the effects may or may not be different for each of the following disabled groups, as compared with nondisabled groups: physical activity to prevent cardiac disease in people who have mobility impairment; frequent self-monitoring and recording of blood glucose to help control diabetes in people who have severe visual impairment; or use of medications that were originally developed for postmenopausal women to prevent bone loss in young adult women who have spinal cord injuries.

Until people with disabilities are routinely included in research, we cannot know if differences may emerge for those with disabilities in general or with particular disabilities, just as differences have emerged for factors such as gender, race, and comorbidities. This deficiency of evidence has been identified in several major U.S. publications on health care for people with disabilities as one cause contributing to the lack of structural support for reasonable accommodations within the American health care system (2–6).

Disability and universal design: Definitions and context. Historically, definitions of disability have focused on differences between “normal” persons and those who lack a usual range of abilities. After World War II, such concepts coalesced into a medical model of disability. In this model, disability is viewed as a problem caused by disease, trauma, or other health condition requiring medical care. The problem of disability belongs to the disabled individual, who has responsibility for complying with curative efforts, striving to overcome the disability and adjusting to it (4).

During the disability rights movement of the 1970s and 1980s, persons with disabilities asserted that the major source of their functional limitations was not derived from themselves and their disabilities but from the failure of physical and social environments to accept and accommodate them. They emphasized that they are persons first and individuals with disabilities second, they have many abilities, and they are more disabled by environments than by their sensory, physical, or cognitive limitations (4).

In 2001, the World Health Organization published the International Classification of Functioning, Disability and Health (ICF) (11). This model synthesizes the medical, social, and environmental perspectives into a biopsychosocial approach. Disability is defined functionally as an “umbrella term for impairments, activity limitations or participation restrictions.” The ICF explicitly acknowledges that disability involves “… a dynamic interaction between health conditions (diseases, disorders, injuries, traumas, etc.) and contextual factors,” particularly environmental factors that “interact with all the components of functioning and disability.” Rather than being seen as an all-or-nothing phenomenon, disability is seen as a continuum and as an experience that all people may have at some time in their lives (4). The Committee on Disability in America of the Institute of Medicine has recommended adoption of the ICF framework by governmental agencies involved in disability monitoring (12).

The concept of Universal Design (UD)—defined as “the design of products and environments to be usable by all people, to the greatest extent possible, without the need for adaptation or specialized design”—emerged during the 1990s and was originally developed for architecture (13). A classic example of UD is inclusion of a requirement for curb cuts in building codes. Before curb cuts were the norm, people in wheelchairs had little access to public spaces. Now, wheelchair access to such places as public buildings, recreational facilities, or parks is at least theoretically possible throughout the United States. Furthermore, curb cuts make traveling through traffic areas more convenient for many nondisabled persons, such as those riding bicycles, pushing strollers, or pulling wheeled luggage.

Concepts of UD are now used in a wide variety of contexts. When applied to education, UD for Learning provides for a flexible system through which a curriculum can be accessible and useful to a classroom with students of widely divergent abilities and backgrounds (14). In health care, UD has been
applied to diverse topics, including general health care (15), medical devices (16), and diabetes self-management education (17).

**UDR**

We propose UDR—defined as the design of research so that all people can be included as potential participants, to the greatest extent possible, without the need for adaptation or specialized design—as a new model for research (18). UDR is a simple idea, with potentially systemwide, complex implications for researchers and health care providers.

**A few simple rules for UDR.** In the formative work *Crossing the Quality Chasm: A New Health System for the 21st Century*, Plsek suggests “a few simple rules” to guide system change, including (i) setting the general direction or goals; (ii) defining boundaries, prohibitions, or limitations; and (iii) providing guidelines, resources, and support for implementation (19). In the spirit of Plsek’s suggestions, we offer the following “few simple rules” for UDR: (i) plan your research to include all potential participants who meet the inclusion criteria, regardless of their current abilities or disabilities; (ii) do not create exclusion criteria unless there is a compelling scientific rationale; (iii) provide multisensory, flexible options for recruitment, research instruments (such as questionnaires), measurements, and responses from participants, with reasonable accommodations that invite and facilitate participation by persons with disabilities; and (iv) when you do not know how to include someone with a disability, consult someone who does (the potential research participant, another person with that disability who is knowledgeable about the range of methods people use for living fully with it, or a professional who works with persons who have that disability).

**Practical guidelines for implementing UDR.** Many researchers are unfamiliar with the ways that persons with disabilities access information and perform activities of daily living. Therefore, we offer practical guidelines for implementing the simple rules: (i) plan multiple options for people to learn about, respond to, and arrive at opportunities to participate in research (Table 1); (ii) provide multiple means to communicate the information in research instruments and instructions for participants (Table 2); and (iii) provide multiple means of responding to research instruments and self-management interventions (Table 3). These tables do not include an exhaustive set of possibilities. They are based on the authors’ experiences working mainly with persons who have hearing and visual disabilities. We invite comments from researchers with experience including people with other kinds of disabilities in research and look forward to the development of comprehensive guidelines using multiple creative methods for inclusion of persons with disabilities in mainstream research.

**CASE STUDY: AN EXAMPLE OF UDR**

A researcher investigating cognitive impairment after adverse cardiac events became concerned about the validity of standard instruments for measuring cognitive impairment. In particular, one instrument requires reproducing a hand-drawn complex
COMMENTARY

Table 3. Practical UDR guidelines for providing multiple means of responding to research instruments and interventions.

Provide visual, voiced, and tactile means of response to questionnaires and other research instruments.

- For visual response, use both written and picture choices.
- Consider (i) using a VRS to communicate with deaf participants; (ii) allowing Braille responses from Braille writers; (iii) providing an ASL interpreter for deaf participants who use ASL; (iv) using touch screen questionnaires on tablet or pad computers, with visual, tactile, and audio cues; and (v) using telephone interviews, a standard technique that is already accessible to most people.

Provide accessible options for interventions.

- For self-management interventions using technology, ensure that options are available with visual, audible, and tactile output (for example, talking blood pressure and blood glucose meters with large print, insulin pumps with vibrating alarms, talking pedometers, and alarm clocks that talk or have flashing lights).
- For qualitative research that requires participants to keep journals, allow a recorded format for those who keep records as recordings. Consider providing a low-cost digital recorder that can be downloaded into a computer for easy transcription.

Conclusions

We have proposed a few simple rules and practical guidelines for UDR. We hope that UDR will promote inclusion of people with disabilities in health research, increase the generalizability of the results, and improve clinical applicability to entire populations. Furthermore, improved evidence about the health needs of persons with disabilities can be expected to produce improved care, and ultimately improved health, for this large minority population.

REFERENCES AND NOTES

33. Funding: The work on this article was funded by a grant from the National Institutes of Nursing Research: 3P30NR010676-03S1 (S.M.M., principal investigator).  
Competing interests: A.S.W. has been paid as a consultant by Eli Lilly.  
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Sci Transl Med 3, 82cm1282cm12
DOI: 10.1126/scitranslmed.3002133