

# Using the CABLES Model to Assess and Minimize Risk in Research: Control Group Hazards

Gerald P. Koocher

*Graduate School for Health Studies  
Simmons College*

CABLES is both an acronym and metaphor for conceptualizing research participation risk by considering 6 distinct domains in which risks of harm to research participants may exist: cognitive, affective, biological, legal, economic, and social/cultural. These domains are described and illustrated, along with suggestions for minimizing or eliminating the potential hazards to human participants in biomedical and behavioral science research. Adoption of a thoughtful ethical analysis addressing all 6 CABLES strands in designing research provides a strong protective step toward safeguarding and promoting the well-being of study participants.

Key words: human-subjects protection, research ethics, research participants' research risk

When oil companies seek new exploration zones or real estate developers plan to build a shopping center in a meadow or wetlands area, many community and governmental agencies demand completion of an environmental impact statement considering a wide range of well-specified potential ramifications. The same principle applies when permission is sought to change zoning ordinances or to initiate other major changes that have the potential for both benefit and risk in our neighborhoods. We owe no less due diligence to the people who participate in biomedical and behavioral research. Although there are many excellent books addressing the rights of research participants and responsibilities of investigators (e.g., Sales & Folkman, 2000; Sieber, 1992; Stanley, Sieber, & Melton, 1996), there are no well-articulated

models of how one should go about systematically analyzing the design of a particular study across all of the dimensions of risk relevant to the participants.

The CABLES acronym provides a useful model for conceptualizing research risk among both experimental and control group participants by consideration of six distinct domains in which risk of harm to a research participant may occur (i.e., cognitive, affective, biological, legal, economic, and social/cultural). The metaphor is intentional. The six strands of the CABLES model are each intended as distinct supports for a bridge of safety for participants as they venture from entering a study to coping with any aftereffects of the experience. Although the model can be applied to any aspect of research involving human participants, the particular focus for purposes of this article is on issues associated with control groups. People assigned to such experimental conditions in treatment outcome studies may be among the most vulnerable because such participants often harbor some degree of reasonable suspicion that a better, more effective, or less dangerous treatment exists and that they are not getting it.

### THE SIX STRANDS OF THE CABLES MODEL

*Cognitive risks* are threats to the participant's intellectual functioning, learning, academic achievement, and the rational underpinnings of self-esteem. In this category fall all hazards to cognitive functioning that do not result from anatomical or biological changes. Examples of research in this category might include comparative analyses of teaching strategies, remediation of learning disabilities, or problem-solving tasks. Imagine a study of a new experimental high school mathematics curriculum that results in participants from the control group (i.e., enrolled in the standard math curriculum) earning higher or lower scores on the Scholastic Assessment Test. Were the enrolling students alerted to this significant benefit or problem from the outset of their participation? What happens when a randomized clinical trial to test a new remediation strategy for a specific learning disability proves very successful? Do the participants in the control group get the learning disability treatment or math instruction that they missed out on? What if the participants in the control group are offered the newly proven beneficial treatment but have passed through a critical developmental period (e.g., passing a choice point in an educational tracking scheme or completing the college application process) that vitiates the benefits of the program (e.g., the control group members feel "dumber" than their peers, or their lower test scores are all that is on file as they apply for college admission)? Consider the participant challenged to solve difficult or insoluble problems in a school setting as part of a psychological experiment in frustration tolerance. What if the inability to succeed at the challenging task wounds the participant's self-esteem, leading to a loss of motivation that generalizes beyond the laboratory?

*Affective risks* are the hazards of emotional distress both during and following participation in the research. These might include risks of self-discovery when participation in research reveals sides of oneself that the participant would rather not see, as in Milgram's (1983) classic study of obedience. Other emotional risks may occur in tests of flooding or implosive therapy techniques (Boudewyns & Shipley, 1983), where the treatment may seem worse than the symptoms to some participants. Alternatively, participants in placebo control trials where the ineffectiveness of an intervention or placement on a waiting list offered to members of a symptomatic control group may lead them to experience continued distress or give up hope while enrolled in the study.

Emotional risks may also be inherent in studies that involve collection of sensitive data such as HIV sero-positivity or genetic risk status (Bayer, 1989; Burris & Gostin, 1997; Hudson, Rothenburg, Andrews, Kahn, & Collins, 1995; Lapham, Kozma, & Weiss, 1996; Moreno, Caplan, & Wolpe, 1998). Participants entering such studies may not be fully prepared to deal with the consequences of testing positive for HIV. Such discoveries can have legal (e.g., liability and discrimination claims) and economic hazards as well (e.g., loss of employment and inability to obtain insurance). In addition, there can be other risks if one seeks to enroll in a potentially lifesaving clinical trial but is found ineligible, or considerable guilt-driven distress if genetic testing reveals that one individual is unaffected by an ominous gene that is present in other family members.

*Biological risks* refer to the hazards of physical injury or illness as a result of delayed, ineffective, or absent treatment, as a direct or side effect of the intervention, or as a result of investigator negligence. The biomedical ethics literature is replete with stories of such hazards and late effects, ranging from the "medical experiments" conducted in Nazi concentration camps (Annas & Grodin, 1995) to more recent disclosures of radiation experiments using terminally ill medical patients and armed forces personnel conducted by or for the U.S. military and Department of Energy during the Cold War. A good example of control-group risk potential occurred more than 2 decades ago, when computerized research models suggested that a briefer 12- to 18-month course of noxious chemotherapy might be as effective in treating osteogenic sarcoma (i.e., a form of bone cancer) as the lengthy standard course of 36 months. A randomized clinical trial was deemed necessary; however, there was some risk that the shorter course of treatment might result in early relapse by a chemotherapy-resistant tumor cell line. The study went forward with full informed consent of participants, and the shorter course of therapy ultimately proved equally effective.

From a mental health perspective one could cite many psychopharmacology studies, such as the early investigative work with clozapine as a treatment for schizophrenia, in which several deaths from agranulocytosis, a severe drop in white blood cell counts, occurred (Skelton, Pepe, & Pineo, 1995). In such cases members of the group not receiving the drug may fare better than their peers medically, although their psychopathology may worsen or become more entrenched while they receive

less-effective treatments. This is particularly true when a potentially effective treatment is contrasted with a no-treatment control group or when drug “washout” periods intended to precipitate a relapse on withdrawal of the medication are a part of the planned experimental design.

*Legal risks* might include adverse consequences, such as disclosure of sensitive identifiable confidential information, statutorily mandated reporting of abuse or neglect, or even insight-generated legal actions (i.e., litigation begun as the result of self-discoveries made in the course of one’s participation in research). As noted earlier, a number of sensitive areas of medical research, including diagnosis and treatment of people infected with HIV/AIDS and predictive genetic testing, may lead to significant legal risks (Bayer, 1989). Psychosocial research in areas such as child neglect or abuse, child or caregiver substance abuse, and domestic violence can pose similar risk, especially if confidentiality and data access are inadequately protected (Wolf & Lo, 1999).

In one study, for example, an investigator sought to determine how children who had never been sexually abused played with anatomically detailed dolls and contrasted their responses with children who were known sexual abuse victims. In seeking out members for the control (i.e., nonabused) group from among large numbers of nursery school children, it was necessary to screen out children who may have been abused previously. Asking that exclusionary question directly of the parents of prospective participants might conceivably have yielded answers that would require the investigators to report to authorities previously undiscovered cases of suspected child sexual abuse. To avoid this risk, the researchers presented a list of multiple exclusion criteria (e.g., Do not agree to allow your child to participate if he or she has recently been exposed to an infectious disease, does not tolerate interacting with strangers well, is currently enrolled in psychotherapy, or may have been sexually abused in the past). When parents subsequently declined to enroll their children as participants, the investigators did not have any data that might trigger a required report under statutory child-abuse reporting mandates.

*Economic risks* are actual financial hazards associated with actual incurred costs (e.g., transportation to experimenter’s laboratory) or lost opportunity costs (e.g., time and revenue lost from paid employment to enable participation), and remediation of iatrogenic or damages associated with participation in the research. In one actual study of job interview skills using a deception paradigm for the sake of realism, the investigator advertised a highly desirable employment opportunity. Applicants came for interviews only to find out after the fact that there were no actual job openings. Rather, they had been unwitting conscripts in a “naturalistic experiment.” At least one such participant had purchased new clothes and taken unpaid time off from another job to attend the “job interview.”

Another type of example might involve people suffering from symptoms of depression or anxiety who are recruited into a drug study. Such individuals often have difficulty performing work and in other aspects of their personal lives as a result of their illness symptoms. As part of the research protocol, such people may routinely

be asked to take off time from work, arrange child care, pay their own transportation costs, and attend sessions that contain no active treatment components (i.e., if assigned to a control group). In some cases they may be asked to suspend a treatment regimen of some known relative efficacy (e.g., a medication that only partially controls their symptoms) for a period of time during and agree to randomization to a placebo condition. Economic inducements may also raise ethical economic issues. For example, would low-income patients agree to sacrifices such as risky participation or interruption of effective treatment for much needed financial compensation?

Even when deception is not involved and some compensation is offered to participants, the value received may be far less than the minimum wage equivalent of the actual hours spent on the study. Some investigators would respond by arguing that there is intrinsic social value to research participation that cannot be calculated. One must ask whether the participants are fully informed of the likely required time commitment at the outset of recruitment and whether or not there are subtle pressures to remain in the study (e.g., social demand characteristics) even when participants begin to believe that it is not in their financial best interests to do so. In other circumstances, the economic inducement to participate may be excessively enticing to surrogate decision makers. For example, some parents or guardians may be tempted to enroll their children in risky or noxious experimental paradigms because of the compensation offered to the responsible adult (Koocher, 1991; Koocher & Keith-Spiegel, 1990).

*Social and cultural risks* resulting in social rejection or stigmatization are again well illustrated in studies of HIV/AIDS or genetic risks factors (Bayer, 1989; Hudson et al., 1995; Lapham et al., 1996). At the same time, however, even relatively benign studies can lead to a degree of stigmatization, with some members of a group being excluded based on study criteria while many of their friends or classmates are included. In some studies of “gifted” or “socially isolated” children, for example, it can be all too obvious to peers that it is “good” or “bad” to be chosen for a particular research group. Rosenthal’s famous study, “Pygmalion in the Classroom” (Rosenthal & Jacobson, 1992), also illustrated this point well. In this study, teachers who were led to expect positive changes in their students based on bogus psychological test information subsequently rated the students as having fulfilled the prophecy of the phony test data. It appeared that the teachers may have altered their expectations and treated their students more positively, with beneficial results. In some studies from the prevention research literature, at-risk participants are selected for study. Such research often fails to consider the potential consequences of being labeled in this category, especially when the participant at risk becomes known as such to others (e.g., parents, teachers, or community members) and assigned to a control group or an arm of the study that offers no direct benefit or subsequent remediation.

All too often, investigators fail to consider special factors related to race, culture, or ethnicity that may complicate the validity of their research or adequately respect the participants. For example, historical mistrust of “outsider” investigators and ethically

questionable research methods have led some groups and communities to become averse to participation in research (Darou, Hum, & Kurtness, 1993; Gamble, 1993; Harris, Gorelick, Samuels, & Bempong, 1996). In such situations the design of studies and construction of control groups require particularly thoughtful consideration of cultural differences and historical abuses as well as careful community consultation (Fisher & Wallace, 2000; Norton & Manson, 1996).

## SPECIAL QUESTIONS FOR ANALYSIS

In applying the CABLES model, there are a series of special questions coupled to both federal regulations and population vulnerabilities that investigators should consider. These questions should be used to focus attention and guide ethical analysis with respect to the potential consequences of certain types of control group designs. The points to be addressed include problems associated with foreseeable risk, minimal risk, hazards of randomization, losses associated with critical developmental or medical periods, risk associated with treatment as usual (TAU) or standard care control groups, risks that radiate to nonparticipant others, and hazards associated with testing of manual-driven therapies in research paradigms.

### What Is Foreseeable Risk?

The fundamental challenge is making an effort to anticipate all reasonable risks. It is impossible to predict or consider every possible risk in advance. Indeed, participation in research that might place one person at risk might offer promise of significant benefit to another (Sieber, 1992). Nonetheless, it is important to consider potential risks and act to prevent or mitigate their effect. It is possible to use the CABLES model to systematically analyze both likely and remote potential adverse consequences to participants using data collected via reviews of the scientific and professional literature, consultation with experts, and conferring with potential participants or representative members of their community (Melton, Levine, Koocher, Rosenthal, & Thompson, 1988). In addition, obtaining pilot data or holding exit interviews or focus groups with participants after initial stages or termination of the experimental interval can be other appropriate strategies.

An example of foreseeable risk, when psychiatric patients are the research participants, might include the hazard of enrolling suicidal patients in depression studies. Excluding such people might bias the study sample and preclude finding successful therapies for them. Including suicidal individuals might heighten their risk. One illustrative strategy for addressing this risk could be prioritizing the risk status of participants and building special protections into the study (e.g., viewing recent suicide attempters as being at increased risk and monitoring them more closely).

## What Is Minimal Risk?

Federal regulations governing independent review board (IRB) operations allow for certain exceptions to review procedures or types of IRB oversight in so-called minimal-risk research (Code of Federal Regulations, 1999), but what constitutes this level of hazard? Some commentators have explained that this is the same level of risk one might encounter during the course of a normal day. This leads to the logical next question: What is a normal day, anyway? For some people, normal days may include encounters with a schoolyard bully, a skinned knee on the playground, the pressures of a demanding workplace, and home life with a hostile parent or spouse. The CABLES model should assist in identifying reasonably predictable incremental risks that are not already a routine part of the potential participants' lives.

## Hazards of Randomization

As noted earlier, some study participants may be asked to suspend a treatment regimen of some known relative efficacy (e.g., a medication that only partially controls their symptoms) for a period of time during the course of a study and agree to randomization to a placebo condition. Some ethicists argue that investigators should offer to provide free efficacious treatment to participants randomized to no-treatment or placebo-control groups once the study is over. If some intervention is to be offered, will any treatment do? Must it be the same program offered to participants in the active arm of the study, or should the intervention offered be the more effective treatment based on study outcome data? Who should pay for the cost of such services? What happens if the patient has no insurance and the grant-funding agency does not allow for such costs? What if the investigator has no funding available to pay for such after-the-study intervention?

In some studies randomization can lead to potential harms apart from those inherent in the fundamental nature of a clinical trial. For example, being randomized to a "less desirable" study condition may be perceived as an incremental loss or stressor with adverse psychosocial consequences. Consider the following example: A newly diagnosed cancer patient is eligible for a study on adaptive coping that will compare a program of social support enhanced via group therapy (i.e., the treatment group) with a set of reading materials on health promotion and coping with cancer (i.e., the control group). The investigators' primary hypothesis is that the intervention offered to the treatment group may be highly effective in enhancing quality of life and coping with the cancer, in contrast to no treatment or to the group offered the program of reading materials. In the usual manner of obtaining informed consent, the patient would be told of the two arms of the study, agree to randomization, and then be assigned by chance to one or the other. To some participants the assignment itself could easily be seen as an incremental emotional insult (i.e., "First I get

cancer, and then by the luck of the draw I don't get into the support group"), leading to increased frustration or depression.

An example from the psychiatric domain might include a similar paradigm in which the potential patients may already be highly demoralized by their mental disorder, as in major depressive disorders. The project design might offer a promising new intervention to be contrasted with TAU or standard care. Although such studies must be done to scientifically establish relative efficacy, it is unlikely that a patient whose depression was already under control would be a candidate for the study (i.e., "If it's not broken, don't fix it"). Thus, the most likely candidates are those individuals with persistent symptoms for whom we already know that TAU is ineffective. Once again, the potential participant may feel lucky or hopeful if randomized to the promising new treatment, and even more hopeless than ever if assigned to what has already proved unhelpful.

One potential solution to this type of control group problem might be to preresearch randomize potential participants as an initial recruitment step and to determine participant eligibility prior to offering entry into the study. Participants could then be invited into and informed about only the particular study arm for which they are eligible by preassignment. Because preresearch randomization establishes eligibility for only one study condition, it is only necessary in an ethical sense to provide informed consent about study conditions for which the person is eligible. No data need be provided on study conditions for which the participant is ineligible, and therefore no disappointment or frustration about the outcome of random assignment will result.

Opponents of such practices might argue that such participants are not fully informed about the aims of the study or treatments they did not receive. It might also be awkward to subsequently invite such people to enter later studies after their participation in the control group is completed. Another possibility might be to tell potential participants about all aspects of the study, including their initial assignment (even if seemingly less desirable), with the promise of offering the more appealing treatment later if it proves more effective.

## The Hazard of Critical-Period Losses

For some populations and medical or psychological conditions there may be critical periods during which intervention is optimal if the participant is to achieve maximum, or even any, benefit. An intervention that is highly effective during such a period may be ineffective or harmful if provided prior to or following the critical time frame. In such situations certain traditional control-group strategies (e.g., nontreatment, wait list, or staggered entry) may actually be harmful to the participant so assigned. Examples might include certain newly diagnosed cancer patients eligible for psychosocial intervention, very young congenitally hearing-impaired children eligible for cochlear implants, or the classic paradigm, the

Tuskegee syphilis study, in which the progression of the illness was allowed to advance unchecked until irreversible damage or death occurred (Gamble, 1993).

In research with psychiatric patients, a classic example might be studies that involve withholding or planned discontinuation of medication from patients in developing phases of psychotic disorders. In such cases treatment delay may result in irreversible progression of the disease or damage to social, work, and family relationships. If the patient is a child, failure to treat properly and in a timely manner as the result of no-treatment control or suboptimal conditions might result in the participants' missing significant amounts of school or experiencing peer rejection. In addition, participation in experiments that do not go well from the patient's perspective may result in diminished trust, lost enthusiasm, and even simple unwillingness to participate in future mental health treatment programs.

Those seeking potential solutions for such problems can again draw on the CABLES paradigm and routinely assess the potential for critical-period participation risks across the various strands of the model. When such risks are recognized the study can be redesigned, the participants at particular risk can be excluded, or alternative effective interventions can be offered. Participants and data can also be carefully monitored on a regular basis over the course of the project, and, if necessary, the study protocol can be interrupted so that participants are provided constructive intervention as soon as need becomes apparent.

### Hazards of Treatment as Usual or Standard-Care Control Groups

The key question in assessing the ethical merit of such control groups requires that we ask ourselves: Is the usual treatment or standard level of care for the condition in question reasonably effective? Will providing such standard treatment cause significant harm by reason of critical period loss (i.e., irrecoverable loss as a result of delay)? If the nonstandard treatment proves more effective, will it subsequently be provided to the participants who did not receive it initially? Conversely, if the new experimental therapy is expensive (e.g., a new medication) will the participants who do better on the new treatment be able to continue using it after the study ends? The primary ethical value of beneficence (i.e., do no harm) generally requires that TAU or standard care be of at least some benefit and not preclude incremental benefit at a later point in time, should the newer experimental therapy being tested prove to offer such benefits.

### Radiating Risks: Hazards to Participants, Family Members, and Caregivers

In some studies, risks inherent in one person's participation can extend to their peers, classmates, associates at the office, or family members. Such hazards might include: legal consequences of mandated reporting, injury, emotional distress

caused by a participant's uncontrolled symptoms, or the economic costs of enabling the participating person to fulfill research obligations (e.g., time lost from a job, child care costs, and transportation costs). For example, when a child or dependent adult (e.g., physically handicapped, elderly, or otherwise disabled) who enrolls in a research project makes a disclosure that triggers a report to state authorities under mandated reporting statutes, members of the family may be subject to intrusive investigation and even prosecution. In most cases such legislative mandates are intended to protect a vulnerable party, but in many situations the disruption caused in the lives of others can be significant (e.g., if children are placed in foster care while an investigation proceeds or parents need to secure legal representation).

Another example might involve testing of new medication in a double-blind crossover design. During drug washout periods or times when a placebo or new drug may not control symptoms effectively, family members residing with the patient may be subjected to substantial inconvenience, emotional distress, and economic costs (e.g., time lost from work to care for an agitated family member). This type of situation might also lead to difficulties for other nonfamilial caregivers or others in the community. Consider the situation when a patient who is taken off medication or switched to a placebo becomes dangerous to other care providers, coworkers, or social contacts within the institution or community who may not be aware of the changes implemented by the researchers.

In some circumstances, when an adult who is presumed to be competent consents to participate in research that will have such effects radiating to family members, no consent from the family is required, and family members may have no information about or control over the factors contributing to the disruption in their lives. Ethical researchers will consider all reasonably foreseeable disruptions in the lives of those who live with or care for the participants enrolled in studies they oversee, and make appropriate notifications or take cautionary or protective steps as needed.

## Hazards of Manual-Driven Treatment Protocols

Manualized approaches to psychological interventions have become very much in vogue (e.g., Nathan & Gorman, 1998). Such treatment programs rely on a treatment manual, protocol, or set of criteria and instructions for delivering a structured intervention in standardized form. The strengths of such programs include ease of training interveners, consistency in the delivery of the intervention, enhanced fidelity monitoring, and simplified export of intervention across sites and practitioners. Weaknesses include potential insensitivity to individual participants' needs, possibly encouraging participants to continue in nonbeneficial programs rather than seeking more effective intervention, and potential critical-period losses.

Ethical solutions for problems associated with such manual-driven treatments involve incorporating participant-centered criteria for terminating the protocol

when warranted to serve the best interests of the participants. For example, consider an actual occurrence during a research project using a time-delay staggered-entry model to intervene preventively with bereft families (i.e., comparison of a group of families who got the intervention soon after the loss event was contrasted with a group of families who got the same intervention at a later point in time). The study investigated the efficacy of a manual-driven preventive intervention offered to families following the death of a child. The intervention consisted of three 2.5-hr-long sessions provided over a 6-week interval. During the first session with one bereft family, an adolescent sibling of the deceased child expressed troubling, intense suicidal ideation. The investigators immediately recognized that their manualized intervention focused on preventing consequences of protracted grief would not immediately address the urgent needs of the girl who was feeling suicidal. Continuing the research protocol for another 5 weeks would have ignored the instant needs of the participants, who might also have been left with the misleading impression that staying in the study would help in the face of the active suicidal ideation. In consultation with the young woman and her family, the research protocol was terminated and both the teenager and family were immediately redirected to a convenient crisis intervention program. This meant the loss of a participant family in whom several hours of assessment and intervention time had been invested from the study, but clearly served the best interests of the people at risk.

## CONCLUSION

A careful consideration of the manner in which a research protocol and the associated selection of control groups bears on the personal and social ecology of the participant is an ethical necessity in the conduct of research with human participants. Such analyses should consider at least six distinct domains, represented by the acronym CABLES, in which risks to participants—cognitive, affective, biological, legal, economic, and social/cultural—may occur. Only by attempting serious analysis of these six domains and by reassessing them continuously over the course of a study can we truly assure optimal respect for the welfare and protection of research participants and their families.

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