

confidentiality and privacy concerns about Internet use in general, it suggested a paradoxical harm arising from, or accentuated by, debriefing itself. (McCambridge et al. 2013, 45)

The authors state that this feedback led them to rethink debriefing following deception and that they are “considering not doing so” (45). We are inclined to assign this harm not to the debriefing per se, as a reaction to the deception itself. This feedback was also from participants whom the authors describe as nonvulnerable college students; it is reasonable to assume that individuals from more vulnerable populations would react with even greater distrust, especially if it came to light that there had been a series of deceptive studies, for example, by featuring nonefficacious treatment, which only became known after the fact because debriefing was not performed.

Along similar lines, even if one accepts deception generally, we also wonder whether basing the decision to deceive on the likelihood of causing harm has the potential to increase bias and reduce generalizability. In effect, conditioning on the likelihood of promoting harm would mean conditioning on vulnerability, which implies that college students would likely be the population of choice when deception is used in alcohol research. While college students do exhibit high rates of problematic drinking, research that focuses on them is not always applicable to other populations, since college education itself is associated with lower risk overall. For example, low education is associated both with earlier substance abuse (Johnson et al. 1999) and with decreased health more generally (Walsemann, Bell, and Hummer 2012).

In summary, McCambridge and colleagues’ cases do seem limited and are likely not broadly applicable to other contexts. Even if one assumes that their use of deception was acceptable, it is not clear what this would imply for other researchers, or whether choosing study populations based on the likelihood of deception causing harm might itself be methodologically limiting. Despite these concerns, we appreciate their work on this topic and hope that the

discussion that it starts leads to further work to develop a robust case-based framework that will help applied public health researchers better understand how context affects their ethical considerations. ■

REFERENCES

- Fry, G. M. 1975. *Night riders in Black folk history*. Knoxville, TN: University of Tennessee Press.
- Gamble, V. N. 1993. A legacy of distrust: African Americans and medical research. *American Journal of Preventive Medicine* 9(6 suppl.): 35–38.
- Johnson, J. G., P. Cohen, B. P. Dohrenwend, B. G. Link, and J. S. Brook. 1999. A longitudinal investigation of social causation and social selection processes involved in the association between socioeconomic status and psychiatric disorders. *Journal of Abnormal Psychology* 108(3): 490.
- Jones, J. H. 1993. *Bad blood: The Tuskegee syphilis experiment, New and expanded edition*. New York, NY: Free Press.
- Jonsen, A. R. 2001. Casuistry. In *Methods in medical ethics*, ed. J. Sugarman and D. P. Sulmasy, 104–125. Washington, DC: Georgetown University Press.
- McCambridge, J., K. Kypri, P. Bendtsen, and J. Porter. 2013. The use of deception in public health behavioral intervention trials: A case study of three online alcohol trials. *American Journal of Bioethics* 13(11): 39–47.
- Savitt, T. L. 1982. The use of Blacks for medical experimentation and demonstration in the Old South. *Journal of Southern History* 48(3): 331–348.
- Skloot, R. 2010. *The immortal life of Henrietta Lacks*. New York, NY: Macmillan.
- Waite, F. C. 1945. Grave robbing in New England. *Bulletin of the Medical Library Association* 33(3): 272.
- Walsemann, K. M., B. A. Bell, and R. A. Hummer. 2012. Effects of timing and level of degree attained on depressive symptoms and self-rated health at midlife. *American Journal of Public Health* 102(3): 1–7.

Methodological and Inducement Manipulation

Collin O’Neil, Center for Bioethics, New York University

The authors of the target article are far from alone in deploying selective withholding and deception for research purposes, but they are unusually explicit and reflective about their use of these methods (McCambridge et al. 2013). Too often the use of such methods is neither frankly acknowledged nor defended. The authors at several points refer to

an article that my co-author, Franklin Miller, and I published on the ethics and regulation of deception in research (O’Neil and Miller 2009). I take this opportunity to elaborate on a feature of the view that was not emphasized in that article but marks what I believe is the most fundamental difference between McCambridge and colleagues’ approach to

Address correspondence to Collin O’Neil, New York University, Center for Bioethics, 285 Mercer St., New York, NY 10003, USA. E-mail: collin.oneil@nyu.edu

the ethics of deceit and the approach I favor. The authors offer examples of withholding and deceit that fall under two categories that I label “methodological” and “inducement” manipulation. The difference between our approaches explains why they regard these two categories as morally on a par, whereas I see the latter as far more problematic than the former.

The studies that the authors discuss are clearly of low risk. But influencing someone’s behavior via means that depend for their success on ignorance or mistake counts as manipulation, and we have a right not to be manipulated, even when the manipulation is harmless. Furthermore, when a subject’s willingness to participate in a study—that is, to submit to interventions, accept risks, disclose private information, invest time and effort, and so forth—is a consequence of such manipulation, various other rights may be infringed as well. These various rights may be brought under the umbrella of a general right not to be experimented upon or “used” for the benefit of others.

In our article we argued that the only way to avoid infringing the rights of subjects is by securing their authorization for the use of manipulation. To obtain valid authorization from the subjects, they must be made aware that manipulation will take place. They may be kept ignorant of the specific content of the manipulation, but there are limits. To ensure that subjects’ willingness to participate in the study is not a consequence of the manipulation, they must not be kept ignorant of any aspect of the study that would have made them unwilling to participate. And they must also be aware that the project they are asked to participate in is research, or at least a project designed for the benefit of others, even if this information would not have altered their willingness to participate. Subject cannot waive their right against being used for the benefit of others unless they are aware that this is the kind of right they need to waive.

The authors express concern that seeking authorization for manipulation may bias subjects’ responses. I defer to their judgment on this point. Even if getting authorization would be scientifically problematic, it remains the case that without authorization, subjects’ rights not to be manipulated are infringed. But the fact that obtaining authorization would be scientifically infeasible may still be relevant. The right against manipulation is not absolute; it may sometimes be justifiably infringed. If seeking authorization would make the science suffer, then as Paul Ramsey once said of nontherapeutic pediatric trials, perhaps the researchers should “sin bravely” (Ramsey 1976). The fact that unauthorized manipulation wrongs the subjects may imply that researchers acquire obligations to later explain themselves to the subjects, apologize, and perhaps more. But it does not imply that they must never manipulate subjects without their authorization.

I don’t know whether the authors agree that unauthorized manipulation always “sins” against the subjects, and now set this issue aside to focus on the question of justification. Under what conditions might researchers be justified in infringing the rights of subjects? One plausible suggestion is that unauthorized manipulation may be justified when

the study poses no more than minimal risks of harm, and both the manipulation and the absence of authorization for it are necessary to achieve important scientific objectives. This might be a necessary condition on justified unauthorized manipulation—I’m not entirely sure. Where the authors and I clearly part ways is on the question of whether it is sufficient. This matters a great deal when it comes to the evaluation of methodological and inducement manipulation.

Methodological manipulation is for the purpose of preserving the evidential value of the subjects’ responses to the study interventions. In Study A the purpose of keeping subjects in the dark about certain aspects of the study is to minimize the influence of assessment reactivity on their drinking behavior (Kypri et al. 2010). Study C investigates the effect of different sets of expectations about study participation on drinking behavior. To compare the efficacy of different sets of expectations, it is necessary to vary subjects’ expectations about their situation while holding their actual situations constant, which calls for deception (Kypri et al. 2011). In both cases, the purpose of the manipulation is to ensure that the subjects’ drinking behavior can answer the study question.

In Study B there is a clear example of “inducement manipulation,” that is, manipulation for the purpose of getting subjects to participate in a study. In Study B the researchers had grounds for concern that if the intervention groups recognized that the follow-up survey distributed 3 months later was part of the same study they would be less willing to answer the questions than the nonintervention group, compromising the equivalence of the groups. Accordingly, the researchers “abbreviated the alcohol outcomes measures and concealed them within a lifestyle questionnaire” in order to block this recognition and avoid “differential attrition” (McCambridge et al. 2012). The use of manipulation in this case is not (or not only) to secure the probative value of the subjects’ participation within the study, but to influence the participation rates themselves.

McCambridge and colleagues note that “the core rationale for employing deception in these studies is the same in all three cases: Communicating the true nature of the study in advance would interfere with the achievement of study aims” (42). As they emphasize, it is not only methodological manipulation that may be scientifically useful, but also inducement manipulation, since low or unbalanced participation rates can diminish the scientific value of a study. Since the studies are risk-free, the manipulation in each of these studies might satisfy the condition expressed earlier.

But I don’t think that condition goes far enough. I am unconvinced that the researchers may sin bravely in Study B. The reason is this. Although researchers need not always give subjects an opportunity to authorize manipulation to be justified in manipulating them, it seems to me they must at least reasonably believe that if the subjects were given this chance, they *would* authorize the manipulation. (A more careful formulation is the following: The researchers must believe that the subjects’ informed selves, who know everything the researchers know about the study, would advise

their actual incompletely informed selves to authorize the manipulation.)

Suppose that the researchers have reason to suspect that a subject has an aversion to manipulation as such. Or suppose that, although a subject has no problem with manipulation in itself, the researchers suspect that the manipulation will blind the subject to a factor that would have made her unwilling to participate in the study. In neither case would the subjects' informed selves have advised their actual selves to participate. The researchers are involving them in the study against their will, or, more precisely, against the will they would have had if they had been better informed. I don't see how such manipulation could be justified except in extraordinary circumstances.

Now, the authors would not countenance unauthorized manipulation if participation in the studies were risky. They believe that subjects are not to be endangered against their will, even for the sake of important science. But why exactly would it be all right for researchers to get subjects to fill out follow-up surveys against their will? Yes, it's a small thing and the subjects would be at most inconvenienced, but they have no obligation to participate, and even if they did, it doesn't follow that the researchers have the authority to enforce that obligation by fooling the subjects into compliance.

So, if researchers do not actually obtain authorization for manipulation, I think they can be justified in going forward with it only if they believe that the subjects *would* have agreed to participate in the study, had they been adequately informed about it, including the fact that it involves manipulation. In the case of inducement manipulation, not only do the researchers not believe that the subjects would have agreed to participate, they believe that the subjects would *not* have agreed to participate. The whole point of inducement manipulation is to get subjects to participate who would not have done so had they been better informed.

When the manipulation is merely methodological, by contrast, this is not the purpose. The point of methodological manipulation is not to try to increase participation, but only to ensure that the subjects who do participate are generating meaningful data. Moreover, if the subject is aware that she is participating in a study, it may be presumed that the subject would want her participation to generate good evidence. Insofar as manipulation is necessary to ensure this, and as long as there is no reason to suspect that the subject has any intrinsic objection to manipulation, researchers could reasonably believe that the subject would authorize the manipulation. Of course, this shows only that methodological manipulation, unlike inducement manipulation, can meet the hypothetical authorization constraint, not that it always does. ■

REFERENCES

- Kypri, K., J. McCambridge, J. Cunningham, et al. 2010. Web-based alcohol screening and brief intervention for Maori and non-Maori: The New Zealand e-SBINZ trials. *BMC Public Health* 10: 781.
- Kypri, K., J. McCambridge, A. Wilson, et al. 2011. Effects of study design and allocation on participant behaviour. *Trials* 12(1): 42.
- McCambridge, J., P. Bendtsen, M. Bendtsen, and P. Nilsen. 2012. Alcohol email assessment and feedback study dismantling effectiveness for university students (AMADEUS-1): study protocol for a randomized controlled trial. *Trials* 13: 49.
- McCambridge, J., K. Kypri, P. Bendtsen, and J. Porter. 2013. The use of deception in public health behavioral intervention trials: A case study of three online alcohol trials. *American Journal of Bioethics* 13(11): 39–47.
- O'Neil, C., and F. Miller. 2009. When scientists deceive: Applying the federal regulations. *Journal of Law, Medicine & Ethics* 37(2): 344–350.
- Ramsey, P. 1976. The enforcement of morals: Non-therapeutic research on children. *Hastings Center Report* 6(4): 21–30.

Consenting in the Dark: Choose Your Own Deception

Rachel Zuraw, O'Melveny & Myers, LLP

Research ethics aims to preserve the autonomy of human research subjects, and thereby to preserve their trust in researchers. Typically, studies do so by educating participants about the process and goal of the study and gaining their informed consent. Professors McCambridge, Kypri, Bendtsen, and Porter (2013), however, have described the ethical issues presented by public health studies that are only

effective if the participants are not fully informed about the nature or existence of the study. While the authors do an excellent job of describing the dilemma and identifying tools for ethical analysis of deception in research studies, they neglect to make a critical distinction between two types of deceptive studies: studies that deceive participants as to *whether* they are participating in a study,

Address correspondence to Rachel Zuraw, O'Melveny & Myers, LLP, 2 Embarcadero Center, 28th Floor, San Francisco, CA 94110, USA. E-mail: zurawr@gmail.com

Copyright of American Journal of Bioethics is the property of Routledge and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.