in 13 h. This rapid reduction did have a short-term adverse affect, manifested by the appearance of decerebrate posturing 24 h after initiation of therapy. However, this resolved quickly, and at the time of discharge, no neurological deficits were detectable.

Unquestionably, hyperglycemia and hyperosmolarity in our patient were aggravated by the injudicious administration of 50% dextrose, which in a more fragile individual may have exceeded the tolerable limit. Given the ease and rapidity of glucose estimation by reagent strips, the practice of indiscriminate administration of dextrose to comatose patients should, in our opinion, be discouraged.

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Deception in Diabetes Research

Recently, Ziegler et al. (1) used deception with their research subjects to examine the reliability of patient-generated data from self-monitoring of blood glucose (SMBG). In their study, they actively misled 14 patients with type I (insulin-dependent) diabetes into thinking their reflectance meters (Glucometer I) were malfunctioning and then used this opportunity to replace the patients' meters with experimental memory meters: "During a routine visit of the subjects to the outpatient clinic of our department, we took advantage of an alleged malfunctioning of their device to lend them a memory-reflectance meter for a period of 21 days" (1). Patients were not informed that their blood glucose measurements, along with the time and date, were being stored in the memory meters, and they were told to continue to monitor their blood glucose and record the measurements in their logbooks. Ziegler et al. examined the reliability of the patients' recorded measurements by comparing the logbook and memory-reflectance meter recordings.

The use of deception by the physicians in this study concerns me for two reasons. First, deception appears to compromise the patients' privacy. Privacy in this context refers to "the freedom of the individual to pick and choose for himself the time and circumstances under which, and most importantly, the extent to which, his attitudes, beliefs, behavior and opinions are to be shared with or withheld from others"(2). In Ziegler et al.'s study, the measurements in patients' logbooks represent what patients choose to present to the physician. By using covert observations, the physicians took away the patients' ability to control their self-presentation and intruded into their privacy without their consent. This intrusion reduces the patients' autonomy and could be construed as a lack of respect for the person. Second, deception has the potential of undermining the physician-patient relationship. Patients who participated in the study, and those who may become acquainted with the research, may lose trust in their doctors as a result of the deception and, consequently, may be less willing to share significant information with their physicians, or they may actively misrepresent information about their adherence to the therapeutic regimen. These consequences may ultimately lead to poorer patient care.

My concerns about the use of deception in the study by Ziegler et al. are heightened because the presentation of misleading information by the researchers may not have achieved its intended goal—the reduction of measurement reactivity. One of the arguments for using deceptive practices in research studies such as Ziegler et al.'s is that if people know they are being studied (e.g., if patients' SMBG measurements are electronically stored and evaluated by researchers), they may change their behavior and act unnaturally. Researchers using deceptive practices generally argue that deception creates the necessary conditions that allow them to observe patients' natural behavior. The potential flaw in this argument is that some patients may see through the deception or attempt to guess the purpose of the study, which may have occurred in the study by Ziegler et al. if any of the 14 patients were in contact with each other and talked about the sudden "breakdown" and replacement of their meters. The implication is that we cannot be sure that the results of the study represent patients' spontaneous behavior under natural conditions. Ziegler et al. indicate that the "patients were unaware of the storage capacity of the new memory-reflectance meters," but they do not describe the procedures they used to make this determination (e.g., were patients probed to determine if they were suspicious about the true purpose of the study?). Not surprisingly, Ziegler et al. did not consider the patients' level of naiveté as a potential factor explaining the differential level of reliability in the SMBG data.

My concerns about Ziegler et al.'s study are further heightened because the weakness of their design precludes the possibility of arriving at any firm conclusions about the reliability of patient-generated data. Ziegler et al. treated the number of SMBG readings in the memory-reflectance meters as the "true" number of patient readings and viewed discrepancies between the logbooks and memory meters as evidence that the patient was overreporting ("addition of phantom values in logbook") or underreporting ("omission of SMBG measurement from logbook"). The problem with using the memory meter as the true measure of patients' self-monitoring behavior is that individuals other than the patients could have used the memory meter, and/or the

patients could have accurately measured their blood glucose with another device. Ziegler et al. acknowledge these limitations but do not seriously consider how these limitations threaten the validity of their measures of reliability.

Although Ziegler et al. indicate that their study was approved by their ethics committee (Centre Hospitalo-Universitaire de Nancy), they do not provide information about the procedures that were used to address the ethical issues surrounding their study. For example, they do not document what type of consent they obtained from the patients who were participating in the reliability study (this study was part of a larger study looking at continuous subcutaneous insulin infusion) or what type of debriefing (if any) the patients received. In addition, they do not describe patients' reactions to the deception or the impact the deception had on the physicians conducting the study. Although these issues are not commonly addressed in journal articles, they are crucial both ethically and methodologically. I hope that by raising these issues, there will be a renewed interest in evaluating and studying the potential harms and benefits of deception in diabetes research.

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Reply

Noncompliance with treatment is recognized as a major problem in medicine (1). To measure the reliability of self-monitoring of blood glucose (SMBG) in a group of type I (insulin-dependent) diabetic continuous subcutaneous insulin infusion (CSII)-treated patients, we used memory-reflectance meters without telling patients about the storage capacity of these meters. Dedrick believes we used deception in this study (2); we obviously did, but some points of his criticism must be discussed.

Although Dedrick's definition of patient privacy may sound good from a theoretical point of view, it is nevertheless inappropriate for SMBG. SMBG is a cumbersome technique that implies a mutual trust in the doctor-patient relationship. By using a logbook, the patient accepts shedding some of his/her privacy to give the physician clues for better management of insulin dose adjustments. To gain more accurate knowledge on patient adherence and compliance, the physician must become involved in all kinds of problems encountered by the patient. The physician must not give inappropriate advice based on false glycemic data when retrospectively analyzing the adaptation of insulin doses from the patient logbook. CSII is not a treatment without danger. Severe, potentially lethal accidents may occur, e.g., hypoglycemic coma or ketoacidosis. Safety requirements may excuse some amount of intrusion on patient privacy.

Dedrick slightly overreacts when he writes about an alleged "lack of respect for the person," in that this statement is a judgment on our medical behavior in matters of intensified insulin therapy. The patients were never aware of the actual aim of this surveillance, i.e., the computation of a reliability index. All subjects are still regular outpatients (there have been no dropouts) and are currently using memory-reflectance meters knowingly, as are all other patients on CSII. We can assume that they have not lost trust in their doctors. On debriefing, we chose not to tell the patient about the actual aim and yield of this study, but in patients found to be unreliable, we chose to retrain them to perform SMBG.

From a methodological point of view, it is unlikely that the 14 patients could communicate with one another because they were chosen over time (4 wk) among 1500 subjects treated by intensified insulin therapy, 60 of whom were on CSII. All subjects used a reflectance meter. In the case of equipment breakdown, we lent a replacement meter. Moreover, this study was completed with experimental devices before the commercial availability of memory-reflectance meters was advertised in France. This type of study would now be obsolete. As to the degree of naiveté of these patients, we would gladly apply a reliable tool for measuring it. No patient had other reflectance meters available or other diabetic people in his/her family; thus, the likelihood of the patient using another device or of another person using their device is small. In this study, patients with accurate and reliable SMBG tended to have better glycemic control. This may be a good argument against the alleged weakness of our design. Our results are coherent and agree with those reported by Mazze et al. (3) and Williams et al. (4), who used the same methodology.

The ethical problem, however, is obvious. Our ethics committee discussed the design at length and finally gave their consent because *1*) the design was the only way to assess the reliability of SMBG in a group of patients, and *2*) this study had no negative incidence on the individual care of patients. In the words of Haynal and Schulz (1), "the term of non compliance is legitimate when the study of the phenomenon remains on a descriptive level and does not involve a judgment of the patients based on moral considerations." Quantifying noncompliance may be the first step of a long process leading to mutual compliance and confidence, the latter relying on "the best possible equilibrium between the constraints of life-long treatment and the affective needs of patients" (1). Should patients be deceived for their