Editorial

Regimen Adherence: A Problematic Construct in Diabetes Research

Given the presumed relationships between the diabetes treatment regimen, metabolic control of the disease, and the health consequences of diabetes, the extent to which diabetic individuals follow regimen prescriptions is an important area of study. Diabetes investigators have recently focused increased attention on this topic of "adherence" or "compliance" (these terms will be used interchangeably) as well as on other behavioral and psychosocial issues related to diabetes.[1,2] Much of the work on diabetes adherence has been based on concepts and methods developed in the study of compliance to medication regimens used in treating diseases such as hypertension.[3] However, there are distinct problems in directly translating the terminology and measures used in medication compliance research to diabetes; many of these concern the existence and documentation of specific treatment prescriptions. The purpose of this editorial is to point out difficulties with current approaches to diabetes regimen adherence and to propose some possible solutions to these problems.

Haynes[4] has defined compliance as "the extent to which a person's behavior (in terms of taking medications, following diets, or exercising lifestyle changes) coincides with medical or health advice." A construct validity problem arises when applying this definition to diabetes treatment. The critical factor in the above definition is the comparison of actual behavior to a known standard. For some aspects of the regimen (e.g., exercise), prescriptions may never have been given. If they have been given, they may be extremely nonspecific (e.g., "get some exercise," "cut down on what you eat"), not clearly communicated to the patient, and/or not documented in medical records. An additional definitional problem arises because, unlike patients with other diseases, patients with diabetes are frequently encouraged to play a very active role in managing their disease (e.g., by self-regulating the amount of insulin taken). In such cases, there is no set prescription against which the patient's behavior can be assessed; the

actual prescription varies and is subject to patient modification and definition.

Thus, it is often conceptually impossible to examine compliance, since in many cases half of the construct—the regimen prescription—is unavailable. Furthermore, even when data on prescriptions are available, an additional conceptual problem arises that is unlikely to be seen in other areas. Diabetes compliance consists of an interdependent network of regimen behaviors, rather than a single behavior such as taking medication. As we have documented elsewhere,[5] diabetes regimen adherence is not a unitary construct, and level of adherence to one aspect of the regimen (e.g., glucose testing) is often unrelated to degree of adherence to other aspects of the regimen (e.g., dietary modification). Thus, it is inappropriate to refer to patients as "good compliers" or "poor compliers"; instead we must refer to levels of specific self-care behaviors as they occur in relation to specific regimen tasks.

There are several measurement and quantification problems involved in translating the adherence concept to the treatment of diabetes. Some of these problems, such as reliance on self-report measures, lack of standardized or objective measures of compliance, and failure of different measures of the same behavior to correlate with one another, are not unique to diabetes and have been discussed elsewhere.[6,7] There are also pragmatic and ethical difficulties involved, such as gaining access to patients' medical records, and serious validity concerns about the often-used alternative of relying on patient recall of instructions, the fallibility of which has been amply demonstrated.[8] However, we would like to focus on three somewhat more subtle measurement problems that we have encountered in conducting research in this area.

The first problem, which is related to the definitional ambiguity previously discussed, is that there is often a lack of direct correspondence between regimen instructions (e.g., "cut down on red meat exchanges" or "exercise for at least 20 min a day") and measures used to assess adherence (e.g., percent of calories from saturated fats or readings on an activity monitor). A second measurement problem is how to quantify the adherence of patients who exceed their prescriptions. For example, due to some very low regimen prescrip-

tions (e.g., two blood tests per week), we recently had several patients conducting over 200% of their prescribed number of glucose tests. This problem could seemingly be easily resolved by setting all values exceeding the regimen prescription equal to 100%. However, some investigators[9] have persuasively argued that deviations in either direction from a prescription can be deleterious, as in the case of diet and exercise, and that the absolute value of the behavior–prescription discrepancy should be our unit of analysis.

Finally, it is difficult to compare different aspects within a person's regimen (e.g., is conducting 3 of 4 daily glucose tests equivalent to taking 75% of one's shots on time or exceeding a calorie consumption goal by 25%?) and to compare adherence quotients across patients with vastly different regimen prescriptions (e.g., is a person who conducts 2 of 4 prescribed urine tests per day less adherent than one who conducts 2 of 3 assigned blood glucose tests per week?).

Despite all of these problems, adherence issues are important and deserve more study. There are several possible remedies and alternative ways of approaching the problems we have described. One major step would be to reserve the terms compliance and adherence for (the relatively infrequent) cases in which patient behavior is actually compared with a documented, objective prescription. When presenting adherence data, it is important for investigators to present information on regimen prescriptions as well since the interpretation of adherence data can vary considerably depending on the stringency, appropriateness, and complexity of prescriptions given. In some settings, such as large-scale clinical trials, it may be possible to both standardize and document regimen prescriptions. Such an approach has the advantage of minimizing variance in adherence scores due to diverse regimen prescriptions. In large data sets where this is not possible, subsets of patients with relatively homogeneous regimen prescriptions can be formed for analyses (e.g., patients prescribed blood testing versus urine testing; single versus multiple daily insulin injections).

We recommend using a term such as "levels of diabetes self-care behaviors" when analyzing measures such as number of calories consumed or number of glucose tests conducted. Such measures are not the same as adherence but deserve further study. The phrase "levels of self-care behaviors" reminds one that the absolute frequency or consistency of regimen behaviors (e.g., number of days per week on which subjects exercise) can impact on diabetes control independent of what was prescribed. The use of plural nouns in the phrase also reinforces the necessity of studying different behaviors, only some of which may be related to metabolic control, specified psychosocial factors, or other self-care behaviors. Rather than forming an a priori composite or global measure of adherence, investigators are encouraged to first evaluate and present data on relationships among levels of different self-care behaviors.

Regardless of which of the above approaches (or a com-

bination) is taken, an increased focus on within-subject changes in self-care behaviors over time would alleviate several of the problems inherent in trying to relate adherence or levels of self-care behaviors to metabolic control or to psychosocial variables across patients with vastly different and often no regimen prescriptions. Such longitudinal analyses use the subject's own behavior as a baseline for comparison instead of (or in addition to) comparing behavior with a prescription. They also aid in understanding the directionality and temporal ordering of adherence-control relationships. Finally, it is hoped that this editorial may spur researchers in the area to identify and agree on preferred dependent measures in critical areas such as glucose testing and dietary self-care behaviors (e.g., should one analyze exchange deviations, total number of calories consumed, the timing of meals, and/or the percentage of calories from fats versus carbohydrates?).

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