

Implications of Linking Pharmacy and Laboratory Data to Assess Diabetes Care

In principle, it should be simple to link patients' laboratory studies with changes in their medications in order to assess the clinical decisions underlying their care. As individual care providers with an individual patient's chart, we do it all the time. But evaluation of variations in care across patients, across providers, and across health care systems, while desirable, is presently a Herculean task. Such is the task that Wetzler and Snyder set for themselves in a study reported in this issue of *Diabetes Care* (1), in which they sought to determine whether providers met the American Diabetes Association's practice guideline to initiate treatment when the HbA_{1c} concentration was found to be >8%. They have made a good first step and, in the process, have highlighted some of the challenges that must be overcome to apply this strategy more broadly.

The physicians participating in the study were asked to provide patient demographics, laboratory data, and pharmacy data. The pharmacy data consisted only of the date of prescription and the National Drug Code, the code referenced on the package insert which reflects information on the drug, the formulation, and the standard package size. Consequently, the detection of change in drug therapy is limited to only detection of change in type of drug, formulation of the drug, drug package size, or the use of a combination of drugs. The data gathered did not take into account either the prescription instruction or the quantity of drug dispensed if it differed from the standard package size.

What limitations does that introduce? Consider the following two examples:

- A patient with diabetes who has repeated insulin adjustments made without a change in insulin formulation. He or she undergoes a series of provider-guided adjustments that improve the level of glycemic control from that of the conventional group of the Diabetes Control and Complica-

tions Trial (DCCT) to that of the intensively treated group; subsequently, this series of decisions reduces microvascular complications risk by >60%. It is worth noting that there was no significant difference in the quantity of insulin taken between subjects in the two treatment groups in the DCCT. Yet, according to the reported paradigm, the provider would be judged as having made no medication changes, despite an indication.

- A patient with diabetes sees a physician who recognizes that, even though the patient has been given the right drug, he or she is not taking the drug because of a dosing schedule that causes intolerable gastrointestinal side effects and results in nonadherence to the regimen. Advice given to change to an appropriate drug schedule, which would thereby improve adherence and bring about a significant reduction in average glucose and complications risk, would likewise not be detected as a medication change, despite an indication, by the current version of this monitoring system.

The historical context in which the data were gathered for this study, between January 1996 and March 1998, also has a bearing on the interpretation of this study. This period witnessed many changes in diabetes, and getting a snapshot of practice, as the authors tried to do, would have been like chasing a moving target. Metformin had entered the marketplace less than 1 year earlier in April 1995. Acarbose was released just after the beginning of the study period. Troglitazone was released in the middle of the study period (March 1997). During the first year when each of these drugs was available, there was a steep learning curve for providers who chose to use them, requiring weeks to months for feedback on effectiveness in individual patients. There was very limited experience in the U.S. with therapy using combinations of glucose-lowering drugs, and there were few, if any, Food

and Drug Administration indications approved for combination therapy. Most of the experience was concentrated in a subset of physicians with particularly strong interests in diabetes (e.g., endocrinologists and diabetologists). At the beginning of the study period, there were likely a few such physicians among the providers included in this study (member groups of a medical practice trade association), and the frequency of physicians using these approaches would have increased during the course of the study period. In other words, the study methods had a limited ability to detect common treatment responses to elevated HbA_{1c} levels, but had a good ability to detect actions that were not yet prevailing practice in the primary care community. If these interpretations are correct, then the study design was limited in its ability to detect providers who took appropriate actions. This catch-22 makes it hard to separate whether the providers' apparent poor performance reflects reality, the methodological limitations of the study, or both.

The difficulty the authors encountered in assessing decisions underlying diabetes care and the compromises that were necessary in this study are measures of how far we are from being able to compare the decisions made across health care systems. The authors acknowledge the limitations of their approach, and it is important that managers of care understand these limitations as well. My own view is that the ability to track the prescription instruction is essential to an assessment of care. The good news is that recent advances in technology should soon put the level of detail necessary to thoroughly evaluate therapeutic decisions, literally, in the palms of our hands. The approach presented here will not be ready for broad application until it can reflect the level of precision in clinical decision-making that is the hallmark of excellent diabetes care.

ROBERT M. COHEN, MD

From the Department of Medicine and the General Clinical Research Center, the Division of Endocrinology and Metabolism, Vontz Center for Molecular Studies, College of Medicine, University of Cincinnati, Cincinnati, Ohio.

Address correspondence to Robert M. Cohen, MD, Division of Endocrinology and Metabolism, Department of Medicine and General Clinic Research Center, University of Cincinnati College of Medicine, 3125 Eden Ave., Cincinnati, OH 45267-0547. E-mail: robert.cohen@uc.edu.

References

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