Consensus Report of the Coalition for Clinical Research— Self-Monitoring of Blood Glucose

David C. Klonoff, M.D., FACP,[1] Richard Bergenstal, M.D.,[2] Lawrence Blonde, M.D., FACP, FACE,[3]
Suzanne Austin Boren, Ph.D., M.H.A.,[4] Timothy S. Church, M.D., M.P.H., Ph.D.,[5]
Jenifer Gaffaney, M.S., R.D., CDE,[6] Lois Jovanovič, M.D.,[6,7] David M. Kendall, M.D.,[2]
Craig Kollman, Ph.D.,[8] Boris P. Kovatchev, Ph.D.,[9,10] Claudia Leippert, Diabetesberaterin DDG,[11]
David R. Owens, CBE, M.D., FRCP,[12,13] William H. Polonsky, Ph.D., CDE,[14] Gérard Reach, M.D.,[15]
Eric Renard, M.D., Ph.D.,[16] Michael C. Riddell, Ph.D.,[17] Richard R. Rubin, Ph.D., CDE,[18]
Oliver Schnell, M.D.,[19] Linda M. Siminiero, R.N., Ph.D., CDE,[20] Robert A. Vigersky, M.D., COL MC,[21]
Darrell M. Wilson, M.D.,[22] and Alison Okada Wollitzer, Ph.D.[6]

Abstract

The Coalition for Clinical Research—Self-Monitoring of Blood Glucose Scientific Board, a group of nine academic clinicians and scientists from the United States and Europe, convened in San Francisco, California, on June 11–12, 2008, to discuss the appropriate uses of self-monitoring of blood glucose (SMBG) and the measures necessary to accurately assess the potential benefit of this practice in noninsulin-treated type 2 diabetes mellitus (T2DM). Thirteen consultants from the United States, Europe, and Canada from academia, practice, and government also participated and contributed based on their fields of expertise. These experts represent a range of disciplines that include adult endocrinology, pediatric endocrinology, health education, mathematics, statistics, psychology, nutrition, exercise physiology, and nursing. This coalition was organized by Diabetes Technology Management, Inc. Among the participants, there was consensus that:

1. protocols assessing the performance of SMBG in noninsulin treated T2DM must provide the SMBG intervention subjects with blood glucose (BG) goals and instructions on how to respond to BG data in randomized controlled trials (RCTs);

2. intervention subjects in clinical trials of SMBG-driven interventions must aggressively titrate their therapeutic responses or lifestyle changes in response to hyperglycemia;

3. control subjects in clinical trials of SMBG must be isolated from SMBG-driven interventions and not be contaminated by physician experience with study subjects receiving a SMBG intervention;

4. the best endpoints to measure in a clinical trial of SMBG in T2DM include delta Hemoglobin A1c levels, hyperglycemic events, hypoglycemic events, time to titrate noninsulin therapy to a maximum necessary dosage, and quality of life indices;

continued →

Abstract cont.

5. either individual randomization or cluster randomization may be appropriate methods for separating control subjects from SMBG intervention subjects, provided that precautions are taken to avoid bias and that the sample size is adequate;

6. treatment algorithms for assessing SMBG in T2DM may include a dietary, exercise, and/or medication intervention, which are all titratable according to the SMBG values;

7. the medical literature contains very little information about the performance of SMBG in T2DM from RCTs in which treatment algorithms were used for dysglycemic values; and

8. research on the performance of SMBG in T2DM based on sound scientific principles and clinical practices is needed at this time.

J Diabetes Sci Technol 2008;2(6):1030-1053