Appendix 2. Pooled RCT Outcomes Measures

Demographic Measures

All clinical trials used a standardized health outcomes questionnaire developed by the proposed investigators and containing the demographic variables: age, sex, marital status (married, divorced, separated, widowed, never married, domestic partner), self-reported race/ethnic origin (white, Hispanic, Black, Asian-American/Pacific Islander, American Indian/Alaskan Native, Other – with option to specify), occupation "employed" [professional executive, small business/administration, white collar/clerical, blue collar/factory/industry], "not employed" [student, retired, or "other" (care for children, household work, volunteer) with text description]; highest level education completed [8th grade or lower, high school-did not graduate, high school diploma, some college or Associate degree, college degree (4 years), graduate/professional or equivalent degree]; family income level (< $15,000/yr.; $15,000-$24,999/yr.; $25,000-$39,999/yr.; $40,000-$59,999/yr., $60,000-79,999/yr., $80,000-$149,999/yr., $150,000 or higher/yr.) and disability (text description). In many studies, in addition to the above self-reported coding for race and ethnicity there was also separate coding on the clinical case report form (CRF) completed by the investigator. The data can therefore also be cross-classified so that we can compare categories of racial and ethnic identification.

Quality-of-Life Measures

All studies included the following patient-centered health outcomes variables measuring mental and emotional health, physical health status, cognitive functioning and work/role disability.

Perceived Health - Five linear analogue questions concerning self-assessment of physical, emotional and social functioning (Range: 1-10);

Functional Health Status ([1]) - 12 physical functioning levels ranging from strenuous activities to basic activities, such as dressing, bathing and eating (Range 0-20);

Diabetes-Specific Symptom Interference - 7 questions concerning diabetes-specific symptom interference with daily functioning, e.g. social events, exercise and physical activities, and work effectiveness (Range: 100-600);

General Symptom Interference - 7 questions concerning health-related interference with daily functioning, e.g. social events, exercise and physical activities, and work effectiveness (Range: 100-600);

Symptoms and Side-Effects Distress – 54 questions including diabetes-specific and general symptoms (prevalence, frequency and distress severity) (Range: 100-600);

Mental and Emotional Health - 24 questions encompassing both psychological well-being and psychological distress (Range: 100-600);

General Health Perceptions - 11 questions on sleep disturbance, vitality and general health (Range: 100-600);

Cognitive Function and Performance - 15 questions assessing self-reported cognitive acuity, memory, reasoning and disorientation and 6 questions on self-rated cognitive performance (Range: 100-500);

Sexual Satisfaction and Dysfunction - 5 gender-specific questions on sexual functioning. (If this scale is missing in a large proportion of subjects, i.e. subjects are not sexually active, this scale is not included in the Overall QOL Composite) (Range: 100-600);

Health Care Utilization - 5 questions concerning frequency of hospitalizations, physician visits, home health visits, general assistance with daily living and calls to health care workers (Count days over past 4 weeks);

Work/Disability - Three questions involving bed days, missed work and reduced activities (Count days over past week). All these scales have been extensively validated as described in studies referenced in Section 6.4.3. The scales of psychological distress, well-being and perceived health are the original items from the Rand Health Insurance Study ([1]) which were the long-form of the current SF-36.

Patient Treatment Preference and Satisfaction Measures

An important component of the PCORI's definition of patient-centeredness takes into account factors related to the patient's "preferences". Measures of satisfaction included:

Overall Treatment Satisfaction (Module A): 71 items assessing efficacy, flexibility, side effects, convenience, burden, preference/advocacy, social, general satisfaction, pain, social, hassle, and interference including the following subscales:

Advocacy: 2 items on recommending and advocating the treatment to other persons with diabetes, including family and friends.

Burden: 14 items concerning multiple aspects of burden of the therapeutic regimen including adherence, diet, exercise, performing daily activities, participating in social activities and enjoying life.

Convenience: 6 items relating to ability to remember taking medication, overall convenience, being pleased with convenience, amount of time required to manage diabetes.

Efficacy: 3 items on the patient's perception of the treatment's ability to control blood sugar.

Flexibility: 4 items on how flexible the treatment is for scheduling and allowing variability in meals and overall flexibility.

General Satisfaction: 4 items on general satisfaction and being pleased with current medication.

Hassle: 8 items specific to the amount of bother and hassle of the regimen including dosing, treatment supplies, carrying supplies, supply disposal, pain and discomfort, and worries about hypoglycemia and hyperglycemia.

Interference: 11 items concerning how much the diabetes medication interferes with daily routine, meals, recreation, family life, sleep schedules, energy levels, making plans, traveling, having fun and overall quality of life.

Pain: 3 items concerning pain and discomfort.

Preference: 2 items rating how strong the desire to search out other regimens that might be better and to continue on current regimen.

Side effects: 5 items concerning gaining weight, unpleasant feelings, distress with hypoglycemia and hyperglycemia.

Social: 9 items rating the treatment's interference with social interactions with family and friends, travel, having fun, and problems in performing work and social roles.

Overall Satisfaction: mean of the 12 individual general satisfaction scales.

Satisfaction with Insulin (Module B): 7 items assessing satisfaction with insulin without regard for specific delivery system by measuring convenience, burden, social and general satisfaction.

Comparative Preference: 13 items concerning a direct comparison of preference for either inhaled or injected insulin (with prior experience as the reference), with items covering ease, convenience, flexibility, efficacy, social functioning, and preference. **Clinical Data:** While clinical variables in the study databases are more variable between studies, they generally include measures of therapeutic efficacy such as HbA1c and fasting plasma glucose, Certain studies also include more extensive data on adverse events, hypoglycemia, laboratory assessments, blood pressure, heart rate, weight, and height.

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