Original Investigations JAMIA

Research Methods ■

Columbia University's Informatics for Diabetes Education and Telemedicine (IDEATel) Project:

Rationale and Design

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Abstract The Columbia University Informatics for Diabetes Education and Telemedicine (IDEATel) Project is a four-year demonstration project funded by the Centers for Medicare and Medicaid Services with the overall goals of evaluating the feasibility, acceptability, effectiveness, and cost-effectiveness of telemedicine in the management of older patients with diabetes. The study is designed as a randomized controlled trial and is being conducted by a state-wide consortium in New York. Eligibility requires that participants have diabetes, are Medicare beneficiaries, and reside in federally designated medically underserved areas. A total of 1,500 participants will be randomized, half in New York City and half in other areas of the state. Intervention participants receive a home telemedicine unit that provides synchronous videoconferencing with a project-based nurse, electronic transmission of home fingerstick glucose and blood pressure data, and Web access to a project Web site. End points include glycosylated hemoglobin, blood pressure, and lipid levels; patient satisfaction; health care service utilization; and costs. The project is intended to provide data to help inform regulatory and reimbursement policies for electronically delivered health care services.

■ **J Am Med Inform Assoc.** 2002;9:49–62.

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This project was supported by cooperative agreement 95-C-90998 from the Centers for Medicare and Medicaid Services (CMS; formerly Health Care Financing Administration).

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Received for publication: 5/15/01; accepted for publication: 10/9/01.

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The Centers for Medicare and Medicaid Services (CMS; previously the Health Care Financing Administration), the federal agency responsible for administering the Medicare program, does not currently reimburse health care providers for health care services delivered electronically to patients, except under a small number of limited demonstration projects. Reimbursement requires face-to-face interaction between provider and patient. In rural areas, access to face-to-face care may be impeded by geographic distance, weather, and provider shortages. In urban inner cities, with predominantly minority populations, obstacles to access include language, culture, low educational attainment, disempowerment, lack of social support for health-related behaviors and activities, and provider shortages. Telemedicine supports interactions that are both distant and asynchronous. These capabilities have the potential to improve access and thereby contribute to reductions in disparities among sociodemographic groups in access to care, quality of care, health outcomes, and health status.[1]

The Balanced Budget Act of 1997 mandated that the Health Care Financing Administration conduct a demonstration project to evaluate the feasibility, acceptability, effectiveness, and cost-effectiveness of advanced computer and telecommunication technology ("telemedicine") to manage the care of people with diabetes. A consortium (Table 1) led by Columbia University was selected to conduct this project. An award was made effective Feb 28, 2000, for a four-year project. In this paper we describe the rationale, target populations, intervention strategy, study design, and evaluation plan for the Informatics for Diabetes Education and Telemedicine (IDEATel) project.

Background and Rationale

Diabetes mellitus is costly and common in the Medicare-eligible population, and its high prevalence and complexity pose major clinical challenges to effective case management using telemedicine. An estimated 15.7 million people in the United States have diabetes,[2] and 18 to 20 percent of men and women 60 to 74 years of age are affected. As many as one third of those affected are undiagnosed.[3]

This already high prevalence continues to increase because of the aging of the population and the rising prevalence of obesity. The prevalence of type 2 diabetes, which accounts for 90 to 95 percent of all diagnosed cases in adults, increases markedly with age and obesity, and African-Americans and Hispanics are at almost twice the risk of non-Hispanic whites. The American Diabetes Association (ADA) estimates that, in 1997, diabetes cost Americans $98.2 billion, including $44 billion in direct medical costs.[4] Those over 65 years of age account for two thirds of all costs.[4] The long-term chronic complications of diabetes are responsible for most of the morbidity, mortality, and cost. Diabetes mellitus is the leading cause of end-stage renal disease (ESRD) in the United States, accounting for approximately 40 percent of incident cases.[5] In 1995, the number of persons with diabetes who were on dialysis or had had a kidney transplant exceeded 98,000.[6] Because of the aging of the population and the increasing age-specific incidence of diabetes, the prevalence of ESRD is increasing. The adjusted costs per case are also rising. Average annual Medicare payments per case (in 1996 U.S. dollars) were $53,659 for ESRD due to diabetes.[7]

Diabetes is the leading cause of blindness in adults 20 to 74 years of age.[6] Diabetes-related blindness increases with age, with higher rates among minorities,[8] and is almost invariably preceded by diabetic retinopathy.[8,9] Annual dilated eye examinations are an effective screening modality in both type 1 and type 2 diabetes, since early retinopathy can be effec-

Table 1 ■

IDEATel Project Consortium

Columbia University, New York, New York:
Department of Medicine/Division of General Medicine
Department of Medical Informatics
Naomi Berrie Diabetes Center
New York Presbyterian Hospital, New York, New York:
Harlem Hospital Center, New York, New York:
Department of Medicine/Division of General Medicine
Harlem Renaissance HealthCare Network, New York, New York
The Hebrew Home for the Aged at Riverdale, Bronx, New York
State University of New York (SUNY) Upstate Medical University, Syracuse, New York:
Department of Medicine, Division of Endocrinology, Diabetes and Metabolism
Department of Family Medicine
Joslin Diabetes Center (Syracuse)
University Hospital, Syracuse, New York
Arnot Ogden Medical Center, Elmira, New York
Bassett Healthcare, Cooperstown, New York
Samaritan Medical Center, Watertown, New York
Olean General Hospital, Olean, New York
American Diabetes Association, Alexandria, Virginia
American TeleCare, Inc., Eden Prairie, Minnesota
Gentiva Health Care, Inc., Melville, New York
Verizon, Inc., Reston, Virginia
Crosshair Technologies, Inc., Scarsdale, New York

tively treated with laser photocoagulation,[10] but a recent national survey found that 28 to 29 percent of people with diabetes who are over 65 years of age reported that they had not had a dilated eye examination in the previous year.[11]

Diabetic neuropathy, a major risk factor for lower extremity amputation, occurs in 60 to 70 percent of people with diabetes.[6] Hypertension is also common and clinically important,[12] affecting 60 to 65 percent of people with diabetes.[6]

Data for both type 1 and type 2 diabetes show that improved glycemic and blood pressure control lessen the incidence and progression of the microvascular complications of diabetes, including neuropathy, nephropathy, retinopathy, and blindness.[8,13–17] Most diabetes-related mortality is due to macrovascular disease, specifically, coronary artery and cerebrovascular disease. Appropriate treatment of hypertension and dyslipidemia has been shown to decrease these serious complications and to be cost-effective.[17–21] Lowering LDL (low-density lipoprotein) cholesterol in patients with diabetes but without known cardiovascular disease is as effective as lowering lipids in patients with known heart disease but without diabetes.[22] Thus, extensive evidence from clinical trials and observational studies supports the benefit of improving management of type 2 diabetes to prevent morbidity and mortality from both micro- and macrovascular disease.[13–40]

Medical informatics involves the study of various types of information and knowledge and the methods by which needed knowledge can be delivered during the process of care.[41] Availability of the right knowledge at the right time has the potential to affect prevention, patients' day-to-day activities, diagnosis, and treatment decisions.[42–46] New reimbursement models and easy connectivity via the Internet have stimulated investment in information systems that directly influence patient behavior,[47] and investigators have shown the benefits of several approaches to acquiring and delivering clinical and educational material.[48]

Although telemedicine technologies hold promise in many specific areas[49] and efforts have been made to evaluate a variety of activities involving different applications of telemedicine, the gaps in this knowledge base are substantial, as documented by recent overviews.[50–55] One comprehensive review of published telemedicine experience identified 455 telemedicine projects, of which 362 were in the United States and 50 provided services in patients' homes.[55] As reviewed in these reports, the relative lack of substantive evaluation data is related to many issues, including the underlying difficulty and cost of conducting robust evaluation, lack of studies using randomized designs with controls, small sample sizes, short-term follow-up, and lack of multidisciplinary evaluation teams with experience in the use of well-developed measures of clinical effectiveness, process of care, and cost. Thus, despite the obvious promise of this technology, the clinical effectiveness of telemedicine, both in general and in specific clinical contexts, its acceptability to providers and patients, its costs, and its relative cost-effectiveness all remain poorly documented.[51,52,55] The IDEATel project is intended to address these gaps.

Target Populations

The populations targeted by the IDEATel project are those with the greatest need for intervention. Eligibility criteria require that participants have diabetes mellitus and live in a federally designated medically underserved area at time of enrollment, defined by either of the two federal methodologies used for this purpose—medically underserved areas (MUAs) or health professional shortage areas (HPSAs). The urban component enrolls patients living in Harlem, Washington Heights, and Inwood in northern Manhattan, each of which is either MUA, HPSA, or both. The population of these areas is predominantly African American or Hispanic, with the majority of the Hispanic population having come originally from the Dominican Republic. In contrast to those originating in Puerto Rico, people in this group speak relatively little English. The intervention is therefore conducted in both English and Spanish in the urban component.

The rural component enrolls participants across the entire geographic span of upstate New York, an area nearly 800 miles in breadth. The medically underserved census tracts are interspersed throughout this area. The hubs of recruitment are physician networks centered in Elmira, Watertown, Cooperstown, Olean, and Syracuse. The patients in these groups are predominantly non-Hispanic white.

Intervention

Participants randomized to the intervention group receive a home telemedicine unit (HTU) (American Telecare Inc., Eden Prairie, Minnesota) with four main functions: synchronous videoconferencing, self-monitoring of fingerstick glucose and blood pressure, messaging, and Web access. The device is a Web-enabled computer with modem connection to an existing telephone line (Table 2).

Table 2 ■

Telemedicine Intervention Capabilities for Patients, Primary Care Providers, and Nurse Case Managers

Patients:
Videoteleconferencing
Web-based educational materials
Clinical data entry (glucose, blood pressure, diet, weight)
Clinical data review
Computer-generated alerts and reminders
E-mail
Monitored chat groups
Primary care providers:
Electronic case management of diabetes patients
Training and education
E-mail
Nurse case managers:
Videoteleconferencing
Archive of stored images (e.g., foot ulcer monitoring)
Web-based educational materials
Clinical data review
Computer-generated alerts and reminders
Workflow management
Automated QA feedback on patient panels
E-mail
Monitoring of patient chat groups

The HTU has several components: a video camera that provides 8 frames/sec video and a microphone for voice conferencing with nurse case managers at the Berrie Diabetes Center at Columbia University (urban component) or the Joslin Diabetes Center at SUNY Upstate Medical University (rural component); an FDA-approved home glucose meter and blood pressure cuff connected to a generic medical device data port, so that home readings can be uploaded into a high-performance computer database (the New York Presbyterian Hospital clinical information system repository[56–59]) that supports patients' access to their own clinical data through graphical and other data displays; secure messaging, including e-mail; and access to a special educational Web page in English and Spanish, created for the project by the American Diabetes Association.

The nurse case managers are trained in diabetes management and in the use of computer-based case management tools that facilitate interactions through videoconferencing with patients.

Medicare beneficiaries with diabetes make an average of 6.8 provider visits per year.[60] The intervention seeks to extend these interactions by incorporating telemedicine technology into clinical care using approaches justified by behavioral theory[61–63] and prior intervention research. The approach is patient-targeted and aims to build self-reliance, elicit well-defined behaviors, and reduce provider burden by empowering patients. The intervention strategy also draws on a growing body of research suggesting that telephone outreach is an efficacious strategy for influencing health-related behaviors,[64] that tailored messages are an important strategy for influencing behavioral change,[65,66] and that videotelephone contact may be more effective than voice-only contact.[67]

We hypothesized that the intervention will improve patient outcomes by several mechanisms. More frequent interactions between patients and providers will enable patients to initiate more rapid behavior changes (e.g., self-monitoring, compliance) as well as changes in their treatment regimens, without an office visit. Closer monitoring (e.g., glucose, blood pressure, diet) will be coupled with quicker feedback from the provider. In this way, better and more rapid glucose and blood pressure control may be achieved and maintained.

Face-to-face interaction by videoteleconferencing with a case manager will enhance compliance and promote maintenance as well as initiation of positive behavior changes. Having visible contact with a health care provider is important to most patients, especially when the provider is knowledgeable, empathic, and interested in the patient's diabetes as well as in the patient as a person. In allocating telemedicine case manager time, we projected one full-time equivalent for each 200 diabetic patients, allowing ample time for one contact every two weeks, but with higher intensity during periods when needed.

Finally, patients' diabetes educational needs are now usually addressed through on-site classes and print materials, but the all-at-once approach may produce information overload rather than useful learning and enhanced self-efficacy for participation in care. Education and information in small pieces, related in time to patient-specific information needs, may be a more effective way to provide self-management education for diabetes. Education and information are available in this way from the case managers and from the project Web site.

The case managers actively invite and coach patients to use these information resources. For example, to a patient who is having difficulty controlling diet, the case manager might suggest a chat group and point to specific educational and motivational resources. Access to monitored chat groups, where patients can learn from each other, share problems and solutions, and gain and give psychological support, may also enhance effective learning for sustained behavior change.

We use version 2.2b (updated May 2000) of the Veterans Health Administration (VHA) *Clinical Practice Guidelines for the Management of Diabetes Mellitus in the Primary Care Setting*.[68] These guidelines are flexible, annotated, evidence based, and algorithmic in format. They were designed with input from a number of federal health–related agencies, including the VHA; the Diabetes Division of the National Institute for Diabetes, Digestive and Kidney Diseases; the Division of Diabetes Translation, Centers for Disease Control and Prevention; the Office of Managed Care, CMS; and the Pharmacoeconomic Center of the Department of Defense, United States Air Force. The content of other guidelines, especially those of the American Diabetes Association, have been largely incorporated in the VHA guidelines. The majority of these algorithms are suitable for automation and incorporation into triggers in the case management software. Case managers are trained to follow these algorithms.

Intervention subjects are assigned to a project case manager under supervision of diabetologists at the Joslin Diabetes Center in Syracuse and the Naomi Berrie Diabetes Center in New York City. Case managers interact with patients using the HTU and case management software. The primary care physicians of intervention patients retain full responsibility and control over their patients' care. When a case manager believes that a change in management is indicated, he or she contacts the primary care physician (by e-mail, fax, or phone) just as a visiting nurse going physically to the home would do. This avoids disruption of established relationships and patterns of care and ensures continuity of care for intervention patients after the project ends.

Evaluation Plan

The CMS is conducting its own evaluation of the IDEATel project through an independent contractor. This approach will enhance the objectivity of the findings and give credence to policy recommendations that derive from them. In addition, we are conducting a project evaluation that addresses selected dimensions of the comprehensive evaluation framework for telemedicine published by the Institute of Medicine.[51]

Study Design

Participants are randomized to a telemedicine intervention group ($N = 750$) or a control group ($N = 750$) receiving usual care. The technical component of the intervention was frozen at the start of the trial. It would not be ethical or practical to freeze the medical content of the intervention, and we therefore allow the standards of medical care for diabetes in both intervention and control groups to reflect new knowledge over the course of the project. Each subject is enrolled in the project for two years, receiving either telemedicine or usual care for this period of time.

Half of the participants come from the urban component and half from the rural component. As described earlier, eligibility for participation requires that subjects be Medicare recipients, have diabetes mellitus, and live in a federally designated medically underserved area at time of enrollment. Exclusion criteria include cognitive, visual, or medical impairment to a degree that would preclude meaningful participation (Table 3). A telephone eligibility assessment is done prior to enrollment. Each subject enrolled in the study has a primary care physician, and randomization is within blocks defined by primary care physician patient panels.

Study Outcomes

Feasibility is assessed by whether the implementation is successful. Acceptability is assessed by whether participants can use the devices effectively, like the devices and the electronic service delivery model of care, and are satisfied with their care. We are sensitive to the potential concern that telemedicine may be perceived as a less expensive substitute for face-to-face care for the poor. Effectiveness is evaluated by comparing mean and adjusted mean levels of outcomes in the intervention vs. control groups. The main study outcomes are glycosylated hemoglobin level, blood pressure level, and cost of care. Cost-effectiveness is assessed on the basis of effectiveness, measures of health care service utilization, and technology and service costs of the intervention.

Important secondary outcomes include lipid levels, smoking, quality of life, and patient satisfaction. Secondary process-of-care outcomes include receipt of recommended diabetes-specific health care services (e.g., dilated eye examination, foot examination), compliance, education and knowledge, and health beliefs. Evaluation data (Table 4 and Appendix) are collected from all participants at three visits: baseline (visit 1), one-year follow-up (visit 2), and two-year follow-up (visit 3). Additional evaluation data are collected from all participants by telephone at baseline and at three-month intervals between the in-person visits. These data focus on health care utilization but also include assessment of family support, smoking status, and quality of life.

Table 3 ■

Exclusion Criteria

Variable	Measure	Source of Measure
No diabetes	Does not meet clinical criteria of fasting blood sugar levels 126 mg/d or non-fasting 200 mg/dl when not taking glycemic control medication for diabetes	American Diabetes Association[71]
Moderate or severe cognitive impairment	The Comprehensive Assessment and Referral Evaluation (CARE) Diagnostic Scale (Cognitive Screen)	CARE[72–75]
Severe vision impairment	Three severe items from the Vision Scale are used to exclude persons with severe vision impairment	Functional Vision Screening Questionnaire,[76] modified by the Lighthouse for the Blind from the Vision Disorder subscale of the Comprehensive Assessment and Referral Evaluation (CARE)[73,77]
Severe impairment of mobility	Ten items (4 exclusionary) measuring ability to walk, use a wheelchair, and transfer to and from bed	Institutional Comprehensive Assessment and Referral Evaluation (INCARE)[78–80]
Severe impairment of fine motor coordination	Two items used to exclude those unable to hold and move objects; push-buttons and use telephone or home telemedicine unit	IDEATel staff in collaboration with telemedicine technical and clinical staff
Severe comorbid conditions	Comorbid conditions likely to result in death or severe disability prior to completion of the study	IDEATel staff in collaboration with a diabetologist and clinical staff
Severe expressive or receptive communication impairment	Inability to communicate will interfere with the administration of the intervention by nurse case managers	INCARE[78–80]
Severe hearing disorder	These items are helpful in determining either exclusion or need for implementation of aids (e.g., a voice amplifier for the phone) to facilitate communication	INCARE[78–80]
No available free electrical outlet for Home Telemedicine Unit		
Spends more than 3 months at another location	Would dilute exposure to intervention	

Table 4 ■

IDEATel Study Outcomes

Clinical Outcomes	Services Utilization, Quality of Life and Satisfaction	Process of Care	Case Mix or Control Variables
Glycosylated hemoglobin Blood pressure Lipid level Smoking Urine microalbumin	Health care service utilization: Medications and supplies Hospitalization and emergency room Physician services Homecare Family care Quality of life (QOL): Diabetes-related QOL General QOL Depression Satisfaction	Patients: Compliance Health habits Self-monitoring Providers: Dilated eye exam Lipid profile Foot care	Demographic variables Functional status Vision impairment Health status/comorbidity Severity of disease Social support

Intervention Implementation Tracking

All interactions of intervention group participants with the HTU are logged. These include contacts with the nurse case manager, the project Web page, the project monitored chat room, and the clinical database in which participants view their own clinical data. These log data are used to track the volume and content of electronic services delivered to intervention group participants (implementation tracking). Statistical modeling will be used to identify intervention components and process-of-care elements associated with improvement in outcomes in the intervention group.

Sample Size and Least Detectable Differences

We projected that attrition rates at two years will be 15 percent in the intervention group and 20 percent in the control group, or that approximately 1,240 of the original 1,500 people randomized will complete the study. Alpha was set at 0.05 (two-sided) and beta at 0.80. Statistical analysis is based in intention to treat. For an intervention effect on systolic blood pressure of 5 mm Hg reduction, unadjusted for clustering, with 600 completers in each group, power is 0.97; for an effect of 3 mm Hg, power is approximately 0.68. For glycosylated hemoglobin, a difference in mean glycosylated hemoglobin level of 0.6 percent (7.9 vs. 8.5 percent in the two groups) can be detected with a sample size on 138 per group; adjustment for the cluster effect (patients clustered by physician panel) increases this number to 207 per group. Power calculations were also made for longitudinal random effects models under different scenarios for cluster effects for participants within physician panels and for repeat measures. These calculations showed that the study is powered to detect differences of these magnitudes overall and also, possibly, in subgroups defined by race/ethnicity or by urban/rural source.

Policy Implications

The IDEATel project is designed to provide data that will inform policy formation in several areas. The first, alluded to earlier, is to demonstrate the feasibility of a large-scale, Web-based system for electronic delivery of health care services that complies with the data security requirements of the Health Insurance Portability and Accountability Act (HIPAA).[69] Second, if the intervention improves process and outcomes of care for persons with diabetes, and the cost-effectiveness of electronic health care service delivery is supported by project findings, policies regarding reimbursement are likely to evolve. Questions that will need to be addressed depend in part on the payment mechanisms used to reimburse care. For example, the question of what constitutes a reimbursable service unit is central in a fee-for-service payment environment, whereas in a capitated environment the preferences of patients for electronic rather than face-to-face services may be more important in deciding whether to permit substitution of electronic services. Reimbursement policies will also require standards of documentation, for purposes of audit and quality review, and separation of technology costs (e.g., networks, databases, servers, and personnel to maintain them) from services costs (e.g., physician and nurse care manager time). Third, the legal environment in which the medical and nursing professions are credentialed, licensed, held accountable, disciplined, and insured for malpractice are largely based on individual state laws in the 50 states. There are differences among states in almost all these areas, and a variety of limitations resulting from state-based licensure impede the electronic delivery of health care services across state boundaries.[70]

In summary, the IDEATel project is a large, complex project designed to provide data relevant to policy formation for deployment of telemedicine. No single study can provide definitive answers to all or even most key questions. The complex, multifactorial, and behavioral nature of the intervention makes the study vulnerable to secular trends in diabetes care and technology development that may lead to convergence between the intervention and control groups. Nonetheless, the overall scope, design, and evaluation plan are intended to focus on realistic and informative endpoints, and the project provides an opportunity to address important questions about the use of telemedicine in everyday clinical practice.

The authors gratefully acknowledge the contributions of Dr. Paul D. Clayton to the conceptualization of this project and to the creation of the medical informatics infrastructure at Columbia-Presbyterian Medical Center.

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Appendix begins on following page.

Appendix

Summary of Variable Category, Constructs, Measures, Sources, and Psychometric Properties of Outcome Measures in IDEATel

Variable Category/Construct	Measure	Source of Measure	Populations for Normative Data	Reliability Estimate
Clinical Outcomes				
Glycosylated hemoglobin	HbA_{1c} (reduction in mean levels)	12-hr fasting blood samples	NA	$\geq$0.90
Blood pressure	Systolic and diastolic (reduction in mean levels)	Three readings separated by 1 min, using the Dinemap PRO 100 automated device	NA	$\geq$0.90
Lipid levels	Total, LDL and HDL cholesterol, and triglyceride levels	12-hr fasting blood samples	NA	$\geq$0.90
Smoking	Questions reviewed by a study consultant who is an expert on smoking and diabetes	Questions taken from Centers for Disease Control and Prevention control survey smoking questionnaire[81] and the tobacco cessation questionnaire developed for the Tobacco Cessation Clinic at Columbia-Presbyterian Medical Center	NA	—
Urine microalbumin	Urine microalbumin: creatinine ratio	Spot urine specimen	—	—
Service Utilization, Quality of Life, and Satisfaction				
Health care service utilization: Medications and supplies Hospitalization, emergency room, and use of urgent care center Physician service use Home care Family care	Lists of health insurance categories from Health Care Financing Administration (HCFA), American Association for Retired Persons, and Island Peer Review Organization Service use questions from modification of ADA survey, Hebrew Home for the Aged at Riverdale (HHAR) service use survey, and NY State Department of Health and HHAR activities-of-daily-living and informal service use measure for adult clients of health care day-centers[82] The HHAR/United Hospital Fund (UHF) community-based study on home car[83–85]	American Diabetes Association (ADA)[86]	Developed for use with elderly community residents	Interrater reliability range, 0.70–0.95[82]

Quality of life:				
Diabetes-related quality of life Emotional adjustment	Problem Areas in Diabetes (PAID-2) scale: two subscales, global concerns about diabetes, and interpersonal relationships	Welch et al.[87] Polonsky[88]	Normative data for elderly patients; mean age range 63–67 yr	Cronbach alpha, 0.95
General quality of life: Depression/demoralization	SHORT-CARE depression scale	Gurland et al.[72,74,89] Golden et al.[73]	Several large probability - samples of elderly community residents	Cronbach alpha, 0.87 for development samples.[73] In a subsequent study,[90] the interrater reliability coefficient, using a sample of 13 raters and 8 videotapes, was 0.94 Cronbach alphas ranged from the 0.70s to the 0.90s across other community and institutional samples
Satisfaction with care:	Diabetes Quality Improvement Project (DQIP)[91] and ADA Patient Satisfaction Survey[92]	HCFA[91] ADA[92]	NA	NA
Process-of-Care (Intermediate) Outcomes				
Compliance with care plan, health care practices (e.g., alcohol use)	Diabetes self-care activities (alcohol items from a multi-ethnic study of atherosclerosis)	Toobert et al.[93]	Three studies: average ages, 60.8–67 yr; range, 42–75 yr	Range of average inter-item correlations, 0.20–0.78; test–retest reliability, 0.43–0.58
Provider practices: Dilated eye exam <1 yr Lipid profile <2 yr Foot care <1 yr with Semmes-Weinstein monofilaments Self-monitoring of blood glucose Self-monitoring of blood pressure (if hypertensive)	Patient Satisfaction Survey that also assesses the frequency of specific practices of health care providers during the previous 12 mo; e.g., how often a provider performed examinations associated with diabetes care	ADA[92]	NA	NA

Continued on following page

Summary of Variable Category, Constructs, Measures, Sources, and Psychometric Properties of Outcome Measures in IDEATel, *continued*

Variable Category/Construct	Measure	Source of Measure	Populations for Normative Data	Reliability Estimate
Process-of-Care (Intermediate) Outcomes, *continued*				
Education and knowledge	Diabetes Quality Improvement Project (DQIP)	HCFA[91]	NA	NA
Health beliefs	Three items measuring beliefs that caring for diabetes will lead to improvements in health	Diabetes Quality-of-life Clinical Trial Questionnaire[94]	Mean 58.2 in sample of patients with type 2 diabetes	NA
Self-efficacy	Self-efficacy shown to be significant predictor of initiation and continuation of self-care behavior	Shortridge-Baggert et al.[95]	Convenience sample of 94 non-elderly patients (Netherlands)	Cronbach alphas: 0.81 (patient), 0.90 (informant)
Access to care	Questions examining environmental, transportation, and isolation factors that may limit access to care	Developed by diabetologist for IDEATel project	NA	NA
Intervening/Case Mix or Control Variables				
Generic function and health: Activities of daily living	Comprehensive Assessment and Referral Evaluation (CARE) activities-of-daily-living scale	CARE[73,77,96,97]	Several probability samples of elderly patients	Interrater intraclass correlation coefficient in 0.90s; Cronbach alphas of 0.95 for development samples[73] and 0.84 in the Systolic Hypertension in the Elderly (SHEP) study.[90]
Vision impairment	CARE/Lighthouse for the Blind functional vision scale	Functional vision screening scale[76] modified by Lighthouse for the Blind from vision disorder subscale of CARE[73,77]	Several probability samples of elderly community residents;	Internal consistency of scale: 0.80 and 0.85 in two CARE vision development samples, 0.92 in replication sample[73]

			samples of elderly patients with low vision	
Health status (measures also considered by some to be quality-of-life measures)	One item from SF-12 and several items from other health measures, and a self-report version of the Charlson Comorbidity Index	Medical Outcomes Study, Short-Form 36[98] CARE[99] Diabetes Quality-of-Life Clinical Trial Questionnaire[94] Visual analog scales[100] Charlson Comorbidity Index[101]	Charlson: hospital inpatients and female patients with breast cancer	NA
Disease-specific health				
Severity of illness	Type 2 diabetes symptom checklist: case mix variables measure severity and duration of symptoms associated with diabetes; six symptom dimensions addressed—hyperglycemic, hypoglycemic, ophthalmologic, psychological, cardiovascular, and neuropathic	Grootenhuis et al.[102]	Samples of elderly patients; mean age, 65 ± 11yr	Internal consistency estimates, measured by Cronbach alpha: range 0.76–0.95 Test–retest reliability measured by Pearson product moment correlations: range 0.79–0.94
Illness burden	Diabetes Hassles Scale	Greenfield et al.[103]		
Social support	Kin and non-kin social support and close contact	Family Support Measure (FSM)[104] Lubben Social Support[105]	Scales developed for use in elderly populations	FSM: NA Lubben: Cronbach alpha, 0.70
Demographic and Descriptive Data				
Age Sex Race Ethnicity Marital status Education level	Race/ethnicity[107–109]: Office of Management and Budget directives—race as five categories, including combinations of mixed races; separate designation of ethnic group membership	Census classifications		
Occupation Income and sources Acculturation (Latino subjects)[106]	Occupation codes from Bureau of Labor Statistics (http://www.bls.gov)			

NOTES: Health care service utilization data are collected by telephone every 3 mo. Other outcome data are collected annually during in-person visits. NA indicates not available.

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