

DIABETES DATA COLLECTION PROTOCOL

The American Medical Group Association serves the needs of group practices committed to providing the highest quality cost-effective health care to their patients. AMGA is dedicated to the continuous improvement of the Group Practice of Medicine. In order to promote and improve medical care by group practices, AMGA and over 50 of its members have agreed to participate in a project that will expand the use of patient outcomes measurement in routine medical care. The focus of the effort will be patients diagnosed as having diabetes or asthma, and patients undergoing hip replacement or cataract surgery.

Throughout the project, the participating group practices will attempt to accomplish the following:

- Assess the health status of particular groups of patients and track changes in their clinical and functional status over time.
- Assess the effectiveness of treatment alternatives based on the effect on patients' overall health.
- Enhance continuous quality improvement efforts by using outcomes information to target areas needing improvement.
- Evaluate patient outcomes across systems of care.
- Provide better feedback to physicians and staff.

QUESTIONS OF INTEREST REGARDING DIABETES

- What impact does treatment have on functional status and well-being?
- Does patient perception of health vary with degree of control and complications?
- Is there a correlation between outcomes and degree of compliance?
- Can health status changes predict future complications?

DATA COLLECTION PROCEDURES

THE SAMPLE

Each clinic should attempt to obtain a cross section of diabetics 18 years of age and older seen at their clinic. The inclusion criteria should be formally defined by each clinic and presented to AMGA for future reference. To attain the goal of enrolling a minimum of 200 patients, groups with large diabetic populations may wish to obtain a random sample, while smaller groups may need to enroll patients on a sequential basis. As a data validity measure, each clinic must determine the total number of diabetics seen, as well as the total number enrolled in the study, so that a comparison can be made.

INSTRUMENTS

All data collection instruments must be labeled with identification numbers for patient, physician, and clinic. If the clinic has labels available, these will be affixed to the instruments; otherwise the identification box must be manually completed (with patient ID, Physician ID, and Clinic ID codes).

All project sites enrolling diabetic patients will use the following data collection instruments:

1. *Personal Identifiers Form:* While all clinics must collect this data, the use of this particular form is optional. It may be used as a cover sheet to keep the forms organized.
2. *Face Sheet:* This form is for internal use only, and will not be submitted to AMGA or a data pool. Intended to be used as part of a tickler file system, it may be customized for each clinic, as long as it provides a system for assessing the quality of data capture.
3. *Patient Log:* This form will document information about all patients eligible for the study and dates of enrollment (or reasons for non-enrollment if not enrolled). The log will be an essential part of the tickler system, as well as allow clinics to determine an accurate denominator (enrolled

versus eligible patients).

4. *Personal Characteristics Form*: The demographic and comorbidity data on this form must be collected for basic data analysis. This form will be completed by the patient at the time of enrollment and annually thereafter.
5. *Health Behaviors Survey*: The health behaviors questions on this form will provide information about lifestyle and health risks. This form will be completed by the patient at the time of enrollment and once per year thereafter.
6. *Health Status Questionnaire*: This form includes functional status and well-being questions, as well as depression screening questions. It will be completed at each study visit.
7. *Patient Questionnaire, Diabetes Form 2.1*: This form asks the patient about his/her diabetes, and must be completed at each study visit.
8. *Physician Questionnaire, Diabetes Form 2.2*: This form is for a clinical evaluation of the patient's diabetes, and must be completed by the physician at the baseline visit.
9. *Physician Questionnaire, Diabetes Form 2.3*: This form is for a clinical evaluation of the patient's diabetes, and must be completed by the physician at each follow-up visit.

NOTE: For Physician Questionnaire, Diabetes Form 2.2 and 2.3, refer to Diabetes Form 2.2 and 2.3 Instructions for specifications and/or clarifications for form completion.

10. *Process Information Form*: This form will be completed by the patient at the time of enrollment. Since the form will be used to evaluate the data collection process, this form must be filled out last.
11. *Loss to Follow-Up Log*: This form will document information about all patients who are eligible and participating in the project, but who have been lost due to follow-up (are no longer participating in the study due to death, refusal to participate, relocation, etc.). Reasons for patient loss due to follow-up will be documented.

I. Time Frame for Data Collection

- a. Initiation of the project

Physicians and staff:

- Develop a schedule and tickler file system
- Assign responsibilities for form submission
- Submit sampling protocols to AMGA
- Write cover letters/scripts explaining the project to patients

- b. Patient's first visit to physician

Patient:

- Personal Identifiers Form
- Personal Characteristics Form
- Health Behaviors Survey
- Health Status Questionnaire 2.0
- Patient Questionnaire Diabetes Form 2.1
- Process Information Form (must be last form completed)

Physician:

- Physician Questionnaire Diabetes Form 2.2

- c. Follow-up after initial assessment (12 months and annually thereafter)

Patient: Personal Characteristics Form (necessary only at annual visits)

- Health Status Questionnaire
- Patient Questionnaire Form 2.1
- Health Behaviors Survey (necessary only at annual visits)

Physician:

- Physician Questionnaire Form 2.3

II. Patient Questionnaire

Prior to the visit or at the time of patient encounter, the staff will:

- a. Affix identification labels to the appropriate forms.
- b. Record date of visit and any other information requested on the front of the form.
- c. Give questionnaires to the patient and explain that his/her responses to the questions will help improve the clinic's care for all patients and that his/her answers will be kept confidential.

Suggested Script: “_____ is committed to **measuring quality of care**. Since you are going to see your doctor today, please complete these questions about your diabetes and your overall health. It will take you about **20–30** minutes. You will also be asked to complete the questionnaires again in six months, twelve months and annually thereafter.

We consider this information as important to you and to your doctor as a lab test or x-ray. **Your answers are important and will help your physician understand how you are doing, so please fill out the questionnaires completely.**”

The description of the purpose of these questionnaires is very important. It should be described consistently by all persons distributing the questionnaires to patients. Project sites may wish to incorporate a cover letter into their patient questionnaires that provides the description and purpose of the study and also provides instructions to the patient for correctly and accurately completing the patient questionnaire. If the patient should require assistance, the questions should be **read rather than interpreted**. If you believe that more assistance was given than just reading the questionnaire, please note that fact in the “Administrative Use Only” box on the front of the questionnaire.

- d. Review forms for completeness and discuss with the patient any questions left unanswered or that have been marked with multiple responses.

If the patient refuses to complete the questionnaires, record the reason on the front of the questionnaire in the box marked “ADMINISTRATIVE USE ONLY”. Please code the refusals as follows:

Time: Patient does not have the time

Read: Patient could not read form

Conf: Perceived violation of confidentiality

Unab: Unable to complete

Other: Any other stated reason (e.g. altered mental status)

- e. It is desirable to have the patient complete the **entire** form by the end of the physician visit.
- f. Place a card for each patient in a tickler file (computerized or manual) at the time of the initial visit, noting the date at which six month and annual follow-ups should occur.
- g. Return all completed forms to the Project Coordinator.
assistant teams may differ in who completes clinical measurements. The key is that the **forms are completed.**)
- d. Verify that the physician form is complete.
- e. Return the completed form to the Project Coordinator.

III. Physician Questionnaire

At the time of each patient visit that qualifies for a data collection target time, the staff will:

- a. Affix an identification label to the Physician Questionnaire Form 2.2 or 2.3.
- b. Record date of visit.
- c. Give the form to the physician to begin completing the physician's portion. (Some physician/

IV. Patient Follow-up Questionnaires

Patient follow-up questionnaires will be completed at 12 months, and annually after the initial visit according to the following schedule:

<u>Target for Data Collection</u>	<u>Acceptable Window for Data Collection</u>
12 month	6–18 months after initial visit
24 month (2 year)	19–30 months after initial visit
36 month (3 year)	31–42 months after initial visit

The collection of data should occur on the first visit within each window. If there are multiple visits within a given window, individual clinics will decide if they wish to collect additional information closer to the target dates. For example, if a patient is seen for their first follow-up visit 17 months after enrollment, and returns for a follow-up visit 19 months after enrollment, they would complete documents pertaining to the 24 month target for data collection. It will be an individual clinic's decision whether or not to collect additional data if the patient has another visit closer to the 24 month target.

Since the validity of the study depends upon the data collected, a properly maintained tickler file for each patient is crucial. The tickler file on each patient will be updated with six-month and annual follow-up dates. Staff will be responsible for ensuring data collection occurs within the proper time periods.

At the twelve month and subsequent annual visits, the patient will again be asked to complete the Personal Characteristics Form, the HSQ 2.0, the Patient Questionnaire Diabetes Form 2.1, and the Health Behaviors Survey.

V. Forms Editing

Forms should be reviewed for completeness by staff while the patient is still in the office. The project coordinator will again review the forms for completeness and will attempt to contact the patient/physician for missing responses.

VI. Sample Log

All patients eligible for the study should be included in a log that records the following information:

- Unique identification number
- First three letters of patient's last name
- Birth date and Sex
- Enrollment in study? (yes/no and date)
- Reasons for non-enrollment (space for comments)
- Data collection window (which target time is it?)

DIABETES PHYSICIAN QUESTIONNAIRE
FORMS 2.2 and 2.3 INSTRUCTIONS

HISTORY:

Question 2n—Previous vascular procedure—This refers to any non-cardiac vascular surgery

Question 4—For the purpose of the initial visit, #4 questions should be answered for episodes within the last year. On return visits, form 2.3 #3 questions should be answered for episodes that have occurred since the last form was completed.

TREATMENT: All questions refer to the **current** treatment, not the treatment that was initiated at the time of the visit.

LABORATORY ASSESSMENT: At patient entry into the study, this refers to whether or not the test was performed within the last year. On subsequent forms, it is the most recent value since the last form was completed. The laboratory tests that are listed on the form are not required to be performed, but should be ordered according to the physician's usual practice.