

American Medical Group Association Outcomes Measurement Consortia

ASTHMA DATA COLLECTION PROTOCOL

OUTCOMES MEASUREMENT CONSORTIA (OMC)

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 60 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 with asthma, diabetes, hypertension, and low back pain, and patients undergoing hip replacement, total knee replacement, or cataract surgery.

Objectives of the OMC include:

- 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 ASTHMA

- How does the management of asthma change over time?
- Does management of asthma differ between primary care and specialties?
- Is there geographic variation in outcomes?
- Do outcomes differ according to race and other demographic variables?
- Can an efficient and accurate data collection tool be developed?
- Can useful information be gained from pooled data?
- Can data be feasibly collected across systems of care including primary and specialty care?
- Is collected data useful in the formulation of practice guidelines?
- Does immediate access to outcomes data have an affect on the long term outcome?
- Difference in HSQ scores between PCP and specialists?
- Difference in HSQ score between Allergists and Pulmonologists?
- Do people who use inhaled steroids show an increase in Quality of Life?

THE SAMPLE

Eligible enrollment: All patients 15 years of age or older with diagnosed asthma, who have been seen for the diagnosis of asthma in the past, are on asthma medications, or have an exacerbation of asthma at the participating clinics. All levels of severity should be included. The sample will consist of all consecutive eligible patients. Patients presenting with an acute exacerbation of asthma will not be enrolled in the study at that visit. However, exercise induced asthma patients are to be included in the study. Patients will be excluded when their primary diagnosis is COPD or CHF.

Sample size:

If the clinic foresees having a large number of eligible asthma patients, the site may institute systematic sampling. The clinics will attempt to enroll patients evenly throughout the year to reduce the effect of seasonal variation, and will adjust their sampling formula periodically if necessary. A cap of 150% of the monthly target of 15-20 patients is recommended to reduce the effect of seasonal variation. A monthly patient log should be kept that records both the total number of patients eligible to be included in the study sample and those that actually become part of the study sample (enrolled versus eligible patients). The attached sampling procedure is recommended [Appendix A]. If clinics choose to use another sampling technique, they must submit a copy of their proposed sampling procedure to AMGA.

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 asthma 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 once per year thereafter.
5. *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 (or by mail if there is no office visit during a particular data collection window).
6. *Patient Questionnaire, Asthma Form 10.1*: This form asks the patient about his/her asthma, and must be completed at each study visit (or by mail if there is no office visit during a particular data collection window).

NOTE: Patient Questionnaire, Asthma Form 10.1, Question 15—A physician or member of the health care staff may wish to aid the patient in specifying which type of inhaler is used. Assistance with answering this question will augment adequate and valid data collection.

7. *Physician Questionnaire, Asthma Form 10.2*: This form is for a clinical evaluation of the patient's asthma, and must be completed by the physician at each study visit. If there is no office visit during the data collection window, then the physician form will not be completed, and a notation will be made on the patient face sheet/tickler file.

Clarification: Physician Questionnaire, Asthma Form 10.2, Question 7—"added" medication signifies the initial prescription of and use of a new drug.

8. *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 (after all other forms given to the patient).
9. *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.

DATA COLLECTION PROCEDURES

1. Tracking System

Prior to project initiation, staff will develop methods, forms, and schedules for tracking patients, verifying eligibility, and assuring that data are collected at the appropriate times. Staff should fill out the patient log and face sheet for each eligible asthma patient.

2. Forms to be Completed

2A. Patient Questionnaires

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

- a. Affix an identification label to the first page of all data collection forms to be completed by the patient and physician (or fill out manually if no labels available).
- b. Record the date and complete any other information requested on the front of the forms.
- c. Give the questionnaires to the patient and explain that his/her responses to the questions will help improve the clinic's care to all patients and that his/her answers will be kept confidential.

Suggested Script: _____ *is committed to **assessing the quality of care**. Since you are going to see your doctor today, please complete these questions about your asthma 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 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 any questions left unanswered with the patient.

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 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. Make sure that the patient completes the **entire** form by the end of the physician visit. If the patient cannot stay long enough to complete the form, ask that he/she take the form home to complete and mail it back as soon as possible. Give him/her a postage paid envelope. Note on the patient's tickler file that he/she received the form, and schedule a date to follow-up regarding the form's completion.
- f. Place a card for each patient in a tickler file (computerized or manual) at the time of the initial visit, noting the dates at which six month and annual follow-ups should occur.
- g. Return all completed forms to the Project Coordinator.

2B. Physician Questionnaire

At the time of patient visit, the staff will:

- a. Affix an identification label to the Physician Questionnaire Form 10.2 (or fill in information manually if no labels available).
- b. Record date of visit.

- c. Give the form to the physician for completion. (Some physician/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.

2C. Patient Follow-up Questionnaires

Patient follow-up forms will be completed six months, and annually after the initial assessment. The objective is to collect data as close to the targeted collection time as possible. However, since not all patients will be seen in the clinic at exactly six, twelve, or 24 months, etc. following enrollment, data may be submitted within a reasonable range of time surrounding the target date. For example, the acceptable data collection window for the six-month target is three to nine months. If the patient is seen more than once within the data collection window (and they have filled out forms more than once), the Project Coordinator will submit only the data collected at the visit closest to the target date.

Staff will check with the appointments secretary to see whether the patient has been scheduled for a physician visit during the target time. If so, staff will attempt to collect data during this office visit. If a scheduled visit is not made by one month after the target date (and one is not scheduled to occur within the data collection window), the forms will be sent to the patient by mail. Patients will receive the questionnaires with a cover letter from their physician and a self-addressed, stamped envelope for returning the forms. The cover letter will ask the patient to bring the forms with them if they plan to make an office visit within the next month, or return the forms by mail if they do not plan to make an office visit. Physician data will be missing if the patient mails in the forms, so every effort should be made to collect data at an office visit. If the patient does mail the forms back, and subsequently makes an office visit within the same data collection window, then the physician will fill out the forms at that visit.

Mailing Procedure

- a. If no visit has occurred within one month after the target date (ie. 7, 13, 25 months, etc.), follow-up forms will be sent to the patient.
- b. If the patient has not returned the questionnaire within two weeks of sending it, a reminder card will be sent.
- c. If the end of the data collection window approaches (ie. 8, 14, 26 months, etc.) and the patient has still not returned the completed questionnaire, staff will place a phone call to the patient and try to elicit the responses to the questionnaire over the phone. Staff will note on the front of the questionnaire that answers were obtained by phone. If patient refuses, no further attempts will be made to obtain information until the patient's next physician visit.
- d. The tickler file on each patient will be updated (whether or not he/she completed the questionnaires).

2D. Physician Follow-up Evaluations

At each subsequent office visit that qualifies for the study (ie. 6, 12, 24 months, etc.), the staff will:

- a. Affix an identification label to the front of the Physician Questionnaire Form 10.2.
- b. Record date of visit.
- c. Give the form to the physician to complete the physician's portion.
- d. Check form for completeness.
- e. Return completed form to the Project Coordinator.

3. Time Frame

- a. Initiation of the project

Physicians and staff:

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

b. Initial enrollment—patient’s first study visit to physician

Patient fills out:

- Patient identifiers form
- Personal Characteristics form
- Health Status Questionnaire
- Patient Questionnaire (Asthma Form 10.1)
- Process Information form (must be last form completed)

Physician fills out:

- Physician Questionnaire Form 10.2

Staff must handle the following:

- Printing labels/manually labeling all OMC forms
- Patient Log
- Patient Face Sheet
- Tickler File for follow-up

c. 6 month follow-up visit (3 to 9 months after initial assessment)

Patient fills out:

- Health Status Questionnaire
- Patient Questionnaire (Asthma Form 10.1)

Physician fills out:

- Physician Questionnaire (Form 10.2)

Staff updates:

- Patient log
- Patient face sheet
- Tickler file for follow-up

d. Annual follow-up visits (9 to 15 months after initial visit, 21 to 27 months after initial visit, 33 to 39 months after initial visit, etc.)

Patient fills out:

- Personal Characteristics (demographic & comorbidity form)
- Health Status Questionnaire
- Patient Questionnaire (Asthma Form 10.1)
- Process Information Form—must be filled out last

Physician fills out:

- Physician Questionnaire (Form 10.2)

Staff updates:

- Patient log , Patient face sheet , Tickler file for follow-up

4. Forms Editing

Forms should be scanned 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.

5. Sample Log

All patients sampled for the project should be included in a log that records the following information:

- Unique identification number
- First three letters of patient’s last name
- Birth date
- Sex
- Enrollment in study? (yes/no and date)
- Reasons for non-enrollment (space for comments)

APPENDIX A Procedure for Randomly Selecting Patients

It might be feasible to follow-up all of the asthma patients in some of the larger group practices; and that once the desired sample size was determined, selection of the sample randomly could be accomplished.

Most clinics make use of chart numbers—or medical records numbers—which are unique patient identifiers whose terminal digits are distributed quite randomly. Chart numbers are readily available and will be simpler and cheaper to use than truly random numbers.

Procedure

1. Determine your sampling fraction—in other words, decide what proportion of eligible asthma patients you want to select. For example, in a given time period you anticipate that you will have 500 eligible asthma patients, and you want to select 220 of them. The sampling fraction would be $220 / 500 = .44$.
2. Select patients for whom the last two digits of the chart number are less than your sampling fraction (times 100). Continuing the above example, patients whose chart numbers are '65127343' and '7200800' would be selected because their terminal two digits are '43' and '00', both lower than '44'. On the other hand, patients with chart numbers '65127344' and '7200899' would not be selected because their terminal two digits ('44' and '99') are not lower than '44'.
3. Monitor your patient accrual periodically and adjust the sampling fraction if you find that you are accruing too few patients (or too many). Continuing the above example, if after a month you find that there aren't as many eligible patients as you initially anticipated and that in order to get 220 patients in the desired time frame you need 55% of all eligibles from now on rather than the initial estimate of 44%, then you may change your sampling fraction, and start selecting eligible patients with chart numbers whose terminal digits are below '55'.

Comment

This procedure won't work well if the terminal digits of chart numbers are not randomly distributed. So it is necessary to find out how these numbers are assigned and confirm that there is no tendency for the last two digits to be related to occupation, year of birth or anything else that could possibly be related to the data. For example, the above procedure would be flawed if new asthma patients request and get chart numbers with low terminal digits in order to get their outcomes measured, or if some other study is already allocating asthma patients to one or another kind of management according to chart number.

If you need advice determining how big a sample you need, or what your sampling fraction should be, or how to monitor patient accrual and readjust your sampling fraction, or whether your chart numbers are "random enough", you should consult with a statistician (AMGA can help).