

*American Medical Group Association  
Outcomes Measurement Consortia*

**TOTAL HIP REPLACEMENT DATA COLLECTION PROTOCOL**

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*REVISION—APRIL 15, 1995*

**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 effort to systematically improve the quality of medical care in group practices, AMGA and over 50 of its members are participating in a collaborative effort to measure patient outcomes, compare their outcomes with other populations, and use the information to refine processes of care. To date, the focus of this effort is patients diagnosed as having diabetes, low back pain, or asthma, hypertension, and patients undergoing hip/knee replacement or cataract surgery.

Objectives of the OMC include:

- Assessing the health status of particular groups of patients and tracking changes in their clinical and functional status over time.
- Assessing the effectiveness of treatment alternatives based on the effect on patients' overall health.
- Assessing the feasibility of collecting outcomes data as part of routine medical care.
- Enhancing continuous quality improvement efforts by using outcomes information to target areas needing improvement.
- Evaluating patient outcomes across systems of care.
- Providing better feedback for physicians and staff.
- Improving the quality of information available to patients to aid them in making decisions about their care.

**QUESTIONS OF INTEREST REGARDING HIP REPLACEMENT**

- Are there differences in outcomes of hip replacement across medical groups? If so, what are the correlates of these differences, i.e., surgeons, sites, devices, treatment processes, organizations, patients?
- Do variations in surgical interventions influence outcomes?
- What is the impact of comorbid conditions on longitudinal outcomes of patients with hip replacement?

**THE SAMPLE**

This sample includes adults over 21 years of age having total hip replacement surgery at participating clinics, excluding hip replacement patients with acute fractures. As a data validity measure, each participating clinic must provide the total number of consecutive patients enrolled and the total number of hip replacements performed.

**THE 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. If not, the identification box must be manually completed.

All participating sites will use the following data collection instruments:

1. **Personal Identifiers Form:** This form is for collecting a uniform set of basic patient information such as name, Social Security number, and address. While all clinics must collect this data, the use of this particular form is optional.
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, and will 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 Pre-op Assessment, Hip Replacement Form 13.1.** This form requests information from patients regarding pain and functional status in relation to their hip(s). The form also queries the patient about their expectations (in terms of pain relief and increased functional status after surgery). It must be completed by the patient prior to surgery.
7. **Physician Pre-op Form 13.2.** This history and clinical evaluation form must be completed by the physician/staff prior to surgery.
8. **Patient Follow-up Assessment, Hip Replacement Form 13.3.** This form requests information from patients regarding pain and functional status in relation to their hip(s). In addition, the form queries the patient about their post-op recovery and satisfaction with the care they received.
9. **Day of Surgery Form, Hip Replacement 13.4a.** This form requests information about the hip replacement surgery and related medical care. It should be completed by the physician on the day of surgery.  
**NOTE:** For Day of Surgery Form, Hip Replacement 13.4a, specific coding instructions are needed for Question 5 (Type of Prosthesis). Refer to Hip Replacement Prosthetic Device Coding Sheet and Coding Instructions for coding assistance.
10. **Hospital Discharge Form, Hip Replacement 13.4b.** This form requests information about the patient's post-op care, complications, and discharge plan. It should be filled out by the physician/staff on the day of discharge from the hospital.
11. **Postoperative Evaluation Form, Hip Replacement 13.4c.** This clinical evaluation form must be completed by the physician/staff at each study visit after surgery.
12. **Surgeon Information, Hip Replacement Form 13.5.** This form provides information about the education and experience of the surgeon, and should be filled out by the surgeon annually.
13. **Process Information Form:** This form will be completed by the patient at the time of enrollment and at subsequent annual exams. 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).
14. **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 loss due to follow-up will be documented.  
**NOTE:** For all patients who have been lost due to follow-up, Hip Replacement Form 13.5 (Surgeon Information) should still be completed to collect information on medical practice.

## 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 is collected at the appropriate times. Staff should fill out the Patient Log and Face Sheet for each eligible hip replacement patient. The physician should fill out the Surgeon Information Form 13.5 before beginning data collection (and once per year thereafter).

### 2. Forms to be Completed

#### 2A. Patient Preoperative Assessment

At the patient's *last preoperative visit before surgery*, the staff will:

- a. Affix an identification label to the following:
  - Personal Identifiers Form
  - Personal Characteristics Form
  - Health Status Questionnaire
  - Pre-op Patient Form 13.1
  - Process Information Form (must be last form completed).
- b. Record the date and complete any other information requested on the front of the form.
- c. Give the questionnaires to the patient and explain that his/her responses to the questions will help improve the clinic's care for all patients.

A suggested script: “\_\_\_\_\_ is committed to **measuring the quality of care**. Since you are scheduled for hip replacement surgery, please complete these questions about your hip and your overall health. It will take you about **15-20** minutes. As part of your follow-up, the doctor will also be asking you to complete similar questionnaires at office visits after surgery. 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 the questionnaires out 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 requires assistance, the questions should be **read rather than interpreted**. If you believe that more assistance was given than just reading the questionnaire, please make a note 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 questionnaire in the box marked “ADMINISTRATIVE USE ONLY”. 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.g. altered mental status)

- e. Make sure that the patient correctly responds to and 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 self-addressed, postage-paid envelope. Note on the patient's tickler file that the he/she received the form, and schedule a date to follow-up regarding the form's completion.
- f. Return all completed forms to the Project Coordinator.

## 2B. Physician Preoperative Forms

At the last visit before surgery, the staff will:

- a. Affix I.D. label to the Physician Preoperative Assessment Form (13.2).
- b. 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.**)
- c. Verify that the physician preoperative section is complete prior to surgery.
- d. Return the completed forms to the Project Coordinator.

## 2C. Physician Day of Surgery Forms

The staff will:

- a. Affix an identification label to the Day of Surgery Form 13.4a. Record hospital ID code on the upper right corner of the form beneath the label.
- b. Record date of surgery.
- c. Give the form to the physician for completion.
- d. Check the form for completeness.
- e. Place a card for each patient in a tickler file (computerized or manual), noting the surgery date and the date at which six-week follow-up should occur.
- f. Return the completed form to the Project Coordinator.

## 2D. Physician Hospital Discharge Forms

On the day the patient is discharged, the physician/hospital staff should complete the Hospital Discharge Form 13.4b. Physicians must be made aware of the information requested in the form so they can dictate the required information if the form is to be completed by someone other than the physician. The staff will:

- a. Affix an identification label to the Hospital Discharge Form 13.4b. Record hospital code on the upper right corner of the form beneath the label.
- b. Record date of discharge.
- c. Give the form to the physician/staff for completion.
- d. Check the form for completeness.
- e. Return the completed forms to the Project Coordinator.

## 2E. Patient Follow-Up Assessments

At every postoperative visit, the staff will follow the same protocol as for the pre-op assessment. Forms to be completed by the patient include:

Patient Follow-up Assessment Form 13.3

Health Status Questionnaire

Personal Characteristics Form \*\*

Process Information Form (last form completed) \*\*

\*\* Note that Personal Characteristics and Process Information Forms will be filled out only at annual visits, and the Personal Identifiers will be filled out only once (upon enrollment). Staff should be sure to verify the surgery date. If a patient has multiple appointments within a window, data collected at the point closest to the targeted observation window should be submitted to the data pool.

## 2F. Physician Postoperative Forms

At all postoperative visits beginning at six weeks post-op (data collection windows begin at 21-63 days), the physician will fill out form 13.4c for all subsequent follow-up visits. If a patient has multiple appointments within a window, data collected at the point closest to the targeted observation window will be submitted to the data pool.

### 3. Target Times for PATIENT Data Collection

The time frames for data collection will be as follows:

<u>Target Time</u>	<u>Data Collection Window</u>
3 months post-op	64 to 112 days post-op (9 weeks to 4 months)
12 months post-op	241 to 547 days post-op (9 months to 1_ years)
24 months post-op	548 to 912 days post-op (1_ to 2_ years)

### Target Times for PHYSICIAN Data Collection

<u>Target Time</u>	<u>Data Collection Window</u>
6 weeks post-op	21 to 63 days post-op (3 to 9 weeks)
3 months post-op	64 to 112 days post-op (9 weeks to 4 months)
6 months post-op	113 to 240 days post-op (4 to 9 months)
12 months post-op	241 to 547 days post-op (9 months to 1_ years)
24 months post-op	548 to 912 days post-op (1_ to 2_ years)

### 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
- Sex
- Surgery date
- Left or right hip (operated on)
- Enrolled (yes/no)
- Reasons for non-enrollment (comment space)

### 6. Data Collection Flow Charts

To assist groups in developing data collection protocols, each clinic will draft a flow chart of the process they intend to use in-house. The flow chart should include specific duties such as explaining the forms to patients, setting up and maintaining a tickler file, and reviewing forms for completeness (etc.). The flow charts will be submitted to AMGA and then distributed to all hip replacement project participants for review.

## Hip Replacement Prosthetic Device Coding Instructions

Question #5 of Hip Replacement Form 13.4a asks for the type of prosthesis that was used on each patient in the study. To accurately complete the question in a manner that is compatible with the data base, the following sequence of steps should be applied:

1. There are **5** spaces to record the brand or manufacturer of the acetabulum component. From the device list, select the brand or manufacturer that most closely describes the component used. **Place the corresponding number in the first space (and if Miscellaneous/other selected, in the first and second space)**. Leave the remainder of the spaces blank. Do not zero fill. There are **12** spaces allotted for style or model. **In the first space, record the style/model (either 1,2, or 3). In the second space, record type of fixation, i.e. either 1 or 2.**
2. There are also **5** spaces available for recording the brand or manufacturer of femoral components. From the device list, select the brand or manufacturer that most closely describes the component used. **Place the corresponding number in the first space (or the first and second spaces if Miscellaneous/other is selected)**. Leave the remainder of the spaces blank. Do not zero fill. There are **12** spaces allotted for style or model. In addition to style or model, you will also use these 12 spaces to record head diameter, head material, stem material, stem fixation, porous coating, other coatings, and stem length. Again, do not zero fill blank or empty spaces. Take special care to be sure that the correct response is placed in the proper space. For example, always record femoral style in the first space after model; record head diameter in the second space, head material in the third space, stem material in the fourth space, stem fixation in the fifth space, porous coatings in the sixth space, other coatings in the seventh space and stem length in the eighth space.

Although this may seem complicated at first, it is our assumption that most surgeons will use one or two combinations consistently. If so, the same sequences of numbers will be recorded repeatedly.

An example of the coding system is attached.

**AMGA Outcomes Measurement Project  
Hip Replacement Prosthetic Devices  
Coding Sheet**

**Acetabulum**

- A. Manufacturer (Brand)
  - 1. Biomet
  - 2. DePuy
  - 3. Howmedica
  - 4. Joint Medical Products
  - 5. Kirschner Orthopedic Division
  - 6. Osteonics
  - 7. Protek
  - 8. Smith Nephew Richards
  - 9. Zimmer
  - 10. Miscellaneous/Other
- B. Style (Model)
  - 1. All Polyethylene
  - 2. Metal Backed
  - 3. Other
- C. Fixation
  - 1. Screw Fixation
  - 2. Bone Cement Fixation
  - 3. Press Fit Fixation

**Femoral Components**

- A. Manufacturer (Brand)
  - 1. Biomet
  - 2. DePuy
  - 3. Howmedica
  - 4. Joint Medical Products
  - 5. Kirschner Orthopedics Division
  - 6. Osteonics
  - 7. Protek
  - 8. Smith Nephew Richards
  - 9. Zimmer
  - 10. Miscellaneous/Other
- B. Style
  - 1. DRG Hip
  - 2. Non DRG Hip

**Femoral Components (continued)**

- C. Head Diameter
  - 1. 22mm
  - 2. 28mm
  - 3. 32mm
  - 4. 26mm
- D. Head Material
  - 1. Stainless Steel
  - 2. Cobalt Chrome
  - 3. Titanium
  - 4. Ceramic
  - 5. Other
- E. Stem Material
  - 1. Stainless Steel
  - 2. Cobalt Chrome
  - 3. Titanium
  - 4. Other
- F. Stem Fixation
  - 1. Porous Bone Ingrowth
  - 2. Smooth Interference Fit
  - 3. Bone Cement
- G. Porous Coatings
  - 1. Porous: Complete  
(greater than 80%)
  - 2. Porous: Partial  
(40% to 79%)
  - 3. Porous: Minimal  
(0% to 39%)
  - 4. Other Porous Coating
  - 5. None
- H. Other Coatings
  - 1. Pre-Coat PMMA
  - 2. Coating HA (hydroxyapatite)
  - 3. Coating TCP
  - 4. Other Coating
  - 5. None
- I. Stem Length
  - 1. Normal Length Stem
  - 2. Revision or Long Length Stem