

*American Medical Group Association  
Outcomes Measurement Consortia*

**TOTAL KNEE REPLACEMENT DATA COLLECTION PROTOCOL**

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*REVISION—APRIL 15, 1995*

**QUESTIONS OF INTEREST REGARDING TOTAL KNEE REPLACEMENT**

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

**THE SAMPLE**

This project will include adults over 21 years of age having total knee replacement surgery at participating clinics. Patients presenting with **any** type of knee fracture will be excluded. As a data validity measure, each participating clinic must provide the total number of consecutive patients enrolled in the project **and** the total number of knee replacements performed. All patients sampled for the project (enrolled or not enrolled) should be documented in a log that records the following information:

- Patient identification number
- First three letters of patients last name
- Sex
- Surgery date
- Left/Right knee (or both) operated on
- Enrolled (yes/no)
- Reasons for non-enrollment (if any) (comment space)

**THE INSTRUMENTS**

All data collection instruments must be labeled with identification numbers for patient, physician, and clinic/site. The identification box located in the top right-hand corner of each form must be completed, either manually or by affixing a label containing identifying information.

All project sites will use the following data collection instruments:

1. **Face Sheet:** This form is for internal use only, and will not be submitted to the aggregate data pool. Intended to be used as part of a tickler system, it may be customized for each clinic, as long as it provides a system for assessing the quality of data capture.
2. **Patient Log:** This form will document information about all patients eligible for the study and dates of enrollment (or reasons for non-enrollment). The log should be an essential part of the tickler system, and will allow clinics to determine an accurate denominator (enrolled vs. eligible patients).
3. **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.

4. *Health Status Questionnaire*: This form included functional status and well-being questions, as well as depression screening questions. It will be completed by the patient at each office visit.
5. *Patient Pre-Op Assessment, Total Knee Replacement Form 16.1*: This form requests information from patients regarding pain and functional status in relation to their knee(s). This form includes questions from the WOMAC Osteoarthritis Index. 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.
6. *Physician Pre-Op Evaluation, Total Knee Replacement Form 16.2*: This history and clinical evaluation form must be completed during the patient's last visit prior to surgery.  
**\*\*NOTE: Appendix I (Comorbidity Dictionary) should be used to answer Question 8 on Total Knee Replacement Form 16.2.**
7. *Patient Follow-Up Assessment, Total Knee Replacement Form 16.3*: This form requests information from patients regarding pain and functional status in relation to their knee(s). This form includes questions from the WOMAC Osteoarthritis Index. In addition, the form queries the patient about their post-op recovery and satisfaction with the care they received. It must be completed by the patient at each post-operative visit after surgery.
8. *Day of Surgery Form, Unilateral or First Knee, Total Knee Replacement Form 16.4a*: This form requests information about the total knee replacement surgery for unilateral procedures and related medical care. It should be completed by the physician following surgery.
9. *Day of Surgery Form, Bilateral or Second Knee, Total Knee Replacement Form 16.4b*: This form requests information about the total knee replacement surgery for the second knee of bilateral procedures. This form contains side-specific questions. It should be completed by the physician following surgery.
10. *Implant Code Form, Total Knee Replacement Form 16.4c*: This form requests information pertaining to the knee implant. It should be completed by **each** physician participating in the study for designation of the knee prosthesis implant code to be used on Total Knee Replacement Forms 16.4a and 16.4b. This form must be completed for **each** type of knee implant that is used. Appendix II should be referred to to determine implant code designation.
11. *Hospital Discharge, Total Knee Replacement Form 16.5*: This form requests information about the patient's post-op care, complications, and discharge plan. It should be filled out at the time of patient discharge from surgical hospitalization.
12. *Physician Post-Op Evaluation, Total Knee Replacement Form 16.6*: This clinical evaluation form must be completed at each post-op patient visit.
13. *Surgeon Information, Total Knee Replacement Form 16.7*: This form provides information about the education and experience of the surgeon. It must be completed by **each** surgeon participating in the study. The form should be completed once at baseline and once annually thereafter.
14. *Process Information Form*: This form will be the **last** form to be completed by the patient at the time of enrollment and at subsequent annual office visits. Since the form will be used to evaluate the data collection process, this form **must** be filled out after all other forms have been given to the patient.
15. *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 continue to participate, relocation, etc.). Reasons for loss-due-to-follow-up will be documented.

## DATA COLLECTION PROCEDURES

### Tracking System

Prior to project initiation, staff involved at the project site should develop systems and schedules for tracking patients, verifying eligibility, and assuring that data will be collected at the appropriate times (window periods). Tracking systems should be documented through flow-charting or similar techniques.

### Data Collection Window Periods

The time frames for data collection will be as follows:

<u>Target Time</u>	<u>Data Collection Window</u>
Surgical post-op	Day of Surgery to 20 days post-op
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 months to 9 months)
12 months post-op	241 days to 547 days post-op (9 months to 1 1/2 years)
24 months post-op	548 days to 912 days post-op (1 1/2 to 2 1/2 years)

\*\*NOTE: 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**.

### Forms to be Completed

#### A. Pre-Operative

1. Patient: Personal Characteristics Form  
Health Status Questionnaire  
Patient Pre-Op Assessment—Form 16.1  
Process Information Form
2. Physician: Physician Pre-Op Evaluation—Form 16.2

#### B. Surgical Post-Op

1. Physician: Day of Surgery—Form 16.4a  
Day of Surgery—Form 16.4b (if applicable)  
Implant Code Form—Form 16.4c  
Hospital Discharge—Form 16.5  
Surgeon Information—Form 16.7

#### C. 6 weeks, 3 months and 6 months Post-Op

1. Patient: Patient Follow-Up Assessment—Form 16.3  
Health Status Questionnaire
2. Physician: Physician Post-Op Evaluation—Form 16.6

#### D. 12 months and 24 months Post-Op

1. Patient: Patient Follow-Up Assessment—Form 16.3  
Health Status Questionnaire  
Personal Characteristics Form  
Process Information Form
2. Physician: Physician Post-Op Evaluation—Form 16.6  
Surgeon Information—Form 16.7

### Collecting Information from the Patient—Forms 16.1 and 16.3

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 descriptions 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. **The means by which data is collected from the patient should be recorded in the “Administrative Use Only” boxes located on the face page of each questionnaire.**

If the patient refuses to complete the questionnaires, record the reason in the “Administrative Use Only” box. Refusals should be recorded as follows:

Time:	Patient does not have time
Read:	Patient could not read the form
Conf:	Patient perceived violation of confidentiality
Unab:	Patient unable to complete
Other:	Any other stated reason (e.g. altered mental status)

If the patient cannot stay long enough to complete the forms, the patient may be provided with a self-addressed, postage-paid envelope, in order for he/she to complete the forms at home.

If a patient does not return for his/her follow-up visit during a specified window period, every means should be attempted to obtain follow-up data. Follow-up data collection forms for the patient may be mailed and accompanied by a self-addressed, postage paid envelope, data forms may be administered to the patient via conversation by phone, etc. If it is felt that the patient may be lost-due-to-follow-up, attempts should be made to support this reasoning. Local post offices may be contacted to assess whether a patient has moved and local and national death registries may be contacted to assess whether the patient has died during the follow-up period. Reasons for a patient no longer participating in the study should be documented in the Loss-to-Follow-Up Patient Log.

#### **Using the Implant Code Form (16.4c)**

When new types of knee implants are introduced at a project site, the Implant Code Form must be reintroduced to the physician(s) and xerox copies of the Implant Code Forms should be submitted to AGPA for implant code designation.

Appendix II (Implant Code Key) of the data collection protocol will continuously be updated to supply project sites with designated codes for the Day of Surgery Form 16.4a and 16.4b.

## APPENDIX I—COMORBIDITY DICTIONARY

### PHYSICIAN PRE-OP EVALUATION TOTAL KNEE REPLACEMENT FORM 16.2

#### QUESTION 8—COMORBIDITIES

a) **None**

b) **Congestive Heart Failure**

c) **Hypertension**

d) **Ischemic Heart Disease**

Previous MI, CABG, or PTCA; and/or on drug therapy for HTN, angina, CHF. Drugs include beta blockers (Tenormin, Inderal), Nitroglycerine preps, Calcium blockers (Cardizem, Diltiazem, Verapamil, Digoxin [Lanoxin]), or diuretics (Lasix, Hydrodiuril, etc.). Heart murmur (e.g. mitral prolapse) will be excluded.

e) **Cerebral Vascular Accident (CVA)**

History of CVA with mild paresthesia or ataxia, history > 2TIAs, aneurysm or partial occlusion with no continuing symptoms. History of CVA resulting in hemiplegia, paraplegia, quadraplegia; acute subarachnoid hemorrhage, frequent TIAs.

f) **Chronic Lung Disease (including asthma, bronchitis, COPD, or emphysema)**

Also includes chronic pulmonary fibrosis. On drug treatment; e.g. bronchodilators (Bronkaid, Alupent, Ventolin, etc.), corticosteroids —either oral (Prednisone, Prednisolone, Medro/Solumedrol) or inhalants (Beclomethasone, Azmacort, etc.). Also includes home oxygen treatment. Includes antibiotic treatment in conjunction with the above mentioned drug treatments. Excludes all other antibiotic use.

g) **Renal Disease**

Uncomplicated, history: Acute, uncomplicated UTI, recent history (< 3 months ago) of uncomplicated nephritis, history (< 6 months ago) of nephrolithotomy or ESWL

Uncomplicated, acute: Acute nephritis, nephrolithiasis, mild renal artery stenosis, chronic UTI

Complicated, acute: (BUN > 40 or Creat > 3), obstructive uropathy, renal failure, encephalopathy, moderate/severe renal artery stenosis, working renal transplant

h) **Hepatic Disease**

(Chronic Liver Disease). Clinical diagnosis of cirrhosis of liver, chronic active hepatitis, alcoholic hepatitis. Excludes mere abnormal liver enzymes of uncertain cause, fatty liver or chronic persistent (as opposed to active) hepatitis. Also excludes chronic carriers of hepatitis viruses B or C, unless also diagnosis of entities listed above.

i) **Gastro-intestinal Disease**

History of ulcer < 1 year; mildly symptomatic gastritis or diverticulitis; intermittent irritable bowel syndrome; active ulcer controlled by medication; controlled diverticulitis; hiatal hernia with reflux esophagitis; polyp removal < 1 month; ulcerative colitis with minor manifestations or complications; any active GI condition resulting in perforation hemorrhage, obstruction, peritonitis, or fistula, includes ulcers, diverticulitis, appendicitis, enteritis or ulcerative colitis, hiatal with anemia or aspiration pneumonia.

j) **Arthritis (in areas other than knee)**

(Inflammatory Arthritis). Includes rheumatoid arthritis; Reiter's; Marie-Strumpell Spondylitis; Juvenile RA; tophaceous gout. Excludes degenerative joint disease ("osteoarthritis") and infrequent spells of gout.

k) **IDDM**

(Diabetes Mellitus, Type I). Insulin dependent.

l) **NIDDM**

(Diabetes Mellitus, Type II). Non-insulin dependent. Must be treated with oral drug therapy; Glyburide (Micronase, Diabeta), Glipizide (Glucotrol), Dymelor, Chlorpropamide (Diabinese). Excludes patients with diet only treatment.

m) **Peripheral Vascular Disease (PVD) (arterial, venous)**

History of peripheral vascular reconstruction; symptoms suggestive of significant peripheral vascular problems;

physical examination suggestive of potential for wound healing problems.

**n) Sciatica or chronic back problem**

Self-reported mild radicular symptoms without functional alteration; self-reported severe symptoms without functional alteration; some functional alteration due to symptoms (work, ADL).

**o) Neuromuscular disease (i.e. peripheral neuropathy, myasthenia gravis)**

Dizziness, numbness, seizures by history (controlled), syncope by history; ataxia, partial paralysis, seizures (uncontrolled), bedridden.

**p) Cognitive Impairment (i.e. dementia, post-traumatic brain dysfunction)**

Self-care (ADL) requiring supervision.

**q) Hearing Impairment**

Hearing problem not corrected by hearing aid; hearing limited to one ear; hard of hearing; deaf

**r) Mental Illness**

Self-care requiring supervision.

**s) Substance Abuse (including ETOH)**

Confirmed through medical chart notes; “heavy drinker”, previous history of alcoholism treatment program, previous history of withdrawal, or “averages 4 or more drinks per day”; inappropriate use of prescription drugs, use of street drugs.

**t) Malignancies (excluding basal cell carcinomas of the skin)**

(History of cancer). Excludes non-metastatic skin cancer.

**u) Leg ulcers**

History of leg ulcers requiring surgical treatment; current active leg ulcers with potential to impair healing.

**v) Bleeding Disorders**

Use of chronic anticoagulant therapy; previous diagnosis of clotting disorder which would require prophylaxis at time of surgery or interfere with surgical treatment.

**APPENDIX II**  
IMPLANT CODE KEY

Total Knee Replacement Implant Device Codes

Three digit code to be used on Form 16.4a item #8 and Form 16.4b item #5

**Zimmer**

- *Install/Burnstein*
  - Metal back (titanium) Tibia **(111)**
  - Metal back (cobalt-chromium) Tibia **(112)**
  - Box Femur Design and All Poly Tibia **(113)**
  - Box Femur/Peg Tibia Design and Titanium Alloy Tibia **(114)**
  - Constrained condylar/Posterior stabilized; Intramedullary stem Tibia/Femur **(115)**
  - Total condylar/Posterior stabilized, Lipped Tibia; Intramedullary stem Tibia **(116)**
  - Constrained-condylar, Lipped Tibia **(117)**
- *Miller Gallente II*
  - Total condylar/PCL preserving and Flat Tibia **(120)**
  - Lipped Tibia Type **(121)**
- *Duracon* **(130)**
- *CCK* **(140)**

**Howmedica**

- *Duracon*
  - Flat and Lipped Tibia and Intramedullary stem Tibia **(230)**
  - Posterior stabilized type and Fin Tibia design **(231)**
  - Constrained condylar type and Fin Tibia design **(232)**

**J&J**

- Metal back (cobalt-chromium) Tibia **(360)**
- *PFC* Cobalt chromium Tibia **(370)**

**Osteonics**

- *SCR*
  - Unilateral design **(480)**
  - Unimedial design **(481)**
- *Deltafit All Poly*
  - Lipped Tibia and Cemented Tibia, Patella, and Femur **(590)**
  - Lipped Tibia and Cemented Tibia and Patella and Cementless Femur **(591)**
- *Deltafit*
  - Lipped Tibia and Cemented Tibia, Patella, and Femur **(500)**
  - Flat Tibia and Cemented Tibia, Patella, and Femur **(501)**
  - Flat Tibia and Cemented Tibia and Patella and Cementless Femur **(502)**
  - Lipped Tibia and Cemented Tibia and Patella and Cementless Femur **(503)**

**Depuy**

- *AMK*
  - PCL preserving type with pre-coating **(601)**
  - Total Condylar and PCL preservingtype and Cementless Femur **(602)**
  - Total Condylar and PCL; Cementless Femur, Tibia and Cemented Patella **(603)**
  - Total Condylar and PCL type; Cemented Tibia, Femur, and Patella **(604)**
  - Total Condylar/PCL/Posterior Stabilized; Cementless Femur and Tibia **(605)**
  - Total Condylar/PCL/Posterior Stabilized; Cemented Femur, Tibia, Patella **(606)**
- *Universal* **(613)**

**Kirschner**

- *TC IV* **(701)**
  - Richards **(801)**
  - Dow Corning **(901)**
  - Other **(000)** If this code is entered the physician must complete form 16.4c.