SUMMARY REPORT

ICD-9-CM Coordination and Maintenance Committee
Volume 3, Procedures
December 4, 1997

Patricia E. Brooks, Co-Chairperson
Centers for Medicare and Medicaid Services

INTRODUCTIONS AND ANNOUNCEMENTS

The members of the Committee and the participants introduced themselves. It was stated that the purpose of the Committee is to provide a public forum to discuss proposed changes to the ICD-9-CM coding system. The first day of the meeting, December 4, 1997, was conducted by the Centers for Medicare and Medicaid Services (CMS) which is responsible for procedures. The second day, December 5, 1997, was conducted by the National Center for Health Statistics (NCHS) which is responsible for diagnoses. NCHS prepares a separate summary of the meeting along with handouts on diagnoses issues.

TIME FRAMES FOR CODING REVISIONS

It was explained that revisions to ICD-9-CM are made once a year, effective October 1 of each year. Major changes in those time frames were announced in the Prospective Payment System, Final Notice, published August 29, 1997. (Volume 62, Number 168, page 45970). Beginning with the FY 1999 update, the hospital prospective payment updates must be published as a proposed rule by April 1 and as a final rule by August 1 of each year. Therefore decisions on final ICD-9-CM code revisions must be made one month earlier this year. This allows for very little time after the December 1997 meeting for comments. Participants were urged to send any written or electronic comments as soon as possible and by at least early January. Any complicated suggestions that cannot be easily resolved will therefore be carried over for the FY 2000 updates.

November 1997: Meeting notice and agenda for the December ICD-9-CM Coordination and Maintenance (C&M) Committee Meeting posted on the CMS Home Page under Public Affairs/What's New.

December 1997: Last ICD-9-CM C&M Committee Meeting at which proposed code revisions can be considered for the next Addendum. This proposed Addendum will be effective October 1998.

Dec/January: Electronic versions of the December ICD-9-CM C&M Committee Meeting Summary Report will be available on the CMS Home Page under Public Affairs/What's New.

January 5, 1998: Deadline for receipt of final public comments on proposed code revisions. Clinical specialists are consulted to ensure that proposed code revisions are clinically correct.

January 12, 1998: Formulation of final code revisions and the initiation of the final clearance process begins within CMS.

April 1998: Final code revisions are published in the **Federal Register** as part of the Prospective Payment System proposed notice, mandated by Public Law 99-509.

April 3, 1998: Those members of the public requesting that topics be discussed at the June meeting should have their requests in to CMS for procedures and NCHS for diagnoses.

May 1998: ICD-9-CM Coordination and Maintenance Committee meeting announcement posted on the CMS Home Page under Public Affairs/ What's New.

June 4-5, 1998: ICD-9-CM Coordination and Maintenance Committee meeting. First meeting where code revisions are considered for finalization in October 1999.

June/July, 1998: Electronic versions of the June ICD-9-CM C&M Committee Meeting Summary Report will be available on the CMS Home Page under Public Affairs/What's New.

Summer 1998: ICD-9-CM Volume 3 Addendum are published on CMS's Home Page and provided to the American Hospital Association for publication in **Coding Clinic for ICD-9-CM**.

August 1, 1998: Final notice for Prospective Payment System published.

September 1998: Complete, updated ICD-9-CM is available on CD ROM through the Government Printing Office at (202) 512-1800.

November 1998: ICD-9-CM Coordination and Maintenance Committee meeting. Last meeting to discuss proposed code revisions for October 1999.

OCTOBER 1, 1998 PROPOSALS

Topics discussed at the June 5 and December 4-5,1997 meetings are under consideration for implementation October 1, 1998. The participants were urged to offer their suggestions both at the meeting and later in writing. All comments must be received by January 5, 1998 to be considered.

OCTOBER 1, 1998 ADDENDUM

CMS will place the October 1, 1998 procedure addendum on its Home Page. Addendum for Volume 3, ICD-9-CM, Procedures, which was implemented October 1, 1997 is now available on CMS's Home Page under Stat and Data, Public Use Files. This can be accessed at:

http://cms.hhs.gov

NCHS will place their October 1, 1998 diagnosis addendum on their Home Page as follows:

http://www.cdc.gov/nchswww/about/otheract/icd9/icd9hp2.htm

A copy of the complete addendum for both procedures and diagnoses will be given to the American Hospital Association to be published in **Coding Clinic for ICD-9-CM**.

ELECTRONIC VERSIONS OF ICD-9-CM, VOLUME 3

The complete electronic version of ICD-9-CM is available on a CD ROM from the Government Printing Office. The version includes all three volumes of ICD-9-CM as well as the official coding guidelines. This can be ordered as follows:

Government Printing Office
(202) 512-1800
Order # 017-022-01392-4, $18 (October 1997 version, FY-1998)

AGENDA
ICD-9-CM COORDINATION AND MAINTENANCE COMMITTEE
Department of Health and Human Services
CMS Auditorium
7500 Security Boulevard
Baltimore, MD
ICD-9-CM Volume 3, Procedures
December 4, 1997

Patricia E. Brooks
Co-Chairperson

9:00 a.m. - 4:00 p.m.
ICD-9-CM Volume 3, Procedure presentations and public comments

Topics

1. **Update on the ICD-10 Procedure Coding System**
   Pat Brooks
   Robert Mullin, MD - 3M HIS

2. **Platelet Inhibitors**
   Ann B. Fagan
   Michael Linkoff, MD -Cleveland Clinic

3. **Injection or Infusion of Thrombolytic Agent**
   Ann B. Fagan
   Ted Love, MD - Consultant, Mass. General, Attending VA Med. Ctr., UCSF
   Nancy Ashley, RN - Regional Clinical Coord., Great Lakes Region

4. **Stereotactic Radiosurgery**
   Amy L. Gruber
   Rebecca L. Emerick, MS,MBA,CPA - International Radiosurgery Support Association
   Tomasz Helenowski, MD - Chicago Institute of Neurosurgery and Neuroresearch

5. **Artificial Skin Grafts**
   Amy L. Gruber
   Robert W. Gillespie, MD
   Arnold Luterman, MD - American Burn Association

6. **Cardiomyostimulator**
   Ann B. Fagan
   Michael A. Acker, MD - Hospital of the University of Pennsylvania

7. **Amnioinfusion**
   Amy L. Gruber

8. **Percutaneous Vascular Puncture Closure**
   Ann B. Fagan
   Mitchell Krucoff,MD,FACC,FCCP - Duke University Medical Center
   Suzanne W. Crater, CCRN,MSN - Duke University Medical Center

9. **Addenda**
   Amy L. Gruber

Summary of Meeting:

A complete report of the procedure portion of the meeting held December 4, 1997, including handouts, will be available on CMS's Home Page within one month of the meeting. Written summaries will no longer be routinely mailed. The summary can be accessed under Public Affairs/ What's New on CMS's Home Page at:

http://cms.hhs.gov/

Copies of the diagnosis portion of the meeting held on December 5, 1997 will be available on the National Center for Health Statistic's (NCHS) Home Page at:

http://www.cdc.gov/nchswww/about/otheract/icd9/icd9hp2.htm

1. Update on the ICD-10 Procedure Coding System

Pat Brooks provided an overview of the contract to develop ICD-10-PCS and on the testing phase. Robert Mullin, MD reported on the design of the new system. ICD-10-PCS is a procedure coding system being developed by CMS under a contract with 3M/HIS as a replacement for Volume 3 of ICD-9-CM. CMS is in the third and final year of this project which is briefly described below.

Year 1: Complete first draft of system

Year 2: External review and limited testing

Copies of system supplied to physician specialty groups
Development of training manual
Training at American Health Information Management Association (AHIMA) annual meeting
Informal testing

Year 3: Formal independent review and testing

Review comments from specialty groups
Independent testing
Final version produced

TESTING OF ICD-10-PCS- PROJECT OVERVIEW

INDEPENDENT REVIEWERS

CMS is using the Clinical Data Abstraction Centers (CDACs), two of its contractors, to perform the independent review. CMS awarded two CDAC contracts on August 26, 1994 to DynKePRO in York, PA and FMAS in Columbia, MD. A brief overview of the CDACs is as follows:

CDACs Primary Task: The CDACs primary task is to collect clinical data from about 1.5 million medical records over 5 years. They request medical records, track the records, abstract clinical data, and forward the clinical data to CMS for dissemination to the PROs. The primary end product of the CDAC contracts is accurate and reliable clinical data in sufficient quantities to support the analytical efforts of the PROs as they carry out the Health Care Quality Improvement Program (HCQIP). The CDACs also perform special studies such as the testing of ICD-10-PCS.

CDAC Contracts: The CDAC contracts are 5-year contracts consisting of a 2-year base period and three 1-year options. The contracts are currently in the first option year which ends on August 31,1997. The contracts are scheduled to continue through August 31, 1999. A determination will be made for each of the option years on whether or not to continue the contracts.

TIME LINE:

May - June 1997 Training of independent reviewers (CDACs)

July - December 1997 Testing

- A formal independent test of the suitability of ICD-10-PCS as a replacement for ICD-9-CM Volume 3, procedures will be conducted. A sample of 5,000 medical records will be included from records obtained by the two Clinical Data Abstraction Centers (CDACs). The sample will include only medical records containing at least one operating room procedure. The medical records will then be coded using ICD-10-PCS. The contractor will keep detailed notes of any difficulties or omissions found in either the tabular or the index section of the new system. Terms needing additional clarification would be noted. Procedures for which no code could be found would be identified. Abstraction sheets will be completed on each record coded and these sheets will be sent to 3M/HSI for review and update to the system.

- In December a subset of 100 medical records will be recoded blindly by the CDACs using ICD-9-CM and ICD-10-PCS. At this point CDACs coders should be experienced in using ICD-10-PCS. The two systems will be compared with information gathered on ease of use, time to identify codes, error rates, problems, and any other issues identified.

February 1998

- The CDACs will submit a draft report of their findings.

March 1998

- The CDACs will submit a final report of their findings.
- 3M/HIS will issue a final draft of ICD-10-PCS including revisions made as a result of testing and clinical comments made from physician specialty groups.

ANALYSIS AND TESTING BY OTHERS

CMS encourages other groups to test the system and send in their analysis. Copies of the 1997 draft have been provided to those on the Technical Advisory Panel which includes representatives from the American Health Information Management Association, American Hospital Association, and the American Medical Association as well as others.

COPIES OF ICD-10-PCS

Copies of ICD-10-PCS including a paper describing how it was developed and a training guide are available on CMS's Home Page under Stats and Data, Public Use Files.

Copies may also be ordered from 3M/HIS as follows:

Terry Dogali
3M Health Information Systems
100 Barnes Road
Wallingford, CT 06492
Phone (203) 949-0303
Fax (203) 949-6331

Diskette version : $40
Paper Version of Volume I and II: $100
Training manual: $20

2. Platelet Inhibitors

Michael Linkoff, MD provided a clinical overview of platelet inhibitors. Ann Fagan then led a discussion of the proposed code. There was support for the creation of the new code.

3. Injection or Infusion of Thrombolytic Agent

Ted Love, MD and Nancy Ashley, RN provided a clinical overview of thrombolytic agents and the patients who use them. Ann Fagan described the proposed new code. There was support for the new code. One participant suggested that the term "platelet inhibitor" should be removed from code 36.04, Intracoronary artery thrombolytic infusion, since this is not how platelet inhibitors are administered. It was also suggested that an excludes note be added to 36.04 to exclude injections and refer the coder to proposed new codes 99.10, Injection or infusion of thrombolytic agent, or 99.20, Injection or infusion of platelet inhibitor. Others felt that it was more appropriate to place an excludes note under proposed new code 99.10.

4. Stereotactic Radiosurgery

Rebecca Emerick, MS, MBA, CPA and Tomasz Helenowski, MD provided a clinical overview on the various types of technologies utilized in performing stereotactic radiosurgery. Amy Gruber described the proposal to subdivide code 92.3, Stereotactic radiosurgery. There was a great deal of discussion on this topic. Some felt that it was inappropriate to subdivide the code and identify the type of equipment since they felt the machines all gave similar results with physicians of equal skill. They felt that there was no purpose in having data of this nature. There was some concern expressed about how such data might be used. Others felt the opposite. They felt that having this type of data would provide the ability to study outcomes. It was pointed out that published articles on this topic may well be severely criticized for not have precise data on the types of modality used. Some felt that the data might show that some types of cases are better served by one specific type of equipment. Others felt this would not be the case. One participant urged CMS to provide detail within codes whenever the system allowed. It was felt that it was better to describe what was done to the patient in as much detail as possible.

There was much discussion on fractionated radiosurgery. One participant felt that fractionated radiosurgery should be identified as fractionated radiotherapy since it does not meet the definition of radiosurgery in which a single high dose of radiation is delivered. Another participant identified fractionated radiosurgery being performed with multi-source photon as well as particulate and should be listed as inclusion terms under proposed codes 92.32, Multi-source photon radiosurgery and 92.33, Particulate radiosurgery.

One participant asked if the coder would be able to identify the type of equipment from the documentation in the record. A physician and hospital administrator both stated that this information was clearly documented in the medical record. In addition to the proposed codes, it was recommended that a new code, 92.39, Stereotactic radiosurgery, not elsewhere classified, be created to capture those cases where the technology is not identified in an existing code.

5. Artificial Skin Grafts

Although the American Burn Association had submitted a request for two new codes prior to the meeting, they presented a new proposal during the meeting which is as follows:

86.94 Application of prosthetic implant to regenerate the dermal layer of the skin

Includes:

- Artificial skin, NOS
- Integumentary matrix implants
- Decellularized allodermis
- Creation of "Neodermis"

Excludes:

- Procedures classifiable to category 86.6
- Temporary skin closures
- Cultured allogeneic cells or tissue

There was support for this new procedure code which is a permanent prosthetic implant that is not excised from the wound bed. The American Burn Association and other participants agreed that there was not a need for a new code that was previously recommended for the application of a prosthetic implant for permanent replacement of the epidermis by cultured autologous tissue which can continue to be captured under category 86.6, Free shin graft.

6. Cardiomyostimulator

Michael Acker, MD provided a clinical overview of the use of the cardiomyostimulator and Ann Fagan described the code proposal. It was agreed that this technology belongs in the area of biological assist systems. It was suggested that the note be changed from Two- stage open procedure to Two-step open procedure. It was also recommended that when one changes the batteries for these implanted cardiac devices, this step is quite similar. Code 37.63, Replacement and repair of heart assist system, should be changed/modified to make it more generic.

7. Amnioinfusion

Amy Gruber presented this topic for discussion. The American College of Obstetrics and Gynecologists (ACOG) was consulted on this topic and concurred with CMS's recommendation to create a new code to capture amnioinfusion. There was support from the participants to create a new code.

8. Percutaneous Vascular Puncture Closure

The clinical portion of this presentation was provided by Mitchell Krucoff, MD, with support from Suzanne Crater, CCRN, MSN. Ann Fagan presented the coding portion of the topic. CMS's recommendation was that no new code be created, as closure of a blood vessel can be considered inherent to the procedure. Dr. Krucoff presented educational information pointing out that vessel closure devices shortened the length

of time the patient was uncomfortable, and that tracking of such devices would be beneficial for patient outcome studies. Some commenters responded that there would be value to being able to identify procedures in which this type of device was used. Additional comments were sought from the audience on a write-in basis.

9. Addenda

Amy Gruber described the proposals to the addenda. It was suggested that instead of deleting the index entry under:

Resection
ventricle (heart) (left) 35.34

the modification should be:

Resection
ventricle 37.35
infundibula 35.34

PLATELET INHIBITORS

Issue:

Effective October 1, 1986, CMS created a code intended to describe the infusion of platelet inhibitors: 36.04, Intracoronary artery thrombolytic infusion. In retrospect, it turned out that this code did not meet industry needs with respect to approach. Therefore, we are re-addressing this topic in order to create a code which will better meet statistical gathering requirements. Additional background can be found in the **Federal Register**, August 29, 1997, page 45975, subsection II.B.3.c.

Background:

Degenerative atherosclerosis, the narrowing of arteries due to plaque formation over time, results in clinical conditions characterized by partial vascular occlusion and ischemia (e.g. stroke, peripheral vascular disease, and coronary artery disease). Advanced coronary artery disease deprives the heart muscle of blood and oxygen, affects more than 6 million Americans and accounts for approximately 500,000 deaths annually. Patients suffering from acute artery disease are responsible for over 2 million U.S. hospital discharges each year. These acute ischemic coronary syndromes (AICS) represent a spectrum of medical conditions, including acute myocardial infarction (AMI) and unstable angina (UA).

When blood supply becomes severely interrupted by the presence of a thrombus, a vascular occlusion comprised primarily of aggregated platelets stabilized by the protein fibrin, an AMI may result causing irreversible injury and death of heart tissue. Intermediate between stable coronary artery disease and AMI is UA, which presents in the form of chest pain at rest and is caused by plaque rupture. Goals in the management of AICS include: (1) the stabilization of an evolving coronary occlusion, (2) restoration of coronary blood flow, (3) alleviation of chest pain symptoms, and (4) prevention of AMI and sudden death.

The treatment of coronary artery disease historically has involved modestly effective pharmaceutical therapies (i.e., oral aspirin and intravenous dosing of heparin). However, over the last 25 years, more aggressive revascularization or reperfusion techniques, including coronary artery bypass grafting (CABG), percutaneous transluminal coronary angioplasty (PTCA), and thrombolysis have been embraced. Despite the introduction of these surgical and interventional techniques, patients suffering from AICS still confront a death and AMI rate of 10-15 percent caused largely by persistent coronary thrombus and myocardial ischemia.

Research on the pathophysiology of AICS has revealed that platelet aggregation plays a pivotal role in the development of these syndromes. Platelets, which control bleeding and regulate hemostasis, normally circulate in an inactivated state but transform to an activated state in the presence of plaque rupture or mechanical injury. Upon vascular injury, proteins in the blood and vessel wall are exposed, causing platelets to adhere to the wall of the damaged blood vessel. Platelets then become activated, which is followed by platelet aggregation, a process which proceeds uncontrolled in a population of patients. This results in vascular occlusion (clot, thrombus), and which is mediated by the recently discovered cell surface receptor known as glycoprotein (GP) IIb/IIIa. Recognizing the primary role of platelet aggregation in AICS, newer pharmaceutical approaches to improving outcomes in AICS patients have focused on more potently preventing the aggregation of platelets to prevent arterial thrombus formation and subsequent occlusion.

Each platelet contains about 100,000 copies of cell surface receptor GP IIb/IIIa. The final common pathway to platelet aggregation involves expression of GP IIb/IIIa on the platelet, which then facilitates cross-linking of platelets by binding fibrinogen (a fibrin precursor). The event multiplied many times over results in thrombus formation.

Antagonists directed at the platelet receptor GP IIb/IIIa provide the most complete inhibition of platelet aggregation and arterial thrombus formation in the treatment of AICS known to date. The use of GP IIb/IIIa inhibitors offers significant hope in the treatment of these life-threatening events. Clinical trials conducted to date in over 30,000 patients have demonstrated that adding this novel class of therapeutics to current treatments will yield more effective total patient care and reduced event rates during the hospitalization period, an absolute benefit that is sustainable over a long term.

This class of inhibitor drugs is currently being studied in stroke patients as well, and is expected to revolutionize the management of these patients.

Recommendation:

We recommend the creation of a new code describing this class of pharmaceuticals and specifying the method of administration.

99.2 Injection or infusion of other therapeutic or prophylactic substance includes injection or infusion given:

hypodermically
intramuscularly (acting locally or systemically)
intravenously

new code: 99.20 Injection or infusion of platelet inhibitor

Glycoprotein IIb/IIIa
GP IIb/IIIa
GP IIb-IIIa

We intend to add appropriate "code also" note(s) in other categories, such as 36.x, Operations on vessels of heart, and/or 37.x, Other operations on heart and pericardium.

INJECTION OR INFUSION OF THROMBOLYTIC AGENT

Issue:

Should a new code be created for injection or infusion of thrombolytic agent? This procedure is currently coded to 99.29, Injection or infusion of other therapeutic or prophylactic substance. However, 99.29 is a crowded code, containing injections of many substances. This makes tracking and outcome studies of a specific therapy difficult, if not impossible.

Background:

This topic was brought to the attention of the ICD-9-CM Coordination and Maintenance Committee through coding questions from the industry.

The discussion today will center on thrombolytic therapy for acute myocardial infarction (AMI) and intracranial stroke. Limiting the discussion to these two sites is

not meant to imply that these are the only sites in which thrombolytic therapy treatment is effective.

Myocardial Infarction

Cardiovascular diseases are responsible for over a million deaths a year in the United States. Myocardial infarction (MI) accounts for over half of this mortality. Many MI patients die before reaching the hospital. Before 1960, even those hospitalized experienced a 30% mortality rate. In the early 1970s, the in-hospital mortality rate decreased to 15% with the advent of cardiac arrhythmia monitoring, electrical defibrillation, and the presence of trained nurses in the specialized coronary care units (CCUs).

Today, the in-hospital mortality rate for many acute MI patients has further declined to 5%. This dramatic reduction in mortality is primarily the result of aggressive treatment of the acute MI patient with thrombolytic agents. A brief review of coronary anatomy, the pathogenesis of acute MI, and the action of thrombolytic agents will aid in understanding how thrombolytic therapy has decreased the mortality associated with acute MI.

Blood is supplied to myocardial tissue by the left coronary and the right coronary artery, both of which originate at the aorta. The left coronary artery divides into two branches; its left anterior descending (LAD) branch supplies blood to the anterior surface of the heart, while the circumflex branch supplies blood to the lateral aspects of the left ventricle. The right coronary artery (RCA) supplies blood to the right ventricle, to the posterior wall of both ventricles, and to the branches that feed the sinoatrial and atrioventricular nodes of the cardiac electrical conduction system.

Myocardial tissue that has an adequate blood supply appears pink and healthy. However, blood flow can be diminished or interrupted by the buildup of arteriosclerotic plaque within the lumen of a coronary artery. The usual result of a sudden rupture of an arteriosclerotic lesion, which leads to the production of a blood clot within the lumen, is complete occlusion of the coronary artery.

An acute coronary thrombus causes the myocardial tissue distal to the occlusion to lose its blood and oxygen supply. The affected area becomes ischemic, but the ischemic tissue remains viable. If the occlusion persists and blood flow is not reestablished, the ischemic tissue gradually becomes necrotic. In about 6 hours, generally, all of the myocardial tissue supplied by the affected coronary artery will be necrotic. The necrotic tissue cannot be restored. Some other conditions however (e.g., collateral circulation or "stuttering infarct"), may maintain tissue perfusion and delay necrosis for longer than 6 hours.

The goal of therapy for the acute MI patient is to rapidly reestablish the blood supply (reperfusion) to the affected myocardial tissue and prevent the progression to necrosis. Timely reperfusion results in preventing or decreasing the area of necrosis. For most acute MI patients, the fastest way to reperfuse the myocardial tissue is to dissolve the coronary artery thrombus with a thrombolytic agent.

Thrombolytic treatment will dissolve the obstructive clot within the lumen of the affected coronary artery. Coronary artery clot formation is usually precipitated by a rupture in the arteriosclerotic lesion, which exposes collagen to the blood stream. Collagen exposure results in platelet aggregation and adhesion, stimulation of the clotting cascade, and eventual formation of the insoluble fibrin clot. Thrombolytic agents stimulate dissolution of the insoluble fibrin strands that form the backbone of the clot. When the thrombolytic agent comes into contact with fibrin, it becomes active and converts clot-bound plasminogen to clot-bound plasmin. The plasmin then breaks down the insoluble fibrin strands, and the clot is dissolved.

Stroke

The use of intra-arterial and intravenous thrombolytic agents has been evaluated in stroke patients in several clinical trials. Recently the Food and Drug Administration (FDA) approved intravenous thrombolytic agents for use in selected patients with ischemic stroke based on the positive results of an NINDS (National Institute of Neurological Disorders and Stroke study) trial. Before the recent NINDS trial, multiple trials of intravenous thrombolytics failed to show a net benefit and found an excess early mortality from brain hemorrhage.

In the NINDS trial, patients treated with intravenous thrombolytic agents within 3 hours of onset of symptoms were at least 30% more likely to have minimal or no disability at 3 months compared with those treated with placebo. However, there were 10-fold increases in the risk of fatal intracranial hemorrhage in the treated group (3% vs 0.3%) and the frequency of all symptomatic hemorrhage (6.4% vs 0.6%) As opposed to the case in other studies, this increase in symptomatic hemorrhage did not lead to an overall increase in mortality in the treated group.

Because of the strict time criteria and significant risk associated with thrombolytic therapy, it is important for hospitals to develop stroke plans with specific strategies and protocols that will achieve rapid initiation of therapy. These protocols require input from a multidisciplinary team of emergency physicians, neurologists, neurosurgeons, internists, nurses, pharmacists, and pre-hospital personnel. The thrombolytic protocol should address the following issues:

- Identification of patients with stroke in the prehospital setting,
- Assurance of prearrival hospital notification,
- Development and maintenance of rapid triage and medical evaluation in the ED,
- Development of a mechanism for rapidly obtaining a noncontrast head CT,
- Identification of who will read the CT,
- Determination of contraindications to thrombolytic therapy,
- Location of thrombolytic drugs and determination of how they will be mixed,
- Designation of who will administer drugs,
- Consultation for atypical cases or hemorrhagic complications, and
- Determination of where (hospital and service) the patient will be admitted.

The NINDS trial was unique in a number of ways that may be important in extrapolating the use of platelet inhibitors in the community. *Careful patient*

selection and strict adherence to the treatment protocol are essential. Thrombolytic therapy is not recommended unless the diagnosis of acute ischemic stroke is established by a physician experienced in diagnosing stroke and unless the CT scan of the brain is assessed by physicians capable of evaluating such images.

The current AHA recommendations for management of acute stroke are:

- Give thrombolytic drugs intravenously with 10% of the dose given as a bolus followed by an infusion lasting 60 minutes.
- Treatment must be initiated within 3 hours of the onset of ischemic symptoms.
- Thrombolytic agents *cannot* be recommended for a person who has had a stroke more than 3 hours earlier, except in an investigational setting.
- Intravenous thrombolytic agents are not recommended when the time of stroke onset cannot be ascertained reliably, including strokes recognized on awakening.

The use of thrombolytic agents carries the real risk of major bleeding. Whenever possible, the risks and potential benefits of thrombolytic therapy should be discussed with the patient and the patient's family before treatment is initiated. The use of thrombolytics in children requires further study. The risk of bleeding in neonates may be particularly high because plasminogen concentrations are often low and homeostatic and fibrinolytic mechanisms are not fully developed. Neonates and infants should be treated only in exceptional circumstances.

Thrombolytic therapy should not be given unless emergency ancillary care and the facilities for handling bleeding complications are available. Patients treated with thrombolytics should be admitted to a skilled care facility (intensive care or stroke unit) that permits close observation, frequent neurological assessments, and cardiovascular monitoring. Careful management of blood pressure is critical. Excessive blood pressure may predispose the patient to bleeding, whereas excessive lowering of blood pressure may worsen ischemic symptoms.

Recommendation:

Establish a code which more accurately defines thrombolytic therapy. Prior to acceptance of any new code, continue to assign this therapy to 99.29, Injection or infusion of other therapeutic or prophylactic substance.

99.1 Injection or infusion of therapeutic or prophylactic substance

new code: 99.10 Injection or infusion of thrombolytic agent
Streptokinase
TPA
Urokinease

Excludes:

- aspirin
- GP IIb/IIIa platelet inhibitors (99.20)
- heparin
- warfarin

STEREOTACTIC RADIOSURGERY

Issue:

Effective October 1, 1995, ICD-9-CM procedure code 92.3 was created to capture stereotactic radiosurgery. There are several approaches (technologies), such as cobalt 60 and linear accelerator, utilized to perform radiosurgery. Should separate codes be created to distinguish between the approaches?

Background:

Radiosurgery refers to the noninvasive destruction of a discrete target area in the brain using the precise delivery of a single high dose of radiation. This procedure has been developed for treatment of brain and skull lesions. The source of the radiation is one of the key differences between these instruments. There are three technologies of radiosurgery based on their source of radiation: single photon source (linear accelerator), multi-source (cobalt 60), and a high energy particulate (particle beam).

The linear accelerator (LINAC), a single source generator commonly used for conventional radiation treatment, is utilized for neurological treatments by the use of a dedicated instrument or with an adapted instrument. To decrease the damage to healthy tissue from the large beam, the linac targets the abnormality from different directions with a moving gantry. The linac produces radiation by using microwave energy to accelerate electrons. The high energy electrons collide with a heavy metal, producing a type of photon radiation called x-rays. The linac can be targeted to within 0.3mm of a vital structure or nerve.

The multi-source photon technology (cobalt 60) naturally emits gamma ray photons from a fixed array of small cobalt 60 sources located within a large hemisphere that surrounds the patient's head. Cobalt 60 can target to within 0.1 mm of a vital structure or nerve. This technology utilizes targeting multiple centers and selective beam blocking to optimally match the shape and volume of the tumor or lesion. This allows for maximum radiation dosing to the entire area being treated.

Particle beam (cyclotron) radiosurgery has special physical properties that produces a completely different type of radiation. With the use of accelerated charged particles, including protons and helium ions, a high dose of radiation can be applied

within the boundaries of a deeply located intracranial lesion. These properties include a well defined range that can be modulated so that the beams stops at the distal edge of the lesion resulting in little or no exit dose, an initial region of low dose as the beam penetrates through tissue followed by a region of high dose at the end of the range of the beam, and sharp lateral edges that can be shaped to conform to the projected of the lesion. There are only three units in the United States being utilized.

Options:

1. Continue to code this procedure to 92.3, Stereotactic radiosurgery.
2. Create four new codes to capture this technology.

   New category 92.3 Stereotactic radiosurgery
   Add inclusion term Radiosurgery targeted to head only
   Add exclusion term Excludes: stereotactic biopsy - see Biopsy

   New code: 92.30 Stereotactic radiosurgery, not otherwise specified
   New code: 92.31 Single source photon radiosurgery
   - Fractionated radiosurgery
   - High energy x-rays
   - Linear accelerator (LINAC)

   New code: 92.32 Multi-source photon radiosurgery

   - Cobalt 60 radiation
   - Gamma irradiation

   New code: 92.33 Particulate radiosurgery

   - Particle beam radiation (cyclotron)
   - Proton accelerator

Recommendation:

Create four new codes to capture this technology.

- New category: 92.3 Stereotactic radiosurgery
  Add inclusion term --- Radiosurgery targeted to head only
  Add exclusion term --- Excludes: stereotactic biopsy - see Biopsy

  New code: 92.30 Stereotactic radiosurgery, not otherwise specified
  New code: 92.31 Single source photon radiosurgery
  - Fractionated radiosurgery
  - High energy x-rays

- Linear accelerator (LINAC)

New code: 92.32 Multi-source photon radiosurgery

- Cobalt 60 radiation
- Gamma irradiation

New code: 92.33 Particulate radiosurgery

- Particle beam radiation (cyclotron)
- Proton accelerator

ARTIFICIAL SKIN GRAFTS

Issue:

How do you code replacement of the skin (dermis and epidermis) by cultured or regenerated autologous tissue? Do the current codes for skin grafts appropriately capture these applications or should new codes be implemented?

Background:

There are several types of biologic skin replacement systems. One such system is indicated for the postexcisional treatment of life-threatening full-thickness or deep partial-thickness thermal injury where sufficient autograft is not available at the time of excision or not desirable due to the physiological condition of the patient. It is contraindicated in the presence of wound infection.

The objective of the system is to regenerate or replace injured human tissue with new functional tissue. It is a dermal bilayer membrane system made up of a three-dimensional porous matrix of fibers of cross-linked bovine tendon collagen and a glycosaminoglycan (chondroitin-6-sulfate) that is manufactured with a controlled porosity and defined degradation rate. The temporary epidermal substitute layer is made of synthetic polysiloxane polymer (silicone) and functions to control moisture loss from the wound.

The collagen dermal replacement layer serves as a matrix for the infiltration of fibroblasts, macrophages, lymphocytes, and capillaries derived from the wound bed. As healing progresses an endogenous collagen matrix is deposited by fibroblasts; simultaneously, the dermal layer is degraded. Upon adequate vascularization of the dermal layer and availability of donor autograft tissue, the temporary silicone layer is removed and a thin, meshed layer of epidermal autograft is placed over the

"neodermis". Cells from the epidermal autograft grow and form a confluent stratum corneum, thereby closing the wound and reconstituting a functional dermis and epidermis.

Another type of biologic skin replacement system is the cultured epidermal autograft (CEA). This is an autologous skin graft for the replacement of the epidermis in patients with deep-dermal or full thickness wounds requiring skin grafting. Autologous keratinocytes are processed to isolate and propagate specific cell types for transplantation. The graft, which is generated from a biopsy of the patient's own skin, provides permanent replacement of the epidermal layer.

Two full thickness (approximately 2 cm x 6 cm) biopsies are obtained from different unaffected sites such as axilla, groin, and abdomen. Expansion of the epidermal cells to provide CEA normally takes 3 to 4 weeks. Early excision (within the first two weeks of the burn) with temporary covering of homograft has been consistently most successful in providing a suitable wound bed for grafting of CEA.

Application of CEA to the wound bed facilitates the process of attachment, replication, and differentiation resulting in a permanent epidermis.

Options:

1. Continue to code these procedures to skin graft codes. The dermal bilayer membrane system should be coded to 86.65, Heterograft to skin. Code 86.66, Homograft to skin, should be assigned to the cultured epidermal autograft.
2. Proposal from the American Burn Association:
   New code: 86.94 Application of prosthetic implant for permanent replacement of the dermis by cultured or regenerated autologous tissue
   - Artificial skin, NOS
   - Creation of neodermis
   - Decellularized allodermis
   - Integumentary matrix implants

   Excludes:

   - Cultured allogeneic cells or tissue
   - Procedures classifiable to category 86.6
   - Temporary skin closures

   New code: 86.95 Application of prosthetic implant for permanent replacement of the epidermis by cultured autologous tissue

   - Cultured epithelial autograft

   Excludes:

- Cultured allogeneic cells or tissue
- Procedures classifiable to category 86.6
- Temporary skin closures or coverings

Recommendation:

Continue to code these procedures to skin graft codes. The dermal bilayer membrane system should be coded to 86.65, Heterograft to skin. Code 86.66, Homograft to skin, should be assigned to the cultured epidermal autograft.

CARDIOMYOSTIMULATOR
Dynamic Cardiomyoplasty

Issue:

There is no specific code for the surgical technique "dynamic cardiomyoplasty".

Background:

In the United States, approximately 4.7 million people have congestive heart failure (CHF) with an incidence of about 400,000 new cases each year. It is the single, most frequent cause of hospitalization in the U.S. For patients with end-stage heart failure who do not respond to standard medical therapy or revascularization, heart transplantation is the accepted therapy. However, donor shortages or other restrictions severely limit the number of patients who receive transplants to about 2,500 each year in the U.S. Implantable mechanical assist devices can play a major role in therapy, but problems exist with thromboembolism, infection, and the indications for use of the devices.

A surgical technique that has become an option for patients with CHF is dynamic cardiomyoplasty. This is an innovative therapy for heart failure patients that provides electrical stimulation to the patient's's own latissimus dorsi muscle, usually the left, which has been wrapped around the failing heart. The concept of using skeletal muscle for cardiac assistance has been researched for many years. However, it wasn't until the discovery that skeletal muscle fibers could be trained to act like cardiac muscle that dynamic cardiomyoplasty could truly evolve in the clinical arena. The first dynamic cardiomyoplasty procedure on a human patient was performed in 1985.

The operation consists of two major steps. The first step consists of dissecting the large latissimus dorsi muscle, taking care to preserve the neurovascular supply

based on the thoracodorsal artery, vein, and nerve. Transposition of this large, fan-shaped muscle into the chest cavity does not perceptibly impair arm movement or function. The distal blood supply from the intercostal vessels are sacrificed. Two special electrodes are then placed intramuscularly with the cathode lead most proximal at the trifurcation of the nerve supply and the anode lead placed parallel by 5 cm. distally. Stimulation thresholds are assessed using a pacing systems analyzer. An opening into the chest cavity is performed by resecting part of the second rib and introducing the entire muscle and the implanted intramuscular leads into the chest. The back incision is then closed.

In the second major step of the procedure, the patient is turned to a supine position, and a median sternotomy is performed. The pericardium is opened so that a flap based on the right side is preserved. The muscle is brought in over the apex of the lung and wrapped around the heart in a posterior approach, going toward the diaphragm and then covering the apex and anterior surface of the heart. Depending on the size of the dilated heart, the entire left ventricle and a variable portion of the right ventricle will be covered. The pericardium is used as a patch to complete the coverage of the right heart.

Two epicardial cardiac pacing leads are inserted into the right ventricle before the completion of the wrap. All leads are then tunneled to a pocket in the upper left quadrant of the abdomen where it is attached to the cardiomyostimulator. The mean skin-to-skin time is approximately six hours, with four hours for the first step, and two hours for the second step.

The intra-operative and post-operative care are critical because of the potential of cardiac failure, arrhythmias, and pulmonary problems. The success of this procedure depends on a multi-disciplinary approach to all facets of dealing with the patients. The stimulation protocol is started two weeks later with a single electrical impulse every other heartbeat. Every two weeks another impulse is added until a pulse train is administered that results in a wave summation and increased evoked skeletal muscle force. The efficacy of assistance is modulated by coordinating the timing of the stimulation of the skeletal muscle with the closure of the mitral valve by the use of echocardiography.

Discussion:

Many codes are required to identify this surgical procedure, and CMS has been encouraged to create one code which would represent all the steps inherent in the procedure. The recommendation is for creation of a new code at 37.67, Implant of cardiomyostimulation system. This code falls into category 37.6, Implantation of heart assist system.

ICD-9-CM procedure codes currently being used to describe the dynamic cardiomyoplasty procedure include:

- 37.4 Repair of heart and pericardium
- 37.74 Insertion or replacement of epicardial lead (electrode) into epicardium

- 37.83 Initial insertion of dual-chamber device
- 37.87 Replacement of any type pacemaker device with dual-chamber device
- 83.77 Muscle transfer or transplantation

Discussion of this issue with the American Hospital Association in March, 1997, led to CMS recommending the following four codes:

- 37.4 Repair of heart and pericardium
- 37.74 Insertion or replacement of epicardial lead (electrode) into epicardium
- 37.81 Initial insertion of single-chamber device, not specified as rate responsive
- 83.82 Graft of muscle or fascia

The above codes were seleced by a cardiothoracic surgeon after review of one operative report. It was his opinion, upon reading the report, that the device used in that procedure was single chambered.

Removal of rib bone(s) is considered inherent to the procedure, and would not be separately coded. Also, this procedure cannot be considered a revascularization, which attempts to get blood vessels to grow from the muscle into the heart. In this case, the muscle is used to help the heart contract.

Options:

1. Do not create a new code encompassing a multitude of procedures. Continue to code each patient according to their unique circumstances.
2. Create a new code which takes into account the parts of the procedure, grouping them into one code.

Recommendation:

Create a new code which will uniquely identify and track this type of procedure.

- 37.6 Implantation of heart assist system
  new code: 37.67 Implantation of cardiomyostimulation system

  Note: Two-stage open procedure consisting of transfer of one end of the latissimus dorsi muscle; wrapping it around the heart; rib resection; median sternotomy; opening of the pericardium; implantation of epicardial cardiac pacing leads into the right ventricle, tunneling and pocket creation for the cardiomyostimulator.

  Question: should an additional code be created for replacement of the cardiomyostimulator, or should 37.8x, Insertion, replacement, removal, and revision of pacemaker device, be utilized? This question assumes that the muscle transfer has remained viable.

AMNIOINFUSION

Issue:

Should a new code be created to capture amnioinfusion?

Background:

Amnioinfusion is the controlled intrauterine instillation of sterile normal saline or lactated Ringer's solution via transcervical or transabdominal. Amnioinfusion may be applied during intrapartum and at the time of labor. The most common application of amnioinfusion is in the treatment of variable decelerations in the fetal heart rate during labor. By artificially increasing the amniotic fluid volume, the umbilical cord is better protected from compression.

Indications for amnioinfusion during intrapartum and at time of labor include: preterm premature rupture of the membranes, oligohydramnios (deficiency in the amount of amniotic fluid), repetitive moderate to severe variable decelerations and to dilute thick meconium. Another use of amnioinfusion is in the instillation of antibiotics into an infected uterine cavity or the uterine cavity of a woman with preterm premature rupture of the membranes. Complications of amnioinfusion include umbilical cord prolapse, chorioamnionitis, uterine overdistention and fetal bradycardia. Some studies have suggested that the use of amnioinfusion is associated with lower cesarean delivery rates and decreased numbers of operative deliveries.

Options:

1. Create a new code to capture amnioinfusion performed during intrapartum as well as at delivery. Add code also instructions at the assisted delivery codes (categories 72, and 73) when the amnioinfusion is performed during labor. If an antibiotic amnioinfusion is performed, code 99.21, Injection of antibiotic, should also be assigned.

   New code: 75.37 Amnioinfusion

   Code also any injection of antibiotic (99.21)

2. Create two new codes to capture amnioinfusion and antibiotic amnioinfusion. Add code also instructions at the assisted delivery codes (categories 72, and 73) when the amnioinfusion is performed during labor.

   New code: 75.37 Amnioinfusion

   New code: 75.38 Antibiotic amnioinfusion

Recommendation:

Create a new code to capture amnioinfusion performed during intrapartum as well as at delivery. Add code also instructions at the assisted delivery codes (categories 72, and 73) for amnioinfusion performed during labor. If an antibiotic amnioinfusion is performed, code 99.21, Injection of antibiotic, should also be assigned.

New code: 75.37 Amnioinfusion

Code also any injection of antibiotic (99.21)

PERCUTANEOUS VASCULAR PUNCTURE CLOSURE

Issue:

There are no specific ICD-9-CM procedure codes describing hemostatic puncture closure procedures.

Background:

The most commonly used method to stop bleeding at the femoral arterial access site following angiography or an interventional procedure is manual or mechanical pressure, i.e., the application of weight by hand or a clamping device onto the artery. This method is slow and may be very uncomfortable. It also requires at least 15 minutes of compression, then four to eight hours of lying flat in bed without moving the affected leg. Many patients complain that this can be the most uncomfortable part of the entire procedure. In addition, hemostasis at the puncture site may be compromised due to the administration of anticoagulant medication (blood thinner) to prevent blood clots and stroke during the catheterization or interventional procedure. Use of this medication may require longer compression and recovery time.

There is a new device on the market which consists of an absorbable collagen/suture/anchor closure system. It is placed by the clinician directly at the femoral arterial puncture site on completion of the procedure, and creates a rapid, secure seal to achieve hemostasis. This puncture closure procedure requires little or no manual compression, minimizes the risk of bruising, and stops bleeding more rapidly than the more commonly used methods of manual or mechanical pressure. Post-procedure discomfort is also reduced when compared to standard closure methods. Additionally, the device allows patients who have undergone diagnostic angiography to ambulate early.

The device is composed of a collagen sponge and a specially designed absorbable polymer anchor that are connected by an absorbable positioning suture. The device seals and sandwiches the arteriotomy between its two primary members, the anchor

and the collagen sponge. Hemostasis is achieved primarily by the mechanical means of the anchor-arteriotomy-collagen sandwich, which is supplemented by the coagulation inducing properties of the collagen.

Discussion:

CMS has received a request that this procedure be given a specific ICD-9-CM code in order to:

1. properly track the utilization, mortality, and morbidity associated with hemostatic puncture closure procedure,
2. identify patients who have undergone this procedure, and
3. track resources associated with this procedure to determine efficacy and cost benefit to the patient and the provider.
   New code 39.44, Percutaneous vascular puncture closure procedure, has been suggested by the requestor. This would fall into the category 39.4, Revision of vascular procedure.

Recommendation:

After review of this request, it was determined that vascular closure is an inherent part of femoral arterial access, and that no new code should be assigned at this time. In addition, the manufacturers of this device anticipate that it *may* allow many in-patient procedures to be performed on an out-patient basis. ICD-9-CM procedure codes are used exclusively for Part A, inpatients.

For inpatient use, ICD-10-PCS (International Classification of Diseases, Tenth Revision, Procedure Coding System) would be the most appropriate place to capture this type of information, specifically under Character 6, "Device", at code **04NK*YZ**, where 0 = Medical and Surgical [section of the book]; 4 = Lower arteries; N = Repair; K = Femoral Artery, right (or 'L' for left); "*" = the appropriate approach; Y = Device NEC; and Z = No qualifier. (Note: ICD-10-PCS is still in draft, and this code should not be viewed as a final code.)

In the meantime, coders should proceed as usual by *not* assigning a code to any closure of the femoral artery access site following angiography or an interventional procedure.

Addenda

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Biopsy

Delete code omentum **54.23**

Add subterm **closed 54.24**

Add subterm **open 54.23**

Add subterm **percutaneous (needle) 54.24**

Biopsy

Delete code peritoneum **54.23**

Add subterm **closed 54.24**

Add subterm **open 54.23**

Add subterm **percutaneous (needle) 54.24**

Delete term Eloesser operation **(thoracoplasty) 33.34**

Add subterm **thoracoplasty 33.34**

Add subterm **thoracostomy 34.09**

Operation

Delete subterm Eloesser **(thoracoplasty) 33.34**

Add subterm **thoracoplasty 33.34**

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Add subterm **laparoscopic 51.88**

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Add subterm **heart 37.32**

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Delete subterm **ventricle (heart)(left) 35.34**

TABULAR LIST

37.32 Excision of aneurysm of heart

Add inclusion term **Repair of aneurysm of heart**

54.24 Closed [percutaneous][needle] biopsy of intra-abdominal mass

Excludes that of:

Delete exclusion term **peritoneum (54.23)**

NEXT MEETING

The next meeting is scheduled for June 4-5, 1998 and will be held at the CMS Auditorium, 7500 Security Boulevard, Baltimore, Maryland. The procedure part will be on June 4 and the diagnosis part will be on June 5 if a two day meeting is necessary. Those who would like to have procedure topics addressed should contact Amy Gruber or Ann Fagan by October 4, 1997. The meeting notice and agenda for the procedure part of the meeting will be placed on the CMS Home Page under Public Affairs/What's New in May 1998.

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NCHS' web site for ICD-9-CM and ICD-10 information:

http://www.cdc.gov/nchswww/about/otheract/icd9/icd9hp2.htm