MEDICAL IMPLANT INFORMATION, PERFORMANCE, AND POLICIES
9630 Gudelsky Drive (Building I)
University of Maryland, Shady Grove
September 19-20, 2002

AGENDA

WORKSHOP CO-CHAIRS : Julia Weertman (Northwestern) and Y.C. Fung (UCSD)

PURPOSE
1) Consider the federal government's role in providing medical implant information for safer healthcare.
2) Evaluate the role for the federal government in extracting and disseminating information gained from explanted medical implants.

GOALS
1) Define the role that the federal government can play in encouraging the use of information acquired from implanted and explanted medical devices for research.
2) Design of a possible structure for federal programs supporting gathering and dissemination of information derived from medical implant retrieval.
3) Design of a federal program to promote implant retrieval for use in research intended to achieve safer health care.

DAY 1 – September 19
(Building I, Auditorium)

7:30 am **Registration**

8:00 am **Purpose and Goals of Workshop**
Julia Weertman and Y.C. Fung

8:15 am **Current Demographics**
"Medical Implant Devices: Data Available from NCHS and the Use of ICD-9-CM for the Coding of Diagnoses and Procedures"
Donna Picket (Center for Healthcare Statistics)
The presentation will provide an overview of data available from the National Center for Health Statistics and highlight ICD-9-CM codes that may be relevant to medical implant device data collection activities.

8:35 am **Medical Devices: Current Information and Policies**
Bill Regnault (FDA)
This talk is a general overview of the Food and Drug Administration's Center for Devices and Radiological Health and the types of information that are acquired and evaluated as part of the Product Approval and Product Performance Assessment Processes.

8:55 am **Keynote Address**
"Patient Education: How Can It Be a Part of Medical Device Improvement?"
Ken Keller (University of Minnesota)
There is a need for a sea change in the regulation of medical devices, eliminating the arbitrary categories of "experimental" and "clinical" and moving from a gatekeeper approach to a continuous and more subtle scheme of oversight and regulation more in keeping with the actual dynamics of technology development. To achieve this change, we will certainly need to educate patients, but we will also need to educate and bring about change in the attitudes and assumptions of physicians, the public and the media. The Internet offers one way of approaching this task, but utilizing it will require a collaborative effort of government and professional organizations.

9:25 am **What Information do Patients Need to Have?**
Laura Quigley (St. Luke's Medical Center)

9:45 am **What Information Can/Should the Federal Government Provide?**
Art Ciarkowski (FDA)

10:05 am **Break**

10:30 am **How Can the Federal Government Provide Information?**
Kevin O'Hara (HealthStream, Inc.)
By creating a fertile environment with standards, systems and services. With the right environment in place, the quantity and quality of information provided by the networked community of interest will greatly exceed what could be provided by the government alone.

10:50 am **Value Gained from Implant Retrieval Research**
Chuck Swanson (Medtronic, Inc.)
This talk will describe the Medtronic systems for implant retrieval/analysis and clinical performance evaluation. In addition, the role of government, manufacturer, and third parties in achieving goals of this workshop will be discussed.

11:10 am **Patient Medical Implant History Record**
"Department of Veterans Affairs: A Site for Medical Implant Device Research"
Danielle Kerkovich (Department of Veterans Affairs)
The VA, as the largest healthcare system in the world, is one of the richest healthcare informatics systems. Therefore, the VA is a logical place for medical implant device informatics research; implementation, maintenance and explant analysis .

11:30 am **Medical Implant Research: Non-technical Issues**
David Smith (Tissue Informatics)
Concerns over misuse of private medical information and use of failure analysis results to sustain liability claims present substantive obstacles to programmatic explant research. Federal support of this research cannot eliminate these concerns, but may help create processes for information collection and distribution that minimize the potential for immediate adverse consequences of disclosure. In addition, timely federal engagement may lead to broad-based acceptance of protocols for in situ research of future tissue-based implants.

11:50 am **Medical Implant Research**
Fred Schoen (Harvard)

12:10 pm **Lunch**

12:30 pm **Breakout Sessions:**

Education and Information
(Building I, Room 101)
Denise Wilson, Chair (University of Washington)
Terrie Cowley (TMJ Association)
Jack Lemmons (University of Alabama at Birmingham)
Facilitator: Hilary Sigmon (NIH/NINR)

Medical Implant Research
(Building I, Room 102)
Renu Virmani, Chair (Armed Forces Institute of Pathology)
Mike Lysaght (Brown University)
Clare Rimnac (Case Western Reserve University)
Regine Sitruk-Ware (Rockefeller University)
Facilitator: Nancy Shinowara (NIH/CSR)

Non-technical Issues
(Building I, Room 108)
Barbara Anderson, Chair (Dow Corning, Corp.)
E. Haavi Morreim (University of Tennessee)
Jur Strobos (Olsson, Frank & Weeda PC)
Facilitator: Bernie Liebler (AdvaMed)

Dimensions of Health Informatics
(Building II, Room 1012)
Henry Heffernan, Chair (NIH)
C. Martin Harris (Cleveland Clinic Foundation)
Kevin Brown (Reward Health Sciences, Inc.)
Facilitator: Christine Kelley (NIH/NIBIB)

5:00 pm **Adjourn for the Day**

6:00 pm **Reception at the Hotel (Gaithersburg Marriott Washingtonian Center)**

7:00 pm **Dinner (on your own)**

DAY 2 – September 20
(Building I, Room 220)

7:30 am **Registration**

8:00 am **Breakout Session Chair Reports**

10:00 am **Break**

10:30 am **Discussion of Recommendations and Development of Executive Summary**

1:00 pm **Adjourn**