STRATEGIC GOAL 5:
Improve the Quality of Health Care Services

Improving the quality of life in the United States includes improving the quality of the health care services that individuals receive by reducing medical errors, improving consumer and patient information, and accelerating the development and use of electronic health information. To achieve this strategic goal, HHS will continue implementation of a variety of strategies designed to improve the delivery of health care services. These strategies include the development and dissemination of evidence based practices, information systems, new technologies for the home and clinical setting, and improved reporting systems for medical errors and adverse events.

HHS makes available leadership to promote the development of a national health information infrastructure that takes advantage of the most current technology available. This will involve attention to the secure and confidential treatment of health information, adoption of national data standards, and research on the applications of a national health information infrastructure that informs consumers, patients, professionals, and other decision makers alike.

This strategic goal highlights four programs including FDA's Medical Product Surveillance Network, FDA's Human Drugs program, Agency for Healthcare Research and Quality's (AHRQ) Prevention Portfolio, and AHRQ's Health IT.

Highlighted Programs

- 5a: FDA Medical Product Surveillance Network
- 5b: FDA Human Drugs Program
- 5c: AHRQ Health IT
- 5d: AHRQ Prevention Portfolio

5a Medical Product Surveillance Network (MedSun)
Food and Drug Administration (FDA)

Significance
The MedSun Network was created to reduce device-related medical errors; serve as an advanced warning system; and create a two-way communication channel between FDA and the user-facility community. The MedSun program is designed to train hospital personnel to accurately identify and report injuries and deaths associated with medical products.

Performance Measure	Fiscal Year 2006		
	Target	Actual	Result
Expand actively participating sites in MedSun Network to 71 percent	71%	86%	Met
Data Source: Center for Devices and Radiological Health, Adverse Events Reports			

Result Analysis
FDA has achieved the MedSun targets for the last four years, and has successfully built a system of 350 facilities. Beginning in FY 2006, FDA is turning its focus from building the system to increasing the participation rate of the facilities in the system.

Trends	Fiscal Year Actual				
Performance Measure	2002	2003	2004	2005	2006
Expand actively participating sites in MedSun Network to 71 percent	80 facilities	206 facilities	299 facilities	354 facilities	86%

Data Collection
FDA uses the services of a contractor to assist with administering the program. The contractor provides reporting assistance, processes reports submitted by participating hospitals, and subsequently releases the reports to FDA and the manufacturers. The contractor also supplies MedSun hospitals with feedback concerning the reports and FDA's use of the data. The report data is held in a database behind FDA's firewall.

Completeness
FDA receives weekly and quarterly reports from the contractor, which assists FDA in monitoring the program. There are regularly scheduled and ad hoc meetings as well that supplement the monitoring. In addition, FDA and the contractor conduct an annual survey of the sites that are participating.

The contractor sends a thank-you response to each reporter when a report is received and follows up with the reporters to ensure the data is complete and accurate. The contractor may edit the report to ensure completeness and then the report is released to the FDA for action.

Reliability
Before a facility is given access to the MedSun system, representatives that will be using the system are required to undergo an orientation program. During the orientation program, MedSun users are required to sign security rules for the system which include password and user-id rules and a designation that the MedSun reports will fulfill the reporting requirements for the Safe Medical Devices Act of 1990. Representatives that generally sign the forms are the risk manager, the biomedical engineer, patient safety officer, or quality assurance people (typically there are two representatives from each site). After the users have attended the orientation, the representatives are given a user-id and password. If a facility decides to leave the MedSun program, that facility is removed from the tracking system and the representative(s) passwords are inactivated.

The contractor maintains a tracking database with detailed information on the user facilities such as size, number of reports submitted, and region. The contractor may enter the name, address, and other facility identifiers to the database, however only one person is tasked with maintaining the tracking database from which all administrative reports are generated. No duplicates can appear in the tracking database because it is programmed to reject duplicates. If a site does not submit a report within six- months, the contractor contacts the facility to follow-up.

5b Human Drugs Program
Food and Drug Administration (FDA)

Significance
FDA's review of Priority New Drug Applications (NDAs) makes a crucial public health impact on thousands of Americans with serious health conditions waiting for important new drug remedies. Priority NDAs, as opposed to Standard NDAs, represent drugs that offer significant treatment or public health advances over existing treatments. For example, drugs for AIDS and cancer typically fall into the priority category. By committing to review and act on priority applications in only six months instead of the standard ten months, FDA ensures that any promising new treatments that are deemed safe and effective reach the public as soon as possible.

Performance Measure*	Fiscal Year 2006		
	Target	Actual	Result
Percentage of Priority NDAs reviewed within six months.	90%	10/2007	Deferred
Data Source: Center-wide Oracle Management Information System and New Drug Evaluation/Management Information System			

*"Reviewed" has been added for clarity and is not the exact wording used in the FY 2007 Congressional Justification.

Result Analysis
There will be at least a six month lag before FY 2006 actual data will be available, since applications that are submitted to FDA at the end of fiscal year need to be reviewed before the performance data can be calculated. However, FDA has consistently met this goal in the past, and the timely achievement of high-quality drug reviews in recent years reflects the importance of managerial reforms and substantial additional resources provided under the Prescription Drug User Fee Act (PDUFA).

Trends	Fiscal Year Actual				
Performance Measure	2002	2003	2004	2005	2006
Percentage of Priority NDAs reviewed within six months.	100%	100%	96%	10/2006	10/2007

Data Collection
FDA has a detailed process in place for tracking information related to PDUFA goal dates. Meta data about the application itself, the date of receipt, review assignments, activities, and actions are all captured in a corporate management information system. Staff are trained on how to enter data and there are quality assurance methods used to ensure the accuracy of the data entered.

Completeness
Data collection and entry procedures for tracking applications and PDUFA goal dates are very detailed and thorough. The software applications tied to the corporate management information system have built in security and data quality control mechanisms. These internal controls combined with training and standard operating procedures available to staff entering data serve as tools to validate and verify the completeness and accuracy of data.

Reliability
PDUFA goal date performance is highly scrutinized by all levels of management at FDA. The numbers of priority applications reviewed and acted upon at FDA each year are manageable (typically only a few dozen annually). Management are aware of the applications and timeframes of actions, and therefore, will be very aware of the rare instances when a priority application will miss a PDUFA goal date. In that way, management awareness serves as another layer of quality check in the reliability of the data reported about priority NDAs from the corporate information system.

5c Health IT
Agency for Healthcare Research and Quality (AHRQ)

Significance
In "Crossing the Quality Chasm" (2001), the Institute of Medicine emphasized the importance of improved health care delivery systems to improved health outcomes, and called out health information technology (HIT) as an innovation that supports such improvement. Other recognized studies and reports contain similar findings.

AHRQ's current HIT portfolio is comprised of grants and contracts designed to explore strategies for successful planning and implementation of HIT and accompanying interventions in communities, and to demonstrate the value of HIT to improved patient safety, quality, and costs of care. These goals underlie the President's desire to have electronic health records (EHRs) for most Americans by 2014. AHRQ's HIT projects span the spectrum of HIT adoption, with a particular focus on small and rural practices. This research is foundational to building a nationwide electronic health information exchange (HIE) network, which is necessary for supporting robust personal health records (PHRs) and EHRs, clinical decision support, health research, and population health. For example, by capturing high-quality clinical and administrative data electronically and storing it in standardized form, and by using secure and appropriate ways to access such data across settings, a PHR or EHR will be able to provide more complete critical information to health professionals at the point of a patient's care, thereby reducing errors and improving care quality.

Performance Measure	Fiscal Year 2006		
	Target	Actual	Result
By 2014, most Americans will have access to and utilize a Personal Electronic Health Record (EHR)	AHRQ will partner with one major HHS Operating Division to expand the capabilities of the EHR	Pursuant to American Health Information Community (AHIC) May 2006 recommendation, AHRQ is collaborating with Centers Medicare and Medicaid Services (CMS) to support faster development of improved Personal Health Records (PHR)	Met
	The core capabilities and function of the Personal Health Record (PHR) will be delineated	AHRQ is participating fully in the AHIC Consumer Empowerment Workgroup activities to establish the core capabilities of PHRs 2006 is defining key elements of a PHR	Met
Data Source: http://www.hhs.gov/healthit/documents/Presentations051606.pdf - goal 1 - slide 40 http://www.hhs.gov/healthit/ahic/ce_archive.html - goal 2 - page 30, recommendation 19 http://www.hhs.gov/healthit/ahic/ce_materials.html - goal 2 - Workgroup Member List			

Result Analysis
AHRQ has met its goals through participation in the Consumer Empowerment Workgroup of the American Health Information Community (AHIC) and through implementing the recommendation of the AHIC to partner with the Centers for Medicare and Medicaid Services (CMS) to improved Personal Health Records and Electronic Health Records. The program was implemented in FY 2005 and no historical data exist before that time.

Trends	Fiscal Year Actual				
Performance Measure	**2002**	**2003**	**2004**	**2005**	**2006**
By 2014, most Americans will have access to and utilize a Personal Electronic Health Record (PHR)	N/A	N/A	N/A	AHRQ funded a phased EHR improvement that implemented interoperability with other public/private providers.	Pursuant to AHIC May 2006 recommendation, AHRQ partnered with CMS on PHR technology

Data Collection
For the first goal, the recommendation was discussed and adopted at the AHIC meeting on May 16, 2006. For the second goal, records of the Consumer Empowerment Workgroup of the AHIC were used.

Completeness
AHRQ's collaboration with CMS to advance personal health records comes at the direction of HHS Secretary Michael O. Leavitt. AHRQ offers publicly available meeting minutes as data that verifies that order in a complete way. The AHIC meeting on May 16th, 2006, the Electronic Health Record Workgroup recommended that: "HHS, through CMS, AHRQ, other interested Federal agencies, and private-sector partners, should pilot programs that measure and demonstrate the value of an electronic registration summary and medication history to patients with chronic disease and their clinicians. The sponsoring organizations should strive to implement pilot programs that meet all the objectives identified by the Workgroup no later than December 31, 2006, and an evaluation of the initial results should be reported to the Community by June 30, 2007." This recommendation was adopted by Secretary Leavitt. We have had subsequent meetings and email discussions to develop this collaboration.

Reliability
Data to support the achievement of both goals is found in the records of the AHIC, an entity subject to the Federal Advisory Committee Act. AHIC meetings are open and the records are publicly available. Data is verified against transcripts, proceedings and minutes of the meetings referenced.

5d Prevention Portfolio
Agency for Healthcare Research and Quality (AHRQ)

Significance
The mission of the Prevention Portfolio is to increase the adoption and delivery of evidence-based clinical prevention services to improve the health of all Americans. We seek to accomplish our mission through two main avenues: work in support of the United States Preventive Services Task Force (USPSTF), and Portfolio efforts aimed at dissemination and implementation of the Task Force's recommendations. As the USPSTF makes evidence based recommendations, it is AHRQ's job to disseminate information to clinicians and the general public as quickly as possible. Accomplishing this more quickly puts actionable information into the hands of clinicians, guiding them to perform indicated services and not to perform services for which the evidence indicates more harm than benefit. The benefit of disseminating information is increasing delivery of appropriate clinical preventive services.

Performance Measure	Fiscal Year 2006		
	Target	Actual	Result
Measure #1: Increase the quality and quantity of preventive care delivered in the clinical setting especially focusing on priority populations	Establish baseline for reach of evidence-based preventive services through use of products and tools.	1.)Views and downloads of electronic content: • USPSTF recommendations: 4,242,074 • General Preventive services: 1,621,848 • Preventive Services Selector tool: 13,496 • National Guideline Clearinghouse related to USPSTF recommendations: 359,634* 2.) Dissemination of published products: • 2005 Clinical Guide: 11,021 • Consumer products: 352,216 • Adult Preventive Care Timeline: 1,819 • Journal publications: - Pediatrics, 2 publications, circulation 63,000 - Annals of Internal Medicine, 1 publication, circulation 92,756	Met
Measure #2: Improve the timeliness and responsiveness to the USPSTF	Decrease the median time from topic assignment to recommendation release.	Four topics released to date in FY 2006, time from assignment to release ranged from 14 to 30 months, median time 25 months.	Met
Measure #3: Increase the number of partnerships that will adopt and promote evidence-based clinical prevention	Increase the number of partnerships adopting evidence-based clinical prevention by 5%	**Federal partners** – 10 **Non-Federal partners** - 10 Primary Care Orgs - 2 Health Care Insurance Industry - 2 Consumer Organization - 3 Employer Organizations - 6 Other organizations	Met

Data Source: Web trends, AHRQ Publications Clearinghouse, National Guideline Clearinghouse, Preventive Services Selector Tool, Evidence Based Practice Center task order documents, and the Prevention Portfolio's tracking database of USPSTF topics for management purposes.

* Data for the National Guideline Clearinghouse are for 7/1/05 - 6/30/06

Result Analysis

AHRQ has met the target for Measure #1 - Establishing baseline date for the reach of evidence-based preventive services through use or products and tools - by collecting data from several sources including AHRQ website data from the Office of Communication and Knowledge Transfer (OCKT), views and downloads on the USPSTF recommendations on the National Clearinghouse website, and data on distribution of printed materials via the AHRQ Publications Clearinghouse. For Measure #2 – Decrease the median time from topic assignment to recommendation release – this target was met through processes that are either internally maintained by the Prevention team through use of task order documents from the Evidence Practice Centers, internal work tracking databases for the team, or are a matter of public record (e.g. date of publication of a manuscript in a medical journal). Measure #3 – increase the number of partnerships promoting evidence-based clinical prevention by 5 percent - was met by obtaining a count of active partnerships with the Prevention Portfolio in FY 2006. This count was derived from Agency documentation of portfolio activities.

Trends	Fiscal Year Actual				
Performance Measure	**2002**	**2003**	**2004**	**2005**	**2006**
Measure #1: Increase the quality and quantity of preventive care delivered in the clinical setting especially focusing on priority populations	N/A	N/A	Expert opinions regarding best practices for delivering clinical preventive services obtained through stakeholder meetings and focus groups. Developed Train the Trainer program	**Cervical Cancer**: - % of women (18+) who report having had a Papanicolau smear within the past 3 years – 81.3% **Colorectal Cancer:** - % of men & women (50+) report they ever had a flexible sigmoidoscopy/colonoscopy – 38.9% - % of men & women (50+) who report they had a fecal occult blood test (FOBT) within the past 2 years – 33%	1.)Views and downloads of electronic content: • USPSTF recommendations: 4,242,074 • General Preventive services: 1,621,848 • Preventive Services Selector tool: 13,496 • National Guideline Clearinghouse related to USPSTF recommendations: 359,634*

				Cardiovascular Disease: - % of people (18+) who have had blood pressure measured within preceding 2 years and can state whether their blood pressure is normal or high – 90.1% - % of adults (18+) receiving cholesterol measurement within 5 years – 67.0%	2.) Dissemination of published products: • 2005 Clinical Guide: 11,021 • Consumer products: 352,216 • Adult Preventive Care Timeline: 1,819 • Journal publications: - Pediatrics, 2 publications, circulation 63,000 - Annals of Internal Medicine, 1 publication, circulation 92,756
				Cardiovascular Disease and Cancer: - % of smokers receiving advice to quit smoking – 60.9%	
Measure #2: Improve the timeliness and responsiveness to the United States Preventive Services Task Force	N/A	N/A	N/A	**9 recommendations** released **78% current** within National Guideline Clearinghouse standards (reviewed within 5 years) **100% of recommendations** related to Institute of Medicine priority areas for preventive care current within National Guideline Clearinghouse standards **Develope**d new topic criteria, submission, review, and prioritization processes with new USPSTF topic prioritization workgroup	Four topics released to date in FY2006, time from assignment to release ranged from 14 to 30 months, median time 25 months.

Measure #3: Increase the number of partnerships that will adopt and promote evidence-based clinical prevention	N/A	N/A	Produced fact sheets Partnered with professional societies and advocacy groups	**Federal partners** – 8 **Non-Federal partners** - 10 Primary Care Organizations - 2 Health Care Delivery Organizations - 1 Consumer Organization - 3 Employer Organizations - Other organizations – 3	**Federal partners** – 10 **Non-Federal partners** - 10 Primary Care Organizations - 2 Health Care Insurance Industry - 2 Consumer Organization - 3 Employer Organizations - 6 Other organizations

Data Collection
Measure #1: USPSTF data is captured using a statistical package – Web trends. This process captures downloads for specific pages and the numbers are automatically generated and compiled. AHRQ Publications Clearinghouse dissemination data is maintained by the Clearinghouse with records for requests and shipments. AHRQ maintains internal records of actual Government Printing Office publication printings and delivery receipts. National Guideline Clearinghouse data is captured on website hosted by ECRI (formerly Emergency Care Research Institute). The Preventive Services Selector Tool is hosted on web site by EEI Communications.

Measure #2: Evidence Based Practice Center task order documents, including Monthly Status Reports are maintained by the Prevention Portfolio; copies are part of the Evidence-based Practice Center contract files. AHRQ Prevention Portfolio staff maintains a password-protected tracking database of USPSTF topics for management purposes.

Prevention team leaders (Drs. Miller and Barton) participate in a bi-weekly conference call with the EPC contractors during which time task order documents and monthly status reports are reviewed and data verified. For work that is internal to AHRQ (for example the release of a USPSTF recommendation and accompanying evidence review only through our website) the weekly Prevention team meetings are used to review and verify data about decisions such as when to publish, what format to use, etc. Electronic mail provides a record of drafts of documents during the editing process and dated near-final and final drafts of documents are saved in a structured way on the team's computer drive which is accessed by team members from OCKT and CP3.

Measure #3: AHRQ Prevention Portfolio staff maintains internal tracking documents of partnerships including IAAs and other contractual documents, and a password-protected tracking database of prevention partners/activities for management purposes.

Completeness
The methodology and rationale used to determine recommendations are published in peer- reviewed journals to insure transparency and to further the field of evidence-based practice. Dissemination of the recommendation is accomplished by print and electronic publication and by the creation of new products and tools directed at specific audiences. Developing and sustaining public and private partnerships are important steps for the Portfolio in effectively and efficiently facilitating the use of evidence-based recommendations and effective delivery system designs.

- Measure #1 - the data as shown is current through the end of June 2006, unless otherwise specified.
- Measure #2 – these data are completed with a high degree of confidence as they represent processes that are either internally maintained by the Prevention team (e.g. task order -documents from the

Evidence Practice Centers, internal work tracking databases for the team) or are a matter of public record (e.g. date of publication of a manuscript in a medical journal).

- Measure #3 – these data are completed with a high degree of confidence as they represent partnerships that are developed and maintained by the Prevention team.

Reliability
Measures #1: For website tracking, information is generated and tallied in a spreadsheet, with a breakout for recommendations and all other Preventive Services materials. A documentation specialist does the special tabulation, which is then reviewed and verified by our lead programmer. This data is then sent to the Electronic Dissemination Advisor for final review and approval for release.

Measures #2 and #3: Data is verified against transcripts, proceedings, and Agency documentation of portfolio activities. The Prevention Portfolio uses both printed as well as computer-saved documents such as agendas for conference calls whenever possible in order to track relationships with external partners. The Prevention Portfolio calendar, saved in Outlook, serves as one source of confirmation. Electronic mail correspondence, saved in mail folders specific to the project or partner, serve as records of ongoing work and consultation. The Prevention Portfolio provides highlights for the CP3 Biweekly Report to the Agency Director, which serves to document main accomplishments (such as the publication of a joint project from the USPSTF/Prevention Portfolio from AHRQ, and the Advisory Council on Immunization Practices from the CDC). In addition, where new products are a result of partnerships with external organizations, copies of the actual product serve to document the collaboration.