SECTION 6
PERFORMANCE MONITORING

INTRODUCTION

Performance monitoring includes establishing goals and providing good communications and feedback between the Project Office, the CCC, and the CCs.

QA goals are set for many WHI tasks. The goals are based on criteria appropriate to assure the scientific integrity of the data, previously published standards of quality and safety, and/or ranges of performance. Goals are quantified as Meets/Exceeds Goal and Borderline for each of the Priority 1 and 2 activities listed in *Section 1.1.1 - Priorities*, wherever possible. These goals imply a criterion level of quality below which performance is unacceptable. These goals help point out where corrective actions need to be taken. Updated goals are communicated to CCs via manual revisions or Bulletins.

Regular communication is an essential part of feedback and it occurs in a variety of ways within WHI. Routine written and electronic communications regarding changes in protocol and procedures are described in *Section 2 - Documentation*. Lines of communications between WHI staff and WHI committees are described in *Vol. 1, Section 1 - Protocol, Part 10 - Study Organization* and *Vol. 2, Section 1.4 - Study Communications.*

- Regional and national conference calls provide an effective means of sharing information and problem solving for a variety of CC operational issues. See the description of the structure and functions of the regional and national PI and Staff Committees in the WHI Protocol, located in *Vol. 1 - Protocol and Policies.*

- The WHI e-mail system, Microsoft Outlook, provides a fast and convenient way to transmit many communications throughout WHI. The use of e-mail is the preferred method for distributing many communications. PIs and other WHI staff who do not have direct access to e-mail may be able to access it through the Internet. Where possible, distribution of minutes and other communications via e-mail is encouraged.

Providing feedback in a timely and useful way is important for maintaining and improving performance at all levels. Different ways of providing this feedback include the methods of QA described in earlier sections, including manual updates, training and recertification, CC observations, QA visits, and review of reports.

This section includes:

- CC goals,
- A description of the performance monitoring plan, and
- A description of mechanisms for providing information to the WHI committee structure.

6.1 Goals

An exceeds goal level is defined to assist in maintaining high standards. A borderline category is defined with the concept that measures below this level requires prompt action. Clinical Centers are encouraged to use these levels to monitor their own activities. Examples of reports available for CCs to monitor the particular activities are also listed below. For some activities CCs have additional reports available. Additional reports are being developed to assess areas not yet addressed.

The exceeds and borderline levels for both CT and OS are intended to complement the overall goals as stated in the protocol. In most cases, the exceeds goal levels are greater than the protocol defined goals, while borderline levels will not meet such goals. The CCC and PMC will also use these as guidelines to determine whether some additional assistance may be required in particular areas.

6.1.1 Priority 1 Activities

Goals for the Priority 1 activities (see *Table 1.1 - WHI QA Priorities*) are given below. Those marked with an asterisk (*) indicate protocol assumptions. CCs are urged to aim high as these activities are critical to the study's ability to address the scientific questions of the study.

6.1.1.1 CT Consents

	Meet/Exceeds Goal Level	Borderline Level	WHIP #
Tasks occurring before consent signed	0%	≤ 2%	–

6.1.1.2 CT Randomizations

	Meet/Exceeds Goal Level	Borderline Level	WHIP #
HRT	100% of goal*	–	1109
DM	100% of goal*	–	1109
CaD	100% of goal*	–	1125
Age	100% of goal*	–	1107
Minority	100% of goal*	–	960

6.1.1.3 CT Intervention, Adherence, Retention, and Safety

HRT	Meet/Exceeds Goal Level	Borderline Level	WHIP #
Combined dropout from intervention and loss to follow-up	< 7% (year 1) then < 4%* for subsequent years	≤ 11% (Year 1) then ≤ 8% for subsequent years	–
Adherence (≥ 80% of pills taken)	≥ 90%	≥ 80%	PMC Report
Endometrial aspiration entry rates	≥ 95%	≥ 85%	–
Safety procedures completed	≥ 100%	–	–
Unblinding rate	< 1%	–	PMC Report

DM	Meet/Exceeds Goal Level	Borderline Level	WHIP #

DM	Meet/Exceeds Goal Level	Borderline Level	WHIP #
Stop Intervention or stop Follow-Up	≤ 3 %	–	748
C-I % energy from Fat	≥ 15 (target of 13%* plus 2%)	≥ 11% (target of 13%* minus 2%)	PMC Report
Decline over time in C-I % energy from fat	≤ ¼% decline/year	≤ ¼% decline/year	PMC Report
Number of women waiting > 20 weeks for group formation	≤ 6 participants	≤ 12 participants	1110
Year 1 individual session completion	≥ 95%	≥ 85%	588, 1110
Year 1 session attendance, cumulative across sessions 1 – 18 (PMC monitors session 12 as a marker for session attendance.)	≥ 80%	≥ 70%	PMC Report
Year 1 session completion, cumulative across sessions 1 – 18 (PMC Monitors session 12 as a marker for session attendance.)	≥ 95%	≥ 85%	PMC Report
Year 2+ session attendance	≥ 80%	≥ 70%	588
Year 2+ session completion	≥ 95%	≥ 85%	588
Self-monitoring scores obtained for designated sessions (Year 1 Sessions 4, 8, 12, 16)	≥ 95%	≥ 85%	588
Self-monitoring scores obtained for sessions 1 - 18, cumulative (PMC monitors Session 12 as a marker for score collection)	≥ 90%	≥ 80%	588
% of participants reporting score > 125% of goal for fat gram goal, Cumulative (Marker Sessions 8, 12, 16; semi-annually Year 2+)	≤ 10%	≤ 15%	588
Completion of required Additional Assistance contacts	≥ 95%	–	1164, 1165
AV1 without having started intervention	0%	–	1134
% of participants reporting score < 4 servings of f/v daily, cumulative (Marker Sessions 12, 16; semi-annually Year 2+)	≤ 10%	≤ 15%	588, 1105
% of participants reporting score < 5 servings of grains daily, cumulative (Marker Session 16; semi-annually Year 2+)	≤ 10%	≤ 15%	588, 1105

Dietary Assessment	Meet/Exceeds Goal Level	Borderline Level	WHIP #
4DFR Documentation Errors	< 4 errors of 75% of 4DFRs documented	–	935
4DFR Screening Errors	< 6 unacceptable 4DFRs per document/year	–	949

CaD	Meet/Exceeds Goal Level	Borderline Level	WHIP #
Combined dropout from intervention and loss to follow-up	< 7% (Year 1) then < 4%* for subsequent years	≤ 11% (Year 1) then ≤ 8% for subsequent years	744
Adherence (≥ 80% of pills taken)	≥ 90%	≥ 80%	PMC Report

Contact Schedule	Meet/Exceeds Goal Level	Borderline Level	WHIP #
6-week HRT phone call	95%	90%	1131
4-week CaD phone call	95%	90%	–
Semi-annual contact completion	95%	90%	1140, 1141, 1143
Semi-annual contact in ± 4 week window	90%	80%	1140, 1141, 1143
1 year annual contact	98%	95%	1140, 1141, 1143
Semi-annual contact in ± 4 week window	90%	80%	1140, 1141, 1143
For CT, no contact for 27 months for CT starting in Year 3	≤ 1%	≤ 1½%	–
For CT, decline in no contact for 27 months for CT in subsequent years after Year 3	≤ ½%	≤ 1% decline	–
For OS, no contact for 27 months starting in Year 3	≤ 1½%	≤ 2%	–
For OS, decline in no contact for 27 months in Years 5, 7, 93	≤ 1% decline during Years 5, 7, 9	≤ 1½% decline during Years 5, 7, 9	–
Lost to follow-up	≤ 3%*	--	–
Completeness: designated forms and procedures completed at routine contacts	90%	80%	–
Timeliness: data entered within 2 weeks (± 14 days) of data collection	90%	80%	1112
Encounters in WHILMA without data	< 2%	–	1112

6.1.1.4 CT Primary Outcomes

	Meet/Exceeds Goal Level	Borderline Level	WHIP #
Form 33 collection at 6 months and Year 1	≥ 98%	≥ 90%	–
Decline over time in Form 33 collection	≤ ½% decline/year, going no lower than 93%	≤ 1% decline/year, going no lower than 85%	–
Form 33D collection at 6 months and Year 1	≥ 99%	≥ 95%	–
Decline over time in Form 33D collection	≤ ½ decline/year, going no lower than 94%	≤ 1% decline/year, going no lower than 90%	–
Number of cases assigned to adjudicator within 6 weeks	≥ 80%	–	1263, 1264
Number of cases adjudicated within 14 days	≥ 80%	–	1263, 1264
Timeliness of cases closed within 14 weeks of Form 33 collection	≥ 80%	–	1262, 1266
Local adjudication agreement with central adjudication	≥ 95%	–	–

6.1.2 Priority 2 Activities

OS Primary Outcomes	Meet/Exceeds Goal Level	Borderline Level	WHIP #
Form 33 collection at Year 3	≥ 98%	≥ 90%	–
Decline over time in Form 33 collection	≤ ½% decline/year, going no lower than 93%	≤ 1% decline/year, going no lower than 85%	–
Form 33D collection at Year 3	≥ 99%	≥ 95%	–
Decline over time in Form 33D collection	≤ ½% decline/year, going no lower than 94%	≤ 1% decline/year, going no lower than 90%	–

CT/OS Biological Specimens

	Meet/Exceeds Goal Level	Borderline Level	WHIP #
Blood Collection			
Aliquots in WHILMA matching with data from McKesson	≥ 98%	≥ 95%	1041, 1042
Completeness of blood collection	≥ 95%	≥ 90%	1044
Aliquot discrepancies	< 2%	≤ 5%	1946
Urine Collection			
Aliquots in WHILMA matching with data from McKesson	≥ 98%	≥ 95%	1042, 1047
Completeness of urine collection	≥ 95%	≥ 90%	1045

CT/OS Baseline and Follow-up Predictive Data

	Meet/Exceeds Goal Level	Borderline Level	WHIP #
Exposure Update			
Completion of OS exposure update	≥ 95%	≥ 90%	–
Decline over time in completion of exposure update	≤ 1% decline/year, going no lower than 90%	≤ 1½ decline/year, going no lower than 80%	–
ECGs			
ECGs in WHILMA matching with data from EPICARE	≥ 98%	≥ 95%	1021, 1022
Grades 4-5	< 5%	≤ 10%	1023

	Meet/Exceeds Goal Level	Borderline Level	WHIP #
Bone Densitometry			
Bone Densities in WHILMA matching with data from UCSF	≥ 98%	≥ 95%	1051, 1052
Completeness of collection	≥ 95%	≥ 90%	–
Data			
Missing predictor data	< 5%	–	–
Data within range checks	≥ 98%	–	–

6.1.3 Priority 3 Activities

	Meet/Exceeds Goal Level	Borderline Level	WHIP #
OS Enrollment	100% of goal*	–	1126

6.2 Performance Monitoring Plan

The performance of all CCs are reviewed on a regular basis following a 4-step Performance Monitoring Plan. This plan includes CCC and Performance Monitoring Committee (PMC) review of all CC operations and performance based on the performance goals described in *Section 6.1 - Performance Goals*.

In June 1995, the CCC implemented a four-step plan for monitoring and assisting CC performance. The purpose of the four steps is to reinforce good performance, to identify clinic-specific performance issues in a timely fashion, and to provide assistance or institute corrective action if performance is inadequate. The Clinical Facilitation Center (CFC) at the Bowman Gray School of Medicine provides major support for these functions. The four monitoring levels are described below.

6.2.1 Level 1: Routine Performance Monitoring and Follow-up

CCC quality assurance staff and lead staff liaisons regularly contact the clinic lead staff, review database reports, and perform QA checks for all clinics. They monitor clinic-specific and study-wide performance in key areas to provide timely and routine feedback on performance to clinics where appropriate. They also provide assistance (e.g., advice, training) where performance needs improvement.

Both the CCs and CCC can run QA reports and each is responsible for reviewing the reports. CCC staff review both the summary and detail QA reports to identify potential problems and trends at CCs based on the performance goals given in *Section 6.1 - Performance Goals*. Other recipients of the monthly reports are responsible for reviewing reports as follows:

- Study Monitoring reports: The CC PIs and Project Office review the reports with attention to how well the CCs are reaching their recruitment goals and other performance measures.

- Detail CC QA Reports: CC Clinic Managers review each report to identify problems and solutions, implement corrective action, and report the action to the CCC.

- Detail Subcontractor Reports: Subcontractor PIs are responsible for reviewing each report, identifying solutions to problems as needed, implementing corrective action, and reporting the action to the CCC.

CCs performing in the Good/Excellent range require no action, and monthly monitoring continues as usual. CCs performing below the Good/Excellent range for 1-2 months receive CCC assistance to improve performance. Taking into account each CC's circumstances and depending on the particular report, the appropriate action for the CCC may include:

- A simple discussion to encourage a better performance, pointing out the performance goals,
- Discussions to help identify problems and investigate ways to improve performance,
- Recommendations to perform additional observations, and/or
- Requesting or requiring retraining and recertification.

CCs performing below the Good/Excellent range for 3 months result in CCC-CC interactions and a request for the CC to develop a specific written plan to improve performance.

Subcontractors may identify problems at the CCs during the routine processing and review of data from the CCs. They contact the CC directly or through the CCC, and may help identify the problem and a solution. For consistent problems, the subcontractors also notify the CCC of the problem and inform the CCC of the actions they have already taken.

6.2.2 Level 2: Performance Monitoring Committee

The PMC was formed with the implementation of the 4-step performance monitoring plan. The PMC membership includes two members from the CFC, two members from the Project Office, and two members from the CCC. The PMC monitors a composite of CC performance measures, reviewing and noting persistent concerns in clinic performance.

The PMC meets via regular conference calls. Before each routine call, narrative summaries of performance for each clinic to be discussed are circulated to all PMC members. The summaries include information from routine Level 1 monitoring activities by CCC lead staff liaisons as well as updated information about the functioning of the CC. During the review of the clinic summaries, the PMC determines the assistance or other action that may be needed. The PMC also identifies the person(s) who will, if asked, carry out such activities and identifies any study-wide issues to be brought to the attention of the Steering Committee. After the call, a letter summarizing the PMC discussion is sent to the PI of the clinics reviewed, pointing out areas of good performance and areas needing improvement. The PMC reviews all 40 clinics at least once each year.

During the call, the PMC also completes debriefings on completed PMC visits and calls with clinics and reviews materials received from CCs in response to specific PMC requests from a previous call. Specific or persistent issues and clinics needing improvement are addressed more frequently.

6.2.3 Level 3: Follow Up on Persistent Issues

The CFC is responsible for seeing that the recommended activities identified by the PMC are carried out in a timely fashion. The CFC staff conducts these interactions where appropriate or requests assistance from another person or group with specialized expertise in the area of concern. A Level 3 site visit or conference call may be conducted with one to three members from the CFC, Project Office and/or CCC, but without selected PIs or lead staff from the other clinics. The PMC holds conference calls with CCs, where possible, rather than delaying a visit due to scheduling difficulties. This is especially effective when the CC has a specific issue that can be discussed on a call; for example, strategies for HRT-only recruitment.

6.2.4 Level 4: Performance Enhancement Site Visit.

If the interactions with the PMC do not yield timely results, or if there are sufficiently serious clinic issues, a Level 4 performance enhancement site visit is conducted. In addition to CFC staff, the site visit team will typically include investigators and staff from other WHI clinics and a representative from the Project Office and the CCC. The composition of the site visit team depends, in great part, on the specific problem areas to be addressed. The CFC takes the lead in coordinating and arranging these visits, prepares a written report summarizing the site visit team's finding (for review by the site visit team), submits the report to the chair of the PMC, and monitors the progress toward achieving site visit recommendations. A copy of the final report is sent to the clinic, Project Office, and CCC.

The PMC makes one visit to each clinic for a particular problem area (e.g., recruitment, adherence) and refers further issues to the Project Office. This separation of PMC and NIH site visits helps to clarify and maintain the CC enhancement function of the PMC visit and separate out any contract issues addressed in NIH site visits. Follow-up on the same issue is done by phone, email, or mail. Any further visits to the clinic on that issue are within the domain of the Project Office.

After a PMC visit, the chair of the visit team prepares a PMC Visit Report, describing the visit, the CC's strengths, issues reviewed, and the PMC recommendations. A draft of the report is circulated to the PMC Visit members before being finalized and sent to the CC PI. The PMC monitors changes the CCs make following discussions on the PMC call and following a PMC visit:

- Monitoring materials requested and received from CCs. All requests are listed on a table showing date requested, date received, assigned PMC member, and date reviewed. This table is included and reviewed on each PMC call.
- Document the CC response to the PMC visit recommendations. A table listing the recommendations included in the PMC Visit report and the status of each of the recommendations is prepared.

- Solicit feedback on the PMC visit team's effectiveness. A PMC Visit Survey is sent to all CCs receiving a PMC visit after the final report has been sent. The survey asks for feedback on the visit content, format, and visitors, and asks for suggestions for improvements.

6.3 Feedback Mechanisms

In addition to the regular PMC monitoring plan, feedback of study wide performance is provided to specific WHI Committees on a quarterly basis.

- Feedback of summary performance results is provided to each related CC PI and Clinic Manager in the PMC report distributed to each CC quarterly. A hard copy is sent to each CC PI and Clinic Manager, and an electronic copy is included in the electronic files distributed to each CC.

- The following types of feedback are given to listed Committees:
  - Outcomes QA to Morbidity and Mortality Committee
  - HRT Intervention QA to the Hormone Replacement Committee
  - DM Intervention QA to the Dietary Modification Committee
  - CaD Intervention QA to the CaD Committee
  - Predictive Data/Specimens QA to the Observational Study and Design and Analysis Committees
  - Consent, Eligibility, and Enrollment QA to the Steering Committee

- The PMC reports progress of CC monitoring and follow-up to the Steering Committee on a monthly basis.

Section 6
Performance Monitoring

Table of Contents

Contents		Page
Introduction		**6-1**
6.1	**Goals**	**6-2**
6.1.1	Priority 1 Activities	6-2
	CT Consents	6-2
	CT Randomizations	6-2
	CT Intervention, Adherence, Retention, and Safety	6-2
	CT Primary Outcomes 6-4	
6.1.2	Priority 2 Activities	6-5
6.1.3	Priority 3 Activities	6-6
6.2	**Performance Monitoring Plan**	**6-7**
6.2.1	Level 1: Routine Performance Monitoring and Follow-up	6-7
6.2.2	Level 2: Performance Monitoring Committee	6-8
6.2.3	Level 3: Follow Up on Persistent Issues	6-8
6.2.4	Level 4: Performance Enhancement Site Visit.	6-8
6.3	**Feedback Mechanisms**	**6-10**