

March 14, 1994

1. Transmitted is a new chapter to Department of Veterans Affairs, Veterans Health Administration Manual M-2, "Clinical Programs," Part VI, "Pathology and Laboratory Medicine Service," Chapter 14, "Measuring Patient Outcome."

2. Principal changes are:

a. Paragraph 14.01: Defines the purpose of the chapter to measure outcome of patient care based on laboratory tests.

b. Paragraph 14.02: Establishes policy for detecting errors, preventing failures of quality, and designates the Chief, Pathology and Laboratory Medicine Service, as the responsible official for continuous outcome measurement.

c. Paragraph 14.03: Establishes methods for measuring outcome.

d. Paragraph 14.04: Defines mandated programs for measuring outcome.

e. Paragraph 14.05: Defines mechanisms to prevent errors.

f. Paragraph 14.06: Identifies risk factors for reporting failures of laboratory quality.

g. Paragraph 14.07: Defines mechanisms for reporting failures of laboratory quality.

h. Paragraph 14.08: Defines clinical outcome monitors and risk factor indicators.

i. Paragraph 14.09: Provides references.

3. Filing Instructions

Remove pages

Insert pages

14-i
14-1 through 14-4
14A-1 through 14A-2
14B-1
14C-1
14D-1 through 14D-6
14E-1 through 14E-10

4. RESCISSIONS: None.

~~S/3/14/94 by Dennis Smith for~~
John T. Farrar, M.D.
Acting Under Secretary for Health

Distribution: RPC: 1285 is assigned

FD

Printing Date: 3/94

CONTENTS

CHAPTER 14. MEASURING PATIENT OUTCOME

PARAGRAPH	PAGE
14.01 Purpose	14-1
14.02 Policy	14-1
14.03 Methods for Measuring Patient Outcome	14-1
14.04 Mandated Programs	14-2
14.05 Laboratory Error Prevention and Error Detection	14-2
14.06 Identifying Risk Factors for Laboratory Quality	14-3
14.07 Reporting failures of Laboratory Quality	14-3
14.08 Utilizing Clinical Indicators as Measures of Laboratory Outcome	14-4
14.09 References	14-4
APPENDICES	
14A Mandated Components of the Pathology and Laboratory Medicine Service Quality Assurance Program	14A-1
14B Type of Laboratory Quality Assurance Program	14B-1
14C Systematic Laboratory Errors	14C-1
14D List of Required Pathology and Medicine Service Risk Factors Outcome Monitors	14D-1
14E Laboratory Critical Indicators Excerpted from the Quality Improvement Checklist	14E-1

CHAPTER 14. MEASURING PATIENT OUTCOME

14.01 PURPOSE

This chapter outlines policies and methods that must be utilized in VA (Department of Veterans Affairs) Central Office and VA medical centers to measure the actual outcome of patient care based on laboratory tests.

14.02 POLICY

a. Prevention and detection of true laboratory error requires that each VA Pathology and Laboratory Medicine Service and ancillary testing site institute policies, monitors and internal VA standards that will detect and prevent failures of quality. All areas of the laboratory and ancillary testing sites will be subject to continuous outcome measurement to assure consistent high quality performance. (See par. 14.05 and app. 14D.) This is the responsibility of the Chief, Pathology and Laboratory Medicine Service, at each VA medical center.

b. The Director, Pathology and Laboratory Medicine Service, VA Central Office, provides policy and direction for measuring patient outcome for laboratory tests and transfusion practices in all VA medical centers by providing written policies and nationwide inspection, accreditation and proficiency testing activities.

14.03 METHODS FOR MEASURING LABORATORY TESTING OUTCOME

a. Methods for measuring patient outcome performed at each VA medical center include, but are not limited to:

- (1) Mandated peer review.
- (2) Self-assessment and educational programs for individual physicians.
- (3) Focused policies that mandate internal review.
- (4) Continuous monitoring for all high-risk areas of laboratory practice.

b. A complete and comprehensive DHCP (Decentralized Hospital Computer Program) laboratory computer system and a software package that performs QC (quality control) and QA (Quality Assurance) checks, and measurements of deviations from accepted standards are provided in each VA medical center to assist in the use of these methodologies. NOTE: This software package is also a reliable source of data collection for outcome measurement.

c. Numerous policies, established by VA's Central Office of Quality Management, Clinical Programs, and Operations and directed towards detecting and preventing patient injury, and implemented at each VA medical center, have

March 14, 1994

M-2, Part VI
Chapter 14

M-2, Part VI
Chapter 14

March 14, 1994

been integrated into a comprehensive TQI (Total Quality Improvement) program. A detailed description is found in appendix 14A and appendix 14B.

NOTE: VA Central Office Pathology and Laboratory Medicine Service provides guidelines for QI (Quality Improvement) for laboratory testing by systematically and periodically reviewing the results of all of the quality management activities; see appendix 14A.

14.04 MANDATED PROGRAMS

Mandated programs for quality control and quality assurance are provided in appendix 14A. The results of these programs provide continuous feedback through the Laboratory Quality Scorecard (LQS) from (see Ch. 2, App 2B) all VA medical centers to VA Central Office. They also function as a conduit of information from each individual laboratory through the medical center's Quality Management Coordinator, to the VA Central Office of Operations, and directly to the VA Central Office Pathology and Laboratory Medicine Service Quality Management Coordinator. The majority of these programs are required to meet VA's congressional mandate in Public Law 102-139 (September 28, 1991) to provide standards and programs that meet the requirements of the Clinical Laboratory Improvement Amendment of 1988. (See Federal Register, Sept. 1, 1992, Public Health Service Act, Section 353(f), 42 U.S.C. Section 263a(f).)

14.05 LABORATORY ERROR PREVENTION AND ERROR DETECTION

a. Two systematic internal mechanisms must be in place to prevent errors in blood transfusion, laboratory, and surgical/cytopathology testing (app. 14C) at each VA medical facility.

(1) The first system, error prevention, includes all of the programs for inspection, accreditation, proficiency testing, and policies mandated by VA Central Office, and local laboratory and medical center policies for quality improvement.

(2) The second system, error detection, operates in the internal laboratory environment. The components of error detection include daily:

- (a) QC, standards and calibrators.
- (b) Supervisory review of test results.
- (c) Surgical and cytopathology peer review of tissue diagnoses.
- (d) Computerized QC and QA checks (DHCP).

b. In the patient care environment, VA studies show that injuries, or death, due to laboratory errors are rarely caused by technical, or mechanical, problems. They are primarily caused by human failure in the following categories, in order of frequency of occurrence:

- (1) Blood transfusion clerical and/or misidentification of patient on clinical services, 43 percent.
- (2) Blood typing, crossmatch or antibody identification, 23 percent.
- (3) Surgical pathology tissue diagnoses, 16 percent.

M-2, Part VI
Chapter 14

March 14, 1994

(4) Laboratory medicine (chemistry, hematology, microbiology, etc.) test results interpretation and/or timeliness of results, 11 percent.

(5) Phlebotomy, delay, or computer-related areas, 7 percent.

c. Appendix 14D provides a list of mandated risk factor monitors for the most critical outcome, process and structure elements of laboratory quality management. These risk factor monitors are strongly recommended for use in each VA medical center main

clinical laboratory, and in ancillary testing sites that perform laboratory tests for patient care.

d. Appendix 14E provides a list of the monitors required by VA Central Office for Quality Management using the QUIC (Quality Improvement Checklist).

14.06 IDENTIFYING RISK FACTORS FOR IMPROVING LABORATORY QUALITY

a. Failures in laboratory quality are identified through the nine major quality management programs described in appendix 14A using all of the reporting mechanisms that are mandated in appendix 14B. These range from reports of inspection of laboratories and blood banks to proficiency testing reports on individual laboratory physicians and cytotechnologists.

b. Failure in laboratory inspection, accreditation and proficiency testing will be centrally reviewed by VA Central Office Pathology and Laboratory Medicine Service. Repeated failures of quality will be immediately reported to the VA medical center Director by letter and/or telephone call by the Laboratory Quality Management Coordinator and the Director, Pathology and Laboratory Medicine Service. Reports of corrective action are required to be returned by the medical center Director within the time specified in each letter, to satisfy Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requirements for accreditation. NOTE The College of American Pathologists and the JCAHO have a reciprocal agreement to inspect and accredit VA laboratories (see M-2, Pt. VI, Ch. 13).

14.07 REPORTING FAILURES OF LABORATORY QUALITY

a. There are several mechanisms for the reporting of failures of laboratory quality. The most common is by written report of an inspection, accreditation or proficiency testing body. Others arrive through VA's PIR (Patient Incident Reporting) Program, from Inspector General Reports, and from VA's Office of General Counsel.

b. All VA medical center laboratories that perform tests for patient care must report any incident which results in a failure of the laboratory's quality management system with an injury to a patient using VA Form 10-2633, "Report of Special Incident Involving a Beneficiary."

(1) The definitions of incidents requiring reports can be found in M-2, part I, chapter 35.

(2) Copies of this report, and the findings of the local investigation board, for each event which causes patient injury must be sent to the Director, Pathology and Laboratory Medicine Service, VA Central Office.

NOTE: This must be performed manually if the VA medical center does not have version 2.0 (or greater) of the DHCP Patient Incident Reporting software,

March 14, 1994

M-2, Part VI
Chapter 14

M-2, Part VI
Chapter 14

March 14, 1994

which allows the automation of several activities in processing VA Form 10-2633, and provides a reporting mechanism to the Regional Director's offices.

c. All VA medical center Pathology and Laboratory Medicine Services will use a continuous feedback mechanism program that provides bi-directional, integrated, continuous monitoring of quality elements. These elements will be used by VA Central Office Pathology and Laboratory Medicine Service to calculate error rates and risk factors for laboratory tests in each VA medical center.

14.08 UTILIZING CLINICAL INDICATORS AS MEASURES OF LABORATORY
QUALITY

a. A comprehensive list of laboratory Clinical Outcome Monitors and Risk Factor Indicators used by each VA medical center to report areas of high risk and define a laboratory's risk factor indicators in the performance of tests is provided in appendix 14D.

b. The VA medical center's DHCP system will be used to collate the required monthly review of high risk clinical indicators for each VA medical center laboratory.

c. Each VA medical center laboratory and ancillary testing site that performs tests for patient care will also utilize the clinical indicators in QUIC to measure outcome. (See app. 14E.)

14.09 REFERENCES

a. Travers, E. M., and Barbour, G., "Measuring Laboratory Testing Outcome with Nation's Largest Multihospital System;" 1993 (In press).

b. Brennan, T.A., Leape, L. L., Laird, N. M., Herbert, L., et.al., "Incidence of Adverse Events and Negligence in Hospitalized Patients; Results of the Harvard Medical Practice Study (I)," New England Journal of Medicine, 1991; 324:370-76.

c. Leape, L. L., Brennan, T.R. Laird, N., Lawthers, A. G., et al., "The Nature of Adverse Events in Hospitalized Patients; Results of the Harvard Medical Practice Study (II)," New England Journal of Medicine, 1991; 324:377-84.

d. Brennan, T. A., Herbert, L. E., Laird, N. M., Lawthers, A. G., "Hospital Characteristic Associated With Adverse Events and Substandard Care," Journal of the American Medical Association, 1991; 265:3265-69.

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14A

M-2, Part VI
Chapter 14
APPENDIX 14A

March 14, 1994

MANDATED COMPONENTS OF THE LABORATORY QUALITY ASSURANCE PLAN

~~This page not available on WANG~~

~~A copy may be made in the Under Secretary for Health's Library
Room 662, Techworld~~

14A-11

14A-11

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14A

M-2, Part VI
Chapter 14
APPENDIX 14A

March 14, 1994

MANDATED COMPONENTS OF THE LABORATORY QUALITY ASSURANCE PLAN
Continued

~~This page not available on WANG~~

~~A copy may be made in the Under Secretary for Health's Library
Room 662, Techworld~~

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14B

M-2, Part VI
Chapter 14
APPENDIX 14B

March 14, 1994

TYPES OF LABORATORY QUALITY IMPROVEMENT PROGRAMS

~~This page not available on WANG~~

~~A copy may be made in the Under Secretary for Health's Library
Room 662, Techworld~~

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

SYSTEMATIC LABORATORY ERRORS

~~This page not available on WANG~~

~~A copy may be made in the Under Secretary for Health's Library
Room 662, Techworld~~

14B-14

14B-14

LIST OF RECOMMENDED PATHOLOGY AND LABORATORY MEDICINE
RISK FACTOR OUTCOME MONITORS

1. CLINICAL LABORATORY MONITORS

a. Outcome (output)

(1) Accuracy of Laboratory Testing

Risk Factor Indicator: Incidence of errors by type, by clinical significance and cause.

(2) Appropriateness of Turnaround Time for Emergency Requests

Risk Factor Indicator: Incidence of occurrence screen reports or patient incident reports associated with delays.

(3) Communication of "Critical" Values

Risk Factor Indicator: Appropriate communication and documentation of "panic" values.

(4) Employee Safety

(a) Risk Factor Indicator: Rate of job related injuries.

(b) Risk Factor Indicator: Compliance with mandatory training requirements.

b. Process (application)

(1) Appropriateness of Laboratory Test Requests

(a) Risk Factor Indicator: Inappropriate serial orders.

(b) Risk Factor Indicator: Inappropriate urgency requested.

(c) Risk Factor Indicator: Inappropriate blood culture requests.

(d) Risk Factor Indicator: Inappropriate coagulation test requests.

(2) Appropriateness of Specimens Submitted

(a) Risk Factor Indicator: Inappropriate specimens (Quality insufficient, labeling, error, leaking, etc.).

(b) Risk Factor Indicator: Inappropriate preservation of specimen

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

(3) Effectiveness of Inpatient Phlebotomy Performed by the Laboratory

(a) Risk Factor Indicator: Rate of successful venipunctures

(b) Risk Factor Indicator: Turnaround time for emergency requests for phlebotomy

(c) Risk Factor Indicator: Rate of contaminated blood cultures

(4) Appropriateness of Patient Identification

(a) Risk Factor Indicator: Mislabeled specimens.

(b) Risk Factor Indicator: Missing, incorrect or non-readable patient identification armbands.

(5) Appropriate Reporting of Laboratory Test Results

(a) Risk Factor Indicator: Accurate reporting of results via computer, i.e., result in computer matches the hard copy of the result in the chart.

(b) Risk Factor Indicator: Appropriate entry of corrected test results.

(c) Risk Factor Indicator: Appropriate charting of test results and tissue reports, for example SF 518, Blood Transfusion Requisitions, surgical, cytology, and autopsy reports and laboratory medicine test results.

(6) Reference Laboratory Performance

(a) Risk Factor Indicator: Incidence of complaints regarding the quality of results.

(b) Risk Factor Indicator: Delays in reporting of results.

c. Structure (input)

(1) Accuracy of Laboratory Testing (external Quality Improvement)

Risk Factor Indicator: Acceptable performance in the CAP proficiency testing survey program.

(2) Compliance with Accrediting Agency and Regulatory Requirements

Risk Factor Indicator: Acceptable performance on external inspections, i.e., CAP (College of American Pathologists), AABB (American Association of Blood Banks), JCAHO (Joint Commission on Accreditation of Healthcare Organizations), and FDA (Food and Drug Administration), and NRC (Nuclear Regulatory Commission).

(3) Incident Report Rate

Risk Factor Indicator: Rate of occurrence screens/patient incident reports complaints involving laboratory.

2. TRANSFUSION MONITORS

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

a. Outcome (output)

(1) Appropriateness of Red Blood Cell Requests

(a) Risk Factor Indicator: Concurrent and retrospective evaluation of transfusion indications of each non-preoperative request and preoperative request, respectively.

(b) Risk Factor Indicator: Retrospective evaluation of transfusion indications for all single unit transfusions.

(2) Appropriateness of Fresh Frozen Plasma Requests

Risk Factor Indicator: Concurrent and retrospective evaluation of transfusion indications of each request.

(3) Appropriateness of Platelet Requests

Risk Factor Indicator: Concurrent and retrospective evaluation of transfusion indications of each request.

(4) Appropriateness of Cryoprecipitate Requests

Risk Factor Indicator: Concurrent and retrospective evaluation of transfusion indications of each request.

(5) Appropriateness of Autologous Transfusion Program

Risk Factor Indicator: Rate of autologous transfusion compared to allogeneic (homologous) transfusion.

(6) Transfusion Reaction Rate

Risk Factor Indicator: Number and type of transfusion reactions.

(7) Incidence of Transfusion Transmitted Diseases

Risk Factor Indicator: Number, type, and incidence of transfusion-transmitted diseases, including, but not limited to, hepatitis, HIV (Human Immunodeficiency Virus), HTLV-1 (both clinical disease and seroconversions).

b. Process (application)

(1) Appropriateness of Red Blood Cell Requests

(a) Risk Factor Indicator: Adherence to the MSBOS (Maximum Surgical Blood Order Schedule) for preoperative requests.

(b) Risk Factor Indicator: Crossmatch: Transfusion Ratio.

(2) Appropriateness of Patient Identification

(a) Risk Factor Indicator: Mislabeled blood specimens.

(b) Risk Factor Indicator: Missing patient identification armbands.

c. Structure (input)

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

(1) Appropriateness of Blood Transfusion Consent

Risk Factor Indicator: Appropriate charting of blood transfusion consent according to local policy, i.e., separate form or not in chart.

(2) Appropriateness of Autologous Transfusion Program

14B-20

14B-20

(a) Risk Factor Indicator: Underutilization rate, i.e., patients also requiring allogeneic (homologous) transfusion.

(b) Risk Factor Indicator: Overutilization rate, i.e., outdating of unused units.

(3) Incidence of Blood Product Labeling Errors

Risk Factor Indicator: Labeling errors, i.e., errors which may potentially result in inappropriate transfusion of blood to a patient and might adversely affect the patient.

(4) Accuracy of Laboratory Testing

Risk Factor Indicator: Incidence of errors, by type, by clinical significance and cause.

(5) Appropriateness of Turnaround Time for Emergency Requests

Risk Factor Indicator: Incidence of occurrence screen reports or patient incidence reports associated with delays.

3. ANATOMIC PATHOLOGY MONITORS

a. Outcome (output)

(1) Appropriateness of Turnaround Time for Emergency Requests

Risk Factor Indicator: Incidence of deferred diagnoses on frozen section.

(2) Communication of Significant Diagnoses

(a) Risk Factor Indicator: Documentation of physician notification if a diagnosis of malignancy is made on tissue and review of the patient's diagnoses on file reveals that no prior malignancy existed or that this malignancy represents a new primary site, excluding basal cell carcinoma and carcinoma in situ.

(b) Risk Factor Indicator: Documentation of physician notification if peer review reveals a major discrepancy, i.e., change in diagnosis or therapy is necessary.

b. Process (application)

(1) Appropriateness of Material Submitted for Surgical and Cytopathology Diagnoses

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

(a) Risk Factor Indicator: Unsatisfactory histological slide preparation, i.e., quality of section, quality of stain and quality of coverslipping.

(b) Risk Factor Indicator: Unsatisfactory quality of slides prepared from bone marrow aspirates.

(c) Risk Factor Indicator: Unsatisfactory stain quality for bone marrow slide preparations, i.e., both aspirates and sections and other tissue sections and cytologic preparations.

14B-22

14B-22

(2) Appropriateness of Frozen Section Requests

Risk Factor Indicator: Inappropriate urgency (i.e., requests for which the surgeon is no longer available to receive the report)

(3) Accuracy of Surgical Pathology Reports

(a) Risk Factor Indicator: Correlation of diagnoses made on frozen sections compared to that on permanent sections

(b) Risk Factor Indicator: Correlation of diagnoses reported with that of review by a second pathologist.

(4) Accuracy of Cytology Reports

(a) Risk Factor Indicator: Correlation of diagnoses reported with that reviewed by a second pathologist.

(b) Risk Factor Indicator: Correlation of diagnoses made on cytopathologic reports with diagnoses on other cytopathology and surgical pathology reports on the same patient.

(5) Accuracy of Autopsy Reports

Risk Factor Indicator: Correlation of postmortem diagnoses with diagnoses reviewed by a second pathologist.

(6) Turnaround Times for Anatomic Pathology Reports

Risk Factor Indicator: Appropriateness of turnaround times for pathology reports to be determined by medical center's Clinical Executive Board.

(7) Appropriateness of Surgical Pathology and/or Cytopathology Reports

(a) Risk Factor Indicator: Incidence of significant typographical or SNOMED coding errors.

(b) Risk Factor Indicator: Incidence of incomplete reports, e.g., omission of staging information, omission of diagnoses.

(c) Risk Factor Indicator: Incidence of inadequate information on requisition forms.

c. Structure (input)

(1) Appropriateness of Premortem Diagnosis

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

Risk Factor Indicator: Correlation of premortem and postmortem diagnoses.

(2) Accuracy of Surgical Pathology Reports

(a) Risk Factor Indicator: Acceptable performance on external proficiency testing, i.e., AFIP (Armed Forces Institute of Pathology).

(b) Risk Factor Indicator: Incidence of cases identified for re-review by Tissue Committee, or other clinical conferences.

14B-24

14B-24

(3) Compliance with Accrediting Agency and Regulatory Requirements

Risk Factor Indicator: Acceptable performance on external inspections, i.e., CAP, AABB, JCAHO, FDA, and NRC.

(4) Incidence Report Rate

Risk Factor Indicator: Rate of occurrence screens/patient incident reports/complaints involving anatomic pathology

4. FIGURE 1

	<u># Monitors</u>	<u># Indicators</u>
1. Clinical Laboratory		
a. Outcome	4	5
b. Process	6	16
c. Structure	3	3
2. Blood Bank		
a. Outcome	7	8
b. Process	2	4
c. Structure	5	6
3. Anatomic Pathology		
a. Outcome	2	3
b. Process	7	12
c. Structure	4	5
TOTALS	40	62

LABORATORY CRITICAL INDICATORS EXCERPTED FROM THE
QUALITY IMPROVEMENT CHECKLIST (QUIC)

1. QUESTION

a. During your last Joint Commission on Accreditation of Healthcare (JCAHO) survey, how many Type I Recommendations were received by Pathology and Laboratory medicine service and ancillary testing sites:

(1) Were received: _____

(2) Have been resolved: _____

b. Rationale. JCAHO seeks to measure whether healthcare facilities have systems and structures in place to assist in the delivery of quality healthcare and services. Based on these surveys the JCAHO gives recommendations regarding deficiencies in specific standards. The more serious of these recommendations are termed "Type I Recommendations." The number of Type I Recommendations received is a measure of the lack of compliance with JCAHO standards and the facility's ability to implement processes to evaluate the quality of services provided. Compliance with these standards and accreditation by the JCAHO is a high priority in Department of Veterans Affairs (VA).

c. Definitions

(1) Type I Recommendations. The more serious deficiencies reported in the main JCAHO survey report. These recommendations (their number and weight) will determine the accreditation status. They must be addressed either through written reports prepared by the facility or focused surveys.

(2) JCAHO Survey. Medical centers use the Hospital Accreditation Program (HAP) Report. Independent Outpatient Clinics (OPCs) report from the last ambulatory care survey.

(3) Resolved. A written response from JCAHO accepting VA medical facility plan or the intent of the plan.

d. Possible Sources of Data

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

- (1) Office of Chief of Staff
- (2) Office of Director
- (3) Facility's most recent official JCAHO survey report

2. QUESTION

a. Have all the recommendations from the following surveys been resolved?

NOTE: NA can only be used as a response if you do not have a Nuclear Medicine Service.

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14E

M-2, Part VI
Chapter 14
APPENDIX 14E

March 14, 1994

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

	NA	YES	NO
(1) College of American Pathologists (CAP):	_____	_____	_____
(2) American Association of Blood Banks (AABB):	_____	_____	_____
(3) Nuclear Regulatory Commission (NRC):	_____	_____	_____
(4) Food and Drug Administration (FDA):	_____	_____	_____
(4) Office of Inspector General (OIG):	_____	_____	_____

b. Rationale. CAP, AABB, NRC, FDA, and OIG are all external reviewers which survey facility compliance with various laws, regulations, standards and guidelines. The resolution of recommendations provided by these various groups is an important measure of compliance with these respective requirements.

c. Definitions

(1) Recommendation. An identified deficiency in meeting a specified requirement listed on the final report issued by CAP, AABB, NRC, FDA, or OIG. They include only formal recommendations. For example, OIG reports often contain an attachment containing suggested areas for improvement. These are not considered recommendations for purposes of this report.

(2) Resolved. A written response from the surveying body (CAP, AABB, NRC, FDA, OIG) accepting the medical facility plan or the intent of the plan.

NOTE: If there have been no recommendations from any of these surveys, please answer the question with "yes."

d. Possible Sources of Data

- (1) Office of Chief of Staff; and
- (2) Final reports from CAP, AABB, NRC, FDA, or OIG.

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14E

M-2, Part VI
Chapter 14
APPENDIX 14E

March 14, 1994

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

3. QUESTION

a. What is the incidence of needlestick injuries among employees?

Cumulative Full-time Employee Equivalent	(FTEE)	Rate
Number of needlesticks		
_____	_____	_____

Does the employee health program have an established procedure for treatment of needlestick injuries?

YES _____

NO _____

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14E

M-2, Part VI
Chapter 14
APPENDIX 14E

March 14, 1994

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

b. Rationale

(1) Blood-borne pathogens such as Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV) can be transmitted from patients to healthcare workers by means of puncture wounds from needles and other sharp objects. The incidence of needlestick injuries can be reduced by the education of healthcare workers about the handling and disposal of needles and sharps, and by an active safety program. NOTE: Prior studies have shown that the incidence of needlestick injuries is highest among nurses, housekeepers, laboratory workers, and physicians.

(2) Any employee who is exposed to blood-borne pathogens as a result of a needlestick should be evaluated and treated according to a standard protocol which may include ascertainment of the employee's and the patient's serologic status (e.g., antibodies to HBV and to HIV) and, depending on the serologic status, treatment with hepatitis-immune globulin and/or zidovudine (AZT). Pre- and post-test counseling and careful attention to employee and patient confidentiality are essential ingredients of the postexposure protocol.

c. Definitions

(1) Needlestick. Wound caused by a needle, or wounds from other sharp objects. NOTE: This indicator does not pertain to exposures of employees when patients' body fluids are splashed on them.

(2) Cumulative FTEE. An average of all clinical and administrative staff as of the end of the reporting period.

(3) Employees. Cumulative FTEE

d. Possible Sources of Data

(1) Office of Director;

(2) Office of Chief of Staff;

(3) Employee health service;

(4) VA medical center safety officer; and

(5) 830 cost report.

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14E

M-2, Part VI
Chapter 14
APPENDIX 14E

March 14, 1994

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

e. Calculation. For the reporting period between April 1, and September 30, total FTEE year-to-date should be reported as cumulative FTEE.

$$\frac{\text{Numerator} = \text{Number of needlestick injuries}}{\text{Denominator} = \text{Cumulative FTEE for reporting period}} \times 100 = \text{Rate}$$

f. References

(1) Marcus, R., and the Center for Prevention and Disease Control (CDC) Cooperative Needlestick Surveillance Group, "Surveillance of Health Care Workers Exposed

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14E

M-2, Part VI
Chapter 14
APPENDIX 14E

March 14, 1994

to Blood From Patients Infected with the Human Immunodeficiency Virus," New England Journal of Medicine, 319: 118-23; 1988.

(2) DeLaune, S., "Risk Reduction Through Testing, Screening, and Infection Control Precautions with Special Emphasis on Needlestick Injuries. Infection Control Hospital Epidemiology, 1990; 11 (supp.): 563-5.

(3) Public Health Service statement on: "Management of Occupational Exposure to Human Immunodeficiency Virus, Including Considerations Regarding Zidovudine Post-exposure Use," Morbidity and Mortality Weekly Report (MMWR), 1990; 39/No. RR-1:1-14.

(4) Recommendation of the Advisory Committee on Immunization Practices (ACIP) "Protection Against Viral Hepatitis," MMWR 1990; 39/No. RR-2:1-26.

4. QUESTION

a. What is the VA medical center autopsy rate for the survey period?

Number of Autopsies	Total Number of Deaths	Percent
_____	_____	_____

b. Rationale

(1) In the past 50 years, autopsy rates have fallen in American hospitals from over fifty percent to as low as three percent in some metropolitan hospitals. Many factors have contributed to this decline in autopsy rates. They range from belief by physicians that sophisticated modern technology leaves no diagnosis unmade, to concern about litigation over findings, lack of direct reimbursement, family wishes, religious beliefs, and the lengthy time to obtain full reports. Nonetheless, several studies have shown that 10 to 20 percent of autopsies involved unexpected findings.

(2) Autopsy provides a "gold standard" for clinical diagnostic accuracy and represents the most definitive quality assurance measurement tool for testing premorbid diagnostic hypotheses and confirming results of non-invasive tests regarding anatomic pathology. Death certificate listing of cause of death is best tested by autopsy findings. Reports of autopsy findings, especially when at variance with clinical diagnoses, discussed in medical staff meetings and shared with practitioners, is a powerful tool for improving quality of care.

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

c. Definition

Autopsy. A thorough examination of the body after death which includes gross examination of all body parts, cavities and organs and microscopic evaluation of selected tissues plus other specialized tests as indicated. The autopsy may be limited to certain areas because of interest, or at request of next-of-kin.

d. Possible Source of Data

- (1) QUIC software extract report;

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14E

M-2, Part VI
Chapter 14
APPENDIX 14E

March 14, 1994

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

- (2) Decentralized Hospital Computer Program (DHCP) database;
- (3) Medical Administration Service (MAS); and
- (4) Patient Treatment File (PTF).

e. Calculation. Deaths from community nursing homes, VA nursing homes and domiciliarys, and fee basis are not included in this autopsy rate.

$$\text{Numerator} = \frac{\text{Number of autopsies for the medical center during the survey period}}{\text{Denominator} = \text{Number of deaths during the survey period}} \times 100 = \text{Percentage}$$

f. References

- (1) Anderson, R. E., Hill, R.B., Gorstein F., "A Model for the Autopsy-based Quality Assessment of Medical Diagnostics," Human Pathology, 1990; 2:174-181.
- (2) Hill, R. B., Anderson, R. E., Vance, R. P., " The Autopsy: A Professional Obligation Dissected (editorial)," Human Pathology, 1990; 2:127.
- (3) Gloth, F. M. II, Burton, J. R., "Autopsies and Death Certificates in the Chronic Care Setting," Journal of the American Geriatric Society, 1990; 2:151-155.
- (4) Pelletier, L.L. Jr., Klutzow, F., Lancaster, H., "The Autopsy: Its Role in the Evaluation of Patient Care," Journal of General Internal Medicine, 1989; 7-8:300-303.
- (5) Landefeld, C.S., Goldman, L., "The Autopsy in Quality Assurance: History, Current Status, and Future Directions," Quality Review Bulletin, 1989; 2:42-8.
- (6) Goldman, L., Sayson, R., Robbins, S., et al., "The Value of the Autopsy in Three Medical Eras," New England Journal of Medicine, 1983; 308:1000-5.

5. QUESTION

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14E

M-2, Part VI
Chapter 14
APPENDIX 14E

March 14, 1994

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

a. What is the average processing time for STAT Complete Blood Count (CBC) and chemistry electrolyte panel?

(1) During regular hours _____

(2) During irregular hours _____

b. Rationale. Rapid processing time of urgently needed tests is indicative of appropriate and efficient handling of such specimens. Delays in processing may lead to delays in treatment which may reduce the quality of patient care.

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14E

M-2, Part VI
Chapter 14
APPENDIX 14E

March 14, 1994

c. Definitions

- (1) Regular Hours. 7:00 A.M. to 5:00 P.M., Monday through Friday.
- (2) Irregular Hours. 5:00 P.M. to 7:00 A.M., Monday through Friday, weekends, and holidays.
- (3) Processing Time. Elapsed time between specimen arrival at the laboratory and date and time completed.
- (4) CBC. CBC and/or CBC with automated differential.
- (5) Electrolyte Panel. Most commonly ordered chemistry panel, or panels, which minimally include electrolytes, but which do not usually exceed seven tests

d. Possible Sources of Data

- (1) QUIC software extract report;
- (2) DHCP: Laboratory package; and
- (3) Pathology and Laboratory Medicine Service workload.

e. Calculation. Two calculations are required, one for regular hours) and one for irregular hours.

$$\text{Numerator} = \frac{\text{Total processing time for stat CBC and chemistry electrolyte panels for 7 calendar days during regular(or irregular) hours}}{\text{Average time}}$$

$$\text{Denominator} = \text{Total stat CBC and chemistry electrolyte panels processed tests during that same period}$$

f. References

- (1) Barnett, R. N., McIver, D. D., and Forton, W. L., "The Medical Usefulness of STAT Tests," American Journal of Clinical Pathology, 1978; 69:520-24.

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

(2) Kost, G. J., "Critical Limits for Urgent Clinician Notification at US Medical Centers," Journal of the American Medical Association, 263(5):704-707.

(3) Belsey, R., "Controlling the Use of STAT Testing," Pathologist, 1984; 8:474-77.

6. QUESTION

a. Is there a mechanism for promptly notifying the responsible physician of a "critical lab value"?

YES _____ NO _____

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14E

M-2, Part VI
Chapter 14
APPENDIX 14E

March 14, 1994

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

b. Rationale. Certain laboratory values, e.g., hyperkalemia, hypoglycemia, or hyperglycemia, among others, indicate the need for immediate therapy; therefore, the responsible physician must be alerted promptly. CAP requires that the laboratory have a notification protocol and a list of critical limits that will trigger the notification process. Documentation of contact should also exist. The most frequent communication breakdown occurs when the responsible physician cannot be reached and a message is left with the intermediary.

c. Definitions

(1) "Critical" Values. The range of values and the specific analyses which qualify as "critical" values are defined by the medical staff and the Ancillary Testing Committee, and approved by the Clinical Executive Board (CEB).

(2) Mechanism. Method is outlined in clinical laboratory manual, nursing service manual, or minutes of the CEB.

d. Possible Sources of Data

- (1) Local nursing service manual;
- (2) Local clinical laboratory procedure manual;
- (3) DHCP, the Laboratory Package; and
- (4) CEB minutes.

e. References

(1) Kost, G. J., "Critical Limits for Urgent Clinical Notification at US Medical Centers," Journal of the American Medical Association, 1990; 63(5):704-707.

(2) Lundberg, G. D., "Critical Value Notification, an Established Practice Policy," Journal of the American Medical Association, 1990; 63(5):709.

7. QUESTION

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14E

M-2, Part VI
Chapter 14
APPENDIX 14E

March 14, 1994

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

a. What is the rate of blood tests per patient days of care (PDOC) in acute medicine and surgery?

Number of Blood Tests	Total PDOC	Rate
_____	_____	_____

b. Rationale. When laboratory tests are inappropriately ordered or unnecessarily repeated, healthcare costs rise. Proper utilization management requires sound clinical judgment which minimizes patient risk and discomfort while improving cost- effectiveness of laboratory testing.

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14E

M-2, Part VI
Chapter 14
APPENDIX 14E

March 14, 1994

c. Definitions

(1) PDOC. The number of days of care for an in-patient, occurring between admission and discharge in the survey period in which they occur. Excluded are: pass days, authorized absences, carryover days, days for patients in neurology, psychiatry, rehabilitation and all extended care beds (nursing home care units and intermediate medicine).

(2) Laboratory Blood Tests. All laboratory blood tests specifically identified in the QUIC user manual.

d. Possible Source of Data. QUIC software extract report.

8. QUESTION

a. How many hemolytic transfusion reactions occurred during the survey period?

b. Rationale. Hemolytic transfusion reactions are due to an ABO (this acronym signifies the names of the blood groups in the immunohematologic process of compatibility testing) incompatibility and may be a result of a clerical, nursing, technologist, or physician error and are a serious patient care concern. Causes of such errors should be promptly identified and corrected to prevent further compromise to quality of care in transfusion therapy.

c. Definition

Transfusion Reactions. A reaction due to ABO incompatibility recognized during the survey period.

d. Possible Sources of Data

- (1) Director of Blood Bank;
- (2) Tissue Transfusion Committee; and
- (3) DHCP, the Occurrence Screening Package

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

e. References

- (1) M-2, Part I, Chapter 12.
- (2) M-2, Part VI, Chapter 5.
- (3) Huestis, D. W., Bove, J. R., et al., Blood Transfusion, 4th Edition, Boston, Little, Brown, 1988.
- (4) Davis, K. G., Abbott, R. L., "Delayed Hemolytic Transfusion Reactions: Review of Three Cases," Medical Journal, August 1982; 1:335-37.

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14E

M-2, Part VI
Chapter 14
APPENDIX 14E

March 14, 1994

(5) Pineda, A. A., Taswell, H. F., Brzica, S. M. Jr., "Delayed Hemolytic Transfusion Reaction: An Immunologic Hazard of Blood Transfusion," Transfusion, 1978; 18:1-7.

(6) Schorn, T. F., and Knospe, W. H., "Fatal Delayed Hemolytic Transfusion Reaction Without Previous Blood Transfusion," Annual of Internal Medicine, 1989; 110:241-42

9. QUESTION

a. What percent of Staphylococcus aureus isolates were resistant to methicillin?

Number of Resistant Isolates	Total Number of Isolates	Percent
_____	_____	_____

b. Rationale

(1) Although there is no evidence that methicillin-resistant staphylococcus aureus (MRSA) is any more virulent or pathogenic than methicillin-sensitive staphylococcus aureus, MRSA infections and outbreaks in the hospital are very costly to contain and eradicate. MRSA patients must be isolated, and universal (or contact) precautions must be used by hospital personnel caring for them. At times it becomes necessary to close operating rooms or intensive care units to end an outbreak.

(2) The prevalence of MRSA varies across hospitals, even in the same city. On average, the prevalence of MRSA is about 15 percent in United States hospitals. Large urban and tertiary care facilities are at highest risk for outbreaks. Also, in some areas, a substantial and increasing proportion of residents of nursing home care facilities in the community are asymptomatic MRSA carriers. When these persons are admitted to the hospital, they may become point sources for MRSA outbreaks.

(3) Comparison of MRSA prevalence is only appropriate within an institution as the information is usable to detect new outbreaks. Comparisons with other facilities are usually meaningless.

c. Definitions

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14C

M-2, Part VI
Chapter 14
APPENDIX 14C

March 14, 1994

(1) Isolates. Specimens of body fluids from patients and staff from which MRSA were cultured and antibiotic susceptibilities were done. Isolation of the organism is the indicator, without regard to whether the organism was associated with colonization or with infection.

(2) Resistance to Methicillin. Determined on the basis of standard microbiologic techniques.

(3) Antibiotic Used to Identify MRSA. Examples: methicillin, oxacillin, nafcillin.

d. Possible Sources of Data

(1) QUIC software extract report; and

March 14, 1994

M-2, Part VI
Chapter 14
APPENDIX 14E

M-2, Part VI
Chapter 14
APPENDIX 14E

March 14, 1994

(2) DHCP, the Laboratory Package and/or Microbiology Trend Report

e. Calculation. All MRSA isolates from different sites of the same patient are counted, but repeated MRSA isolates from the same site of a given patient are counted only once.

$$\frac{\text{Numerator} = \text{Number of MRSA isolates}}{\text{Denominator} = \text{Total number of Staphylococcus aureus isolates cultured with antibiotic susceptibilities}} \times 100 = \text{percentage}$$

f. References

(1) Strausbaugh, L. J., Jacobson, C., et al., "Methicillin-resistant Staphylococcus Aureus in Extended Care Facilities: Experiences in a Veterans Affairs Nursing Home and a Review of the Literature," Infection Control Hospital Epidemiology, 1991; 12:36-45 (Portland).

(2) Cederna, J. E., Terpenning, M. S., et al., "Staphylococcus Aureus Nasal Colonization in Nursing Home: Eradication with Mupirocin," Infection Control Hospital Epidemiology, 1990; 11:3-6.

(3) Murray-Leisure, K. A., Geib, S., Gracely, D., et al., "Control of Epidemic Methicillin-resistant Staphylococcus Aureus," Infection Control Hospital Epidemiology, 1990; 11:343-50.

(4) Boyce, J.M., "Increasing Prevalence of Methicillin-resistant Staphylococcus Aureus in the United States," Infection Control Hospital Epidemiology, 1990; 11:639-42.

(5) "Methicillin-resistant Staphylococcus Aureus Outbreak at a Veterans Affairs Medical Center: Importance of Carriage of the Organism by Hospital Personnel," Infection Control Hospital Epidemiology, 1990; 11:291-6 (Charleston SC).

(6) Jones, R. N., Barry, A. L., et al., "The Prevalence of Staphylococcal Resistance for Penicillin-ase-resistant Penicillins," Diagnosis of Microbiology Infection Disorder, 1989; 12:385-94.

(7) Clinical Lab Standards of American Society of Microbiology.