Subject: LAB 12 QUALITY ASSURANCE PROGRAM - PERFORMANCE IMPROVEMENT PLAN

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Reviewed By: Zuretti MD, Alejandro (11/13/2014 11:04:00 AM)
Supporting Documents: Approval Workgroup: Laboratory Administration Approval Group
Revision: 3
PURPOSE: As part of University Hospital of Brooklyn’s ongoing quality improvement program, the Department of Clinical Pathology will maintain a planned and systematic performance improvement program for monitoring and evaluating the quality and appropriateness of laboratory services and for identifying and resolving problem.

POLICY: The Performance Improvement Program of the Department of Pathology has as its goal the effective measurement and assessment of the quality of clinical laboratory services at UHB. The Committee will meet monthly to discuss quality assessment activities related to the services provided (See attached Performance Improvement Plan).

RESPONSIBILITY:

- The Clinical Laboratory Director is responsible for establishing and implementing a Clinical Laboratory performance improvement plan. (Attachment 1) The plan shall integrate Clinical Laboratory quality assessment/improvement, continuous quality improvement (CQI) and quality control activities into a system that will foster improvement in patient care. The director also shall delegate responsibilities for monitoring, action, evaluation and reporting.

- The Clinical Laboratory Director or Designee will review and approve by signature, Laboratory Policies and Procedures yearly.

PERFORMANCE MEASURES:

At the meetings of the committee the following will be included in the agenda.

1. Indicators updates, reports, trend analysis

2. Incident Reports/Action Reports

3. Complaint Investigation Reports

4. Employee Incident/Accident Reports

5. Proficiency Tests – Outcomes; Exception Reports

6. Accrediting Agencies – New/changed standards; accreditation reports

7. Compliance with Performance evaluations, mandatory training, annual health assessment.

8. Other pertinent issues brought to the attention of the committee.

9. Issues to be forwarded to UHB Quality Management/PI department.

10. Pathology performance improvement indicators are presented to the Executive Performance Improvement Council on a quarterly basis for review.

11. Outreach activities.
Annual Plan for Improvement of Organizational Performance and Patient Safety

Department of Pathology

University Hospital of Brooklyn
A. PURPOSE:

The Plan for Improvement of Organizational Performance and Patient Safety (the “Plan”) provides the framework to plan, develop, assess and improve the quality and safety of patient care in the Department of Pathology (the “Department”), University Hospital of Brooklyn.

Health care in the Department of Pathology should be

Safe – avoiding injuries to patients from the care that is intended to help them;

Effective – providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding under-use and over-use, respectively);

Patient-centered – providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions;

Timely – reducing waits and sometimes harmful delays for both those who receive care and those who give care;

Efficient – avoiding waste, including waste of equipment, supplies, ideas and energy;

Equitable – providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socio-economic status.

B. OBJECTIVES

The specific purpose of the Plan is to achieve optimum outcomes of care and to minimize the risk of harm to patients, visitors and staff by establishing an environment that encourages and facilitates:

- Recognition and acknowledgement of risks and unanticipated adverse events;
- Review of reported risks to identify underlying causes and system changes needed to reduce the likelihood of recurrence;
- Investigation of factors that contribute to unanticipated adverse events;
- Actions to reduce these risks and adverse events;
- Reporting internally on risk reduction initiatives and their effectiveness;
- Sharing of knowledge to effect organizational and behavioral changes in healthcare practice internally and with other departments;
- Focus on processes and systems with minimization of individual blame or retribution for involvement in a medical/healthcare error;
- Prospective analysis of selected healthcare services before an adverse event occurs to identify system re-design that will reduce the likelihood of error;
- Departmental learning about medical and healthcare errors and performance improvement principles and practices;
- Integration of performance improvement and patient safety priorities into the new design and re-design of all relevant Departmental facilities, processes, functions and services;
- Systematic and interdisciplinary planning, analysis and monitoring of performance to improve and sustain advances in structures, processes and outcomes of patient care;
- Regular re-assessment and establishment of Departmental performance improvement priorities;
- Meeting and exceeding the expectations of patients, visitors, and staff;
- Research into ways to improve patient safety and quality.

C. MEMBERS:
- Associate Directors Clinical Laboratories
- Chairman, Performance Improvement Committee, Department of Pathology
- Director, Clinical Laboratories
- Physician Representatives from Divisions (Anatomic Pathology and Clinical Pathology)
- Resident, Department of Pathology
- UHB Senior Administrator
- Laboratory Administrator
- Laboratory Supervisors
- Hospital Quality Management

D. COMMITTEE MEETINGS:
Meetings are held on the fourth Tuesday of the month.

E. SCOPE:
The scope of the Plan, its implementation, and evaluation of its effectiveness involves the entire Department, all its services, all professionals and staff, and is continuous. The Plan commits the Department, with support from the Hospital Department of Quality Management and Regulatory Affairs, to the continuous design, monitoring of performance, analysis of data and dissemination of information, and improving and sustaining performance while undertaking a proactive approach to the identification and mitigation of risks of errors.

F. PROGRAM:
1. 2011 -2012 Goals for Improvement of Organizational Performance:
   a. Provision of Care, Treatment and Services:
      i. To achieve and sustain 100% compliance with the National Patient Safety Goals.
      ii. To continue implementation of evidence-based practice.
   b. Management of Medications:
      i. To achieve 100% in compliance with proper ordering and administration of medications staff.
   c. Management of Information:
      i. To achieve and sustain 100% compliance with timeliness and legibility of documentation management.
1. **Leadership and Reporting Relationships**

The Chairman, Department of Pathology, as chief of service, is responsible for the Department’s Program for Organizational Performance and Patient Safety. Under the supervision of the Chairman, the Director of The Clinical Laboratories provides oversight of the Program. The Department Chairman appoints a senior Pathology attending physician as chairperson of the Departmental Performance Improvement Committee and all members of the Committee.

The Laboratory Director is responsible for reporting to the Executive Performance Improvement Council the results of the Department’s Performance Improvement activities, as well as for ensuring that the Departmental Committee receives and takes appropriate actions based upon feedback from EPIC.

The Pathology Interdisciplinary P.I. Program, in addition to dissemination of information to the departmental clinical staff, reports results from the program to several committees in the hospital. Formally the data from the program is reported quarterly to the Hospital’s Executive Performance Improvement Committee (EPIC). The Pathology P.I. Committee also refers data on an “as needed” basis to the various clinical and administrative departments within the hospital.

The Department Chairman and Director of the Clinical Laboratories or their designees are also members of committees that deal with quality issues in the hospital including the Executive Performance Improvement Committee (EPIC) and the Executive Committee of the Medical Board.

2. **Activities**

Successful implementation of the Performance Improvement and Patient Safety Program (the “Program”) in support of this Plan requires interdisciplinary actions to achieve the purposes set forth above. The interdisciplinary Departmental Program has three major components: Indicators; Case reviews; Education.
3. **Indicators for assurance of clinical quality and of regulatory compliance**

The indicators that are utilized in the Pathology PI program are both hospital-wide indicators and unit-specific indicators. The Pathology specific indicators are based on standard Laboratory volume and outcome indicators. Benchmarks are used, where applicable, for comparisons. The Pathology specific benchmarks were taken from industry best-practices, including UHC and various specialty societies. Examples of indicators are listed in the table, below:

**Hospital Wide Indicators**
- Transfusions
- Complaints
- Falls
- Patient Waiting Time
- Point of Care Testing
- Improvement Among Caregivers
- Compliance With National Patient Safety Goals
- Communication/Disclosure
- Timeliness
<table>
<thead>
<tr>
<th>Laboratory Section/Service</th>
<th>Topic</th>
<th>Description (Performed Monthly)</th>
<th>Objectives</th>
<th>Responsible</th>
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</thead>
<tbody>
<tr>
<td>Blood Bank</td>
<td>1. Turn Around Time (Min)</td>
<td>Median Transit Time, Intra-laboratory Turnaround Time, and Total Turnaround Time of 95% of Specimens</td>
<td>High Volume</td>
<td>UHB</td>
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<tr>
<td></td>
<td>2. Blood Unit Utilization (%)</td>
<td>Units of Blood Cross-matched Compared to Units of Blood Transfused (CT Ratio)</td>
<td>Financial</td>
<td>TJC</td>
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<td>3. Specimen Acceptability (%)</td>
<td>Blood Bank samples unacceptable for measurement divided by total number specimens received.</td>
<td>High Volume</td>
<td>UHB</td>
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<td></td>
<td>a. By Service</td>
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<td></td>
<td>b. ED</td>
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<td>c. Cord specimens</td>
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<td>Microbiology</td>
<td>1. Blood Culture Contamination Rate (%)</td>
<td>Number of Contaminated Blood Cultures divided by Total Number of Positive Blood Cultures</td>
<td>High Volume</td>
<td>UHB</td>
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<tr>
<td>Hematology</td>
<td>1. Turnaround Time for ED Specimens (Min)</td>
<td>Transit Time, Intra-laboratory Turnaround Time, and Total Turnaround Time of 95% of Specimens</td>
<td>High Volume</td>
<td>UHB</td>
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<tr>
<td></td>
<td>a. PT</td>
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<td>b. APTT,</td>
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<td>c. CBC</td>
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<tr>
<td>Hematology contd’</td>
<td>2. Turnaround Time for ED Stroke Patients Tests (%)</td>
<td>% of ED PT, APTT, and CBC results completed within 45 minutes</td>
<td>Problem Prone</td>
<td>NYS DOH</td>
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<tr>
<td></td>
<td>a. PT</td>
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<tr>
<td></td>
<td>b. APTT</td>
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<td></td>
<td>c. CBC</td>
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<td>Timeliness of Critical Value Calls (%)</td>
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<td>Number of Critical Value call completed within fifteen (15) minutes divided by the total number of Specimens requiring Critical Value Report Calls</td>
<td>Problem Prone</td>
<td>NYS DOH</td>
</tr>
<tr>
<td>Chemistry/Blood Bank</td>
<td>1. Turnaround Time (Min)</td>
<td>Transit Time, Intra-laboratory Turnaround Time, and Total Turnaround Time of 95% of Specimens.</td>
<td>High Volume</td>
<td>UHB</td>
</tr>
<tr>
<td></td>
<td>a. Troponin</td>
<td></td>
<td>Problem Prone</td>
<td>UHB</td>
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<td>b. Basic Metabolic Panel</td>
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<td></td>
<td>2. ED Hemolyzed Specimen Rejection Rate (%)</td>
<td>ED Hemolyzed rejected specimens divided by total number of ED specimens</td>
<td>Problem Prone</td>
<td>UHB</td>
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<tr>
<td>Virology</td>
<td>1. Expedited HIV specimen testing (%)</td>
<td>Number of expedited requests on newborns divided by the number of newborn births</td>
<td>Problem Prone</td>
<td>NYS DOH</td>
</tr>
<tr>
<td></td>
<td>2. Expedited HIV Testing Turnaround Testing (%)</td>
<td>Specimens Completed Within 12 hours Divided by the Total Number of Specimens Tested</td>
<td>Problem Prone</td>
<td>NYS DOH</td>
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<tr>
<td>Accessioning</td>
<td>1. AM Inpatient Specimen Collection TAT</td>
<td>Accessioning &amp; Intra-laboratory Turnaround</td>
<td>High Volume</td>
<td>UHB</td>
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<td>OPD</td>
<td>1. Pt. Phlebotomy Waiting Time (Min)</td>
<td>Time Patients Wait For Phlebotomy</td>
<td>Alignment with strategic goals</td>
<td>UHB</td>
</tr>
<tr>
<td>Histocompatibility</td>
<td>1. Delinquent Sera (%)</td>
<td>Number Sera Not Received in 30 days Divided by the Number of Active Potential Recipients</td>
<td>Problem Prone</td>
<td>UHB</td>
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<td>2. Deceased Donors Specimen Turnaround Times (%)</td>
<td>Number of Deceased Donors With Specimen TAT &lt; 7 hours Divided By Total Number of Specimens.</td>
<td>Problem Prone</td>
<td>UHB</td>
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<td>3. Unacceptable Specimens (%)</td>
<td>Number of Hemolyzed Specimens Divided by Total Number of Sera.</td>
<td>Problem Prone</td>
<td>UHB</td>
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<tr>
<td>POC</td>
<td>Competent Operators (90)</td>
<td>Number of Testing Personnel Competency Up to Date Divided by Number of Testing Personnel</td>
<td>Problem Prone</td>
<td>CLIA ’88</td>
</tr>
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| POCT contd’               | 2. ED Glucose Errors (%)  
  a. No Physician Order  
  b. Improper Pt. ID | Number of Erroneous Glucose Results divided by total number of Glucose Results | Problem Prone | CLIA ’88, NYS DOH |
|                           |       |                                 |            |             |
| Bay Ridge                 | Timeliness of critical Value Calls (%)  
  2. Turnaround Time for UCC Specimens (Min)  
  a. PT/APTT  
  b. CBC  
  c. BMP | Number of Critical Value call completed within fifteen (15) minutes divided by the total number of Specimens requiring Critical Value Report Calls  
  Transit Time, Intra-laboratory Turnaround Time, and Total Turnaround Time of 95% of Specimens | National Patient Safety Goal  
  High Volume | TJC  
  UHB |
| Surgical Pathology        | Delayed Turn Around Time (%)  
  a. Biopsies  
  b. Surgical Specimens  
  Deficient Clinical Information on Requisitions (%)  
  Consultation | Number of Specimens With Delayed Turn Around Time (TAT) Divided by the Total Number of Specimens.  
 Number of Specimens Deficient in Pertinent Clinical Information on Surgical Pathology Requisitions Divided by the Total Number of Surgical Pathology Specimens/Requisitions.  
 Surgical Pathology Consultations: number of major discrepant diagnosis over the total number of cases sent out | High Volume  
 Problem Prone  
 Alignment with strategic goals | TJC  
 UHB  
 UHB |
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<tr>
<td>Surgical Pathology Cont’d</td>
<td>Delayed Frozen Sections (%)</td>
<td>Number of Frozen Sections TAT Delayed (&gt;20 minutes) Divided By Total Number of Frozen Sections</td>
<td>Problem Prone</td>
<td>TJC</td>
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<td>Discrepant Clinical Diagnosis (%)</td>
<td>Number of Specimens Clinical Dx and Path Permanent Section Dx Disagree Divided by Total Number of Cases Compared</td>
<td>High Impact</td>
<td>CAP</td>
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<td>Specimens lost during processing (%)</td>
<td>Specimens lost during processing Divided by Total Number of Specimens Processed</td>
<td>High Impact</td>
<td>UHB</td>
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<tr>
<td>Autopsy Pathology</td>
<td>Delayed Routine Autopsy Turn Around Time (%)</td>
<td>Number of Routine Autopsy Cases Delayed Divided by the Total Number of Routine Autopsy Cases Signed Out.</td>
<td>Problem Prone</td>
<td>CAP</td>
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<tr>
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<td>a. Preliminary Report (&gt;1 Working Day)</td>
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<td>b. Final Report (&gt;30 Working Days)</td>
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<td>Delayed Neuropathology Autopsy Cases (%)</td>
<td>Neuropathology Autopsy Cases Requiring More than 60 working days To Signout Divided the Total Number of Neuropathology Autopsy Cases Signed Out.</td>
<td>Problem Prone</td>
<td>CAP</td>
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<td>Inaccurate Identification of Cadavers (%)</td>
<td>Number of Cadavers Inaccurately Identified Divided by the Total Number of Cadavers Identified.</td>
<td>Problem Prone</td>
<td>UHB</td>
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<tr>
<td>Cytopathology</td>
<td>Delayed Case Turn Around Time (%)</td>
<td>Number of Cases Delayed Divided By the Total Number of Cases.</td>
<td>High Volume</td>
<td>TJC</td>
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<td></td>
<td>a. Gyn Cases (1 Day)</td>
<td>Number of Cases in SIL Category Divided by the Total Number of Cases.</td>
<td>High Impact</td>
<td>CAP</td>
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<td></td>
<td>b. Non-Gyn Cases (2 Days)</td>
<td>Number of Cases in HGSIL Category Divided by the Total Number of Cases.</td>
<td>High Impact</td>
<td>CAP</td>
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<td>Cases Classified as SIL (%)</td>
<td>Number of scanty and inadequate specimens submitted divided by the total number of specimens submitted.</td>
<td>High Impact</td>
<td>CAP</td>
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<td>Cases Classified as HGSIL (%)</td>
<td>Number of Cytology Cases/Surgical Biopsy Discrepant Correlations Divided Total Number of Cytology Cases/Surgical Pathology Cases Correlated.</td>
<td>High Impact</td>
<td>CAP</td>
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<td>Unsatisfactory Specimens For Pap (%)</td>
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<td></td>
<td>Cytology/Surgical Pathology Discrepant Specimen Correlation (%)</td>
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1. **Case reviews to identify new opportunities for quality improvement and patient safety**

The second part of the Pathology PI program consists of case reviews. All case reviews are coordinated through the PI Chairman. Cases for review are selected from internal referrals, patient relations referrals (e.g. patient complaints), hospital incident reports, and other hospital services referrals. Any referral that has a quality of care component is peer-reviewed. All physician faculty members, in the Department of, are expected to take part in the departmental PI program and can be assigned cases for review. For physicians and other staff credentialed through the medical board, copies of case reviews in which they were involved are kept in their departmental quality file and used during the re-credentialing process.
2. **Education and in-service training to ensure that attending physicians, residents, and staff maintain current knowledge of regulatory requirements and public health alerts**

The Departmental compliance program ensures the Department’s practices adhere to federal laws, state laws, and hospital policies. Each month at the PI Committee meeting any updates or clarifications from the various regulatory bodies are discussed as they pertain to Pathology. After a new material is discussed in the PI meeting, attending physician, resident physician and staff education or in-service training is conducted. The Laboratory Administrator is responsible for in-servicing the non-physician staff. The Clinical Laboratory Director is responsible for educating the physicians. Faculty are typically educated during the monthly departmental faculty meetings and through periodic electronic mailings.

Routine areas for compliance review include relevant updates, alerts, and changes in standards from the following agencies:

- **Centers for Medicare and Medicaid Services**
- **New York State Department of Health**
- **Joint Commission on Accreditation of Health Care Organization**
- **College of American Pathologists**

4. **Additional Program Elements**

Additional program elements include the following:

a. All departments and employees within the Hospital (patient care and non-patient care departments) are responsible for reporting healthcare safety risks and occurrences. The Hospital has implemented Incidence/Occurrence Reporting (UHB Policy & Procedure RM-1) to ensure reporting. Summary data from the event reports are aggregated and reported periodically to the Safety Committee and to the Executive Performance Improvement Council who determine further risk reduction activities as appropriate.

b. Upon identification of a medical/healthcare error, the health care professional will immediately

   i. Perform necessary healthcare interventions to protect and support the patient’s clinical condition;
   
   ii. As appropriate to the occurrence, perform necessary healthcare interventions to contain/minimize the risk to others;
   
   iii. Contact the patient’s attending physician and other physicians, as appropriate, to report the error, carrying out any physician orders as necessary;
iv. Preserve any information related to the error or occurrence, including physical evidence (e.g., removal and preservation of blood units for a suspected transfusion reaction, or preservation of IV tubing, fluids, bags and/or pumps for a patient with a severe drug reaction from and IV medication, or preservation of any medication labels for medications administered to the incorrect patient). Preservation of information includes documenting the facts regarding the error or occurrence to the unit manager and to the organization’s Risk Management office using the event reporting system;

c. The Program includes a periodic assessment of patients, families, and staff (including Medical Board) opinions, as appropriate, regarding perceptions of risks to patients, the culture of the healthcare environment in respect to facilitation of safe practices, and suggestions for improving patient safety and clinical outcomes.

d. Patients and, when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes, as well as when the outcomes differ significantly from the anticipated outcomes, following guidelines outlined in UHB Policy & Procedure RM-9 Medical Disclosure.

e. Staff will educate patients and their families about their role in helping to facilitate the safe delivery of care. Patient and family safety education interventions will be documented in the patient’s medical record. Additionally, the Hospital continues to focus on ongoing patient safety initiatives, such as the National Patient Safety Goals.

f. Staff will receive education and training during their initial orientation and on an ongoing basis regarding job-related aspects of patient safety including the need and methods to report medical/healthcare related errors. Because the optimal provision of healthcare occurs in an interdisciplinary manner, staff will be educated and trained on interdisciplinary approaches to patient care.

g. Medical /healthcare errors and occurrences, including sentinel events, will be reported internally and externally as provided for in relevant hospital policies. External reporting will comply with all state and federal laws and regulations.

5. Prioritization and Plan Development

The criteria used to prioritize opportunities for improvement include, but are not limited to,

- Issues of non-compliance with laws and regulations;
- Sentinel Events;
• Opportunities with critical impact on patient care and safety;
• Opportunities with significant impact on patient care and safety;
• Problem prone areas;
• High volume/High risk potential activities;
• Opportunities with significant financial impact; and
• Opportunities with significant impact on public relations.

Based on these criteria, the global performance improvement priorities are:

- Quality of outcomes
- Quality of service
- Cost.

Performance improvement priorities and activities may be re-prioritized based on significant Departmental or Hospital performance findings or changes in regulatory requirements, patient population, environment of care, and expectations and needs of patients, staff or the community. Priorities may be re-set by the Department or by the Executive Performance Improvement Council in consultation with Senior Leadership and the Medical Board Executive Committee.

6. Monitoring and Evaluation

The monitoring and evaluation method selected for the Program is the PDCA process. The steps include the following:

- Plan the improvement and continued data collection
- Do the improvement and continued data collection
- Check and study the results
- Act to hold the gain and to continue to improve the process.

7. Coordination and Management of Data

The PI Chairman, with support from the Department of Quality Management and Regulatory Affairs, is responsible for ensuring that information gathering, data aggregation and report scheduling are performed consistent with this Plan.

The assessment and analysis of data will be accomplished by the medical, professional, and non-clinical staff through individual participation, through departmental performance improvement committees, or in committees of the Medical Board or the Hospital, as appropriate to the issues being considered.

The Quality Management and Regulatory Affairs department’s functions include, but are not limited to the following:

- Ensure the integration of information among the medical, professional and non-clinical staff and committees;
- Develop standardized formats for reporting from departmental committees to Executive Performance Improvement Council;
- Establish mechanisms for data collection, data and data-base management, and data presentation;
- Support the performance of the Sentinel Event root cause analyses and action plan development and tracking to goals;
- Ensure the reporting of appropriate data to the appropriate peer review processes of the Medical Board, including the compilation of performance improvement information that is required for review as part of the reappointment process;
- Advise and educate the committee and staff about data collection, display and interpretation.

G. **Confidentiality**

All information that is required to be collected and maintained pursuant to the Plan is strictly confidential and cannot be released unless such disclosure is specifically required by law and is stated in the Administrative Policies of University Hospital of Brooklyn. Any questions concerning disclosure of Performance Improvement materials or information should be directed to Office of Legal Affairs, SUNY Downstate Medical Center. In accordance with Section 6527 of the New York State Educational Law, except under extremely limited circumstances, neither the proceedings nor records relating to the performance or medical review functions are subject to disclosure. Additional, all information and activities required by the Medical Malpractice Reform Act of 1985 are further insulated from disclosure by Section 2805-m of the New York State Health Law.

H. **Adoption of Plan**  
The Plan has been reviewed and adopted by the Director of Department, the Chairman of Pathology, and the Chief Medical Officer as attested by the signatures below:

<table>
<thead>
<tr>
<th>Chairman, Department of Pathology PI Committee</th>
<th>Date</th>
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<tbody>
<tr>
<td>Director, Clinical Laboratories</td>
<td>Date</td>
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<tr>
<td>Chairman, Department of Pathology</td>
<td>Date</td>
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<tr>
<td>Chief Medical Officer</td>
<td>Date</td>
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<td>Interim Assistant Medical Director for Quality of Care</td>
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Director of Interdisciplinary Performance Improvement and Patient Safety Program

Job Description

1. Manage Pathology Performance Improvement Program
   a. Chair monthly UHB Pathology P.I. meeting
   b. Supervise collection of monthly indicators
   c. Analyze and interpret data
   d. Develop new indicators
   e. Help implement changes based on data

2. Manage Physician Peer Review Program
   a. Coordinate physician case reviews
   b. Coordinate ad hoc Sentinel Event / NYPORTS cases

3. Manage patient satisfaction program
   a. Support patient relations quarterly patient satisfaction survey
   b. Investigate and answer all written complaints
   c. Refer all quality issues from written complaints for peer review

4. Serve as department liaison for quality management
   a. Work with departmental P.I. Manager as departmental link to the hospital quality management program
   b. Educate staff with respect to changes in regulations