

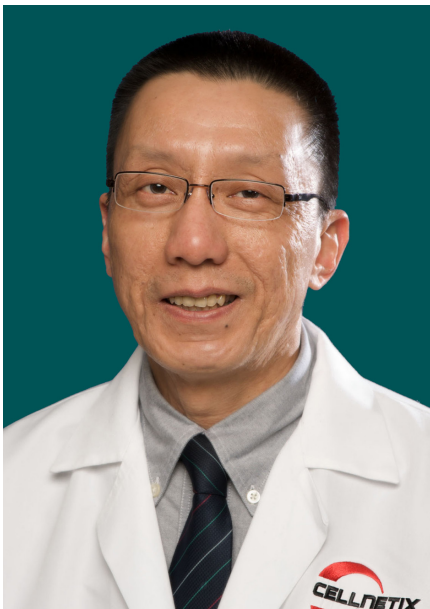
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The Role of Pathologists in ACOs

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include pathology groups. Lab services account for 10% of the costs of healthcare but influence 70% of decisions.

The College of American Pathologists (CAP) recently published a white paper "Contributions of Pathologists in Accountable Care Organizations: A Case Study".¹ In this case study, staff from CAP sought to gain an understanding of how some pathology practices have been able to take leading roles in ACOs. The paper discusses how pathologists have added value at three institutions through:

1. Development of protocols for laboratory ordering;
2. Population health management;
3. Improving physician access to actionable data from laboratory;
4. Greater collaboration with other clinicians.

In this article, we present some of the ACO relevant initiatives that CellNetix laboratory medical directors and pathologists have introduced to create value at Providence Regional Medical Center at Everett (PRMCE). CellNetix

INTRODUCTION

Accountable Care Organizations (ACOs) are provider-based organizations that take responsibility for meeting the health care needs of a defined population with the goal of simultaneously improving health, improving patient experience and reducing per capita costs. It is the latest trend to restrain the growth in US healthcare spending. It represents an attempt to address the

problems of a fragmented, largely fee-for-service-based medical care system that rewards provision of services rather than achievement of outcomes, contributing to rapid growth in health care spending (now over 17% of GDP) and a system in which as much as 30% of costs are generated because of overuse, underuse, and misuse of health care services.

Successful ACOs will need to

medical directors have introduced similar initiatives at Providence St Peters, Providence Olympia, Swedish Hospitals, Northwest Hospital, Deaconess Hospital (Spokane) and Mat-Su Regional (AK).

PRMCE colloquially known as "Prov Everett" is a 468 bed full-service medical center and one of the largest hospitals of Providence Health and Services, the largest faith-based healthcare system in the Northwestern United States. It serves patients from Snohomish County, Skagit County, Whatcom County, Island County, and San Juan County, Washington.

Blood Management Program

Although the blood supply today is thought to be the safest it has ever been, blood transfusion still has risks, both infectious and non-infectious. Infectious risks remain because blood donors do not always remember their travel or drug histories. Non-infectious complications include minor reactions like febrile and urticarial reactions, to severe ones like alloimmunization, circulatory overload, transfusion related acute lung injury and graft versus host disease.

At PRMCE, we have a prospective (real-time) audit - review of individual transfusion requests before issuing of blood components. If the patient's hemoglobin, hematocrit, platelet count or INR fall outside transfusion triggers (transfusion triggers are based on recommendations from the AABB), the medical director reviews the clinical charts and notes the clinical indications. When the clinical

documentation is unclear, the clinician is called. The medical director also prepares a quarterly report of all transfusions that fall outside triggers for the division chiefs.

The number of blood units transfused has dropped more than 5% between the beginning of 2011 to the end of 2012, even though the patient days, admissions, surgeries and deliveries have increased by 8.6%, 11.6%, 15% and 15% respectively.

This drop is significant when considering the cost of blood products:

Packed red blood cells - \$200-300

Fresh frozen plasma - \$75-85

Platelets - \$550-600

Tests Utilization

Dr. Curtis Hanson of Mayo Medical Laboratories defines tests utilization as a "strategy for performing appropriate laboratory and pathology testing with the goal of providing high-quality, cost-effective patient care."

Laboratory testing on inpatients usually is reimbursed under a diagnostic-related group (DRG) - the hospital is paid a fixed rate for the DRG diagnosis regardless of how many tests are ordered. Reducing laboratory testing will, therefore, reduce costs and improve the finances of the hospital.

Our guiding principles for tests utilization control are:

1. The interest of the patient comes first
2. The focus is on good medical practice - test utilization

strategies that are supported by literature or data

3. Order tests that are required for clinical decision making during the inpatient stay

Tests management control is about appropriate utilization to achieve efficient and cost effective care, and not just cost containment. Quality of care and patient safety is never compromised. If the focus is solely on money, clinicians will be skeptical and the effort will have mediocre success.

We have introduced several initiatives that are supported by literature.

The first example is cytogenetics and Fluorescent In-Situ Hybridization (FISH) tests for hematologic malignancies. Both conventional cytogenetics and FISH panels cost \$400-500.

Dr. Paul Kurtin of Mayo's Division of Hematopathology, shared their experience of diagnostically efficient, cost effective test use for hematologic malignancies in the December 2012 edition of CAP Today.² Mayo's practice data show that cytogenetics and FISH in staging bone marrows does not improve sensitivity for lymphoma pickup above morphology and phenotyping, and Myelodysplastic Syndrome (MDS) FISH adds little value when the conventional cytogenetics study has 20 or more metaphases. We have adopted these practices after discussion with our oncologists.

Anatomic pathology services should also be considered as best practices for resource utilization are set forth in the setup of an ACO.

CellNetix has recently implemented a new testing paradigm for Helicobacter pylori testing on gastric biopsy samples. The historical practice in our community for many years had been "up front" immunohistochemical testing of all gastric biopsies performed to rule out gastritis. Recent literature suggests that upwards of 90% of H. pylori infections can be diagnosed by routine hematoxylin and eosin staining alone with IHC testing likely only needed in 10% of cases in which a specific interpretation is not possible on routine staining. Based upon the newer literature³ we have implemented a new approach to the work up of gastric mucosal biopsies obtained by endoscopy in which the routine H&E stained slides are first viewed by the pathologist of record and IHC testing is ordered only if needed to refine the diagnosis. This change in practice pattern has the potential to result in significant cost savings without diminishing quality of care.

To tackle the expensive, lower volume send-out tests, the laboratory medical director had discussions with the directors of oncology and neurology who became strong advocates in their departments for limiting the use of certain esoteric laboratories.

Many of the laboratory tests, especially genetic tests, that are sent out to these laboratories have turnaround times that are in weeks. These tests can be ordered during outpatient visits as they are not required for clinical management during the inpatient stay. An example is the complete ataxia (movement disorder) evaluation that has DNA sequencing analysis for detecting mutations of multiple genes that has

a turnaround time of 35 days; the average inpatient stay is 4.6 days.

Pathologists-driven gatekeeping measures are supported by an interdisciplinary body (Pharmacy & Therapeutics committee) and the Medical Directors Council chaired by the Chief Medical Officer. Their support is crucial or the tenure of the laboratory medical director may be short.

Administering Cost Effective Laboratories

Chemistry instruments currently in use are sophisticated and have good precision. We compared the original and repeated values of various analytes at their critical values and found no discrepancies. We stopped repeating critical values for many chemistry analytes in 2010 and this has lessened the work for technical staff and improves the turnaround time. This practice change was supported by a CAP Q-Probes study "Utility of Repeat Testing of Critical Values"⁴ that concluded that repeat testing is an unnecessary step that delays the reporting of critical results.

Optimizing Protocols

Massive hemorrhage is a common complication in a number of clinical settings - trauma, cardiovascular and hepatobiliary procedures can frequently result in massive bleeding; postpartum hemorrhage events can complicate labor and delivery; and diverticulosis or varices can lead to significant gastrointestinal bleeding. Traditionally, resuscitation has been initiated with large volumes of crystalloid, accompanied by packed red blood cell (pRBC) therapy. However, newer military

and civilian studies show that the presence of coagulopathy is associated with poorer outcomes in patients with severe hemorrhage.

We have instituted a massive transfusion protocol (MTP) since December 2010 that includes early administration of plasma and platelets - the ratio of packed RBC to plasma was determined by the anesthesiology, obstetrics, emergency room, trauma and lab medical directors. We worked closely with nursing educators on the roles of nursing and laboratory staff during massive hemorrhage. MTP packs containing three O-negative packed red cells and two AB thawed plasma are stored in refrigerators in the emergency department and surgery so transfusion can be started immediately while the blood bank prepare the next round of type specific pRBC, platelets, and thaw fresh frozen plasma. The protocol was recognized as an "Exceptional Practice" by a recent Joint Commissions survey team.

Insourcing the Right Tests

Insourcing of tests can improve turnaround times and help physicians with decision making, some of which can decrease cost of drugs for the hospital.

Heparin-induced thrombocytopenia (HIT), formerly HIT type II, is a prothrombotic and potentially lethal disorder that occur in 0.2% to 5% of heparin-treated adults. The cardinal feature of HIT is thrombocytopenia. However, thrombocytopenia occurs in as many as half of all patients admitted to intensive care units.

When HIT is strongly suspected, physicians usually stop all heparin,

including heparin-containing flushes and catheters and promptly initiate a nonheparin parenteral anticoagulant. Two common non-heparin parenteral anticoagulants are argatroban (\$1,000 per 250 mg vial) and bivalirudin (\$700 per 250 mg vial). This group of drugs account for the highest expense in our formulary.

Because of the challenges of clinical diagnosis, physicians rely heavily on laboratory testing. The most widely used immunologic assay is the polyspecific solid-phase ELISA that has excellent negative predictive value. At PRMCE, we run the ELISA daily (previously a send out test with 2-3 days turnaround time) and negative results are reported the same day so physicians can discontinue the expensive drugs. Our 2011 data showed more than 90% of ELISA are negative; we save approximately \$50,000 when we don't have to give additional doses while waiting for test results.

The ELISA has poor positive predictive value. We have improved the specificity of the ELISA by incorporating magnitude of optical density (OD) of the ELISA, use of IgG specific ELISAs and heparin confirmation step. The laboratory medical director is available for consultation for equivocal results.

Close Collaboration with Clinicians

As targeted therapies for non-small cell lung cancers have become standard of care with specific anti EGFR and anti ALK medications moving into the medical oncology arsenal,⁵ the need for molecular testing to identify patient's who may benefit from such therapies is paramount. This testing is

comparatively expensive. In some centers, a "shotgun" approach to testing has been implemented in which all newly diagnosed adenocarcinomas of the lung undergo a panel of tests for molecular / genetic aberrations. At PRMCE, these new lung cancer patients are reviewed at the multidisciplinary lung cancer conference allowing for excellent communication between pathologists, surgeons, medical oncologist, radiation oncologists, pulmonologists, social services, and specialists in end of life care. This approach allows for a more refined approach to molecular test ordering and implementation in which the disease stage, patient's performance characteristics and relevant literature can be discussed. After such discussions, polymerase chain reaction testing and fluorescence in situ hybridization testing can be performed on the limited subset of patient's for whom targeted drug therapies may actually be implemented. By using this system, we prevent potentially "unnecessary" and expensive molecular testing in approximately 75% of patients with newly diagnosed primary adenocarcinomas of the lung.

This PRMCE case study demonstrates the meaningful impact that pathologists can have on cost and quality while optimizing patient care. As the medical directors of Hospital Clinical labs, pathologists need to be actively involved in both the design and implementation of ACOs and we believe that the successful models will do that.

Dr. Chong obtained his medical degree from the National University of Singapore and his MBA from the University of Dubuque in

Iowa. He is board certified in Anatomic and Clinical Pathology as well as Hematopathology. Dr. Chong completed a fellowship in Hematopathology from the M.D. Anderson Cancer Center in Texas.

Additionally, Dr. Chong completed residencies in Anatomic and Clinical Pathology at the Cleveland Clinic Foundation and in Histopathology at the Singapore General Hospital. He was also a medical officer in Internal Medicine and Community Medicine at the Ministry of Health in Singapore.

Dr. Chong joined CellNetix Pathology & Laboratories in 2010 and is currently the Clinical Laboratory Medical Director at Providence Regional Medical Center in Everett.

Dr. Sturgis joined the Everett staff of CellNetix in 2007, coming from Evanston, Illinois, where he was Director of Cytopathology at Evanston Northwestern Healthcare, as well as Assistant Professor of Pathology at Northwestern University Feinberg School of Medicine. He is a nationally recognized figure in Cytopathology and recently served as a member of one of the NCI Thyroid State of the Science Committees. Dr. Sturgis also functions as a reviewer for Cancer Cytopathology, Diagnostic Cytopathology, and Acta Cytologica.

Dr. Sturgis completed his Medical Degree at the University of Kansas School of Medicine. He is board certified in Anatomic and Clinical Pathology and in Cytopathology. Dr. Sturgis completed a fellowship in Cytopathology at M.D. Anderson Cancer Center in Houston and has additional sub-specialty expertise

in Fine Needle Aspiration and Pulmonary Pathology.

In 2011, he was appointed to the College of American Pathologists (CAP) Cytopathology Committee. The members of this committee function as an interface between the CAP and pathologists/hospitals in North America and abroad through work on educational programing, interlaboratory comparisons, proficiency testing,

quality assurance, performance improvement programs, cytopathology practice guidelines, and new technical developments in the field.

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