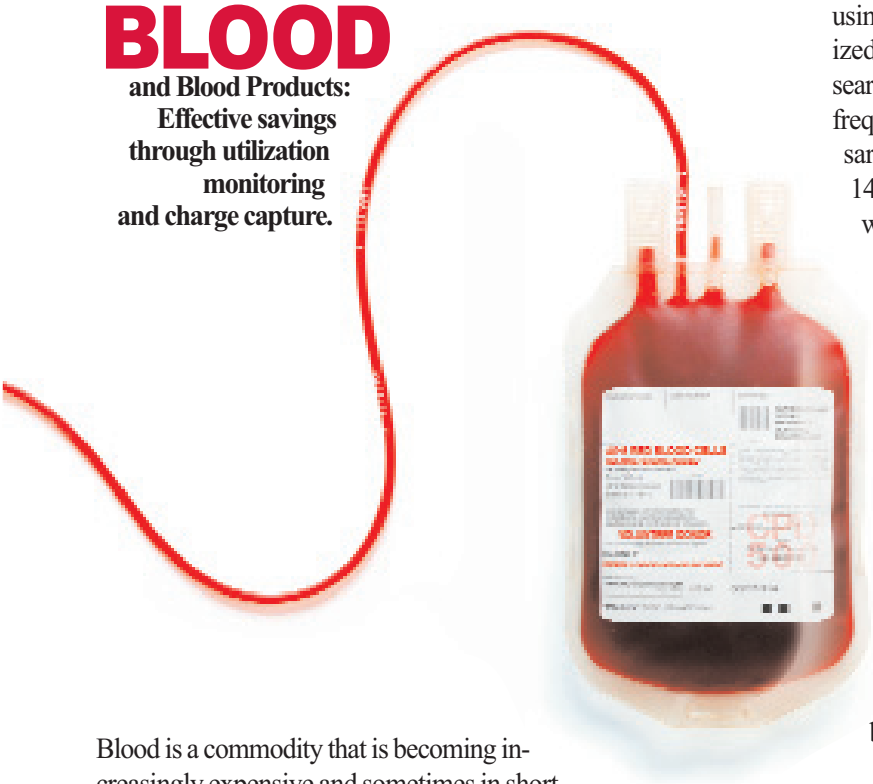
TRUSENT℠ NEWS
SOLUTIONS
A Healthcare Consulting Company
Fall/Winter 2013

126 East King Street
Lancaster, PA 17602-2893
ph: 717.399.1562 1.866.588.3444
www.trusentsolutions.com

BLOOD

and Blood Products: Effective savings through utilization monitoring and charge capture.



Blood is a commodity that is becoming increasingly expensive and sometimes in short supply mandating the rational use of blood and blood products through transfusion practices.[1] Many hospitals obtain blood and blood products from the Red Cross. The American Red Cross is the nation's largest blood collection organization, supplying more than 40 percent of the blood and blood products used in the United States. Each year they distribute 6 million units of red blood cells to approximately 3,000 hospitals and transfusion centers across the country.[2] It has been estimated that one unit of blood costs a hospital $278 from the American Red Cross and costs the organization up to $1,100 to acquire, test, store and transport according to a 2012 study.[3] Red blood cell transfusions are one of the most frequently performed procedures in United States hospitals, with one in ten inpatients receiving one or more units of blood.[4] The Joint Commission along with the American Medical Association has identified transfusion overuse as an area for concern. The group's recommendations included benchmarking and reporting physician metrics relative to their peers. The work group pointed out that there are many trials and guidelines available that are not being followed. As such, more guidelines are not the answer. The best solution to achieve sustainable progress in the use of blood and blood products is changing behaviors. This is best accomplished when supporting data are available.[5]

In May 2012, the American Association of Blood Banks issued updated guidelines recommending a restrictive transfusion strategy of using a hemoglobin trigger of 7 to 8 grams per deciliter in hospitalized, stable patients.[6] A study conducted by Johns Hopkins researchers in 2012 found wide variation in the use of transfusions and frequent use of transfused blood in patients where it was not necessary. A healthy adult's normal hemoglobin level is approximately 14 grams per deciliter. Recent studies suggest physicians can safely wait until hemoglobin levels fall to 7 or 8 before transfusing, even in some of the sickest patients.[7] Dr. Lawrence Goodnough, director of transfusion services at Stanford Hospital commented earlier this year that many physicians still use the 10 grams per deciliter hemoglobin level, which was pronounced more than three decades ago, as a trigger to automatically give a transfusion.[8]

Regions Hospital in St. Paul implemented a restrictive strategy for their joint surgery program resulting in only 5 percent of joint surgery patients receiving transfusions and a cost savings of $229,000 over two years.[9] Minneapolis-based Allina Health implemented a restrictive strategy of reducing the transfusion trigger from 8 to 10 grams per deciliter to 7 grams per deciliter in 12 hospitals and have used 14,000 fewer units of blood since January 2010.[10]

With a decrease in utilization, it becomes even more important to compliantly capture the costs associated with the blood bank services provided. From the laboratory perspective, that means capturing the costs for common services such as typing, screening, cross matching, platelet pooling, and splitting of units when they are ordered and provided. The CPT codes used for these common services include:

CPT Code	Description
86850	Antibody screen, RBC, each serum technique
86900	Blood typing; ABO
86901	Blood typing; Rh(D)
86922	Compatibility test each unit; antiglobulin technique
86923	Compatibility test each unit; electronic
86965	Pooling of platelets or other blood products
86985	Splitting of blood or blood products, each unit

There are also a host of other codes found in the Transfusion Medicine section (CPT codes 86850 – 86999) of the CPT Manual covering other blood bank services such as unit screening for antigens, pretreatment of RBCs or serum for antibody identification and screening for hemolysins to name a few. (cont. pg. 2)

[1]Ansari, S. and Szallasi, A. (2012). Blood management by transfusion triggers: when less is more. Blood Transfusion, 10:28-33. [2]American Red Cross. (2013). Lifesaving Blood. www.redcross.org, retrieved October 22, 2013: from http://www.redcross.org/what-we-do/blood-donation. [3]Frank, S.M. (2012, April 24). Johns Hopkins study shows wide variation in transfusion use in operating rooms. Hopkins Medicine, retrieved: October 22, 2013: www.hopkinsmedicine.org. [4]The Patient Safety Movement (2013, January 13). Action Plan to Address Red Blood Cell Transfusion Overuse. Patientsafetymovement.org, retrieved October 22, 2013: from http://patientsafetymovement.org/pdf/Solution-3%20-%20RBC%20Overuse%20-%20January%2013,%202013.pdf. [5]Shander, A. (2012, September 14) Appropriate Blood Management. Proceedings from the National Summit on Overuse. pp. 14-16. [6]AABB Press Release (2012, March 27). AABB Clinical Practice Guideline on Red Cell Transfusion Annals of Internal Medicine. www.aabb.org, retrieved October 22, 2013: from http://www.aabb.org/pressroom/pressreleases/ Pages/pr120327.aspx. [7]Frank, S.M. (2012, April 24). Johns Hopkins study shows wide variation in transfusion use in operating rooms. Hopkins Medicine, retrieved: October 22, 2013: www.hopkinsmedicine.org. [8]Allday, E. (2013, May 28) Are blood transfusions overused? SFGate, retrieved: October 22, 2013: www.sfgate.com. [9]Benson, L. (2013, October 7). More Minnesota hospitals reduce unnecessary blood transfusions. Minnesota Public Radio, retrieved October 22, 2013: minnesota.publicradio.org. [10]Olsen, J. (2013, October 21). At Twin Cities hospitals, doing more with less blood. Star Tribune, retrieved October 22, 2013: www.startribune.com.

Not only should the procedures performed by the blood bank be included in the Charge Description Master, but some data mining and/or claims analysis should be used to verify that these charges ultimately follow through to the final bill.

Implementing a restrictive transfusion strategy can save a hospital on transfusion costs, but with that strategy it is increasingly important to compliantly capture all the charges associated with the blood and blood products that are worked up and transfused

Recently Released Emergency Care Statistics

The Centers for Disease Control and Prevention (CDC), National Center for Health Care Statistics (NCHS) recently reported a significant increase in the percentage of hospital Emergency Department (ED) visits during which a patient was seen by a physician assistant or nurse practitioner. Between 2000 and 2010, this percentage increased from 7% to 17%. The percentage of ED visits during which a patient was seen by a physician assistant or nurse practitioner and did not see a physician increased from 3% in 2000 to 7% in 2010. The study was done as part of the National Hospital Ambulatory Medical Care Survey.

In 2010, the number of persons aged 65 and older was 40.3 million. This is an increase of 5.3 million people since 2000. The NCHS also reported that a total of 19.6 million ED visits were made by individuals in this age group during 2009-2010. NCHS reports this represents 15% of all ED visits in the United States. ED visits in the age group due to injuries accounted for 29.1 % during 2009-2010. During this same period, approximately 38.3% of patients in the 65 and over age group arrived at the ED via ambulance. And, approximately 36.5% of ED visits resulted in a hospital admission for this age group in 2009-2010. In the 75 to 84 and 85 and over age groups, 37.2 % and 43.3 % of ED visits resulted in hospital admissions.

To read more, see Albert, M.D., Michael et al, Emergency Department Visits by Persons Aged 65 and Over: United States, 2009-2010, NCHS Data Brief, No. 130, October 2013
www.cdc.gov/nchs ■

The Relationship Between Internal Audit and Compliance and Evaluating Compliance Effectiveness

The U.S. Department of Health and Human Services, Office of Inspector General's (OIG) Supplemental Compliance Program Guidance for Hospitals[1], noted that effective compliance programs generally include regular self-assessment and enhancement of the existing compliance program. The guidance further notes that "[h]ospitals should regularly review the implementation and execution of their compliance program's elements. This review should be conducted at least annually and include an assessment of each of the basic elements individually, as well as the overall success of the program." OIG's Supplemental Compliance Program Guidance for Nursing Facilities, contains similar language.[2]

The Institute of Internal Auditors' (IIA) International Standards For The Professional Practice of Internal Auditing (Standards) at standard 2110 Governance[3], indicates internal audit must assess the governance process including the "design, implementation and effectiveness of the organization's ethics-related objectives, programs and activities."[4] IIA's Practice Advisories 2110-2 Governance: Relationship with Risk and Control[5] and 2110-3 Governance Assessments notes the interconnectedness of governance, risk management and internal controls.[6] A look at the international banking supervisory authorities view on the relationship between Internal Audit and Compliance is informative and consistent with IIA's mandatory standards and strongly recommended guidance.

In June 2012, the Basal Committee on Banking Supervision[7] (Committee) published The internal audit function in banks. Principle 7, which states that: [t]he scope of the internal audit function's activities should ensure adequate coverage of matters of regulatory interest within the audit plan." At Principal 7, item (d) 39. and 41, states: "[t]he scope of the activities of the compliance function should be subject to periodic review by the internal audit function. The audit of the compliance function should include an assessment of how effectively it fulfills its responsibilities."[8] In April 2005, the Committee published Compliance and the compliance function in banks. Principal 8, Relationship with Internal Audit states "the scope and breath of the activities of the compliance function should be subject to periodic review by the internal audit function."[9]

In a 2006 article titled "Roles and Responsibilities - Corporate Compliance and Internal Audit," author Mark P. Ruppert noted the views of a focus group of Health Care Compliance Association and Association of Healthcare Internal Auditors members. "The Focus Group identified that internal audit['s]… work is governed by formal standards for the conduct of its work." Because compliance professionals are generally specialists not trained and experienced in auditing and accounting, compliance professional can reap many benefits from interaction with Internal Audit. The universe of risks for Internal Audit

extends beyond compliance risks and it is Internal Audit's world-view that can further enhance Compliance and their larger contextual understanding of compliance risks. At the same time, Internal Audit can equally benefit from interaction with the clinical, health information management and the other specialists that are typically part of compliance teams. Clearly, communication between Internal Audit and Compliance is advantageous to both.

Evaluating the design and effectiveness of the compliance function can be one aspect of Internal Audit's scope of work dependent on the engineering of the two functions within the organization. The Internal Audit Department can assess the design and effectiveness of compliance provided Internal Audit maintains its functional independence and auditor objectivity. Combining both departments has its operational benefits stemming from economies and efficiencies but, also has risks, including the preclusion of Internal Audit from evaluating the design and effectiveness of the Compliance function if independence and objectivity are not preserved.■

[1] OIG Supplemental Compliance Program for Hospitals, Notices, 70 Fed. Reg. 4874 (January 31, 2005).
[2] OIG Supplemental Compliance Program Guidance for Nursing Facilities, Notices, 73 Fed. Reg. 56848 (September 30, 2008).
[3] The IIA defines governance as "the combination of processes and structures implemented by the board to inform, direct, manage and monitor the activities of the organization toward the achievement of its objectives."
[4] (2012). International Standards For The Professional Practice of Internal Auditing (Standards) Standard 2110 and 2110.A1 Governance (p. 11). Institute of Internal Auditors (IIA).
[5] The IIA defines control as "any action taken by management, the board and other parties to manage risk and increase the likelihood that established goals will be achieved."
[6] (2012). Practice Advisory 2110-2 Governance: Relationship With Risk and Control and Practice Advisory 2110-3 Governance: Assessments. Institute of Internal Auditors.
[7] Created in 1974, the Basal Committee on Banking Supervision was established by central bank governors of the Group of Ten countries. Current membership is comprised of certain countries in Africa, the Americas, Asia, Europe, the Middle East, Oceania and Southeast Asia. The committee does not issue mandatory rules. Each country decides whether to implement the Committee's recommendations through their own legislative or regulatory process. (http://en.wikipedia.org)
[8] (2012) The internal audit function in banks (p 9). Basel Committee on Banking Supervision. Bank for International Settlement
[9] (2005) Compliance and the compliance function in banks (p.15). Basel Committee on Banking Supervision. Bank for International Settlement

Internal Audit, Compliance and Legal Interaction

In Thomas Reuters Accelus' The State of Internal Audit 2013 survey of 1,100 internal auditors spanning the globe and representing all sizes of internal audit departments from highly regulated industries, the frequency of interaction with Compliance and Legal were reported as follows:[1]

	Compliance		Legal	
	2102	2013	2012	2013
Weekly	32%	25%	13%	15%
Monthly	27%	18%	22%	19%
Quarterly	14%	10%	16%	13%
Annually	3%	4%	3%	4%
Ad Hoc	19%	25%	37%	40%
Not Sure	6%	18%	8%	9%

Thomas Reuters Accelus Cost of Compliance Survey 2013 surveyed over 800 compliance professionals from the global financial services industry. Survey participants were asked: "In an average week, how much time does your compliance team spend consulting with Legal, Internal Audit and Risk functions on compliance issues?" This information while not specific to the healthcare industry, may be viewed as an communications / interaction "indicator". Respondents reported the following:[2]

	Legal			Internal Audit			Risk		
	2011	2012	2013	2011	2012	2013	2011	2012	2013
<1hr.	31%	30%	28%	52%	52%	45%	32%	30%	33%
1-3	31%	37%	38%	29%	28%	33%	31%	30%	35%
4-7	17%	18%	17%	12%	12%	12%	22%	19%	17%
7-10	12%	7%	7%	4%	4%	5%	6%	7%	5%
>10	9%	8%	10%	3%	4%	5%	9%	8%	10%

The global survey found that 40% of United States financial services firms spent four or more hours interacting with Legal, representing the highest percentage of interaction from among the global areas surveyed. [3] ■

[1] Cowan, Michael, Hammond, Susannah and Walshe, Jane, (2013) The State of Internal Audit 2013, Thomas Reuters Accelus
[2] Hammond, Susannah and Walshe, Jane, (2013) Cost of Compliance Survey 2013, Thomas Reuters Accelus
[3] Ibid.

Sampling for Compliance: Selection Methods

The Institute of Internal Auditors (IIA) International Standards for the Professional Practice of Internal Auditing at Standard 2320 Analysis and Evaluation states: "Internal auditors must base conclusions and engagement results on appropriate analysis and evaluations."[1] Sampling is a method used to gather information about a population. Sampling selection methods are varied.

Sampling is an essential component to the compliance audit and monitoring functions. Sampling can be either statistical or non-statistical and involve retrospective or prospective claims, line items or other sample units. It is used in combination with other evidential gathering methods including inquiries and document analysis to measure characteristics within a population. Statistical sampling has two essential requirements, random selection and mathematical quantification. While statistical sampling has such benefits as the mathematical expression of the reliability of the results through the confidence level and confidence or precision interval, statistical sampling is not always appropriate. An analysis of the complete universe is sometimes more economical and efficient if the universe is small rather than selecting a sample. Also, where the analyst is determining the existence of an extremely rare instance or where complete accuracy or precise results is required, sampling is not appropriate.[2] In non-statistical sampling, the results apply only to the sample items analyzed. "Non-statistical sampling may be used when results are needed quickly and needed to confirm a condition rather than being

(cont. pg. 4)

analyzed. "Non-statistical sampling may be used when results are needed quickly and needed to confirm a condition rather than being needed to project the mathematical accuracy of the conclusions." [3] In statistical sampling, a sample can be obtained through random selection where each sample item has an equal chance of selection. The selection method can be unrestricted or selected systematically using a random start with a fixed interval. In stratified random sampling, the sample frame[4] is divided into strata. Each stratum have common characteristics, such as all claims with certain codes for a date of service period distinct from the date of service periods in other strata, or where reimbursement amounts are grouped and laddered. The sample items are then randomly selected by stratum. One of the benefits of random sampling is it is considered more objective than non-statistical judgmental selection methods.[5]

Some non-statistical judgmental selection methods include haphazard selection. Haphazard selection is often used in sampling where the analyst will, without conscious bias, select sample items to obtain sample items from throughout the sample frame. Judgmental selection also includes purposefully selecting certain items known or suspected to be of higher risk.[6]

Some non-statistical sample selection methods with modification can become random. One such selection method, block selection where certain letters of the alphabet are selected for analyzing patient accounts or accounts payable for certain time fractions such as days, weeks or months are used. If there is a sufficient number of sample items selected and the blocks are randomly chosen, the sampling could be termed cluster sampling. In the cluster, the block is the sample unit and all, for example the accounts or claims in the sample unit, are the analysis units. Another such non-statistical selection method uses fixed interval as the selection method. The analyst selects every Xth item as the fixed interval. If a random start to the interval is used, the selection method could be termed systematic selection, a statistical sampling selection method.[7]

In our next edition, we will discuss detection sampling. ■

[1](2012). International Standards For The Professional Practice of Internal Auditing (Standards) (p. 15). Institute of Internal Auditors.
[2]Wilburn, Arthur, (1984) Introduction, Practical Statistical Sampling for Auditors (Statistics: Textbooks and Monographs) (Vol. 52: pp: 1-19). New York: Marcel Dekkar, Inc.
[3](2012). Practice Advisory 2320-3: Audit Sampling. Institute of Internal Auditors,
[4]"Sampling frame is the actual set of units from which a sample has been drawn..."Statistics.com The Institute for Statistical Education
[5]Op. Cit. 2.
[6]Op Cit. 2
[7]Op. Cit. 2

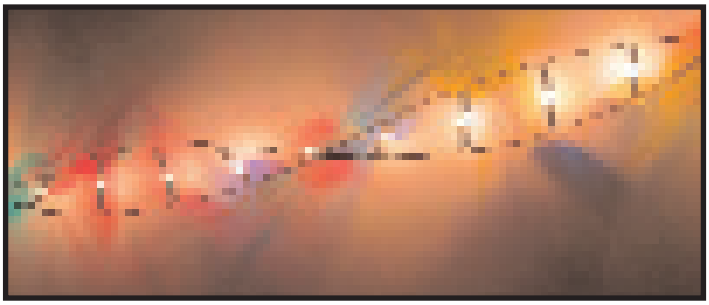
Breast Cancer Therapy Efficacy Monitoring

The American Society of Clinical Oncology (ASCO) and College of American Pathologists (CAP) issued updated HER2 testing guidelines October 7, 2013. These guidelines helped to clarify the protocol to follow should a HER2 test result in an "equivocal" finding.[1]

As research into the humane genome proceeds, researchers are learning more about gene changes that cause cancer and lead to the development of new drug classes that target these changes. These types of drugs work differently from standard chemotherapy drugs and often have less severe side effects. Approximately 1 in 5 patients with breast cancer have cancer cells with too much of the growth-promoting protein HER2/neu (HER2).[2] This means that the cells of these cancers have extra copies of the HER2 gene and are referred to as HER2 positive cancers.[3] Breast cancers with too much of this protein tend to grow and spread more aggressively without special treatment. The HER2 gene, officially named avian erythroblastic leukemia viral oncogene homolog 2 (ErbB2), is found on chromosome 17.[4]

Herceptin® (trastuzumab) is a monoclonal antibody that binds to HER2 preventing the activation of the pathway promoting proliferation and survival of breast cancer cells. Herceptin has been approved by the FDA for the treatment of breast cancer only if the tumor overexpresses HER2.

From a claims monitoring perspective, patients receiving Herceptin treatment (HCPCS code J9355) should have had HER2 testing prior to the initiation of treatment. A false HER2-positive can result in 52 weeks of chemotherapy and trastuzumab exceeding $50,000 plus the expense of relieving side effects.[5] There are several methods for determining HER2 status, each with its own CPT code assignment. The ASCO/CAP guidelines recommend that HER2 status be determined on the basis of one or more HER2 test results (negative, equivocal or positive) either by immunohistochemistry (CPT code 88360 [morphometric analysis, tumor immunohistochemistry 9e.g., Her-2/neu, estrogen receptor / progesterone receptor) quantitative or semiquantitative, each antibody; manual] or 88361 [if computer assisted], 88342 immunohistochemistry or immunocytochemistry, each separately identifiable antibody per block, cytologic preparation, or hematologic smear; first separately identifiable antibody per slide]) or in situ hybridization (CPT code 88367 [morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; using computer assisted technology] or 88368 for manual methods). When the initial result is equivocal, immunohistochemistry and in situ hybridization codes would be expected based on the guidelines.[6] The guidelines note that there was insufficient evidence to support the use of microarray assays to determine HER2 status at this time. We would also expect CPT code 88305 (Level 4 surgical pathology, gross and microscopic examination; breast,



biopsy not requiring microscopic evaluation of surgical margins or lymph node biopsy) or 88307 (Level 5 surgical pathology, gross and microscopic examination; breast, excision of lesion, requiring microscopic evaluation of surgical margins) for pathologic examination of the breast biopsy.

The estrogen receptor status helps guide treatment. Breast cancers that have a large number of estrogen receptors (estrogen receptor-positive [ER+] tumors tend to be linked to better survival than ER- tumors and can be treated with hormone therapies such as tamoxifen. Hormone receptor negative cells can only be treated with chemotherapy.[7]

The FDA has also approved pertuzumab (Perjeta) (HCPCS code C9292) in combination with trastuzumab (HCPCS code J9355) and docetaxel (HCPCS code J9171) for women with metastatic HER2 positive breast cancer.[8] Additionally, lapatinib (Tykerb®) and T-DM1 (Kadcyla) are available for HER2 positive patients.[9] As of October 24, 2013, HCPCS codes have not yet been assigned to these new therapies.

The standard therapy for HER2 negative, receptor positive breast cancer is bevacizumab (Avastin) (HCPCS code J9035) plus weekly paclitaxel (Taxol) (HCPCS code J9265).[10]

There are several metrics that come into play and data mining queries developed around them.

- As previously mentioned, was a HER2 test (CPT codes 88360 or 88361 or 88367 or 88368) with the surgical specimen (CPT codes 88305 or 88307) prior to initiation of Herceptin therapy (HCPCS code J9355)?
- Was the ER receptor status positive (ICD-9-CM code V86.0) or negative (ICD-9-CM code V86.1)?
- Was a patient receiving tamoxifen (CPT code 4179F) with a negative receptor status (ICD-9-CM code V86.1)?
- Does the patient receiving Herceptin therapy (HCPCS code J9355) have a diagnosis of breast cancer (ICD-9-CM codes 174.0 – 174.9 malignant or 238.3 for tumor of uncertain behavior)?
- Did a patient with a diagnosis of breast cancer (ICD-9-CM codes 174.0 – 174.9) receiving bevacizumab (HCPCS code J9035) and paclitaxel (HCPCS code J9265) have HER2 testing prior to initiation of therapy?■

[1]Wolf, A.C., et al. (2013, October 7). Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer. Archives of Pathology Laboratory Medicine Special Article ASCO/CAP HER2 Testing Guideline Update.
[2]Targeted Therapy for Breast Cancer (2013, October 1) American Cancer Society.
[3]Targeted Therapies for Breast Cancer Tutorial (2013, October 24) National Cancer Institute, Internet.
[4]ERBB2 (2011, March) Genetics Home Reference, U.S. National Library of Medicine.
[5]Bob Carlson. (2008, Sept-Oct) HER2 Tests: How Do We Choose? Biotechnology Healthcare, 5(3): 23-27.
[6]Wolf, A.C., et al. (2013, October 7). Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer. Archives of Pathology Laboratory Medicine, Special Article ASCO/CAP HER2 Testing Guideline Update.
[7] (2012, December 12). In-Depth Report: Prognosis. The New York Times, retrieved: October 24, 2013: Health.nytimes.com.
[8] (2012, October 16). Treatment Options for HER2-Positive Breast Cancer Expand and Evolve. National Cancer Institute, NCI Cancer Bulletin, retrieved: October 24, 2013: www.cancer.gov.
[9] Chustecka, Z. (2013, October 15) Updated Guidelines for HER2 Testing of Breast Cancer. Medscape Medical News, retrieved October 24, 2013: from: http:// www.medscape.com/viewarticle/812582.
[10] Hudis, C.(2010, December 17) Case Discussion: HER2-Negative Metastatic Breast Cancer. Medscape Education Oncology, retrieved October 24, 2013: from: http://www.medscape.org/viewarticle/733864.

Molecular Pathology (Part 1)

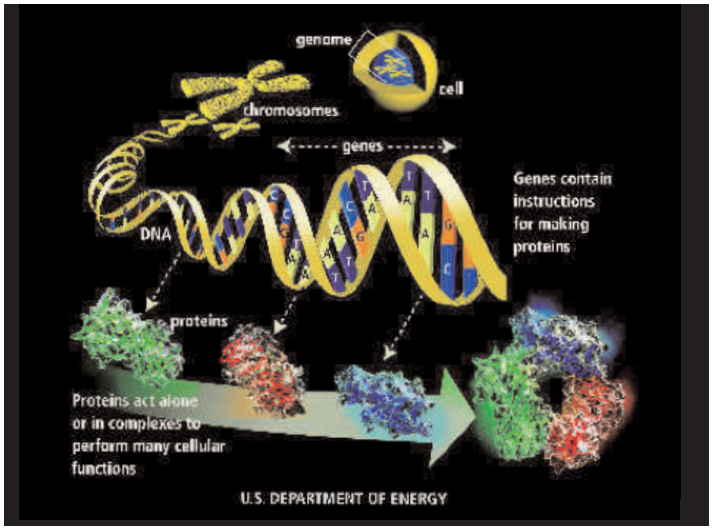
Definitions and Concepts of Molecular Pathology Testing

This two part series of articles is intended to provide a framework of understanding molecular pathology coding. Part 1 presents an overview of the terminology and concepts used in molecular pathology testing. and some examples that build upon the concepts presented. Part 2 presents an overview of CPT code changes in the molecular pathology section for 2014.

Stedman's defines molecular pathology as the study of biochemical and biophysical cellular mechanisms as the basic factors in disease.[1] A more understandable definition from Wikipedia is an emerging discipline within pathology which is focused in the study and diagnosis of disease through the examination of molecules within organs, tissues or bodily fluids.[2]

The nucleus of a cell contains 46 chromosomes (23 pair) containing the blue prints for the human body. This complete set of instructions is the genome. Each chromosome is made of the familiar double helix structure of DNA. There are 4 nucleic acids that in various combinations strung together compose the strands of DNA.[3] Each group of 3 DNA pairs code for an amino acid and is known as a codon. Amino acids then form the building blocks for proteins. The sections of DNA containing the instructions (codons) for making specific proteins are called genes. A gene may contain instructions for multiple proteins.[4] The following graphic from the U.S. Department of Energy depicts these relationships.

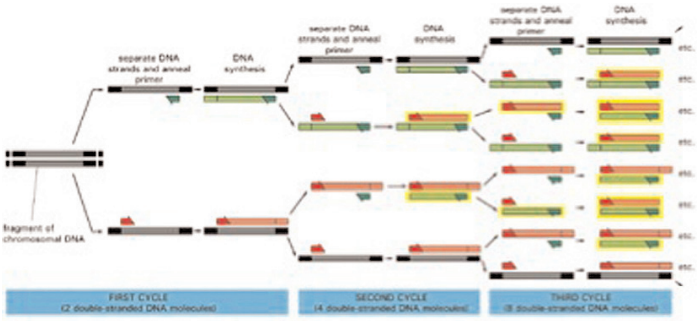
The field of molecular pathology uses various methods to analyze the DNA sequences in genes for anomalies to diagnose disease, predict the prognosis of disease, guide therapy, and evaluate the susceptibility to disease.[5] The 23 pairs of human chromosomes are estimated to include about 20,000 to 25,000 genes with each gene coding for one protein.[6] (cont. pg.6)



While a number of techniques are available to analyze DNA, they all start with the collection and processing of the appropriate specimen. This is followed by extraction, purification, isolation, and quantitation which formed the basis for the obsolete stacked CPT codes used for molecular pathology.

Because a gene is found on only one strand of DNA per nucleated cell, it is necessary to amplify that portion so it is detectible. The mainstay technique in DNA amplification is the Polymerase Chain Reaction (PCR) technique. Using PCR millions of copies of a section of DNA are made in just a few hours from a minimal amount of specimen. PCR is composed of three basic steps:[7]

- Separating the Target DNA (Denaturation): During this step, the DNA is heated to no more than 90 degrees Celsius causing the double-stranded DNA to separate into two separate strands.
- Binding Primers to the DNA Sequence (Annealing): PCR primers (short pieces of synthetic DNA) are used to target specific sequences of DNA. These primers will bind, or anneal, only to sequences on either side of the target DNA region. Primer binding occurs between 40 and 60 degrees Celsius. Two primers are used, one for each of the separated DNA strands. The primers are used to mark the sequence to be copied in the next step.
- Making a Copy (Extension): Nucleotides are added to the solution and the temperature is increased to approximately 72 degrees Celsius. Beginning at the regions marked by the primers, nucleotides are added to the annealed primers by DNA polymerase to create a new strand of DNA complementary to each of the single strand templates. After completion, two copies have been made. This completes one cycle. The cycle begins again using the new duplicated copies and after approximately 30 or 40 PCR cycles, more than one billion copies of the original DNA segment have been made.

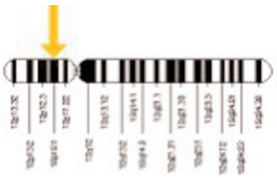


Molecular Pathology Testing Application Examples and Associated CPT Coding

In this segment of Part 1, we provide some insight into some applications for molecular pathology testing and CPT code assignments.

As previously discussed, DNA is composed of nucleic acids. A group of three nucleic acids (codon) code for an amino acid. Amino acids in-turn come together to make proteins. This is important as mutations in the DNA sequence can have downstream effects on the end product protein.

CPT code 81275 (KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene)(e.g., carcinoma) gene analysis variants in codons 12 and 13)[9] is used for detection of the K-Ras mutation which occurs in over 90% of pancreatic carcinomas. In most cases, the K-Ras mutation involves a change in the amino acid coded for at codon 12 and in rare exceptions, codon 13.[10] This mutation results in the inactivation of the protein GTPase causing continual signal transmission, stimulating downstream signaling pathways involved in cell growth, proliferation, invasion, and metastasis.[11] A 2006 study found the K-Ras mutations are a predictor of resistance to cetuximab therapy and associated with a worse prognosis.[12] The National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) and FDA recommend KRAS mutation testing before initiation of Epidermal Growth Factor Receptor (EGFR) therapy (cetuximab (Erbitux) and panitumumab (Vectibix)).[13] The K-Ras gene is located on chromosome 12 from base pairs (DNA pairs) 25,358,179 to 25,403,869.[14]



Mutations in the gene for VKORC1 (vitamin K epoxide reductase complex, subunit 1) correlate with warfarin sensitivity and resistance while mutations in the CYP2CP gene are associated with impaired warfarin metabolism. Warfarin is an anti-thrombotic agent with a narrow therapeutic range. There were over 30 million prescriptions in the United States for warfarin in 2004 including up to a million new patients initiated on therapy each year. Each year 800 reports are made to the FDA associated with emergency room visits from adverse drug reactions from warfarin.[15] Variations in the VKORC1 gene may explain 30% of the variability in drug response between patients and changes in CYP2C9 may explain 10% of dose variation. Identification of these warfarin sensitive variants of the VKORC1 and CYP2C9 genes may allow a more individualized therapy and reduced risk of bleeding complications.[16] Vitamin K is essential for blood clotting but must be activated. The VKORC1 gene codes for the enzyme needed to activate vitamin K. The VKORC1 gene is located on chromosome 16 from base pairs (DNA pairs) 31,102,174 to 31,106,698.[17]

The CYP2CP gene is located on chromosome 10 from base pair (DNA pair) 96,698,349 to 96,749,485.

Testing for mutations in the CYP2CP gene are captured with CPT code 81227 (CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9)(e.g., drug metabolism), gene analysis, common variants (e.g., *2, *3, *5, *6)) and analysis of the VKORC1 gene is captured with CPT code 81355 (VKORC1 (vitamin K epoxide reductase complex, subunit 1)(e.g., warfarin metabolism), gene analysis, common variants(e.g., -1639/3673)).[18]

The AGTR1 (angiotensin II receptor, type 1) gene provides instructions for making the angiotensin II type 1 receptor (AT1 receptor). This protein is part of a system that regulates blood pressure and fluid and salt balance in the body. Angiotensin II binds to the AT1 receptor causing

blood vessels to constrict resulting in increased blood pressure. Binding of angiotensin II also stimulates production of the hormone aldosterone, which triggers the absorption of water and salt by the kidneys also contributing to increased blood pressure. The gene is located on chromosome 3 from base pair (DNA pairs) 148,415,657 to 148,460,789.[19]

Testing for the AGTR1 gene is captured with CPT code 84100 (AGTR1 (angiotensin II receptor, type 1) (e.g., essential hypertension), 1165A>C variant)

The Molecular Pathology section of the CPT Manual saw the brunt of 2014 Pathology and Laboratory updates. A new table was added that crosswalks the abbreviated gene name with the full gene name, commonly associated proteins/diseases, and CPT Code(s). This section also contains new or revised text for nine CPT codes encompassing 589 gene examples.

Part 2 of this series will provide an overview of the 2014 CPT changes to the Molecular Pathology section of CPT. The Molecular Pathology section of the CPT Manual saw many of the 2014 Pathology and Laboratory updates. While the section of the CPT Manual contains only a few codes, they cover a multitude of genes.■

[1] Stedman's Medical Dictionary (2006). Lippincott Williams & Wilkins, retrieved October 23, 2013: www.medilexicon.com.
[2] Wikipedia (2013, October 18). retrieved October 23, 2013: en.wikipedia.org.
[3] Reusch, W. (2013, May 5) Nucleic Acids. Retrieved October 23, 2013: from: www2.chemistry.msu.edu/faculty/reusch/virtxtjml/nucacids.htm.
[4] American Medical Association (2014 edition) Current Procedural Terminology Manual.
[5] University of Wisconsin School of Medicine and Public Health (2013, January 31) Medical Student Education, Molecular Diagnostics Rotation. Department of Pathology and Laboratory Medicine, retrieved October 23, 2013: www.pathology.wisc.edu.
[6] Petty, Y (2005) DNA Tutorial. Retrieved October 23, 2013L from: www.dnatutorial.com/DNAChromosomes.shtml. [7] Roche Medical Systems (2013, October 23) PCR: How We Copy DNA. Retrived October 23, 2013: from: Molecular.roche.com/pcr/Pages/Process.aspx.
[8] Alberts, B, et. al. (1994). DNA Cloning. Molecular Cell Biology of the Cell. 3rd edition. Garland Science, New York.
[9] American Medical Association, 2014 edition, Common Procedural Terminology Manual.
[10] Hruban, Ralph The Genetics of Pancreatic Cancer – The Discoveries K-Ras Mutations. Johns Hopkins University. pathology/jhu.edu/pancreas/geneticsweb/K-ras.htm.
[11] Quest Diagnostics (December 2012) KRAS Mutation Analysis. Quest Diagnostics Test Guide
[12] Lievre, A., et. al. (April 2006) KRAS mutation status is predictive of response to cetuximab therapy in colorectal cancer. Cancer Research. 15;66(8):3992-5.
[13]Access Genetics KRAS Mutation Analysis in Colorectal Cancer. www.access-genetics.com/resources/KRAS/KRAS_ TECH_Sheet.pdf. Accessed October 23, 2013.
[14] U.S. Library of Medicine (October 21, 2013) KRAS. Genetics Home Reference.
[15] Flockhart, DA, et. al. (2008) Pharmacogenetic testing of CYP2C9 and VKORC1 alleles for warfarin. Genetics in Medicine. 10:139-150.
[16] Quest Diagnostics (accessed October 23, 2013) CYP2C9 and VKORC1 Mutation. Quest Diagnostics Test Guide
[17] U.S. National Library of Medicine (October 21, 2013) VKORC1. Genetics Home Reference. [18] American Medical Association, 2014 edition, Common Procedural Terminology Manual. [19] U.S. National Library of Medicine (October 21, 2013) AGTR1. Genetics Home Reference.

Interviewing and Non-Verbal Cues

Communication, technical, analytical, critical judgment and interpersonal skills are integral to the success of compliance professionals. Inquiries made thought an interview process are one evidence gathering method used by compliance professionals, auditors and analysts. Each professional understands the need to hone their interview skills including the importance of interpreting verbal and non-verbal communication cues. You may have heard of a non-verbal cue termed "duping delight." This is the smile that an interviewee may make shortly after answering an inquiry. The smile is disjointed with the description of an event provided in response to the preceding inquiry. It is as if to say, "Hooray, I fooled you." Pamela Myers author of Liespotting, discusses this and demonstrates through video clips techniques, such as being attentive to "duping delight" to detect deception in the TED video "How to Spot a Liar." In mid-October 2013, this video had over 2.5 million views. Clearly, it is an area of interest to many people. To view the video, access www.ted.com.

It is often thought and noted in articles that a lack of eye-contact indicates deception. According to Ms. Myers, this is not so. In fact, the opposite is true. Interestingly, Ms. Myers notes that an individual may make more eye contact than they typically make when being deceptive. Although the video did not note this, the amount of eye contact can vary for different cultures.

One non-verbal cue that was not specifically discussed by Ms. Myers and that falls into the realm of micro movements is termed "three-whites." This cue was discovered by Japanese researchers. This method is taught to investigators where videotapes of the eye movements of suspects during interrogations may be used to illustrate the micro movement. This is an involuntary movement where the upper white of the eye along with the whites on the two sides is revealed in less than a second. Micro movements are indicative of certain emotions such as anxiety rather than as an indicator of deception. Detecting non-verbal cues is enhanced when two interviewers participate in the interview process, one that dynamically asks questions and the other in an interview supportive role that includes watching body language.

Some neurolinguist researchers have found that the direction of eye movements (right and left and up, down and to the sides) can provide insight into whether a topic, be it visual or auditory, is being recalled from memory or created. There is scientific dispute supported by scientific studies on the lack of validity of this cue. As such, reliance on this cue is very questionable.

Sometimes it not about deception but speaker reception including your own communication of non-verbal messages when conducting an interview. The amount of movement of the body, including arms and legs and their positions can also provide a non-verbal communication cue. Extended legs, in combination with other non-verbal cues, such as crossed arms may indicate the individual is distancing or disagreeing with the speaker's position. The amount and type of demonstrative hand gestures, body posture and their timing can be telling.

Whether it be facial expressions, body posture and position, voice speed and rhythm changes from baseline or demonstrative gestures it is important that the cue is based on peer reviewed published scientific evidence that is generally accepted. Otherwise, reliance on such cues as an expert could receive a Daubert challenge. According to Ms Myers not one non-verbal cue but cue clusters should be taken into account. Such cue clusters may give further insight into inquiry responses that can lead you in the direction of areas where further exploration may be useful. But, be careful to rely on cues with a scientific basis and that incorporate cultural sensitivity. This is one area where there are a number of supposed cues not all scientifically supportable and of questionable cross-cultural reliability. ■

ICD-10…Are You Ready To Be Paid?

On January 16, 2009, the Federal Register published that ICD-10-CM (for diagnoses) would be the medical data code set standards for services performed in all healthcare settings. ICD-10-PCS (for procedures) was published as the medical data code set standard for hospital settings. The CPT (for procedures) code set would remain the code set utilized for reporting procedures in settings that currently utilize CPT which includes physician practices.

The implementation of ICD-10-CM is not a code set "upgrade" that the electronic health record systems will take care of for practices. It is a revenue cycle initiative that directly involves physician and provider documentation. Clinical documentation drives the patient severity, physician quality scores, and reimbursement. Although the final compliance date was changed to October 1, 2014, there are steps that physician practices should take now or already have completed.

The implementation and communication plans should by now be documented. The impact assessment, training gap analysis, and identification of areas (electronic and paper-based) where ICD-9-CM codes are located should be documented. Budgets should reflect the loss in productivity (physicians, coders, and billers), hardware and system issues, enhanced training, to name a few of the associated operational matters. The actual cost of implementing ICD-10-CM will depend upon the numbers of systems, interfaces, business processes, policies and procedures revisions needed, payers tested and contracts renewed in addition to the extent of customization to current systems, training needs, size of the practice, extent of coding validation required and the amount of external assistance that is needed.

In order to comply with the ICD-10-CM mandate and be paid for services on October 1, 2014, clinical documentation must be more specific than is required by ICD-9-CM. In order to identify a practice's risk areas, comparative analysis should take place to identify service lines or specific providers which do not currently document specific enough to assign an ICD-10-CM code. The first step is to identifying those services which are a practice's highest reported ICD-9-CM codes. Next, identify a sample and code these cases in ICD-10-CM. This comparative analysis will provide the practice with critically important data points which may be incorporated into the practice Clinical Documentation Improvement plan.

Tip One: If there is a physician that requires continuing queries, then this will be magnified with ICD-10-CM.
Tip Two: If a practice has high utilization of unspecified codes in ICD-9-CM, then this is a risk area for the practice in ICD-10-CM.

The steps that a practice takes today to improve the clinical documentation will benefit the practice in ICD-9-CM as well as ICD-10-CM.

During the implementation process, a practice should be mindful of staff retention. Professionals trained in ICD-10-CM will be in high demand and practices would be wise to develop a staff retention plan associated with the ICD-10-CM implementation. It would be unfortunate if a practice spent resources to adequately train staff only to see them recruited by another practice that did not prepare well for ICD-10-CM compliance. ■

The implementation process for physician practices must be well-planned and well-managed. Proper planning, preparation, and follow-up throughout the continuum are critical for a successful implementation.

Reference: Code of Federal Regulations, (45 CFR 162), 2009. Department of Health and Human Services. HIPAA Administrative Simplification: Modifications to Medical Data Code Set Standards To Adopt ICD–10–CM and ICD–10–PCS. Available online at http://www.gpo.gov/fdsys/pkg/FR-2009-01-16/pdf/E9-743.pdf