

A Matrix Model For Phlebotomy Quality Assurance

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The current standard references on phlebotomy provide details on quality assurance (QA) policies and quality control measures required for phlebotomy practice. A noticeable deficiency, however, is the lack of an overarching conceptual framework on phlebotomy QA that can be used to categorize what part of the phlebotomy process these measures affect and what general considerations need to be addressed for a comprehensive QA program. The guidelines and standards of various regulating and accrediting agencies are similar in this respect. We address this deficiency in this article by presenting a model for organizing phlebotomy QA data in a matrix format.

The model conceptual framework matrix was originally developed as a means to better organize program content for a continuing education program on phlebotomy QA presented by one of the authors. It stems from what would need to be considered in order to fulfill the following purpose of phlebotomy related to clinical laboratory operation: To provide blood specimens, obtained with no harm to the patient and phlebotomist, that will produce valid results from clinical laboratory testing. Based on this definition of purpose the goals of phlebotomy quality assurance are to:

1. Maximize test result validity
2. Minimize patient trauma
3. Minimize the potential for phlebotomist injury

(Note that minimizing patient trauma refers to both the physical and psychological trauma associated with the phlebotomy procedure.)

The 4 x 4 x 3 matrix is organized into three dimensions (see figure) and contains 48 cells. Each of the cells of the matrix represents a particular aspect of phlebotomy practice that contributes to a successful QA program, e.g., how training can be used to effect patient well-being during the collection phase of phlebotomy. Phlebotomy practice is segmented into three phases that are analogous to the pre-analytical, analytical and post-analytical framework commonly used to describe clinical laboratory practice. The analogous phases are pre-collection, collection and post-collection. Pre-collection includes, but is not solely limited to, test ordering, patient preparation and training. The collection phase applies to procedures directly involved in acquiring blood specimens by various techniques. Post-collection activities encompass what occurs once the specimen has been obtained.

A second axis corresponds to the goals of phlebotomy and includes patient test management (PTM), as defined by the Clinical Laboratory Improvement Amendments of 1988 and patient and phlebotomist well-being. PTM is divided into identification and specimen suitability phases. Specimen suitability is defined as the degree to which a correct specimen is obtained and specimen integrity maintained during those activities that are under the control of phlebotomists. The final axis involves process considerations and equipment that are necessary to effectively accomplish quality goals. These include training, technique, QA monitoring and equipment. The framework is applied to individual tests that comprise a clinical laboratory's test menu. The information needed to fill each cell may be similar or redundant for many of the same tests, leading to an economy of effort in the development of the matrix. However, much of the information for many of the tests will be unique, either due to the nature of the test or to the specific clinical environment in which the specimens are collected.

If used to develop a phlebotomy QA program, each individual cell should be considered for a particular test. For example, personnel responsible for a phlebotomy operation would need to ask about the equipment considerations during the collection phase, when drawing a complete blood count that would maximize specimen suitability. Similarly, for the same procedure, they would need to consider what techniques (or procedures) in the post-collection phase would lead to appropriate patient test management regarding specimen identification. If each cell is considered systematically, the matrix

facilitates the development of a QA program for various procedures by ensuring that no important consideration is overlooked.

For QA programs, the matrix approach has three potential benefits. First, by considering each cell for each test on the menu, phlebotomists can determine if important considerations had been overlooked in the past. Second, the matrix can serve as a means of systematically examining test result validity problems that may be related to phlebotomy operation. Third, the matrix can be used as an integral component of continuous quality improvement (CQI) efforts.

Continuous quality improvement focuses on improving processes, as well as the performance of individuals on an ongoing basis. Part of the CQI process involves identifying aspects of practice where improvements need to be made. Using the data already contained in the phlebotomy QA matrix-specific aspects of practice can be readily targeted for improvement based on various criteria, e.g., the expert's knowledge of problem-prone areas, implementation of a new practice, etc. Once the aspects of practice have been targeted, specific, measurable quality indicators can be developed, and additional CQI data can be collected and analyzed. Thereafter, a specific action plan can be implemented to further improve the phlebotomy process. Evaluation of the completed CQI process may ultimately lead to the revision of the phlebotomy QA matrix by providing new information related to test collections. As this cyclical process continues, the matrix will become more individualized for a specific clinical setting.

While the matrix can be developed as a printed manual, the data entry and retrieval associated with it best suggest creation of a computerized database. Since a three-dimensional database may be difficult to visualize and use, we suggest constructing the database as a series of three, two-dimensional tables for each test. The tables would correspond to the pre-collection, collection and post-collection phases and provide information for each of the 16 cells that cross-reference the goals and the process/equipment axes. Such a computerized database could be made available institution-wide and could incorporate user-friendly search features that would allow phlebotomists and other health care personnel to rapidly retrieve valuable QA specifics on individual laboratory tests.

Additionally, authors of phlebotomy textbooks, guidelines and standards can use the matrix model to provide a consistent, all-encompassing conceptual framework within which to organize information on phlebotomy QA. Educators can also use the model as a means of organizing program content and helping students to internalize a systematic way of thinking about phlebotomy QA.

In summary, the matrix approach to phlebotomy QA provides a systematic conceptual framework for organizing phlebotomy QA data and developing and improving QA programs. Based on considerations needed to effect the goals of a quality phlebotomy service, it links the phases of phlebotomy, the goals of QA related to phlebotomy and the process and equipment considerations needed to accomplish those goals. We hope that the matrix model will be adapted and tested by clinical laboratories to determine its merit in actual practice and to effect future improvements in the model.

Reference:

1. Clinical Laboratory Improvement Amendments of 1988 (CLIA 88); Final Rule, 42 CFR Parts 405 et al., Federal Register, Volume 57, Number 40, February 28, 1992

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Editorial

Using a novel approach, Drs. Raymond and Nina Olesinski have developed "A Matrix Model for Phlebotomy Quality Assurance." This framework affords us a good blueprint for developing and improving quality assurance programs.

In "Phlebotomy in the Home Care Setting," Lynn Hadaway gives us an overview of the complexities involved in collecting and managing blood specimens from patients outside the traditional health care settings.

"In Control" addresses a major concern to all of us in the health care industry by providing an update on the risk of occupationally-acquired HIV infection in health care workers. Certainly, the fact that HIV infection may appear in all patient groups and in all areas of the United States underscores the need for infection control practices and the use of Universal Precautions.

Jean Stockbower, Ph.D.
Editor

Health Care Workers and HIV Infection: An Update on Exposure Risk and Seroconversion

As of December, 1997, the Centers for Disease Control and Prevention (CDC) received reports of 54 documented cases of U.S. health care workers with occupationally-acquired human immunodeficiency virus (HIV) infection. In addition, there were reports of another 132 health care workers with possible occupationally-acquired HIV infection but these were lacking documentation of a specific exposure.¹

CDC defines a "documented case" as one in which HIV seroconversion is temporarily associated with an occupational exposure.²

The one exception to this definition is a person who worked with concentrated HIV in a laboratory whose infection was determined by DNA analysis to be that of the laboratory strain.²

Of the 132 health care workers who are considered to be possible cases, each reported that their infection was occupationally-acquired, although the transmission of infection after a specific exposure was not documented. However, no other risk for HIV infection was identified. (see table on page 4)

The transmitting fluid in the 54 documented cases of HIV included blood (49), visibly bloody fluid (1), unspecified fluid (1), and concentrated virus in a laboratory setting (3). The types of exposure consisted of percutaneous (46), mucocutaneous (5), percutaneous and mucocutaneous (2), and uncertain (1).¹

Cumulative Risk

The cumulative risk of HIV infection from occupational exposures in a health care setting depends on three factors: first, the prevalence of HIV infection among patients; second, the risk of HIV transmission after a single exposure; third, the nature and frequency of exposure.²

In a CDC survey of 20 acute care hospitals in 15 cities, it was determined that the HIV seroprevalence among patient populations varies widely ranging from 0.2 percent in Utah and Nebraska, to 14.2 percent in a hospital in New York City. Only 32.4 percent of the HIV-positive patients presented symptoms attributable to HIV infection. HIV seroprevalence was highest among men 25-44 years old, and among patients presenting with pneumonia, other infections, or drug-related conditions.

Certainly the fact that HIV infection is in all areas of the United States and in all patient groups underscores the need for infection control practices and the use of universal precautions.

Based on limited data, CDC has estimated that approximately 500,000 percutaneous blood exposures may occur annually among hospital-based health care workers in the United States. Approximately 5,000 of these exposures may involve percutaneous injuries involving HIV-infected patients, resulting in approximately 15 (0.3 percent) HIV infection transmissions to health care workers annually.²

Of the 6,202 health care workers followed prospectively after a percutaneous exposure to HIV-infected blood, 20 (or 0.32 percent) became infected. The risk estimate of 0.3 percent represents an average of many types of percutaneous exposures to blood from patients in various stages of HIV infection. The risk in any one percutaneous exposure probably varies with two factors: the volume of blood injected and the stage of illness in the source patient, a factor which affects the concentration of the virus in the blood.

The risk after a mucous-membrane exposure is not well-defined, but has been estimated at 0.09 percent. This is based on only one known seroconversion in six studies: a nurse in Italy who, while manipulating an arterial catheter, had her hands, eyes, and mouth splashed with a large quantity of blood from a patient with asymptomatic HIV infection.²

The risk of infection after a skin exposure to HIV-infected blood is unknown, but believed to be less, as none of the health care workers enrolled in prospective studies have seroconverted after an isolated skin exposure. Of the 2,712 health care workers involved in a prospective study at the National Institutes of

Health, none of those who recalled skin contact with HIV-infected blood seroconverted. It should be noted that, although HIV has been detected in a variety of body fluids, occupational transmission to health care workers has been documented only for blood and visibly bloody fluids.

Serological Testing of Health Care Workers

Studies performed on 41 health care workers following occupationally-acquired HIV infection, and reported to CDC through December 1994, documented that these individuals had negative tests for HIV antibodies, from nine months before and up to 26 days after their occupational exposure. The results show seroconversion in health care workers with occupationally-acquired HIV infection will usually occur within six months of exposure.³

In this study, only two (5 percent) of the 41 were seronegative for longer than six months after exposure, but both were seropositive for HIV antibodies within twelve months of the injury. Of the two late seroconverters, one was seronegative on four occasions, between day 4 and 27 weeks, before showing seropositivity at approximately ten months after exposure. The second late seroconverter had a complicating simultaneous infection with hepatitis C virus (HCV), with an abnormal immune response. Four of the health care workers took post-exposure Zidovudine prophylaxis. Each reported an acute retroviral syndrome within six weeks of their exposure, and each of the four seroconverted to HIV within six months. This data suggest that Zidovudine prophylaxis does not delay the development of HIV antibodies beyond six months.

It is proper to perform serological testing of health care workers exposed to HIV-infected material for at least six months, as recommended by the Public Health Service. However, one must recognize that, in rare instances, evaluation for late seroconversion may be needed in cases of simultaneous occupational exposure to HIV and HCV, or if clinical symptoms or signs of HIV infection occur more than six months after exposure.

References:

1. Centers for Disease Control and Prevention. HIV/AIDS Surveillance Report 1997; 9 (2): 21, Table 16.
2. Bell, D.M., Occupational risk of human immunodeficiency virus infection in health care workers: an overview, *American Journal of Medicine*, 1997; 102 (5B): 9-15.
3. Ciesielski, C.A., Meller R.P., Duration of time between exposure and seroconversion in health care workers with occupationally-acquired infection with human immunodeficiency virus, *American Journal of Medicine*, 1997; 102 (5B): 115-116.

Technical Questions and Answers

Q. Why are expiration dates placed on evacuated blood collection tubes and what do the dates mean?

A. The expiration date is a reflection of the shelf life of the product. Shelf life data are derived from functional testing of each product. Samples of products are stored and periodically tested to determine if they perform according to specifications. This testing is an ongoing process. The expiration date is based on loss of vacuum over time and any changes in the functionality of the additive. If an expiration date is stated as a month and year only (i.e. September 1998), the product expires on the last day of that month and should not be used past that date.

Q. What is the minimum amount of blood necessary for accurate results in an EDTA tube?

A. Excess EDTA causes shrinkage of red cells, with resulting decreases in hematocrit, mean corpuscular volume (MCV) and red cell distribution width (RDW). Artfactual changes are also seen on morphology smears prepared from this type of specimen. Sedimentation rates using modified Westergren or Wintrobe technique performed from such a specimen can give erroneous results due to alterations in cell size and shape. Quantities of EDTA in excess of 2.0 mg/mL initiate these changes. Since all EDTA tubes are optimized at 1.5 mg/mL, the 2.0 mg/mL concentration is achieved at 75% draw volume. Also, significantly under-filled liquid EDTA tubes result in erroneous results due to dilution of the blood sample. When filled to proper volume, this dilution effect is minimal and insignificant: 1% in 4,5,7 and 10 mL sizes; 2% in 2, 2.5 and 3 mL sizes.

Additives: EDTA

Salts of ethylenediaminetetraacetic acid (EDTA) are commonly used to anticoagulate blood specimens. EDTA and its various salts prevent clotting of blood by chelating calcium, which is necessary in the coagulation cascade. Once calcium is removed from the blood, both intrinsic and extrinsic events, which cause clotting, are stopped. Both the conversion of prothrombin to thrombin and the action of thrombin on fibrinogen to form fibrin are inhibited.

EDTA is available as free-acid, disodium, dipotassium and tripotassium salts. The two salts most commonly used in evacuated blood collection tubes are dipotassium and tripotassium. Dipotassium is used in a dry form and tripotassium is used as a liquid. The liquid further enhances the anticoagulant activity and causes a 1 to 2% dilution of the blood.

The EDTA salts are desirable for use in hematology testing (CBC, WBC differential and platelet counts) because cellular components of the blood are preserved. EDTA is also the preferred anticoagulant for reticulocyte counts, flow cytometry, and can be used for lead testing. EDTA is not an acceptable anticoagulant for coagulation testing, nor should it be used for calcium, iron, alkaline phosphatase, creatinine kinase or leucine aminopeptidase determinations, due to its chelating properties.

Reference:

NCCLS Document H35-T, Vol. 12, No. 17, Tentative Standard, September, 1992.

Medical Lore

Hildegard of Bingen - Medieval Healer

"Poet, prophet, mystic, composer, moralist, counselor to kings and church leaders, author, scholar, scientist, and herbalist, she is best known today for her visionary religious and philosophical works, as well as for her music."

Hildegard of Bingen (1098-1179) was undoubtedly the most accomplished abbess of the Middle Ages. Considered the first German woman physician, she was highly regarded during her time as a healer. She is also thought of as the mother of German botany.

Hildegard was born near Mainz, Germany, the tenth child of a noble family. She was promised to the church by her parents and began instruction in religion, Latin, and music at age eight. By age eleven, she had taken her vows. Years later, in 1136, she became abbess of the Benedictine convent at Disibodenburg. In 1147, she founded her own convent in Rupertsburg near Bingen, overlooking the Rhine River.

To Hildegard, healing was both medical and miraculous. She wrote, "These remedies come from God and will either heal people or they must die, for God does not wish them to be healed."

Hildegard composed two treatises on natural history and medicine, *Physica* and *Causae et curae*, known in English as the *Book of Simple Medicine* and *Book of Composed Medicine*. *Physica* is an encyclopedia characterizing elements, fish, birds, mammals, precious stones, trees and over 200 herbs and plants. *Causae et curae* describes the nature and form of many diseases along with medical and herbal treatments. She also espoused the curative virtue of precious stones. For example, she regarded sapphires as good for the eyes and as an anti-aphrodisiac; amethyst was used to treat rash.

Hildegard adopted the ancient concept that the world is composed of four elements - fire, air, water and earth. These are represented in the human body of four cardinal humors - cholera (yellow bile), blood, phlegm, and melancholy (black bile). Harmony among these elements resulted in health; disharmony or imbalance was illness.

"As long as the flow of the humors in a person functions properly and maintains warmth, moisture, blood and flesh, then the person enjoys good health. But as soon as they flow all at once in excess and without caution, they create sickness and cause death," she noted.

Like other medieval monastic healers, Hildegard looked to plants for cures. Each plant was believed to be hot, cold, moist or dry, and these attributes determined its suitability as a treatment for a given illness. For example, Hildegard's cure for migraine was a mixture of aloe (hot), myrrh (dry) and poppy oil (cold), mixed with flour. She considered fennel an all-purpose herb that promoted general good health; it is still eaten today as a digestive aid. Hildegard also used fennel in combination with other herbs to treat respiratory ailments.

"Those who cough should take fennel and dill in equal parts, add one-third of a part of horehound and boil the herbs in wine, strain through a linen cloth, drink and the cough will disappear."

She also prescribed fennel as a remedy for afflicted blue eyes; herbal remedies of the time were often determined by eye color. If brown eyes were hurting, the herb used was rue. Hildegard regarded bright eyes as a sign of life, and dull eyes as a sign of death. She is credited with introducing the use of eyebright (*Euphrasia officinalis*) as an eye remedy; it has since been shown to be astringent and anti-inflammatory.

Nearly one thousand years have passed since Hildegard's medical writings and most view her medicine as folkloric. Some, however, compare her use of herbs, diet and natural remedies to achieve health to today's holistic medicine. In his recent book, *Migraine*, neurologist Dr. Oliver Sack refers to the allusions

to the migranous visions of Hildegard of Bingen. These visions resulted in her doing tapestries which personify a migraine aura - a phenomena described by many migraine sufferers.

A woman of boundless energy, Hildegard is still known today for her poetry and music. These poetry and dramatic compositions, complete with her own melodies, make her one of the earliest identifiable composers and a reasonably documented musical personality. In late 1994, Angel Records produced an album of her liturgical music, called "Vision," which was given a modern interpretation by synthesist Richard Souther.

Hildegard's influence was considerable in her own time and lasted far into the Renaissance when the first printed editions of many of her writings were published. Attention to her continues today, with many scholars, composers and others interested in Hildegard's writing, music and her place in history.

References:

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2. "Hildegard of Bingen," *Dictionary of Scientific Biography*. Charles E. Gillespie, Editor, Vol. VI, Charles Scribner's Sons - New York, P. 396-398.
3. *Migraine* (book review), Seymour-Diamond, *JAMA* V. 271, N. 6, p.478, Feb. 9, 1994.
4. "Sisters Are Doing It For Themselves," Jeff Gordinier, *Entertainment Weekly*, p. 74, Nov. 1994.

Phlebotomy in the Home Care Setting

by Lynn C. Hadaway, M.Ed., RNC, CRNI

The need to obtain blood samples outside traditional health care settings continues to increase. Several factors are contributing to this trend including shorter hospital stays, an aging population, increased monitoring of medication levels, and the provision of blood samples required by insurance companies during the application process. Concurrent advancements in intravenous therapy have also supported the requisite need for care in the home and work settings. Home care blood collections require special considerations compared to routine hospital-based blood draws, several of which will be addressed here.

Obtaining the Specimen

When collecting blood specimens in the home, the blood can be drawn by any one of the following ways:

1. Direct venipuncture, using an evacuated tube, blood collection needle or winged needles and a needle holder.
2. Venipuncture with a syringe, where the blood is then transferred from the syringe into an evacuated tube. (Not recommended with a sharp device; perform with caution using a non-sharps device. See Safety Tips).
3. Venous line draw where blood is drawn directly into an evacuated tube with a luer adapter and needle (direct method).
4. Venous line draw where a syringe is filled with blood and the evacuated tubes are filled from the syringe (indirect method).
5. Arterial line draws with a syringe.

The focus of this article will be on venous line draws, with a discussion of the types of lines a patient may have in place and how they can be accessed. As mentioned above, specimens are obtained by venipuncture or from a variety of vascular access devices. Venipuncture is one of the most common health care procedures. Success depends upon the skill of the nurse performing the procedure and the condition of the patient's veins. Limitations in peripheral veins are caused by chronic diseases, hydration status, number of previous venipunctures, and age. As we age, the skin, subcutaneous layer, and blood vessel integrity changes, increasing the difficulty with venipuncture. Chronic diseases such as diabetes and hypertension change the characteristics of veins making the vein walls feel thick and hard. With inadequate fluid intake or an excessive loss of fluid, veins do not easily distend with tourniquet application.

Minor complications following venipuncture include bruising and hematoma formation. Venipuncture can also produce a vasovagal reaction, characterized by feeling faint, dizzy or lightheaded, hot or cold; nausea and vomiting; profuse sweating; decreases in blood pressure and heart rate; and possible loss of consciousness. This occurs more frequently in younger men and those with a history of these reactions during other venipunctures or health care procedures.^{1,2} When there is a history of such reactions, the procedure should be performed with the patient in the supine position.³

Types of Vascular Access Devices

Patients may have a variety of vascular access devices that can be used to obtain blood samples, thus eliminating the need for peripheral venipuncture. In home care, the most common devices include implanted ports, tunneled catheters, and peripherally inserted central venous catheters (PICCs). These catheters have their tips located in the superior vena cava, the site of rapid blood flow. An implanted port is composed of a port body and catheter. The port body is a small reservoir covered by a dense silicone septum and is totally implanted under the skin. The port body is palpated and a special needle with a deflected tip is used to puncture through the skin and septum, providing immediate access to the central venous system. The pocket for the port body is surgically created and may be located in the chest or arm. A tunneled catheter enters the vein under the clavicle and exits the skin at a site lower on the chest wall. A tunnel in the subcutaneous tissue is surgically created between the vein entry site and the skin exit site.

There is a Dacron cuff around the catheter circumference. With the catheter and cuff located inside the tunnel, the subcutaneous tissue grows into the cuff creating a mechanical barrier to microorganisms and anchoring the catheter in place.

A PICC is inserted by peripheral venipuncture in the antecubital fossa of the upper extremity. The catheter is threaded in the vein up the arm and into the central venous system.

Problems Associated with Catheter Blood Collections

Catheters are used primarily for the infusion of fluids and medications. They may be used for obtaining blood samples although success rates depend upon many factors. These catheters, especially PICCs, have soft flexible walls that may collapse when high negative pressure is applied. This usually does not cause catheter damage but it does occlude the aspiration of blood and can compromise the quality of the specimen.

Fibrin accumulates on the outer catheter surface and creates a valve-like effect around the catheter tip. This is known as persistent withdrawal occlusion indicating that fluid can be flushed into the catheter but blood cannot be aspirated. Fibrin and blood clots may also accumulate inside the catheter lumen and occlude the lumen for aspiration of blood.

Other factors that prevent the aspiration of blood from catheters include impingement of the catheter tip against the vein wall and the "pinch-off" syndrome where the catheter is pinched between the clavicle and first rib. Repositioning the patient may relieve these obstructions. This includes assisting the patient to change from a sitting to a lying position, rolling from one side to the other, raising or lowering the upper extremities, and coughing.

When any type of vascular access device is used, a small sample (at least the catheter dwell volume) must be withdrawn and discarded to ensure valid test results. The discarded sample typically contains saline and heparin used to maintain catheter lumen patency. However, any infused drugs may also interfere with laboratory results. Examples of situations that raise concern include infusion of heparin when PTTs are needed, and aminoglycoside or vancomycin infusion immediately preceding peak levels. Additionally, small amounts of fibrin and drug precipitate can adhere to catheter walls causing small quantities of drug to be withdrawn with the sample. For infants and small children, the initial sample may be reinfused rather than discarded due to concerns about total blood volume. In these cases, the initial sample is drawn into a heparinized syringe connected to a stopcock; another syringe attached to the opposite side of the stopcock is used to withdraw the sample; and the initial sample is reinfused.

Another concern with using catheters is the risk of introducing microorganisms and the risk of infection. Disrupting a "closed" vascular access has the potential for contaminating the blood stream. All infusions through the catheter must be stopped for at least one full minute, the discard sample and the sample for testing withdrawn, the catheter flushed with normal saline, and the catheter locked with heparin or the infusions resumed. Depending upon the equipment used, this may result in excessive manipulation of the catheter hub that increases the possibility of contamination.

Safety

Regardless of the procedure used to obtain the blood sample, prevention of needle stick injuries must be of paramount concern. Health care workers face serious risk of acquiring bloodborne pathogens such as hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV). The risk of occupational infection by bloodborne pathogens is related to the prevalence of infection in the patient population, along with the frequency and type of exposure events. This risk can and should be minimized by use of products that house the needle after use and prevent the possibility of accidental injury.

Products with safety features are available for most techniques. Drawing blood into syringes, then transferring to the appropriate tubes increases the potential for blood contact and should be avoided. (See Safety Tips)

Sample Handling

Specimen handling and transportation is of equal importance to the integrity of the test results. Packaging requirements, means of delivery and the appropriate laboratory for testing are top concerns that should be addressed and established prior to specimen collection.

The health care worker performing the procedure may be expected to deliver the specimen, however the lab may be located outside of their designated territory. Travel time will decrease the health care worker's availability to other patients. A family member may be available to make the delivery instead of the nurse. Time between obtaining the sample and running the test is another factor in obtaining accurate results, depending on the stability of the analytes to be measured.

The specimen must be packaged to prevent tube breakage, spillage, and exposure to temperature extremes. If breakage occurs, packaging should contain the blood without leakage from the bag or box. If a spill occurs, a spill kit must be available for proper clean up. Packages must be labeled with "Biohazard" stickers. Temperature control is accomplished with ice and coolers. This is a higher priority during warm or hot seasons and warmer locations in the country.

Laboratory Considerations

The choice of laboratory is usually determined by the payer of the service; often the insurance company or managed care organization play this role in today's environment. The physician may prefer the hospital laboratory because of familiarity with methods and processes, but this may be at odds with the payer preferences. These differences should be resolved prior to blood collection.

The hospital may require the person delivering the blood sample to register through the outpatient department which can involve some waiting time. When the hospital laboratory is chosen, results from the inpatient and outpatient periods can be directly compared without concern for deviation related to different processing and analytical methods.

The home care professional must know other factors about the laboratory operation such as their hours of operation, information about the types of tubes to draw for the test ordered, the methods to preserve the sample during transportation, the amount of time between drawing the sample and analyzing the sample, and any limitations in the services they perform. Conflicts between the home care needs and laboratory services must be anticipated and resolved. For example, the diagnosis of a catheter-related bloodstream infection (CR-BSI) requires the culture of catheter segments by semiquantitative or quantitative methods. The clinical definition of CR-BSI usually includes colony counts, however the laboratory may provide organism identification only.

Communication

The final step is communication of the test results to the appropriate individuals including the nurses at the home care agency; the physicians providing primary care and consulting services; and the pharmacist at the infusion services provider. A clearly defined process is required to identify and ensure accurate result reporting to the appropriate people for each patient. Changes in the prescribed medications may be indicated to produce the desired therapeutic response or to avoid serious complications from the medications being infused.

Conclusion

Obtaining and processing blood samples in home care requires a collaborative effort between the patient, the home care professional(s), the physician(s), the pharmacist(s), and the laboratory. While it is not as simple as taking the sample to another floor in the same building, the importance of quality lab results is just as critical in the home care setting as in the hospital.

Reference:

1. Galena, H.J., Complications occurring from diagnostic venipuncture. *Journal of Family Practice*, 1992. 34(5): p. 582-584.
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Becton Dickinson VACUTAINER Systems New Product News

VACUTAINER Brand K2 EDTA Tubes Pre-certified For Low Level Lead Testing

The Centers for Disease Control and Prevention (CDC) initiated a program in the United States to eliminate lead poisoning in children by the year 2010. Part of this program included a recommendation to screen all children aged 6 months to 6 years for lead poisoning by direct measurement of whole blood lead. Free erythrocyte protoporphyrin (FEP) was the standard method of screening for lead poisoning, but has subsequently been found insensitive to low levels of lead, when acceptable lead levels were reduced from 25 g/dL to 10 g/dL.

Venous blood is the specimen preferred over capillary sampling because of possible falsely elevated values from soiled fingertips. The CDC recommends that laboratories qualify each lot of tubes used for lead testing.

Becton Dickinson VACUTAINER Systems will release a low volume draw K2 EDTA tube that is pre-certified for tube lead content for accurate lead determination tests. Reorder number 367855 is a 3ml draw VACUTAINER® Brand 13x75 PLUS K2 EDTA with a tan HEMOGARD® Closure.

Lead levels are certified at manufacturing to not exceed 2.5 parts per billion (ppb), thereby eliminating the need of the facility to routinely qualify tubes for lead content. This is the only evacuated blood collection tube on the market that addresses the needs of this critical testing with a virtually unbreakable, low volume draw tube with a safety closure. This product in use with the VACUTAINER® Brand SAFETY-LOK™ Blood Collection Set will provide a safer, more accurate system for obtaining venous samples for lead testing on children.

For more information about this product, contact your Becton Dickinson VACUTAINER Systems Representative or use the enclosed reply card.