Biospecimen Collection, Processing, and Analysis: New Challenges for Oncology Nurses

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Objectives: *To provide an overview of emerging applications for and challenges associated with biospecimen collection for evaluating personalized disease risk and/or treatment response in cancer clinical trials.*

Data Sources: *Published nursing and medical literature.*

Conclusion: *Blood- and tissue-based biomarkers are increasingly utilized to identify the molecular signatures of disease that can inform the determination of a course of treatment in a very precise manner. There are challenges for the oncology nurse related to specimen collection, processing, analysis, and translation to precision treatment.*

Implications for Nursing Practice: *It is important for nurses to have appropriate training and a working understanding of the procedures for biospecimen collection and how biospecimen analyses can inform precision assessment of risk and prognosis.*

Key Words: *Biospecimens, biomarker, specimen collection*

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OVER the span of a few decades a transition has occurred, from a woman undergoing general anesthesia not knowing if she would have breasts when she awakened, to asking if she had local or metastatic breast cancer with lymph node involvement, to asking if she had triple-negative disease that may or may not respond to single-agent chemotherapy. A few decades ago, a drop of blood was used to determine blood type; biopsies were believed to enhance the likelihood of metastases; and nursing assessment for a person believed to have cancer was limited to palpation and examination of x-rays.

Today, that drop of blood provides much more information by essentially opening a window into an individual's genetic makeup and risk profile. The biopsy tissue not only places the cancer into one of a multitude of subgroups toward which therapies can be targeted, but some portion of the tissue can also be preserved for use in future research, the bounds of which are as yet unimaginable. The nurse is expected to coordinate the correct collection of the blood and tissue, mediate the overlapping needs of the clinical and research teams, and help the patient navigate a maze of information systems that will help them understand risk, diagnosis, and treatment data at an individualized level.

Evaluating the patient's health status, assessing risk of cancer, assisting in determining the course of treatment, and monitoring the response to that treatment continue to define the job of the oncology nurse.[1] The basics of the nursing process have not changed. However, the complexity, required knowledge, and expectations of the oncology nurse have changed dramatically over the past decade. Palpating a tumor or visualizing it on an x-ray may help diagnose cancer but provides insufficient additional information. Determining the course of treatment and monitoring the response requires learning about the tumor at the molecular level.[1] Complicating the issue is the fact that the same specimens required for the assessment of health status, risk, and response in the cancer patient may be the same specimens required for eligibility assessment and the endpoints for a clinical trial. The potential exists for one goal to "trump" the other.

Specimen Collection Basics

Blood Collection

In both clinical and research settings, blood collection has the advantage of being minimally invasive and specimens are often more quickly analyzed. Planning and preparation is required to assure collection of specimens needed for clinical and research protocol-specific analyses. Blood collection supplies must be organized and at hand before placing the tourniquet because the longer the tourniquet is in place, the higher the risk of hemoconcentration of non-filterable elements such as proteins in the blood.[2]

Placement of the tourniquet for venipuncture is affected by the health status and diagnosis of the patient. For example, the tourniquet should be not placed on the affected arm from a mastectomy unless ordered by a physician.[3] If the blood must be drawn from the same arm as an intravenous access site, then the tourniquet must be placed several inches above the site and only tight enough to restrict superficial venous flow. Tourniquets should not be left in place longer than 2 minutes before being loosened.

Collection tubes may contain a preservative or anticoagulant, either in liquid form or coating the inside of the tube, dependent on the type of analysis needed (Table 1). They are distinguished by a color-coded cap, which until its expiration date, maintains a partial vacuum inside the tube. There is some variability among manufacturers in the color of the top and presence or absence of clot activators or gel. Details for collection for a clinical trial will be found in the research protocol, lab manual, and/or specimen kit instructions. Importantly, the tubes must be filled in a specific order to prevent cross contamination of blood additives within the collection tubes (Fig. 1).

The vacuum contained within the tube determines how much blood will be collected for a complete tube fill. The closer to the expiration date, the weaker the vacuum may be within the tube. If a tube does not fill completely, such as only half or a third of the tube filled, additional tubes can be added to obtain the required amount of blood. After the tube is filled with blood, the tubes must be gently inverted until the bubble at the top of the tube moves to the bottom of the tube and vice versa. Blood-filled tubes should be gently inverted at least five to 10 times. Tubes that require clot formation, such as the no-additive red top tubes or the serum separator tubes (often called tiger tops), should sit at room temperature for at least 30 minutes to allow the clot to form.

The post-collection processing of blood specimens is also critical. Centrifugation, or rapid spinning, results in separating or fractionating the components within the tube according to their density. The most dense blood components will be in the bottom of the tube, and the least dense components will be at the top. Centrifugation speeds, duration, and temperature can affect the quality of the specimen. If the speed and duration of the centrifugation process are correct, there will be very distinct layers not unlike an oil and vinegar salad dressing that has been allowed to settle. Centrifugation that is too fast or too long will damage the cell components. If the speed is slow or the duration too short, the layers will not be distinct and easily separable.