TRALI is best described by defining signs and symptoms of the reaction, including dyspnea (difficulty breathing), cyanosis (bluish skin color), hypotension, fever and chills along with physical findings such as bilateral pulmonary edema. The symptoms typically begin within 1-2 hours of transfusion and usually are present by 4-6 hours. It is more often associated with transfusion of whole blood, packed red blood cells (pRBCs) and fresh frozen plasma (FFP).

Since classic TRALI episodes have been seen in recipients of blood that came from male donors who do not have antibodies and have never been transfused, there is another hypothesis for the cause. This hypothesis proposes that biologically active lipids in stored blood components may enhance polymorphonuclear cell NADPH oxidase activity. Both donor and recipient factors seem to be important since not everybody who receives a unit containing antileukocyte antibodies is at risk. However, the evidence that biologically active lipids cause TRALI is limited and may not be sufficient to warrant avoiding cellular components stored for more than 10 days.

TREATMENT
Corticosteroids, epinephrine and diuretics have been used traditionally to treat TRALI. However, since the pulmonary edema in TRALI is not related to fluid overload or cardiac dysfunction, it is logical that maintaining an adequate circulating volume would be the most beneficial and appropriate therapy. Treatment requires stopping the transfusion and giving oxygen and cardiovascular support. The use of corticosteroids remains controversial since the pulmonary edema is not secondary to volume overload. Diuretic use may be detrimental and could lead to hypotension and decreased cardiac output.

PREVENTION
After the transfusion has been discontinued and oxygen and supportive therapy have been initiated, the blood center then must evaluate the donor. The donors of all components transfused within six hours of initiation of the reaction should be screened for the presence of granulocyte and HLA class I antibodies. A large number of donors are involved, female donors or multiparous female donors can be screened for antibodies first. To prove the diagnosis, the antibody present in the donor should correspond to an HLA or granulocyte antigen present in the recipient (or donor).

One of the reasons it has taken 15 years for TRALI to become widely recognized is that technology for laboratory confirmation has only become available approximately in the last five years, e.g., solid-phase technology such as flow cytometry. ELISA-based techniques are also available. Both are prone to ambiguity of interpretation than cellular assays.

Remind everyone of the importance of patient safety. That’s why we check every unit of blood and platelet before it goes into a patient. We test for antibody and make sure the donor is compatible. Then we test for HLA and other antigens. We check for HLA and other antigens. This helps us make sure that we are only giving blood to patients who are compatible with the donor. By doing this, we can prevent any potential complications that may arise from mismatched blood transfusions.

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References:
Departs from the SNF on a brief leave of absence, typically accompanied by a relative or friend, obtains services that are subject to consolidated billing but fails to inform the SNF. This results in the services being furnished to the resident by an entity that may not have a valid arrangement with the SNF. SNFs can act to prevent such problems from arising by ensuring that each resident (or his or her representative) is fully aware of the applicable requirements.

Problem scenario 1: A SNF elects to utilize an outside supplier to furnish a type of service that is subject to Part A consolidated billing, but fails to inform the supplier that the resident receiving the service is covered in a Part A stay. While it is recognized that inadvertent errors may occur, a SNF should not only make a good faith effort to furnish accurate information to its supplier, but should have a ‘written agreement’ in place that provides for direct reimbursement of the supplier once an error is called to its attention. If the SNF refuses to pay the supplier even after notification of the error, it is subject to potential civil monetary penalties. However, in entering into such an arrangement, the SNF cannot function as a ‘middleman’ for Medicare, and must actually exercise professional responsibility and control over the arrangement for service. The long-term care facility requirements for program participation further provide that under such an arrangement, the SNF must specify in writing that it assumes responsibility for the quality and timeliness of the arranged-for service.

Problem scenario 2: A resident who temporarily departs from the SNF on a brief leave of absence, typically accompanied by a relative or friend, obtains services that are subject to consolidated billing but fails to inform the SNF. This results in the services being furnished to the resident by an entity that may not have a valid arrangement with the SNF. SNFs can act to prevent such problems from arising by ensuring that each resident (or his or her representative) is fully aware of the applicable requirements.

Supplier Responsibility
While the SNF itself should take reasonable steps to prevent such problems from arising, the supplier is also responsible for complying with the consolidated billing requirements. Prior to furnishing services to a Medicare beneficiary, the supplier should routinely ascertain whether the beneficiary is currently receiving any comprehensive Medicare benefits under consolidated billing. The existence of such an agreement also provides both parties with a means of resolution in the event that a dispute arises over a particular service. Under an ‘arrangement,’ Medicare’s payment to the SNF represents payment in full for the arranged-for service, and the supplier of the service must look to the SNF (rather than Medicare Part B) for its payment. In entering into such an arrangement, the SNF cannot function as a ‘middleman’ for Medicare, and must actually exercise professional responsibility and control over the arranged-for service. The CMS does not prescribe the actual terms of the SNF’s written agreement with its supplier, such as the specific amount or timing of the supplier’s payment. Those conditions are to be arrived at through direct negotiation between the parties to the agreement. However, in order for a valid ‘arrangement’ to exist, the SNF must have a written agreement in place with its supplier, which specifies how the supplier is to be paid for its services. The existence of such an agreement also provides both parties with a means of resolution in the event that a dispute arises over a particular service.

Did You Know?
This year’s annual additions, deletions, and revisions for ICD-9-CM codes are effective for services provided or on or after October 1, 2004. CMS will no longer allow a 90-day grace period from October 1 through December 31 for the annual ICD-9-CM updates because the HIPAA Transaction and Code Set Rule requires the use of medical code sets that are valid at the time the service is provided.

Reminder:
This is the second in a three-part series of laboratory methodology descriptions. Part 1 was published in the June 2003 issue of the Laboratory Dimensions.

Immunometric Procedures
Radioimmunoassay (RIA) — uses fixed-dose, low-level, radioactive isotope labeled antigen (“tracer”) to compete with unlabeled antigen from the patient specimen for a fixed number of antibody binding sites. The free antigen-enzyme complexes resulting from competition with measured antigen in the sample forms color-change products of enzyme-substrate interaction or inhibition to measure the antigen-antibody reaction. (See EMIT, ELISA, MAC, and MEIA)

Enzyme multiplied immunoassay technique (EMIT) — the antigen being measured competes for a limited number of antibody binding sites with enzyme labeled antigen. The free antigen-enzyme complex resulting from competition with measured antigen in the sample forms color-change products proportional to the concentration of antigen present in the specimen.

Enzyme-linked immunosorbant assay (ELISA) — can quantitate either antigen or antibody; enzyme-labeled antibody or antigen is bound to a solid support (e.g., tubes, beads, microtiter plate wells, plastic tubes or wires). After adding patient specimen and substrate, antigen, antibody or complex are detected by a color change.

Microparticle enzyme immunoassay (MEIA) — solid phase support consists of very small microparticles in liquid suspension. Specific reagent antibodies are bound to the microparticles. Antibodies in liquid solution. Solid-phase involves the use of antibody bound to solid support (e.g., tubes, glass beads or plastic fins). Reactivity remaining after washing is inversely proportional to the concentration of antigen in the sample.