Summary
For the past several years, bacterial contamination of platelets has been the greatest transfusion-transmitted infectious risk in the United States; this risk has been significantly higher than the risk of transfusion-transmitted viral infection. Bacterial contamination of platelet components occurs because the storage temperature for platelets (20-24 C) facilitates bacterial growth. Approximately 1 in 1,000 to 3,000 platelet units may be contaminated with bacteria.\(^1,^2\) Transfusion-transmitted sepsis has been recognized and culture-confirmed in at least 1 of 100,000 recipients,\(^3\) and has led to an immediate fatal outcome in 1 of 500,000 recipients.\(^3\) The actual risk of transfusion-associated sepsis has likely been higher, because infections resulting from contaminated blood components are underreported.

Over the past year, blood collection facilities and transfusion services have implemented procedures to detect bacterial contamination in platelet units in order to reduce these morbidity and mortality risks (see Appendix 1). The sensitivity of these bacterial detection procedures is currently unknown. Although the current risk of transfusing a bacterially contaminated platelet unit cannot be accurately estimated, it is likely that this risk has been substantially reduced. Nevertheless, some units with bacterial contamination will escape detection using current procedures. This document is being provided to alert clinicians of this ongoing risk of posttransfusion bacterial infection in order to facilitate a) their management of patients receiving platelets and b) the management of donors referred for follow-up for positive bacterial cultures in donated platelet units.

It is critical that clinicians be aware of the problem of bacterial contamination of blood components, particularly platelets, and consider the possibility of bacterial contamination when investigating transfusion reactions. Clinicians should collaborate with hospital transfusion services and blood collection center personnel to manage suspected infections...
in blood donors and patients (blood component recipients). In addition, when necessary, notification of health departments should occur (see Appendix 2).

**Blood Transfusion Recipients**

Protocols should be in place to help clinicians recognize and manage transfusion reactions, including those potentially caused by bacterial contamination.

If bacterial contamination of a component is suspected, the transfusion should be stopped immediately, the unit should be saved for further testing, and blood cultures should be obtained from the patient. Bacterial isolates from cultures of the recipient and the unit should be saved for further investigation.

Posttransfusion notification of appropriate clinical personnel is needed if cultures performed by the blood center or transfusion service identify slow-growing bacteria after the associated product has been released from inventory or transfused.

**Blood Donors**

For any gram-negative or clinically significant gram-positive organism, it is recommended that the donor be carefully examined for evidence of occult infection, particularly if the microorganism identified could be potentially harmful to the donor or if the microorganism has been detected previously in the same donor. Any microorganism of public health significance identified in donors or recipients will require notification of the appropriate state and local public health department. In addition, the culture isolate should be saved for confirmation of identity and further investigation.

AABB offers the following evaluation and management recommendations to address the three most common situations clinicians may face: the clinician is contacted with information involving bacterial contamination of a blood component after it has been transfused; a recipient develops posttransfusion bacteremia after receiving platelets; a blood donor is identified as possibly infected and referred to a clinician for medical follow-up.

**A. The clinician is contacted by the blood collection facility or transfusion service with information involving blood or a blood component with bacterial contamination after it has been transfused.**

1. The minimal evaluation of a patient suspected of having received a bacterially contaminated platelet transfusion should include the following:
   - Culture of any residual component, if available, to confirm the initial result.
   - Blood cultures of the patient, even in the absence of apparent sepsis, to be certain that clinically silent infections are not missed.
2. Any isolates (i.e., microorganisms obtained from the residual component and/or patient cultures) should be retained until the case investigation is completed. This permits detailed studies to determine if the microorganisms are linked.

3. Results of the patient’s clinical and laboratory workup should be promptly communicated to the transfusion service medical director, who, in turn, should report these findings to the collection facility; these data will help determine the significance of the platelet test result.

B. A blood or blood component recipient has signs or symptoms consistent with posttransfusion bacteremia.

Because no test is 100% sensitive, false-negative results of platelet screening for bacterial contamination will occur.

1. Transfusing physicians should continue to evaluate all transfused patients with onset of signs or symptoms consistent with bacteremia or sepsis for post-transfusion bacterial infection, even when a bacterially tested component has been infused.

2. The minimal evaluation of a patient with suspected sepsis following platelet transfusion should include the following:
   - Culture of any residual component, if available.
   - Blood cultures of the patient.

3. Any isolates (i.e., microorganisms obtained from the residual component and/or patient cultures) should be retained until the case investigation is completed. This permits detailed studies to determine if the microorganisms are linked.

4. Results of the patient’s clinical and laboratory workup should be promptly communicated to the transfusion service medical director, who, in turn, should report these findings to the collection facility; these data will help determine the significance of the initially negative test result.

C. A blood donor presents to a clinician with a report of possible infection with bacteria discovered during the blood donation process.

1. Donors with potentially medically significant microorganisms may be advised by the collection facility to see their physician for further evaluation. Evaluation of the donor by the physician should begin with a thorough clinical history and a physical examination. Follow-up investigations might include blood cultures, other body-site cultures, and additional tests as appropriate.

2. Communication between the blood center physician and the clinician should facilitate management of the donor. Identification of a culture indicating endogenous bacteremia will likely result in deferral of the donor from future
blood donation. To resume donation, the blood collection facility may require
the donor to be cleared by the clinician and the blood center medical director;
this reentry could be based on the donor successfully completing treatment.

References

1. Dodd RY. Bacterial contamination and transfusion safety: Experience in
microbiologic surveillance program to detect and prevent the transfusion
2001;41:1493-9.
Appendix 1. Background Material on Efforts to Limit and Detect Bacterial Contamination of Platelets

Bacterial contamination of platelet components is the second most common cause of transfusion-related deaths in the United States. To address this risk, AABB adopted a standard that requires blood collection and transfusion service members to limit and detect bacterial contamination in all platelet components. No detection method has been universally adopted for this purpose and regardless of the method, screening of platelets for bacteria is unlikely to detect all bacterial pathogens.

Bacterial contamination of a blood component often is not considered in the differential diagnosis of posttransfusion illness because signs and symptoms (including fever, rigors, and change in blood pressure) resemble those expected from either an immunologically-mediated transfusion reaction or from sepsis associated with underlying diseases and therapies. Gram-positive organisms (eg, Staphylococcus epidermidis) found on skin are the most frequent contaminants of platelet units. Although less commonly recognized as contaminants, gram-negative bacteria (eg, Serratia, Enterobacter, and Salmonella spp.) cause more severe and often fatal infections.

The AABB Standard. To address the risk of bacterial contamination, effective March 1, 2004, AABB adopted Standard 5.1.5.1 (Standards for Blood Banks and Transfusion Services, 22nd edition), which requires all accredited institutional members to “implement measures to limit and detect bacterial contamination in all platelet components.” The College of American Pathologists has also added a query on such testing to the transfusion medicine checklist of its Laboratory Accreditation Program.

At this time, no single test is used to detect bacteria in platelet units. In practice, the type of platelet donation (apheresis or whole-blood-derived platelets) has dictated the bacteria detection approach. Most blood collection centers culture apheresis platelets (derived from single donors) and release the unit after the culture has incubated between 12 and 36 hours. In most cases, screening of whole-blood-derived platelets (pooled from 4 to 6 donations) for bacteria is conducted by hospital transfusion services. Many hospitals have implemented point-of-use tests, such as glucose and pH measurement, to screen whole-blood-derived platelets; these tests are insensitive, resulting in more frequent false-negative results.

Guidance for Implementation of the AABB Standard. In an effort to improve screening for bacteria and reporting of results, AABB has provided guidance on standardized definitions for test results, investigation and product management of implicated platelet units with positive tests, management of other components (co-components) associated with the same donation, and further characterization of detected organisms.

This guidance for the blood collection or transfusion service recommends that the following actions be taken:
1. **When Bacterial Contamination Is Found in the Unit After Transfusion**

Because culture-based tests take variable amounts of time to generate positive results, bacterial contamination may be identified after the unit has been released and transfused.

- Prompt notification to the transfusing physician with all available information must be made according to local operating procedures either by the transfusion service or the facility performing the testing.

- All test results should be reported to the transfusion service medical director and the transfusing physician as soon as possible.
  - A Gram’s stain should be performed immediately on any retained portion of the unit.
  - The microorganism should be identified and susceptibility testing performed promptly.

- Posttransfusion patient follow-up care will depend on the clinical status of the transfused patient and the judgment of the transfusing physician. Direct communication between the medical director of the testing facility and the transfusion service medical director, and between either of these individuals and the transfusing clinician, is important for optimal management of patient care decisions.

2. **When Possible Donor Infection Associated with Organisms Found on Bacterial Testing Is Suspected**

Before the performance of confirmatory assays, initial-positive test results include both true- and false-positive results. The initial-positive test result may be either true contamination introduced from the donor or during handling, or a false-positive result. The initial test may be a false-positive result because surrogate tests (eg, pH, glucose) have poor specificity or, for culture-based tests, because contamination was introduced in the laboratory at the time of culturing.

True-positive results may occur with a wide variety of microorganisms; while some may be of little or no clinical significance to the donor, others may be significant. A true-positive result is most often caused by skin flora (resulting from incomplete skin decontamination or a skin plug). However, a true-positive result can also be the result of microorganisms that may be of clinical significance to the donor, including those that cause bacteremia. The presence of a Gram-negative organism (eg, *Escherichia coli*) is most often caused by occult bacteremia. All gram-negative organisms should be considered potentially significant for the donor’s health. Gram-positive organisms (eg, *Staphylococcus epidermidis*) are likely to be either skin commensals or environmental contaminants. However, some gram-positive organisms (eg, *Staphylococcus aureus, Streptococcus pneumoniae*) may be from endogenous bacteremia in the donor. For example, an organism such as *S. aureus* may originate from bacteremia in a patient.
whose osteomyelitis was incompletely treated. Moreover, some organisms may have low pathogenicity, but may indicate a significant underlying disease (eg, *Streptococcus bovis* bacteremia associated with colon cancer).

- Blood collection facilities must notify donors of any medically significant abnormality discovered either during the interview or as a result of laboratory testing, in compliance with Standard 5.2.2 of the 23rd edition of AABB *Standards for Blood Banks and Transfusion Services*. Facilities are advised to refer donors with potentially significant results for medical follow-up. Criteria for deferral from future blood donation are established by the Food and Drug Administration or applicable State Department of Health (or applicable regulatory agency), or by guidelines from the facility medical director; they are based on the severity and transmissibility of the disease and on the availability of a confirmatory test.

- Certain microorganisms are of important public health significance, regardless of effects on donor health. These microorganisms require additional consideration and reporting according to local and national guidelines (see Appendix 2: Examples of Organisms of Public Health Significance).
# Appendix 2. Examples of Organisms of Public Health Significance*

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<thead>
<tr>
<th>Bacterial Category A Agents of Bioterrorism</th>
<th>Action</th>
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<tbody>
<tr>
<td><em>Bacillus anthracis</em></td>
<td>Immediately report to public health authorities</td>
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<tr>
<td><em>Yersinia pestis</em></td>
<td>(Save isolates for confirmatory identification and further action)</td>
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<tr>
<td><em>Francisella tularensis</em></td>
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<td><em>Clostridium botulinum</em></td>
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**Other selected bacteria associated with nationally notifiable diseases**

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<th>Action</th>
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<tr>
<td><em>Listeria monocytogenes</em></td>
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<td><em>Salmonella spp. (all spp.)</em></td>
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<tr>
<td><em>Shigella spp. (all spp.)</em></td>
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<tr>
<td><em>Group A streptococci</em></td>
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<td><em>Streptococcus pneumoniae</em></td>
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<td><em>Neisseria meningitidis</em></td>
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<td><em>Neisseria gonorrhoeae</em></td>
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<tr>
<td><em>Reporting requirements may vary by state; follow reporting criteria set forth by local authorities.</em>*</td>
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** See [http://www.cdc.gov/epo/dphsi/PHS/infdis.htm](http://www.cdc.gov/epo/dphsi/PHS/infdis.htm) for complete list.