

# **BACTERIAL CONTAMINATION OF PLATELETS**

**Committee Update**

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**Bacterial Contamination of the Blood Supply**

**FDA Program Summary**

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I will approach the summary of this program by providing a point-counterpoint of issues raised in a similar program summary 4 years ago in 1995 by Merlyn Sayers, M.D., Ph.D.<sup>1</sup> At that time Dr. Sayers commented that transfusion-associated sepsis was not a new concept. In 1999 not much has changed, it is still not a new concept. However, there are now many new approaches, new hopes, new research efforts, and a new enthusiasm for the eradication of bacterial contamination of the blood supply. There is far less inertia than there was in 1995 to actually effect a cure for this problem. In addition, and importantly, there are new monies being provided by federal and private agencies.

In 1995, Dr. Sayers pointed out that the impetus for further studies on bacterial contamination of the blood supply was in part due to a mini-epidemic of *Yersinia enterocolitica*. In 1999 there is also an impetus to eliminate bacterial contamination of blood. Now, however, the impetus is due to the desire to achieve a zero-risk blood supply, to promote the public health, and to further public trust and confidence in the blood supply. A worldwide effort is now underway which encompasses not only concerns over bacterial contamination of allogeneic blood donation but also autologous blood donation. Indeed, autologous donor blood may be at higher risk of bacterial contamination than allogeneic donor blood due to the presence of occult bacterial infections in some of the autologous donor/patients.

In 1995 Dr. Sayers commented on the absence of good data in this area. In 1999, in contrast, there are large amounts of data actively being collected under the BaCon study sponsored by the American Association of Blood Banks, FDA, CDC and American Red

blood supply and pathogen inactivation. In Canada Transfusion Safety Officers are being installed in hospitals as part of a major educational effort. What are still needed, however, are efforts to ensure increased physician and other healthcare provider training, and increased recognition and reporting of septic transfusion reactions, both targeted to the myriad of small hospitals around the country. In this regard, FDA regulations regarding reporting of septic transfusion reactions should be extended to unregistered facilities. This would appear, to me, to be better and more effective than wishing and hoping that improved reporting and recognition of septic transfusion reactions will occur spontaneously.

A report of hospital non-compliance in this area during an FDA inspection (Form 483), likely would attract the attention of administrators from hospitals that are currently strapped under enormous fiscal restraints. In my opinion, unless federal regulation requires physicians to become more aware of the potential for a septic transfusion reaction, improvements in reporting and medical care will not occur with any speed. Another approach might be to have the JCAHO become more aware of the importance of this area of transfusion medicine. The JCAHO could link monitoring of cases of transfusion-related sepsis to accreditation, in essence treating occurrence of a septic transfusion as a Sentinel Event. Lastly, an increase in public awareness would do much to improve the support of congressional leaders for this effort.

In 1995 Dr. Sayers reported that more investigation was needed into techniques to detect bacterial contamination of the blood supply. In 1999 there are a large number of such

Increases in governmental regulation, more healthcare provider education, increased public awareness, increased federal funding from NIH perhaps through RFAs or possibly through the SBIR program, will all act synergistically. As was observed in 1995 and as is still true in 1999, no one strategy works best. Furthermore, realizing this is a complex issue, Dr. Sayers and I both believe that some action is better than no action at all.

Perhaps it is appropriate to consider implementing some changes in the rules such as screening units of platelets on day 2 or 3 and if they are found to be sterile, extending their shelf-life to 7 days. This would allow some economic benefit, which could, perhaps, fund the expense of blood cultures and other surveillance costs and at the same time make the blood supply safer and more plentiful.

In conclusion, in 1999 as we face the new millennium, I feel that the best way to ensure a decreased risk of bacterial contamination of the blood supply is through increased federal regulation. However this effort must be supplemented by increased research and research funding, data collection and physician education. Eradication of bacteria from the blood supply is achievable, but as with all things - at a price.

#### References:

1. Klein HG, Dodd RY, Ness PM, Current status of microbial contamination of blood components: summary of a conference, *Transfusion* 1997;37:95-101.