



AMERICAN SOCIETY OF HEMATOLOGY

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2023

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RE: National Heart Lung and Blood Institute (NHLBI) Strategic Vision Refresh Request for Information (NOT-HL-23-118)

Dear Dr. Johnson:

On behalf of the American Society of Hematology (ASH), thank you for the opportunity to provide comments on the National Heart, Lung, and Blood Institute's (NHLBI) refresh of its Strategic Vision to address emerging scientific opportunities in accordance with new National Institutes of Health strategic plan requirements.

ASH represents more than 18,000 clinicians and scientists worldwide committed to studying and treating blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as classical (or non-malignant) conditions such as sickle cell disease, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the fields of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians providing care to patients.

The Society commented on NHLBI's Strategic Visioning in 2016; and, while many areas of the Institute's Strategic Vision refresh are still relevant to hematology, we are limiting our comments to "Supporting women's health through the lifespan," given ASH's more recent policy priority on maternal health and hematology. We feel that attention to this topic area is critical in considering whether additional compelling research questions are needed to drive forward important scientific and health advances. We will also offer our perspective on the challenges or barriers that need to be addressed to support progress in this area.

Supporting Women's Health Through the Lifespan

Perspective on critical research needs or compelling research questions

There is a spectrum of issues (pathobiologic, social, and environmental) that need to be addressed about pregnancy for people with heart, lung, and blood diseases, including hematologic, cardiologic, and pulmonary complications of pregnancy even in people without underlying conditions. Increased research is needed into the lifespan of

reproductive health, including menstruation, contraception, fertility/infertility, and menopause, all which have hematologic implications, such as thrombosis risks. The role of sex as a biological variable in medication studies is another critical research need, across specialties. One example is the failure of trials of anticoagulant and/or antiplatelet studies to consider heavy menstrual bleeding as an outcome.

Perspective on challenges or barriers that need to be addressed to support progress

In bleeding disorders, the lack of inclusion of women on clinical trials of novel therapies for bleeding disorders is a major impediment to improving outcomes and quality of life. Appropriate precautions are needed to avoid teratogenic effects, thrombosis in those using hormonal therapies or otherwise at risk for thrombosis, and iron deficiency anemia. Additionally, current challenges are the disparities in pregnancy complications and birth outcomes based on race, ethnicity, age, and other nonmodifiable risk factors; as well as environmental, and financial (i.e., potentially modifiable) risk factors. Finally, building capacity and promoting research in resource-limited settings needs to be addressed.

Again, the Society appreciates the opportunity to provide input. Please use Kelly Rose, Chief Scientific Officer (krose@hematology.org) as your point of contact should you have any questions.

Best regards,

A handwritten signature in black ink, appearing to read 'R. Brodsky', with a stylized flourish at the end.

Robert A. Brodsky, MD
President