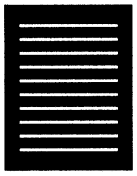
Preface



THE BLOOD DONOR HISTORY QUESTIONNAIRE (DHQ) elicits information from prospective blood donors and represents one of the layers of safety used to determine their eligibility for blood donation (Table 1). The DHQ contains many direct and specific questions about medical conditions, sexual contacts, lifestyle risks, residency in other countries, and recent travel to determine, to the extent possible, that the individual is in good health, will not be adversely affected by the blood donation, and is free of conditions that could affect the safety, purity, or potency of blood and blood components. Based on their answers, individuals may be disqualified from blood donation: temporarily deferred for a certain period of time if the potential risk is transient, indefinitely deferred if there is a possibility for reentry sometime in the future, or permanently deferred if they should never again attempt to give blood. To protect transfusion recipients, individuals are deferred if they have an infectious disease or might have been exposed to infectious diseases that could be transmitted by transfusion or if they have underlying conditions or are taking medications that affect the efficacy or safety of their blood donation. To protect their own health, individuals are also deferred if they report underlying medical conditions or other factors that predispose them to adverse effects of blood donation.

Questioning blood donors about infectious risk factors has been a guiding principle in blood safety since the publication of

Table 1. Layers of Blood Safety

Precautionary	Description
Educational materials (self-assessment)	Donors are provided with educational materials about infectious disease risk factors and are given the opportunity to ask questions to assess their own risk (Appendix 5). They may voluntarily leave the donor center if they realize they should not donate blood.
Donor health history assessment	1. Donor History Questionnaire (DHQ) (Appendix 1). 2. Focused physical examination and labs, as follows: • Temperature. • Blood pressure. • Pulse. • Arm inspection for signs of injection drug use. • Hemoglobin/hematocrit.
Infectious disease testing	All donations are tested for the following relevant transfusion transmitted infections: • HIV: Antibodies to HIV-1/2; HIV NAT. • HBV: Hepatitis B surface antigen; antibodies to hepatitis B core antigen; HBV NAT. • HCV: Antibodies to HCV; HCV NAT. • HTLV-I/II: Antibodies to HTLV-I/II. • West Nile virus: NAT.

	• Syphilis: Antibodies to *Treponema pallidum*. • One-time testing for Chagas disease: *T. cruzi* antibodies (Chagas). • Zika virus: NAT. • Bacteria: Culture or rapid tests (platelet components, only).
Postdonation information, quarantine, retrieval, market withdrawal, recall	Information provided after the blood donation may lead to the identification of unsuitable donations that are retrieved and destroyed, when possible.
Donor deferral registry	A confidential list of deferred donors is maintained to prevent acceptance of ineligible donors for a specific period, indefinitely or permanently.

HIV = human immunodeficiency virus; NAT = nucleic acid testing; HCV = hepatitis C virus; HTLV = human T-cell lymphotropic virus

AABB's *Standards for a Blood Transfusion Service* in 1958. For years before identification of the causative agents, hepatitis B virus (HBV) and hepatitis C virus (HCV), the only safeguard against posttransfusion hepatitis was excluding individuals who reported a history of jaundice or close contact with individuals with hepatitis. Similarly, deferral of individuals in risk groups was the first successful strategy to reduce transmission of human immunodeficiency virus (HIV) through blood transfusion by nearly 90%, even before the virus was identified. With the subsequent introduction and technical advances in infectious disease testing, the utility of donor screening questions has diminished but likely still contributes to the exceptional degree of safety observed today.

An indirect, albeit imperfect, measure of the possible contribution of blood donor selection criteria is the markedly lower prevalence of transfusion-transmitted diseases among blood donors compared to the general population. For example, in 2015, disease prevalence in the US for HIV was 303.5 per 100,000 in the general population compared to 2.6 per 100,000 among blood donors; for HBV, 260 per 100,000 in the general population and 6.5 per 100,000 among blood donors; and for HCV, 1074 per 100,000 in the general population and 19.8 per 100,000 in blood donors (Fig 1).[1-3] Infectious disease marker rates are even lower among repeat blood donors for HIV (1.4 per 100,000), HBV (1.1 per 100,000) and HCV (4.1 per 100,000) (Fig 1).[4,5] Moreover, donor questioning is often the first measure taken, and sometimes the only option, for known or emerging threats to blood safety when a screening test or pathogen reduction strategy is not available.

The challenge remains that donor questioning is not specific (ie, many healthy individuals are deferred) or sensitive (ie, some infected donors do not disclose risk behaviors). In 2015, approximately 7% of the 13.2 million individuals who presented to give blood in the US were deferred because of their responses on the DHQ (Table 2).[5] An important focus of research is generating evidence to enhance the specificity of the donor questionnaire and avoid deferring safe donors, without increasing donor or recipient risk. In addition, US blood

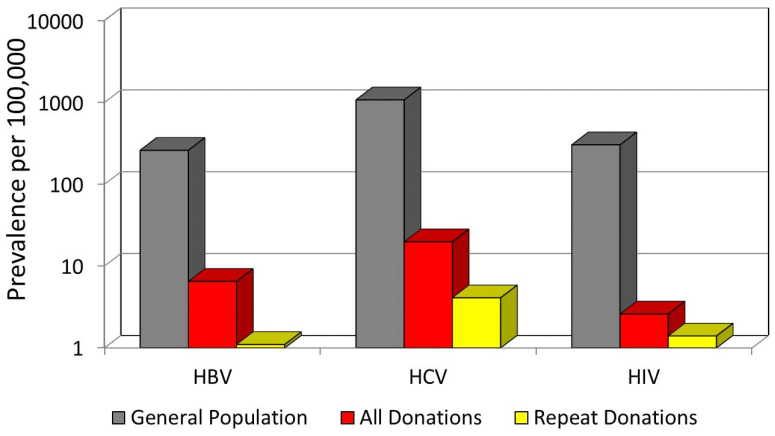


Figure 1. Infectious disease marker prevalence among blood donors compared to the general population, US 2015.[1-4]

Table 2. Common Health History Categories and US Blood Donor Deferral, 2015[3]

	US Deferrals (CY 2015)	
	Number	**(%)**
Travel	113,000	(12%)
Medications	54,000	(6%)
Tattoo and/or piercing	49,000	(5%)
Risk behavior, excluding MSM	16,000	(2%)
Risk behavior, MSM only	8,000	(0.9%)
Other medical reasons	504,000	(55%)
Other categories	166,000	(18%)
Total health history deferrals	910,000	
Total presentations	13, 225,000	

MSM = male-to-male sexual contact.

establishments recorded over 13,000 incidents involving post-donation information in 2015 which would have resulted in donor deferral and prevented collection of blood components had the information been available at the time of donation (Table 3).[6] Donor compliance is incompletely understood, but plays a key role in the efficacy of the DHQ.

In the 10 years since the first edition of this book, there have been significant changes and research developments that have affected the DHQ. Most notably in the US, the deferral for male-to-male sexual contact (MSM) was changed from an indefinite deferral for any history of MSM since 1977, to a 12-month deferral after the last contact. Several questions were removed from the DHQ. Two questions about geographic risk for HIV-1 Group O as result of birth, residency, or blood transfusion in certain West African countries, or sexual contact with partners with such possible exposure, were eliminated when HIV donor screening tests were licensed to detect the rare HIV variant. In addition, the longstanding requirement to question donors about a non-

Table 3. Common Postdonation Information Categories Reported as Biologic Product Deviations to FDA[4]

	US Reports (FY 2016)	
	Number	**Percent**
Travel history - malaria risk	4,184	(31%)
Travel history - vCJD risk	2,102	(16%)
History of male-to-male sex	942	(7%)
Medications, potential teratogens*	880	(7%)
Tattoo and/or piercing	845	(6%)
Other	4,351	(33%)
Total reports	13,304	

*Finasteride, Tegison, Accutane, Avodart, Jalyn, or Absorica. vCJD = variant Creutzfeldt-Jakob disease.

specific history of viral hepatitis after their 11th birthday was eliminated in 2016, in recognition that no bloodborne viruses other than HBV and HCV have been identified to cause chronic posttransfusion hepatitis or significant health risk to recipients. Ongoing efforts to further refine the process of donor selection by modifying the questions or imposing additional criteria in the US will utilize newly established systems to monitor infectious disease markers among blood donors nationwide and evaluate scientific information as it becomes available.[7]

This edition describes the current approach to donor health history assessment and evaluates the available published evidence to support donor eligibility decisions. The intent throughout the chapters is to describe current regulations and standards, identify variability in the practices defined by different blood systems, and provide a framework for decision-making when the evidence is incomplete or absent regarding the possible effect of blood donation on the donors' health or the potential risk to transfusion recipients. Although the focus is on blood components, some chapters briefly discuss human cells, tissues, and cellular- and tissue-based products for comparison of the different policies and relevant regulations.

Chapter 1 provides a historical perspective on donor health history assessment and introduces the DHQ in use at most blood centers in the US. Many other countries, such as Canada and Australia, use similar standardized DHQs, and international comparisons in areas of uncertainty are often interesting and informative.

The book is then divided into three parts, to cover the DHQ questions used to identify donor health issues, recipient risk of transfusion-transmitted diseases, and postdonation eligibility considerations.

Part I addresses the questions about medical conditions used to screen donors for health issues that could affect the safety of their donation. Chapters 2 through 5 discuss the relevance of specific donor health history information (cardiovascular disease, hemostatic disorders, cancer, and medications) to

donor health and recipient safety. Practice varies considerably among blood centers on these topics, and there is often no clear evidence to determine which policy best protects donors and recipients. New to this edition, Chapter 6 addresses unique aspects of accepting healthy individuals with hereditary hemochromatosis as blood donors.

Part II covers issues related to screening donors for risk factors associated with relevant transfusion-transmitted infectious diseases. Chapter 7 covers HIV risk factors. Chapter 8 covers hepatitis risk factors and includes cross-references between the two chapters considering the overlapping risk questions for these blood borne diseases. Chapter 9 addresses the DHQ questions about travel-related risk factors and medical history for screening for malaria, prion diseases, and other emerging infections. Each of these chapters reviews federal regulations and AABB requirements, as well as recent modifications to eligibility criteria and their likely contribution to blood safety.

Part III covers issues that arise after the blood donation. Chapter 10 explores counseling donors about reactive screening test results and management of postdonation information. Because many donors are deferred for false-positive screening test results, Chapter 11 describes the acceptable reentry pathways to requalify previously deferred donors and allow them to donate again.

The editors hope that this book provides the reader with a better understanding of the history, science, and regulatory requirements behind current donor health assessment policies.

We would like to thank all the authors for their contributions, and welcome comments on our collective endeavor, as well as suggestions for any future updates.

Anne Eder, MD, PhD
Mindy Goldman, MD
Editors

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