Preface

This book continues a discussion that began with the author’s previous AABB Press book *Evidence-Based Practice of Transfusion Medicine*. After reviewing, in Chapter 1, whether decisions concerning transfusion-safety interventions can be truly evidence-based, the book examines the most hotly contested policy directions in transfusion medicine today. Such directions include those that 1) may be competing with one another for any additional funds that the US health-care system could make available in the future toward optimally meeting the transfusion needs of all patients, 2) may involve transfers of funds from blood centers to hospitals or vice versa, and 3) may require very major changes in the way that transfusion medicine is practiced.

This book examines the policy directions that are currently (late 2011) being considered in blood safety and often amount to such radical changes in transfusion medicine as to be called “paradigm shifts.” These changes include:

• Moving from allogeneic blood transfusion (ABT) to patient blood management and also from transfusion of stored Red Blood Cells (RBCs) to transfusion of fresh RBCs, the patient’s own freshly shed blood, or even fresh whole blood (Chapters 4 and 7).

• Administering ABT only when empirical evidence indicates that actual (as opposed to postulated) benefit can be expected from the transfusion for a particular patient (Chapter 4).

• Transitioning from the whole-blood collections of the 20th century to the multi-component apheresis collections of the 21st century—whereby RBCs along with platelets and/or plasma could be collected from the same donor at the same time, with all the various components harvested from the same multicomponent apheresis collection reserved for transfusion to the same transfusion recipient (Chapter 4).

• Implementing pathogen reduction for plasma, platelets, and (eventually) RBCs—that is, inactivating microorganisms in blood components with only a modest (and deemed acceptable) decrease in the function of blood cells and plasma proteins (Chapter 5).

To appreciate, and perhaps rank, the expected benefits from these currently debated policy alternatives, Chapters 2 and 3 review the causes of ABT-related mortality. Chapter 5 describes the research method (meta-analysis) developed for disciplined research synthesis and used throughout this book, and Chapter 7 explores the concept of equipoise, which is a prerequisite for undertaking randomized controlled trials.

Chapter 6 examines a policy alternative postulated to increase the infectious risks of ABT, however minimally. This regulatory intervention would call for reducing the donor deferral for men who have had sex with men (MSM) from an indefinite deferral to a 12-month deferral. The intent of that chapter is to illustrate the magnitude of an increase in ABT risk not deemed to be “tolerable” by policy-makers, so as to compare this postulated increase in risk (from reducing the MSM deferral) to the reduction in risk...
expected from the other examined policy directions. Chapter 8 presents a synthesis of the different “paradigm shifts” developing in transfusion medicine today. In so doing, it categorizes the various proposals for enhancing transfusion safety as being most compatible with a “patient-centric” vs “component-centric” approach to meeting patient transfusion needs. It also attempts to define what represents a “paradigm shift” in transfusion medicine.

Four recurring principles have been enunciated by the US Food and Drug Administration (FDA): 1) zero risk is a goal—not a mandate; 2) acceptance of risk is a political decision; 3) acceptance of cost is also a political decision; and 4) decision-making must be transparent. This book is intended to serve the fourth principle and it appraises the evidence vis-à-vis the reduction in the risk of ABT that can be obtained from the various policy alternatives currently being considered in the United States. Although the book concludes that policy decisions in transfusion medicine are based on a wider range of inputs than solely the best research evidence, the orientation of the book is always evidence-based. For readers who wish to undertake a direct assessment of the quality of the original studies referenced in this book, three additional chapters are provided in the electronic supplement. The latter chapters present the technical information on how to perform independent assessments of the quality of published studies, and they are reproduced from the author’s previous AABB Press book Evidence-Based Practice of Transfusion Medicine.

The book may well be controversial, reflecting as it does on questions that amount to major changes in transfusion medicine and on issues that represent long-standing controversies operating at the intersection of medicine, society, and public health (such as blood donation by MSM). Parts of the book may make some transfusion-medicine colleagues uncomfortable, with different parts of the book causing discomfort in different sectors. In pursuing all arguments based on the quality of the available empirical research, the book may even offend some readers—a possibility for which the author apologizes in advance. Nonetheless, the book is intended to be thought-provoking and supportive of open and unfettered debate. The author presents what would be in the transfusion recipient’s best interest given our current capabilities, in the author’s own opinion and based on a synthesis of the available research evidence undertaken personally by him—not what might be cost-effective, operationally welcomed, or equally acceptable by all stakeholders. Thus, the conclusions reached here do not represent any official AABB position, but rather the author’s own opinions. They should not be regarded as AABB recommendations, but as proposals to be subjected to further scrutiny and debate.

The author is grateful to the members of the AABB Press Editorial Board for initially approving the concept for such a controversial book, for reviewing the individual chapters, and for offering him valuable feedback for revisions. The author also declares upfront that he has no conflict of interest of any kind, and that—other than his previous employment by Canadian Blood Services, membership on the Blood Systems Research Institute Scientific Advisory Board, and membership on various AABB committees—he also has no involvement with any organization that has (or could be perceived as having) a financial stake in the outcome of any of the policy directions examined in this book.

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