

Introduction

The project to streamline the uniform Donor History Questionnaire (DHQ) was begun three years ago at the urging of the Food and Drug Administration (FDA). The goal of the project was to bring about major improvements in the blood donor screening questionnaire. To achieve this objective, FDA advocated the formation of a multidisciplinary Task Force under the aegis of the American Association of Blood Banks (AABB). The FDA has had active participation in the process and has provided input on a consistent basis.

The Final Report was submitted to FDA on March 25, 2002 and included goals, rationale and methodologies for changes, results of focus group and cognitive testing and the final documents. (A copy of the Final Report is enclosed for BPAC members who may be unfamiliar with the complete project.) Submitted final documents included a revised full-length donor questionnaire, an abbreviated questionnaire for frequent repeat donors, a medication deferral list, donor pre-screening educational materials and user brochures for the two screening questionnaires. After extensive internal review by FDA, several rounds of clarification and minor modifications by the Task Force, the AABB was given permission in July 2003 to release the full-length questionnaire and user brochure, medication deferral list and educational materials for review by member centers in anticipation of implementation.

Abbreviated Donor Screening Questionnaire (aDHQ)

All donors, including frequent donors, are currently required to answer all UDH questions, even those that pertain to one-time historical events that could never recur (e.g. the use of human pituitary-derived growth hormone, which was no longer available after the early 1980s). Donors and blood centers have long desired an abbreviated questionnaire for frequent donors. In September 1993 and again in March 1994, BPAC reviewed the American Institutes of Research (AIR) study to determine if the blood supply could be improved by using a more effective process to screen donors. A subcommittee of BPAC was formed to study the data from AIR more carefully; that subcommittee supported the use of an abbreviated history for repeat donors, adding that an abbreviated history could be used either with the current interview process or with a computer-assisted process.

As charged by FDA at the October 12, 2000 FDA-AABB sponsored Workshop on Streamlining the Blood Donor History Questionnaire, the Task Force has developed an abbreviated DHQ based on the validated full length DHQ. A copy of the DHQ and aDHQ are attached. The DHQ is marked to indicate specific differences between the screening documents.