

Ensuring the safety of blood products: AABB takes worldwide view in a year of change

The blood bank industry's focus shifted from West Nile virus in 2003 to bacterial screening and automation in 2004. That was one of the key messages conveyed to delegates at the annual AABB meeting in October. The event, in Baltimore, Maryland, drew 6,774 attendees, the highest number since 1997, and hosted 519 exhibitors, representing 190 different companies. Safer blood transfusions, donor recruitment/retention programmes and emerging technologies were other significant themes at the conference, write Kerri Weinert, Carrie Cresenzi and Emily Rizza, of US consultancy Boston Biomedical Consultants (BBC)*

Since its founding 57 years ago, the AABB has changed significantly. Today, the organisation's responsibilities and presence have extended beyond the US, with membership of approximately 1,800 institutions and 8,000 individuals from all 50 US states and 80 foreign countries. In January 2004, the AABB board adopted a new vision statement and revised mission statement emphasising these changes. In addition, the board decided to change the AABB definition from "American Association of Blood Banks" to "Advancing Transfusion and Cellular Therapies Worldwide" to more accurately describe the organisation, its members, and the field of transfusion medicine.

Current US blood donation/supply

Based on preliminary estimates, nearly 15 million units of whole blood were donated in the US in 2004, representing a marginal increase over 2003. The blood supply continues to be negatively impacted by more stringent deferral policies (for example, vCJD) and the ageing population. The World War II generation, once the age group to donate most frequently, now requires an increasing number of blood transfusions itself. In order to maintain current blood supply levels, the younger generations, namely the 17-24 year-old age group, are increasingly targeted by donor centres.

Accordingly, for the first time, the American Red Cross (ARC), America's Blood Centers (ABC), and the AABB joined forces to launch a nationwide blood donation awareness campaign through the Ad Counsel in October 2004. The campaign, expected to last for the next couple of years, will target 17-24 year-olds through television commercials, radio and print advertisements and the internet. The programme is designed to improve the outcomes of traditional recruiting efforts for blood drives, given the boosted awareness.

To improve the reach and efficiency of donor recruitment/retention efforts, an increasing number of donor centres utilise blood collection strategy/marketing companies, such as eDonor (Phoenix, Arizona) and Integrated Marketing Services (Baltimore, Maryland).

Michael Pendelakis, president of eDonor, comments: "Successful donor recruitment strategy is based on three core elements—recruiting new donors, retaining existing donors, and increasing donation frequency." eDonor allows donor centres to select specific donor criteria, customise the method of recruitment, automatically schedule/confirm donor appointments, and establish a retention strategy based on donor-driven preferences.

Automation/NAT-based testing

From a clinical issues standpoint, bacterial screening was a "hot topic" at AABB 2004; at AABB 2003 the "hot topic" was West Nile virus (WNV – see later in this article). Interest in full (walkaway) automation leading to individual donor testing (IDT) remains high. New NAT products shown at this year's AABB conference included Roche's Blood Screening System

200 and Blood Screening System 400. Roche introduced its Blood Screening System 200, which is an upgrade to the company's current Cobas TaqScreen WNV NAT System; the latter is field upgradable to the Blood Screening System 200. The Blood Screening System 200 features the new Hamilton Pipettor with aspiration and dispense profiling, upgraded software, and enhanced data management. Currently in beta testing, with clinicals due to start in the current first quarter of 2005, the Blood Screening System 200 will eventually replace the Cobas TaqScreen WNV NAT System.

Roche presented a paper on its next-generation assay, the TaqScreen Multiplex Assay, which is a five-analyte multiplex assay that tests for HIV-1 (M/O), HIV-2, HCV, and HBV. The test menu for the Blood Screening System 200 will include:

- TaqScreen WNV (under IND now)
- TaqScreen Multiplex Assay (in development)
- TaqScreen Parvo B19 and HAV assays (in development).

Although not shown on the exhibition floor, the Blood Screening System 400, Roche's fully-automated blood screening instrument for IDT, was previewed to VIP customers.

As part of its strategy to meet the needs for automation, Chiron showed its Procleix Tigris and Procleix Optiva Reagent-Addition Station (RAS), which were both shown at AABB 2003. Both products were scheduled for international launch before the second half of 2005; the Procleix Optiva RAS will be submitted for 510(k) approval in the same timeline and is scheduled for launch in the US in 2005.

The company continues to garner premium pricing from its Procleix Ultrio Assay, a multiplex assay for the simultaneous detection of HIV-1 (all sub groups, including O), HCV, and HBV. This product is already available outside the US and is targeted for US approval and launch with the Procleix Tigris in early 2006.

In the future, automation will be key for implementation of IDT, as evidenced by use of Chiron's Procleix Tigris instrument for WNV (IND) testing on single donor samples and relief from labor shortages at blood testing centres. Roche's Blood Screening System 400 will compete with Gen-Probe/Chiron's Procleix Tigris system. Although both Chiron and Roche have developed multiplex assays, the benefit of adding more analytes is still heavily discussed in the industry. Challenges in developing multiplex assays include maintaining adequate sensitivity in detecting all analytes and performing proper RNA and DNA extraction.

On the regulatory front, the FDA released new guidelines, entitled "Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components (including Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV". Two previous draft guidances were combined because they were based on

similar recommendations and considerations.

Emerging analytes – new mandated tests

In NAT, AABB 2004 focused on WNV assay improvement and determination of implementation of IDT. Both Gen-Probe/Chiron and Roche upgraded their WNV assays to improve the specificity and sensitivity, respectively. The trigger point to switch from mini-pool (MP) to IDT, two MP-reactive donations and a weekly rate of 1 in 1000, was discussed at AABB 2004. Parvovirus B19 and HAV continued to be highlighted as possible new mandated NAT tests, with particular emphasis in the plasma industry.

In IA testing, Chagas assay development continued to receive attention at AABB 2004. Abbott had previously developed an enzyme IA (EIA) using whole lysate and introduced the test in Los Angeles, California. More recently, the company modified the assay to use recombinant antigen for more consistent manufacturing based on a two-step format of capturing anti-T cruzi and using mouse monoclonal antibody for detection. Abbott is moving the recombinant antigen to manufacturing and scale up development, and does not anticipate an IND assay until 2006. OCD currently has its Chagas assay in clinical trials, and according to peer leaders, product launch is expected in the next 18 months.

On the topic of vCJD risk, filtration technologies were highlighted; there were no abstracts read on vCJD test development. Pall Medical promoted recently released results from two studies that showed that the Pall Leukotrap Affinity Prion Reduction Filter reduced infectious vCJD prions from red blood cell concentrations to undetectable levels as determined by Western blot. Pall aims to secure CE mark by early 2005 and intends to submit the filter for FDA approval in the second half of 2005.

Automation for IAS-based testing

To meet the needs of higher volume immunoassay (IA) testing, Abbott and Ortho-Clinical Diagnostics (OCD) each promoted their new automated instruments. Abbott showed its PRISM system and is currently completing PRISM licensed assays in the US. In spring 2004, Abbott overcame manufacturing issues and began moving forward in the launch of a complete hepatitis/HIV menu in the US. The Irving, Texas, manufacturing facility passed inspection, and the reagents received pre-approval at Abbott Park. The first assay lots were submitted for FDA approval in November 2004, and Abbott is currently training field and customer support personnel to support the PRISM rollout.

OCD unveiled a prototype of the Ortho Paradigm blood processing system for the first time in the US at AABB 2004. The fully automated instrument, which includes a pipettor system based on TECAN's Freedom EVO product, is expected to be launched in 2007.

Blood grouping and typing (BGT)

The demand for BGT automation in the US continues to grow, supported by a shortage of specialised blood bank technicians and increasing demand for data management and reduced human error. A major focus of the conference was defining criteria for successful implementation of BGT automation in the hospital blood bank. Such criteria were based on instrument features as well as laboratory dynamics, workflow, and budget.

The major BGT companies generated significant attendee interest at the AABB conference through product demonstrations of their fully automated BGT instruments. Immucor highlighted the Galileo BGT system, which was launched in the US in May 2004, nearly two years after its

European release. Utilising the microtitre plate (MTP) format, the Galileo is a high-throughput system appropriate for high-volume hospital blood banks.

In the mid-throughput category, launched in mid-2003, OCD's ProVue system automates card-based BGT testing. Although the current level of acceptance of card-based BGT testing remains lower in the US compared to Europe, the acceptance rate is expected to continue to increase. During the show, OCD also highlighted the new AutoVue Innova, which is currently being rolled out in Europe.

In addition to its high throughput PK-series analyser, Olympus promoted the Tango BGT system, designed for hospital blood banks. The system is scheduled for launch in 2005. Unlike the other BGT competitors, Olympus actively promoted a blood bank data management system, OsYris, which is currently available in Europe.

Bacterial screening

Bacterial screening was also a "hot topic" of AABB 2004. According to an AABB member survey on bacterial detection implementation (May/June 2004), bioMérieux's BactT/ALERT is used in most testing centres, while hospitals use pH and glucose dipsticks. Pall displayed the eBDS, a second-generation system launched in early 2004, in its booth. Verax's PanGenera Detection, which is in pre-clinical trials as a RUO product, was highlighted as a method in the FDA pipeline.

In addition, extending platelet storage to seven days was discussed at the AABB 2004. In October 2003, Gambro's one-litre Extended Life Platelet (ELP) platelet collection/storage bag, part of both the COBE Spectra Apheresis System and the Trima Automated Blood Collection System, was FDA-cleared for seven-day platelet storage. However, the clearance is conditional, and the extended storage claim is allowed when coupled with 100% screening for bacterial contamination using a method cleared by the FDA. To complicate matters, the FDA has not cleared a method for bacterial screening of platelet products in the US; methods are only cleared for quality control testing in the US.

New technologies

Venture startup Bioarray Solutions (Warren, New Jersey) has developed a highly multiplexed assay using its proprietary eMAP technology and BeadChip platform. In collaboration with Dr Marion Reid of the NYBC, testing of blood group antigens at the DNA level (specifically "minor" blood groups such as FYA/B, FY-GATA, DOA/B, and four others) using a novel custom array has been validated (423 samples). Applications for HLA typing, among others, are also under development.

Multiple companies/research institutions presented potential technologies to improve and/or extend beyond the standard card-based, MTP, and conventional tube blood grouping and typing methods at AABB 2004. In collaboration with Prisma Diagnostika, Medion Diagnostics is developing a blood grouping format based on lateral flow that, without centrifugation, facilitates multi-parameter testing in a single assay with stable endpoints.

Additionally, Medion is developing a format for gel-free card that includes an intrinsic microcapillary system designed to better contrast positive and negative results.

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