COMPARISON OF CORD BLOOD BANKING STANDARDS AND VOLUNTARY ACCREDITATIONS

Report of the Quality Standards Committee of the Cord Blood Association

June 2018

Background

Maintaining high quality in cord blood products and services is a major objective of the Cord Blood Association. This objective is achieved, in part, by promoting standards and voluntary accreditation.

CBA-member banks are required to comply with the standards of, and be accredited by, either AABB or the Foundation for the Accreditation of Cellular Therapy (FACT), or an alternative authority whose standards are no less than those of AABB or FACT.

To assist the association and its member banks with this objective, CBA has a Quality Standards Committee whose charter is to "propose and supervise programs that promote high quality in cord blood and related-tissue products and services."

Within the scope of that charter, the Quality Standards Committee was given an assignment by the CBA Board of Directors to "study, compare and evaluate the current systems of standard-setting and accreditation for cord blood banking and seek harmonization of standards and accreditation."

The Board asked that the study identify the similarities and differences in the alternative standards and accreditations to assist banks that are seeking either or both accreditations.

This document is a report of that study.

Report Organization

The report has three parts:

The draft of this report was provided to both AABB and FACT for review and comment, and adjustments were made based on those comments.

STANDARDS DEVELOPMENT

The discussion below explains the process by which standards are developed. It is based on information provided by the accrediting agencies.

AABB	FACT

The Standards Development Process

AABB

The *AABB Standards for Cellular Therapy Services* are developed by the association's Cellular Therapies Standards Committee (CTSC), comprised of volunteer experts in cellular therapies.

Standards are developed according to written policies, processes and procedures. CTSC members acknowledge and agree to abide by AABB's policy on conflicts of interest. All volunteers are subject to other association policies including a code of ethics and compliance with antitrust laws.

The CTSC meets regularly to review, evaluate and discuss potential changes to the standards. The committee then submits draft revisions for an internal technical, legal and regulatory review. The standards are next submitted to the AABB Board of Directors. After a public comment period, the committee reviews and addresses every received comment and edits the draft standards as needed. To achieve transparency, a summary of proposed and final changes is made available during the comment period and when the document is finalized.

The CTSC and the Board of Directors again review the document before it is submitted for publication. The standards are published electronically and in print and are posted on the AABB website.

The CTSC relies on a deliberative, consensus-driven process for the development of standards and consults a variety of sources for input. These include peer-reviewed articles describing changes in science or practice; feedback from regulatory agencies, accred-

FACT

The *NetCord-FACT International Standards for Cord Blood Collection, Processing and Release for Administration* is developed by expert consensus, using best available, evidence-based science, with an emphasis on research findings related to clinical outcomes of cord blood therapy recipients.

In areas where definitive data on clinical outcomes is lacking, the standards are based on available evidence from preclinical studies and accepted scientific theory.

The standards development process begins in a Standards Committee whose members are qualified by direct experience in cord blood banking and cord blood therapies. The process takes approximately 18 months, allowing for in-depth discussions, supporting research, consultations with experts as necessary, and careful review. A Steering Committee, comprised of the chair and co-chairs of the Standards Committee and the co-chairs of working subcommittees, initially conducts an in-person meeting to consider new developments in the field and plan the overall structure of the next edition of the standards.

The Steering Committee then meets monthly to address unresolved issues and maintain consistency of language and format in the standards. When all subcommittee reviews have been completed, a second in-person meeting is conducted to finalize the draft standards for public review.

Subcommittees are responsible for drafting each edition of the standards. They meet weekly by teleconference during the devel-

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ited facilities and assessors; and input from other stakeholders as appropriate. The entire process to develop an edition of standards takes approximately one year.	opment process to discuss potential edits. The resulting draft is posted on the FACT website and distributed for public comment. All comments are reviewed by the Standards Committee and edits to the draft are incorporated as appropriate. The final version is approved by the FACT Board of Directors and the World Marrow Donor Association (WMDA)/NetCord. A new edition of the standards is effective 90 days after publication, and all accredited cord blood banks are expected to be in compliance with the new standards by that time. FACT says that its development of standards for cord blood banking is independent of other FACT cellular therapy standards because of the unique characteristics of the field. The standards have to address the specific aspects of cord blood collection, processing, storage and release for clinical administration. The clinical uses of cord blood are addressed separately within other FACT standards for hematopoietic cell transplantation, immune effector cellular therapy, and regenerative medicine. The clinical services using cord blood are frequently provided by facilities independent of cord blood banks, and those services are required to communicate adverse events and clinical outcomes to the banks. This enables banks to monitor the integrity and outcomes of the cord blood units they distribute, as required by the cord blood standards.
Periodic Updates of Standards	
A new, updated edition of the AABB standards for cellular therapies is published every 24 months.	A new, updated edition of the FACT standards for cord blood banking is published every 36 months.

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Public Comment on New Editions of Standards

Each draft edition of the AABB standards for cellular therapy is published for public comment. In addition, AABB places a public notice in a nationally circulated newspaper announcing the availability of the proposed standards for public comment.

Comments are received from organizations, external agencies and stakeholders, individuals, AABB members and non-members. All received comments are considered and addressed, and a description of each comment is provided to users of the standards.

Each edition of FACT standards for cord blood banking is published for public review and comment prior to implementation. Invitations for comment are also sent to related organizations including FACT's parent organizations, the American Society for Blood and Marrow Transplantation (ASBMT) and the International Society for Cellular Therapy (ISCT), as well as the Cord Blood Association (CBA), and to several regulatory agencies around the world.

The draft standards often are accompanied by questions from the Standards Committee about emerging or challenging issues. FACT says that the 90-day comment period is one of the most important ways for cord blood banks to participate directly in the development of standards.

Interim Standards

AABB can issue interim standards or, if necessary, emergent standards.

Interim standards can be new requirements or changes to existing requirements, and they are issued when the standards committee determines that the change is necessary before the next edition becomes effective. Interim standards have a 30-day public comment period before approval for publication.

Emergent standards, on the other hand, are issued and become effective immediately. They are issued when a delay could affect patient or donor safety, or when required by an extraordinary situation. Emergent standards are not issued for public comment before taking effect, but a process for gathering feedback can be initiated after the release of the standard.

FACT can publish interim cord blood standards based on changes in scientific knowledge or safety, applicable laws and regulations, field experience or other reasons.

It is not necessary that every new finding in the medical literature results in a standards revision. For developments that do not have significant implications for patient safety, the preferred mechanism for update is the normal three-year cycle of new editions. However, when an interim requirement is indicated, the applicable standards subcommittee meets to discuss the issue, determine the need, and draft the standard. The draft is then reviewed by the Steering Committee, legal counsel and the FACT Board of Directors and WMDA/NetCord.

Depending on the urgency, an interim standard may be published for public comment. An interim standard becomes effective 30 days after final publication. At that time, accredited cord blood banks are expected to be in compliance with the new requirement.

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Qualifications of Individuals Who Develop the Standards

The AABB Cellular Therapies Standards Committee is composed of professionals representing all aspects of cord blood banking and transplantation. The committee members include individuals with expertise in donor screening, eligibility determination, cellular product manufacturing, regenerative medicine research, cord blood banking, quality control, infectious diseases and ethics. Additional expertise, if necessary, is available from other specialized AABB committees.

The committee also includes representatives from other organizations including the American Association of Tissue Banks, Associacao Brasileira de Hematologia e Hemoterapia, American College of Obstetricians and Gynecologists, American Society for Apheresis, American Society for Hematology, Food and Drug Administration, International Society for Cellular Therapy, National Marrow Donor Program and the State of California.

AABB evaluates volunteers with respect to education, competence and experience, in addition to expertise in the area for which standards are set. Committee members must also be active AABB members to qualify as voting participants in the standards development process.

The members of the FACT Steering Committee and subcommittees are experts with extensive experience in cord blood banking. This expertise spans the entire spectrum of cord blood personnel, including cord blood bank directors and administrators, collection personnel, processing technicians, quality management professionals, registry experts, and physicians who use cord blood to treat patients.

Active cord blood bank inspectors comprise the majority of the committee members, but others may be chosen for their particular expertise. The committee, as a whole, must also represent public, private and hybrid cord blood banks, and geographic regions around the world.

Upon commencement of a new edition of the standards, recommendations for steering and subcommittee members are solicited from FACT's parent organizations, the American Society for Blood and Marrow Transplantation and the International Society for Cellular Therapy, as well as from the FACT inspectorate, accredited cord blood banks, the National Marrow Donor Program, and the World Marrow Donor Association.

Standards Committee members must document their familiarity and agreement with FACT's policies on confidentiality and duality of interest and submit information about any potential conflicts prior to participating on the committees. Committee members must annually affirm that the information on file with FACT regarding their experience and affiliations is current.

Final Approval of New Editions of Standards

All standards must be reviewed and approved by the AABB Board of Directors.

The FACT Board of Directors and the WMDA/NetCord make the final decision to approve and publish new cord blood standards and interim standards.

ACCREDITATION PROCESS

The discussion below explains the process by which cord blood banks become accredited. It is based on information provided by the two accrediting agencies.

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Minimum Eligibility Requirements	
To apply for accreditation, a cord blood bank must be in operation for a minimum of six months. Although there is no minimum inventory requirement, record review is a part of the assessment process and, therefore, some inventory is necessary. This allows small and new cord blood banks to meet AABB requirements for accreditation. Accreditation may be granted for collection, processing, storage, and cellular therapy clinical activity. Eligibility requirements are the same for all cord blood banks, whether public, private or hybrid.	There are no minimum requirements to apply for accreditation nor a minimum time that a bank must have been in operation. However, at the time of accreditation a cord blood bank must be actively banking and have stored and/or distributed at least 500 units. To be accredited, a bank must be providing complete banking services including collection, processing, storage and release. FACT offers no partial accreditation for a component of cord blood banking. Eligibility requirements are the same for all cord blood banks, whether public, private or hybrid.
On-Site Inspections	
The AABB representatives who perform on-site review and evaluation of cord blood banks are called "assessors." The assessment team is composed of volunteer subject matter experts and an AABB staff lead assessor. The subject matter experts must be professionals currently associated with an AABB-accredited cord blood bank. The size of the team is dependent on the size and complexity of the organization being assessed.	The FACT representatives who perform on-site review and evaluation of cord blood banks are called "inspectors." The inspectors are volunteer peers from the cord blood banking community.

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Assessor and Inspector Qualifications

The minimum qualification requirements for an assessor are:

- bachelor's degree in a biological science
- three years of work experience related to hematopoietic cell (apheresis and marrow), or cord blood activities that must have occurred in the past five years
- direct work experience in product collection and/or product processing, including storage and shipping
- continuing education in the field current to the past year – i.e., specific to cellular product collection or processing activities

Assessor applicants must meet these requirements and be recommended by a current AABB assessor. The application asks the number of relevant procedures and number of years of experience.

The training program for assessors is one of only 15 surveyor training programs to have achieved accreditation by the International Society for Quality in Healthcare (ISQua). All AABB assessors participate in the accredited surveyor training program. They must perform at least two assessments per year and complete 65 hours of continuing education every two years.

The AABB staff lead assessor has a minimum credential of Certified Quality Auditor (CQA), awarded by the American Society for Quality. AABB believes that the lead assessor, as an association employee, provides not only quality systems expertise, but also an additional level of objectivity without any employment-related conflicts of interest.

Inspectors must meet education and experience prerequisites to ensure proficiency in the areas they inspect. General requirements include:

- submission of an inspector application and statement of compliance with policies on confidentiality and duality of interest
- affiliation with a FACT or FACT/NetCord accredited or applicant cord blood bank
- membership in ASBMT or ISCT, or affiliation with a bank that is a member of WMDA/NetCord
- completion of FACT's inspector training program

Inspectors must meet additional qualifications for the areas that they are inspecting:

- Overall Cord Blood Bank – a relevant doctoral degree (MD or PhD), and at least two years of experience in cord blood banking or transplantation, or be an active FACT clinical or bank inspector experienced with cord blood transplantation
- Cord Blood Collection – a relevant doctoral degree (MD or PhD), or a nursing or biological science degree, and at least one year of cord blood bank director or collection supervisor experience
- Cord Blood Processing – a relevant doctoral degree (MD or PhD), or a biological science or medial technology degree, and at least two years of experience as a director or medical director of a cord blood bank processing facility, or supervision of a cord blood bank or cellular therapy product processing facility

FACT believes that practicing professions are best able to inspect cord blood bank operations to confirm compliance with standards.

AABB	FACT

On-Site Evaluations

The AABB visits every facility where processing is performed. For facilities with multiple collection and storage facilities, 1 to 10 percent of the sites are visited every two years. This is rotated so all collection and storage sites are visited over time.

The assessors have assessment tools to guide their evaluations, but it is not a linear checklist. Because the accreditation decision is based on conformance to the standards, assessors use those standards as the basis for their assessment. Assessors may vary the order in which they move through the requirements. The assessment tools are available to all facilities for internal assessments of their own policies, processes and procedures.

During the assessment visit, the staff lead assessor manages and organizes the team members who frequently confer with one another. At the conclusion of the assessment, the team meets with representatives of the facility to summarize findings. An accreditation decision is provided, and a final report is given to the facility. Three outcomes are possible:

- Accreditation granted for the requested and assessed activities
- Accreditation to be granted upon submission of corrective actions and approval after the on-site assessment
- Non-accreditation pending a reassessment

Accreditation renewal visits occur every two years and are unannounced.

The purpose of the on-site review is to verify that a bank's practices are reflective of its policies and comply with FACT standards. FACT asks the bank to submit SOPs and other documentation in advance so that inspectors can study the documents ahead of the visit.

Once on site, the inspectors observe, record and report, using a checklist to achieve comprehensive, consistent inspections. The inspection team members confer with one another during the inspection to compare observations and achieve a complete and thorough evaluation. During an exit interview the inspectors summarize their findings for the cord blood bank management and anyone that management wants to include in the exit interview.

The inspection team does not make the accreditation decision. After the inspection, each inspector prepares a report that is submitted to the inspection team leader, who collates the observations into a single report that is submitted to the FACT Accreditation Committee. To achieve fair, equitable and consistent decisions, the committee makes the accreditation determination, based on the inspection results and other documentation.

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Length of Time to Achieve Accreditation

The cord blood bank's thoroughness of preparation determines the accreditation timeframe. A well-prepared facility can achieve accreditation in nine to 12 months from the initial submission of a self-assessment. Most facilities are able to achieve accreditation within 15 months.

The time between an application and an accreditation decision is typically 15 months. First-time applications may take longer. Accreditation renewals can be shorter.

Quality Audits

AABB assessors use a systems-based approach to identify operational areas where a focused audit is appropriate. A representative sampling of records is reviewed for compliance with the facility standard operating procedures and AABB standards.

Validation assessments of a sampling of facilities are performed. This involves another AABB staff assessor performing a second assessment visit to validate the original on-site assessment.

The Centers of Medicare and Medicaid Services (CMS) also performs validation assessments of AABB as part of the association's deemed status for cellular therapy activities. AABB is a Clinical Laboratory Improvement Amendments (CLIA) provider for multiple cord blood banks and an educational resource for the CLIA program facilities.

Any discrepancies discovered in a CMS audit are published In the *Federal Record*. AABB has a consistent 0 percent disparity rating and has been complimented by CMS for this result.

FACT has an audit process to confirm that inspections are consistent and reproducible. On-site audits are conducted for a sample of cord blood banks throughout the year. The sampled bank being inspected must agree to participate in the audit.

The auditor is a volunteer member of the FACT Quality Management Committee. If deviations from inspection procedures are discovered, the auditor informs the FACT Quality Management Committee which investigates, evaluates and, if warranted, corrects the deviation in conjunction with other relevant FACT committees.

The auditor has full access to documents submitted by the bank, is included on all communications among the bank, inspectors and FACT staff, observes the on-site inspection, and attends all meetings of the inspection team.

In addition to formal audits, cord blood banks and inspection teams are asked to evaluate inspections after they have been completed. The evaluations help identify problems that can be corrected in future inspections.

AABB	FACT

Conflicts of Interest

Upon assignment to a team, assessors are asked to declare that they have no conflicts of interest with the facility being assessed. In the event of a conflict, a replacement assessor is assigned.

A cord blood bank has the prerogative to refuse an assessor if there is a perceived conflict of interest. However, a facility does not have the option to select its preferred assessor.

An assessor may not assess the same facility again for six years.

Inspectors are not assigned to teams where there could be a real or perceived conflict of interest.

A cord blood bank may object to an assigned inspector within five days of receiving notice of the inspection team. If there is an objection, the Accreditation Committee chair assigns an alternative inspector.

Accreditation Decision Appeals

Accreditation decisions can be appealed. The process starts with the Accreditation Committee and, if needed, may continue to the AABB Board of Directors.

If a facility does not agree with one or more assessment findings or the assessment summary report, reconsideration can be requested. The request must be submitted in writing along with supporting evidence to the AABB national office, directed to the attention of the chair of the Accreditation Program Committee.

Within 30 days of receipt of the request and supporting documentation, the chair will convene the Accreditation Review Committee. The committee is composed of the chairs of the Accreditation Program Committee, the Education Advisory Subcommittee, the Quality Systems Subcommittee and the Cellular Therapies Accreditation Committee.

If the facility does not agree with the Accreditation Review Committee's decision, an appeal can be submitted to the AABB President. The President will appoint a hearing body comprised of members of the Board of Directors. A hearing will be held within 30 days, and a decision will be communicated to the facility.

Accreditation decisions can be appealed. A bank may send a written statement to the Accreditation Committee chair outlining reasons for a disagreement with a decision, a citation or a variance.

The appeal, which must be submitted within 30 days after the bank receives written notice of the accreditation outcome, should include complete details and any supporting documentation.

The Accreditation Committee will consider the appeal and provide its decision within 60 days. If the bank still disagrees with the Accreditation Committee, the decision can be appealed to the FACT Board of Directors.

AABB	FACT

Accredited Facility Interim Reports

AABB does not require interim reports between biennial accreditation renewals.

Facilities under an HRSA contract are required to submit interim self-assessments. For those facilities that use the AABB as their HRSA provider, interim reports are submitted on the years without an AABB on-site assessment.

AABB policies require notification of bank management and other substantive changes within the facility.

FACT requires accredited cord blood banks to submit an annual report of the bank's activities and operations, including any significant changes that have occurred during the year – for example changes in key management personnel, types of blood and tissue banked, contracts for services or facilities, and other substantive changes. The bank must also report any adverse events that could compromise patient safety or any government regulatory action against the bank. The annual report:

- ensures that cord blood bank personnel continuously meet the required standards
- identifies any changes in services
- documents the implementation of any required corrective actions
- verifies adverse events are at a minimum and managed appropriately
- documents compliance of HRSA banks with required specifications

If an interim standard has been published during the year, the annual report must show how the standard was addressed and implemented.

AABB	FACT
Interim Inspections	
An interim on-site assessment may be required in response to a complaint, or when a facility is adding new services. Facilities under an HRSA contract are required to submit interim self-assessments.	An interim on-site inspection may be required if a bank has substantial changes between regular inspections. Examples include a bank relocation, a new processing facility, expansion of services and changes in contracted service providers. A factor in determining the need for an interim on-site inspection is the length of time until the banks' next accreditation renewal inspection. An interim onsite inspection may also be triggered by a complaint that a bank is not complying with standards.
Travel Costs for Assessors and Inspections	
Travel costs for assessors are included in the accreditation fee for facilities located in the United States. Additional travel costs are charged for facilities outside of the United States.	Travel costs for inspectors are included in the accreditation fee for facilities located in the United States. There may be additional costs for facilities outside of the United States, if the travel cost substantially exceeds historic averages. To date, no travel surcharge has been assessed to any bank.

AABB	FACT

Accreditation Fees

A one-time application fee for AABB accreditation is $1,533.

After accreditation is awarded, a cord blood bank with 10,000-20,000 new units per year typically pays an annual accreditation fee of $7,835, a bank with 20,000-30,000 new units per year typically pays $8,119, and a bank with more than 30,000 new units per year pays $8,819.

The annual fee breakdown is:

- a base accreditation fee of $6,010, which includes an activity fee of $1,658
- a volume fee, based on the number of new units collected or processed, which ranges from $145 to $2,800

Accredited cord blood banks must also be an AABB institutional member. Annual dues for institutional membership range from $6,155 to $8,900, depending on the number of units collected or released.

Accreditation, activity and membership fees are invoiced annually at the start of the calendar year.

A one-time application fee for FACT accreditation is $5,000.

After accreditation is awarded, a cord blood bank with up to 10,000 units typically pays an annual accreditation fee of $8,500, and a bank with 10,000-50,000 units typically pays $8,765.

The annual fee breakdown is:

- a base accreditation fee of $8,500
- a volume fee for banks with more than 10,000 units, which ranges from $265 to $750
- a surcharge for banks that have more than 50 collection sites, ranging from $1,800 to $3,000

Fees are invoiced annually in the anniversary month of the bank's original accreditation.

STANDARDS COMPARISON

The CBA Quality Standards Committee spent a considerable amount of time comparing the AABB and FACT standards. The task was challenging because of the substantial difference in the scope and organization of the two sets of standards. The comparison is further complicated because the standards are not stationary. Both organizations periodically update their standards with new editions.

For the comparison, the committee evaluated the most-recent editions of standards:

AABB Standards for Cellular Therapy Services, 8th Edition, July 2017

NetCord-FACT International Standards for Cord Blood Collection, Banking and Release for Administration, 6th Edition, July 2016

Presented below are observations about the scope and organization of the two sets of standards, along with a summary of similarities and differences in requirements for facility operations, collection, processing, listing, search, selection, reservation and distribution.

■ Scope

The scope of the two sets of standards differ:

- FACT standards are specific to cord blood banks and release for administration.
- AABB standards are broader, encompassing facilities that process and manufacture a wide variety of cellular products.

■ Organization

The organization of the two sets of standards differ:

- AABB standards are structure according to "quality system essentials," which are divided into key elements of process control.
- FACT standards are organized by workflow of cord blood banking and release for clinical use.

■ Cord Blood Bank Operations

The AABB and FACT standards are similar with respect to operations. Both have requirements for maintaining quality. However, FACT standards are specific to cord blood banking and the AABB standards are intended for a variety of cellular product entities.

An example of this is the requirements for product labeling. Whereas AABB standards are generally applicable to cellular products, the FACT standards are specific to cord blood.

AABB requires that banks implement the ISBT 128 labeling standards by July 1, 2018. Similarly, FACT requires the ISBT 128 labeling standards, but banks that are not in compliance must be in the process of implementing the labeling standards.

Other examples of greater specificity in the FACT standards include the processes for characterization and validation for viability of cord blood cells (specific requirements for CD34+, CD45+) and cord blood units and

the reporting of data to cord blood registries, all of which are detailed in the FACT standards and its accompanying manual. The AABB standards require viability assessment, but do not define a minimum number that can vary by clinical application.

Traceability is well described in AABB standards with a requirement that products be traceable to the donor or source, but there is no requirement for linkage of a cord blood unit to an infant donor. For allogeneic products, FACT standards require validation that the donor and the recipient are different individuals when there is a complete HLA match.

The FACT standards specify continuous safe storage, transport and shipping of cord blood units, but the AABB standards require only an emergency plan. Both sets of standards include procedures for accepting products that have incomplete donor eligibility, but the AABB standards do not require medical histories of first-degree relatives. AABB standards have a general policy on deviations. The FACT standards address unplanned deviations.

The AABB and FACT requirements are similar with respect to equipment controls, supplies and reagents. For inventory management, AABB standards require that facilities have policies, processes and procedures to prevent inventory mix-up. FACT standards on inventory control differentiate between related and unrelated cord blood products.

With respect to inventory transfer, both AABB and FACT have requirements for the transfer of products for clinical treatment, as well as procedures for responding to emergencies and disasters. FACT has additional requirements for inventory transfer if a bank were to cease operations.

AABB and FACT standards both have requirements for storage and preservation, including inspection of incoming products for conformance to standards, record retention, and donor informed consent. There is a difference between the two sets of standards regarding records retention. AABB requires that they be retained in accordance with applicable laws. FACT requires that records be retained indefinitely.

For interruption of operations, the AABB standards require that banks have emergency procedures to respond to disasters or emergencies. The FACT standards provide specific requirements for interruptions in processing operations and the maintenance of units already in storage.

In summary, because the FACT requirements are specific to cord blood banking, compliance can be achieved by following checklists in the standards. The AABB standards are more general. AABB believes that makes its standards more flexible and amenable to innovation.

■ Cord Blood Donor Management and Collection

Both AABB and FACT standards have minimum requirements for product procurement, including donor recruitment, donor evaluation, informed consent, collection, and product transport to a processing facility. . AABB standards have donor management and collection requirements base on the unit being collected and transported. FACT standards are more detailed and specific to cord blood donor management and collection

FACT has requirements for the shipment of supplies and reagents from collection sites to the cord blood bank, including specifications for an outer container validated to maintain an appropriate temperature range. FACT also has specific requirements for cord blood collection kits.

AABB standards are more broadly applicable to a range of cellular products. The requirements are unit specific for shipment of supplies and reagents from collection sites. They require that all materials that come into contact with a product be sterile and appropriate for the intended use, in accordance with the manufacturer's written instruction, and the facility-specific acceptance criteria.

AABB standards have requirements for the training of personnel in cellular product processing and storage. FACT training requirements are specific to cord blood banking personnel, including the use of collection kits and supplies, cleaning the umbilical cord, labeling and verification of donor identity.

Collection practices are more detailed in the FACT standards. AABB has no provision for the potential of a related cord blood unit being used for unrelated donation, or the evaluation process for unrelated donation at the time of collection. AABB standards do not differentiate between allogenic and related units and holds all cord blood units to the same standard.

The two sets of standards differ in the consenting process regarding who can be a language translator. FACT has specific requirements; AABB requires that facilities follow federal, state and local laws regarding who can act as an interpreter.

■ Cord Blood Processing

The required policies and standard operating procedures for product processing are similar in the two sets of standards. FACT standards, being specific to cord blood, are more detailed. AABB standards address cellular therapy products in general and calls out cord blood when the requirements differ.

The AABB standards do not differentiate between related and unrelated products in cord blood processing. Therefore, there are no AABB requirements that correspond to the FACT requirements regarding informed consent for release of a related unit for unrelated use, time limits for initiation of cryopreservation for related and unrelated products, and compliance with applicable law for more than minimal manipulation of a cord blood unit. AABB requirements are the same for related and unrelated products regarding informed consent, product release, initiation of cryopreservation and IND/IDE approval for investigational products.

FACT standards have requirements for sample segments including size, volume, number of maternal samples, retention of samples, product segments, and storage conditions. The AABB standards more simply require that two "integrally attached" segments be cryopreserved with the product.

With respect to cryopreservation, FACT standards have requirements for TNC recovery prior to cryopreservation.

The two sets of standards are equivalent for conditions of cord blood storage, except FACT standards require the minimization and recording of transient warming events. AABB standards require annual stability testing, whereas FACT standards require testing of an annual minimum of three samples for each manufacturing method.

For monitoring and alarm systems there are no significant differences, although FACT standards are more specific.

The AABB and FACT standards are similar regarding product disposition, but differ in specificity for unit testing and maternal testing. Both the AABB and FACT standards require unit testing and acceptance criteria. The AABB standards also reference FDA guidances, BLA requirements and acceptance criteria.

Both AABB and FACT standards require that cord blood units for unrelated use shall be free from microbial contamination.

The AABB standards allow for the release of cord blood units with positive culture. Both the AABB and FACT standards require that the results of positive culture tests for related cord blood units must include the identity and sensitivities of the organisms. The AABB standards detail which processing tests must occur for all cord blood products including ABO/Rh typing, HLA testing, TNC, cell viability, CD 34 assay, and nucleated red cell count. Tests for microbial contamination (culture for aerobic and anaerobic bacterial and fungal elements) are also conducted after processing but before the addition of cryoprotectant.

■ Cord Blood Listing, Search, Selection, Reservation, Release and Distribution

AABB and FACT requirements for cord blood selection and release for administration are similar, undoubtedly because of the requirements of the unrelated donor registries. The FACT requirements are more specific and their organization more structured, which perhaps makes it easier for banks to follow at the time of selection and release, as well as follow-up clinical outcomes data recording. Requirements for listing and search of the cord blood units for unrelated use are not included in the AABB standards.

The FACT standards require that antimicrobial sensitivity should be determined for related cord blood units. The AABB standards require antimicrobial sensitivity testing, but do not differentiate between related and unrelated cord blood units.

Disclosures to clinical programs that are required in the FACT standards, but not in the AABB standards, include (a) any unknown health history of a first-degree-relative, (b) the physical characteristics of the cord blood unit including at a minimum the number and type of bags or compartments used for storage, (c) information about the type of cassette in which the cord blood unit will be shipped, (d) instructions for storage of the unit in the transplant center, and (e) advice that the unit should be received by the clinical program prior to the initiation of the recipient's preparative regimen, unless otherwise directed by the transplant physician.

AABB Standards require that the clinical facility review and verify before administration (1) the unique product identified, (2) product type, (3) name and identifier of the intended recipient, (4) product condition by visual inspection and (5) a summary of the donor eligibility determination. In addition, the clinical program must have policies, processes and procedures for patient care that include the administration of specific therapies and medical interventions, including storage conditions maintained at the administration site.

FACT standards require cord blood banks to obtain clinical data that include the viable nucleated cell yield of the thawed cord blood unit and, annually, any graft-versus-host disease occurrence in unit recipients. AABB standards require the collection of all clinical outcomes data, which includes defined processes and procedures and information about adverse events and patient outcomes for all cell types.

CONCLUSION

This report compares the cord blood banking standards and accreditations of AABB and NetCord-FACT. The CBA Quality Standards Committee hopes that this report will be valuable to member banks as they strive to maintain high standards in cord blood banking.

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