IQPP Donor Health Standard

Committee Final Draft
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Approved xxxxxxx

PLASMA PROTEIN
THERAPEUTICS
ASSOCIATION

Background

The IQPP Donor Health Standard is part of a series of standards that comprise the Plasma Protein Therapeutics Association (PPTA) IQPP Standards Program. PPTA's Voluntary Standards Program provides global leadership for the plasma protein industry's goal of continuous improvement with a focus on safety and quality from the donor to the patient.

This voluntary IQPP Standard was developed by the PPTA IQPP Standards Working Group and was approved by the PPTA Source Board of Directors on xxxxxxx. It supersedes the IQPP Cross Donation Management Standard, Version 3.0, the IQPP Donor Fluid Administration Standard, Version 1.0, and the IQPP Donor Education Standard, Version 3.0 in their entirety.

For questions about this PPTA Voluntary Standard contact IQPP@pptaglobal.org. For more information about the IQPP Standards Program or PPTA, visit www.pptaglobal.org.

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IQPP Standard for Donor Health
Committee Draft 5

1. Introduction

People around the world depend on therapeutics derived from human plasma proteins to treat conditions such as hemophilia, immune disorders and other diseases or injuries. Healthy individuals generously donate their plasma for the production of plasma protein therapies. The health and safety of donors is of the highest importance. Donor health and well-being are a top priority for plasma collection organizations.

This IQPP Standard is part of a series of standards that comprise the PPTA IQPP Voluntary Standards Program. For more information about the program, visit www.pptaglobal.org.

2. Scope

This standard applies to IQPP certified facilities that collect Source Plasma and those applying for certification.

3. Purpose

The purpose of this standard is to establish requirements to help facilities protect the health and well-being of plasma donors.

4. Terms and Definitions

4.1. Cross Donation

A donation pattern in which a donor exceeds the maximum allowable donation frequency by donating at more than one plasma center.

4.2. Donor Recruitment Area (DRA)

An area that has been pre-determined within which a plasma center accepts donors.

4.3. Cross Donation Check System (CDCS)

Electronic database used to identify donors or potential donors who may be at risk for cross donation or who may be cross donating.

4.4. Donor Check Form

Form used between companies in the event that the CDCS is unavailable.

4.5. PPTA ID Number

Unique number assigned by the PPTA to a collection center or corporate headquarters.

4.6. Risk Behavior
Activities that increase an individual's risk of contracting HIV, HCV, or HBV.

4.7. Well-being
A state of good health.

5. Requirements
5.1. Cross Donation Management
5.1.1. Background
A donor may not fully understand the reasons for limiting the number of donations and attempt to donate more often than regulations allow. The requirements in this clause were developed to protect donor health by minimizing the risk of a donor donating in excess of the allowable limits.

5.1.2 Information to be Provided to the Database
5.1.2.1 No later than the end of a center's operating day, the center shall enter into the CDCS the following information from each individual who requested to donate and for whom a Venipuncture was performed in an attempt to complete a donation:

a) first name, middle initial (if applicable), last name
b) date of birth
c) type of donor identification (e.g., SSN, SIN)
d) five-digit identifier (last 5 digits of the donor ID number.)
e) ~~sex,~~
f) date of donation , and
g) PPTA ID # for the center entering the donor information.

5.1.2.2 Companies shall have an identification and notification process in place to inform all known plasma centers within a center's DRA of the opening of a new center and provide all required information to the CDCS no later than 30 days prior to the scheduled opening date.

Centers shall identify all centers within the DRA and enter into the CDCS the PPTA ID numbers of all known centers within their DRA.

5.1.2.3 Each center shall provide the following information to the CDCS:

a) center scheduled operating days, including holidays and unexpected closures; and
b) centers that fall within the center's DRA.

The center shall update this information within one full operating day of a change.

5.1.3 CDCS Queries

When an individual presents at a center for donation, and prior to a donation being obtained, the center shall query the CDCS to determine if the individual is listed.

Where the CDCS is not permissible by law, an alternate national or regional registry, if available, shall be used among centers to determine if a donor is active in more than one center and is exceeding the allowable limit for donations. Where no alternate deferral registry is available, an intra-company process shall be used.

5.1.4 CDCS Disposition of Donors

5.1.4.1 A company shall have a procedure in place stating how it will prevent an individual from donating more often than allowed by regulation.

5.1.4.2 If an individual is found to be listed in the CDCS, the center shall determine whether the individual is knowingly attempting to violate the donation frequency allowed by regulation.

5.1.4.3 An individual who is found to be knowingly attempting to donate more often than regulation allows shall be permanently deferred from all centers involved in the cross donation.

5.1.4.4 An individual who is found to be listed in the CDCS but not knowingly attempting to donate more often than regulation allows shall be informed about the health risks of exceeding the allowable limits and the reasons for the center's concerns for the individual's health and safety should cross donation occur.

5.1.5 Backup Process

5.1.5.1 If, for any reason a center will not open for collections on a regularly scheduled opening day, it shall, as soon as possible, change its schedule in the CDCS to "closed" for that day, or send data to the System indicating that zero donations occurred at the center for the day.

5.1.5.2 In the event that the CDCS is not available to a center for longer than one full operating day, or if a center learns that another center within its DRA has not provided information to the CDCS within the past full operating day of its scheduled operating time, affected centers shall revert to a manual system for checking donors, as follows.

The manual system shall require checking only A1 and AR1 Donors. Each center shall complete a Donor Check Form or equivalent system, listing all A1 and AR1 Donors who requested to donate and for whom a Venipuncture was performed that day and submit to all centers within its Donor Recruitment Area no later than the end of each day of center operation.

5.1.5.3 The form shall include the following:

a) receiving and sending center name, address and PPTA ID number,
b) first Name, middle Initial (if applicable), last name,
c) date of birth,

d) type of donor identification (e.g., SSN, SIN),
e) five-digit identifier (last 5 digits of the donor ID #),
f) Sex, and
g) donor's last two known donation dates in the previous seven days at the center (this includes, where available, dates at other centers under the same corporate ownership; to be completed by the receiving center).

5.1.5.4 The form or equivalent system shall be submitted to all centers within the DRA such that the receiving center should receive the information on the same calendar day that the sending center transmits it.

5.1.5.5 Response shall be returned by the receiving center(s) as soon as possible but no more than one operating day after receipt of the Donor Check form.

5.1.5.6 Forms prepared and received by centers in the DRA shall be retained in accordance with company SOPs.

5.1.5.7 Procedures for review of forms and follow-up actions shall be incorporated into a company's quality system and subject to internal quality audits.

5.1.5.8 When the CDCS becomes available again, centers shall upload to the CDCS the data in accordance with subclause 5.1.2.1 that were collected during the time that the CDCS was not available. The data shall be uploaded by no later than the center's normal Close of Business on the day that the CDCS became available again.

5.1.6 Records
Centers shall keep objective evidence of the use of the System in accordance with the requirements in subclause 5 of this Standard.

5.1.7 Education
Centers shall have in place a process for educating donors on the risks of cross donation. Centers shall inform donors of the center's deferral policy regarding cross donation.

5.1.8 Other
This Standard shall not be interpreted in such a way that it dissuades centers from adopting more stringent requirements.

5.2. Donor Fluid Administration
5.2.1. Background
Plasma donation is a safe procedure which is enhanced by administration of fluids to the donor as part of the donation process. Requirements for fluid administration were developed to enhance donor safety by assisting donors in sustaining hydration on the day of donation.

5.2.2. Fluid Administration

5.2.2.1. Centers shall have in place a program to administer fluids as part of the donation process.

5.2.2.2. Administer a minimum of 250 mL of 0.9% sodium chloride solution (NaCl; saline) intravenously to donors as part of the automated plasmapheresis process.

NOTE: In the United States, industry practice is to use 500 mL of 0.9% NaCl when available.

5.2.2.3. When administration of intravenous NaCl 0.9% is not possible (including but not limited to examples of donors with limited venous access, donor reported complications with NaCl 0.9%, shortage of available NaCl 0.9% solution in the market), administer either:

a) a minimum of 250 mL of an oral electrolyte solution that contains sodium, or
b) a combination of intravenous NaCl 0.9% and an oral electrolyte solution that contains sodium. The total quantity administered shall be, at minimum, 250 mL.

5.2.2.4. If oral fluids are administered, the facility shall take measures to facilitate the successful consumption of the fluids by the donor within the center premises, in accordance with a method documented in the facility's SOPs.

5.2.2.5. Education

Centers shall educate donors on the importance of fluid administration and maintaining appropriate hydration pre- and post- donation.

5.3. Healthy Lifestyle

5.3.1. Plasma centers shall have in place a system to educate donors on risk behavior and other aspects of general well-being as related to the plasmapheresis process.

5.3.2. Each plasma center shall have an electronic, paper, or video-based education system (or materials) of their choosing, to help donors recognize and avoid risk behavior. In their educational materials, companies shall address activities related to the possible contraction of infectious disease.

5.3.3. The donor's comprehension of the information shall be assessed initially in order to assure their understanding of risk behavior. The comprehension assessment methods may be determined by the individual company.

5.3.4. Educational materials shall also be provided to educate donors, on their initial visit, on general well-being practices for plasma donation (e.g., staying hydrated, eating low-fat foods, staying well-rested).

6. Audit and Compliance Verification

6.1. Cross Donation Management

During the IQPP Corporate Audit, auditors shall request the company's SOPs that relate to subclause 5.1. They shall then review the procedures for compliance with subclause 5.1. The auditor shall confirm that procedures for review of forms and follow-up actions are incorporated into a company's quality system and subject to internal quality audits.

During the IQPP Plasma Center Audit, auditors shall review records that relate to subclause 5.1 as well as track through the documentation of several donors for compliance to the requirements in subclause 5.1. Irregularities in conducting donor checks, sharing donor information or actions required in accordance with the Standard may result in issue driven IQPP audits.

6.2. Fluid Administration

During the IQPP Corporate Audit, auditors shall request the company's SOPs that relate to subclause 5.2. They shall then review the procedures for compliance with subclause 5.2.

During the IQPP Plasma Center Audit, the auditor shall observe that the company's SOPs relating to subclause 5.2 are followed.

6.3. Healthy Lifestyle

During the IQPP Corporate Audit, auditors shall request the company's SOPs that relate to subclause 5.3 They shall then review the procedures for compliance to subclause 5.3.

During the IQPP Plasma Center Audit, auditors shall review records that relate to the subclause 5.3 to ensure the plasma center is following the company SOPs.