OBJECTIVES

METHODS

Susan M Corby

Manufacturing

Request to FDA to Allow Deferred Donors to be Used for Reagent Red Cell

Saving Transfusable Group O and Rare Red Cells for Patients; Variance

Without the FDA variance, the availability of group O blood for transfusion is impacted. Given the well documented increasing demand for group O blood supply as total collections decline, this variance will reduce the unnecessary use of transfusable blood units going to manufacturing.

Recruitment is underway to identify donors who are eligible as a reagent donor following the granting of the variance.

3. Use of Finasteride or Dutasteride

Antibodies in patient samples.

One Reagent Donor can save thousands of lives with each donation when they are manufactured into panel or screening cells to identify unexpected antigens in patient samples.

The unintended consequence of the FDA revision of 21 CFR 630.30 published May 23, 2016, was that very medically valuable rare antigen negative group O red blood cell antigens were being provided to manufacturers from donors deferred due to travel or residence outside of US, travel to malarial or vCJD risk areas.

Recruitment is underway to identify donors who are eligible as a reagent donor following the granting of the variance.

1. Travel to or residence in a vCJD risk country

2. Travel to or residence in a malarial risk area

3. Use of Finasteride or Dutasteride

These exceptions pose minimal risk to the safety and health of the donor or those using the manufactured reagents.

Innovative Blood Resources

May 23, 2016, a shortened questionnaire was used for donors of transfusion type ABO blood. Using this data, we have exact numbers of deferred donors and why each donor is deferred per year. These numbers do not account for donors deferred due to medical reasons.

A variance was requested on August 8, 2018 to allow use of donors deferred for residence outside of US, travel to malarial or vCJD risk areas, and the use of Finasteride or Dutasteride.

Innovative Blood Resources

Since all panel cells are group O and typically at least half are Rh(D) negative, the inevitable consequence of this revision is to make these precious units unavailable for transfusion.

These exceptions pose minimal risk to the safety and health of the donor or those using the manufactured reagents.

One Reagent Donor can save thousands of lives with each donation when they are manufactured into panel or screening cells to identify unexpected antigens in patient samples.

Without the FDA variance, the availability of group O blood for transfusion is impacted. Given the well documented increasing demand for group O blood supply as total collections decline, this variance will reduce the unnecessary use of transfusable blood units going to manufacturing.

Recruitment is underway to identify donors who are eligible as a reagent donor following the granting of the variance.

1. Citation: 21 CFR 630.30 implemented May 23, 2016 last updated 4/1/2019

2. Use of Finasteride or Dutasteride

Recruitment is underway to identify donors who are eligible as a reagent donor following the granting of the variance.

3. Use of Finasteride or Dutasteride

Recruitment is underway to identify donors who are eligible as a reagent donor following the granting of the variance.

1. Travel to or residence in a vCJD risk country

2. Travel to or residence in a malarial risk area

3. Use of Finasteride or Dutasteride

These exceptions pose minimal risk to the safety and health of the donor or those using the manufactured reagents.

One Reagent Donor can save thousands of lives with each donation when they are manufactured into panel or screening cells to identify unexpected antigens in patient samples.