Saving Transfusable Group O and Rare Red Cells for Patients; Variance Request to FDA to Allow Deferred Donors to be Used for Reagent Red Cell Manufacturing

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INTRODUCTION/ABSTRACT

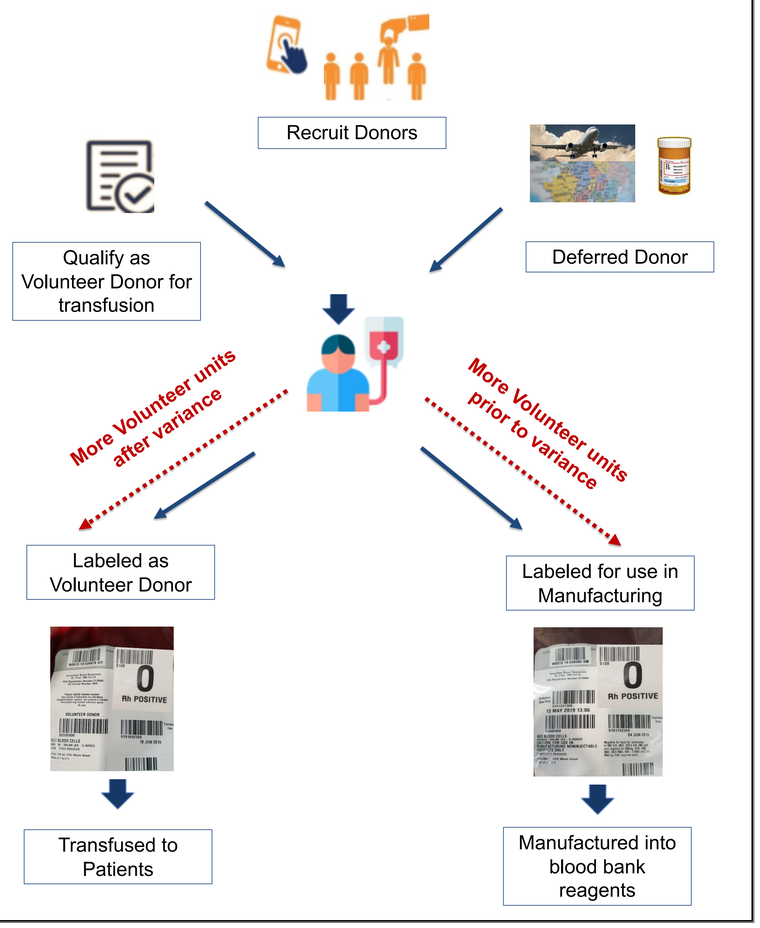
Red cell reagent donors are selected because of their unique combination of red blood cell antigens. Various combinations of these antigens are required to manufacture immuno-hematology reagents. Antibody screening sets are used to detect the presence of antibody, while identification panels help delineate antigen specificity. Each panel contains an array of cells from donors specially selected to assist in antibody identification. Once a donor's unique antigen combination is determined, they are matched with other donors to create a complementary panel. The FDA revision of 21 CFR 630.30 published May 23, 2016, implied that all reagent red cell donors must meet regular blood donor eligibility criteria[1]. 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. Prior to this date, numerous reagent red cells were being provided to manufacturers from donors deferred for clinically minimal risk reasons. A variance was granted by the FDA 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.

OBJECTIVES

- Reduce the number of medically valuable rare antigen negative group O units going to manufacturing.
- Allow the use of donors for manufacturing that are deferred for travel or residence in vCJD or travel in malarial risk areas.
- Allow the use of donors for manufacturing that use Finasteride or Dutasteride.

METHODS

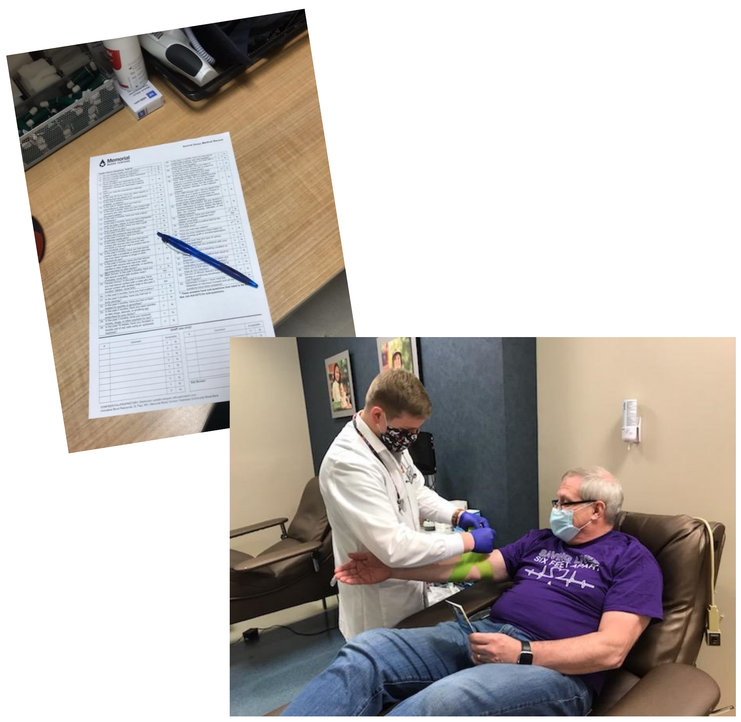
FIGURE 1: VOLUNTEER AND REAGENT DONOR PROCESS



METHODS

- A variance was requested on August 8, 2018 to allow use of donors deferred for a range of clinically minimal risk reasons.
- Previous to May 2016, a shortened questionnaire was used for donors of non-transfusable products.
- FDA responded on August 2019 with a request to narrow the range of deferral reasons.
- A request was submitted to allow use of donors deferred for:
  1. Travel to or residence in a malarial risk area
  2. Travel to or residence in a vCJD risk country
  3. Use of Finasteride or Dutasteride
- The FDA variance was granted on November 4, 2019.
- These exceptions pose little/no risk to the safety and health of the donor or those using the manufactured reagents.
- Recruitment is underway to identify donors who are eligible as a reagent donor following the granting of the variance.

FIGURE 2: DEFERRED REAGENT DONOR ABLE TO RETURN TO THE REAGENT DONOR PROGRAM FOLLOWING THE FDA VARIANCE



RESULTS

- A total of 56 reagent donors were deferred from donating prior to the FDA variance. This is equivalent to over 224 units that were diverted from the transfusable red blood cell inventory to fill the needs for manufacturing reagent red cells.
- The blood center maintains detailed records on all donors in the reagent donor program. Using this data, we have exact numbers of deferred donors and why each donor is deferred per year. These numbers do not account for volunteer/allogeneic donors who were deferred and would be eligible to donate for reagent use during their deferral.

RESULTS

FIGURE 3: REAGENT DONOR RED CELLS MANUFACTURED INTO PANEL CELLS

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

CONCLUSIONS

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 0 Rh positive and negative RBC's are being diverted from the transfusable blood supply and used, instead for manufacturing reagent red cells.

Without the FDA variance, the availability of group O blood for transfusion is impacted. Given the well documented increasing strain on the group O blood supply as total collections decline, this variance will reduce the unnecessary use of transfusable cells for purposes that do not medically require reagent donors to meet all blood donation requirements.

REFERENCES

1. Citation: 21 CFR 630.30 implemented May 23, 2016 last updated 4/1/2019; donor requirements: 660.31.