

Overview

File:	Plasma_DataPartner3_Final Summary Report_3Aug20_IQVIA
Date:	8/3/2020
Objective:	To conduct a feasibility analysis to estimate the incidence of blood components
Background:	CBER is responsible for regulating how blood donations are processed; CBER also reviews and accepts the Circular of Information (labeling) regarding the use of blood for transfusion. Blood, in contrast to other drugs, is of human origin and there is no single manufacturer that can be held responsible for safety, effectiveness, and quality of the products. Instead, the production of blood components is carried out in a decentralized system of blood banks, some of which belong to the healthcare institutions where they are administered to patients with the medical need, and some of which are independent organizations focusing on collection, processing, or distribution. This system presents a challenge to systematic monitoring since data about blood component production and exposure are needed in the context of other patient data representing prior clinical constellation such as indication and comorbidities, and the outcome consequences. To address these challenges, a network of databases in OMOP CDM was established for the BEST Initiative, allowing identification of patients with exposure to blood components. These databases are derived from these EHR databases: - Columbia University Medical Center - Regenstrief Institute - Colorado UC Health System This study is focused on using a labeling and identification system called Information Standard for Blood and Transplant (ISBT) 128. ISBT 128 codes are designed to make medical products of human origin collected at one facility easily managed and read by a different facility. Currently, in the U.S., the governing rules regarding labeling of blood and blood component products are in the Code of Federal Regulations. The FDA does not require ISBT 128 for blood and blood component product labeling in the U.S.; however, the FDA does require that certain information, typically included on ISBT 128 labels, such as the product code and the unique facility identifier, be included on blood and blood component labels. While the FDA does not require ISBT 128, the American Association of Blood Banks (AABB), a leader in the development of standards in blood and blood component collection, processing, and transfusion, does require that blood and blood components be labeled using ISBT 128 at AABB-accredited facilities in and outside of the U.S.¹ ISBT 128 codes summarize all information about the component's Class (e.g. red blood cells), Modifiers (e.g. thawed), and Attributes including Core Conditions (e.g. anticoagulant).² ISBT 128 records from blood banks have the potential to significantly improve the ability to define exposures and blood products for several reasons: 1. ISBT 128 allows studying blood components at greater detail than the rather generic procedure codes. 2. The procedure codes are subject to billing rules, which generally tend to suppress detailed activities that are part of larger procedures. For example, blood transfusions administered to patients receiving trauma care or large surgeries are generally not listed, even when such transfusions happened.³

Study Specifications:

[Study Specifications](#)

Table of Contents

Worksheet	Description
Study Specifications	Displays a table summarizing study specifications
	Figure 1: Collection Method
	Table 1: Modification Method
Plasma Collection Method	Collection method for total number of patients, units, and episodes, within transfusion episode bins, and within units per episode bins
	Table 2: Total Number of Plasma Patients and Units Transfused per Year
	Table 3: Number of Plasma Patients and Units Transfused by Number of Transfusion Episodes per Year
	Table 4: Number of Plasma Transfusion Episodes by Number of Transfused Units per Transfusion Episode Bin per Year
Plasma Modification Method	Modification methods related to plasma that is frozen <=24 hours, room temperature (RT) <=24 hours frozen, thawed, liquid, and fresh frozen
	Table 5: Number of Plasma Patients and Units by Modification Method per Year
Graphs	Graphical representations of results
	Figure 2: Data Partner3: Total Number of Patients Receiving Plasma Transfusions per Year
	Figure 3: Data Partner3: Total Number of Patients Receiving Plasma Transfusions by Number of Transfusion Episodes per Year
	Figure 4: DataPartner3: Total Number of Plasma Units Transfused by Number of Transfusion Episodes per Year
	Figure 5: Data Partner3: Total Number of Plasma Transfusion Episodes by Number of Transfused Units with 1 Transfusion Episode per Year
	Figure 6: Data Partner3: Total Number of Plasma Transfusion Episodes by Number of Transfused Units with 2-5 Transfusion Episodes per Year
	Figure 7: Data Partner3: Total Number of Plasma Transfusion Episodes by Number of Transfused Units with 6-11 Transfusion Episodes per Year
	Figure 8: Data Partner3: Total Number of Plasma Transfusion Episodes by Number of Transfused Units with 12+ Transfusion Episodes per Year
	Figure 9: DataPartner3: Total Number of Patients Receiving Plasma Transfusions by Modification Method per Year
	Figure 10: DataPartner3: Total Number of Plasma Units Transfused by Modification Method per Year
Appendix A-Plasma Codelist	Plasma ISBT Codelist
Appendix B-Additional Definitions	Additional definitions

References:

- ¹"United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128." Version 3.0.0 (2013). <<https://www.iccbba.org/uploads/4a/e3/4ae3b3fd95bae57d4ee0f58ab6c5874f/IG-002-US-Consensus-Standard-Blood-v3.0.0.pdf>>.
- ²"Standard Terminology for Medical Products of Human Origin For Use with Product Description Code Database." Version 7.17 (2018). <<https://www.iccbba.org/uploads/b5/ad/b5ad322bf583e86dd877277c07cde231/Standard-Terminology-for-Medical-Products-of-Human-Origin-v7.17.pdf>>.
- ³U.S. Centers for Medicare & Medicaid Services. National Correct Coding Initiative Edits - PTP Coding Edits. (2018). <<https://www.cms.gov/Medicare/Coding/NationalCorrectCodingInitEd/NCCI-Coding-Edits.html>>.

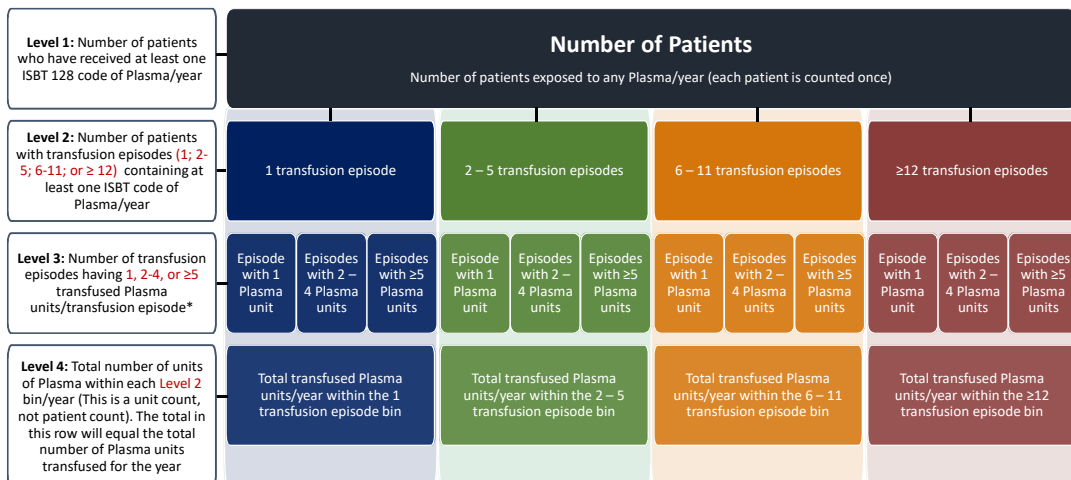
Study Specifications

File: Hemovigilance Study_Exposures_Query Specs
Date: 8/3/2020
Objective: To conduct a feasibility analysis to estimate the incidence of blood components
Data Source: Data Partner 3 EHR
 -Collection Method query executed on 8/28/2019
 -Modification Method query executed on 8/28/2019
Years: 1/1/2012 - 12/31/2018
Exposure Population: All patients with at least one day of enrollment or at least one health encounter in each calendar year within the study period.
Units Count: Number of ISBT 128 code counts of the blood component of interest within the transfusion episode bin in a given year. If transfusion of a specific blood component is given on day #1 (1 unit), day #45 (4 units) and day #46 (10 units), this counts as 15 transfused units of specific blood component within the 2-5 transfusion episode bin. This measurement is at the transfused unit level, it does NOT count patients.

Specifications:

Collection Method

Figure 1. Collection Method



*Note: In reference to collection method, level 3, transfusion episode number of units stratification layer was modified to reflect 1 unit, 2-4 units, and 5 units, respectively. It was necessary to modify the query because following inspection of our data, the sites pooled plasma = 3-4 units, and all sites used either 1 unit or 2-4 units of plasma for most of their transfusions.

Modification Method

Table 1. Modification Method

Number of unique patients with at least one ISBT code with the specified plasma modification (irrespective of all other products received)	Number of transfused units/year with the specified modification (Not patient level count)
That is Liquid Plasma	Total # Units of Liquid Plasma
That is Thawed Plasma	Total # Units of Thawed Plasma
That is Fresh Frozen Plasma, Thawed	Total # Units of Fresh Frozen Plasma, Thawed
That is Plasma Frozen within 24 Hrs, Thawed	Total # Units of Plasma Frozen within 24 Hrs, Thawed
That is Plasma Frozen within 24 Hrs after Phlebotomy held at Room Temperature for 24 Hrs (PF ²⁴ RT ²⁴)	Total # Units of Plasma at Room Temperature

Collection Method

Table 2: Total number of plasma patients and units transfused per year

Collection Method - Plasma	Transfusion Year							
	2012	2013	2014	2015	2016	2017	2018	Total
Total Number of Patients	1,582	1,663	1,789	1,603	1,662	1,481	1,580	11,360
Total Number of Units	12,131	11,855	10,767	8,946	9,112	7,411	7,195	67,417

Table 3: Number of plasma patients and units transfused by number of transfusion episodes per year

Collection Method - Plasma	Transfusion Episodes per Year	Transfusion Year							
		2012	2013	2014	2015	2016	2017	2018	Total
Number of Patients	1	1,164	1,193	1,269	1,153	1,217	1,038	1,217	8,251
Number of Patients	2-5	360	402	456	393	394	403	329	2,737
Number of Patients	6-11	46	54	53	49	40	30	24	296
Number of Patients	>=12	12	14	11	<10	11	10	10	68
	Total	1,582	1,663	1,789	1,595	1,662	1,481	1,580	11,352
Number of Units	1	4,317	3,977	3,962	3,220	3,335	2,588	3,235	24,634
Number of Units	2-5	3,998	4,762	4,482	3,412	3,485	3,103	2,739	25,981
Number of Units	6-11	1,969	1,723	1,433	1,548	834	817	620	8,944
Number of Units	>=12	1,847	1,393	890	766	1,458	903	601	7,858
	Total ¹	12,131	11,855	10,767	8,946	9,112	7,411	7,195	67,417

¹The total patients from Table 3 are less than total patients from Table 2 as there are patients that are masked in Table 3

Table 4: Number of plasma transfusion episodes by number of transfused units per transfusion episode bin per year

Collection Method - Plasma	Transfusion Episodes per Year	Units per Episode	Transfusion Year							
			2012	2013	2014	2015	2016	2017	2018	Total
Number of Transfusion Episodes	1	1	259	289	382	431	512	461	543	2,877
Number of Transfusion Episodes	1	2-4	658	690	686	570	565	475	520	4,164
Number of Transfusion Episodes	1	>= 5	247	214	201	152	140	102	154	1,210
		Total	1,164	1,193	1,269	1,153	1,217	1,038	1,217	8,251
Number of Transfusion Episodes	2-5	1	203	218	325	345	398	440	332	2,261
Number of Transfusion Episodes	2-5	2-4	521	543	659	509	469	475	376	3,552
Number of Transfusion Episodes	2-5	>= 5	212	278	232	157	181	134	150	1,344
		Total	936	1,039	1,216	1,011	1,048	1,049	858	7,157
Number of Transfusion Episodes	6-11	1	39	82	124	106	112	69	70	602
Number of Transfusion Episodes	6-11	2-4	164	217	179	149	134	100	78	1,021
Number of Transfusion Episodes	6-11	>= 5	151	111	83	90	45	55	32	567
		Total	354	410	386	345	291	224	180	2,190
Number of Transfusion Episodes	>=12	1	36	61	32	18	35	60	76	318
Number of Transfusion Episodes	>=12	2-4	28	70	82	53	68	76	51	428
Number of Transfusion Episodes	>=12	>= 5	159	110	68	77	145	58	33	650
		Total	223	241	182	148	248	194	160	1,396

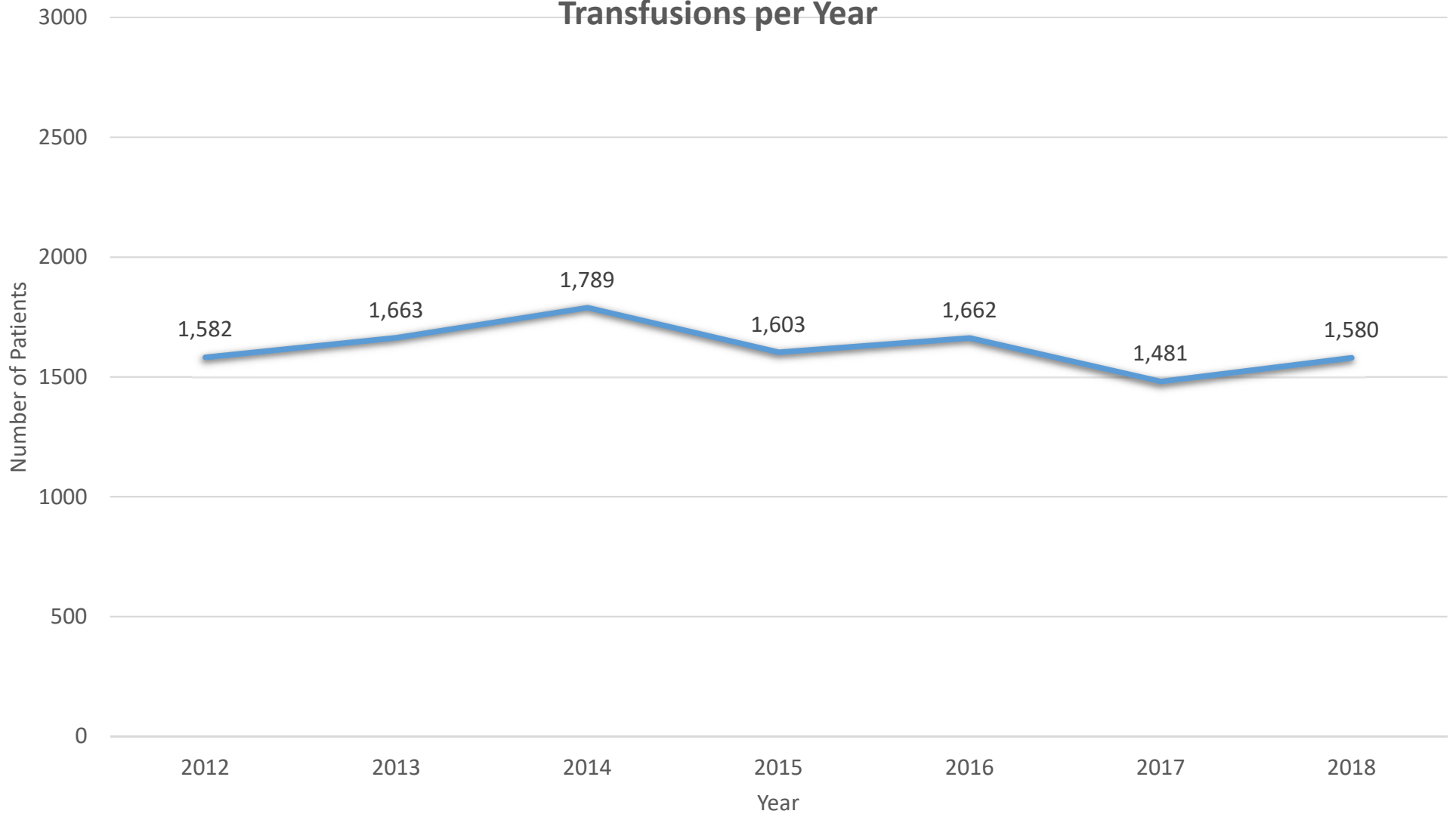
Modification Method

Table 5: Number of plasma patients and units by modification method per year

		Transfusion Year							Total
Modification Method - Plasma		2012	2013	2014	2015	2016	2017	2018	
Number of Patients	Frozen <=24, thawed	210	187	103	207	149	306	796	1,958
Number of Patients	RT <=24 frozen <= 24h, thawed	0	0	0	0	0	0	0	0
Number of Patients	Thawed plasma	<10	<10	685	1,543	1,618	1,408	1,281	6,535
Number of Patients	FFP, thawed	1,545	1,640	1,149	73	75	83	91	4,656
Number of Patients	Liquid plasma	0	0	0	0	0	0	0	0
	Total ¹	1,755	1,827	1,937	1,823	1,842	1,797	2,168	13,149
Number of Units	Frozen <=24, thawed	530	440	205	469	317	762	2,276	4,999
Number of Units	RT <=24 frozen <= 24h, thawed	0	0	0	0	0	0	0	0
Number of Units	Thawed plasma	109	37	4,037	8,358	8,652	6,507	4,762	32,462
Number of Units	FFP, thawed	11,492	11,378	6,525	119	143	142	157	29,956
Number of Units	Liquid plasma	0	0	0	0	0	0	0	0
	Total	12,131	11,855	10,767	8,946	9,112	7,411	7,195	67,417

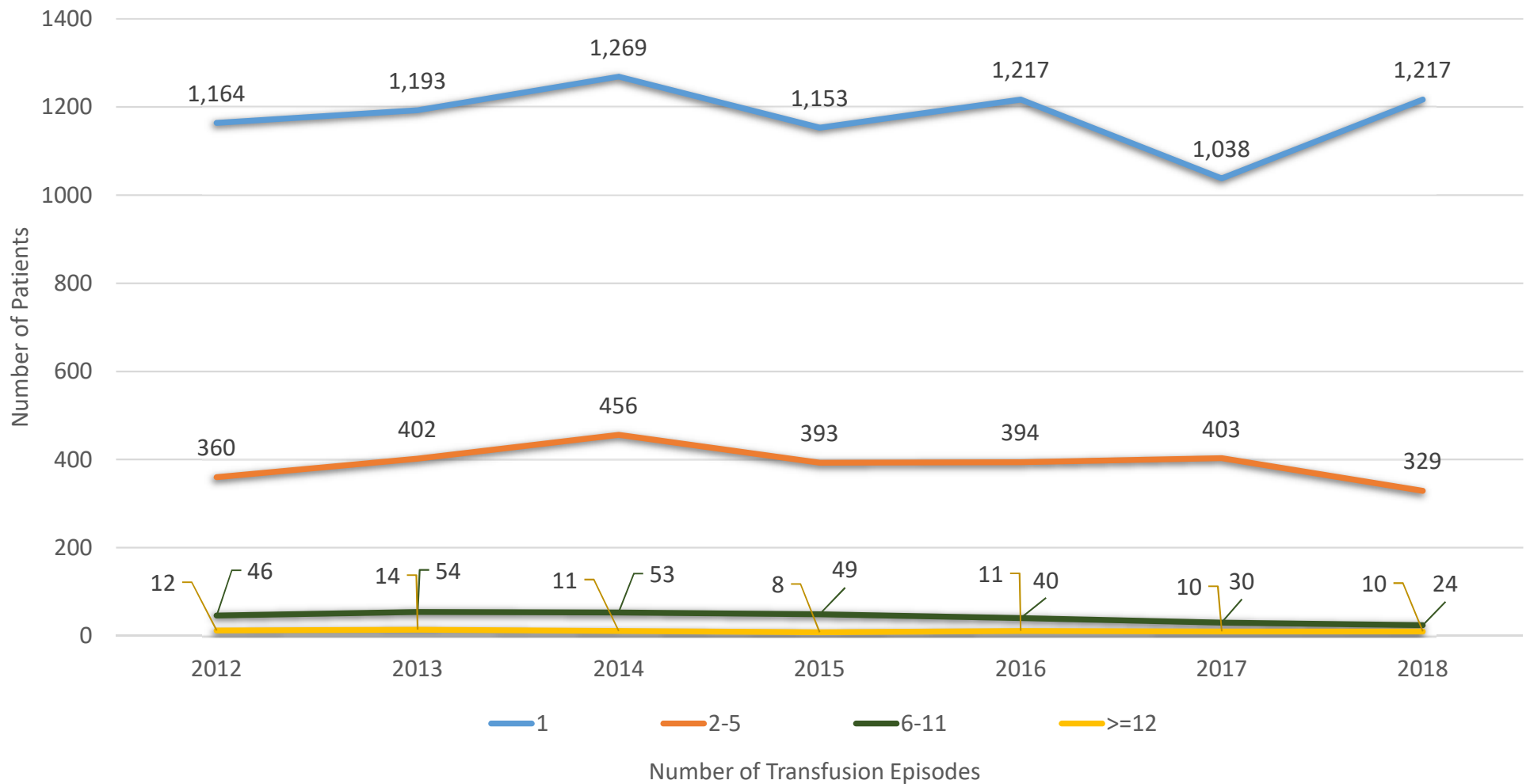
¹Total patients in Table 4 are more than total patients in Collection Method as patients are duplicated in multiple categories of Modification Method

Figure 2: DataPartner3: Total Number of Patients Receiving Plasma Transfusions per Year



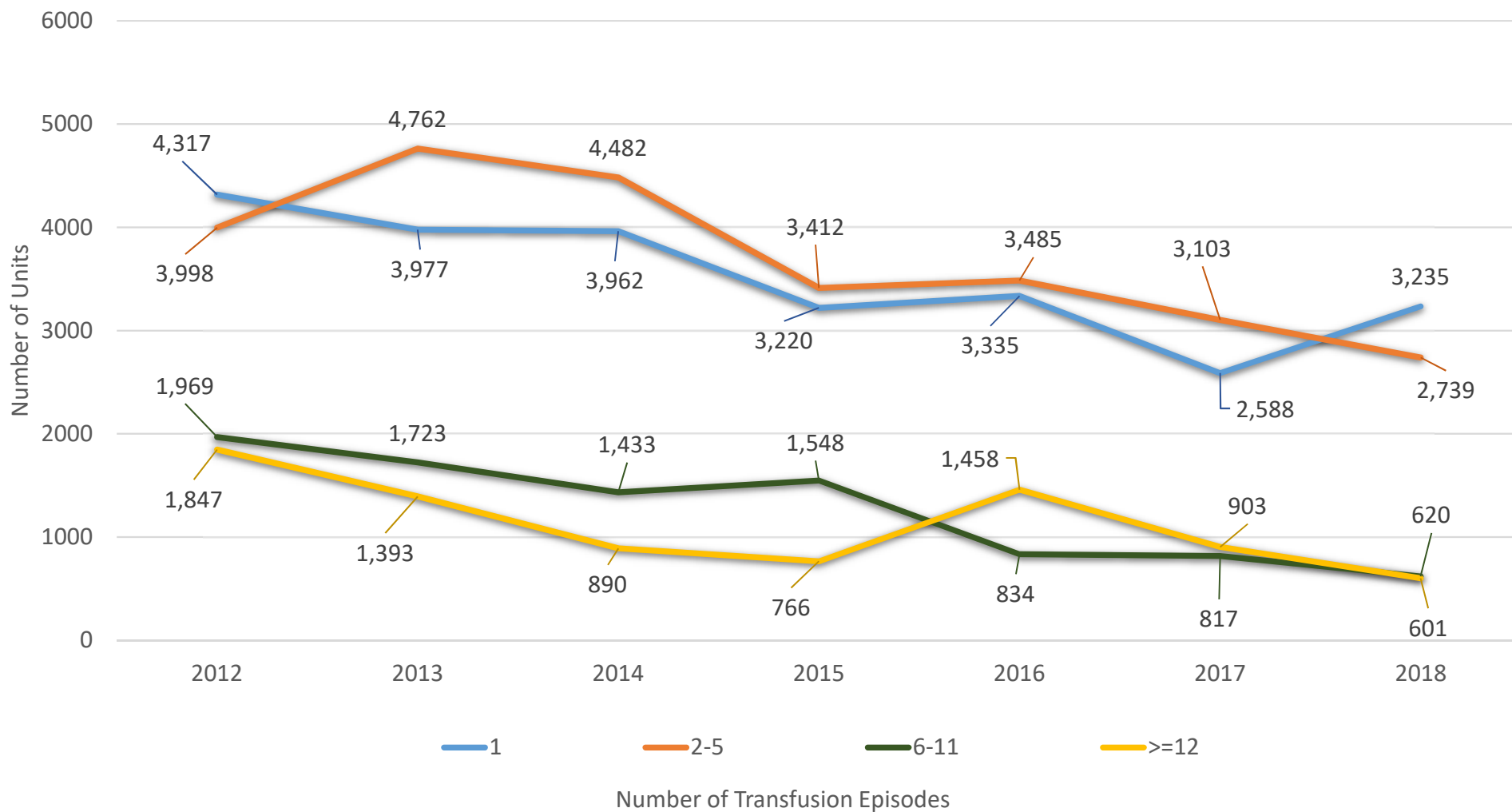
Dates of available ISBT 128 data: 1/1/2012 - 12/31/2018
Analyses conducted 8/28/2019

Figure 3: DataPartner3: Total Number of Patients Receiving Plasma Transfusions By Number of Transfusion Episodes per Year



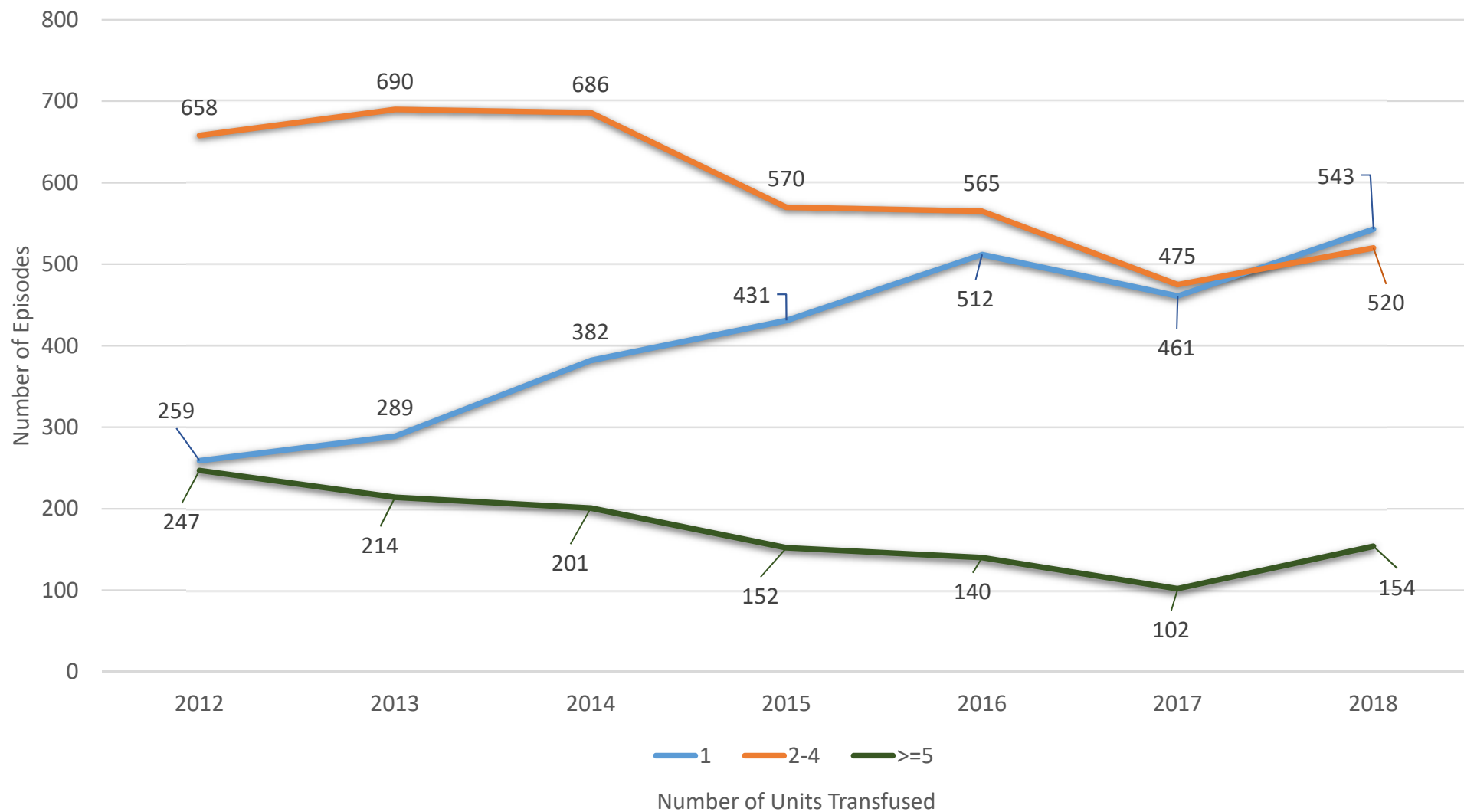
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Analyses conducted 8/28/2019

Figure 4: DataPartner3: Total Number of Plasma Units Transfused by Number of Transfusion Episodes per Year



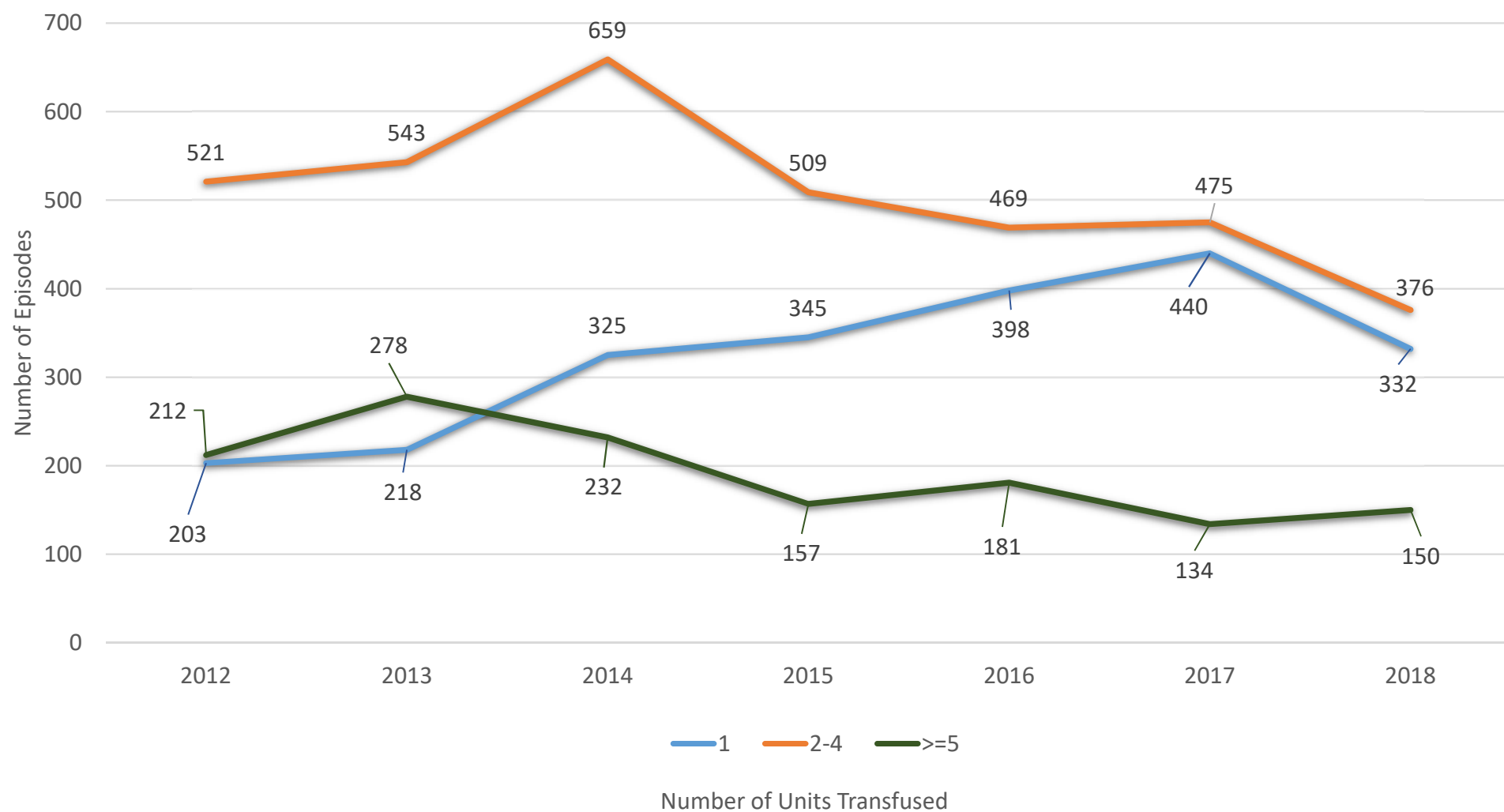
Dates of available ISBT 128 data: 1/1/2012 - 12/31/2018
Analyses conducted 8/28/2019

Figure 5: DataPartner3: Total Number of Plasma Transfusion Episodes by Number of Transfused Units for Patients with 1 Transfusion Episode per Year



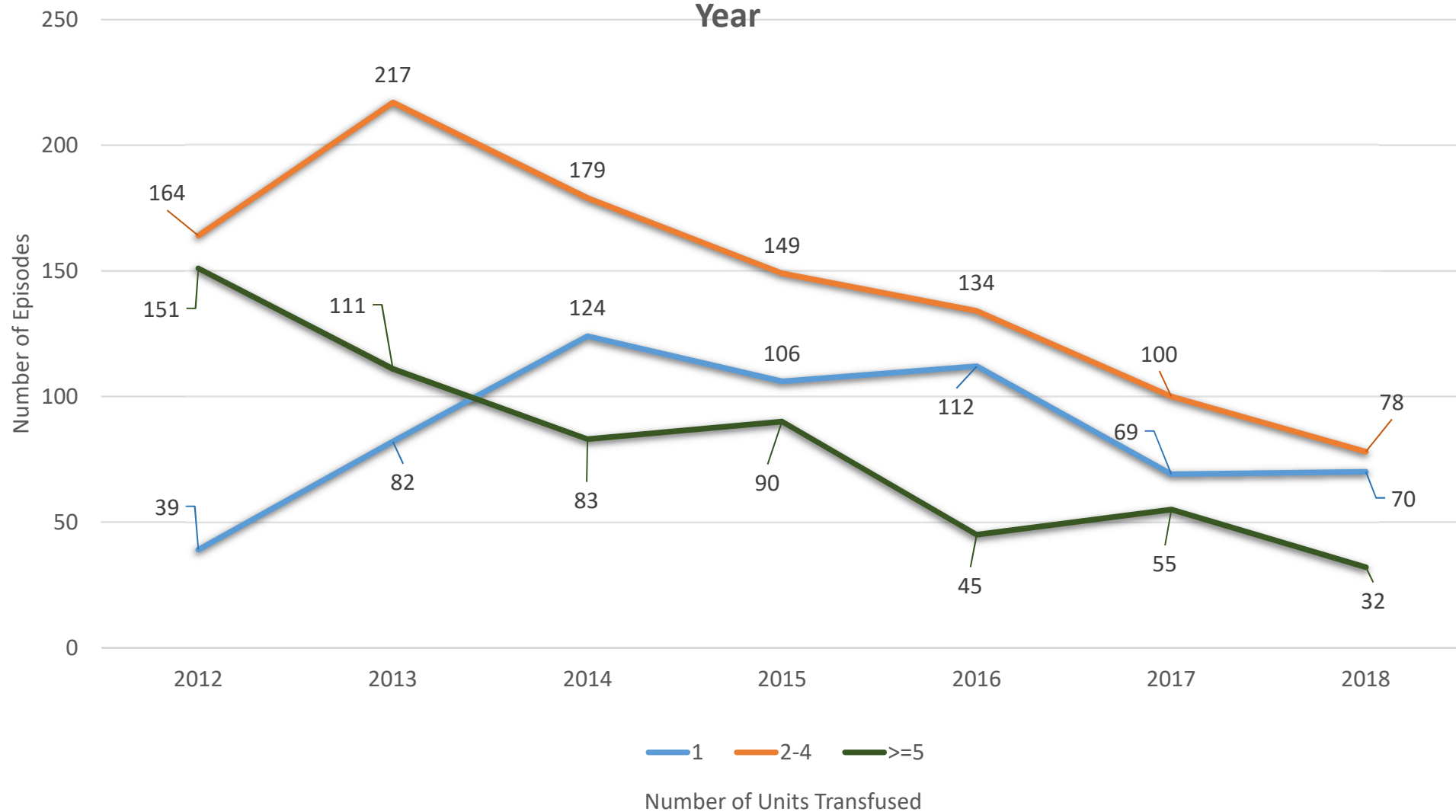
Dates of available ISBT 128 data: 1/1/2012 - 12/31/2018
Analyses conducted 8/28/2019

Figure 6: DataPartner3: Total Number of Plasma Transfusion Episodes by Number of Transfused Units for Patients with 2-5 Transfusion Episodes per Year



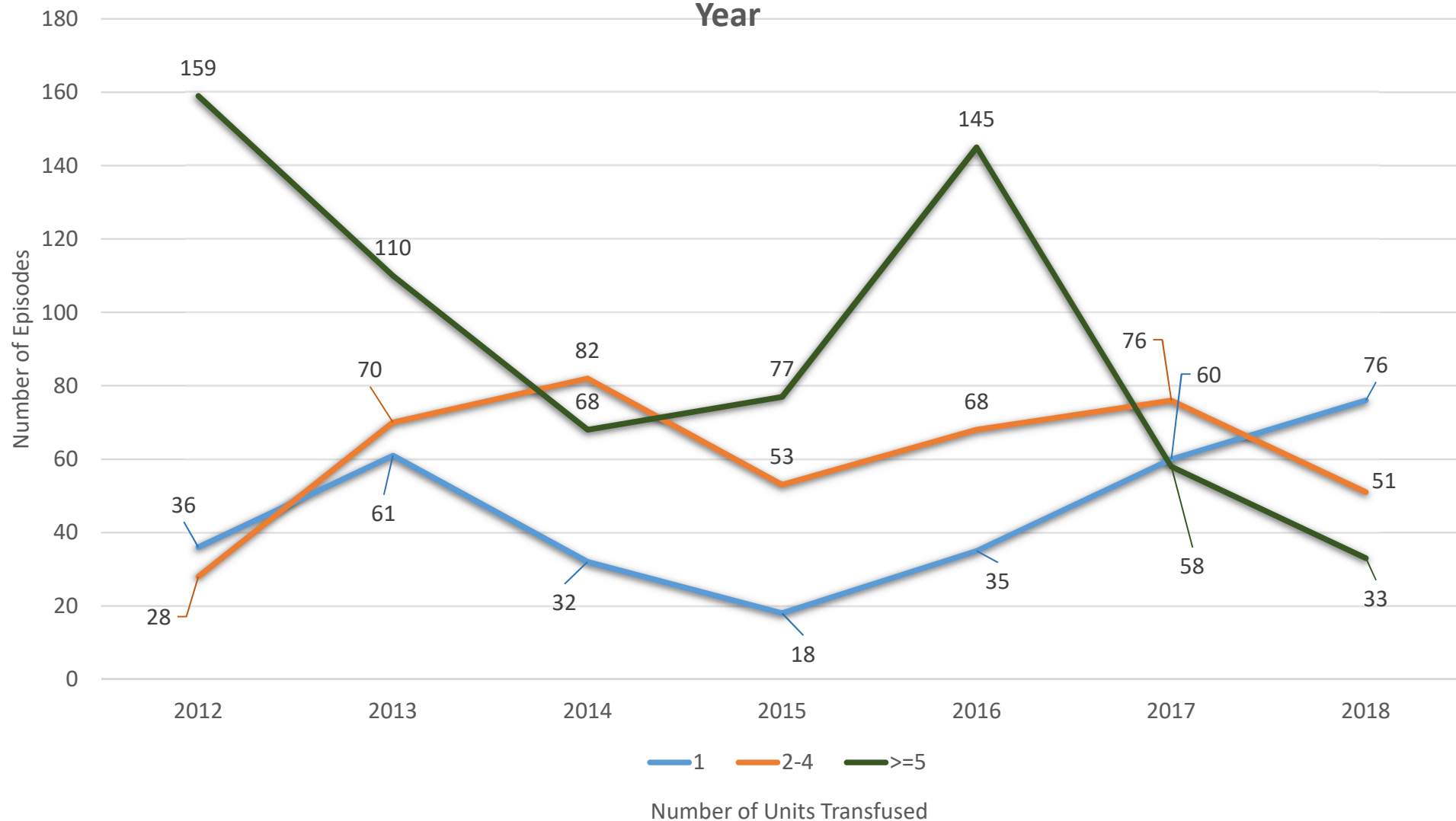
Dates of available ISBT 128 data: 1/1/2012 - 12/31/2018
Analyses conducted 8/28/2019

**Figure 7: DataPartner3: Total Number of Plasma Transfusion Episodes by
Number of Transfused Units for Patients with 6-11 Transfusion Episodes per
Year**



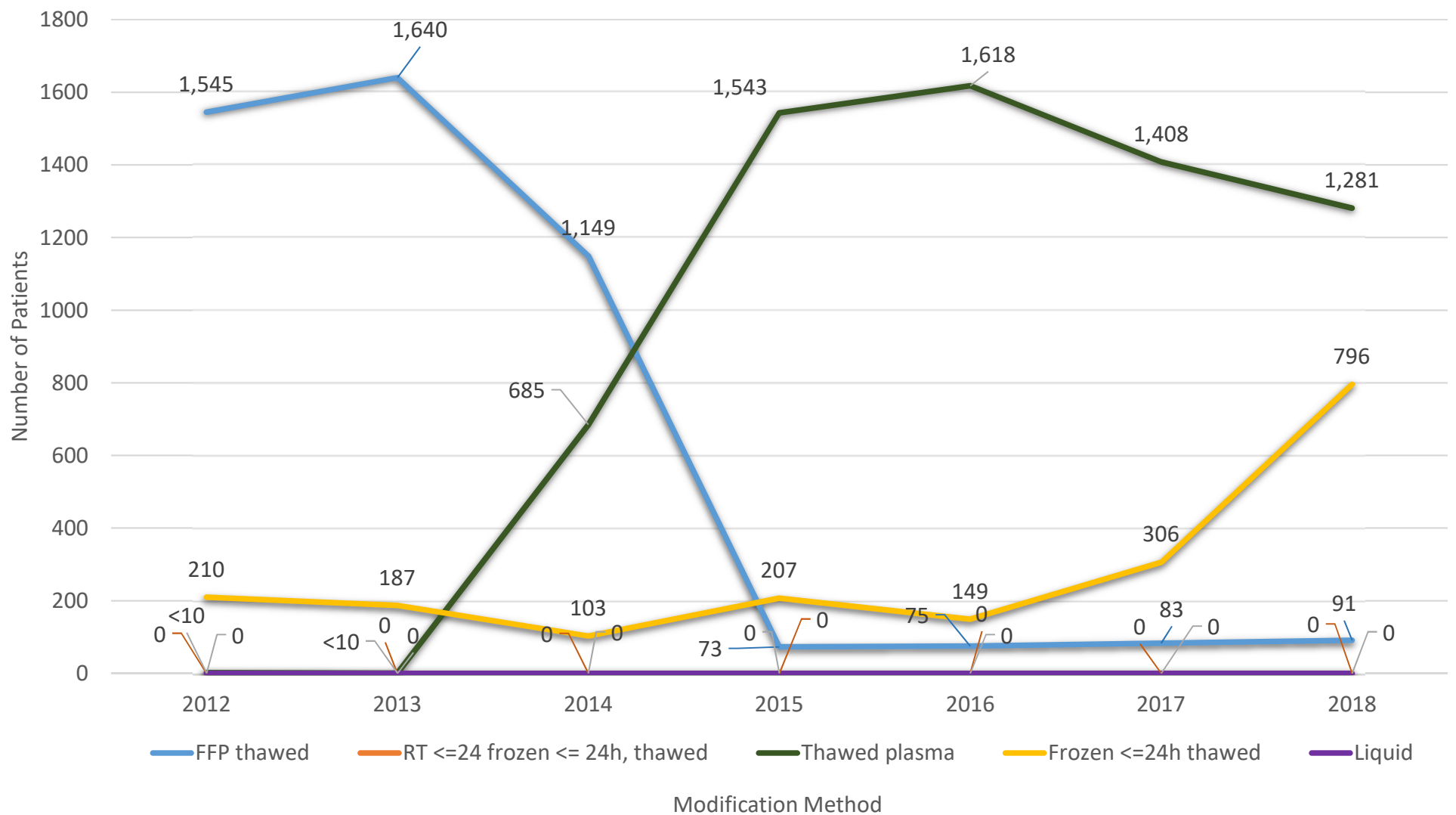
Dates of available ISBT 128 data: 1/1/2012 - 12/31/2018
Analyses conducted 8/28/2019

Figure 8: DataPartner3: Total Number of Plasma Transfusion Episodes by Number of Transfused Units for Patients with 12+ Transfusion Episodes per Year



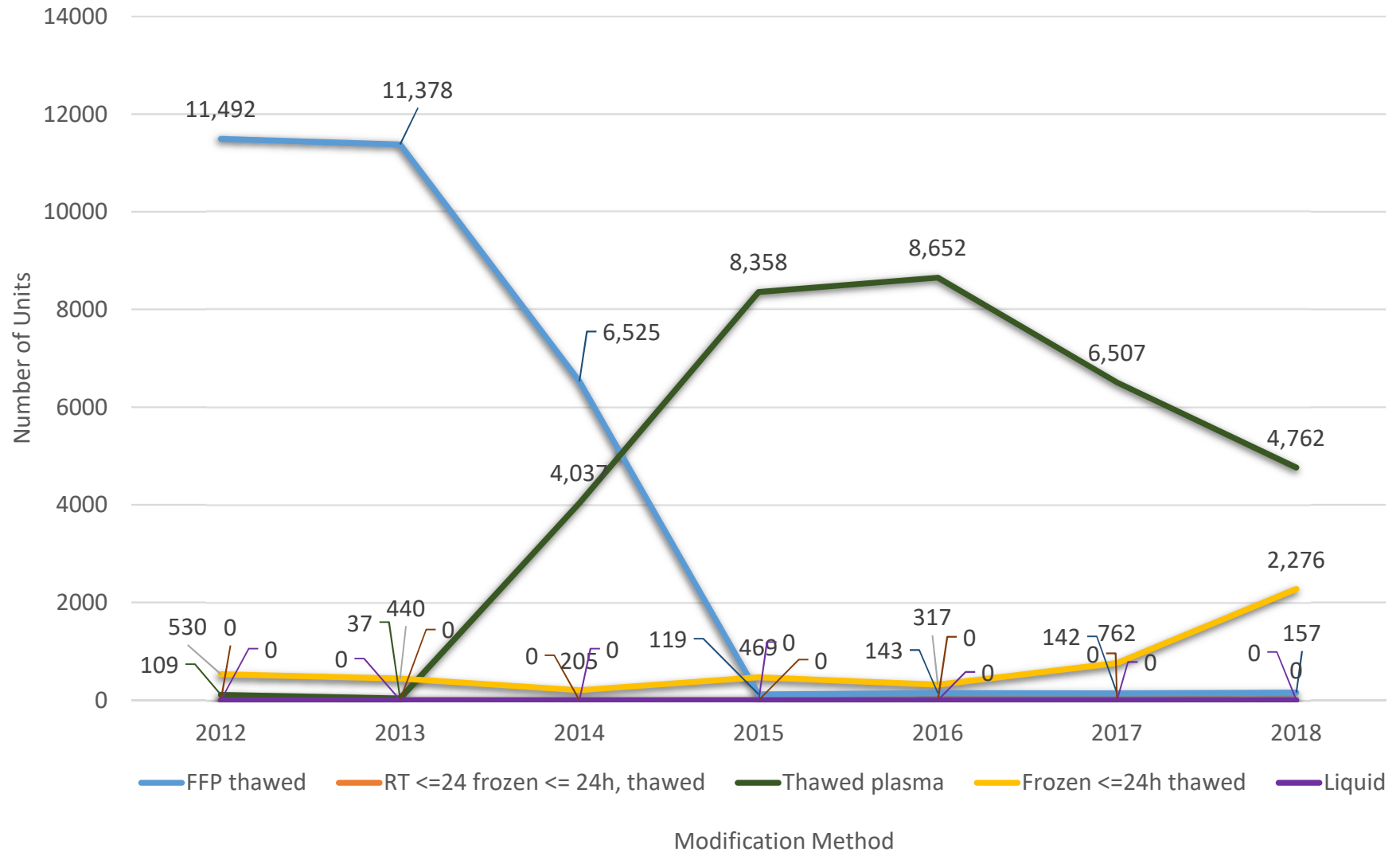
Dates of available ISBT 128 data: 1/1/2012 - 12/31/2018
Analyses conducted 8/28/2019

Figure 9: DataPartner3: Total Number of Patients Receiving Plasma Transfusions by Modification Method per Year



Dates of available ISBT 128 data: 1/1/2012 - 12/31/2018
Analyses conducted 8/28/2019

Figure 10: DataPartner3: Total Number of Plasma Units Transfused by Modification Method per Year



Dates of available ISBT 128 data: 1/1/2012 - 12/31/2018
Analyses conducted 8/28/2019

isbt_class	concept_name	concept_code	concept_id	Modification	Unit Multiplier
FRESH FROZEN PLASMA	Thawed Apheresis FRESH FROZEN PLASMA ACD-A/XX/refg 1st container	E4713	42671216	FFP, thawed	1
FRESH FROZEN PLASMA	Thawed Apheresis FRESH FROZEN PLASMA ACD-A/XX/refg 2nd container	E4717	42671220	FFP, thawed	1
FRESH FROZEN PLASMA	Thawed Apheresis FRESH FROZEN PLASMA ACD-A/XX/refg 3rd container	E4721	42670509	FFP, thawed	1
POOLED FRESH FROZEN PLASMA	Thawed POOLED FRESH FROZEN PLASMA CPD/XX/refg Open	E5298	42671461	FFP, thawed	1
POOLED FRESH FROZEN PLASMA	Thawed Apheresis POOLED FRESH FROZEN PLASMA ACD-A/XX/refg Open	E6097	42676893	FFP, thawed	1
FRESH FROZEN PLASMA	Thawed Apheresis FRESH FROZEN PLASMA ACD-A/XX/refg >=200mL<400mL	E1314	42667484	FFP, thawed	1
PLASMA	Thawed PLASMA CPD/XX/refg Frozen <=24h	E2701	42668827	Frozen <=24h, thawed	1
PLASMA	Thawed PLASMA CPDA-1/XX/refg Frozen <=24h	E2719	42668845	Frozen <=24h, thawed	1
PLASMA	Thawed PLASMA CP2D/XX/refg Open Frozen <=24h	E2732	42668858	Frozen <=24h, thawed	1
PLASMA	Thawed PLASMA CP2D/XX/refg Frozen <=24h	E2737	42668863	Frozen <=24h, thawed	1
POOLED PLASMA	Thawed POOLED PLASMA CPD/XX/refg Open Frozen <=24h	E5275	42671438	Frozen <=24h, thawed	1
POOLED PLASMA	Thawed POOLED PLASMA CPDA-1/XX/refg Open Frozen <=24h	E5307	42671470	Frozen <=24h, thawed	1
POOLED PLASMA	Thawed POOLED PLASMA CP2D/XX/refg Open Frozen <=24h	E5308	42671471	Frozen <=24h, thawed	1
POOLED PLASMA	Thawed Apheresis POOLED PLASMA ACD-A/XX/refg Open Frozen <=24h	E7948	42679099	Frozen <=24h, thawed	1
PLASMA	Liquid PLASMA CPD/XX/refg	E2457	42668978	Liquid plasma	1
PLASMA	Liquid PLASMA CP2D/XX/refg	E2469	42668150	Liquid plasma	1
PLASMA	Thawed Apheresis PLASMA ACD-A/XX/refg RT<=24h frozen<=24h	E7731	42673333	RT<=24h frozen<=24h, thawed	1
PLASMA	Thawed Apheresis PLASMA ACD-A/XX/refg RT<=24h frozen<=24h 1st container	E7750	42673352	RT<=24h frozen<=24h, thawed	1
PLASMA	Thawed Apheresis PLASMA ACD-A/XX/refg RT<=24h frozen<=24h 2nd container	E7751	42673353	RT<=24h frozen<=24h, thawed	1
PLASMA	Thawed Apheresis PLASMA ACD-A/XX/refg RT<=24h frozen<=24h 3rd container	E7752	42673354	RT<=24h frozen<=24h, thawed	1
PLASMA	Thawed Apheresis PLASMA ACD-A/XX/refg RT<=24h frozen<=24h 4th container	E7753	42673532	RT<=24h frozen<=24h, thawed	1
PLASMA	Thawed Apheresis PLASMA ACD-A/XX/refg Open RT<=24h frozen<=24h	E8109	42677761	RT<=24h frozen<=24h, thawed	1
PLASMA	Thawed Apheresis PLASMA ACD-A/XX/refg	E2121	42668349	Thawed plasma	1
PLASMA	Thawed Apheresis PLASMA NaCitrata/XX/refg	E2289	42668517	Thawed plasma	1
PLASMA	Thawed PLASMA CPD/XX/refg	E2684	42668810	Thawed plasma	1
PLASMA	Thawed PLASMA CPD/XX/refg Open	E2691	42668817	Thawed plasma	1
PLASMA	Thawed PLASMA CPD/XX/refg Cryo reduced	E2700	42668826	Thawed plasma	1
PLASMA	Thawed PLASMA CPDA-1/XX/refg	E2702	42668828	Thawed plasma	1
PLASMA	Thawed PLASMA CP2D/XX/refg	E2720	42668846	Thawed plasma	1
PLASMA	Thawed PLASMA CP2D/XX/refg Open	E2727	42668853	Thawed plasma	1
PLASMA	Thawed PLASMA CP2D/XX/refg Cryo reduced	E2736	42668862	Thawed plasma	1
PLASMA	Thawed PLASMA ACD-A/XX/refg	E2756	42668882	Thawed plasma	1
PLASMA	Thawed Apheresis PLASMA ACD-A/XX/refg 1st container	E5548	42671660	Thawed plasma	1
PLASMA	Thawed Apheresis PLASMA ACD-A/XX/refg 2nd container	E5549	42671661	Thawed plasma	1
PLASMA	Thawed Apheresis PLASMA ACD-A/XX/refg 3rd container	E5550	42671662	Thawed plasma	1
PLASMA	Thawed Apheresis PLASMA ACD-A/XX/refg 4th container	E6393	42674231	Thawed plasma	1
PLASMA	Thawed Apheresis PLASMA ACD-A/XX/refg Open 2nd container	E6800	42676474	Thawed plasma	1
PLASMA	Thawed Apheresis PLASMA ACD-A/XX/refg Open 3rd container	E6801	42676475	Thawed plasma	1
PLASMA	Thawed Apheresis PLASMA ACD-A/XX/refg 5th container	E8276	42676942	Thawed plasma	1
POOLED PLASMA	Thawed POOLED PLASMA CPD/XX/refg Open Cryo reduced	E5304	42671467	Thawed plasma	1
POOLED PLASMA	Thawed POOLED PLASMA CP2D/XX/refg Open Cryo reduced	E5305	42671468	Thawed plasma	1
POOLED PLASMA	Thawed POOLED PLASMA CP2D/XX/refg Open	E6036	42679602	Thawed plasma	1
POOLED PLASMA	Thawed POOLED PLASMA CPD/XX/refg Open	E6141	42678508	Thawed plasma	1
POOLED PLASMA	Thawed Apheresis POOLED PLASMA ACD-A/XX/refg Open	E6489	42675744	Thawed plasma	1
FRESH FROZEN PLASMA	FRESH FROZEN PLASMA CP2D/XX/<=-18C	E0713	42666585	FFP, thawed	1
FRESH FROZEN PLASMA	FRESH FROZEN PLASMA CPD/XX/<=-18C	E0701	42666573	FFP, thawed	1
FRESH FROZEN PLASMA	FRESH FROZEN PLASMA CPDA-1/XX/<=-18C	E0707	42666579	FFP, thawed	1
FRESH FROZEN PLASMA	Apheresis FRESH FROZEN PLASMA ACD-A/XX/<=-18C	E0869	42667082	FFP, thawed	1

*Note: Code list reflects codes found within partner databases only. This was due to the need to relabel and assign the modification method categories, and given the master code list contained 3000+ codes, it was more feasible to truncate the code list to include only codes found within our network. Using the master code list the first run, and then the truncated list, the second time, did not change the findings for the collection method query (i.e., number of patients, transfusion episodes, or units transfused).

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Definitions

Number of Transfused Patients: Number of unique patients with at least one ISBT 128 code specific to the blood component of interest in a given year. The patient will be counted only once for a specific blood component. If transfusion of a specific blood component is given on day #1 (1 unit), day #45 (4 units) and day #46 (10 units), this counts as 1 patient with transfusion of specific blood component.

Number of Patients with 1, 2-5, 6-11, or ≥ 12 Transfusion episodes: Number of unique patients binned by number of transfusion episodes in a given year. Transfusion episode is defined as an occurrence of at least one ISBT 128 code specific to the blood component of interest per day, in a given year. If transfusion of a specific blood component is given on day #1 (1 unit), day #45 (4 units) and day #46 (10 units), this counts as 3 RBC transfusion episodes. For the patient level diagram, this patient will be categorized in the 2-5 transfusion episode bin. The patient will be counted only once for a specific blood component.

Number of Transfusion Episodes* having 1, 2-4, or ≥ 5 Transfused units/ Transfusion Episode: Number of ISBT 128 code counts of the blood component of interest per transfusion episode bin in a given year. The patient will be counted once for **EACH** episode for a specific blood component. If transfusion of a specific blood component is given on day #1 (1 unit), day #45 (4 units) and day #46 (10 units), this counts as 3 episodes: one in the 1 unit episode bin, one in the 2-4 units episode bin, and one in the ≥ 5 units episode bin (under the same 2-5 transfusion patient-episode bin).

Total Transfused units in each transfusion episode bin: Number of ISBT 128 code counts of the blood component of interest within the transfusion episode bin in a given year. If transfusion of a specific blood component is given on day #1 (1 unit), day #45 (4 units) and day #46 (10 units), this counts as 15 transfused units of specific blood component within the 2-5 transfusion episode bin. This measurement is at the transfused unit level, it does NOT count patients.

Figure 2 - Definition of Transfusion Episode

Definition of Transfusion Episode:

A transfusion episode is defined as a transfusion of one or more specific blood component(s) on a single day, from 12AM to 11:59PM. All sites are asked to use the end date of the transfusion of the last unit of the specific blood component transfused in the day as the date of the transfusion episode. If the transfusion occurs across more than one day (e.g. 22:00h on Feb 12 to 00:30 on Feb 13), this should be counted as one transfusion episode ending on Feb 13 (and only being counted on Feb 13). If the transfusion includes two units, the first of them ending on Feb 12 at 21:50 and the second unit (from the previous example) ending at 00:30 on Feb 13, these would be counted as two transfusion episodes, one on Feb 12 and one on Feb 13. If the transfusion end date is not available, sites will use the start date of the transfusion to mark a transfusion episode.