

Overview	
File:	Plasma_DataPartner1_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](#)

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- 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/IIG-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>>.

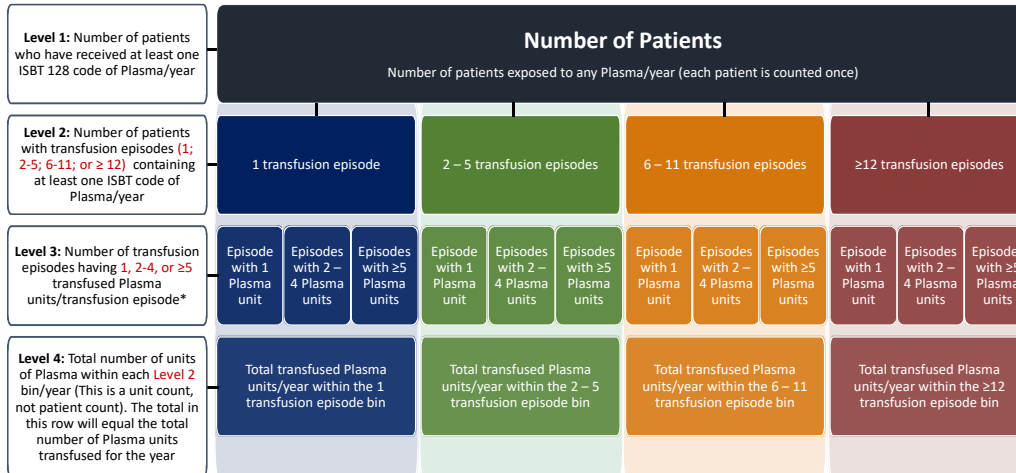
Study Specifications

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 1 EHR
- Collection Method queries executed on 7/14/2019
- Modification Method queries executed on 8/27/2019
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	2,782	2,560	2,558	2,707	2,649	2,391	2,251	17,898
Total Number of Units	10,761	9,094	10,944	9,508	8,413	7,752	9,102	65,574

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	1,840	1,732	1,687	1,812	1,858	1,646	1,599	12,174
Number of Patients	2-5	846	749	760	809	731	677	600	5,172
Number of Patients	6-11	79	60	80	71	46	58	42	436
Number of Patients	>=12	17	19	31	15	14	10	10	116
	Total	2,782	2,560	2,558	2,707	2,649	2,391	2,251	17,898
Number of Units	1	3,539	3,191	3,470	3,419	3,264	2,849	3,715	23,447
Number of Units	2-5	4,600	3,898	4,524	4,403	3,854	3,496	3,804	28,579
Number of Units	6-11	1,503	981	1,542	1,221	673	898	1,062	7,880
Number of Units	>=12	1,119	1,024	1,408	465	622	509	521	5,668
	Total	10,761	9,094	10,944	9,508	8,413	7,752	9,102	65,574

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	846	829	708	846	979	869	655	5,732
Number of Transfusion Episodes	1	2-4	925	864	911	908	839	741	838	6,026
Number of Transfusion Episodes	1	>= 5	69	39	68	58	40	36	106	416
		Total	1,840	1,732	1,687	1,812	1,858	1,646	1,599	12,174
Number of Transfusion Episodes	2-5	1	857	767	680	840	810	735	609	5,298
Number of Transfusion Episodes	2-5	2-4	1,168	1,020	1,134	1,120	946	870	697	6,955
Number of Transfusion Episodes	2-5	>= 5	129	101	150	118	102	92	168	860
		Total	2,154	1,888	1,964	2,078	1,858	1,697	1,474	13,113
Number of Transfusion Episodes	6-11	1	194	148	179	189	130	187	122	1,149
Number of Transfusion Episodes	6-11	2-4	370	279	351	311	181	209	118	1,819
Number of Transfusion Episodes	6-11	>= 5	49	18	72	35	16	29	69	288
		Total	613	445	602	535	327	425	309	3,256
Number of Transfusion Episodes	>=12	1	58	69	134	73	94	60	55	543
Number of Transfusion Episodes	>=12	2-4	254	238	349	135	161	150	92	1,379
Number of Transfusion Episodes	>=12	>= 5	47	35	58	<10	18	<10	32	190
		Total	359	342	541	208	273	210	179	2,112

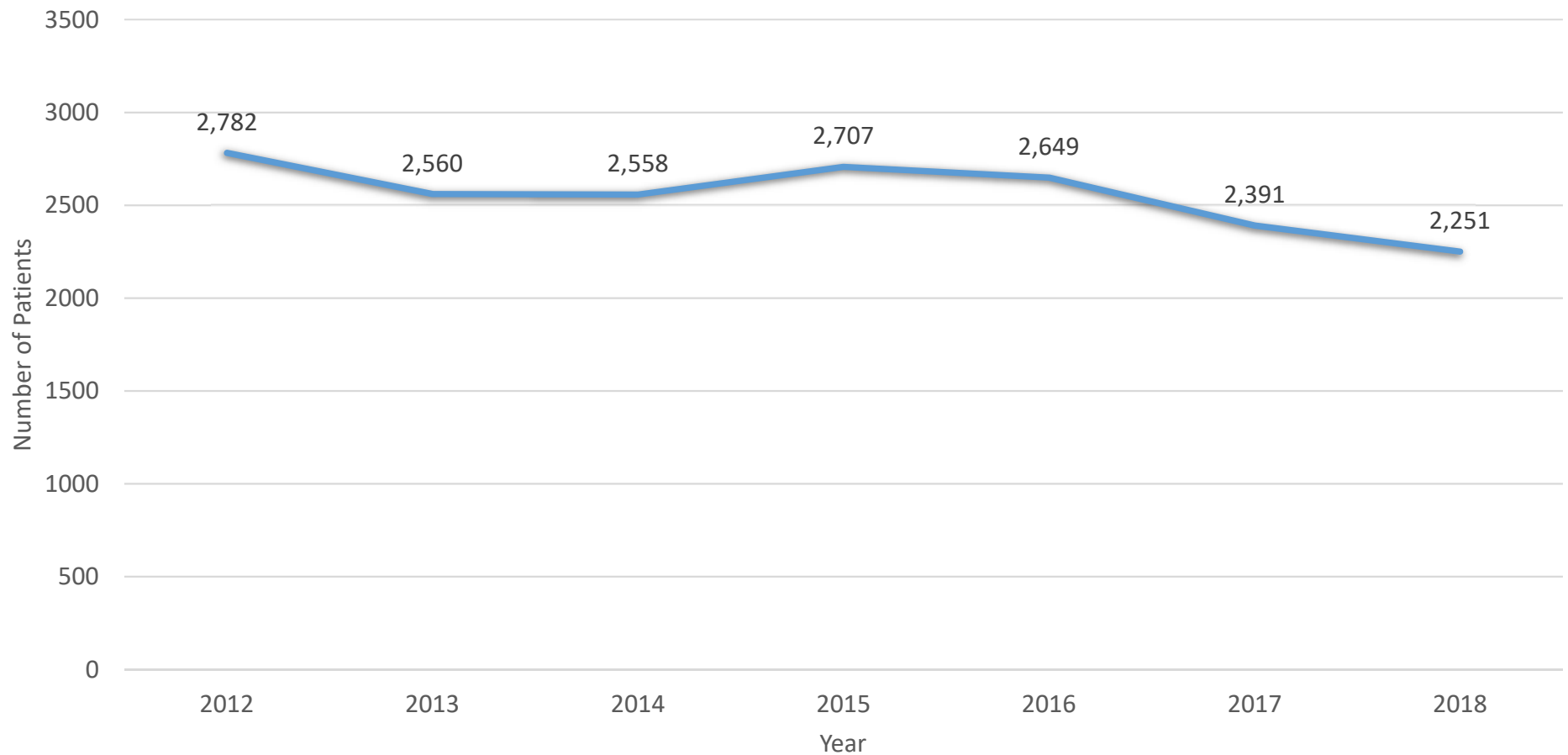
Modification Method

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

		Transfusion Year							
Modification Method - Plasma		2012	2013	2014	2015	2016	2017	2018	Total
Number of Patients	Frozen <=24, thawed	2,342	2,327	2,361	2,560	2,584	2,296	2,147	16,617
Number of Patients	RT <=24 frozen <= 24h, thawed	0	0	0	12	23	24	93	152
Number of Patients	Thawed plasma	114	110	120	132	154	146	156	932
Number of Patients	FFP, thawed	901	841	951	552	53	29	17	3,344
Number of Patients	Liquid plasma	0	0	0	0	0	0	0	0
	Total ¹	3,357	3,278	3,432	3,256	2,814	2,495	2,413	21,045
Number of Units	Frozen <=24, thawed	8,566	7,260	8,650	8,249	7,978	7,324	8,642	56,669
Number of Units	RT <=24 frozen <= 24h, thawed	0	0	0	14	30	25	125	194
Number of Units	Thawed plasma	637	424	375	296	333	348	316	2,729
Number of Units	FFP, thawed	1,558	1,410	1,919	949	72	55	19	5,982
Number of Units	Liquid plasma	0	0	0	0	0	0	0	0
	Total	10,761	9,094	10,944	9,508	8,413	7,752	9,102	65,574

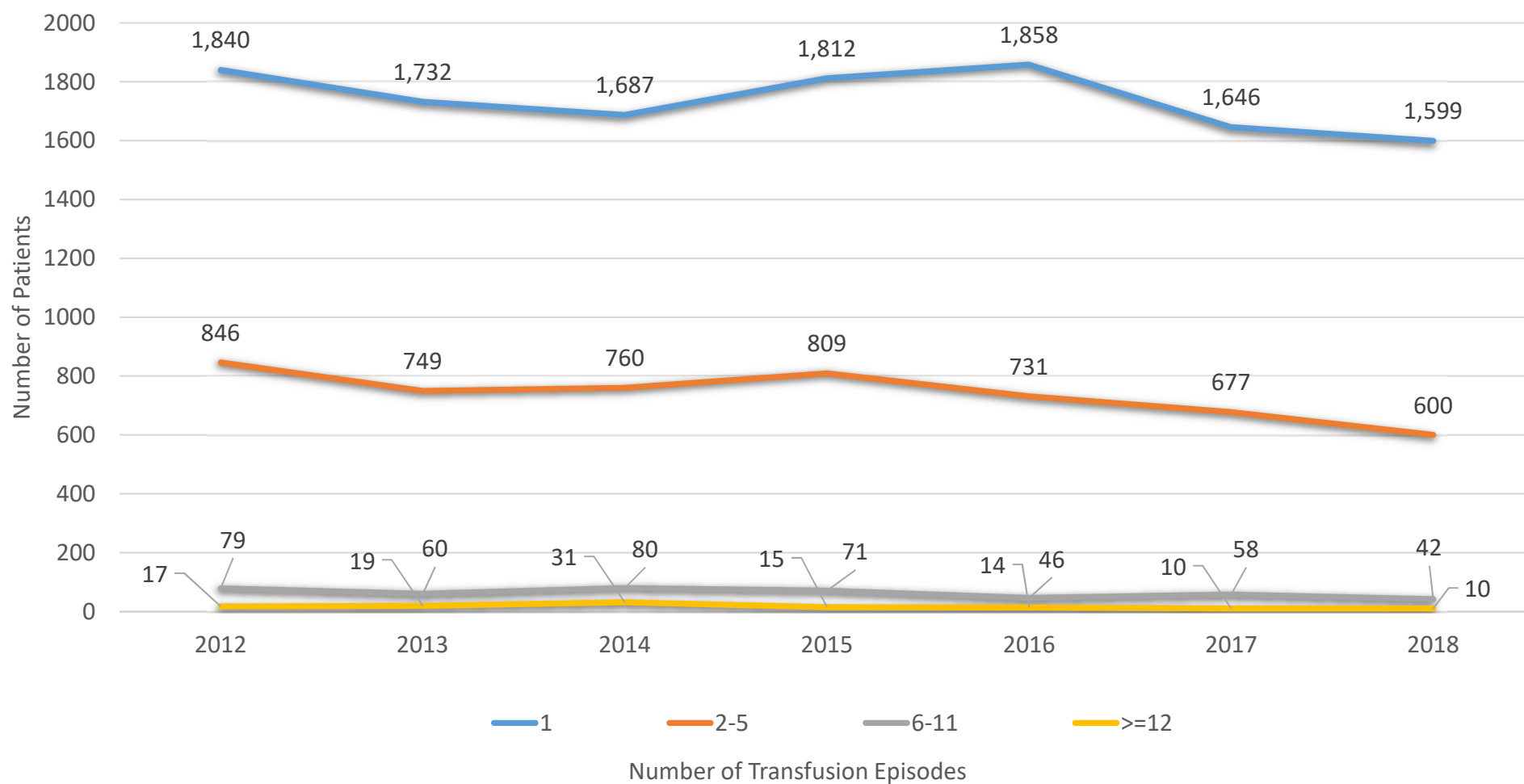
¹Total patients in Table 4 are more than total patients in Collection Method as patients are duplicated in multiple categories of Modification Method

Figure 2: DataPartner1: Total Number of Patients Receiving Plasma Transfusions per Year



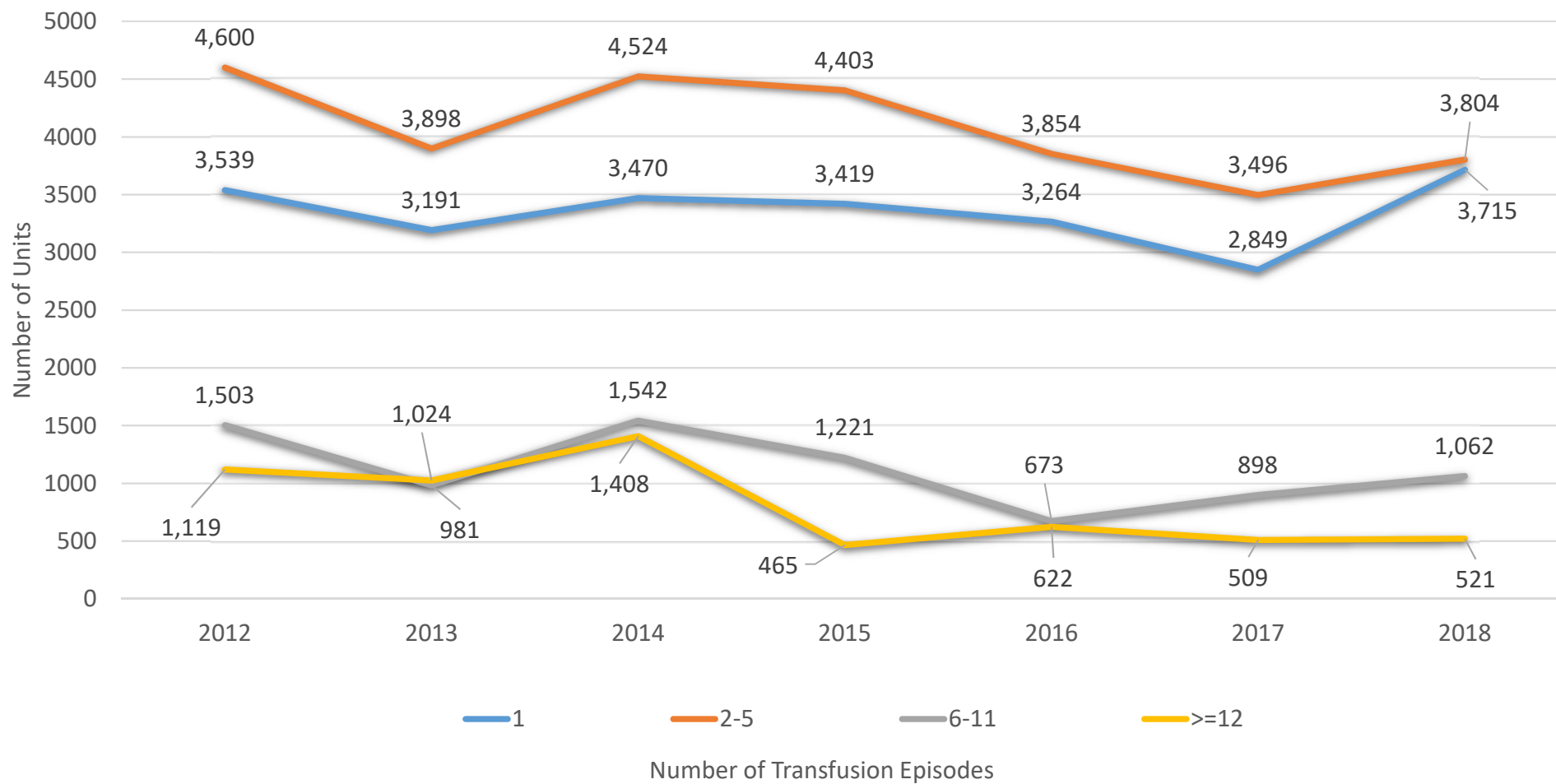
Dates of available ISBT 128 data: 1/1/2012 - 12/31/2018
Analyses conducted 7/14/2019

Figure 3: DataPartner1: Total Number of Patients Receiving Plasma Transfusions by Number of Transfusion Episodes per Year



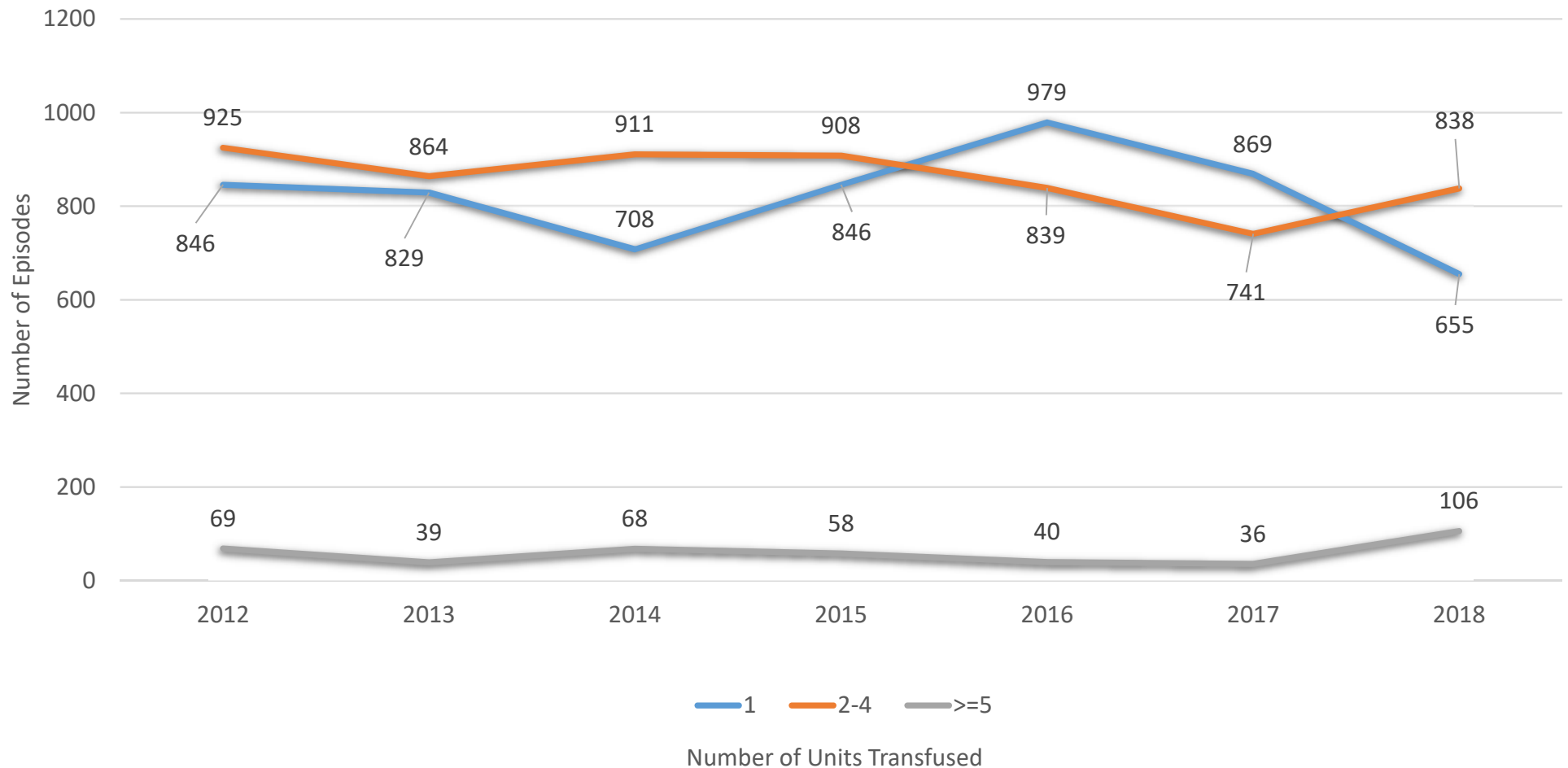
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Analyses conducted 7/14/2019

Figure 4: DataPartner1: Total Number of Plasma Units Transfused by Number of Transfusion Episodes per Year



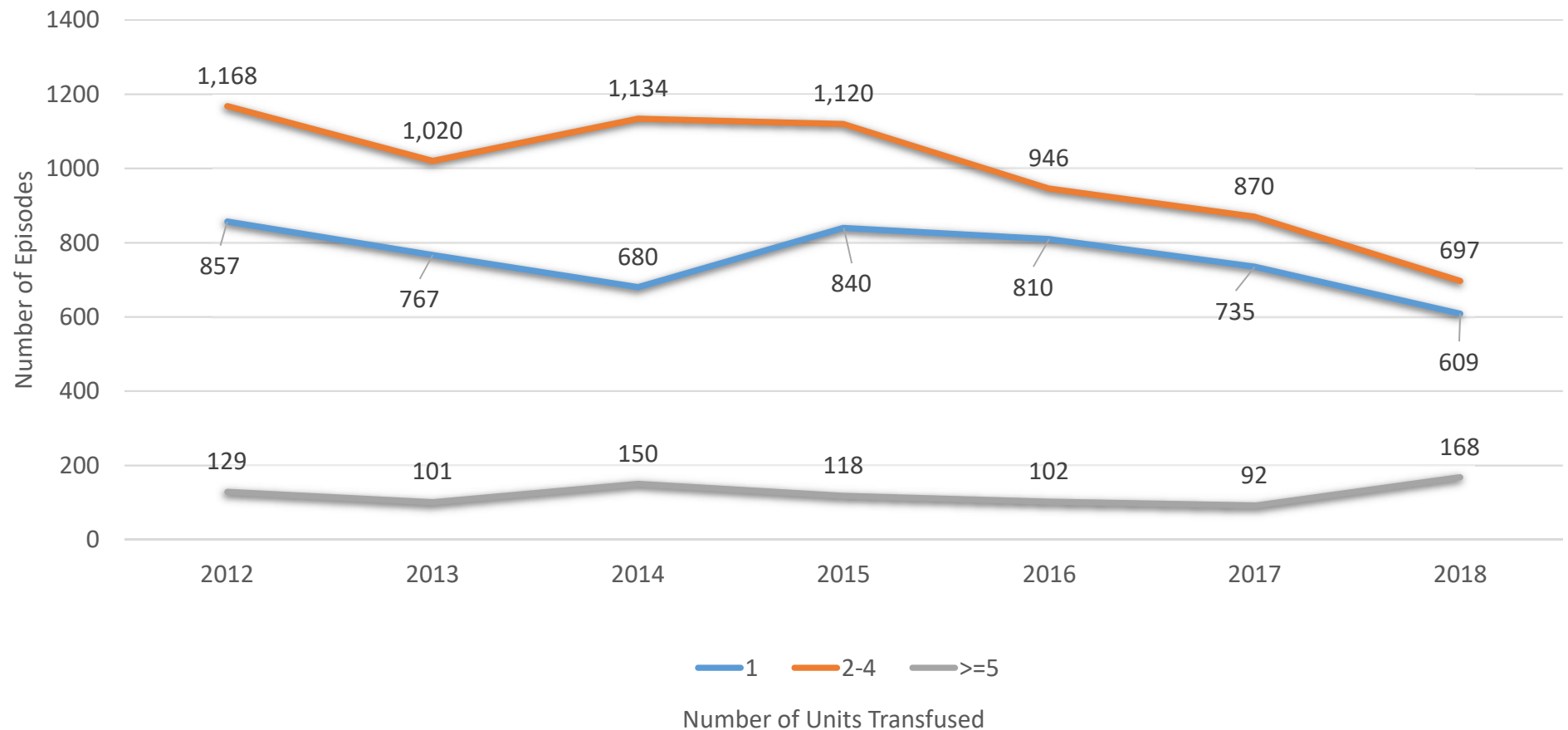
Dates of available ISBT 128 data: 1/1/2012 - 12/31/2018
Analyses conducted 7/14/2019

Figure 5: DataPartner1: Total Number of Plasma Transfusion Episodes by Number of Transfused Units for Patients with 1 Transfusion Episode per Year



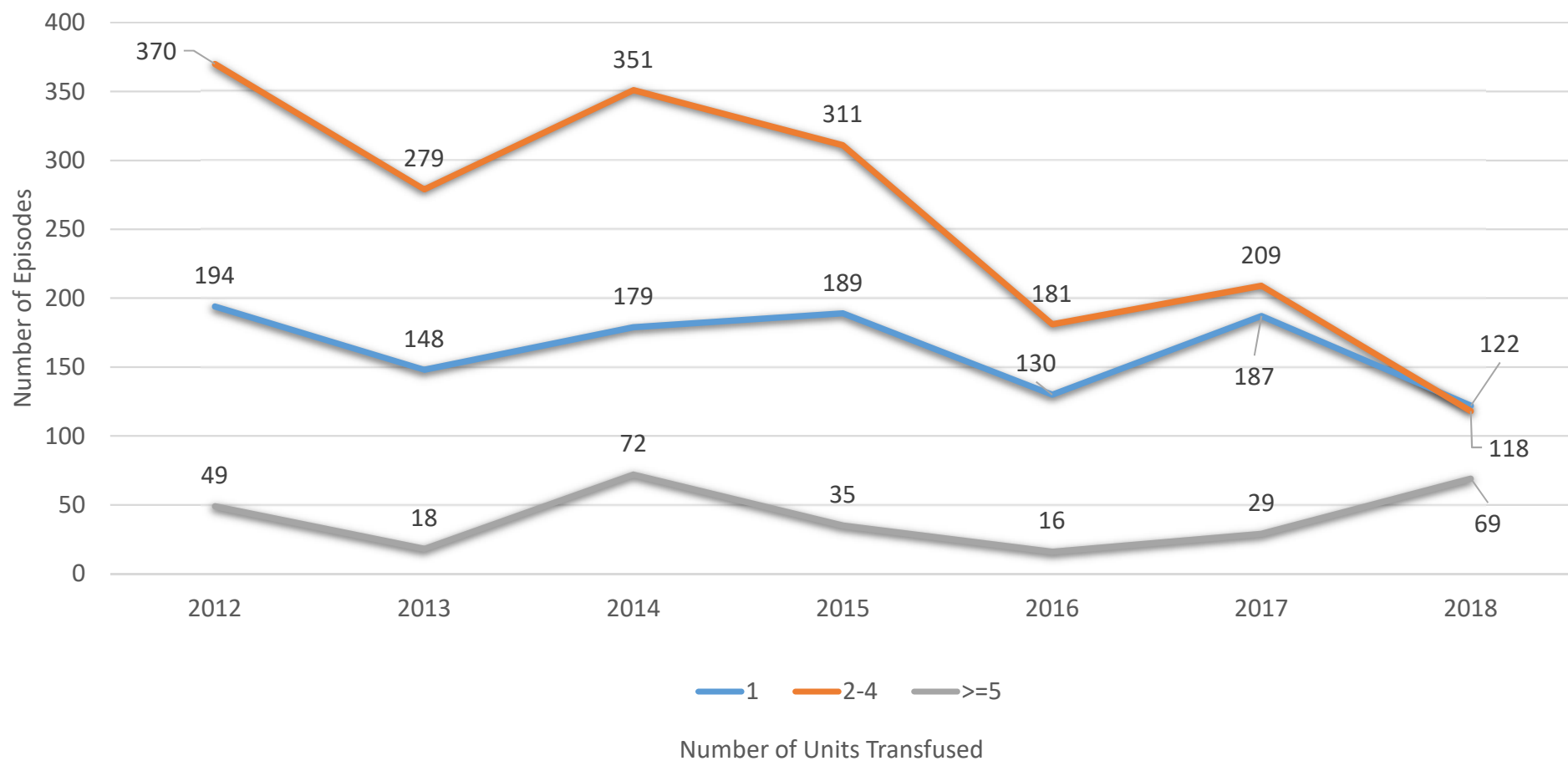
Dates of available ISBT 128 data: 1/1/2012 - 12/31/2018
Analyses conducted 7/14/2019

Figure 6: DataPartner1: Total Number of Plasma Transfusion Episodes by Number of Transfused Units for Patients with 2-5 Transfusion Episodes per Year



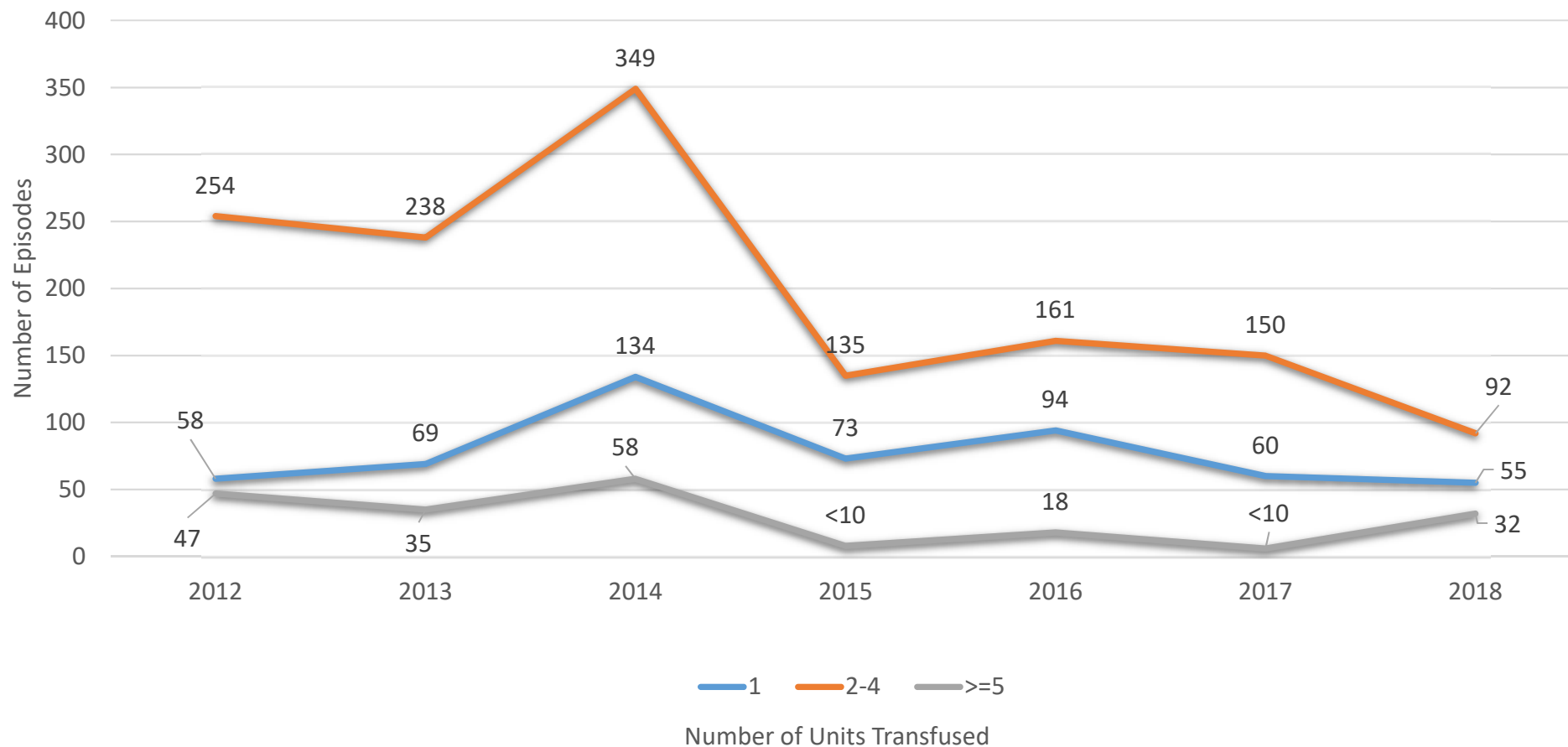
Dates of available ISBT 128 data: 1/1/2012 - 12/31/2018
Analyses conducted 7/14/2019

Figure 7: DataPartner1: Total Number of Plasma Transfusion Episodes by Number of Transfused Units for Patients with 6-11 Transfusion Episodes per Year



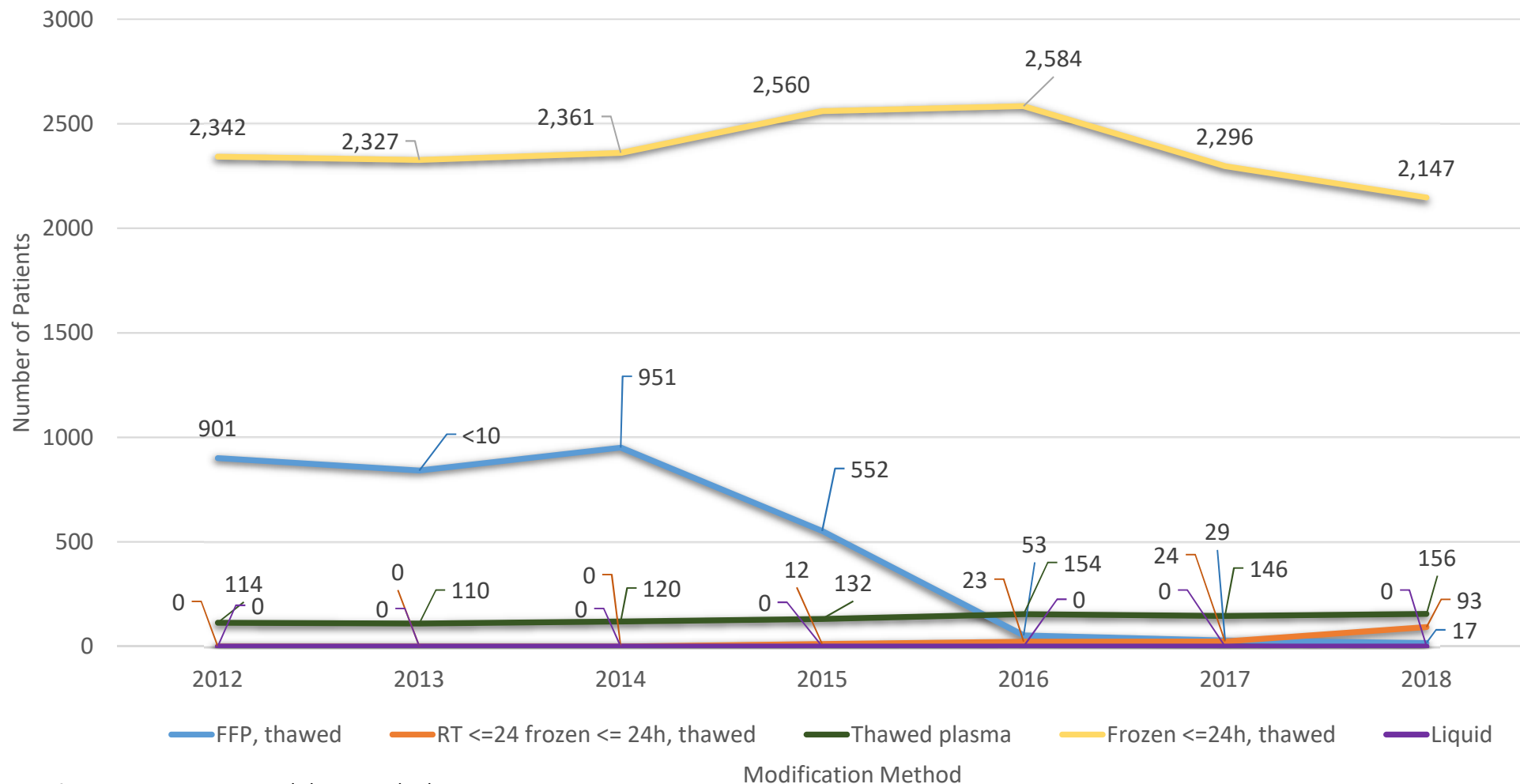
Dates of available ISBT 128 data: 1/1/2012 - 12/31/2018
Analyses conducted 7/14/2019

Figure 8: DataPartner1: Total Number of Plasma Transfusion Episodes by Number of Transfused Units for Patients with 12+ Transfusion Episodes per Year



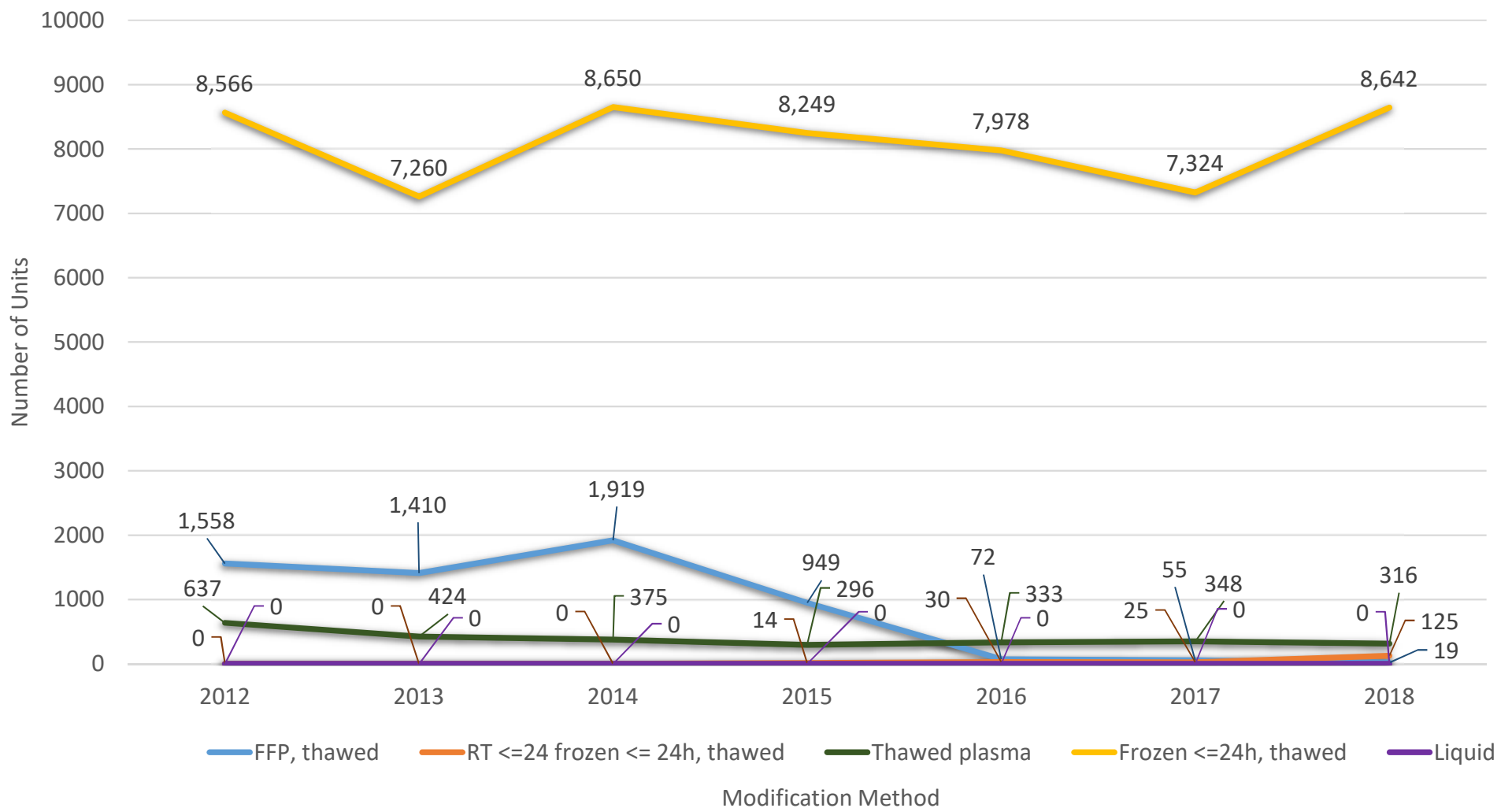
Dates of available ISBT 128 data: 1/1/2012 - 12/31/2018
Analyses conducted 7/14/2019

Figure 9: DataPartner1: 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 8/27/2019

Figure 10: DataPartner1: 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 8/27/2019

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	3
POOLED PLASMA	Thawed POOLED PLASMA CPDA-1/XX/refg Open Frozen <=24h	E5307	42671470	Frozen <=24h, thawed	3
POOLED PLASMA	Thawed POOLED PLASMA CP2D/XX/refg Open Frozen <=24h	E5308	42671471	Frozen <=24h, thawed	3
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 NaCitrate/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	3
POOLED PLASMA	Thawed POOLED PLASMA CP2D/XX/refg Open Cryo reduced	E5305	42671468	Thawed plasma	3
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

*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)

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.