Biological Product and HCT/P Deviation Reports

Annual Summary for Fiscal Year 2018

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I. Summary

FDA requires reporting of certain deviations and unexpected events in manufacturing in accordance with 21 CFR 600.14, 606.171 or 1271.350(b). The following manufacturers, who had control over the product when an event associated with manufacturing (deviation or unexpected event) occurred, are required to submit Biological Product Deviation (BPD) reports to the Center for Biologics Evaluation and Research (CBER), if the safety, purity, or potency of a distributed product may be affected:

- Manufacturers of licensed biological products other than blood and blood components (licensed non-blood) who hold the biological product license [21 CFR 600.14];
- Licensed manufacturers of blood and blood components, including Source Plasma [21 CFR 606.171];
- Unlicensed registered blood establishments [21 CFR 606.171]; and
- Transfusion services [21 CFR 606.171].

In addition, manufacturers of nonreproductive Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) regulated by FDA solely under section 361 of the Public Health Service Act and 21 CFR Part 1271 [21 CFR 1271.350(b)] are required to submit HCT/P deviation reports to CBER, if the deviation or unexpected event involving a distributed product is related to a Core Current Good Tissue Practice requirement [21 CFR 1271.150(b)] and to the prevention of communicable disease transmission or HCT/P contamination.

Detailed information concerning deviation reporting, including guidance documents on BPD reporting for blood and Source Plasma establishments (Ref. 1) and licensed manufacturers of biological products other than blood and blood components (Ref. 2), is available at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations. A guidance document for deviation reporting for 361 HCT/Ps (Ref. 3) is available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deviation-reporting-human-cells-tissues-and-cellular-and-tissue-based-products-regulated-solely.

This annual summary report provides an overview of the reports we received during the fiscal year, including detailed information regarding the number and types of deviation reports received. Each firm responsible for reporting biological product and HCT/P deviations should use this information in evaluating their own deviation management program. We provide combined data received over the last three fiscal years to compare data and highlight changes. However, based on the limited data, we may not be able to determine the reason for changes to the number of reports submitted compared to the previous fiscal year. Starting with this annual summary report, and in support of the CBER's continuous improvement efforts, we will no longer display the BPD data by BPD code.

Detailed information for blood establishments (including Source Plasma) can be found in Appendix A; detailed information for licensed non-blood establishments can be found in Appendix B; and detailed information for 361 HCT/P establishments can be found in Appendix C. Previous summary reports are available at

https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviation-reports-annual-summaries. Our system does not collect the necessary denominator data to calculate genuine rates when evaluating possible trends. Some perspective is gained by reviewing the estimated collections and transfusions made in the United States across several years. For example, in calendar year 2015, an estimated 12.6 million whole blood and red blood cells products were collected with 11.3 million transfusions.[1] In addition, there were 48.7 million Source Plasma donations in 2018.[2]

Table 1 shows the number of reports received and the number of establishments who submitted reports each fiscal year for the past three years for each type of establishment. During fiscal year 2018 (hereafter FY18), encompassing October 1, 2017, through September 30, 2018, CBER's Office of Compliance and Biologics Quality/Division of Inspections and Surveillance entered 46,967 deviation reports into CBER's database. We received more than 46,967 reports, but this summary does not capture data for reports that did not meet the reporting requirements. We notified the reporter when a report was not required. There was a 10.1% decrease in the number of reports we received in FY18 (5,264 reports) compared to FY17. However, the total number of reporting establishments increased from 2,003 in FY17 to 2,105 in FY18. Compared to FY17, there were 86 more blood and Source Plasma establishments, 13 more manufacturers of licensed biological products other than blood and blood components, and three more 361 HCT/P manufacturers reporting in FY18.

[1] Katherin D. Ellingon, et al. continued decline in blood collection and transfusion in the United States-2015. Transfusion 2017;57;1588-1598.

[2] Plasma Protein Therapeutics Association at https://www.pptaglobal.org/images/Data/Plasma_Collection/2009-2018_US_TC.pdf

Table 1 - Total Deviation Reports, FY16 – FY18

Establishment Type	Number of Reporting Establishments			Total Reports Received			*Potential* Recalls		
	FY16	FY17	FY18	FY16	FY17	FY18	FY16	FY17	FY18
Blood/Source Plasma Manufacturers									
Licensed Blood Establishments	226 (98*)	206 (87*)	215 (86*)	18,664	17,956	16,351	467	526	471
Unlicensed Blood Establishments[1]	393	381	377	3,575	3,298	3,509	23	14	8
Transfusion Services[2]	644	697	709	1,956	2,080	2,051	0	0	0
Source Plasma Establishments	506 (20*)	567 (23*)	636(22*)	26,124	28,100	24,279	96	57	124
Sub-Total	*1,769*	*1,851*	*1,937*	*50,319*	*51,434*	*46,190*	*586*	*597*	*603*
Licensed Non-Blood Manufacturers									
Allergenic	6 (6*)	7 (7*)	7 (7*)	89	73	64	4	1	3
Blood Derivative	30 (23*)	23 (19*)	28 (23*)	134	142	137	5	3	3
In Vitro Diagnostic	14 (14*)	10 (10*)	11 (11*)	144	134	105	0	3	3
Vaccine	24 (18*)	17 (15*)	22 (20*)	265	203	194	0	1	0
351 HCT/P	5 (4*)	5 (3*)	6(4*)	19	24	34	0	0	0
Sub-Total	*79 (65*)*	*62 (54*)*	*75 (65*)*	*651*	*576*	*534*	*9*	*8*	*9*
361 HCT/P Manufacturers									
Cellular HCT/P	55	48	49	134	125	150	0	0	0
Tissue HCT/P	47	42	44	125	96	93	17	26	16
Sub-Total	*102*	*90*	*93*	*259*	*221*	*243*	*17*	*26*	*16*
Total	**1,950**	**2,003**	**2,105**	**51,229**	**52,231**	**46,967**	**612**	**631**	**628**

[1]Unlicensed Blood Establishments – unlicensed blood establishments that perform manufacturing of blood and blood components are required to register with FDA.
[2]Transfusion Services – blood banks that perform limited blood and blood component manufacturing (e.g., pooling, thawing, compatibility testing), may or may not register with FDA.
*Number of license holders; one or more establishments operate under one biologics license.

Table 2 shows the number of reports received each fiscal year for the past three years for blood and Source Plasma establishments. Blood establishments submitted 98.4% of the total reports in FY18 and 5,244 fewer reports in FY18 compared to FY17. Licensed blood establishments submitted 35%, unlicensed registered blood establishments submitted 8%, transfusion services submitted 4%, and Source Plasma establishments submitted 53% of the total blood and Source Plasma reports in FY18. Compared to FY17, licensed blood establishments submitted 1,605 fewer reports, unlicensed registered blood establishments submitted 211 more reports, transfusion services 29 fewer reports, and Source Plasma establishments submitted 3,821 fewer reports in FY18.

Table 2 - Blood and Source Plasma Establishments

Licensed Blood Establishments

Manufacturing System	FY16 (#)	FY16 (%)	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)
DE-Post Donation Information	12,978	69.5%	12,792	71.2%	11,497	70.3%
Blood Collection	877	4.7%	918	5.1%	1,209	7.4%
Miscellaneous	1,370	7.3%	1,297	7.2%	1,028	6.3%
Quality Control & Distribution	1,215	6.5%	1,199	6.7%	949	5.8%
DE-Donor Screening	1,390	7.5%	860	4.8%	864	5.3%
Labeling	435	2.3%	471	2.6%	403	2.5%
LT-Routine Testing	193	1.0%	179	1.0%	201	1.2%
Component Preparation	169	0.9%	179	1.0%	164	1.0%
LT- Transfusion-Transmitted Infection Testing	13	0.1%	36	0.2%	21	0.1%
DE-Donor Deferral	24	0.1%	25	0.1%	15	0.1%
Total	**18,664**	100%	**17,956**	100%	**16,351**	100%

Unlicensed Blood Establishments

Manufacturing System	FY16 (#)	FY16 (%)	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)
Quality Control & Distribution	2,005	56.1%	1,816	55.1%	2,028	57.8%
Labeling	807	22.6%	836	25.3%	823	23.5%
LT-Routine Testing	270	7.6%	265	8.0%	296	8.4%
DE-Post Donation Information	326	9.1%	243	7.4%	220	6.3%
Component Preparation	69	1.9%	63	1.9%	88	2.5%
DE-Donor Screening	55	1.5%	36	1.1%	32	0.9%
LT- Transfusion-Transmitted Infection Testing	1	<0.1%	7	0.2%	8	0.2%
Miscellaneous	14	0.4%	8	0.2%	7	0.2%
Blood Collection	21	0.6%	22	0.7%	4	0.1%
DE-Donor Deferral	7	0.2%	2	0.1%	3	0.1%
Total	**3,575**	100%	**3,298**	100%	**3,509**	100%

Transfusion Services

Manufacturing System	FY16 (#)	FY16 (%)	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)
Quality Control & Distribution	1,147	58.6%	1,228	59.1%	1,268	61.8%
Labeling	440	22.5%	514	24.7%	447	21.8%
LT-Routine Testing	364	18.6%	333	16.0%	333	16.2%
Component Preparation	5	0.3%	5	0.2%	3	0.2%
DE-Post Donation Information	NA	NA	NA	NA	NA	NA
Miscellaneous	NA	NA	NA	NA	NA	NA
DE-Donor Screening	NA	NA	NA	NA	NA	NA
Blood Collection	NA	NA	NA	NA	NA	NA
LT- Transfusion-Transmitted Infection Testing	NA	NA	NA	NA	NA	NA
DE-Donor Deferral	NA	NA	NA	NA	NA	NA
Total	**1,956**	100%	**2,080**	100%	**2,051**	100%

Source Plasma Establishments

Manufacturing System	FY16 (#)	FY16 (%)	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)
DE-Post Donation Information	22,314	85.4%	24,230	86.2%	19,924	82.1%
Miscellaneous	2,795	10.7%	3,038	10.8%	3,343	13.8%
Quality Control & Distribution	773	3.0%	626	2.2%	643	2.6%
DE-Donor Screening	183	0.7%	174	0.6%	311	1.3%
Blood Collection	5	<0.1%	9	<0.1%	42	0.2%
DE-Donor Deferral	18	0.1%	16	0.1%	8	<0.1%
Labeling	35	0.1%	4	<0.1%	6	<0.1%
LT- Transfusion-Transmitted Infection Testing	0	0.0%	0	0.0%	2	<0.1%
LT-Routine Testing	0	0.0%	0	0.0%	0	0.0%
Component Preparation	1	<0.1%	3	<0.1%	0	0.0%
Total	**26,124**	100%	**28,100**	100%	**24,279**	100%

DE-Donor Eligibility
LT-Laboratory Testing

Table 3 shows the number of reports received each fiscal year for the past three years for licensed biological products other than blood and blood components (licensed non-blood) manufacturers. Manufacturers of licensed non-blood products submitted 1.1% of the total reports in FY18 and 42 fewer reports in FY18 compared to FY17. Allergenic manufacturers submitted 12%, blood derivative manufacturers submitted 26%, in-vitro diagnostic manufacturers submitted 20%, vaccine manufacturers submitted 36%, and licensed HCT/P manufacturers (351 HCT/Ps) submitted 6% of the total licensed non-blood reports in FY18. Compared to FY17, allergenic manufacturers submitted nine fewer reports, blood derivative manufacturers submitted five fewer reports, in-vitro diagnostic manufacturers submitted 29 fewer reports, vaccine manufacturers submitted nine fewer reports, and licensed HCT/P manufacturers (351 HCT/Ps) submitted ten more reports in FY18.

Table 3 - Licensed Non-Blood Manufacturers

Allergenic Manufacturers

Manufacturing System	FY16 (#)	FY16 (%)	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)
Product Specifications	71	79.8%	67	91.8%	54	84.4%
Quality Control & Distribution	1	1.1%	2	2.7%	4	6.2%
Labeling	11	12.4%	2	2.7%	4	6.2%
Process Controls	2	2.2%	0	0.0%	1	1.6%
Testing	4	4.5%	2	2.7%	1	1.6%
Miscellaneous	0	0.0%	0	0.0%	0	0.0%
Incoming Material	0	0.0%	0	0.0%	0	0.0%
Total	**89**	100%	**73**	100%	**64**	100%

Blood Derivatives Manufacturers

Manufacturing System	FY16 (#)	FY16 (%)	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)
Product Specifications	57	42.5%	70	49.3%	49	35.8%
Quality Control & Distribution	18	13.4%	10	7.0%	23	16.8%
Labeling	11	8.2%	16	11.3%	23	16.8%
Process Controls	18	13.4%	21	14.8%	18	13.1%
Incoming Material	15	11.2%	1	0.7%	14	10.2%
Testing	13	9.7%	13	9.2%	7	5.1%
Miscellaneous	2	1.5%	11	7.7%	3	2.2%
Total	**134**	100%	**142**	100%	**137**	100%

In-Vitro Diagnostic Manufacturers

Manufacturing System	FY16 (#)	FY16 (%)	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)
Product Specifications	97	67.3%	88	65.7%	69	65.7%
Quality Control & Distribution	29	20.1%	26	19.4%	18	17.1%
Labeling	4	2.8%	11	8.2%	15	14.3%
Process Controls	4	2.8%	3	2.2%	2	1.9%
Miscellaneous	1	0.7%	0	0.0%	1	1.0%
Testing	6	4.2%	5	3.7%	0	0.0%
Incoming Material	3	2.1%	1	0.8%	0	0.0%
Total	**144**	100%	**134**	100%	**105**	100%

Vaccine Manufacturers

Manufacturing System	FY16 (#)	FY16 (%)	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)
Product Specifications	103	38.9%	71	35.0%	63	32.5%
Quality Control & Distribution	46	17.4%	41	20.2%	44	22.7%
Miscellaneous	25	9.4%	4	2.0%	29	14.9%
Process Controls	40	15.1%	20	9.8%	24	12.4%
Testing	21	7.9%	24	11.8%	23	11.9%
Labeling	17	6.4%	17	8.4%	7	3.6%
Incoming Material	13	4.9%	26	12.8%	4	2.0%
Total	**265**	100%	**203**	100%	**194**	100%

351 HCT/P Manufacturers

Manufacturing System	FY16 (#)	FY16 (%)	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)
Labeling	14	73.7%	12	50.0%	15	44.1%
Product Specifications	2	10.5%	8	33.3%	10	29.4%
Quality Control & Distribution	0	0.0%	0	0.0%	3	8.8%
Testing	3	15.8%	1	4.2%	3	8.8%
Incoming Material	0	0.0%	0	0.0%	2	5.9%
Process Controls	0	0.0%	1	4.2%	1	2.9%
Miscellaneous	0	0.0%	2	8.3%	0	0.0%
Total	**19**	100%	**24**	100%	**34**	100%

Table 4 shows the number of reports received each fiscal year for the past three years for 361 HCT/P manufacturers. Manufacturers of 361 HCT/Ps submitted 0.5% of the total reports in FY18 and 22 more reports in FY18 compared to FY17. Manufacturers of cellular HCT/Ps (e.g., hematopoietic stem/progenitor cells) submitted 62% and manufacturers of tissue HCT/Ps (e.g., skin, musculoskeletal, cornea) submitted 38% of the total HCT/P deviation reports in FY18. Compared to FY17, manufacturers of cellular HCT/Ps submitted 25 more reports and manufacturers of tissue HCT/Ps submitted three fewer reports in FY18.

Table 4 – 361 HCT/P Manufacturers

Cellular 361 HCT/P Manufacturers

Manufacturing System	FY16 (#)	FY16 (%)	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)
Receipt, Pre-Distribution, Shipment & Distribution	37	27.6%	86	68.8%	118	78.7%
Processing & Processing Controls	75	56.0%	26	20.8%	15	10.0%
Donor Screening	7	5.2%	0	0.0%	12	8.0%
Donor Testing	1	0.8%	3	2.4%	2	1.3%
Supplies and Reagents	5	3.7%	8	6.4%	2	1.3%
Donor Eligibility	0	0.0%	1	0.8%	1	0.7%
Equipment	0	0.0%	0	0.0%	0	0.0%
Storage	2	1.5%	0	0.0%	0	0.0%
Labeling Controls	0	0.0%	0	0.0%	0	0.0%
Environmental Control	0	0.0%	1	0.8%	0	0.0%
Recovery	7	5.2%	0	0.0%	0	0.0%
Total	**134**	100%	**125**	100%	**150**	100%

Tissue 361 HCT/Ps Manufacturers

Manufacturing System	FY16 (#)	FY16 (%)	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)
Donor Eligibility	53	42.4%	28	29.2%	33	35.5%
Receipt, Pre-Distribution, Shipment & Distribution	22	17.6%	31	32.3%	22	23.7%
Donor Testing	16	12.8%	12	12.5%	11	11.8%
Recovery	3	2.4%	3	3.1%	8	8.6%
Processing & Processing Controls	13	10.4%	3	3.1%	6	6.5%
Donor Screening	13	10.4%	11	11.5%	6	6.5%
Equipment	1	0.8%	0	0.0%	3	3.2%
Storage	1	0.8%	1	1.0%	2	2.2%
Supplies and Reagents	3	2.4%	4	4.2%	1	1.0%
Labeling Controls	0	0.0%	3	3.1%	1	1.0%
Environmental Control	0	0.0%	0	0.0%	0	0.0%
Total	**125**	100%	**96**	100%	**93**	100%

In FY18 there were no changes to the Non-Blood BPD Codes or HCT/P Deviation Codes. We modified some of the Blood BPD Codes to clarify reportable events, which contributed to the decrease in the number of reports submitted by blood and Source Plasma establishments. We modified events related to distributed products:

- Collected from a donor who received a tissue allograft or transplanted organ, to limit reporting to a donor receiving a xenotransplantation product as defined in the January 19, 2001 document "PHS Guideline on Infectious Disease Issues in Xenotransplantation",
- Collected from a donor who received medication, to limit reporting to a donor receiving antibiotics, platelet inhibitor drugs or drugs with a teratogenic effect, and
- With a positive bacterial detection test in which an organism was not identified, i.e. false positive.

You may submit questions concerning this summary to:

U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

You may also contact us by email at bp_deviations@fda.hhs.gov, hctp_deviations@fda.hhs.gov, or sharon.ocallaghan@fda.hhs.gov (Sharon O'Callaghan).

II. References

1. Guidance for Industry - Biological Product Deviation Reporting for Blood and Plasma Establishments 10/18/2006 https://www.fda.gov/media/70694/download
2. Guidance for Industry - Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components 10/18/2006 https://www.fda.gov/media/76309/download
3. Guidance for Industry - Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR Part 1271 9/2017 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deviation-reporting-human-cells-tissues-and-cellular-and-tissue-based-products-regulated-solely

III. Appendices

1. BPD Reports Submitted by Blood and Source Plasma Establishments
2. BPD Reports Submitted by Licensed Non-Blood Manufacturers
3. HCT/P Reports Submitted 361 HCT/P Manufacturers

Appendix 1. BPD Reports Submitted by Blood and Source Plasma Establishments

Tables 5 through 20 highlight the most frequent reports submitted in FY18 by each type of blood and Source Plasma establishment compared to reports submitted in FY17. Not all reports submitted are represented in these tables and therefore the numbers of reports listed do not add up to the total reports received listed in the table.

1. Most Frequent BPD Reports Submitted by Licensed Blood Establishments[3]

Of the 16,351 reports submitted by licensed blood establishments in FY18 (Table 2), 11,497 reports (70.3%) involved **post donation information** (Table 5). The number of these reports decreased 10% compared to FY17, which was a decrease of 1,295 reports.

Table 5 - Most Frequent BPD Reports - Post Donation Information From Licensed Blood Establishments

Post Donation Information (PD)	FY17 (#)	FY17 (% of PD)	FY18 (#)	FY18 (% of PD)
Total PD Reports Received	**12,792**	**-**	**11,497**	**-**
Behavior/History	***11,779***	***92.1%***	***10,537***	***91.6%***
Travel to or residence in a malaria endemic area/history of malaria	4,052	31.7%	3,926	34.1%
Risk factors associated with Creutzfeldt-Jakob Disease (CJD) – travel	2,111	16.5%	2,042	17.8%
Donor received tattoo and/or piercing	1,195	9.3%	1,420	12.4%
Received finasteride, etretinate, isotretinoin, dutasteride	877	6.9%	735	6.4%
IV drug use not prescribed by a doctor	304	2.4%	318	2.8%
Male donor had sex with another man	421	3.3%	297	2.6%
Illness	***891***	***7.0%***	***829***	***7.2%***
Post donation illness (not hepatitis, HIV, HTLV-I, STD, cancer or cold/flu related)	817	6.4%	756	6.6%
Fever/diarrhea	427	3.3%	449	3.9%
Infection	251	2.0%	184	1.6%
Testing *	***92***	***0.7%***	***105***	***0.9%***
Tested reactive for HIV prior to donation	33	0.3%	46	0.4%
Tested reactive for Hepatitis C prior to donation	17	0.1%	23	0.2%
Tested reactive for Hepatitis B prior to donation	18	0.1%	14	0.1%
Tested reactive for HTLV prior to donation	0	0.0%	14	0.1%
Not specifically related to high risk behavior	***30***	***0.2%***	***26***	***0.2%***

*Includes testing positive for viral marker prior to donation at another location

[3] Licensed blood establishments do not include Source Plasma establishments, for the purpose of this summary.

Of the 16,351 reports submitted by licensed blood establishments in FY18 (Table 2), 1,209 reports (7.4%) involved **blood collection** deviations or unexpected events (Table 6)**.** The number of these reports increased 32% compared to FY17, which is an increase of 291 reports.

Table 6 - Most Frequent BPD Reports – Blood Collection From Licensed Blood Establishments

Blood Collection (BC)	**FY17 (#)**	**FY17 (% of BC)**	**FY18 (#)**	**FY18 (% of BC)**
Total BC Reports Received	**918**	**-**	**1,209**	**-**
Collection process	***821***	***89.4%***	***1,090***	***90.2%***
Product contained clots or fibrin, not discovered prior to distribution	790	86.1%	1,058	87.5%
Product hemolyzed, not discovered prior to distribution	12	1.3%	19	1.6%
Sterility compromised	***90***	***9.8%***	***104***	***8.6%***
Bacterial contamination	69	7.5%	83	6.9%
Arm prep not performed or performed inappropriately	13	1.4%	16	1.3%

Of the 16,351 reports submitted by licensed blood establishments in FY18 (Table 2), 1,028 reports (6.3%) involved **miscellaneous** deviations or unexpected events (Table 7)**.** The number of these reports decreased 21% compared to FY17, which is a decrease of 269 reports.

Table 7 - Most Frequent BPD Reports – Miscellaneous From Licensed Blood Establishments

MISCELLANEOUS (MI)	**FY17 (#)**	**FY17 (% of MI)**	**FY18 (#)**	**FY18 (% of MI)**
Total MI Reports Received	**1,297**	**-**	**1,028**	**-**
Lookback; subsequent unit tested confirmed positive for:	***1,270***	***97.9%***	***1,011***	***98.3%***
HCV	316	24.4%	310	25.6%
Babesia	484	37.3%	208	17.2%
HBV	172	13.3%	148	12.2%
Anti-HBc positive	95	7.3%	64	5.3%
Zika Virus	92	7.1%	119	9.8%
West Nile Virus	64	4.9%	104	8.6%
HIV	135	10.4%	96	9.3%
Donor implicated in transfusion associated disease	***27***	***2.1%***	***17***	***1.4%***
Babesia	17	1.3%	13	1.3%

Of the 16,351 reports submitted by licensed blood establishments in FY18 (Table 2), 949 reports (5.8%) involved **quality control and distribution** deviations or unexpected events (Table 8). The number of these reports decreased 21% compared to FY17, which is a decrease of 250 reports. There were 141 fewer reports submitted in FY18 compared to FY17 involving bacterial detection testing. In FY18, a report was not required if no organism was identified (e.g., false positive).

Table 8 - Most Frequent BPD Reports - Quality Control & Distribution From Licensed Blood Establishments

QC & Distribution (QC)	FY17 (#)	FY17 (% of QC)	FY18 (#)	FY18 (% of QC)
Total QC Reports Received	**1,199**	**-**	**949**	**-**
Distribution of product that did not meet specifications	***514***	***42.9%***	***453***	***47.7%***
Product QC unacceptable, not performed, not documented, or incomplete	297	24.8%	280	29.5%
White Blood Cell count	100	8.3%	90	9.5%
Platelet count	83	6.9%	52	5.5%
Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or documented	44	3.7%	39	4.1%
Product in which specification other than QC was not met	16	1.3%	36	3.8%
Product identified as unsuitable due to a collection deviation or unexpected event	39	3.3%	32	3.4%
Product identified as unsuitable due to a donor screening deviation or unexpected event	27	2.3%	15	1.6%
Shipping and storage	***167***	***13.9%***	***165***	***17.4%***
Product not packaged in accordance with specifications or no documentation that product was packed appropriately	53	4.4%	48	5.1%
Product arrived at consignee at unacceptable temperature	32	2.7%	40	4.2%
Shipment exceeded time allowed for shipping	18	1.5%	32	3.4%
Positive testing	***327***	***27.3%***	***124***	***13.1%***
Bacterial detection testing	244	20.4%	103	10.9%

Of the 16,351 reports submitted by licensed blood establishments in FY18 (Table 2), 864 reports (5.3%) involved **donor screening** deviations or unexpected events (Table 9). There were four more reports submitted in FY18 compared to FY17 involving donor screening.

Table 9 - Most Frequent BPD Reports - Donor Screening From Licensed Blood Establishments

Donor Screening (DS)	**FY17 (#)**	**FY17 (% of DS)**	**FY18 (#)**	**FY18 (% of DS)**
Total DS Reports Received	**860**	**-**	**864**	**-**
Deferral screening not done or incorrectly performed, including incorrect ID used during search	***458***	***53.3%***	***491***	***56.8%***
Donor not previously deferred	337	39.2%	374	43.3%
Donor previously deferred due to history	60	7.0%	71	8.2%
Donor previously deferred due to testing	61	7.1%	46	5.3%
Donor record incomplete or incorrect	***226***	***26.3%***	***221***	***25.6%***
Donor history questions	205	23.8%	204	23.6%
Incorrect gender specific question asked or incorrect answer	160	18.6%	178	20.6%
Donor gave history which warranted deferral or follow up and was not deferred	***149***	***17.3%***	***124***	***14.4%***
Travel to malaria endemic area/history of malaria	72	8.4%	72	8.3%
Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) - travel	42	4.9%	32	3.7%
Donor did not meet acceptance criteria	***25***	***2.9%***	***26***	***3.0%***

2. Most Frequent BPD Reports Submitted by Unlicensed Registered Blood Establishments

Of the 3,509 reports submitted by unlicensed registered blood establishments in FY18 (Table 2), 2,028 reports (57.8%) involved **quality control and distribution** deviations or unexpected events (Table 10)**.** The number of these reports increased 12% compared to FY17, which is an increase of 212 reports.

Table 10 - Most Frequent BPD Reports - Quality Control & Distribution From Unlicensed Registered Blood Establishments

QC & Distribution (QC)	FY17 (#)	FY17 (% of QC)	FY18 (#)	FY18 (% of QC)
Total QC Reports Received	**1,816**	**-**	**2,028**	**-**
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***1,442***	***79.4%***	***1,611***	***79.4%***
Product not documented or incorrectly documented as issued in the computer	645	35.5%	758	37.4%
Improper product selected for patient	174	9.6%	212	10.5%
Product not irradiated as required	180	9.9%	193	9.5%
Improper ABO or Rh type selected for patient	142	7.8%	132	6.5%
Procedure for issuing not performed or documented in accordance with specifications	87	4.8%	108	5.3%
Product issued to wrong patient	64	3.5%	58	2.9%
Testing not performed, incompletely performed, or not documented	***214***	***11.8%***	***215***	***10.6%***
Antigen screen	39	2.1%	54	2.7%
Antibody screen or identification	57	3.1%	43	2.1%
ABO and/or Rh	32	1.8%	31	1.5%
Compatibility	23	1.3%	31	1.5%
Bacterial testing	32	1.8%	29	1.4%
Distribution of product that did not meet specifications	***113***	***6.2%***	***141***	***7.0%***
Product in which specification other than QC not met	25	1.4%	42	2.1%
Outdated product	21	1.2%	33	1.6%
Product QC unacceptable, not performed, not documented or incomplete	18	1.0%	28	1.4%
Product in which instrument QC, calibration, or validation unacceptable, incomplete or not documented	32	1.8%	25	1.2%
Shipping and storage	***40***	***2.2%***	***48***	***2.4%***

Of the 3,509 reports submitted by unlicensed registered blood establishments in FY18 (Table 2), 823 reports (23.5%) involved **labeling** deviations or unexpected events (Table 11). There were 13 fewer reports submitted in FY18 compared to FY17 involving labeling.

Table 11 - Most Frequent BPD Reports – Labeling From Unlicensed Registered Blood Establishments

Labeling (LA)	FY17 (#)	FY17 (% of LA)	FY18 (#)	FY18 (% of LA)
Total LA Reports Received	**836**	**-**	**823**	**-**
Crossmatch tag, tie tag, to transfusion record incorrect or missing information	***579***	***69.3%***	***556***	***67.6%***
Crossmatch tags or transfused records switched, both units intended for the same patient	155	18.5%	156	19.0%
Recipient identification incorrect or missing	161	19.3%	141	17.1%
Crossmatch tag, tie tag, or transfusion record incorrect or missing or attached to incorrect unit	57	6.8%	68	8.3%
Expiration date or time extended or missing	37	4.4%	38	4.6%
Product type or code incorrect or missing	30	3.6%	35	4.3%
Unit, lot, or pool number incorrect or missing	39	4.7%	21	2.6%
Labels applied to blood unit or product incorrect or missing information	***257***	***30.7%***	***267***	***32.4%***
Extended or missing expiration date or time	91	10.9%	114	13.9%
Irradiation status incorrect or missing	35	4.2%	45	5.5%
Product type or code incorrect or missing	46	5.5%	33	4.0%
Product or anticoagulant volume or weight incorrect or missing	14	1.7%	31	3.8%
Combination of incorrect or missing information	16	1.9%	16	1.9%
Donor/unit number or lot number incorrect or missing	12	1.5%	10	1.2%
Zika virus test status incorrect or missing	30	3.6%	1	0.1%

Of the 3,509 reports submitted by unlicensed registered blood establishments in FY18 (Table 2), 296 reports (8.4%) involved **routine testing** deviations or unexpected events (Table 12). The number of these reports decreased 12% compared to FY17, which was a decrease of 31 reports.

Table 12 - Most Frequent BPD Reports - Routine Testing From Unlicensed Registered Blood Establishments

Routine Testing (RT)	FY17 (#)	FY17 (% of RT)	FY18 (#)	FY18 (% of RT)
Total RT Reports Received	**265**	**-**	**296**	**-**
Testing performed, interpreted, or documented incorrectly	***149***	***56.2%***	***176***	***59.5%***
Compatibility	63	23.8%	71	24.0%
Antibody screening or identification	40	15.1%	38	12.8%
ABO and/or Rh	23	8.7%	36	12.2%
Antigen typing	15	5.7%	19	6.4%
Reagent QC unacceptable or expired reagents used	***65***	***24.5%***	***66***	***22.3%***
Antigen typing	20	7.5%	23	7.8%
Antibody screening or identification	12	4.5%	16	5.4%
ABO and/or Rh	19	7.2%	14	4.7%
Sample (used for testing) identification	***51***	***19.2%***	***54***	***18.2%***
Sample used for testing was incorrectly or incompletely labeled	36	13.6%	29	9.8%
Unsuitable sample used for testing (e.g., too old)	8	3.0%	13	4.4%
Incorrect sample tested	7	2.6%	12	4.1%

Of the 3,509 reports submitted by unlicensed registered blood establishments in FY18 (Table 2), 220 reports (6.3%) involved **post donation information** (Table 13)**.** The number of these reports decreased 10% compared to FY17, which is a decrease of 23 reports.

Table 13 - Most Frequent BPD Reports - Post Donation Information From Unlicensed Registered Blood Establishments

Post Donation Information (PD)	FY17 (#)	FY17 (% of PD)	FY18 (#)	FY18 (% of PD)
Total PD Reports Received	**243**	**-**	**220**	**-**
Behavior/History	***236***	***97.1%***	***206***	***93.6%***
Travel to malaria endemic area/history of malaria	80	32.9%	65	29.5%
Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) – travel	46	18.9%	44	20.0%
History of disease	18	7.4%	23	10.5%
Donor received tattoo and/or piercing	14	5.8%	14	6.4%
Received finasteride, etretinate, isotretinoin, dutasteride	19	7.8%	7	3.2%

3. Most Frequent BPD Reports Submitted by Transfusion Services

Of the 2,051 reports submitted by transfusion services in FY18 (Table 2), 1,268 reports (61.8%) involved **quality control and distribution** deviations or unexpected events (Table 14). There were 40 more reports submitted in FY18 compared to FY17 involving quality control and distribution.

Table 14 - Most Frequent BPD Reports - Quality Control & Distribution From Transfusion Services

QC & Distribution (QC)	FY17 (#)	FY17 (% of QC)	FY18 (#)	FY18 (% of QC)
Total QC Reports Received	**1,228**	**-**	**1,268**	**-**
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***929***	***75.7%***	***934***	***73.7%***
Product not documented or incorrectly documented as issued in the computer	409	33.3%	396	31.2%
Product not irradiated as required	128	10.4%	127	10.0%
Procedure for issuing not performed or documented in accordance with specifications	98	8.0%	105	8.3%
Improper product selected for patient	85	6.9%	95	7.5%
Improper ABO or Rh type selected for patient	71	5.8%	70	5.5%
Testing not performed, incompletely performed, or not documented	***198***	***16.1%***	***222***	***17.5%***
Antigen screen	56	4.6%	67	5.3%
ABO and/or Rh	54	4.4%	56	4.4%
Compatibility	35	2.9%	41	3.2%
Antibody screen or identification	39	3.2%	35	2.8%
Distribution of product that did not meet specifications	***61***	***5.0%***	***62***	***4.9%***
Outdated product	27	2.2%	26	2.1%
Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or not documented	12	1.0%	20	1.6%
Shipping and storage	***36***	***2.9%***	***46***	***3.6%***

Of the 2,051 reports submitted by transfusion services in FY18 (Table 2), 447 reports (21.8%) involved **labeling** deviations or unexpected events (Table 15). The number of these reports decreased 15% compared to FY17, which was a decrease of 67 reports.

Table 15 - Most Frequent BPD Reports - Labeling From Transfusion Services

Labeling (LA)	FY17 (#)	FY17 (% of LA)	FY18 (#)	FY18 (% of LA)
Total LA Reports Received	**514**	**-**	**447**	**-**
Crossmatch tag, tie tag or transfusion record incorrect or missing information	***438***	***85.2%***	***388***	***86.8%***
Recipient identification incorrect or missing	125	24.3%	107	23.9%
Crossmatch tags or transfused records switched, both units intended for the same patient	98	19.1%	99	22.1%
Crossmatch tag or tie tag missing or attached to incorrect unit	54	10.5%	47	10.5%
Unit, lot, or pool number incorrect or missing	33	6.4%	33	7.4%
Product type or code incorrect or missing	26	5.1%	31	6.9%
Expiration date or time extended or missing	21	4.1%	19	4.3%
Labels applied to blood unit or product incorrect or missing information	***76***	***14.8%***	***59***	***13.2%***
Extended or missing expiration date or time	30	5.8%	18	4.0%
Product type/code and expiration date incorrect or missing	16	3.1%	18	4.0%
Combination of incorrect or missing information	14	2.7%	6	1.3%

Of the 2,051 reports submitted by transfusion services in FY18 (Table 2), 333 reports (16.2%) involved **routine testing** deviations or unexpected events (Table 16). The number of these reports was the same compared to FY17.

Table 16 - Most Frequent BPD Reports - Routine Testing From Transfusion Services

Routine Testing (RT)	FY17 (#)	FY17 (% of RT)	FY18 (#)	FY18 (% of RT)
Total RT Reports Received	**333**	**-**	**333**	**-**
Testing performed, interpreted, or documented incorrectly	***209***	***62.8%***	***193***	***58.0%***
Compatibility	97	29.1%	84	25.2%
Antibody screening or identification	55	16.5%	48	14.4%
ABO and/or Rh typing	23	6.9%	24	7.2%
Antigen typing	20	6.0%	24	7.2%
Reagent QC unacceptable or expired reagents used	***70***	***21.0%***	***76***	***22.8%***
Antibody screening or identification	11	3.3%	25	7.5%
Antigen typing	21	6.3%	17	5.1%
Multiple testing	19	5.7%	15	4.5%
ABO and/or Rh typing	13	3.9%	13	3.9%
Sample (used for testing) identification	***54***	***16.2%***	***64***	***19.2%***
Sample used for testing was incorrectly or incompletely labeled	40	12.0%	44	13.2%
Incorrect sample tested	2	0.6%	11	3.3%
Unsuitable sample used for testing	11	3.3%	9	2.7%

4. Most Frequent BPD Reports Submitted by Source Plasma Establishments

Of the 24,279 reports submitted by Source Plasma establishments in FY18 (Table 2), 19,924 reports (82.1%) involved **post donation information** (Table 17)**.** The number of these reports decreased 18% compared to FY17, which was a decrease of 4,306 reports.

Table 17 - Most Frequent BPD Reports - Post Donation Information From Source Plasma Establishments

Post Donation Information (PD)	FY17 (#)	FY17 (% of PD)	FY18 (#)	FY18 (% of PD)
Total PD Reports Received	**24,230**	**-**	**19,924**	**-**
Behavior/History	***22,174***	***91.5%***	***17,275***	***71.3%***
Donor received tattoo and/or piercing	15,997	66.0%	12,838	53.0%
Donor deferred by another center – reason unknown	901	3.7%	891	3.7%
Incarcerated	859	3.5%	864	3.6%
Intimate contact with risk for a relevant transfusion-transmitted infection - HCV	802	3.3%	749	3.1%
Other (unacceptable address; donor comprehension questionable)	600	2.5%	623	2.6%
IV drug use	527	2.2%	599	2.5%
Male donor had sex with another man	251	1.0%	304	1.3%
Testing*	***1,941***	***8.0%***	***1,942***	***8.0%***
Tested reactive at another center, specific testing unknown	1,935	8.0%	1,930	8.0%
Illness	***72***	***0.3%***	***71***	***0.3%***

*Includes testing positive for viral marker prior to donation at another location

Of the 24,279 reports submitted by Source Plasma establishments in FY18 (Table 2), 3,343 reports (13.8%) involved **miscellaneous** deviations or unexpected events (Table 18). The number of these reports increased 10% compared to FY17, which was an increase of 304 reports.

Table 18 - Most Frequent BPD Reports – Miscellaneous From Source Plasma Establishments

Miscellaneous (MI)	FY17 (#)	FY17 (% of MI)	FY18 (#)	FY18 (% of MI)
Total MI Reports Received	**3,039**	**-**	**3,343**	**-**
Lookback; subsequent unit tested confirmed positive for:	***3,038***	***100.0%***	***3,343***	***100.0%***
HCV	1,946	64.0%	1,892	***56.6%***
HBV	641	21.1%	979	***29.3%***
HIV	447	14.7%	463	***13.8%***

Of the 24,279 reports submitted by Source Plasma establishments in FY18 (Table 2), 643 reports (2.6%) involved **quality control and distribution** deviations or unexpected events (Table 19)**.** There were 17 more reports submitted in FY18 compared to FY17 involving quality control and distribution.

Table 19 - Most Frequent BPD Reports - Quality Control & Distribution From Source Plasma Establishments

QC & Distribution (QC)	FY17 (#)	FY17 (% of RT)	FY18 (#)	FY18 (% of RT)
Total QC Reports Received	**626**	**-**	**643**	**-**
Positive testing for	***522***	***83.4%***	***431***	***67.0%***
Antibody screen or identification	521	83.2%	429	66.7%
Distribution of product that did not meet specifications	***19***	***3.0%***	***95***	***14.8%***
Product identified as unsuitable due to a viral testing deviation or unexpected event	9	1.4%	62	9.6%
Product identified as unsuitable due to a collection deviation or unexpected event	2	0.3%	17	2.6%
Testing not performed, incompletely performed or not documented for	***31***	***5.0%***	***66***	***10.3%***
Syphilis	17	2.7%	41	6.4%
Antibody screen or identification	0	0.0%	25	3.9%
Failure to quarantine unit due to medical history	***52***	***8.3%***	***50***	***7.8%***
Post Donation Illness	37	5.9%	33	5.1%

Of the 24,279 reports submitted by Source Plasma establishments in FY18 (Table 2), 311 reports (1.3%) involved **donor screening** deviations or unexpected events (Table 20). The number of these reports increased 78% compared to FY17, which was an increase of 137 reports.

Table 20 - Most Frequent BPD Reports - Donor Screening From Source Plasma Establishments

Donor Screening (DS)	FY17 (#)	FY17 (% of RT)	FY18 (#)	FY18 (% of RT)
Total DS Reports Received	**174**	**-**	**311**	**-**
Donor record incomplete or incorrect	***78***	***44.8%***	***167***	***53.7%***
Donor history questions	33	19.0%	121	38.9%
Donor identification	41	23.6%	45	14.5%
Deferral screening not done or incorrectly performed, including incorrect ID used during search	***32***	***18.4%***	***120***	***38.6%***
Donor not previously deferred	27	15.5%	73	23.5%
Donor previously deferred due to history	5	2.9%	47	15.1%
Donor did not meet acceptance criteria	***45***	***25.9%***	***12***	***3.9%***
Medical review or physical not performed or inadequate	38	21.8%	8	4.6%
Donor gave history which warranted deferral or follow up and was not deferred	***18***	***10.3%***	***12***	***3.9%***
Donor received tattoo and/or piercing	3	1.7%	10	3.2%

Appendix 2. BPD Reports Submitted by Licensed Manufacturers of Biological Products Other Than Blood and Blood Components (Licensed Non-Blood)

Tables 21 through 25 highlight the most frequent reports submitted in FY18 by each type of licensed non-blood manufacturer compared to reports submitted in FY17. Not all reports submitted are represented in these tables and therefore the numbers of reports listed do not add up to the total reports received listed in the table.

Of the 64 reports submitted by allergenic manufacturers in FY18 (Table 3), 84% of the reports were related to product specification (Table 21).

Table 21 - Most Frequent BPD Reports Submitted by Allergenic Manufacturers

Allergenic Manufacturers	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)
Total Reports Received	**73**	**-**	**64**	**-**
Product Specifications	***67***	***91.8%***	***54***	***84.4%***
Product specification not met; contains precipitate	64	87.7%	51	79.7%

Of the 137 reports submitted by blood derivative manufacturers in FY18 (Table 3), 36% of the reports were related to product specification (Table 22).

Table 22 - Most Frequent BPD Reports Submitted by Blood Derivative Manufacturers

Blood Derivative Manufacturers	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)
Total Reports Received	**142**	**-**	**137**	**-**
Product Specifications	***70***	***49.3%***	***49***	***35.8%***
Stability testing failed	33	23.2%	30	21.9%
Potency	21	14.8%	21	15.3%

Of the 105 reports submitted by in-vitro diagnostic manufacturers in FY18 (Table 3), 66% of the reports were related to product specification (Table 23).

Table 23 - Most Frequent BPD Reports Submitted by In-Vitro Diagnostic Manufacturers

In-Vitro Diagnostic Manufacturers	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)
Total Reports	**134**	**-**	**105**	**-**
Product Specifications	***88***	***65.7%***	***69***	***65.7%***
Product specification not met; Unexpected positive, negative, or weak reactions in testing	58	43.3%	41	39.0%

Of the 194 reports submitted by vaccine manufacturers in FY18 (Table 3), 33% of the reports were related to product specifications (Table 24).

Table 24 - Most Frequent BPD Reports Submitted by Vaccine Manufacturers

Vaccine Manufacturers	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)
Total Reports	**203**	**-**	**194**	**-**
Product Specifications	***71***	***35.0%***	***63***	***32.5%***
Product specification not met; appearance	29	14.3%	32	16.5%
Stability testing failed	18	8.9%	17	8.8%

Of the 34 reports submitted by licensed HCT/P manufacturers in FY18 (Table 3), 44% of the reports were related to labeling and 29% of the reports were related to product specifications (Table 25).

Table 25 - Most Frequent BPD Reports Submitted by Licensed HCT/P Manufacturers

Licensed HCT/P Manufacturers	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)
Total Reports	**24**	**-**	**34**	**-**
Labeling	***12***	***50.0%***	***15***	***44.1%***
Product label; incorrect/illegible; recipient identification	12	50.0%	13	38.2%
Product Specifications	***8***	***33.3%***	***10***	***29.4%***
Product specification not met; contaminated with microorganism	7	29.2%	7	20.6%

Appendix 3. HCT/P Deviation Reports Submitted by Manufacturers of 361 HCT/Ps

Tables 26 and 27 highlight the most frequent reports submitted in FY18 by each type of HCT/P manufacturer compared to reports submitted in FY17. Not all reports submitted are represented in these tables and therefore the numbers of reports listed do not add up to the total reports received listed in the table.

Of the 150 reports submitted by cellular 361 HCT/P manufacturers in FY18 (Table 4), 79% of the reports involved receipt, pre-distribution, shipment and distribution and 10% of the reports involved processing and process controls (Table 26).

Table 26 - Most Frequent HCT/P Deviation Reports Submitted by Cellular 361 HCT/Ps Manufacturers

Cellular 361 HCT/Ps Manufacturers	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)
Total Reports	**125**	**-**	**150**	**-**
Receipt, Pre-Distribution, Shipment & Distribution	***86***	***68.8%***	***118***	***78.7%***
Inappropriate distribution; Contaminated or potentially contaminated HCT/P	84	67.2%	117	78.0%
Processing & Processing Controls	***26***	***20.8%***	***15***	***10.0%***
Processing; HCT/P contaminated, potentially contaminated, or cross-contaminated during processing	17	13.6%	12	8.0%

Of the 93 reports submitted by tissue 361 HCT/P in FY18 (Table 4), 36% of the reports involved donor eligibility and 24% involved receipt, pre-distribution, shipment and distribution (Table 27).

Table 27 - Most Frequent HCT/P Deviation Reports Submitted by Tissue 361 HCT/Ps Manufacturers

	FY17 (#)	FY17 (%)	FY18 (#)	FY18 (%)
Total Reports	**96**		**93**	
Donor Eligibility	***28***	***29.2%***	***33***	***35.5%***
Ineligible donor accepted; Risk factors for, or clinical evidence of infection due to RCDAD	23	24.0%	29	31.2%
Final autopsy results received post distribution	7	7.3%	16	17.2%
Receipt, Pre-Distribution, Shipment & Distribution	***31***	***32.3%***	***22***	***23.7%***
Inappropriate distribution; Contaminated or potentially contaminated HCT/P	19	19.8%	15	16.1%