



**2021 Questionnaire Survey Report**  
**on**  
**Incidents, Accidents, and Safety Procedures**  
**Related to Cardiopulmonary Bypass and**  
**Cardiopulmonary Support Systems**

**Safety Control Committee**  
**Japanese Society of Extra-Corporeal Technology in Medicine**  
**(JaSECT)**

# Objectives & Target Years of the Survey

## ◆ Objectives

To enhance the awareness of safety management, promote the advancement of extra-corporeal technology, and improve the medical standards and patient safety by gathering and compiling information on incidents/accidents related to cardiopulmonary bypass (CPB) and cardiopulmonary support (CPS) systems.

## ◆ Target years

2019 and 2020

## Background of the Survey

**Prior questionnaire surveys (and target years) on incidents/accidents conducted by JaSECT Safety Control Committee:**

2010: CPB (2008, 2009)

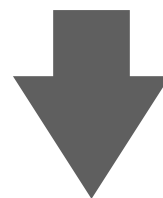
2011: CPS (2009, 2010)

2013: CPB & CPS (2011, 2012)

2015: CPB & CPS (2013, 2014)

2017: CPB & CPS (2015, 2016)

2019: CPB & CPS (2017, 2018)



**This survey is a continuation of ongoing research.**

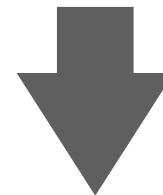
**2021: CPB & CPS (2019, 2020)**

## Subjects

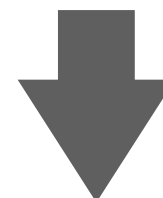
**656 medical institutions with JaSECT members**

## Responses

Response rate: 67.2 % (441/656 institutions)



13 institutions replied but were unable to answer the questions due to a managerial decision and thus excluded from aggregation.



Valid response rate: 65.2% (428 institutions)

# Levels of Impact on Patients

Level	Impact on patients
Level 0	Errors and/or failures were found in pharmaceuticals and/or medical devices that were not used on patient.
Level 1	Errors and/or failures were found in pharmaceuticals and/or medical devices that were used on patient but had no impact on the patient.
Level 2	Caused changes in patient's vital signs and/or necessitated medical examination.
Level 3a	Necessitated minor treatment or procedure (disinfection, cooling, administration of analgesics, etc.).
Level 3b	Necessitated major treatment or procedure (unplanned procedure or treatment, hospitalization, extension of hospital stay, etc.)
Level 4	Resulted in permanent disability.
Level 5	Resulted in death (excluding that caused by natural course of primary disease).



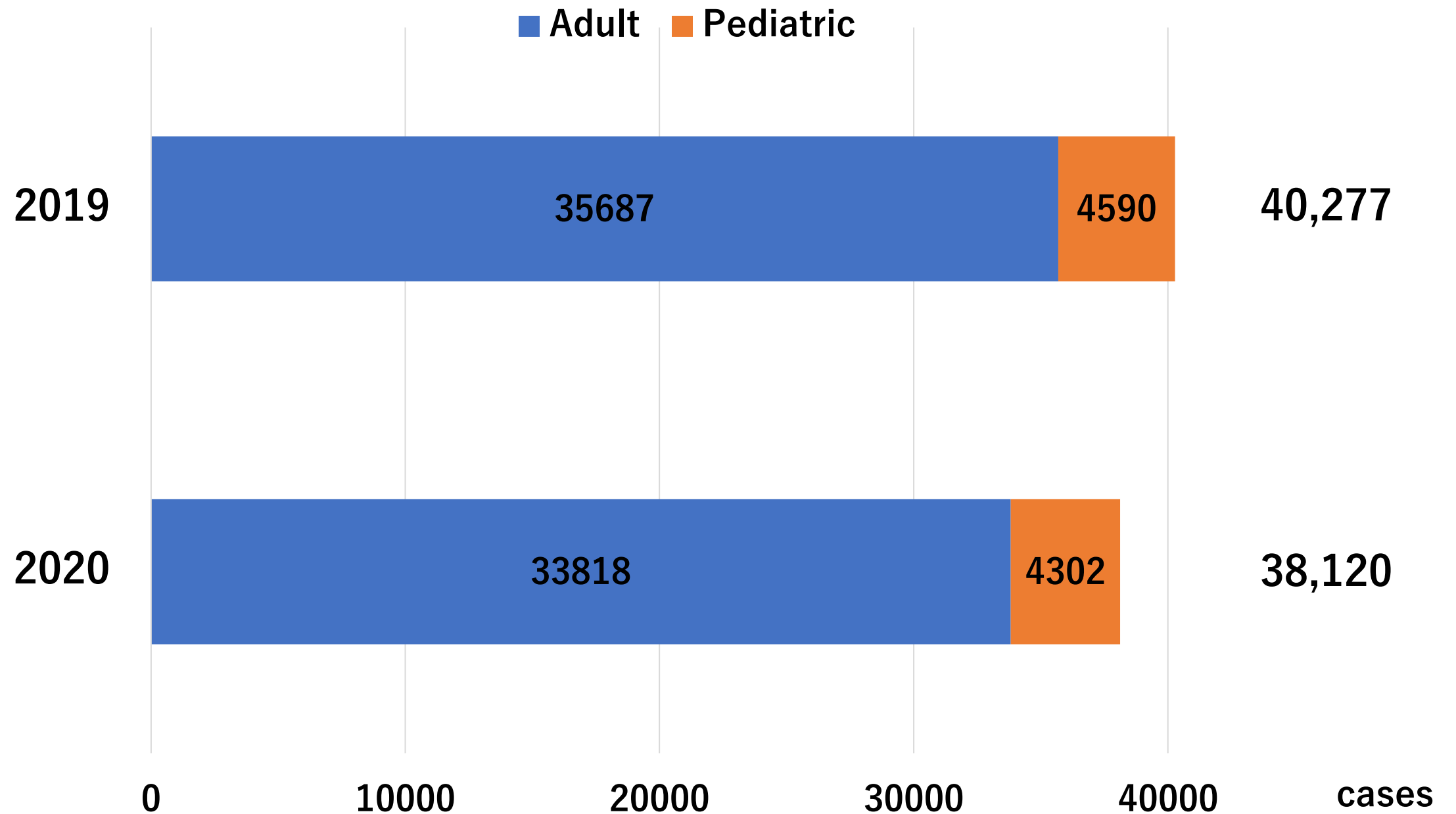
# Aggregation Results

## Cardiopulmonary Bypass (CPB)



# CPB-Related Accidents/Incidents by Demographics

Total CPB-related cases: 78,397 (Adult: 69,505 Pediatric: 8,892)



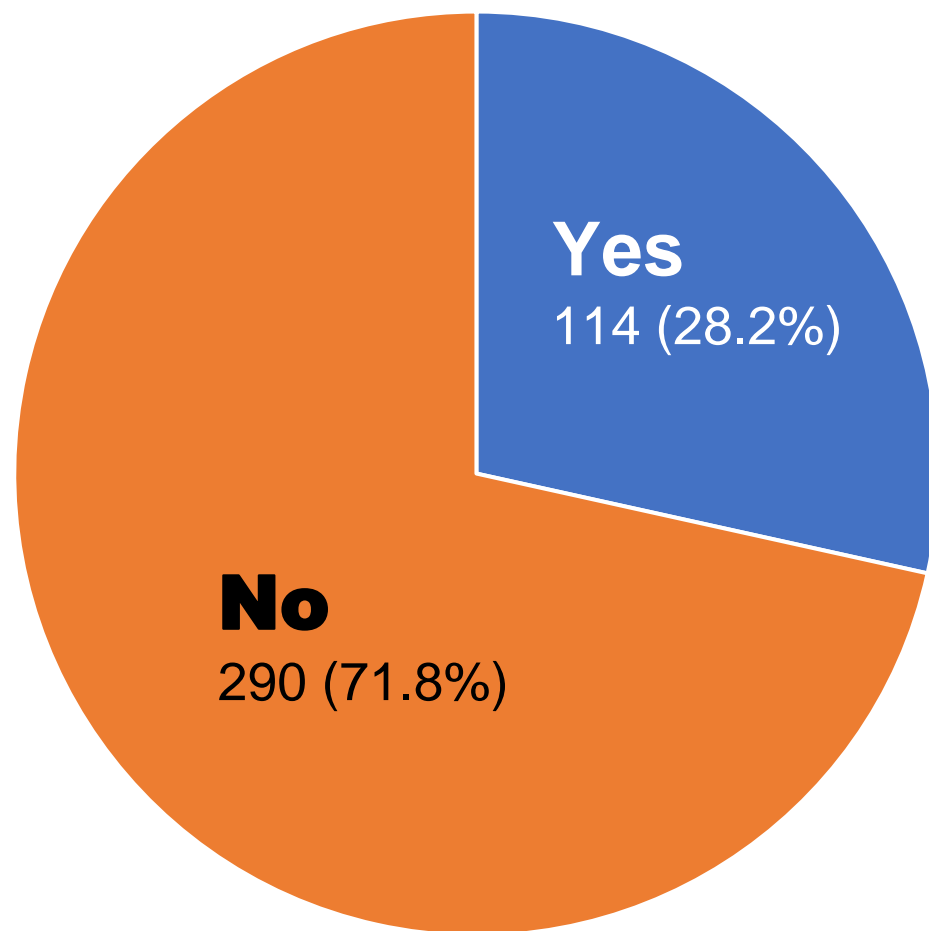
n = 409 insts.

## CPB-Related Accidents/Incidents & Rates

	2021 Survey			2019 Survey			2017 Survey		
	2019	2020	Total	2017	2018	Total	2015	2016	Total
<b>CPB cases</b>	40,277	38,120	78,397	40,786	40,699	81,455	42,303	44,180	86,483
<b>Impact level (0)</b>	259 0.64%	284 0.75%	543 0.69%	379 0.93%	393 0.97%	772 0.95%	431 1.02%	440 1.00%	871 1.01%
<b>Impact level (1 – 3a)</b>	192 0.48%	245 0.64%	437 0.56%	340 0.83%	345 0.85%	685 0.84%	265 0.63%	274 0.62%	539 0.62%
<b>Impact level (3b – 5)</b>	11 0.03%	12 0.03%	23 0.03%	16 0.04%	22 0.05%	38 0.05%	24 0.06%	26 0.06%	50 0.06%
<b>Total</b>	462 1.15%	541 1.42%	1,003 1.37%	735 1.80%	760 1.87%	1,495 1.84%	720 1.70%	740 1.67%	1,460 1.69%



# Did you experience an incident/accident involving a CPB Device?



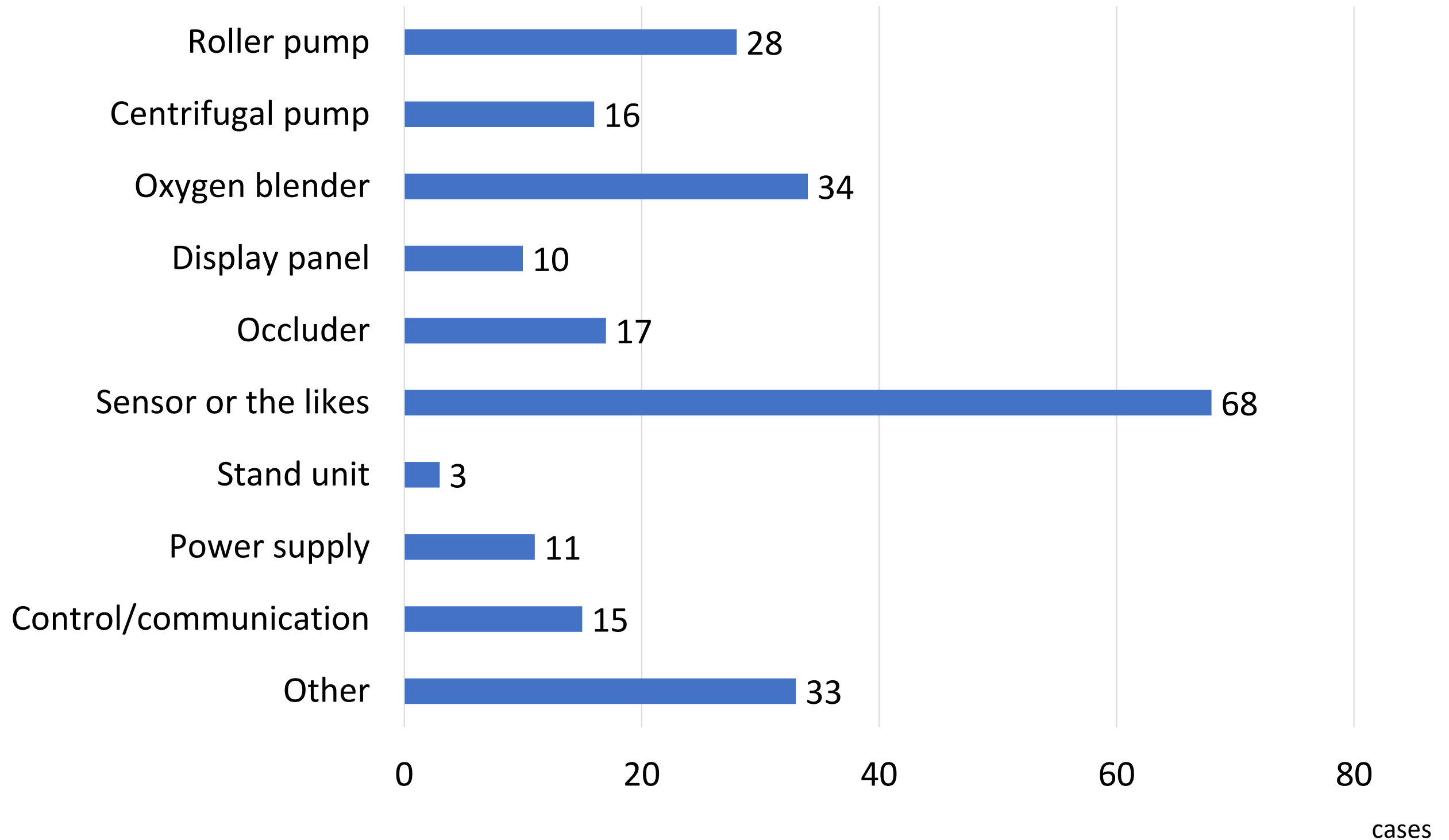
n = 409 (no answer: 5 insts.)

Impact level	No. of cases	Frequency*
0	172	0.22%
1 – 3a	112	0.14%
3b – 5	6	0.01%

No answer: 11 insts.

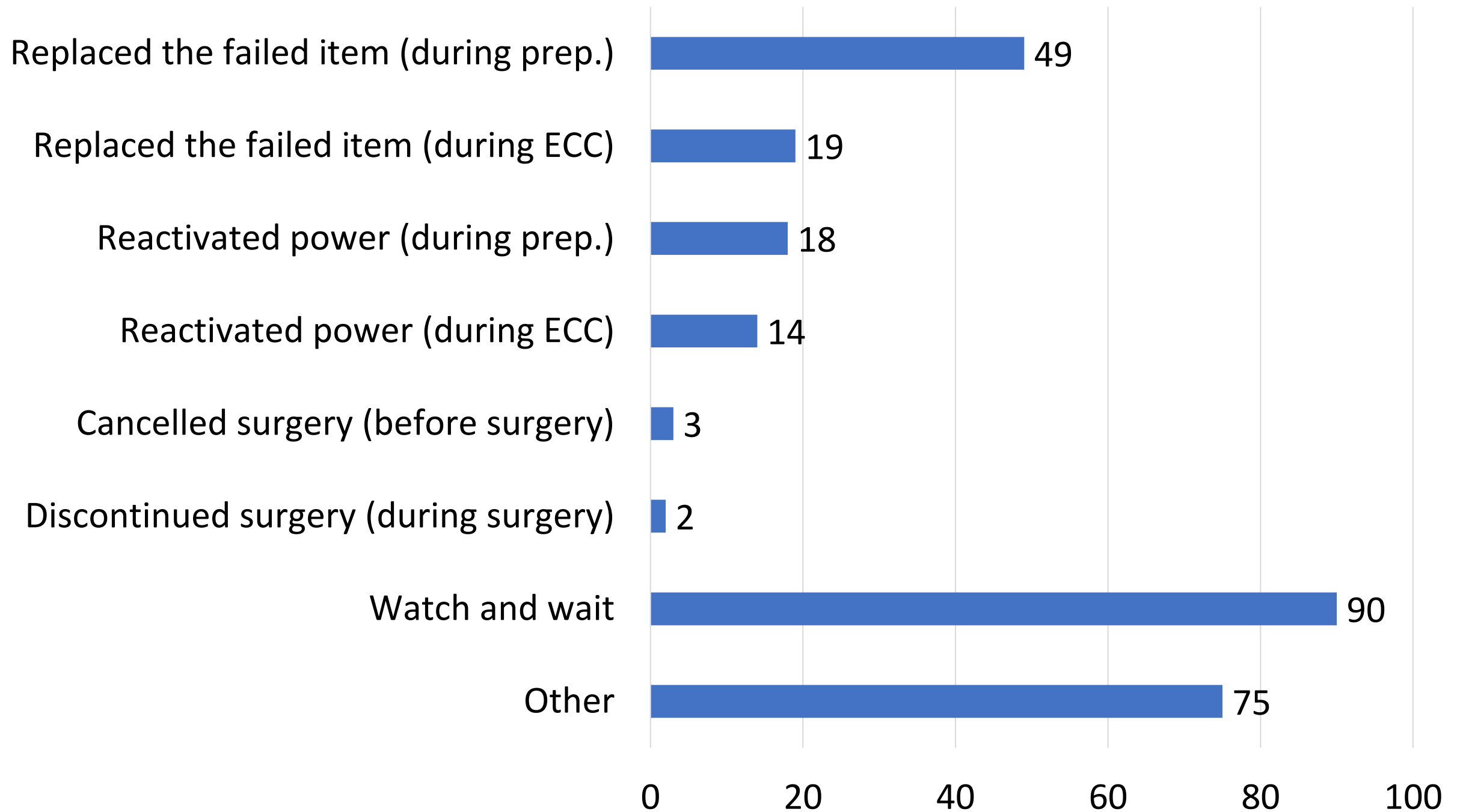
\*Among 78,397 CPB cases occurring during the 2-year period.

# Which of the following was involved in the incident/accident and how many times? (Please choose all that apply.)



In 119 institutions  
(incl. 15 that did not answer the question)

# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



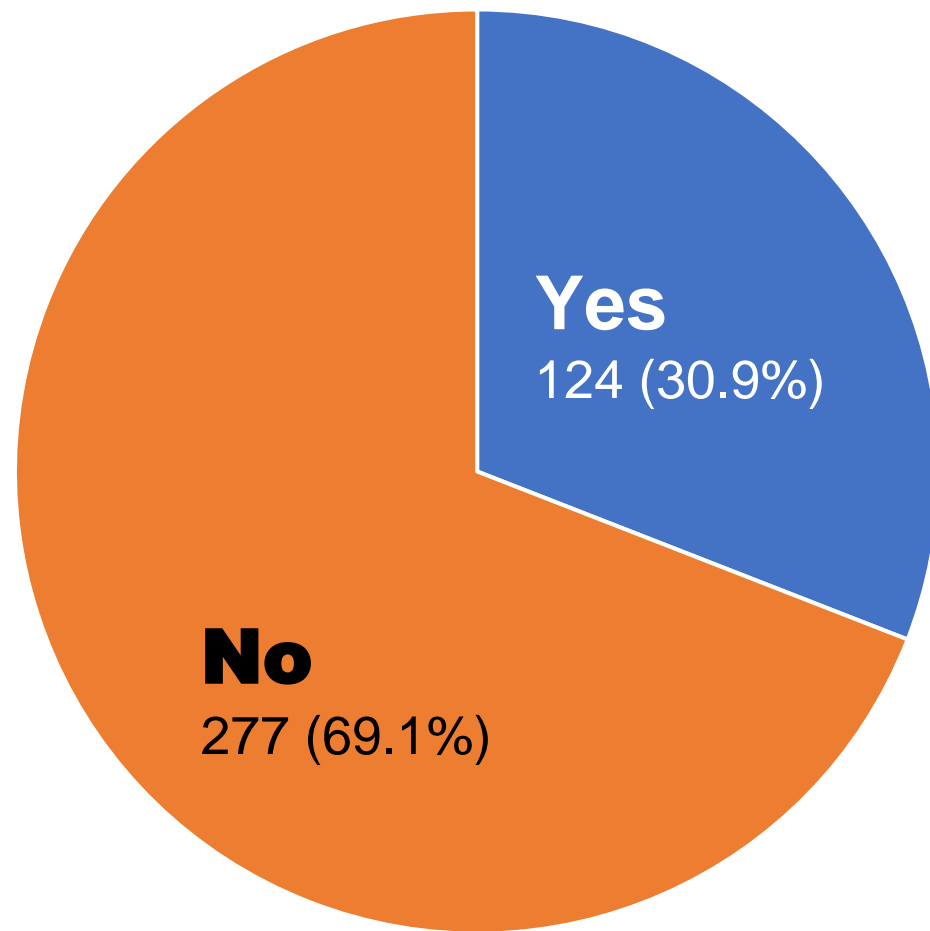
In 119 institutions  
(incl. 18 that did not answer the question)

cases

# CPB Device-Related Incidents & Rates

2021 Survey			2019 Survey		2017 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	172	0.22%	199	0.24%	278	0.32%
1 – 3a	112	0.14%	117	0.14%	65	0.08%
3b – 5	6	0.01%	6	0.01%	12	0.01%
No answer: 11 insts.			No answer: 18		No answer: 16	
*Among 78,397 cases			**Among 81,455 cases		***Among 86,483 cases	

# Did you experience an incident/accident involving an Oxygenator?



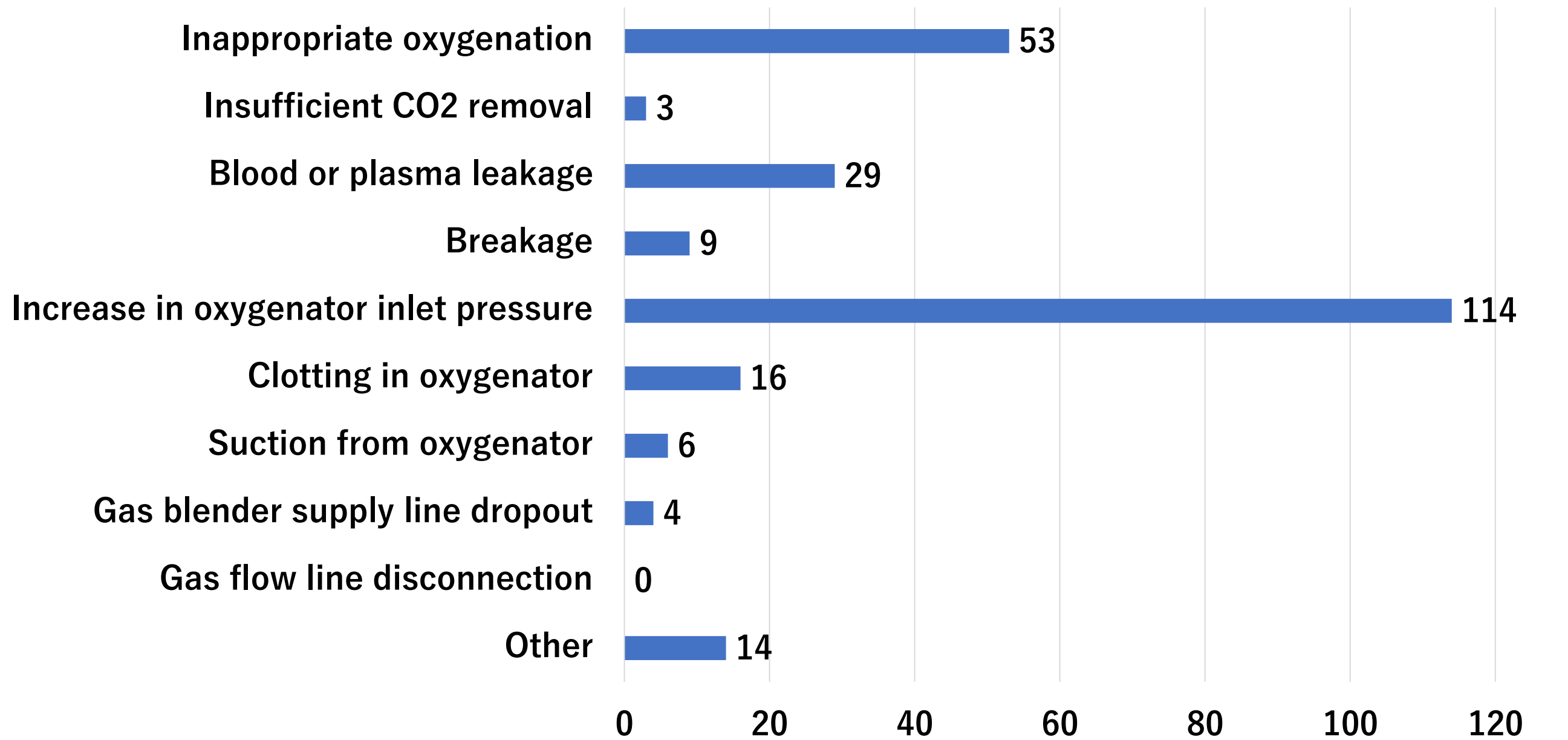
Impact level	No. of cases	Frequency*
0	119	0.15%
1 – 3a	106	0.14%
3b – 5	4	0.01%

No answer: 11 insts.

\*Among 78,397 CPB cases occurring during the 2-year period.

n = 409 (no answer: 8 insts.)

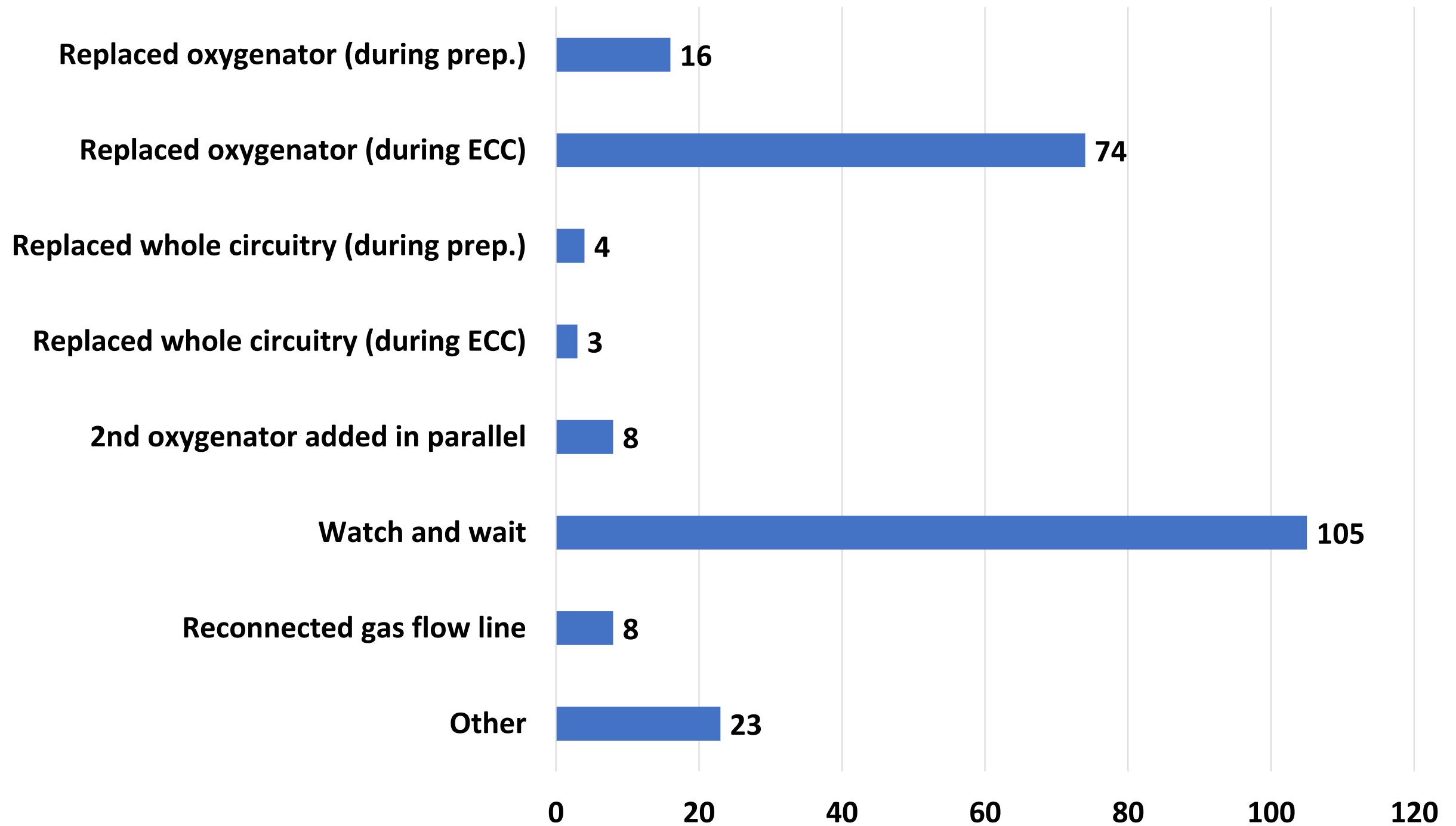
# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 132 institutions  
(incl. 5 that did not answer the question)

cases

# Which of the following actions did you take in response to the incident/accident? (Please choose all that apply.)



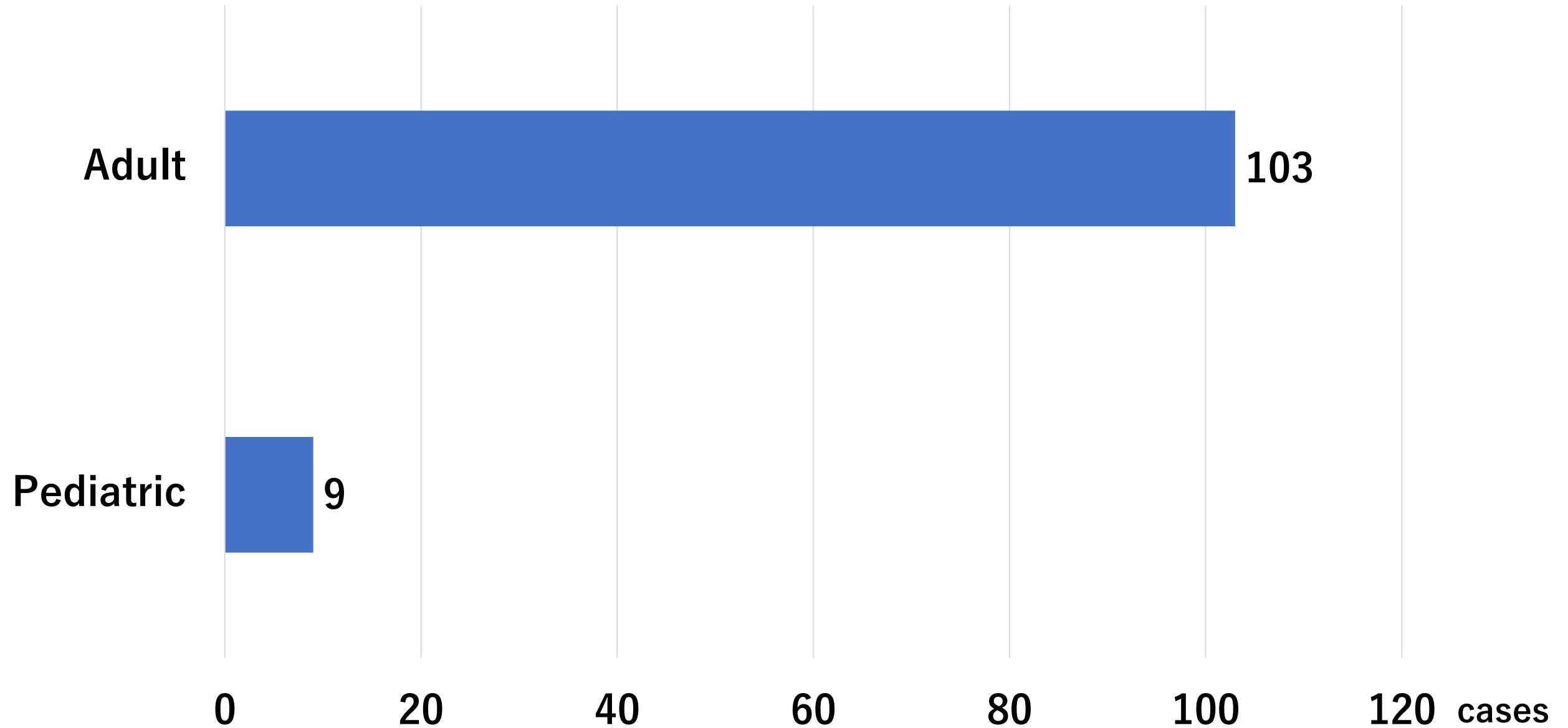
In 132 institutions  
(incl. 6 that did not answer the question)

cases



# No. of Cases by Demographics

(62 institutions that experienced “increase in oxygenator inlet pressure” and/or “clotting”)

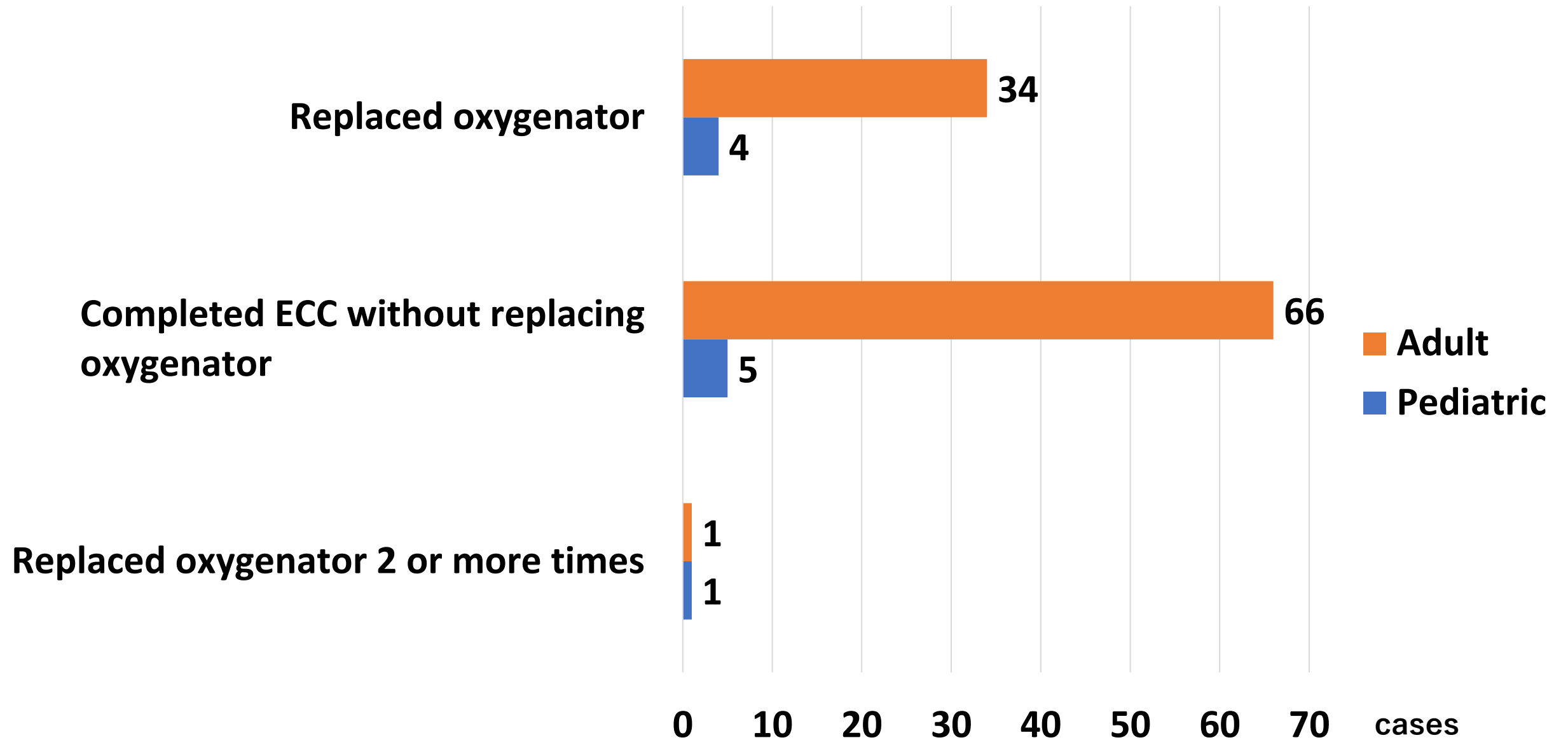


In 62 institutions  
(incl. 1 that did not answer the question)



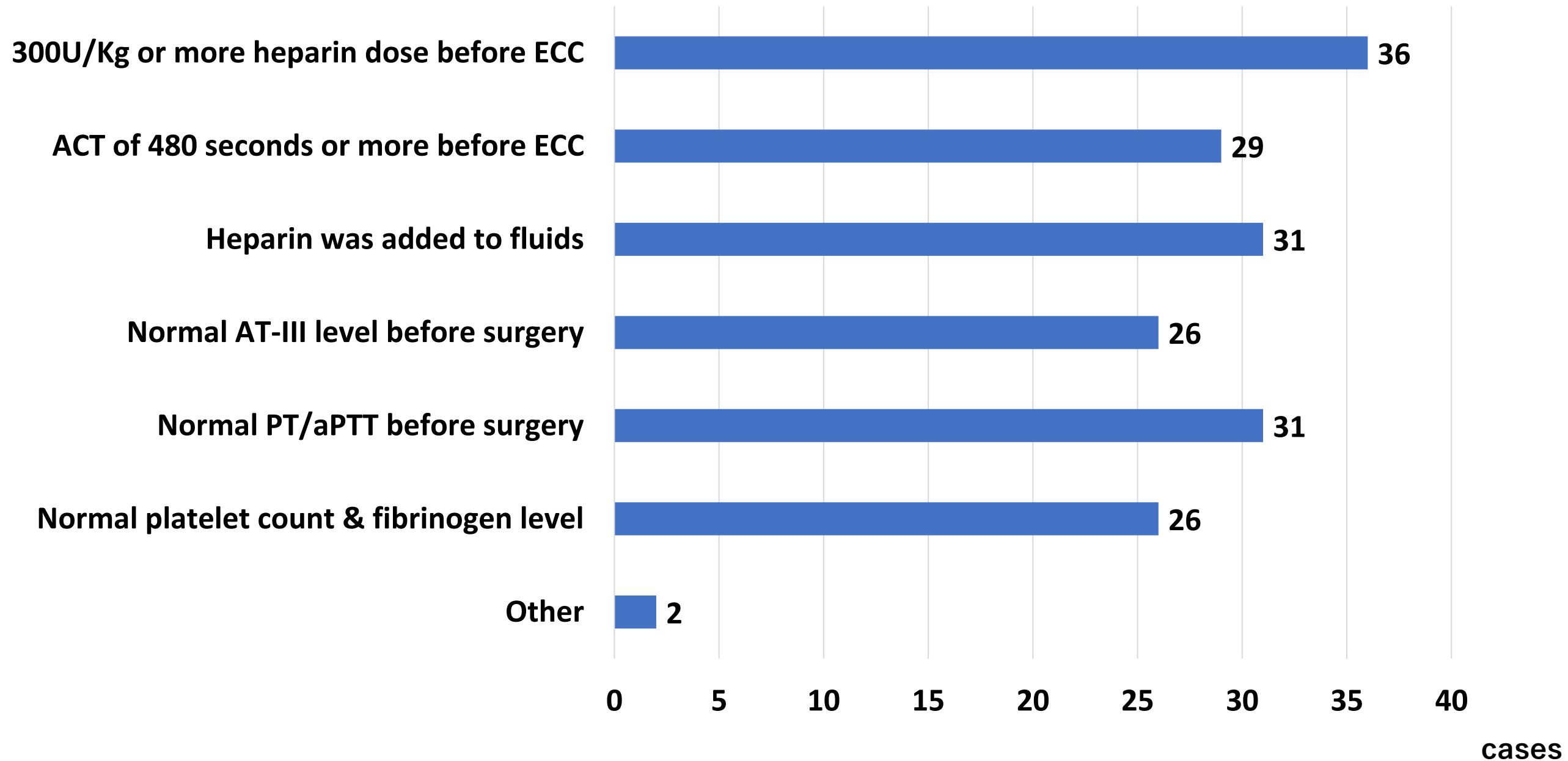
# Did you replace the oxygenator? (Please choose all that apply.)

(62 institutions that experienced “increase in oxygenator inlet pressure” and/or “clotting”)



In 62 institutions  
(incl. 3 that did not answer the question)

# What was the state of the patient when you replaced the oxygenator? (Please choose all that apply.)

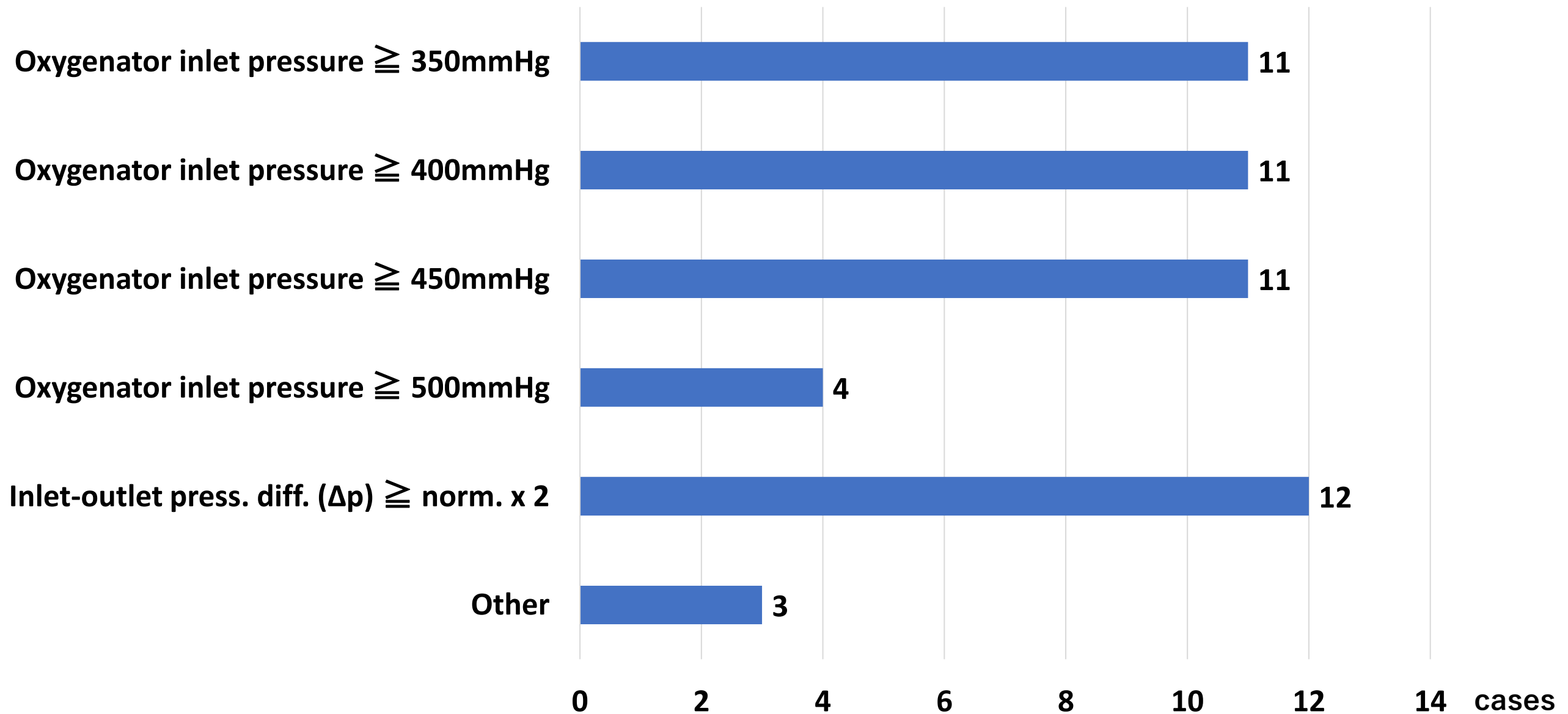


In 31 institutions  
(incl. 2 that did not answer the question)

# What was reason for replacing the oxygenator?

(Please choose all that apply.)

(31 institutions that replaced oxygenator 1 or more times)

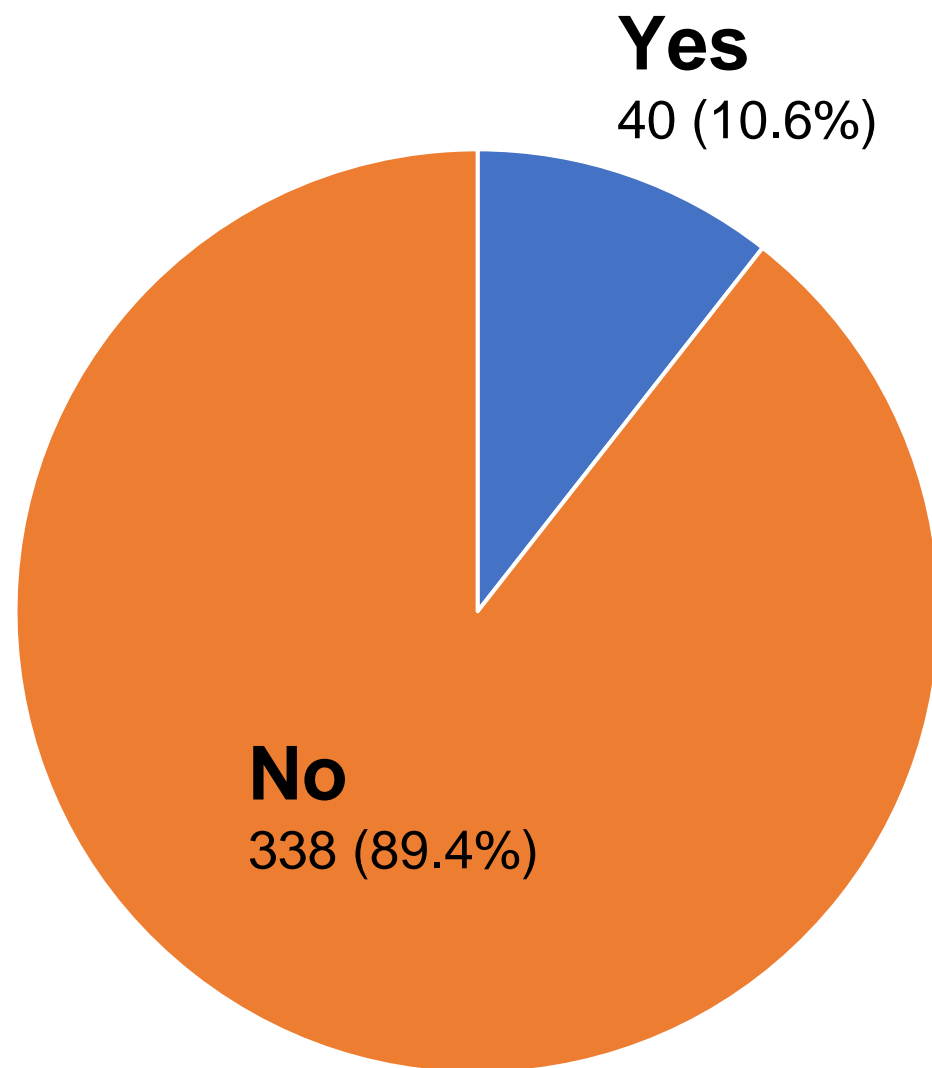


In 31 institutions  
(incl. 1 that did not answer the question)

# Oxygenator-Related Incidents & Rates

2021 Survey			2019 Survey		2017 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	119	0.15%	89	0.11%	96	0.11%
1 – 3a	106	0.14%	120	0.15%	132	0.15%
3b – 5	4	0.01%	12	0.01%	13	0.02%
No answer: 11 insts.			No answer: 11		No answer: 10	
* Among 78,397 cases			** Among 81,455 cases		*** Among 86,483 cases	

# Did you experience an incident/accident involving a Venous or Cardiotomy Reservoir?



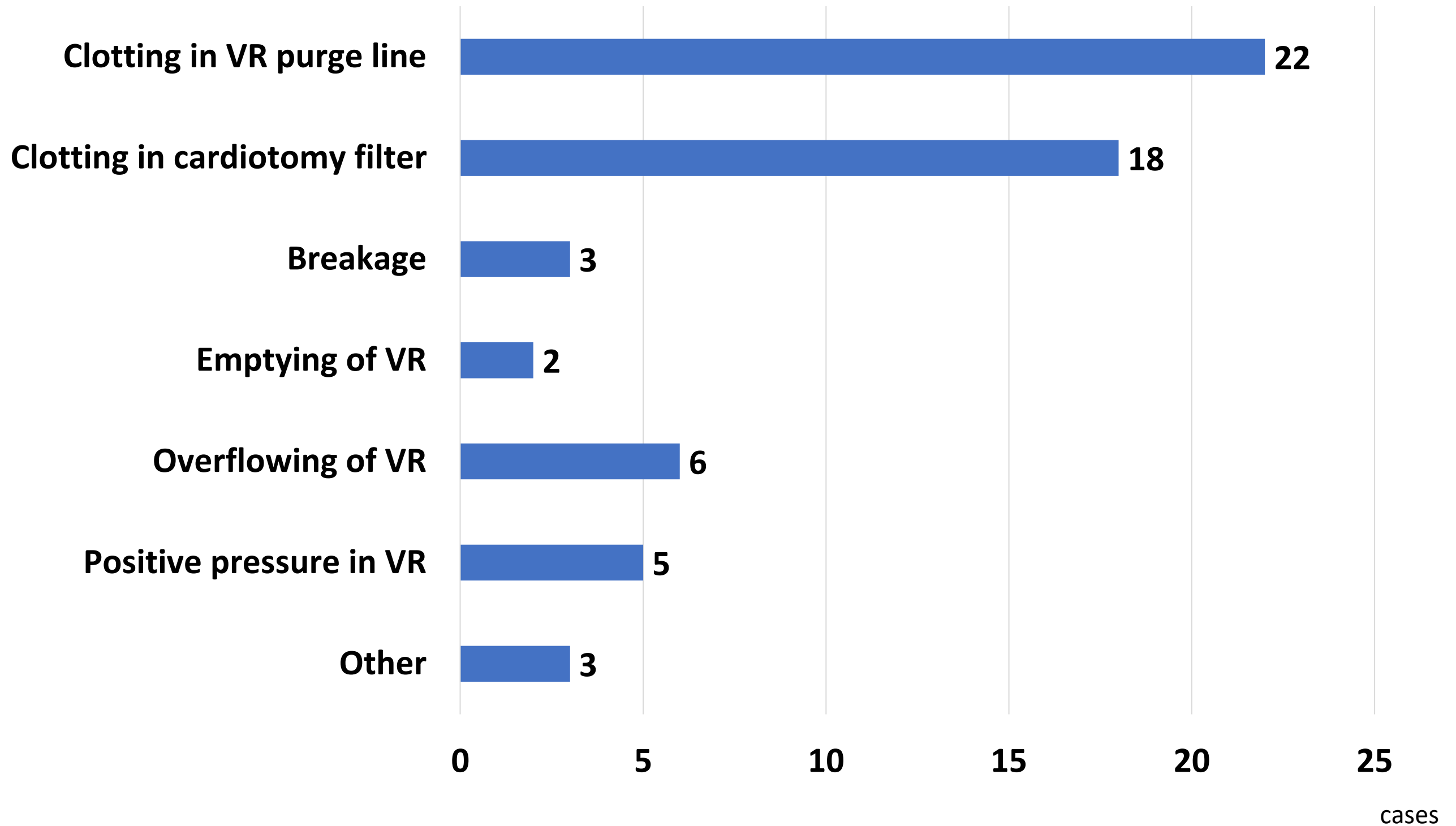
n = 409 (no answer: 31 insts.)

Impact level	No. of cases	Frequency*
0	30	0.04%
1 – 3a	21	0.03%
3b – 5	0	0%

No answer: 33 insts.

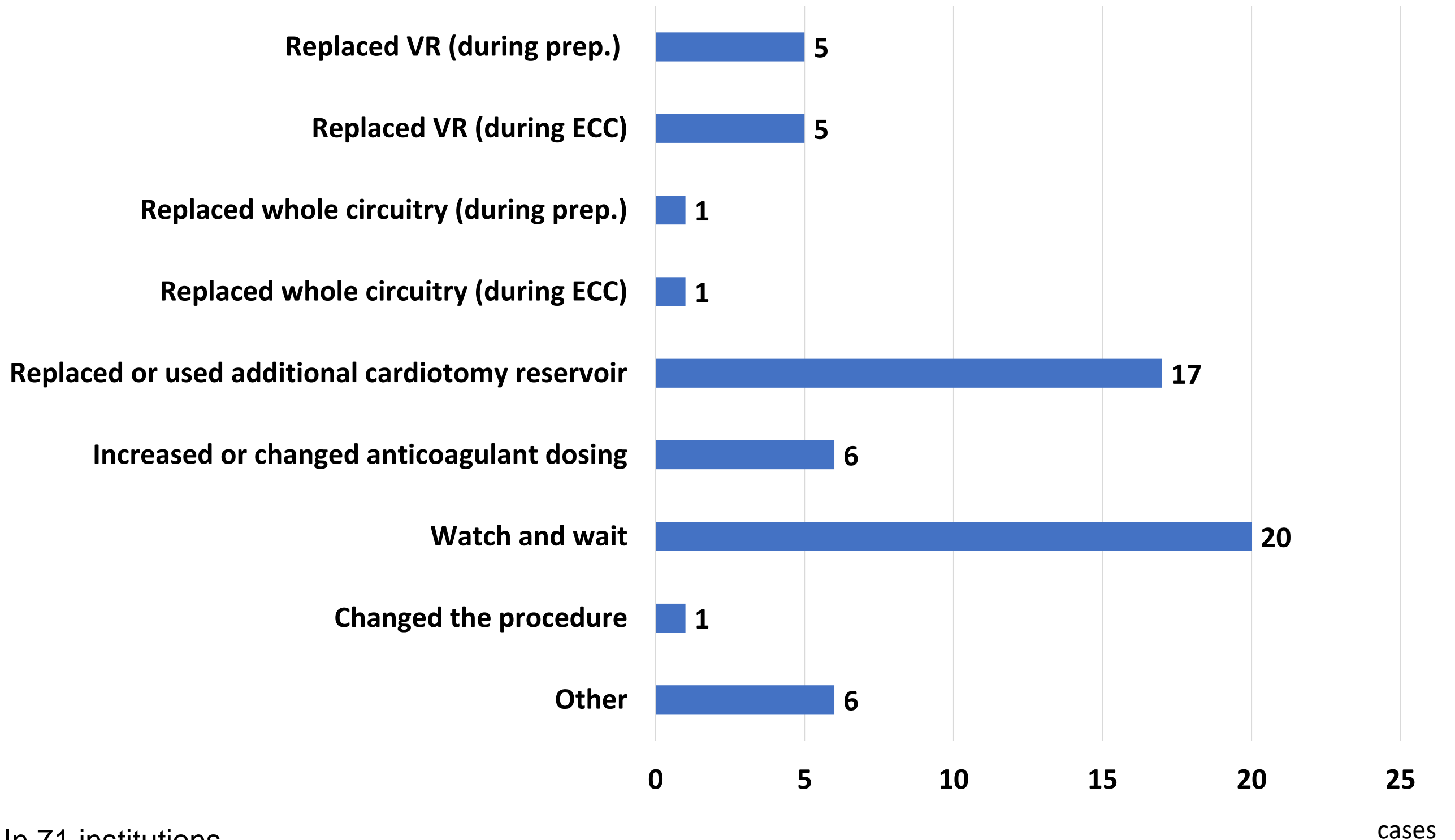
\*Among 78,397 CPB cases occurringg during the 2-year period.

# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 71 institutions  
(incl. 32 that did not answer the question)

# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



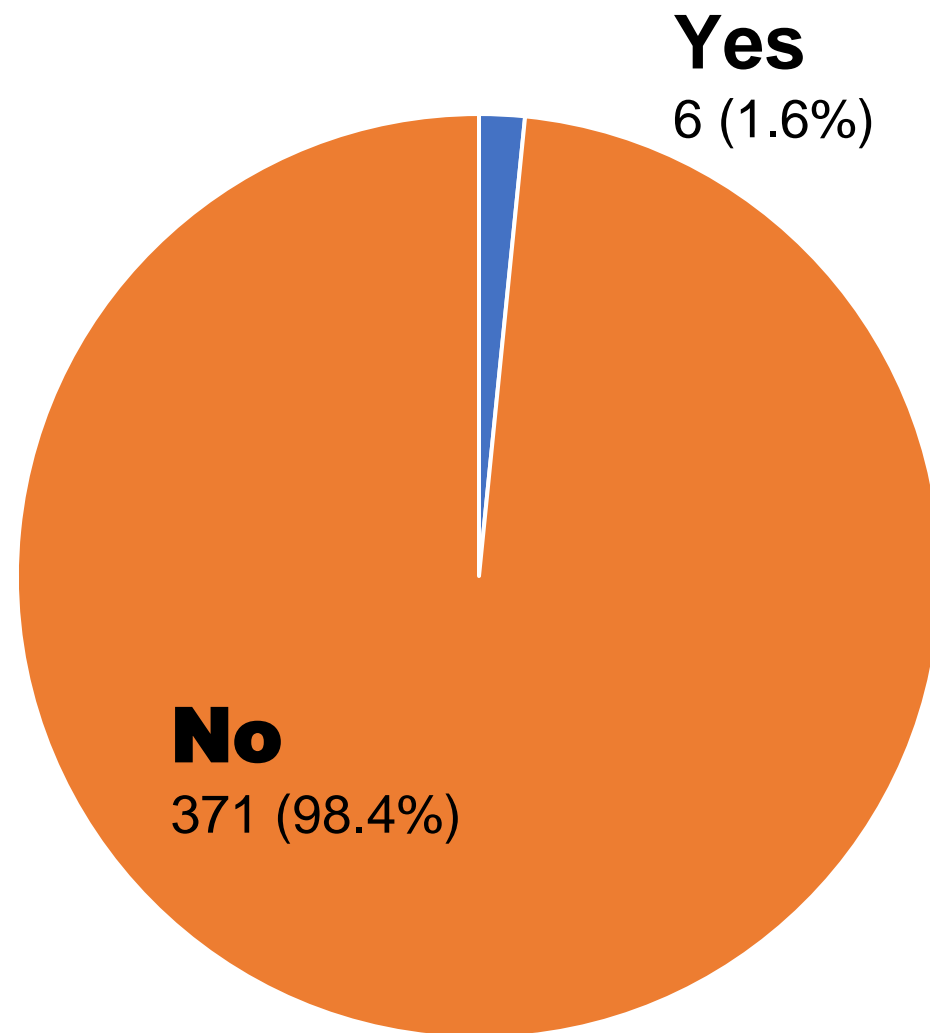
In 71 institutions  
(incl. 32 that did not answer the question)

# Venous-Reservoir-Related Incidents & Rates

		2021 Survey		2019 Survey		2017 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***	
0	30	0.04%	46	0.06%	52	0.06%	
1 – 3a	21	0.03%	36	0.04%	28	0.03%	
3b – 5	0	0%	4	< 0.01%	2	< 0.01%	
No answer: 33 insts.		No answer: 14		No answer: 11			
* Among 78,397 cases		** Among 81,455 cases		*** Among 86,483 cases			



# Did you experience an incident/accident involving an Arterial Line Filter? (excluding oxygenators with built-in filters)



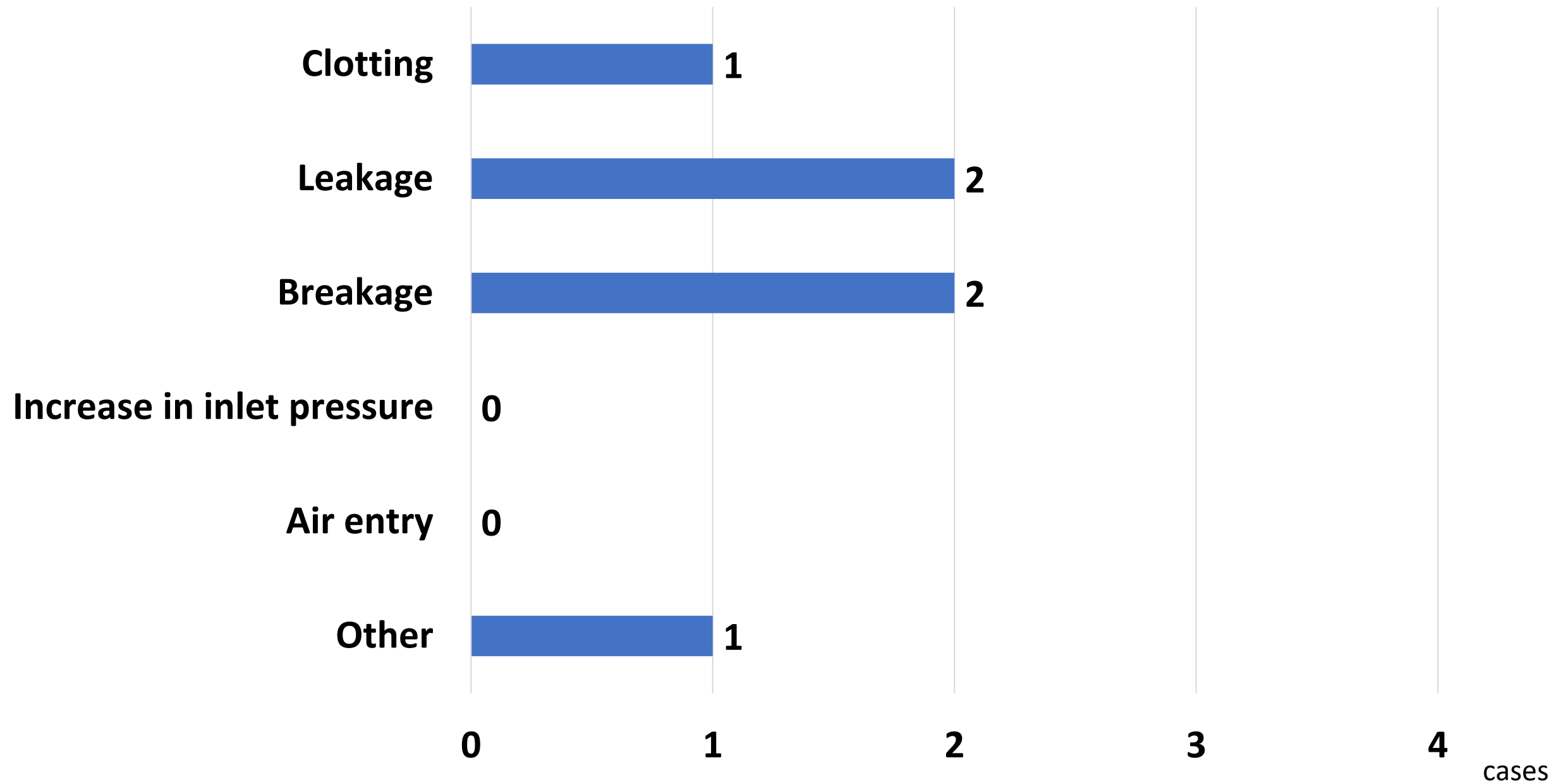
Impact level	No. of cases	Frequency*
0	5	< 0.01%
1 – 3a	1	< 0.01%
3b – 5	0	0%

No answer: 32 insts.

\*Among 78,397 CPB cases occurring during the 2-year period.

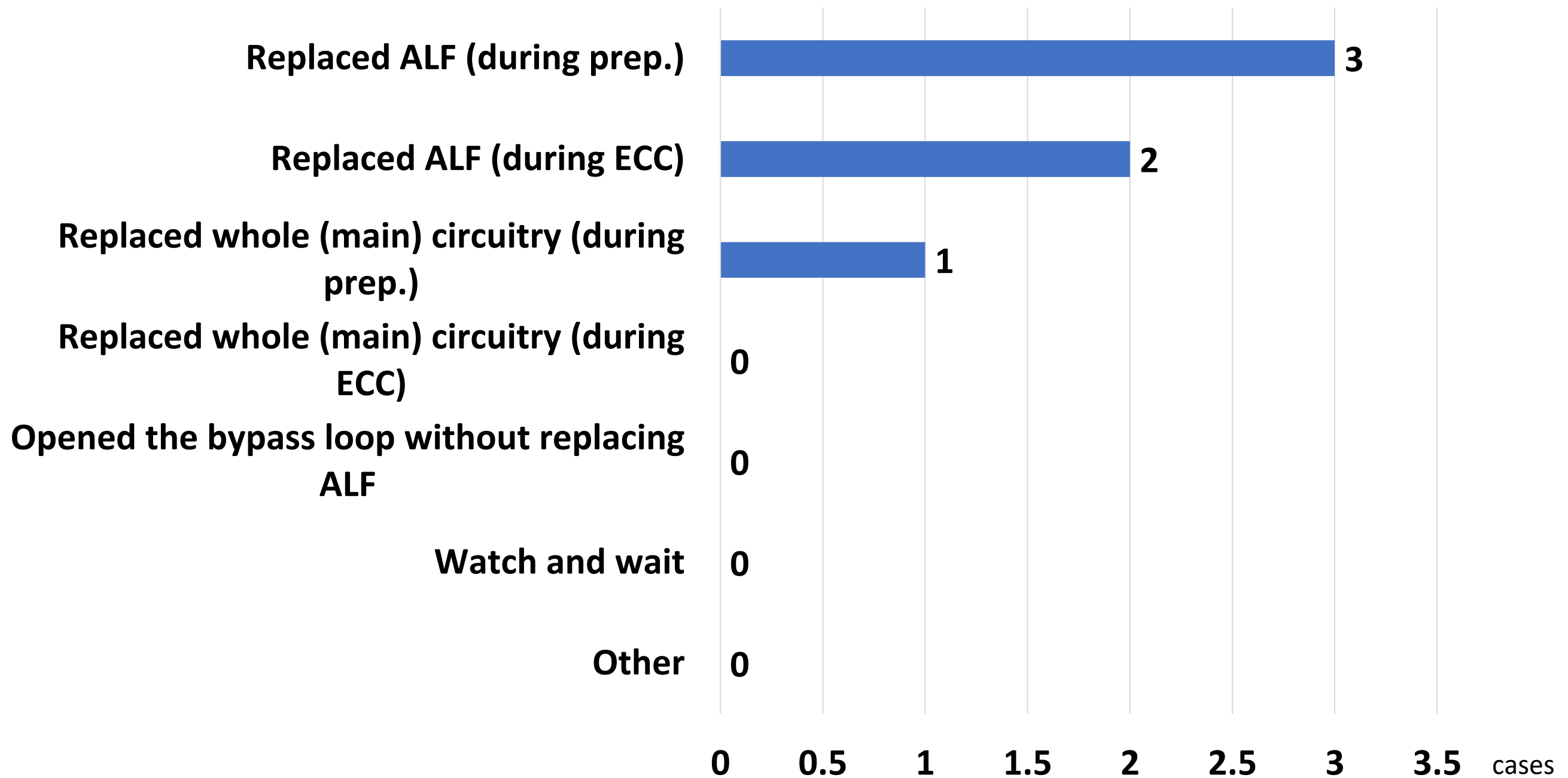
n = 409 (no answer: 32 insts.)

# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 38 institutions  
(incl. 32 that did not answer the question)

# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)

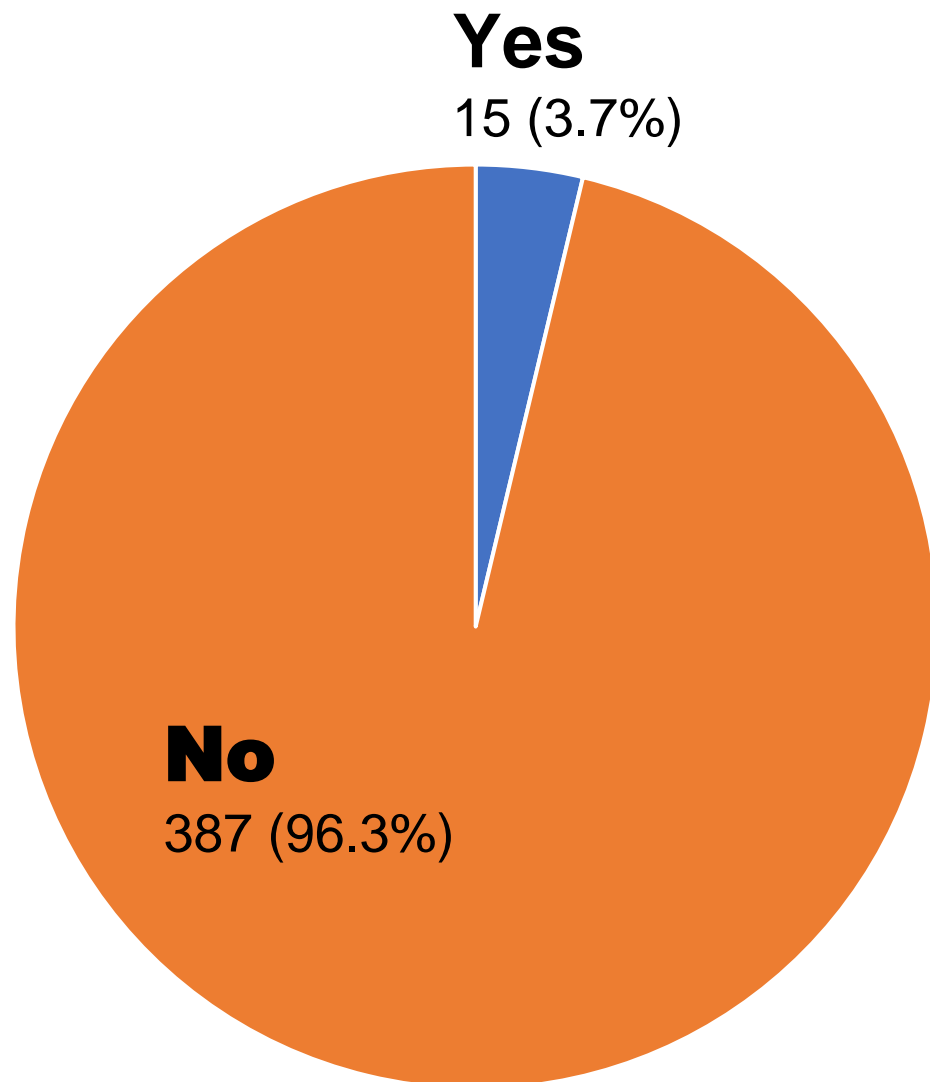


In 38 institutions  
(incl. 32 that did not answer the question)

# Arterial-Filter-Related Incidents & Rates

2021 Survey			2019 Survey		2017 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	5	< 0.01%	6	< 0.01%	17	0.02%
1 – 3a	1	< 0.01%	3	< 0.01%	3	< 0.01%
3b – 5	0	0%	0	0%	0	0%
No answer: 32 insts.			No answer: 13		No answer: 17	
* Among 78,397 cases			** Among 81,455 cases		*** Among 86,483 cases	

# Did you experience an incident/accident related to Blood Supply Interruption due to Blood Pump Failure?



Impact level	No. of cases	Frequency*
0	7	< 0.01%
1 – 3a	8	0.01%
3b – 5	0	0%

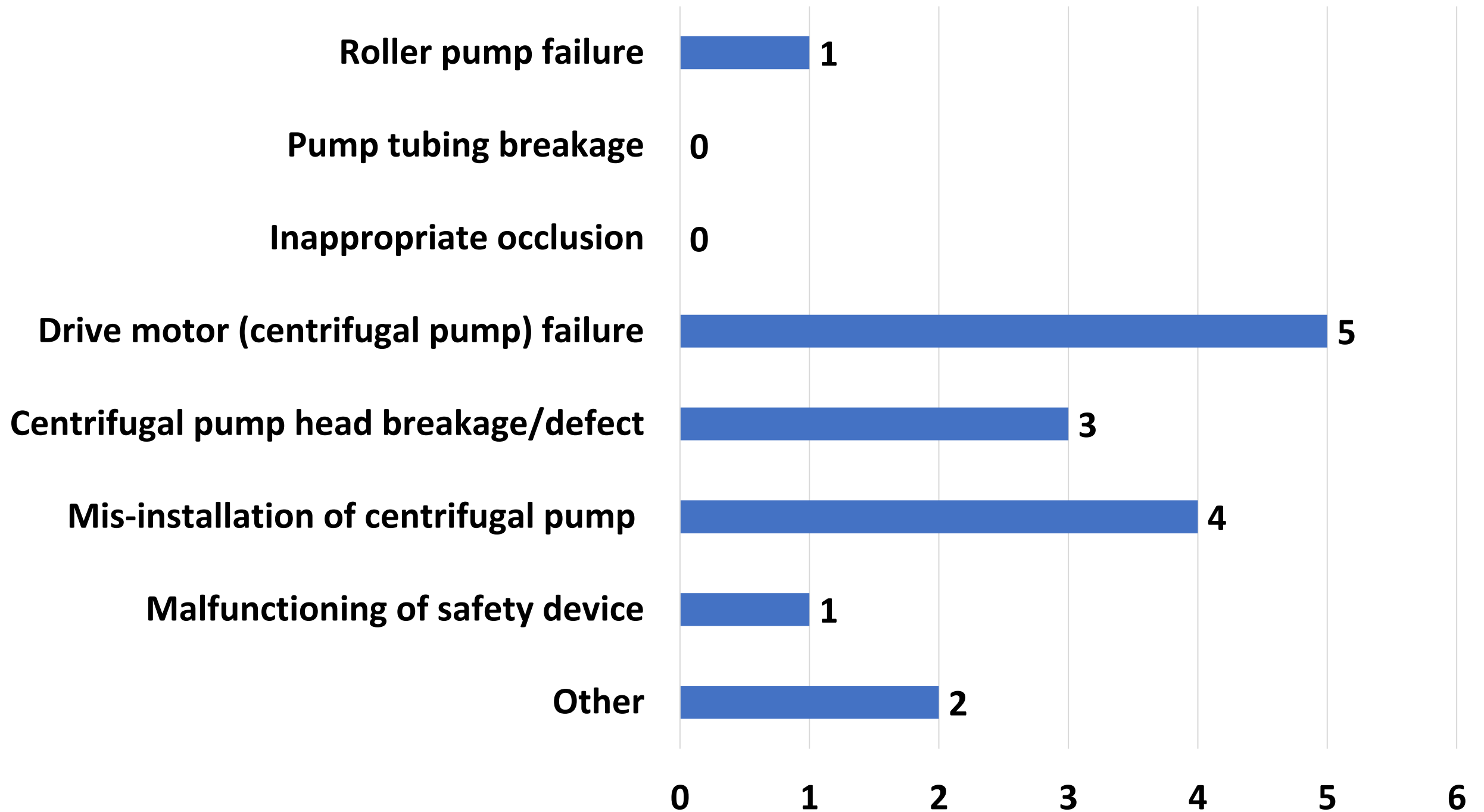
No answer: 8 insts.

\*Among 78,397 CPB cases occurring during the 2-year period.

n = 409 (no answer: 7 insts.)



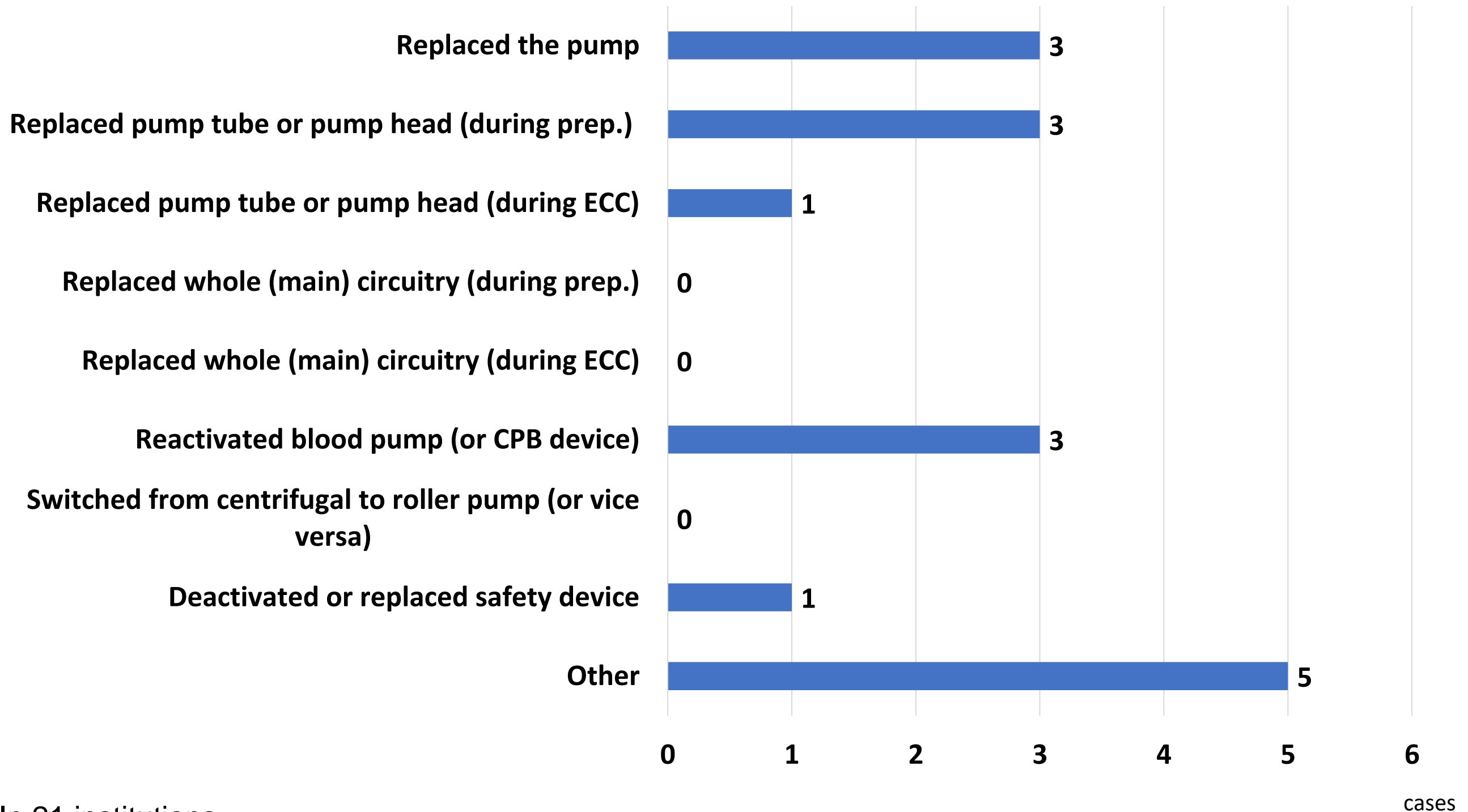
# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 22 institutions  
(incl. 7 that did not answer the question)

cases

# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



In 21 institutions  
(incl. 12 that did not answer the question)

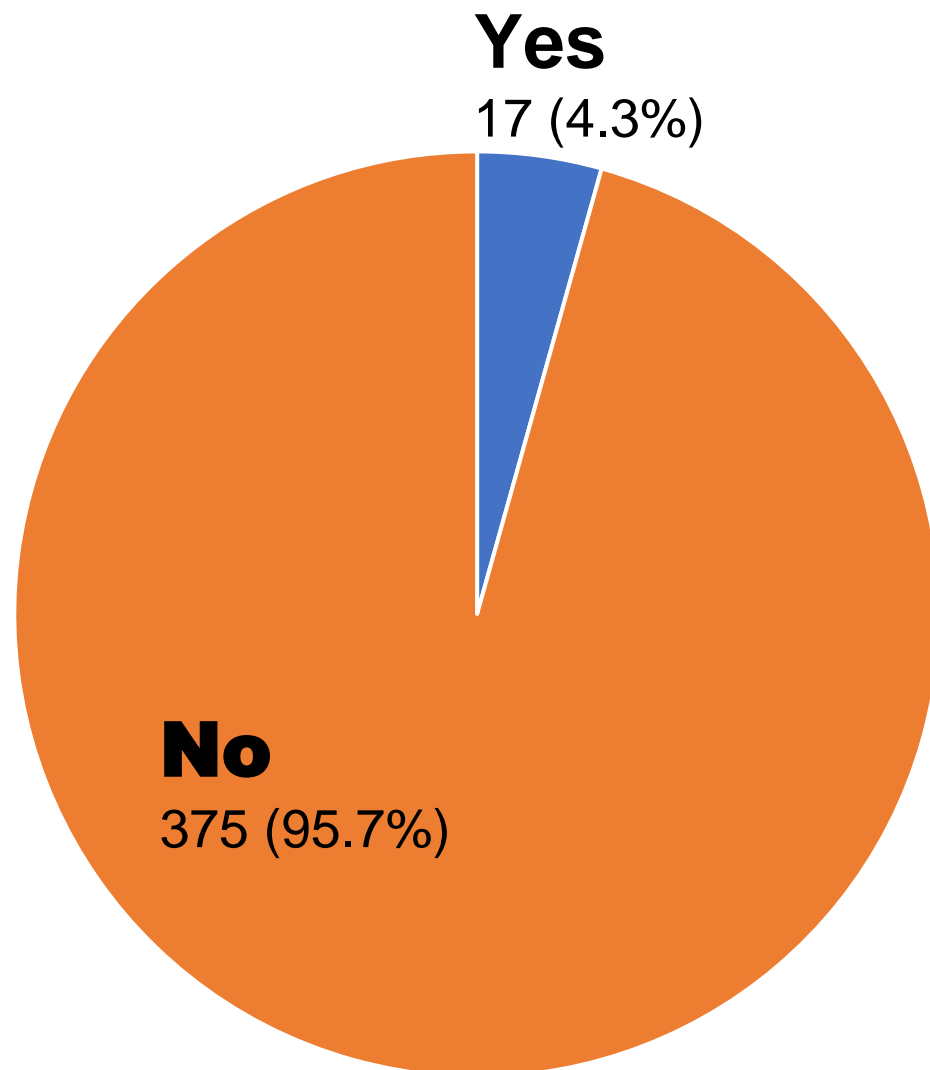


# Blood Supply Interruption Incidents & Rates due to Blood Pump Failure

	2021 Survey		2019 Survey		2017 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	7	< 0.01%	7	< 0.01%	16	0.02%
1 – 3a	8	0.01%	7	< 0.01%	8	0.01%
3b – 5	0	0%	0	0%	0	0%
	No answer: 8 insts.		No answer: 7		No answer: 11	
	* Among 78,397 cases		** Among 81,455 cases		*** Among 86,483 cases	



# Did you experience an incident/accident caused by Mishandling of Blood Pump?



Impact level	No. of cases	Frequency*
0	14	0.02%
1 – 3a	9	0.01%
3b – 5	0	0%

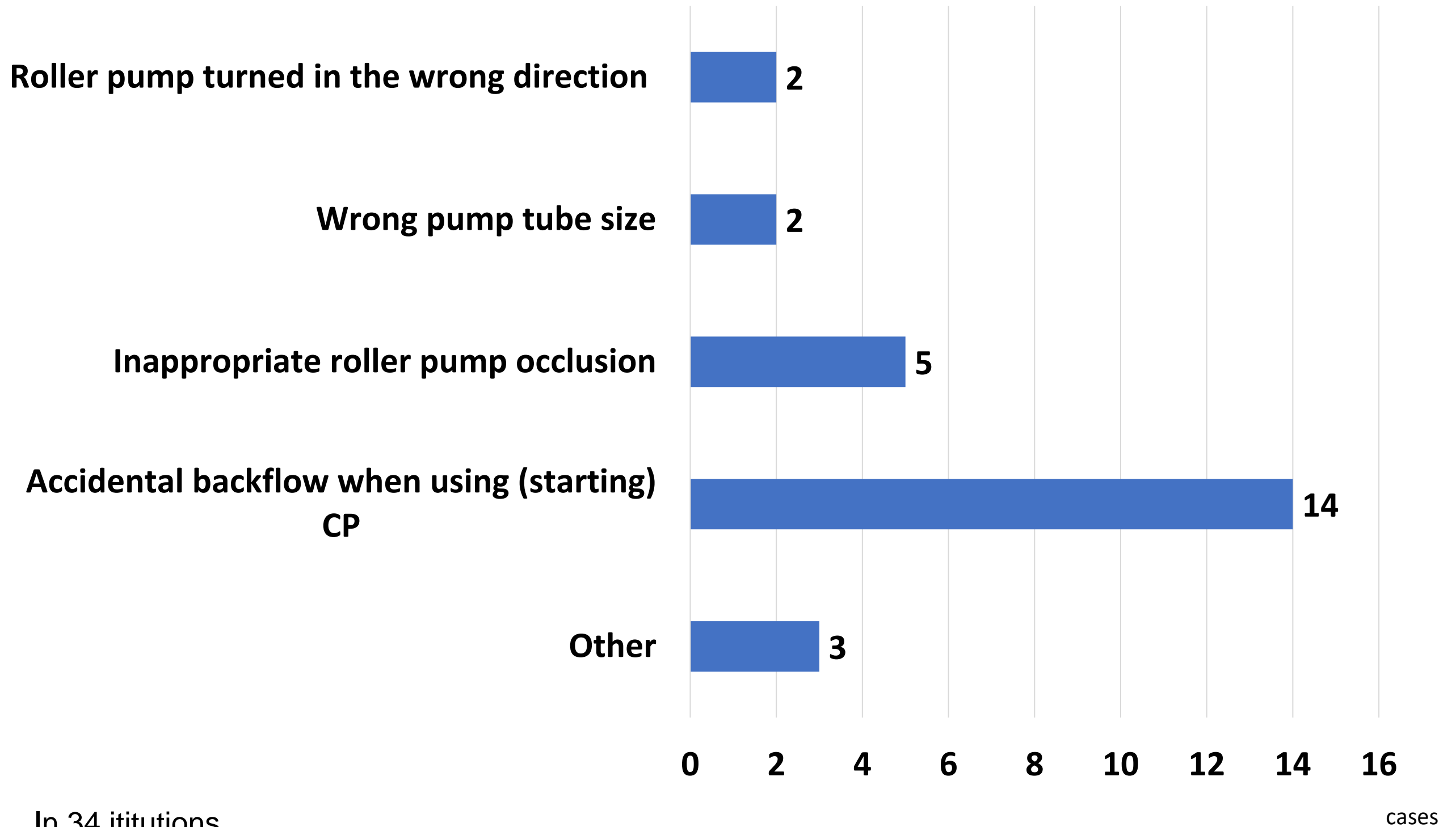
No answer: 17 insts.

\*Among 78,397 CPB cases occurring during the 2-year period.

n = 409 (no answer: 17 insts.)



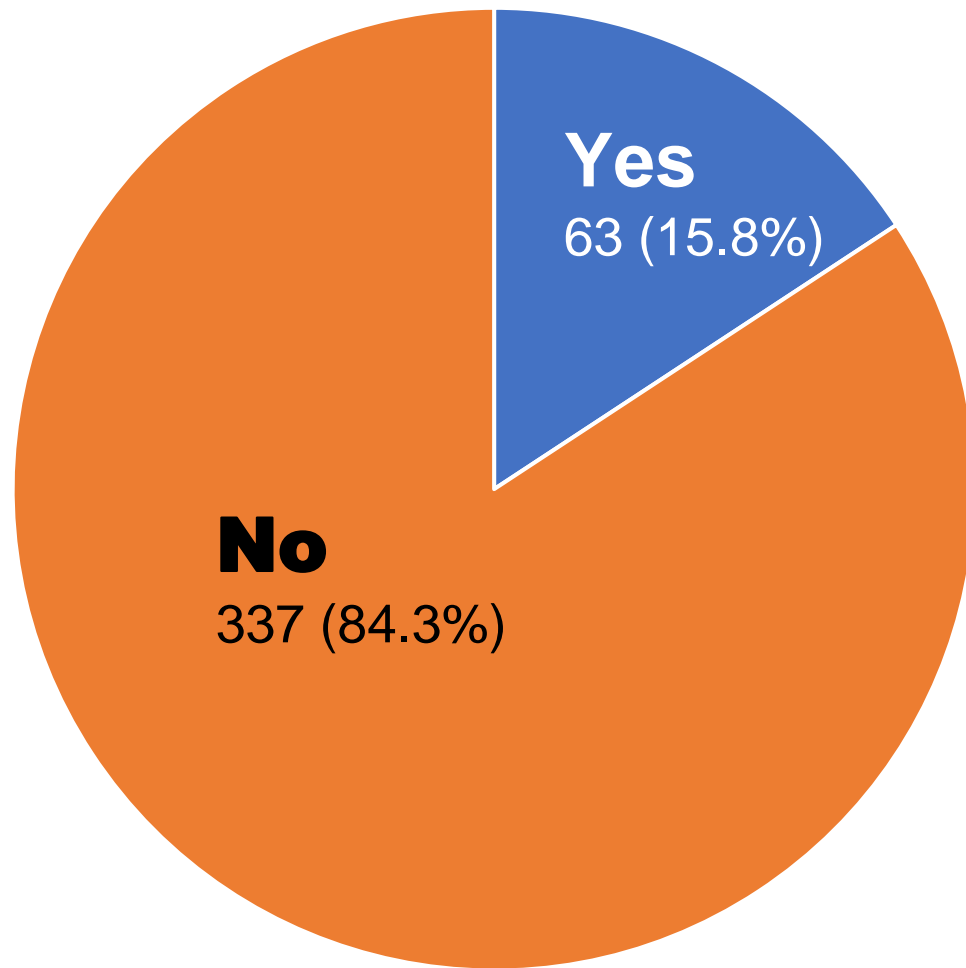
# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



# Blood Pump Mishandling Incidents & Rates

2021 Survey			2019 Survey		2017 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	14	0.02%	12	0.01%	23	0.03%
1 – 3a	9	0.01%	39	0.05%	15	0.02%
3b – 5	0	0 %	0	0%	1	< 0.01%
No answer: 17 insts.			No answer: 23		No answer: 10	
* Among 78,397 cases			** Among 81,455 cases		*** Among 86,483 cases	

# Did you experience an incident/accident involving a Meter or Alarm Device?



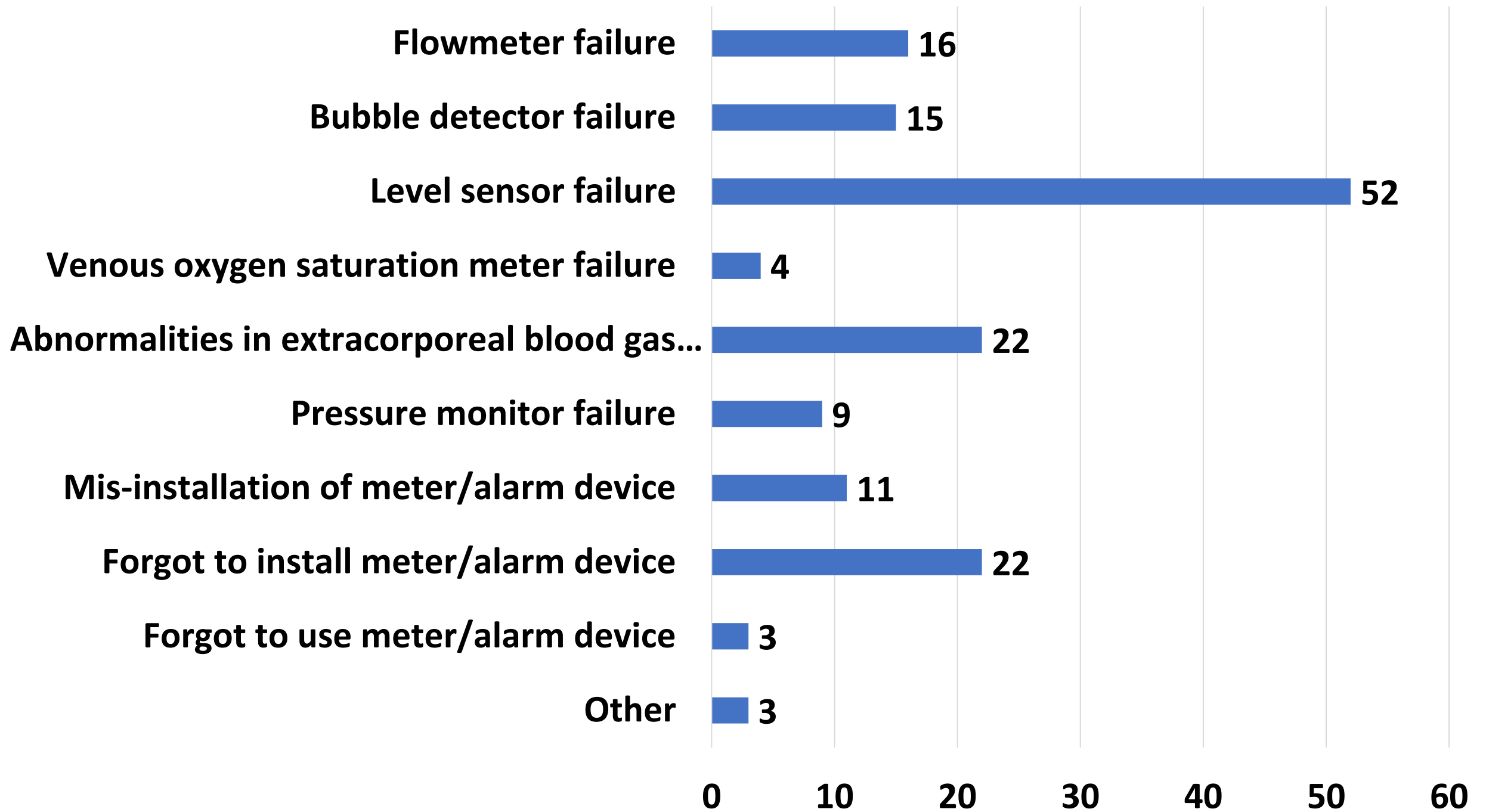
Impact level	No. of cases	Frequency*
0	120	0.15%
1 – 3a	25	0.03%
3b – 5	0	0%

No answer: 13 insts.

\*Among 78,397 CPB cases occurring during the 2-year period.

n = 409 (no answer: 9 insts.)

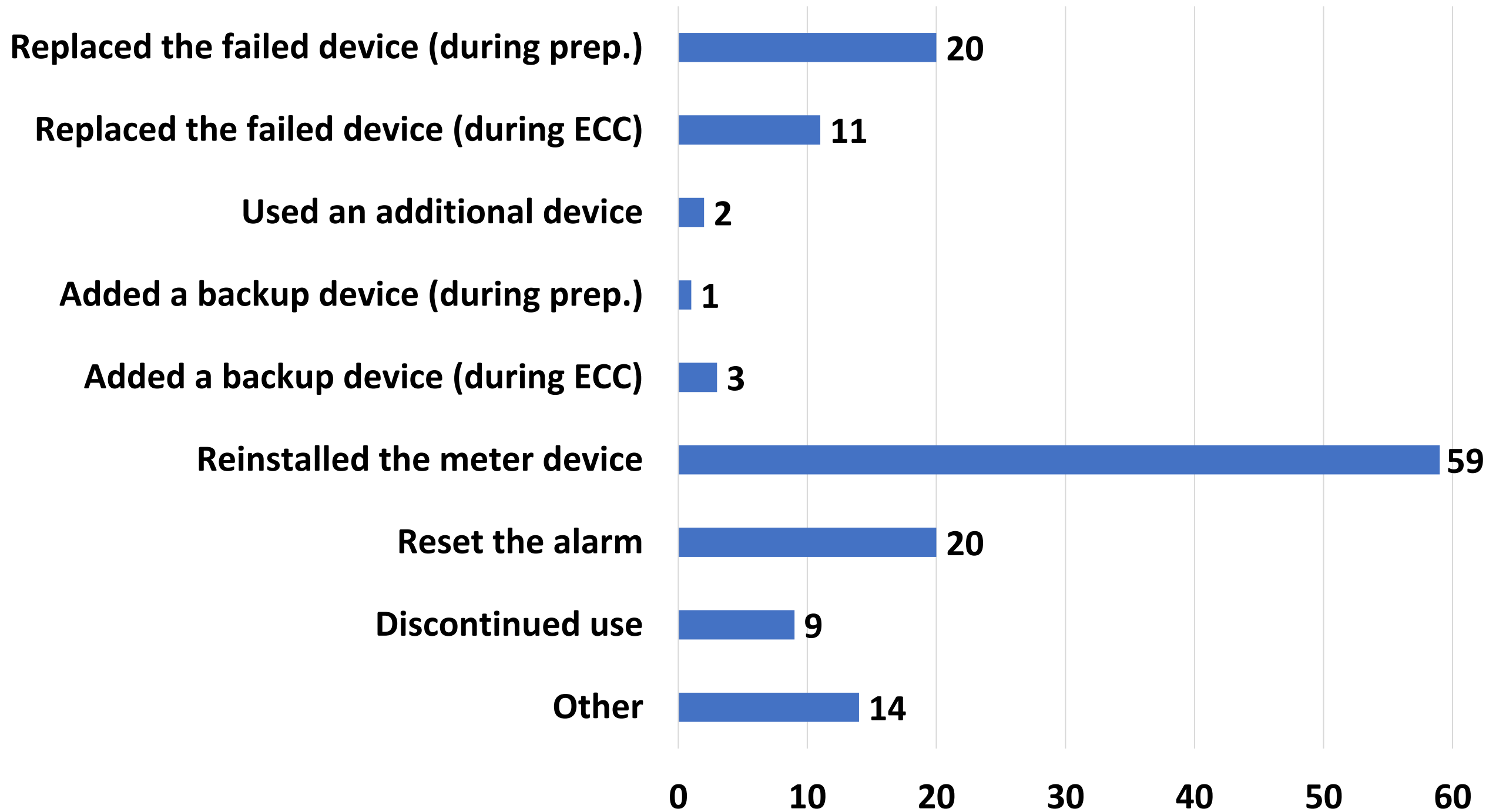
# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 72 institutions  
(incl. 15 that did not answer the question)

cases

# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



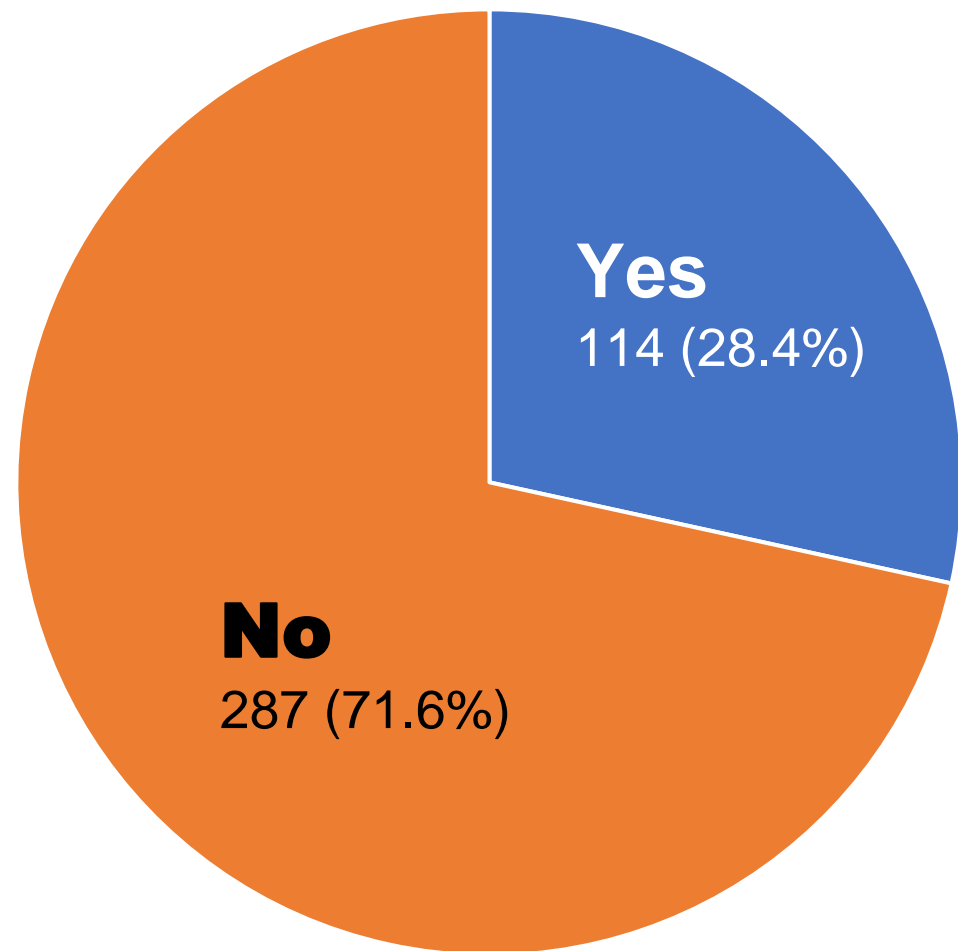
In 72 institutions  
(incl. 18 that did not answer the question)

cases

# Meter/Alarm-Related Incidents & Rates

	2021 Survey		2019 Survey		2017 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	120	0.15%	134	0.16%	167	0.19%
1 – 3a	25	0.03%	26	0.03%	28	0.03%
3b – 5	0	0%	0	0%	0	0%
	No answer: 9 insts.		No answer: 20		No answer: 29	
	* Among 78,397 cases		** Among 81,455 cases		*** Among 86,483 cases	

# Did you experience an incident/accident involving CPB Circuit? (excl. blood pump, oxygenator & arterial filter)



n = 409 (no answer: 8 insts.)

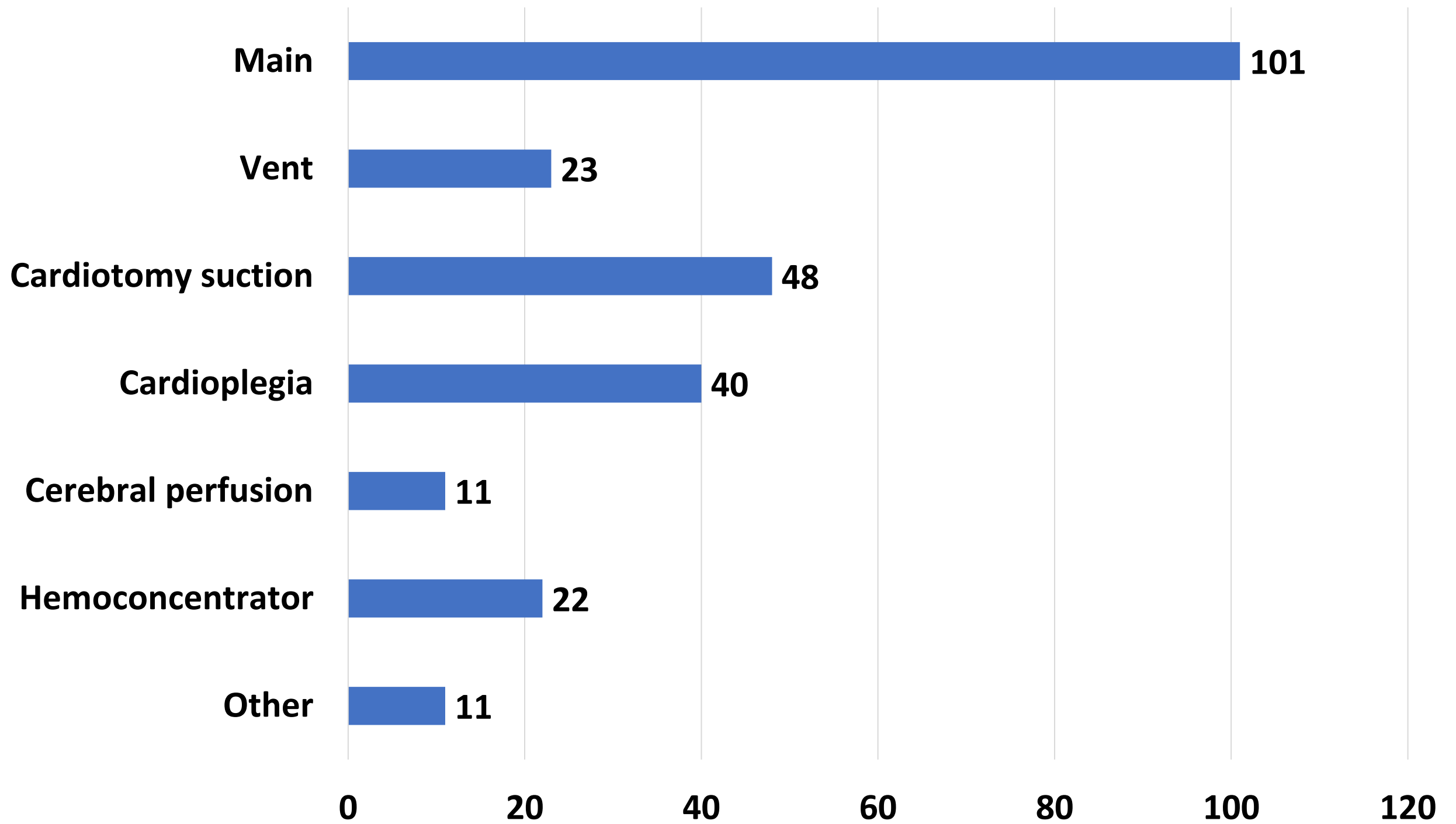
Impact level	No. of cases	Frequency*
0	152	0.19%
1 – 3a	71	0.09%
3b – 5	0	0%

No answer: 13 insts.

\*Among 78,397 CPB cases occurring during the 2-year period.



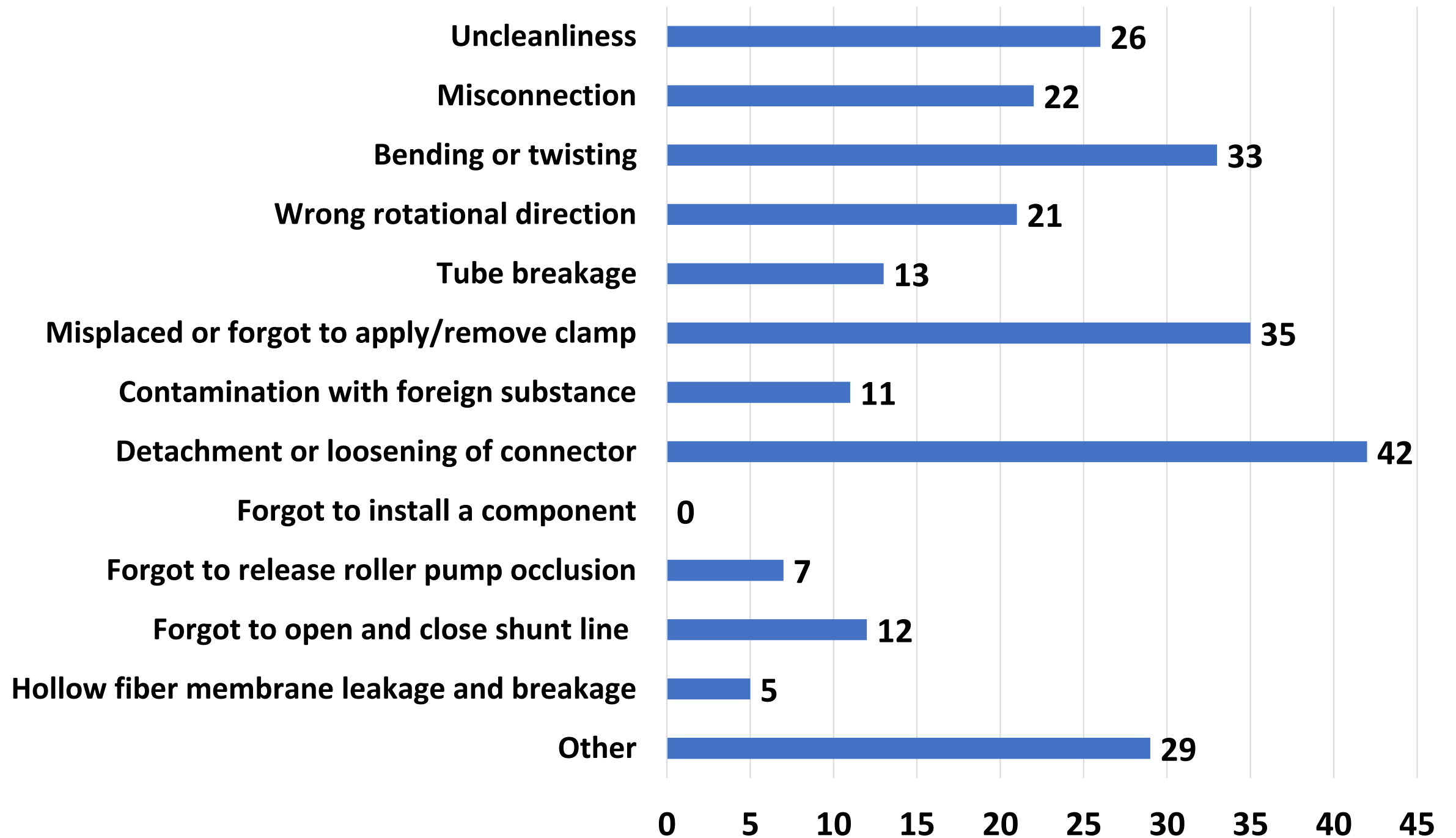
# Which of the following circuit/line was involved in the accident/incident and how many times? (Please choose all that apply.)



In 122 institutions  
(incl. 13 that did not answer the question)

cases

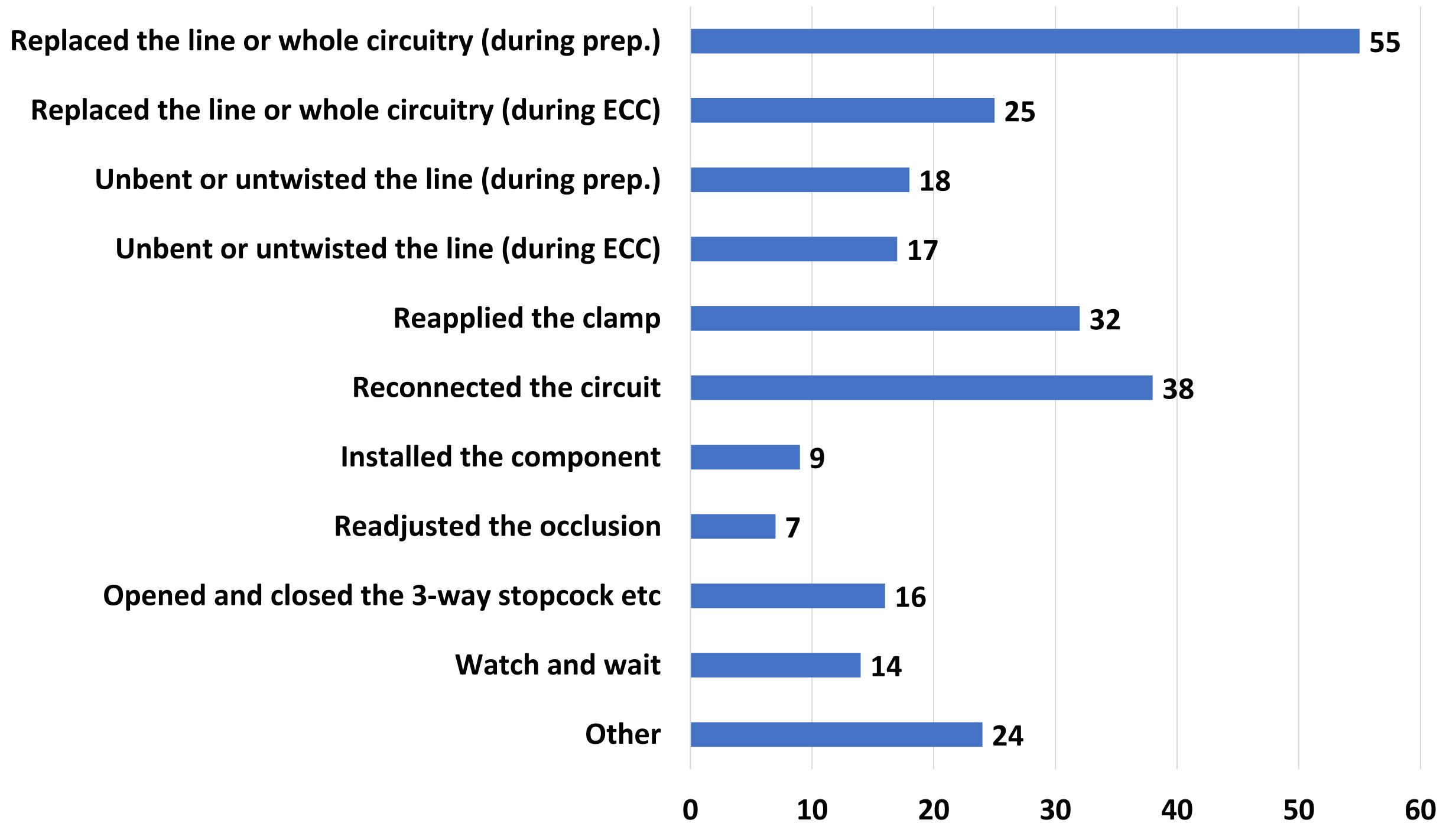
# Which of the following causes was responsible for the accident/incident and how many times? (Please choose all that apply.)



In 122 institutions  
(incl. 7 that did not answer the question)

cases

# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



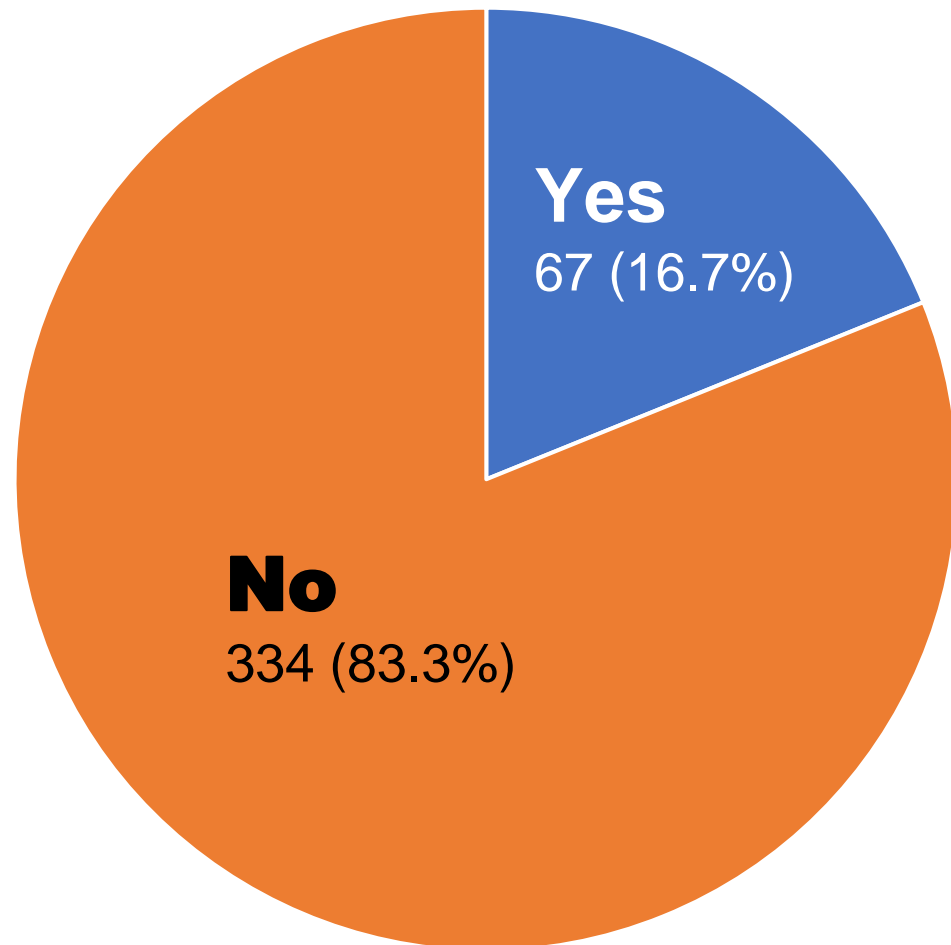
In 122 institutions  
(incl. 10 that did not answer the question)

cases

# CPB-Circuitry-Related Incidents & Rates

2021 Survey		2019 Survey		2017 Survey		
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	152	0.19%	145	0.18%	176	0.20%
1 – 3a	71	0.09%	110	0.14%	74	0.09%
3b – 5	0	0%	2	< 0.01%	6	0.01%
No answer: 13 insts.		No answer: 18		No answer: 17		
* Among 78,397 cases		** Among 81,455 cases		*** Among 86,483 cases		

# Did you experience an incident/accident involving a Cannula?



Impact level	No. of cases	Frequency*
0	48	0.06%
1 – 3a	49	0.06%
3b – 5	11	0.01%

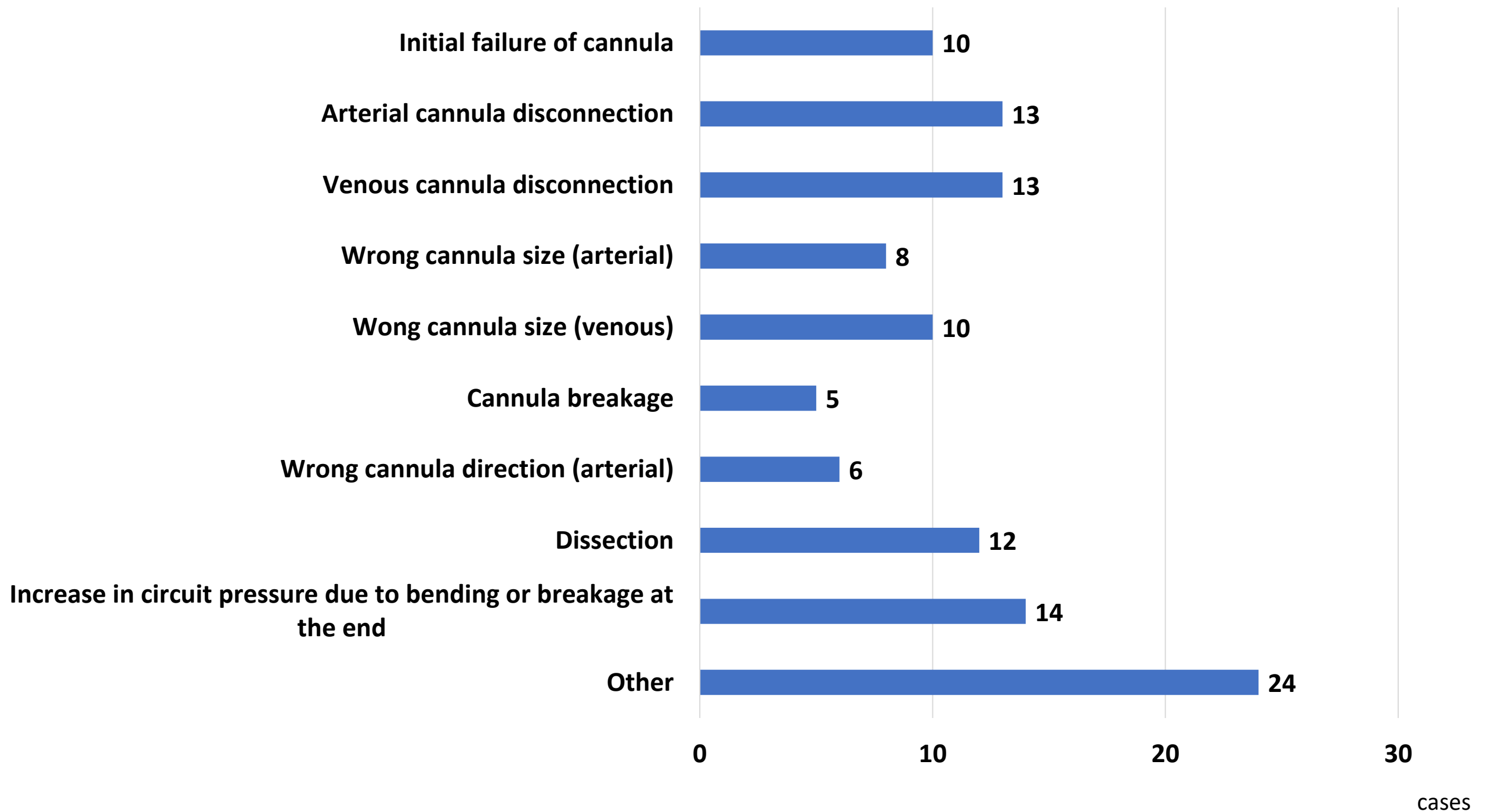
No answer: 10 insts.

\*Among 78,397 CPB cases occurring during the 2-year period.

n = 409 (no answer: 8 insts.)

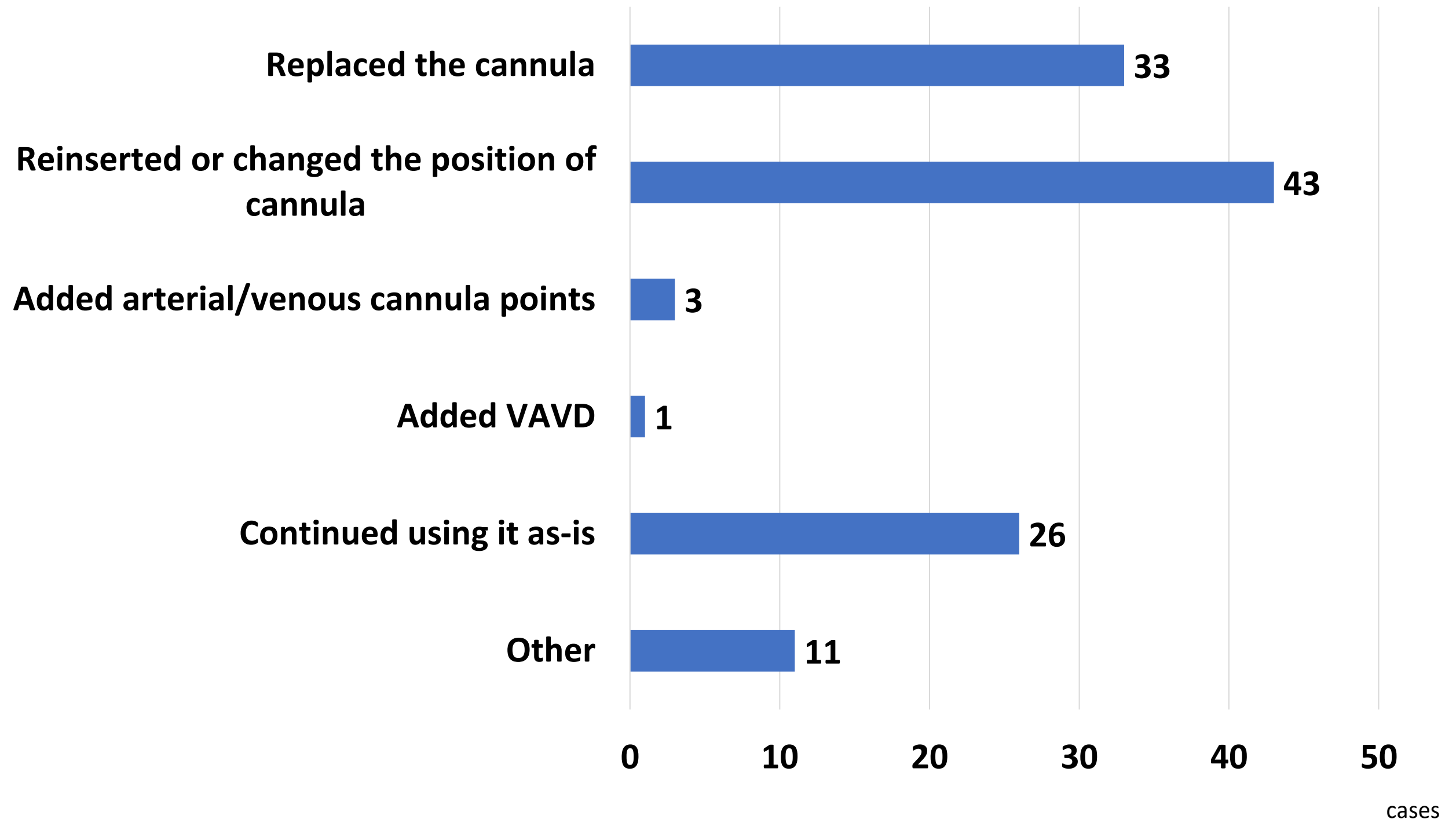


# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 75 institutions  
(incl. 6 that did not answer the question)

# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



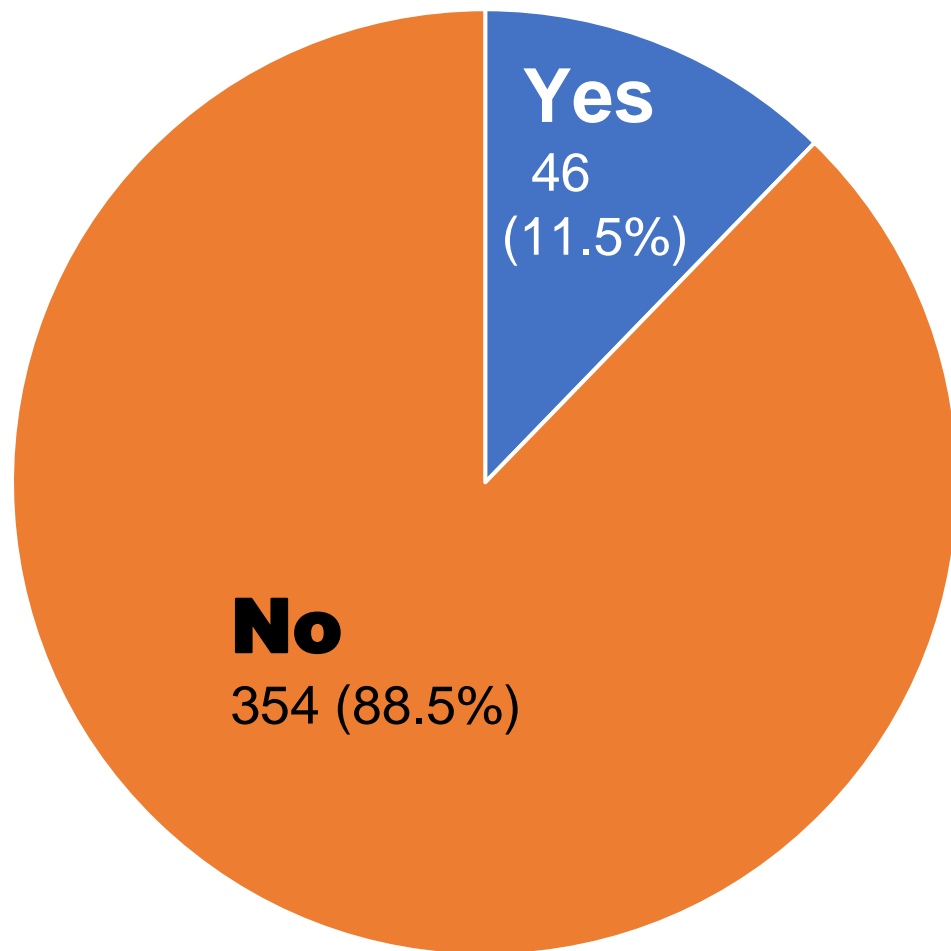
In 75 institutions  
(incl. 7 that did not answer the question)

# Cannula-Related Incidents & Rates

2021 Survey			2019 Survey		2017 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	48	0.06%	41	0.05%	55	0.06%
1 – 3a	49	0.06%	92	0.11%	67	0.08%
3b – 5	11	0.01%	16	0.02%	12	0.01%
No answer: 10 insts.			No answer: 14		No answer: 7	
* Among 78,397 cases			** Among 81,455 cases		*** Among 86,483 cases	



# Was there an instance of Forgetting to Supply Oxygen at the start of ECC?



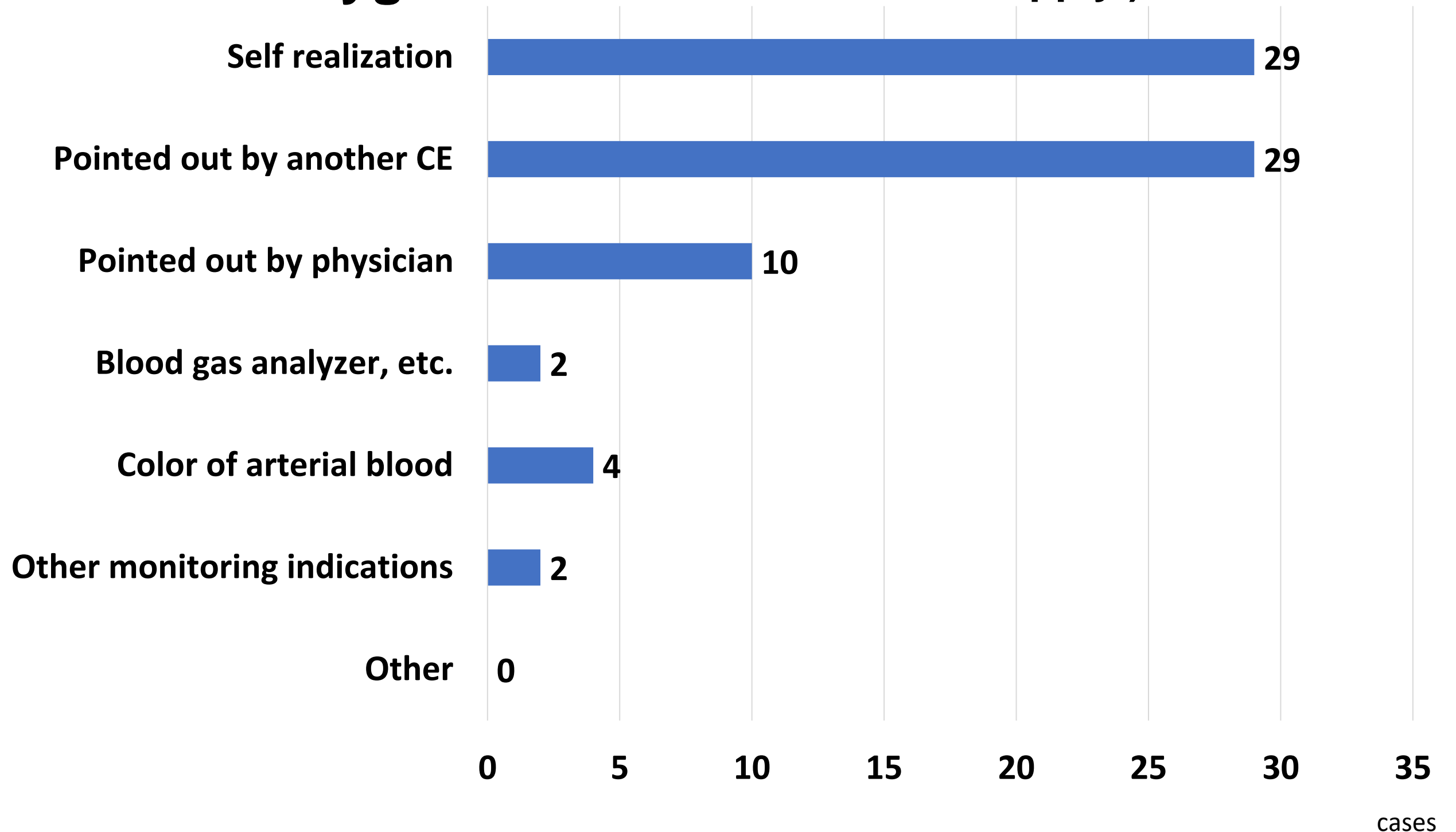
n = 409 (no answer: 9 insts.)

Impact level	No. of cases	Frequency*
0	38	0.05%
1 – 3a	32	0.04%
3b – 5	0	0%

No answer: 9 insts.

\*Among 78,397 CPB cases occurring during the 2-year period.

# What made you realize that you forgot to supply oxygen? (Please choose all that apply.)



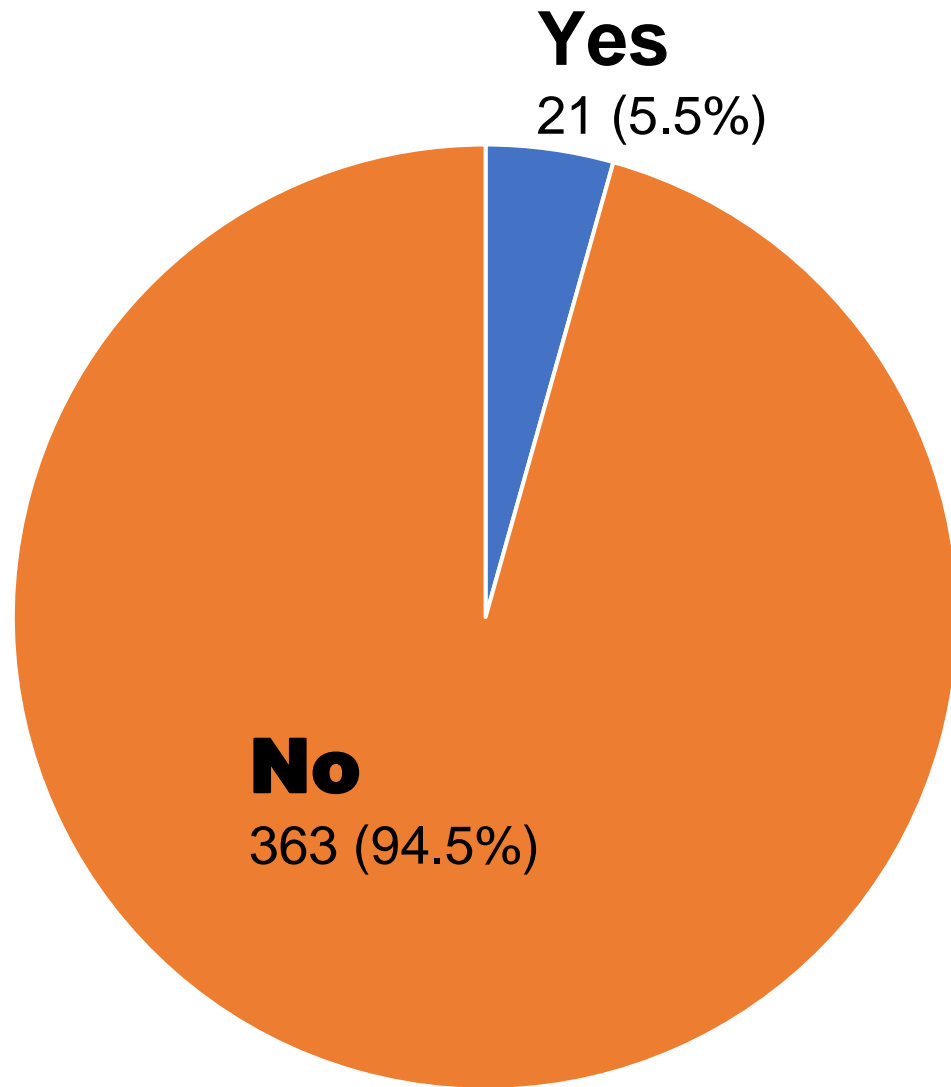
In 55 institutions  
(incl. 9 that did not answer the question)



# Incidents & Rates of Forgetting to Supply Oxygen at the Start of ECC

2021 Survey			2019 Survey		2017 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	38	0.05%	44	0.06%	65	0.08%
1 – 3a	32	0.04%	34	0.04%	46	0.05%
3b – 5	0	0%	0	0%	0	0%
No answer: 9 insts.			No answer: 8		No answer: 6	
* Among 78,397 cases			** Among 81,455 cases		*** Among 86,483 cases	

# Did you experience an Inadvertent Air Entry into the Bloodstream?



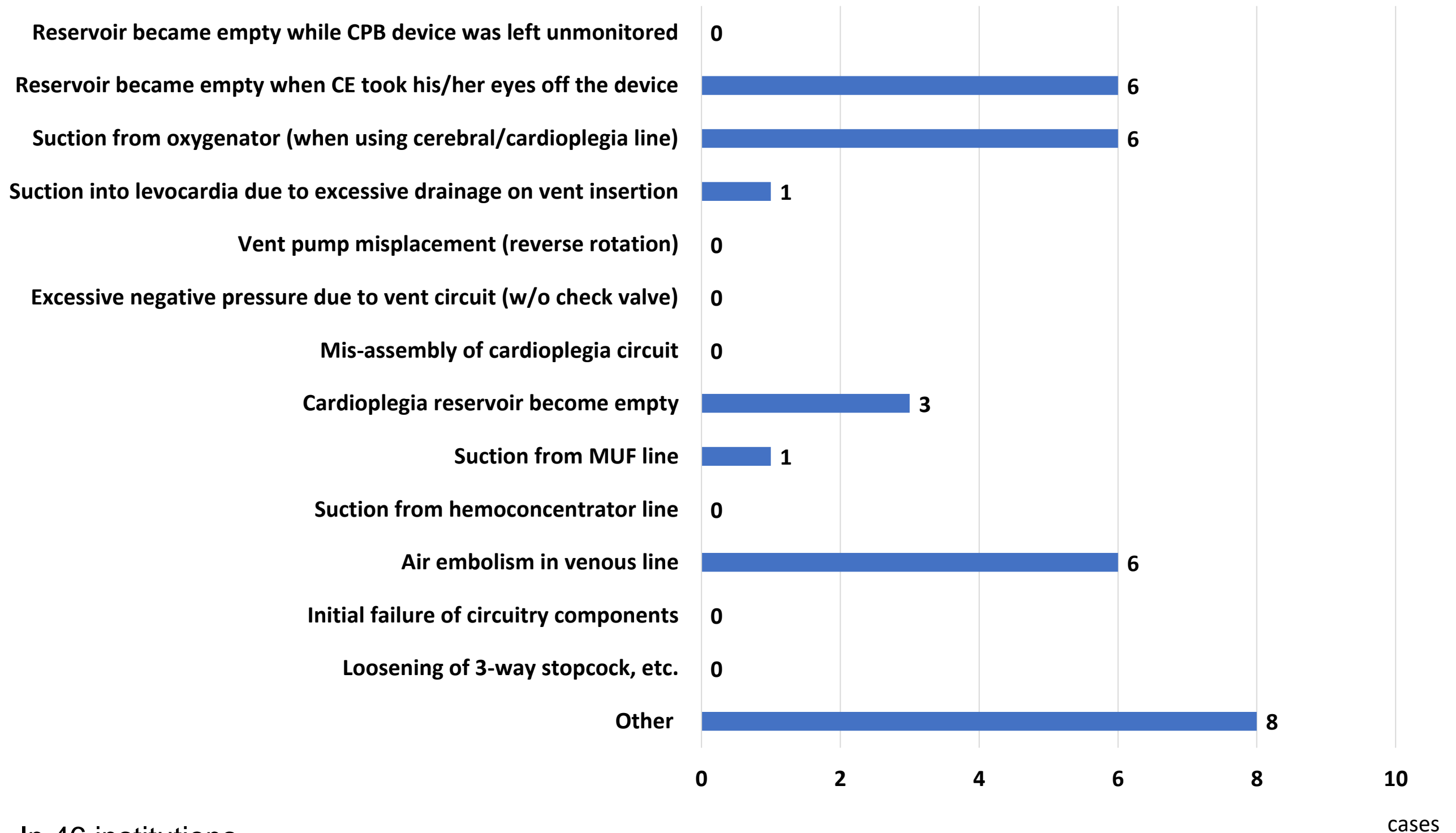
n = 409 (no answer: 25 insts.)

Impact level	No. of cases	Frequency*
1 – 3a	28	0.04%
3b – 5	3	< 0.01%

No answer: 26 insts.

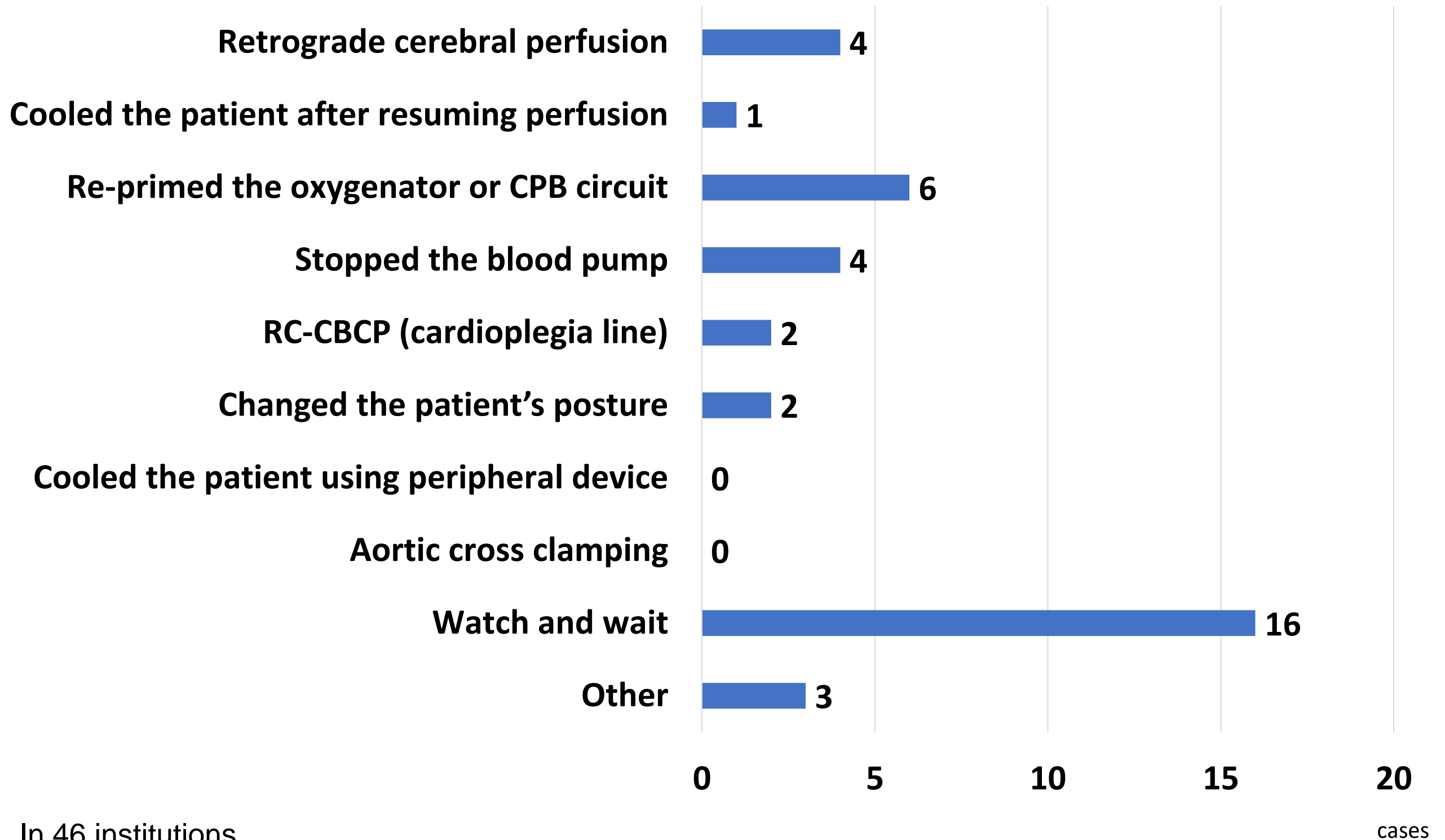
\*Among 78,397 CPB cases occurring during the 2-year period.

# Which of the following caused the air entry and how many times? (Please choose all that apply.)



In 46 institutions  
(incl. 26 that did not answer the question)

# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)

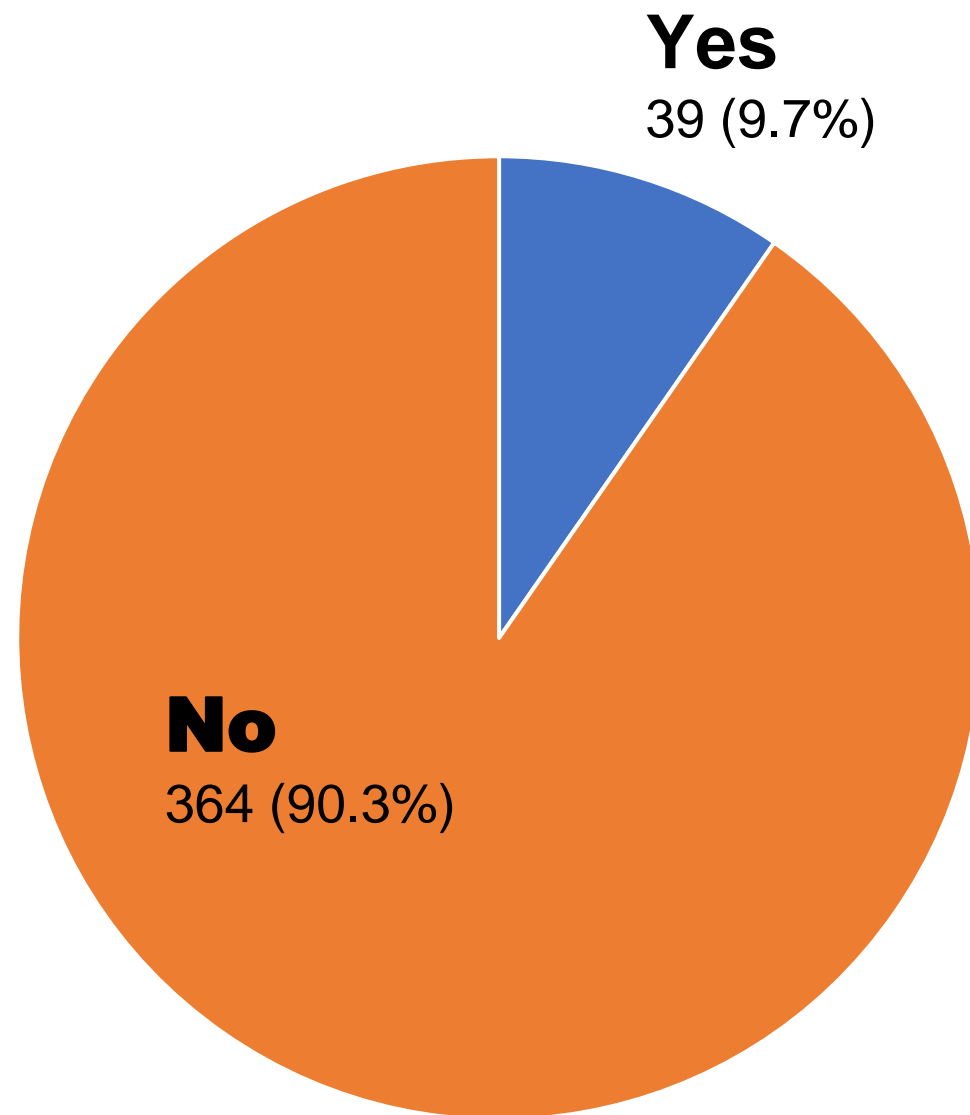


In 46 institutions  
(incl. 26 that did not answer the question)

# Incidents & Rates of Inadvertent Air Entry

2021 Survey			2019 Survey		2017 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	–	–	–	–	–	–
1 – 3a	28	0.04%	17	0.02%	16	0.02%
3b – 5	3	< 0.01%	2	< 0.01%	5	< 0.01%
No answer: 26 insts.			No answer: 26		No answer: 27	
* Among 78,397 cases			** Among 81,455 cases		*** Among 86,483 cases	

# Was there an instance of Unexpected Drainage from Arterial or Venous Cannula after ECC?



Impact level	No. of cases	Frequency*
1 – 3a	42	0.05%
3b – 5	2	< 0.01%

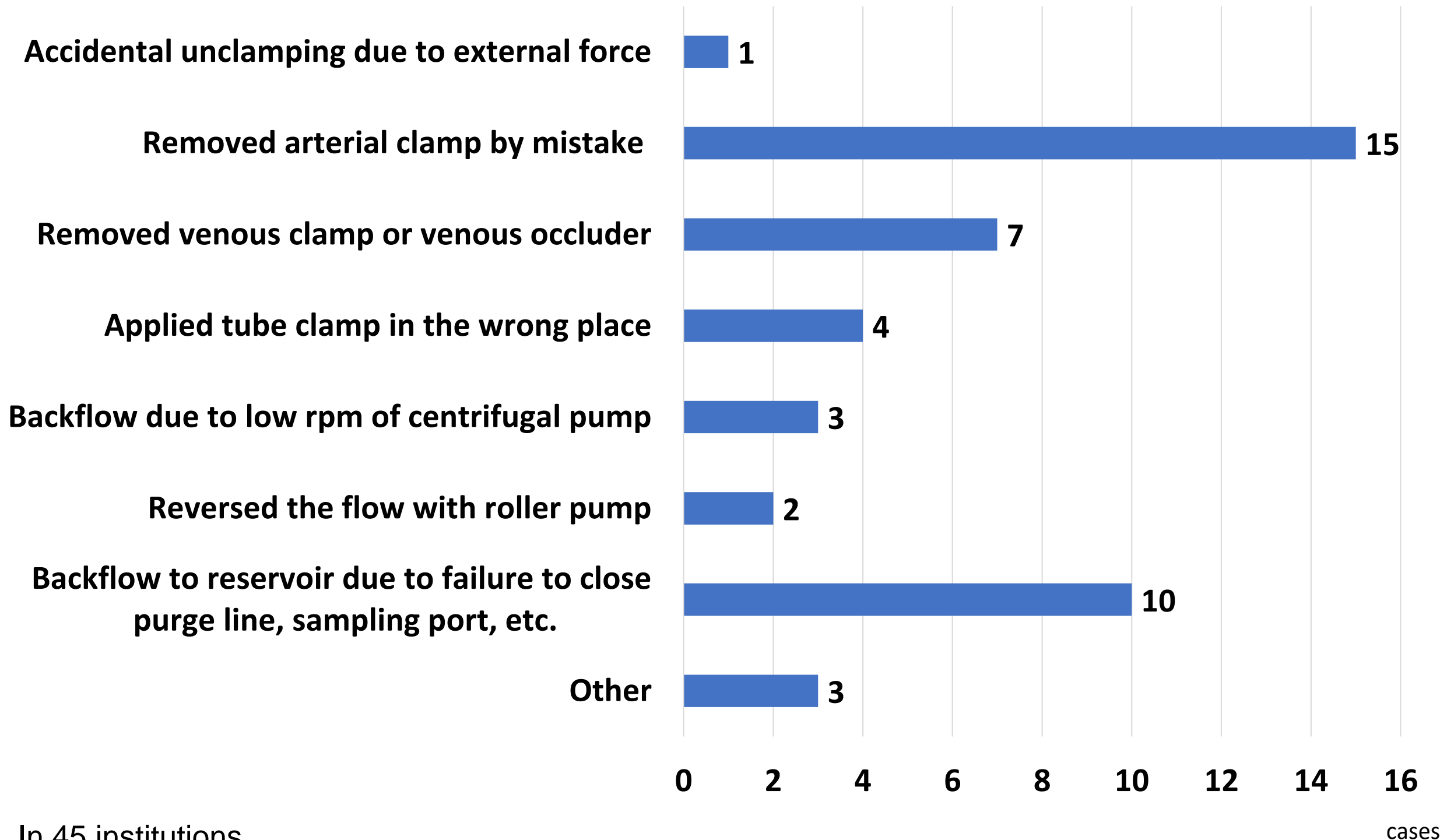
No answer: 6 insts.

\*Among 78,397 CPB cases occurring during the 2-year period.

n = 409 (no answer: 6 insts.)

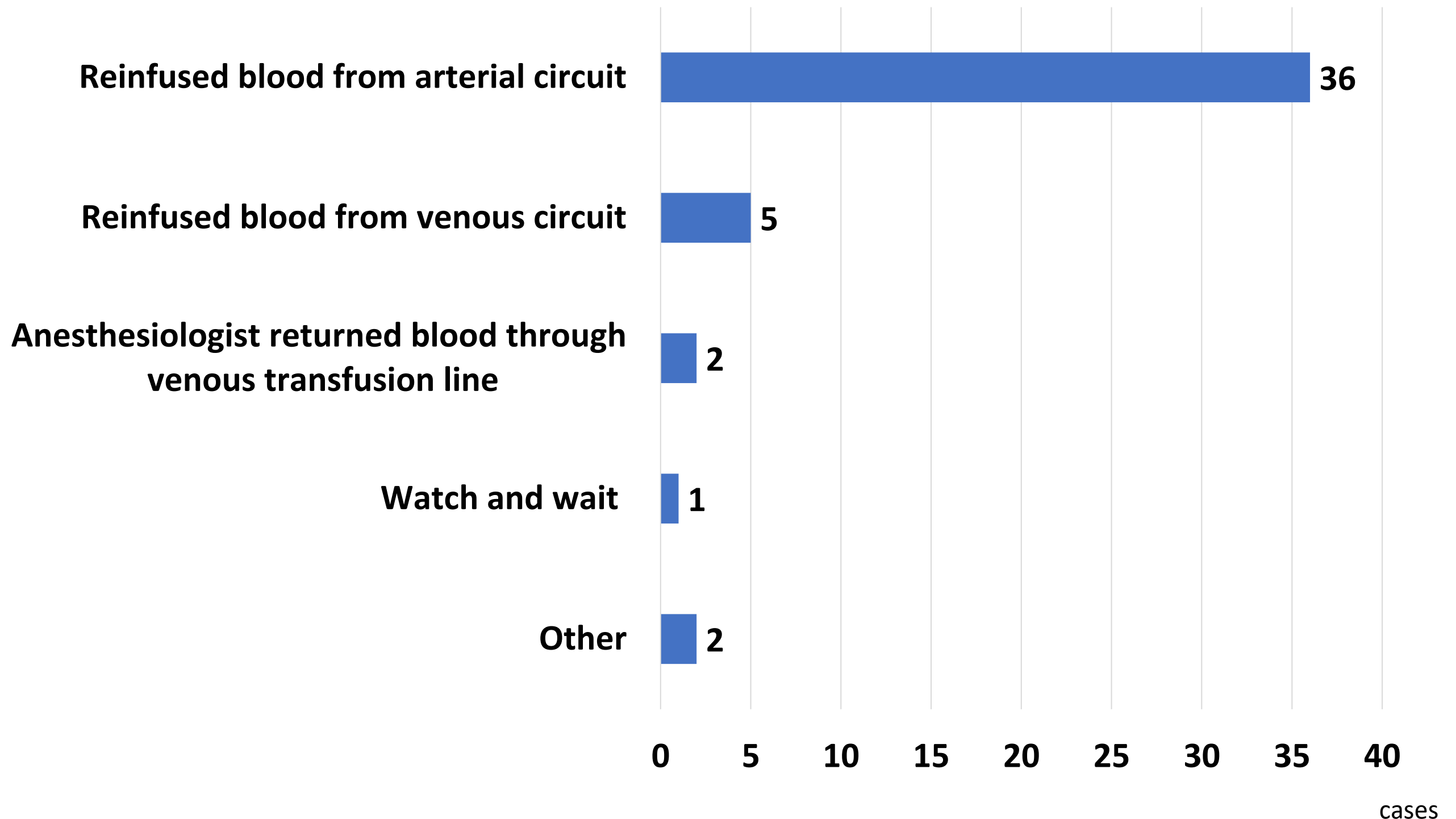


# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 45 institutions  
(incl. 6 that did not answer the question)

## Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



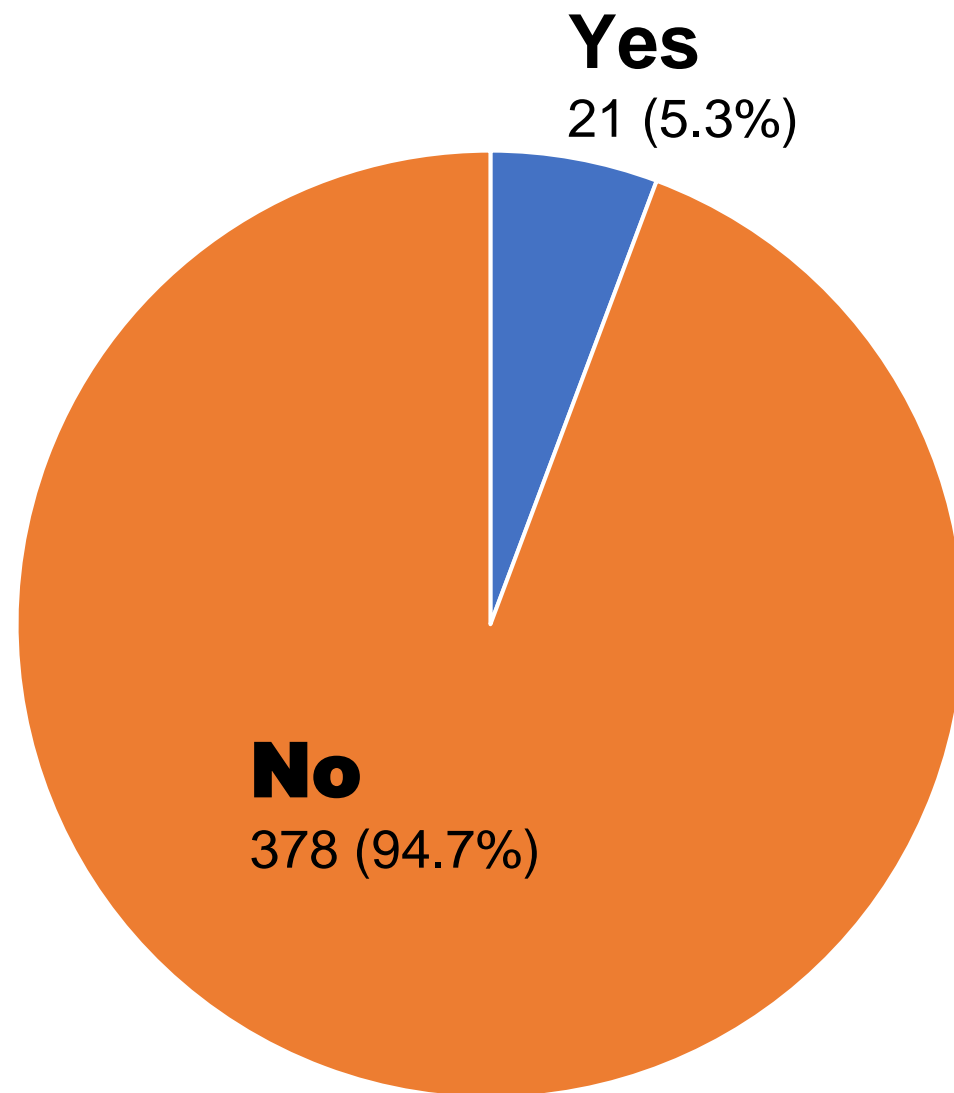
In 45 institutions  
(incl. 7 that did not answer the question)

# Incidents & Rates of Unexpected Blood Drainage after ECC

Impact level	2021 Survey		2019 Survey		2017 Survey	
	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	–	–	–	–	–	–
1 – 3a	42	0.05%	65	0.08%	74	0.09%
3b – 5	2	< 0.01%	4	< 0.01%	2	< 0.01%
	No answer: 6 insts.		No answer: 4		No answer: 11	
	* Among 78,397 cases		** Among 81,455 cases		*** Among 86,483 cases	

# Did you experience a Medication Error?

(excluding errors in cardioplegia)



Impact level	No. of cases	Frequency*
0	1	0.01%
1 – 3a	19	0.02%
3b – 5	0	0%

No answer: 10 insts.

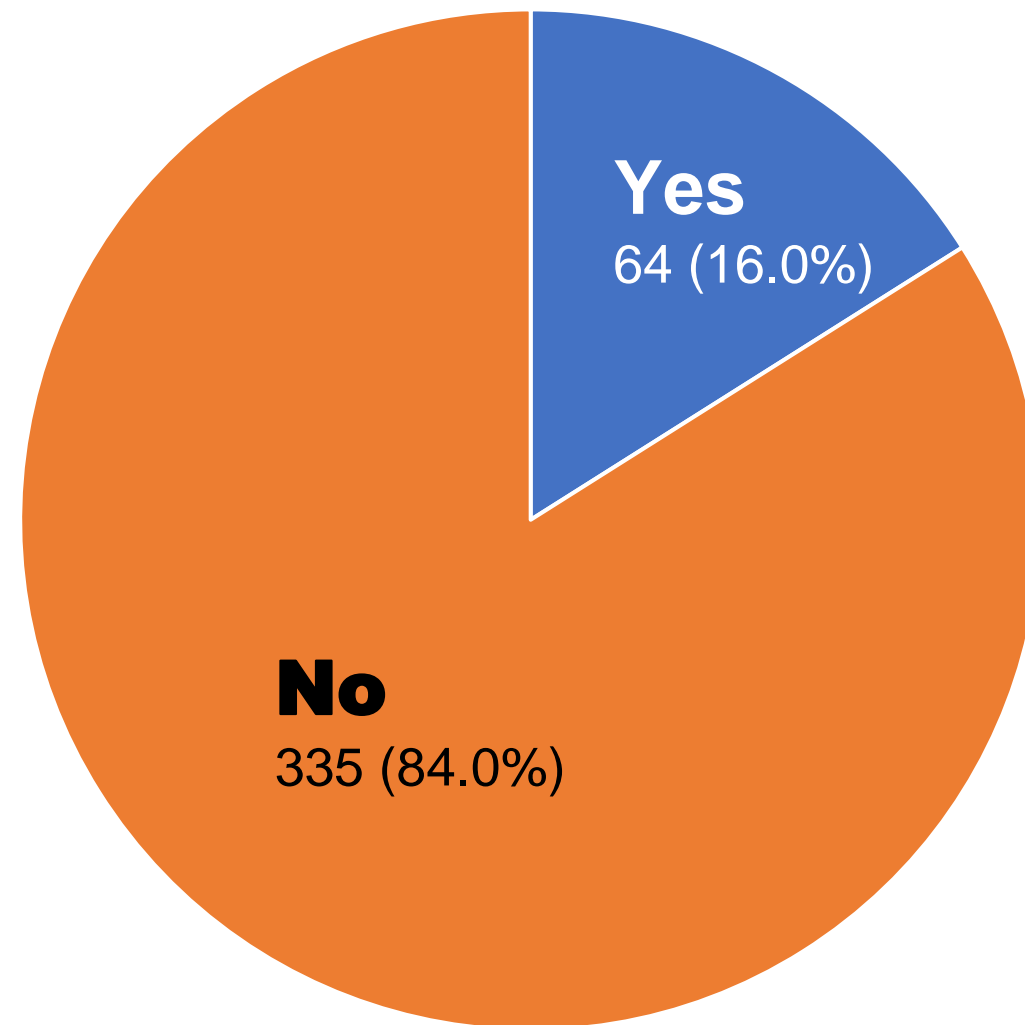
\*Among 78,397 CPB cases occurring during the 2-year period.

n = 409 (no answer: 10 insts.)

# Incidents & Rates of Medication Errors

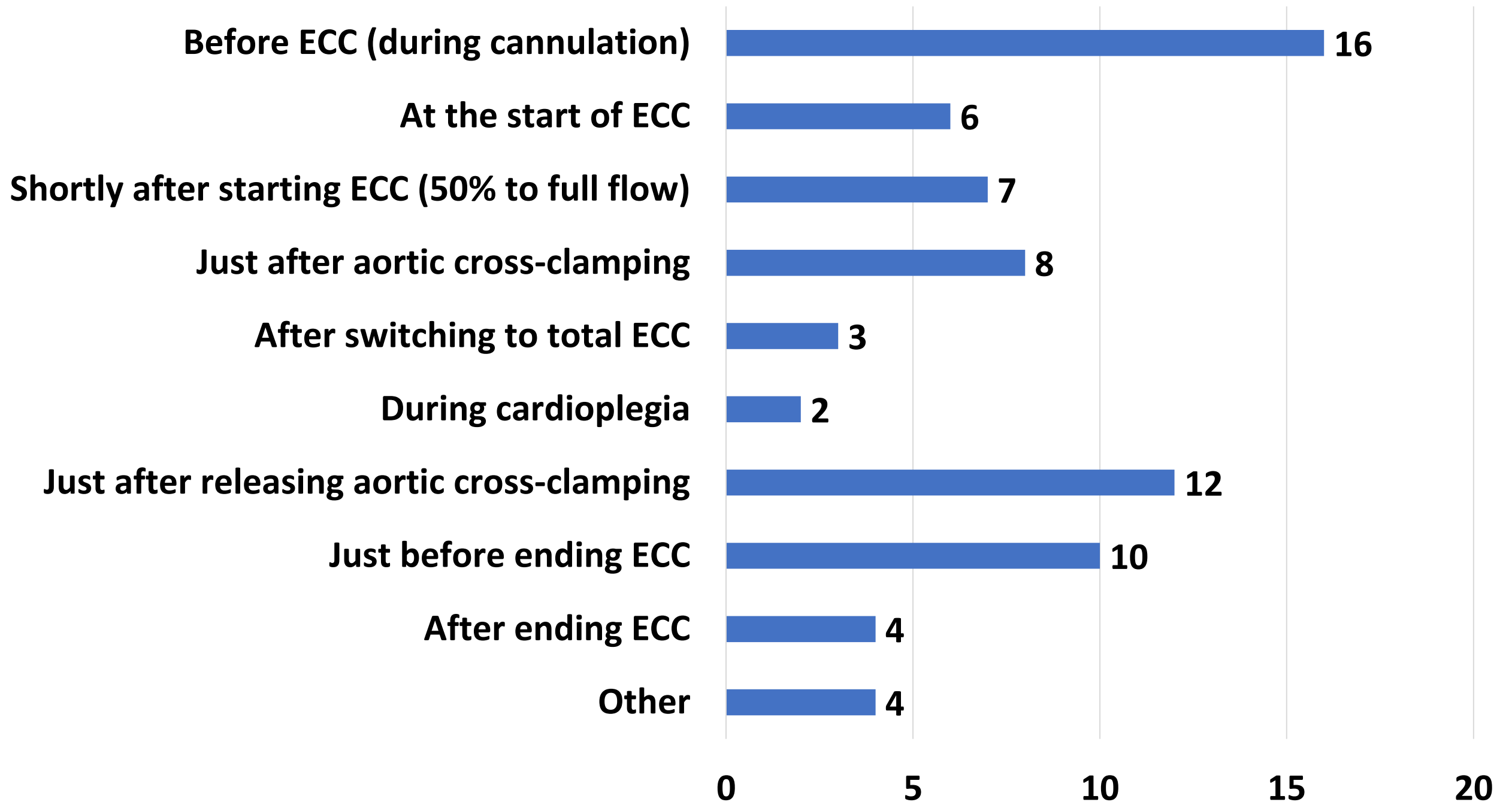
2021 Survey			2019 Survey		2017 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	1	0.01%	8	0.01%	17	0.02%
1 – 3a	19	0.02%	19	0.02%	10	0.01%
3b – 5	0	0%	0	0%	3	< 0.01%
No answer: 10 insts.			No answer: 14		No answer: 1	
* Among 78,397 cases			** Among 81,455 cases		*** Among 76,216 cases	

# Did you experience an Intraoperative Dissection?



n = 409 (no answer: 10 insts.)

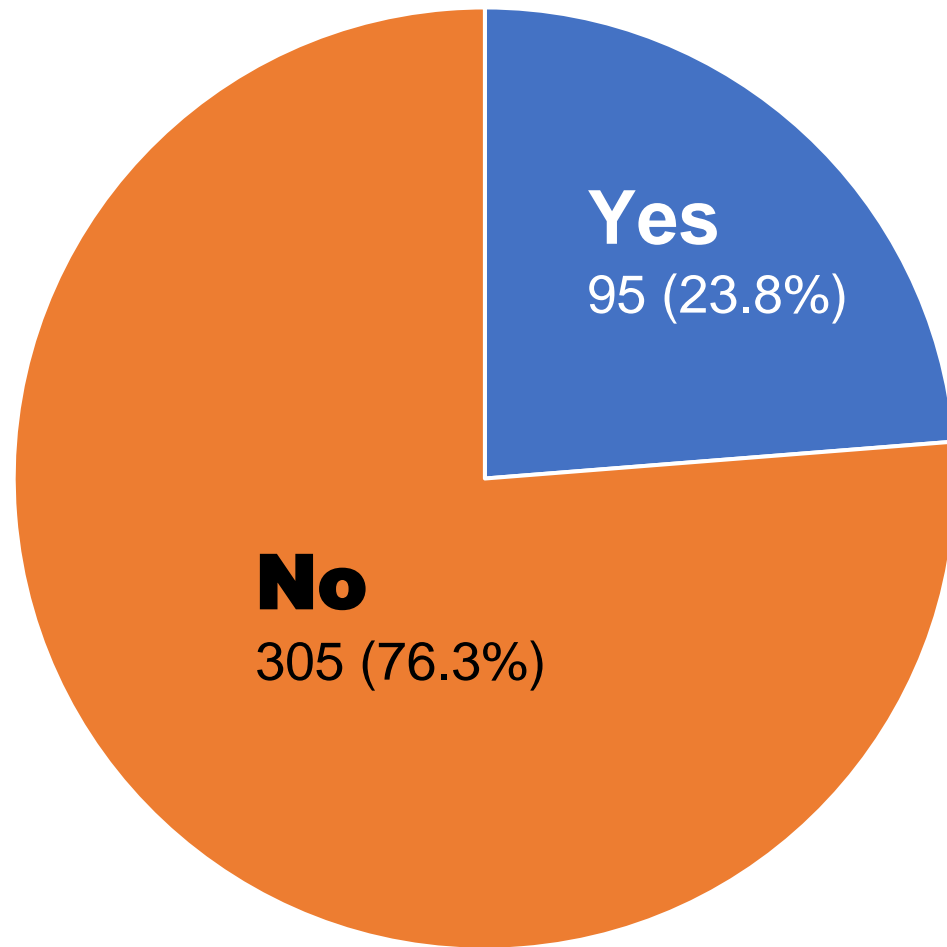
# When did you notice it? (Please choose all that apply.)



In 74 institutions  
(incl. 12 that did not answer the question)

cases

# Did you experience an incident/accident related to Cardioplegia?



Impact level	No. of cases	Frequency*
0	95	0.12%
1 – 3a	87	0.11%
3b – 5	2	< 0.01%

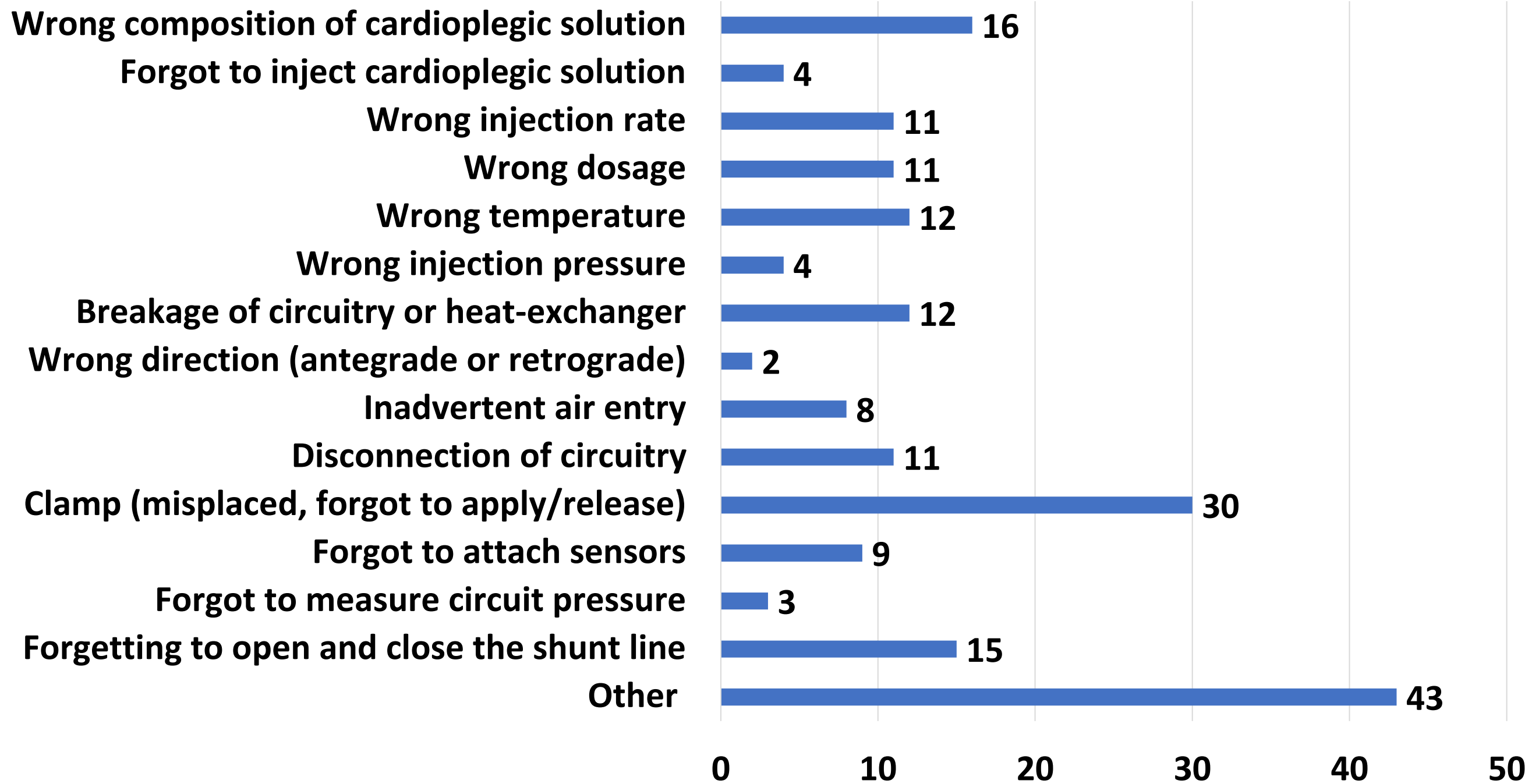
No answer: 16 insts.

\*Among 78,397 CPB cases occurring during the 2-year period.

n = 409 (no answer: 9 insts.)



# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



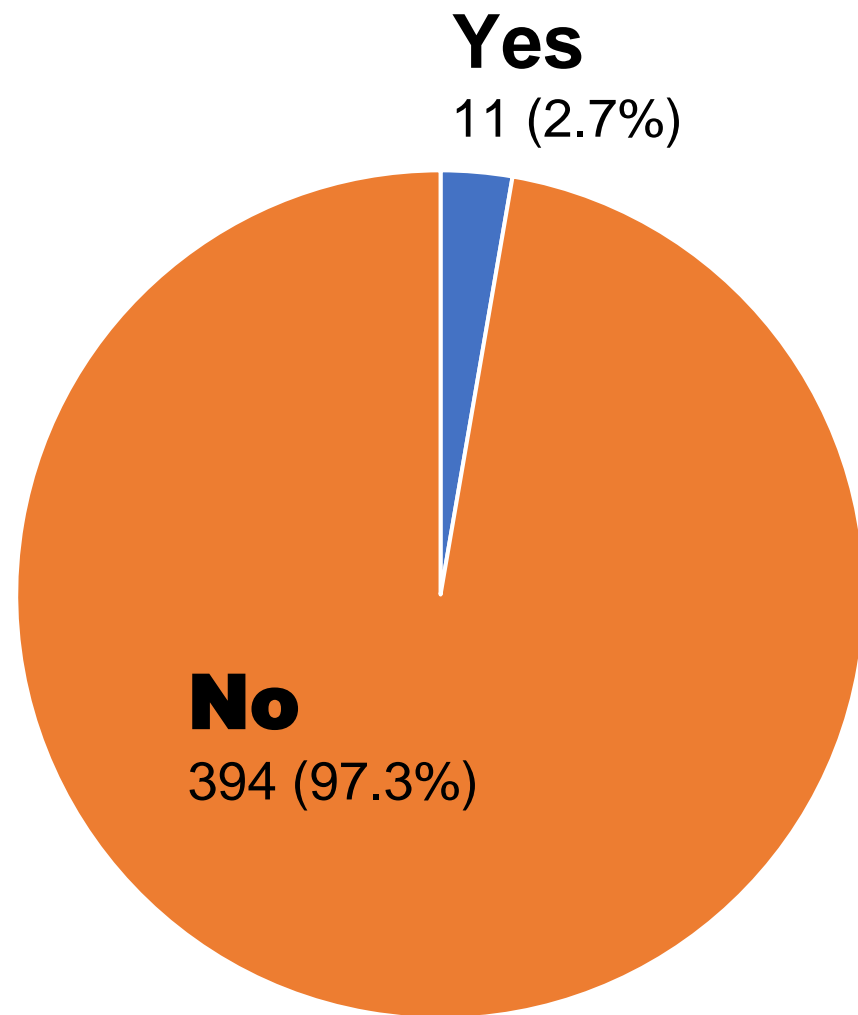
In 104 institutions  
(incl. 16 that did not answer the question)

cases

# Cardioplegia-Related Incidents & Rates

2021 Survey			2019 Survey		2017 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	95	0.12%	136	0.17%	128	0.15%
1 – 3a	87	0.11%	114	0.14%	80	0.09%
3b – 5	2	< 0.01%	2	< 0.01%	1	< 0.01%
No answer: 16 insts.			No answer: 10		No answer: 6	
* Among 78,397 cases			** Among 81,455 cases		*** Among 86,483 cases	

# Did you experience a Power Interruption or Outage during CPB?



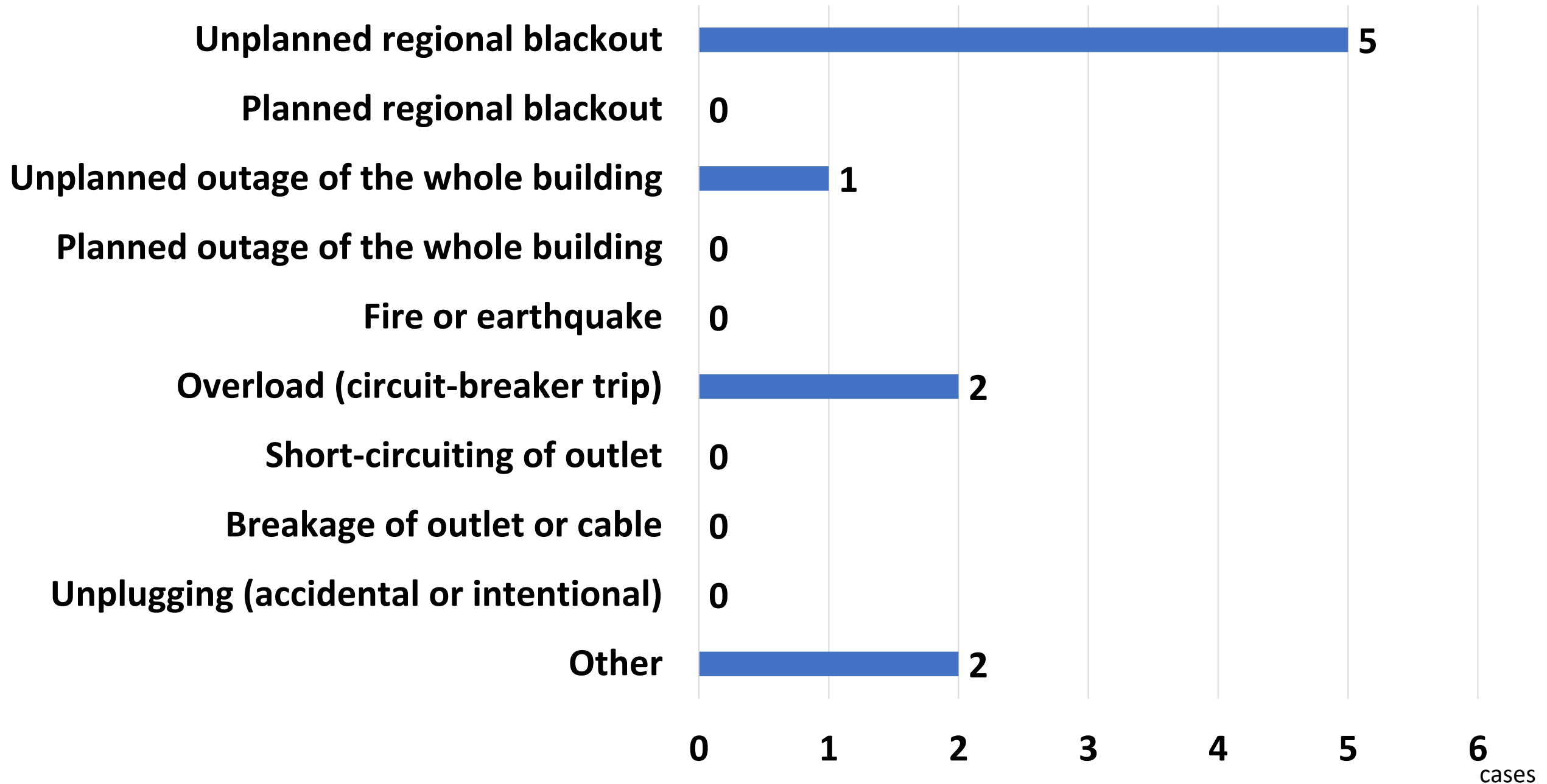
n = 409 (no answer: 4 insts.)

Impact level	No. of cases	Frequency*
0	6	< 0.01%
1 – 3a	3	< 0.01%
3b – 5	0	0%

No answer: 6 insts.

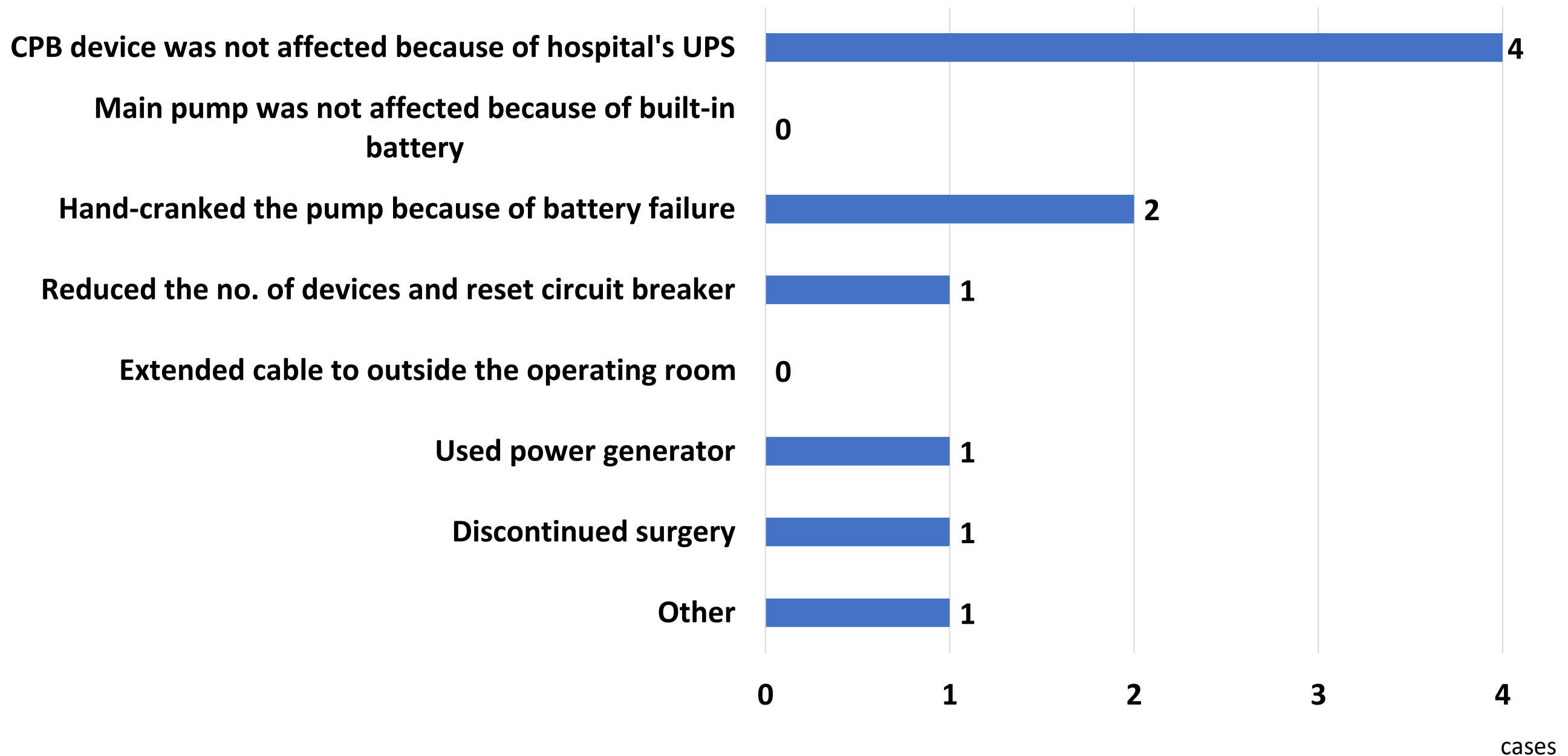
\*Among 78,397 CPB cases occurring during the 2-year period.

# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 15 institutions  
(incl. 5 that did not answer the question)

# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)

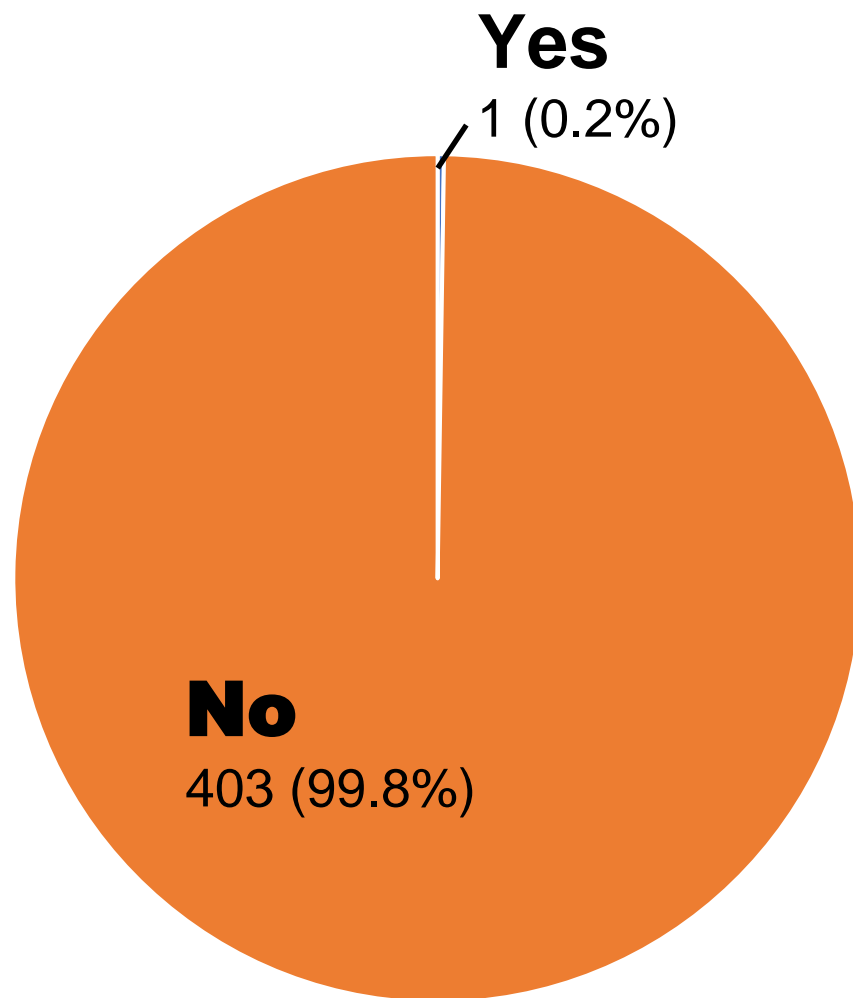


In 15 institutions  
(incl. 5 that did not answer the question)

# Incidents & Rates related to Power Interruption/Outage

Impact level	2021 Survey		2019 Survey		2017 Survey	
	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	6	< 0.01%	11	0.01%	14	0.02%
1 – 3a	3	< 0.01%	5	0.01%	12	0.01%
3b – 5	0	0%	0	0%	0	0%
	No answer: 6 insts.		No answer: 2		No answer: 0	
	* Among 78,397 cases		** Among 81,455 cases		*** Among 86,483 cases	

# Did you experience an Interruption of Medical Gas Supply during CPB?



Impact level	No. of cases	Frequency*
1 – 3a	1	< 0.01%
3b – 5	-	0%

No answer: 5 insts.

\*Among 78,397 CPB cases occurring during the 2-year period.

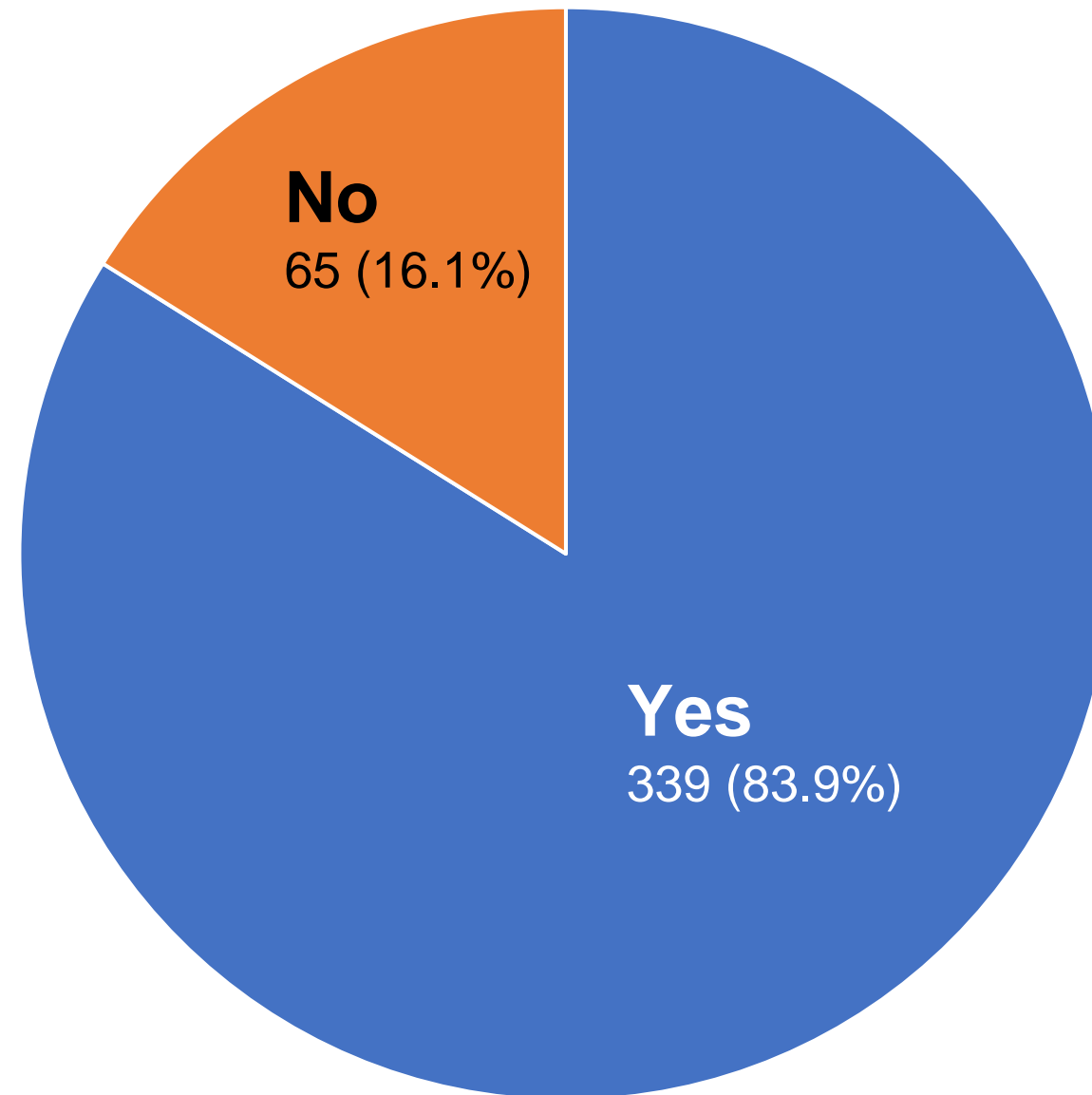
n = 403 (no answer: 5 insts.)

# Incidents & Rates related to Medical Gas Supply Interruption

2021 Survey			2019 Survey		2017 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	-	-	-	-	0	0%
1 – 3a	1	< 0.01%	1	< 0.01%	0	0%
3b – 5	0	0%	0	0%	0	0%
No answer: 5 insts.			No answer: 2		No answer: 8	
* Among 78,379cases			** Among 81,455 cases		*** Among 86,483 cases	



# Do you have an emergency kit in place?

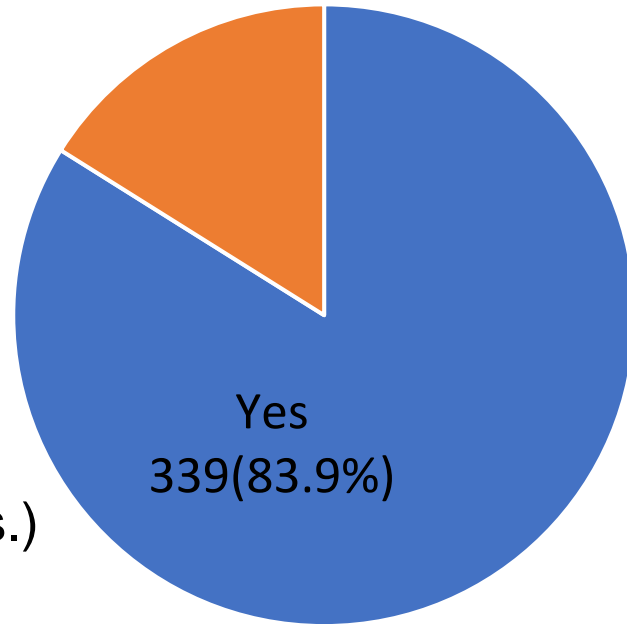


n = 409 (no answer: 5 insts.)

# Do you have an emergency kit in place?

2021

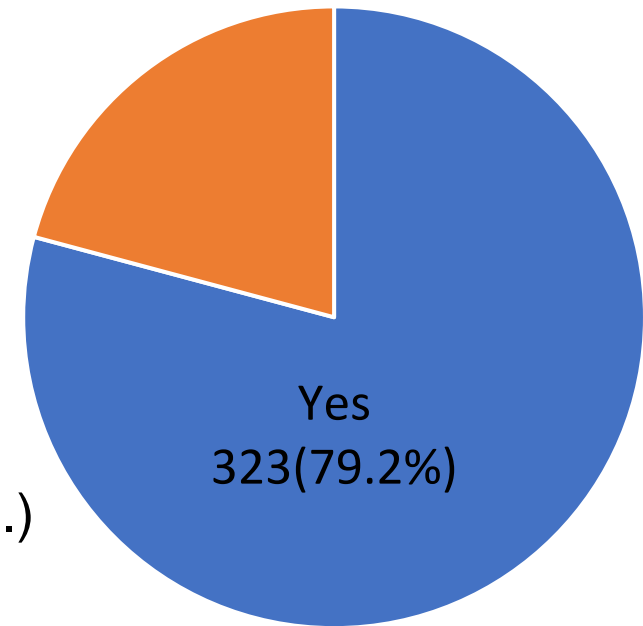
No  
65 (16.1%)



n = 409  
(no answer: 5 insts.)

2019

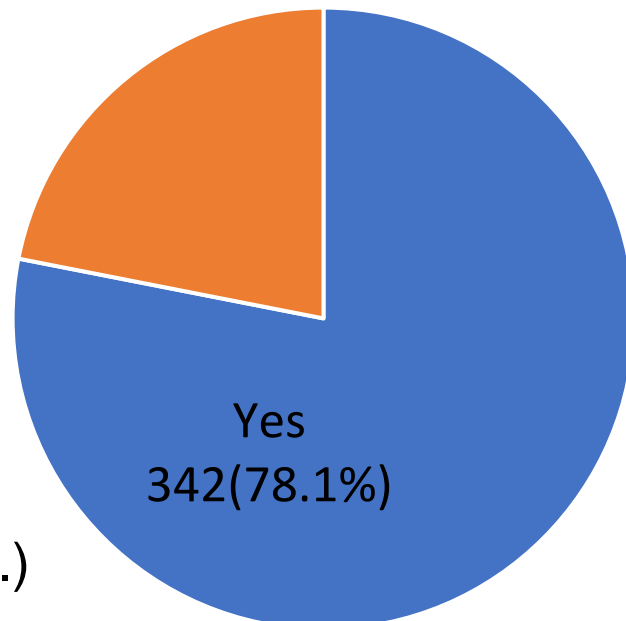
No  
85 (20.8%)



n = 416  
(no answer: 8 insts.)

2017

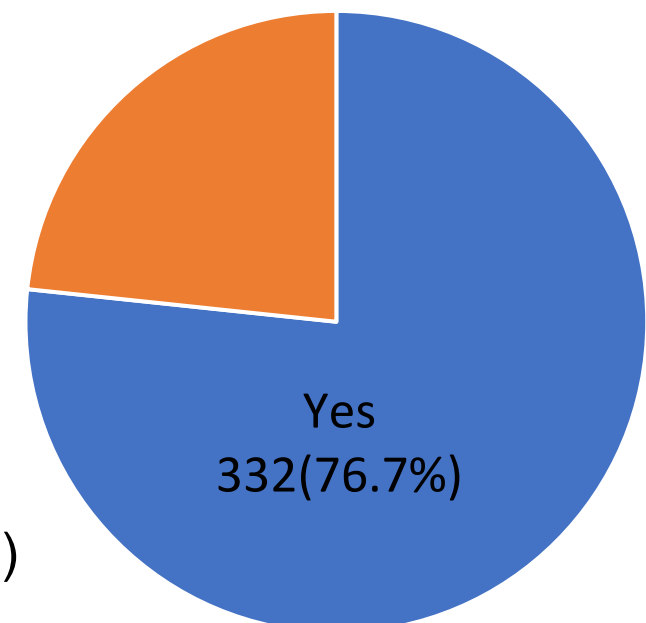
No  
96 (21.9%)



n = 445  
(no answer: 7 insts.)

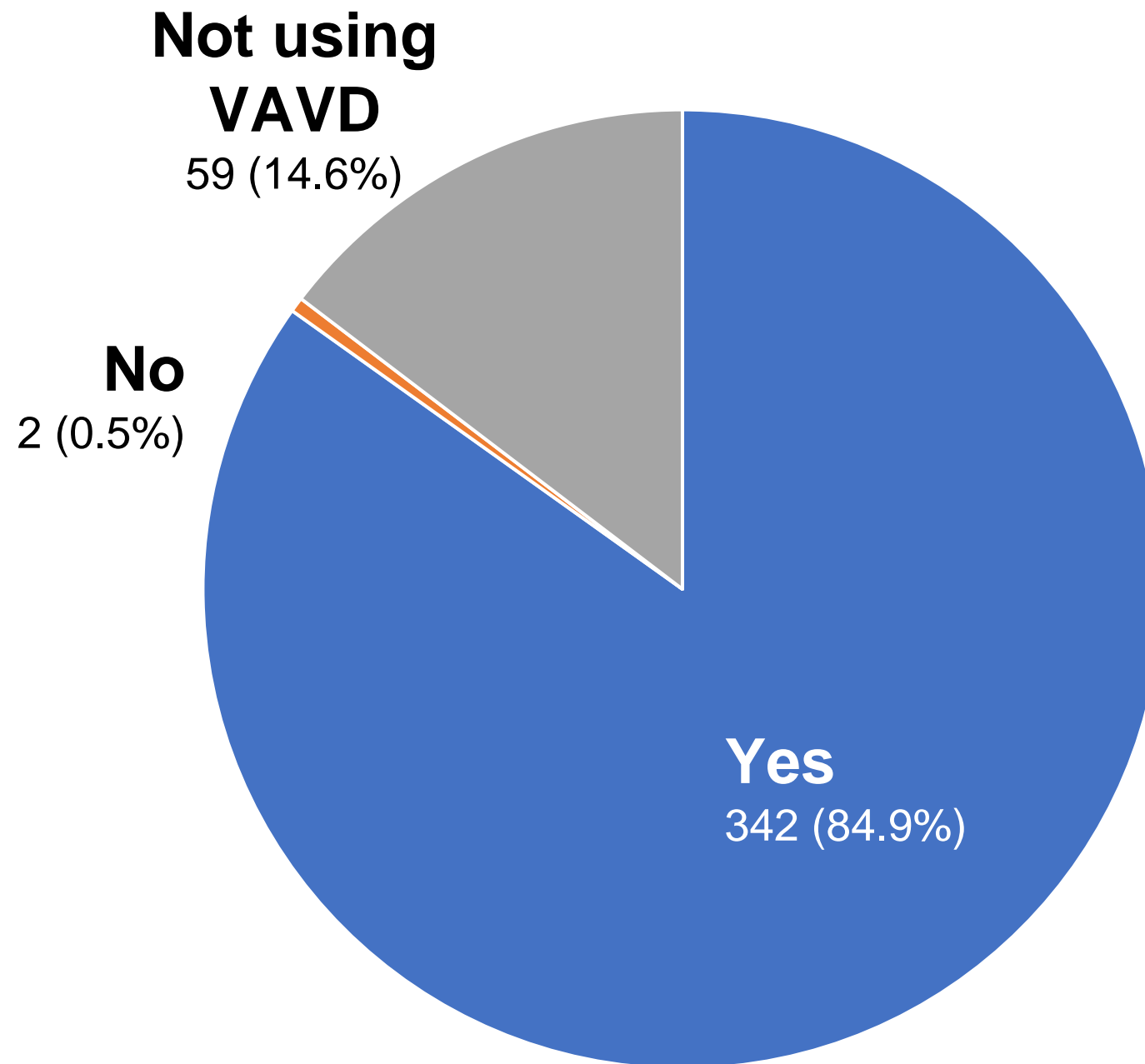
2015

No  
101 (23.3%)



n = 439  
(no answer: 6 insts.)

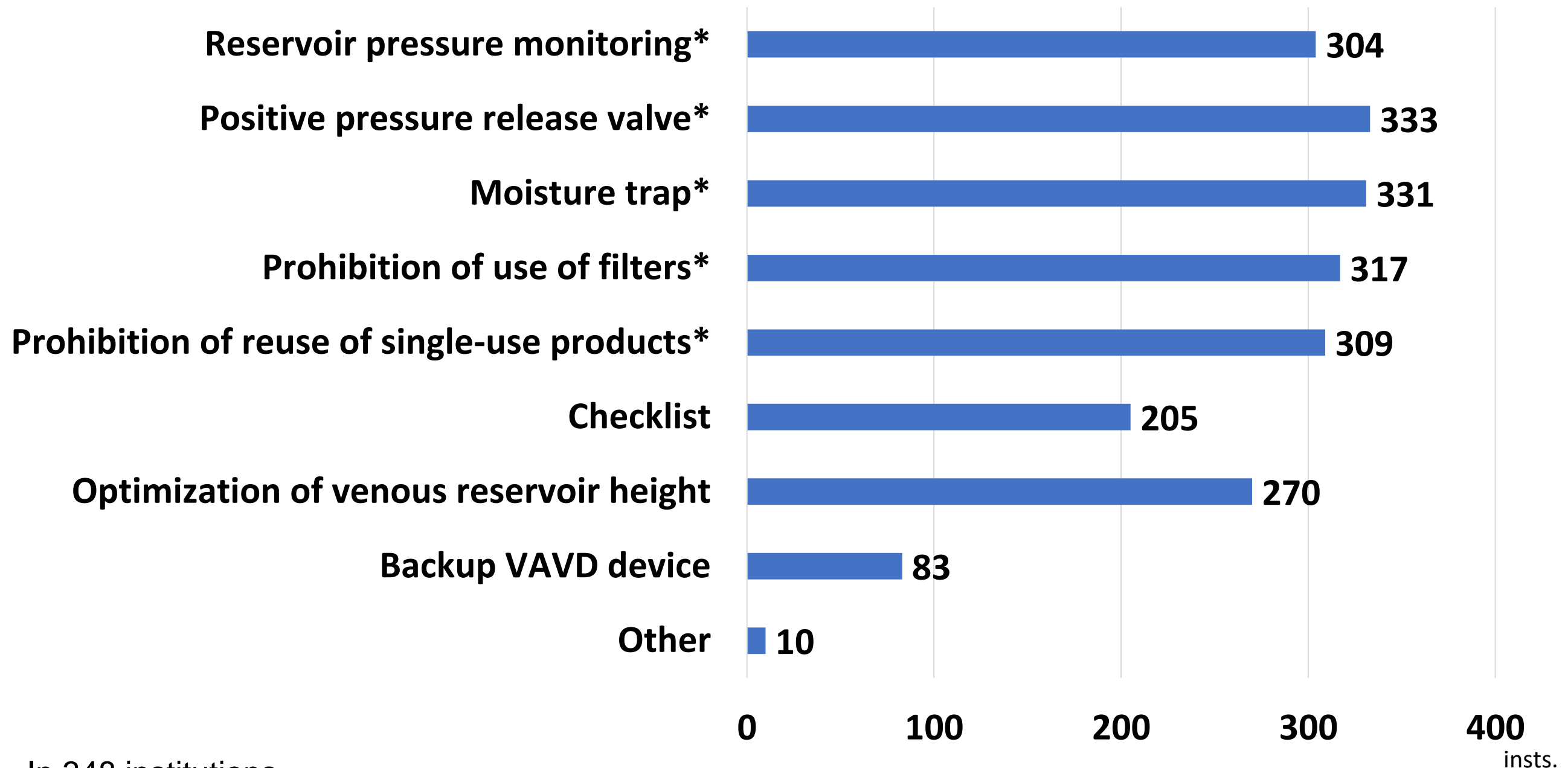
# Do you take safety measures when using VAVD?



n = 409 (no answer: 6 insts.)

# Which of the following safety measures do you take when using VAVD? (Please choose all that apply.)

\*Recommended by 3 academic societies



In 348 institutions  
(incl. 5 that did not answer the question)

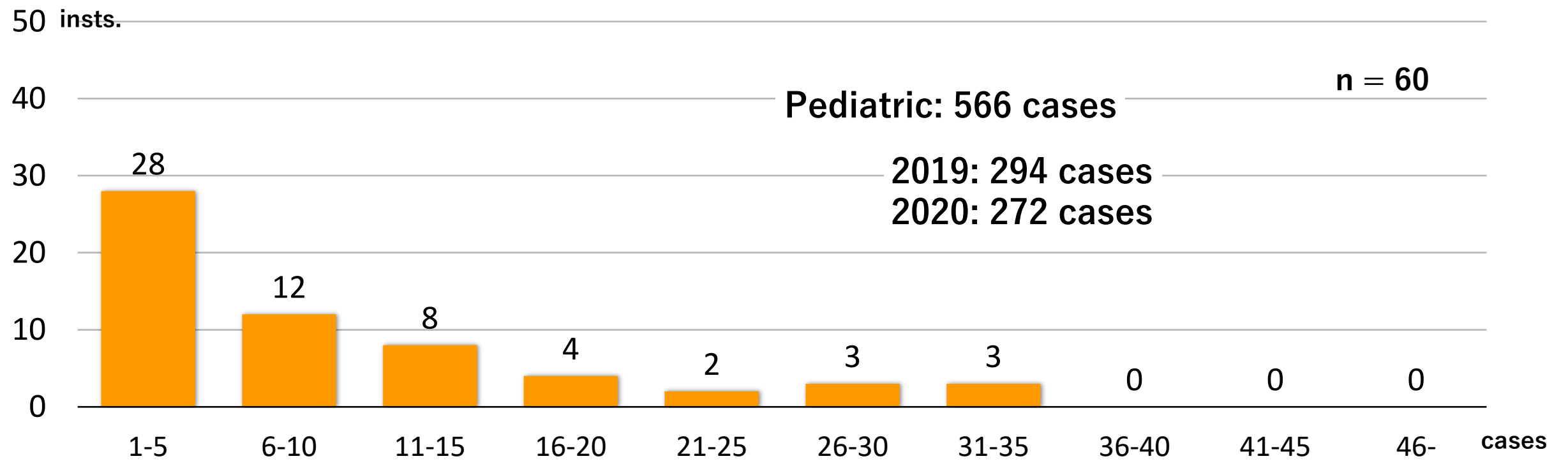
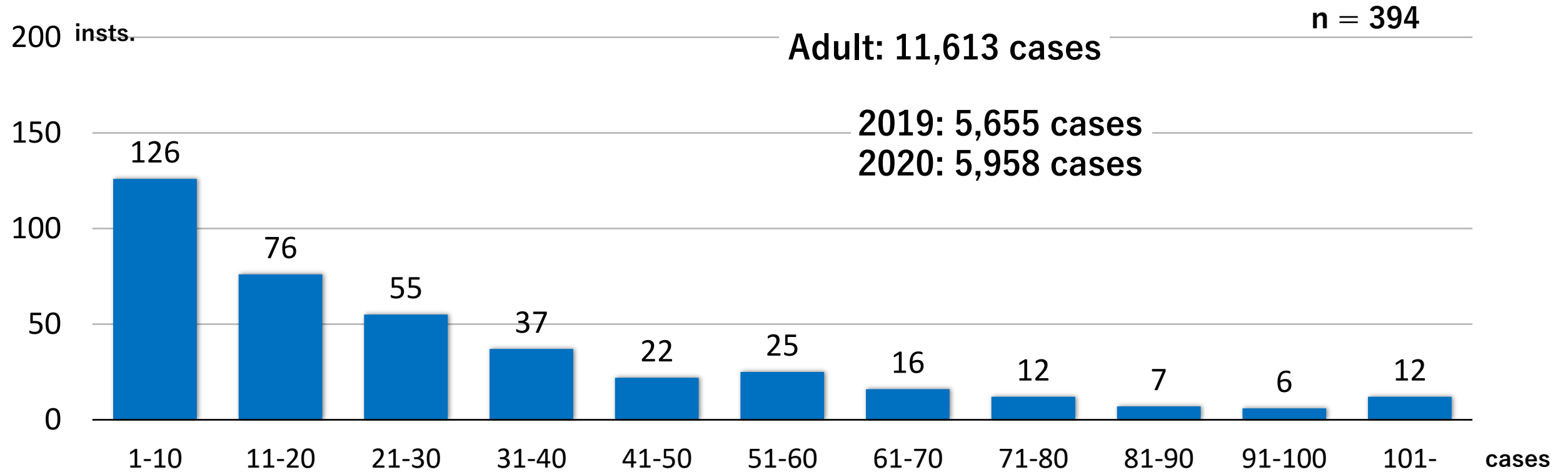


# Aggregation Results

## Cardiopulmonary Support (PCPS/ECMO)



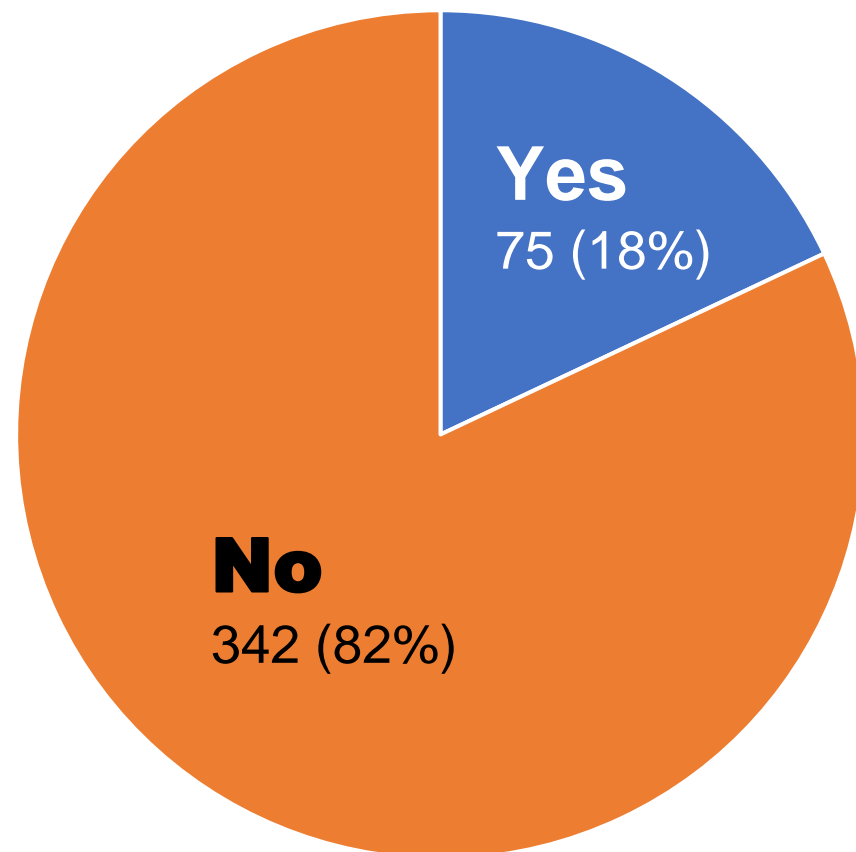
# PCPS/ECMO-Related Cases by Demographics



# PCPS/ECMO-Related Incidents/Accidents & Rates

	2021 Survey			2019 Survey			2017 Survey		
	2020	2019	Total	2018	2017	Total	2016	2015	Total
<b>No. of cases</b>	6,230	5,949	12,179	5,811	5,525	11,336	5,524	4,921	10,445
<b>Impact level (0)</b>	55 0.88%	59 0.99%	114 0.94%	58 1.00%	57 1.03%	115 1.01%	45 0.81%	51 1.04%	96 0.92%
<b>Impact level (1 – 3a)</b>	119 1.91%	105 1.77%	224 1.84%	161 2.77%	128 2.32%	289 2.55%	123 2.23%	92 1.87%	215 2.06%
<b>Impact level (3b – 5)</b>	24 0.39%	22 0.37%	46 0.38%	27 0.46%	23 0.42%	50 0.44%	25 0.45%	12 0.24%	37 0.35%
<b>Total</b>	198 3.18%	186 3.13%	384 3.15%	246 4.23%	208 3.76%	454 4.00%	193 3.49%	155 3.15%	348 3.33%

# Did you experience a Sudden Stop or Deceleration of Blood Pump?



Impact level	No. of cases	Frequency*
1~3a	133	1.09%
3b~5	16	0.13%

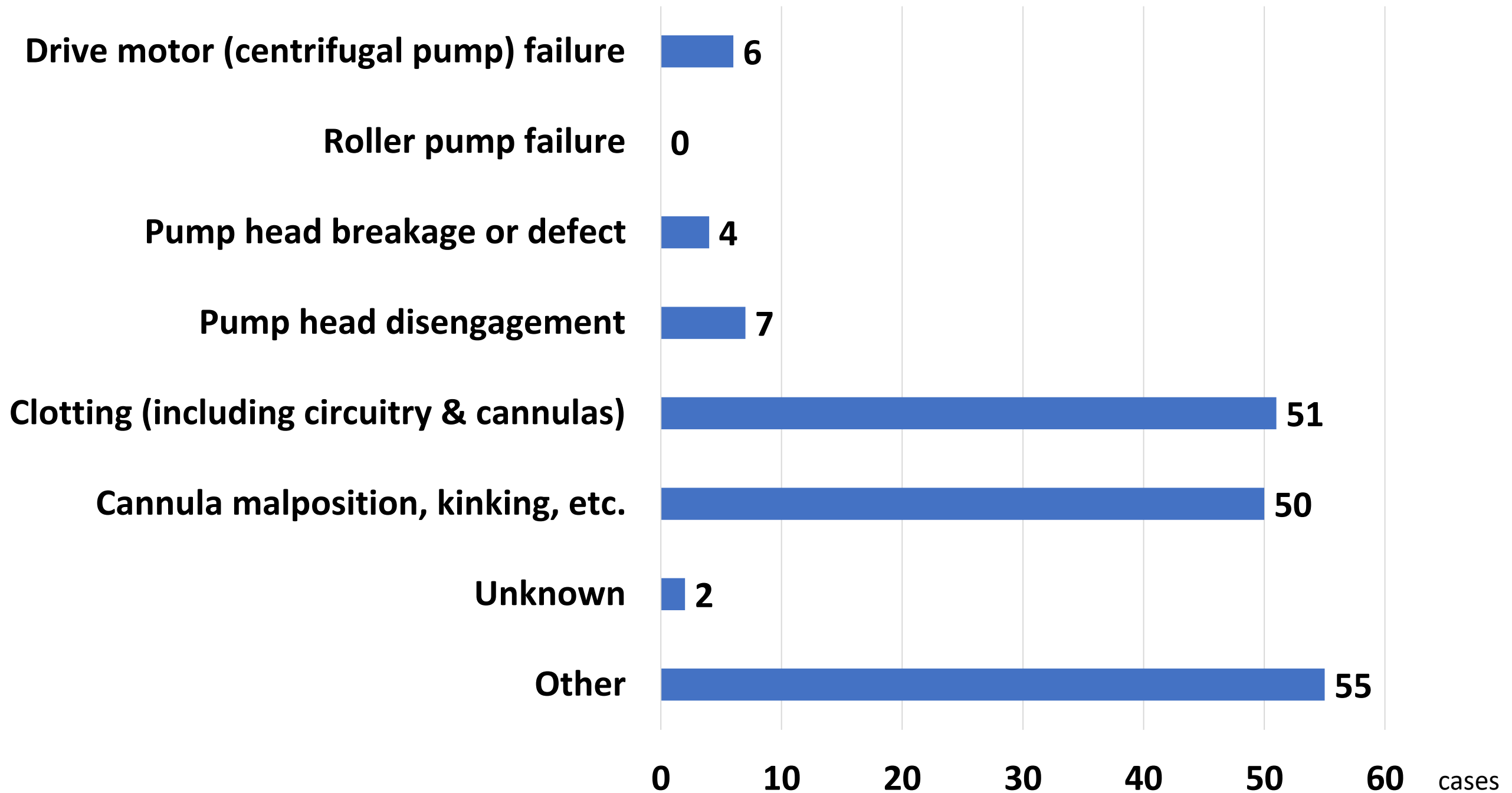
No answer: 12 insts.

\*Among 12,179 CPS cases occurring during the 2-year period.

n = 421 (no answer: 4 insts.)

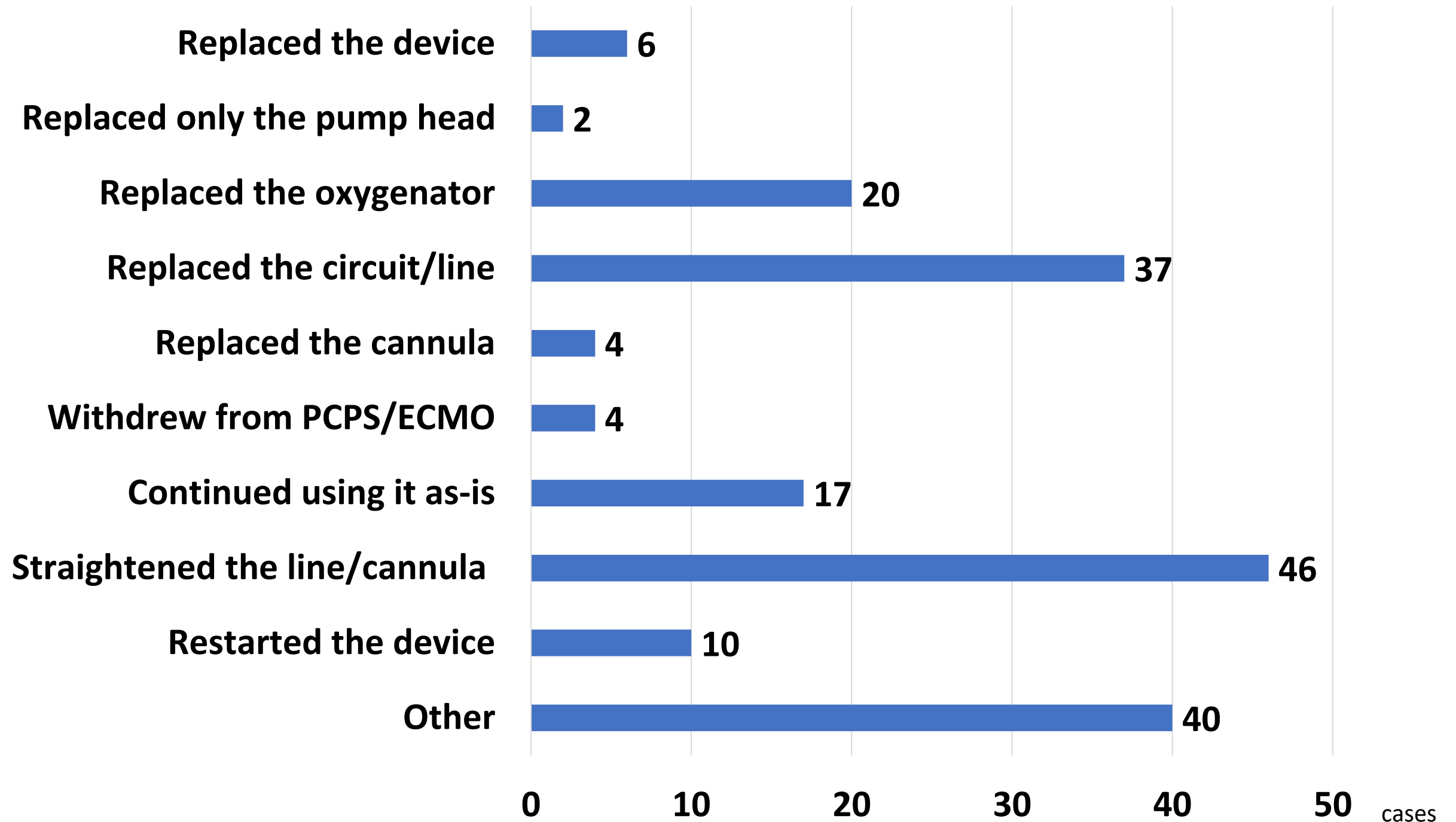


# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 79 institutions  
(incl. 7 that did not answer the question)

# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



In 79 institutions  
(incl. 8 that did not answer the question)

# Incidents & Rates Related to Sudden Stop or Deceleration of Blood Pump

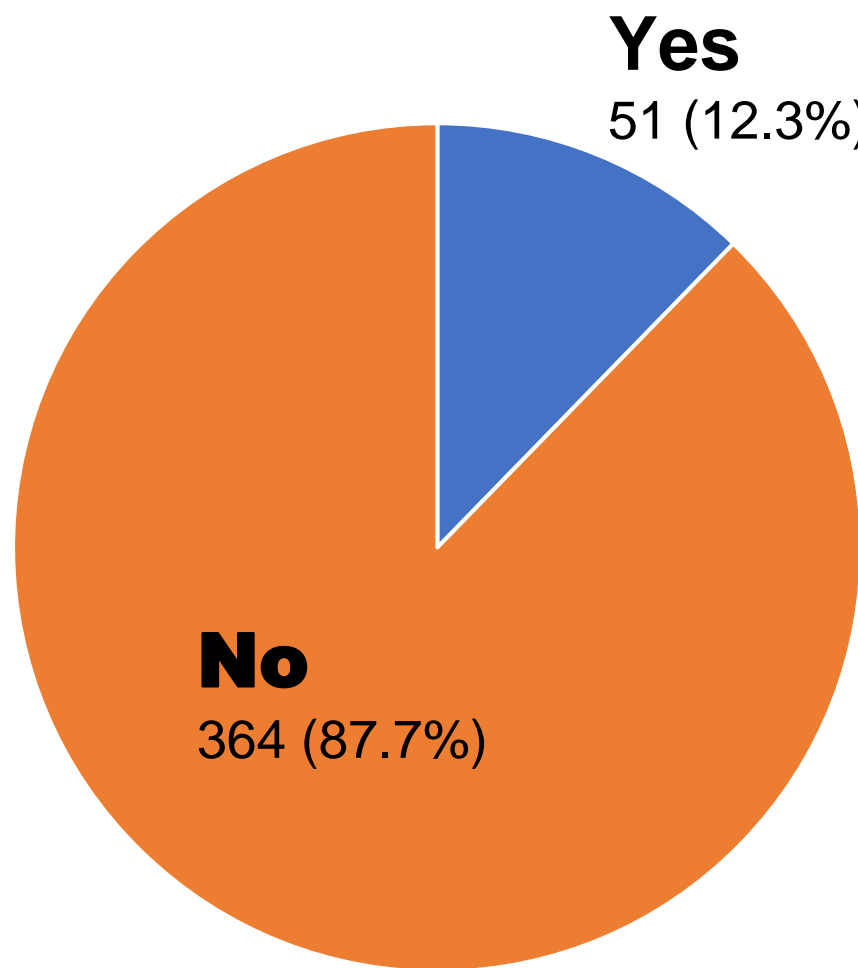
Impact level	2021 Survey		2019 Survey		2017 Survey	
	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	—	—	—	—	—	—
1 – 3a	133	1.09%	69	0.61%	58	0.56%
3b – 5	16	0.13%	8	0.07%	3	0.13%
	No answer: 9 insts.		No answer: 9		No answer: 20	

\*Among 12,179 cases

\*\*Among 11,336 cases

\*\*\*Among 10,445 cases

# Did you experience an incident/accident involving an Flow Sensor?



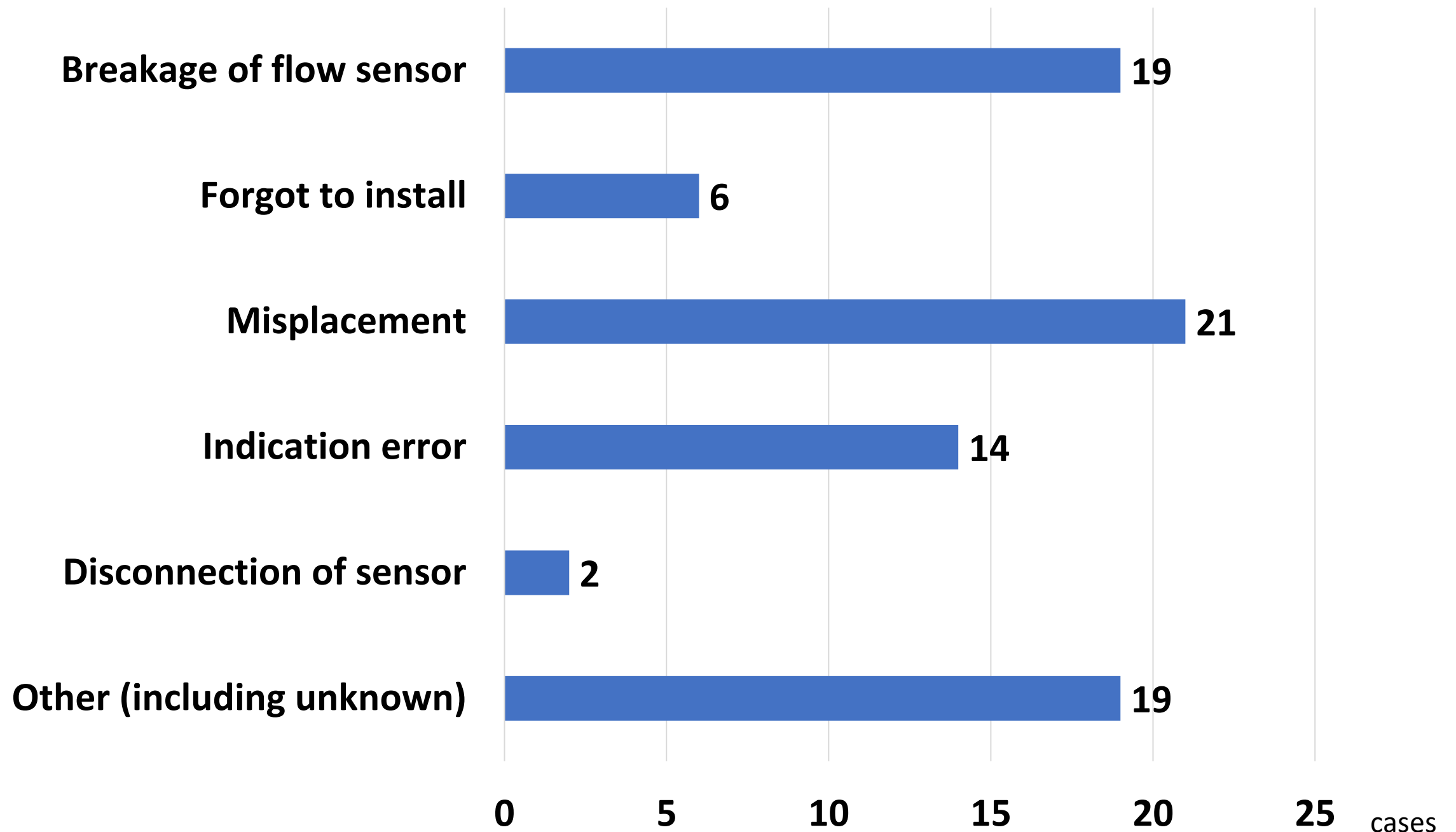
Impact level	No. of cases	Frequency*
0	65	0.53%
1~3a	14	0.12%
3b~5	1	0.01%

No answer: 12 insts.

\*Among 12,179 CPS cases occurring during the 2-year period.

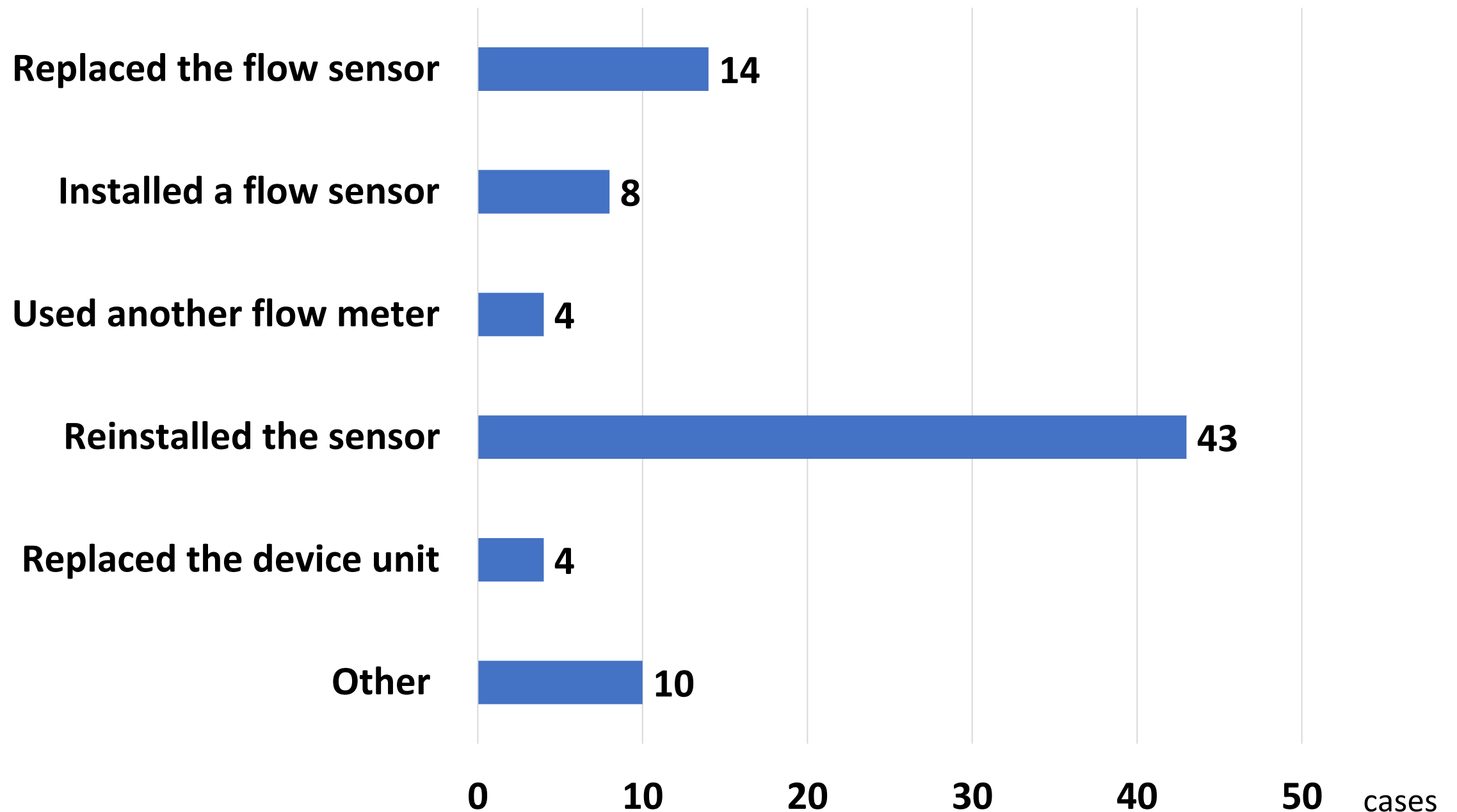
n = 421 (no answer: 6 insts.)

# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 57 institutions  
(incl. 6 that did not answer the question)

# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



In 57 institutions  
(incl. 7 that did not answer the question)

# Incidents & Rates of Related to Flow Sensor

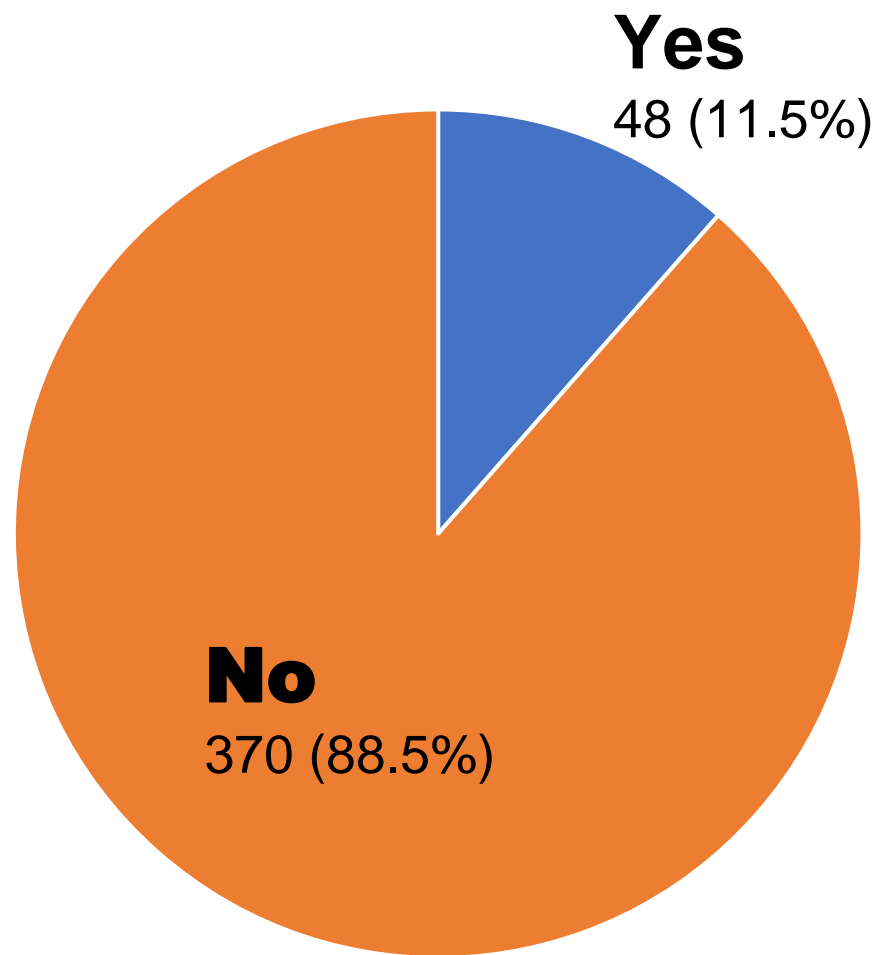
Impact level	2021 Survey		2019 Survey		2017 Survey	
	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	65	0.53%	53	0.47%	52	0.50%
1 – 3a	14	0.12%	34	0.30%	15	0.14%
3b – 5	1	0.01%	1	0.01%	1	0.01%
	No answer: 6 insts.		No answer: 6		No answer: 11	

\*Among 12,179 cases

\*\*Among 11,336 cases

\*\*\*Among 10,445 cases

# Did you experience Aspiration of Air Into the Circuit?



Impact level	No. of cases	Frequency*
1 – 3a	55	0.45%
3b – 5	11	0.09%

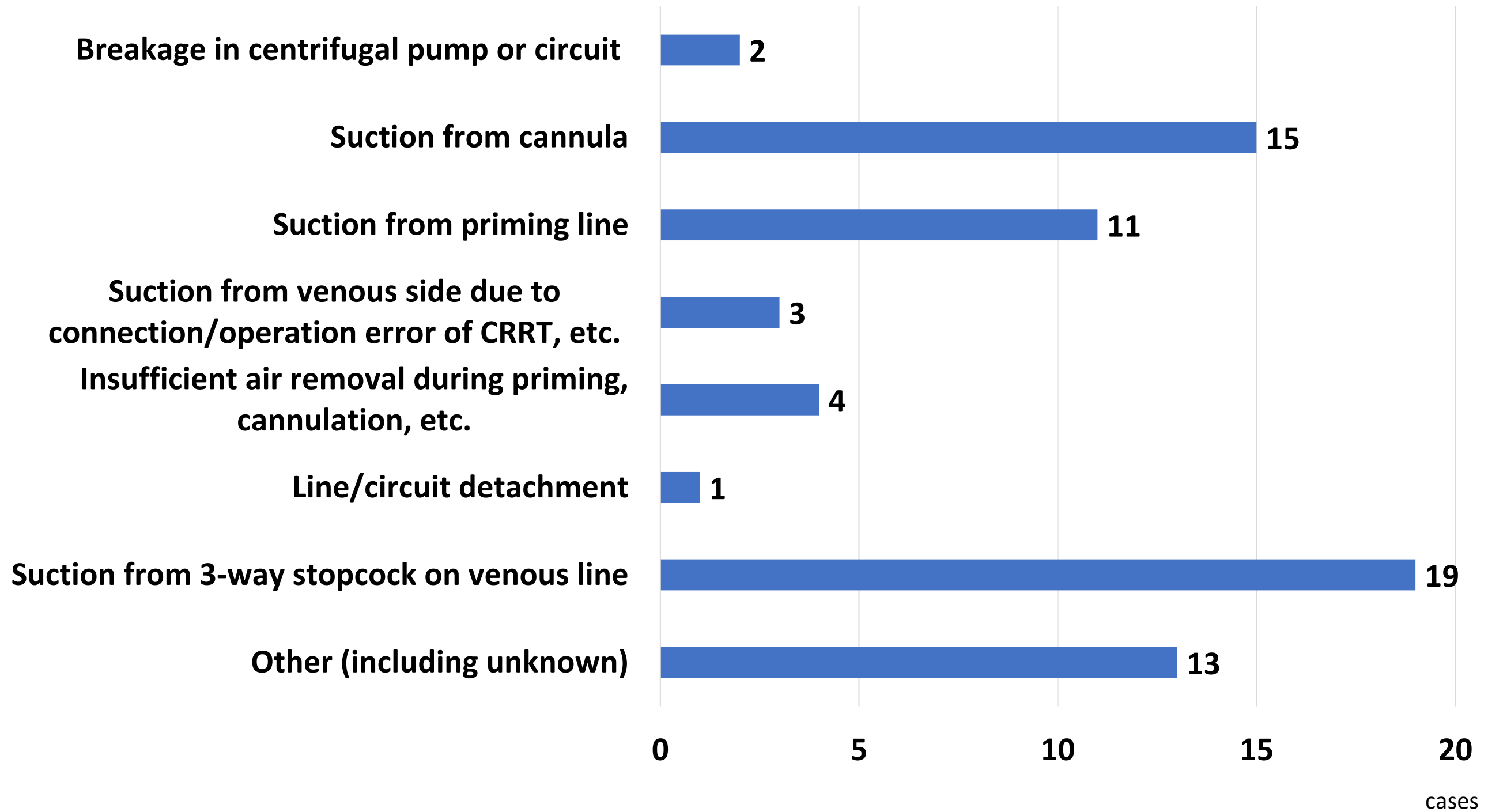
No answer: 5 insts.

\*Among 12,179 CPS cases occurring during the 2-year period.

n = 421 (no answer: 3 insts.)

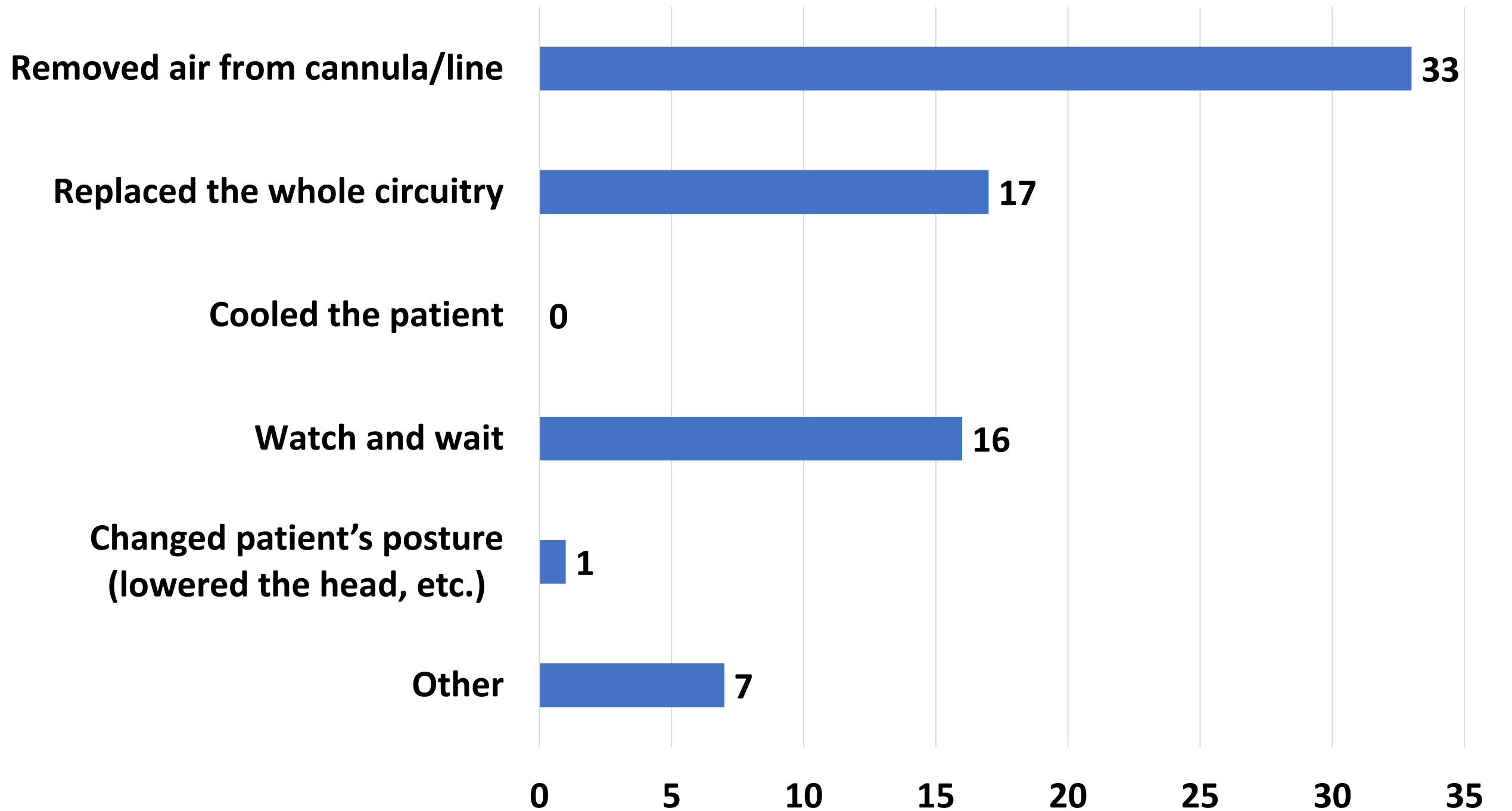


# Which of the following caused the aspiration and how many times? (Please choose all that apply.)



In 51 institutions  
(incl. 3 that did not answer the question)

# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



In 51 institutions  
(incl. 3 that did not answer the question)

cases

# Incidents & Rates of Air Aspiration into Circuit

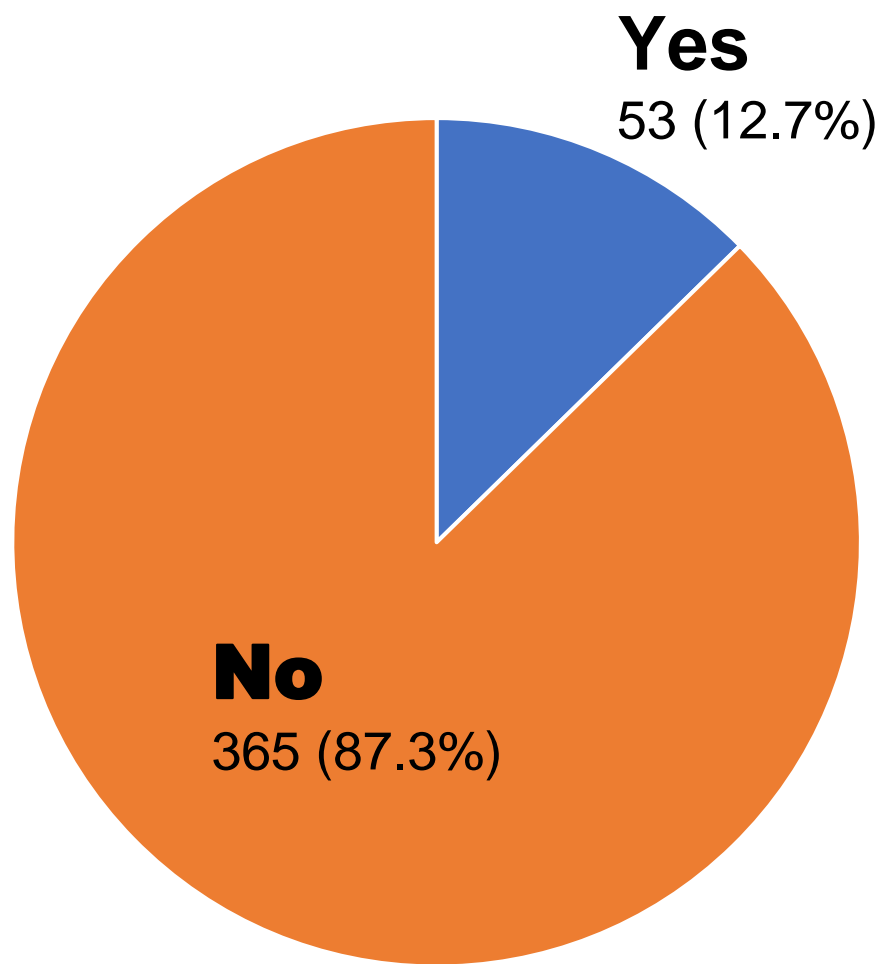
	2021 Survey		2019 Survey		2017 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	-	-	-	-	-	-
1 – 3a	55	0.45%	54	0.48%	49	0.47%
3b – 5	11	0.09%	7	0.06%	9	0.09%
	No answer: 5 insts.		No answer: 5		No answer: 7	

\*Among 12,179 cases

\*\*Among 11,336 cases

\*\*\*Among 10,445 cases

# Did you experience Unexpected Bleeding from the Circuit?



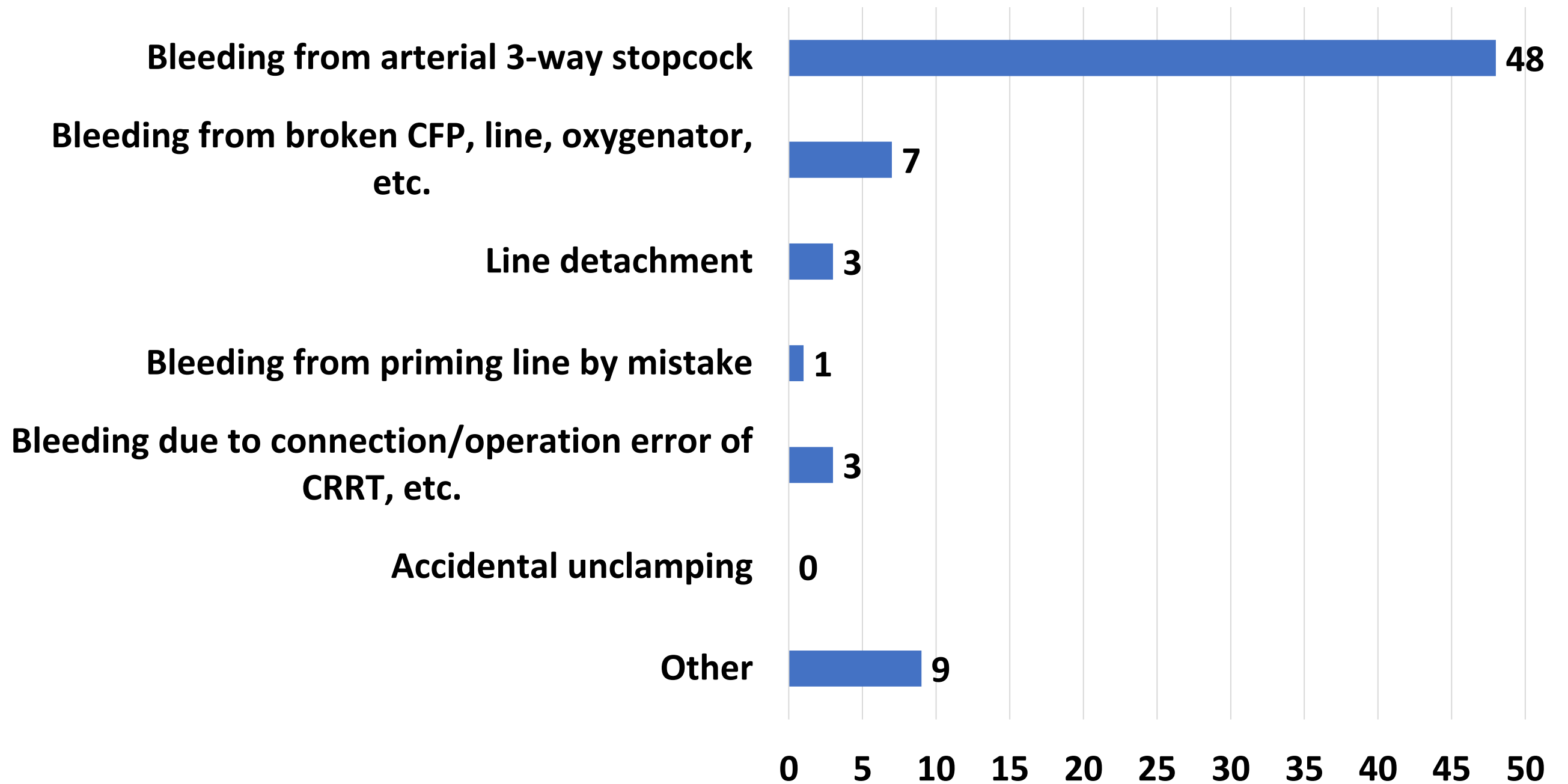
n = 421 (no answer: 3 insts.)

Impact level	No. of cases	Frequency*
1 – 3a	63	0.52%
3b – 5	6	0.05%

No answer: 6 insts.

\*Among 12,179 CPS cases occurring during the 2-year period.

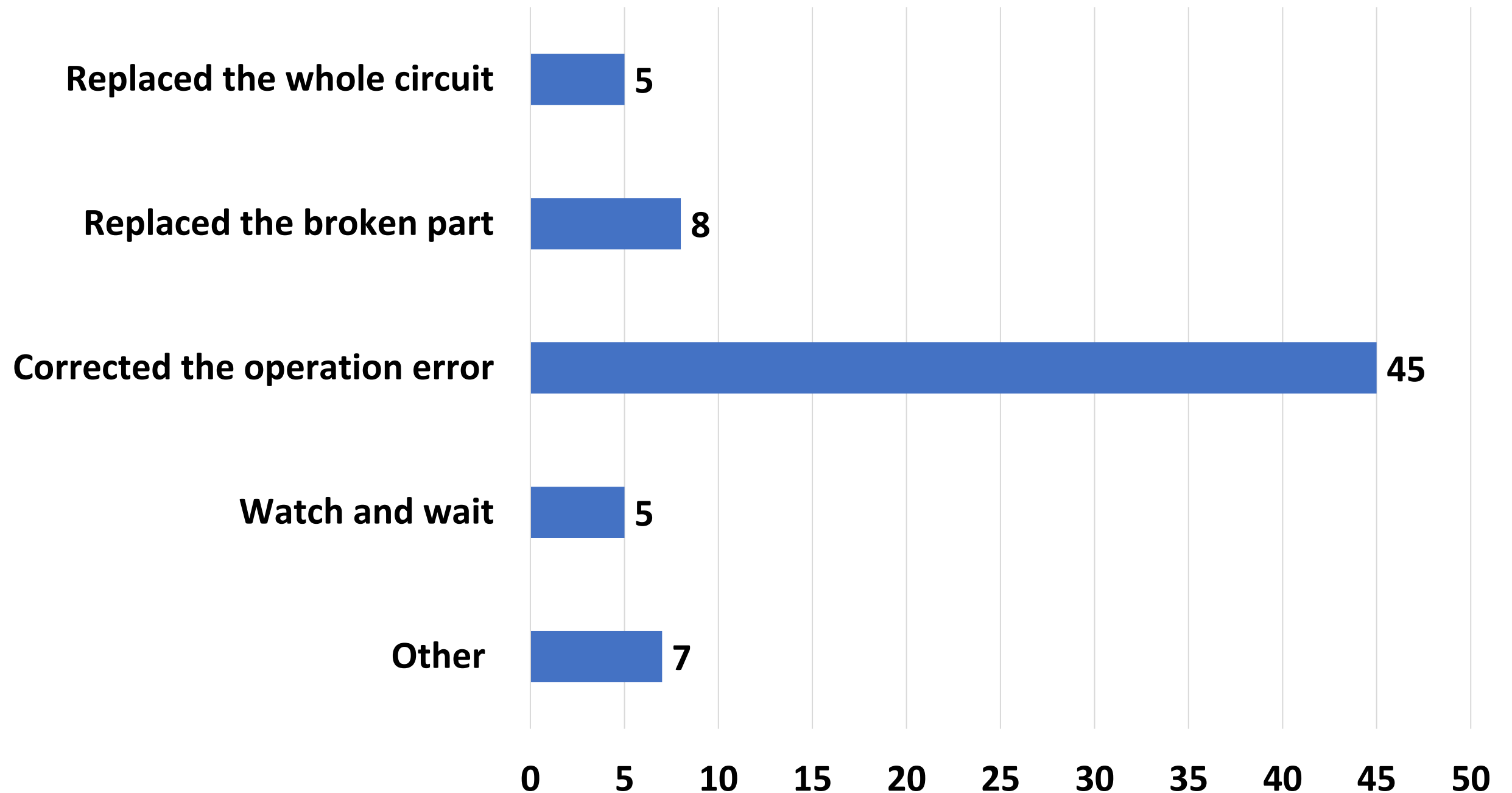
# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 56 institutions  
(incl. 6 that did not answer the question)

cases

# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



In 56 institutions  
(incl. 8 that did not answer the question)

cases

# Incidents & Rates of Unexpected Bleeding from Circuit

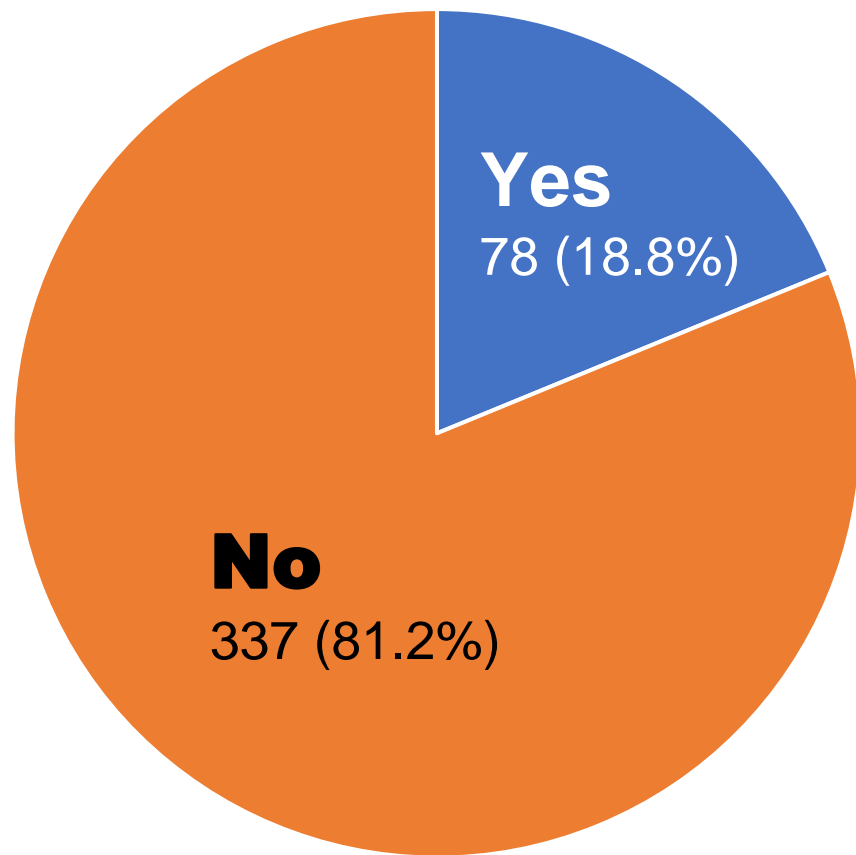
Impact level	2021 Survey		2019 Survey		2017 Survey	
	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	-	-	-	-	-	-
1 – 3a	63	0.52%	56	0.49%	58	0.56%
3b – 5	6	0.05%	2	0.02%	4	0.04%
	No answer: 6 insts.		No answer: 8		No answer: 10	

\*Among 12,179 cases

\*\*Among 11,336 cases

\*\*\*Among 10,445 cases

# Did you experience an incident/accident associated with Cannulation?



n = 421 (no answer: 6 insts.)

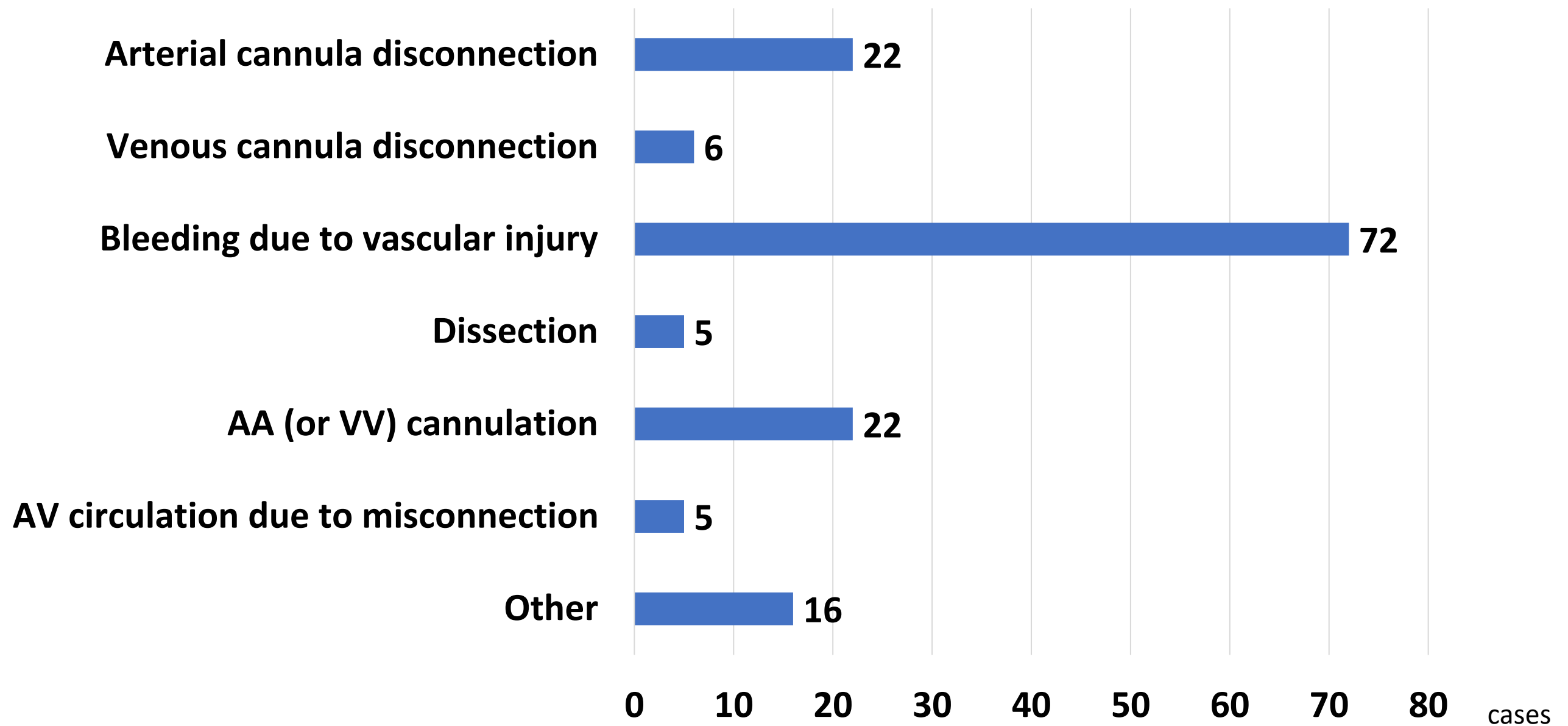
Impact level	No. of cases	Frequency*
0	11	0.09%
1 – 3a	71	0.58%
3b – 5	51	0.42%

No answer: 11 insts.

\*Among 12,179 CPS cases occurring during the 2-year period.

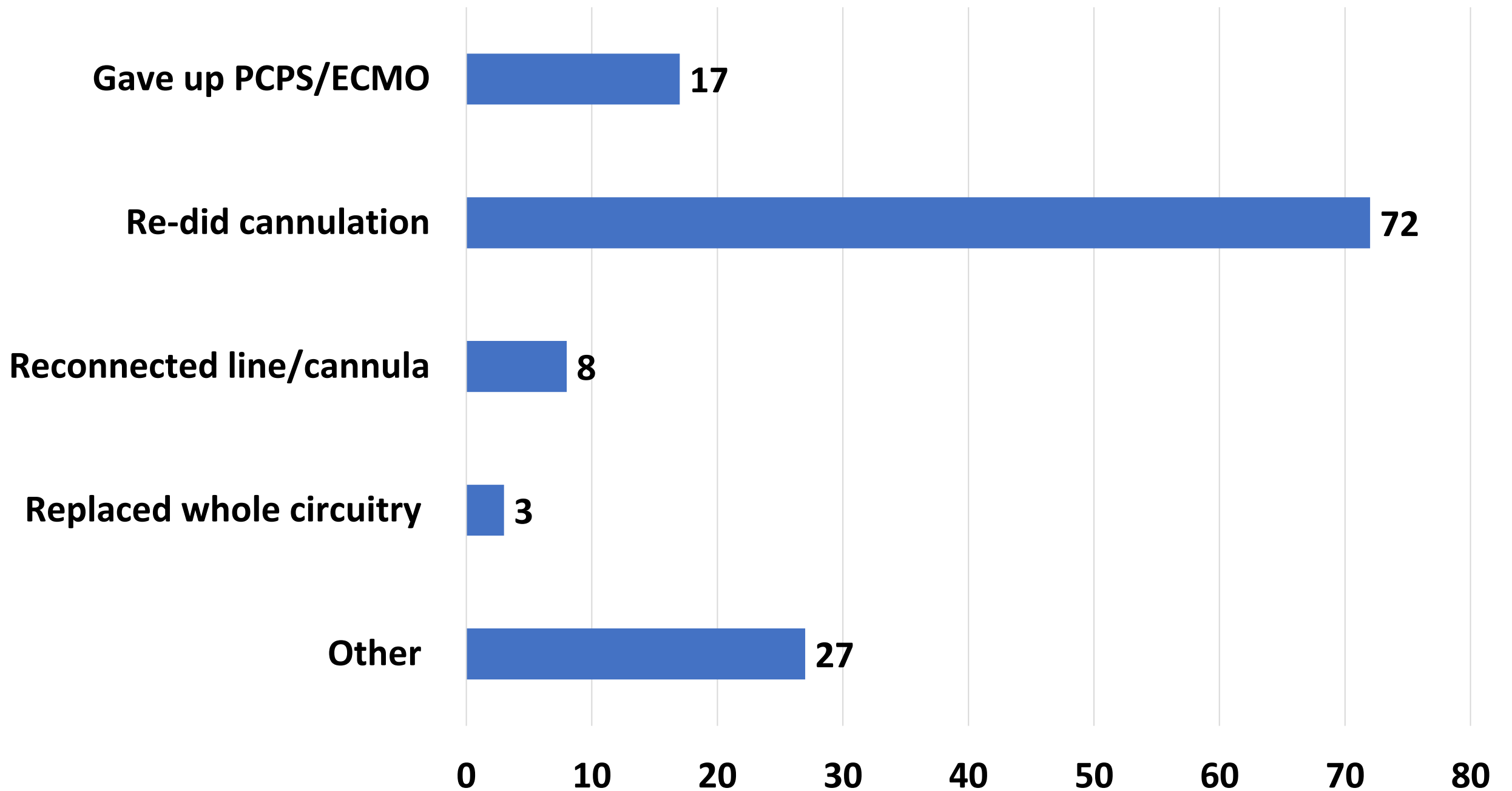


# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 84 institutions  
(incl. 7 that did not answer the question)

# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



In 84 institutions  
(incl. 14 that did not answer the question)

cases

# Incidents & Rates Related to Cannulation

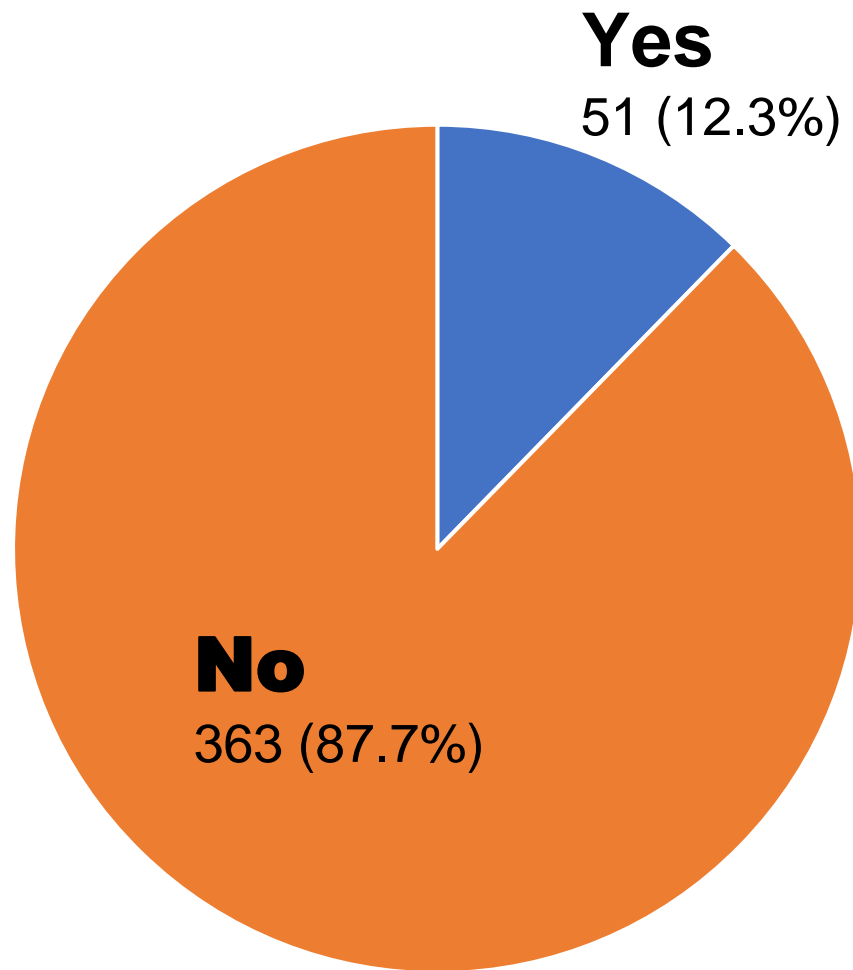
	2021 Survey		2019 Survey		2017 Survey	
Impact level	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	11	0.09%	16	0.14%	13	0.12%
1 – 3a	71	0.58%	74	0.65%	66	0.63%
3b – 5	51	0.42%	40	0.35%	31	0.30%
	No answer: 9 insts.		No answer: 9		No answer: 16	

\*Among 12,179 cases

\*\*Among 11,336 cases

\*\*\*Among 10,445 cases

# Did you experience an incident/accident During Transport to or in CT/Angiography Room?



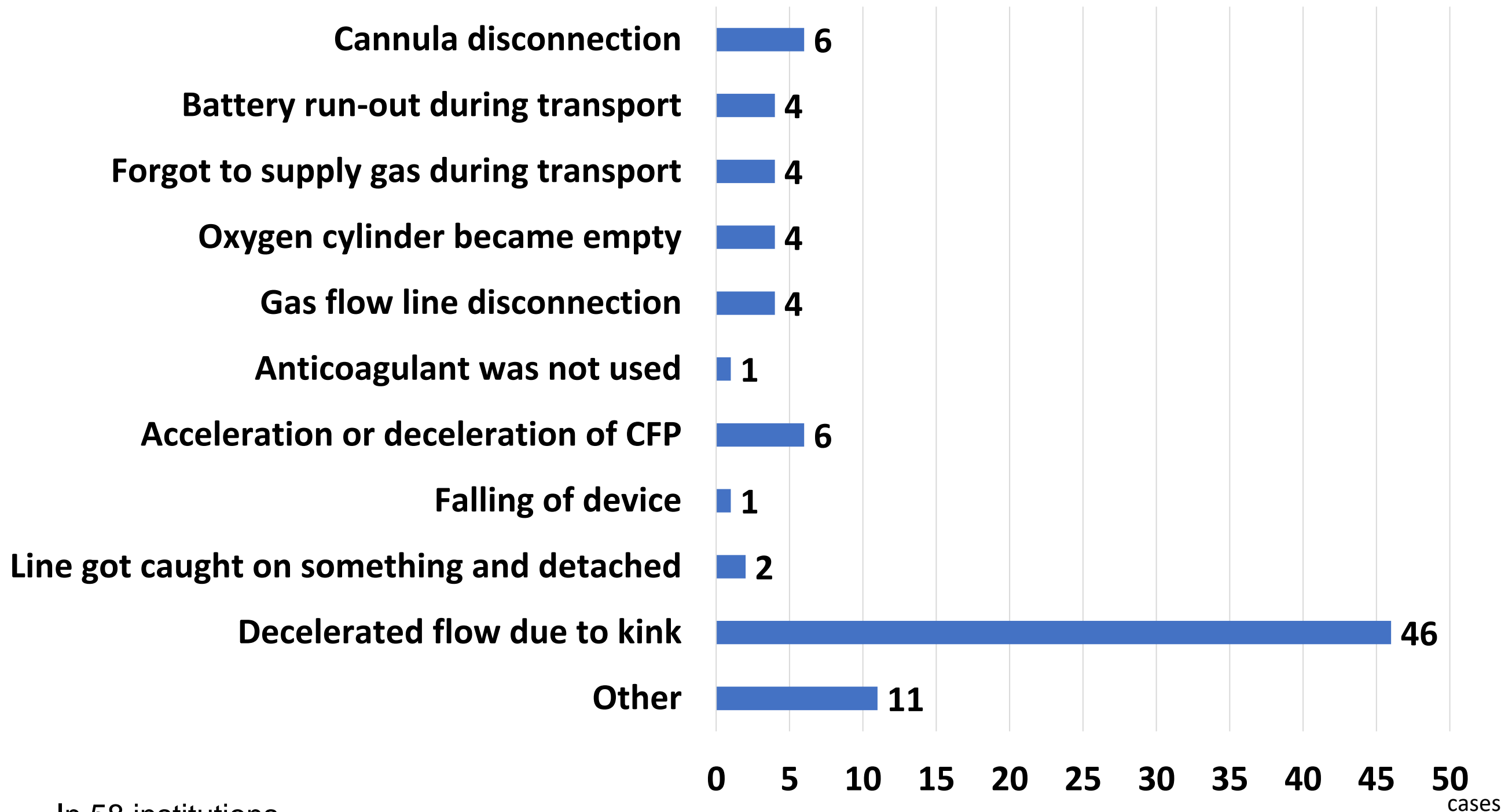
Impact level	No. of cases	Frequency*
1 – 3a	82	0.67%
3b – 5	4	0.03%

No answer: 7 insts.

\*Among 12,179 CPS cases occurring during the 2-year period.

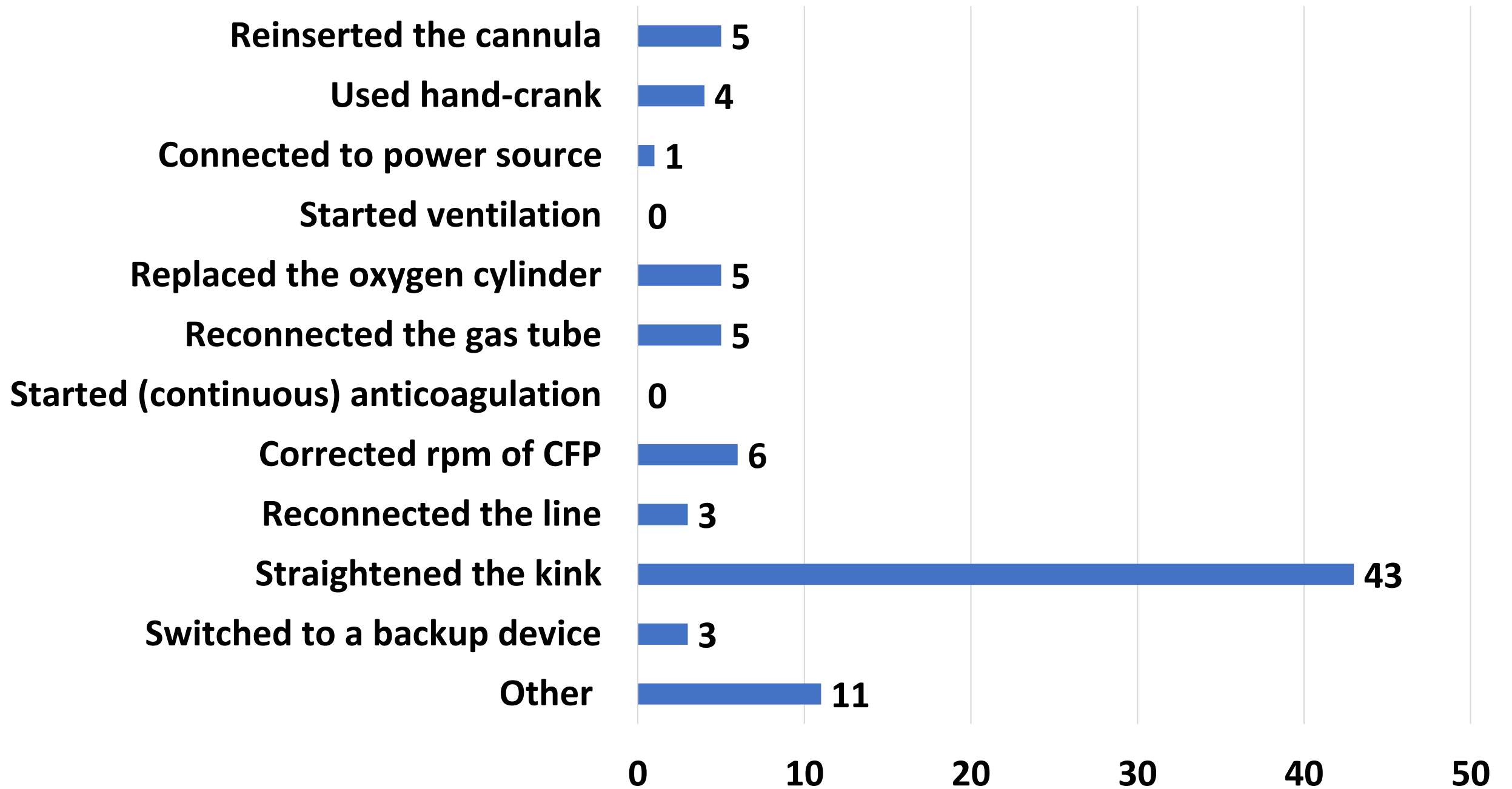
n = 421 (no answer: 7 insts.)

# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 58 institutions  
(incl. 7 that did not answer the question)

# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



In 58 institutions  
(incl. 8 that did not answer the question)

cases

# Incidents & Rates Related to Transport or Destination

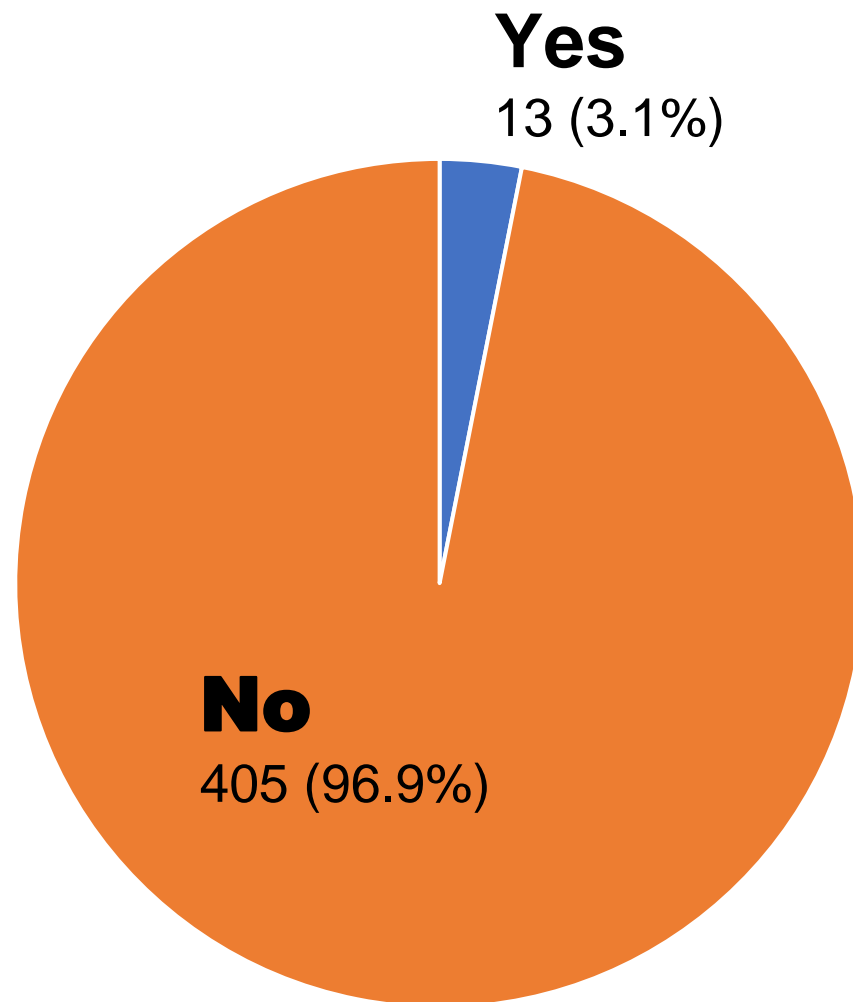
Impact level	2021 Survey		2019 Survey		2017 Survey	
	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	-	-	-	-	-	-
1 – 3a	82	0.67%	92	0.81%	77	0.74%
3b – 5	4	0.03%	5	0.04%	3	0.03%
	No answer: 7 insts.		No answer: 3		No answer: 7	

\*Among 12,179 cases

\*\*Among 11,336 cases

\*\*\*Among 10,445 cases

# Did you experience an incident/accident related to Power Outage or Interruption?



Impact level	No. of cases	Frequency*
0	11	0.09%
1 – 3a	3	0.03%
3b – 5	0	0%

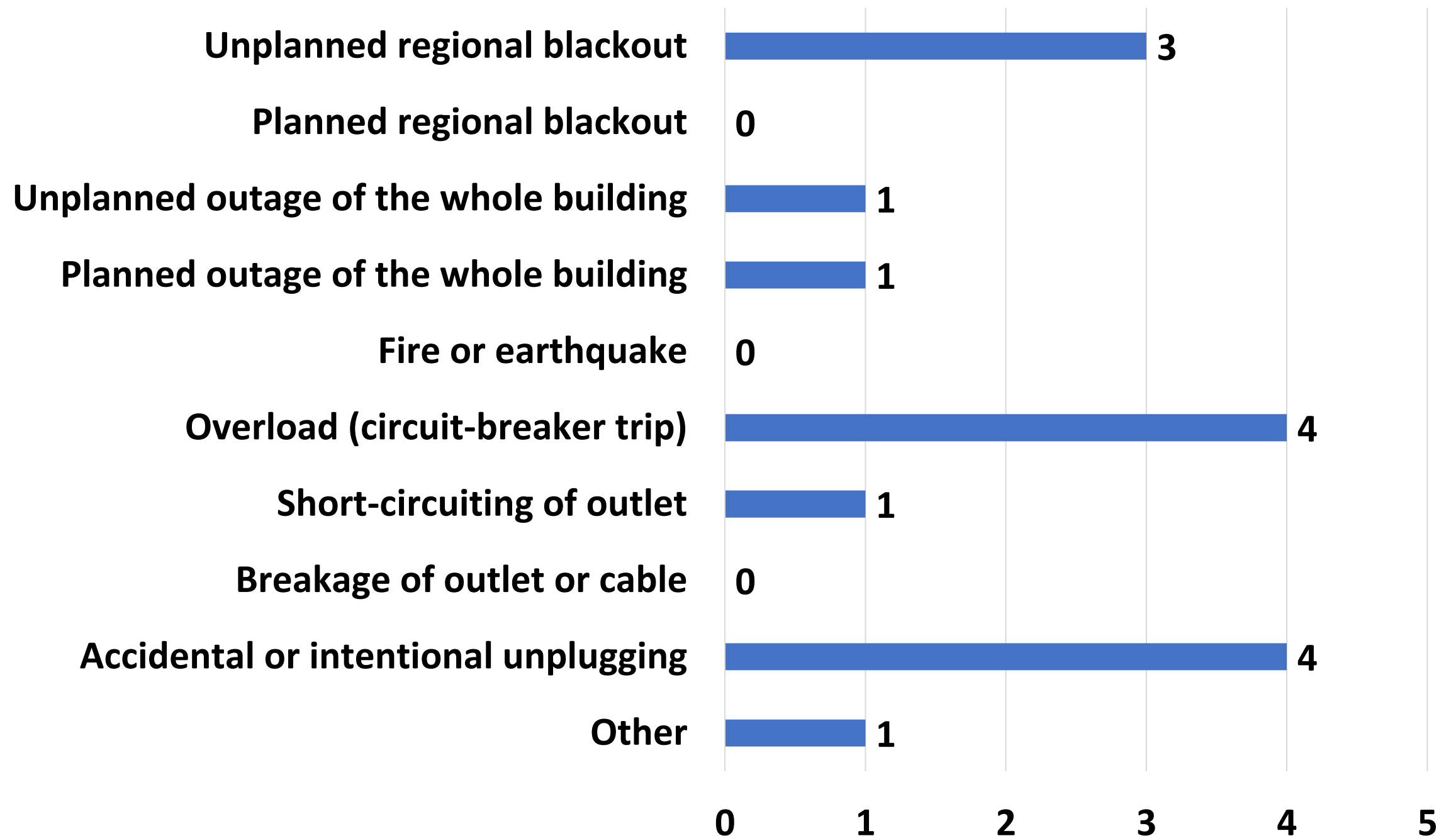
No answer: 4 insts.

\*Among 12,179 CPS cases occurring during the 2-year period.

n = 421 (no answer: 3 insts.)



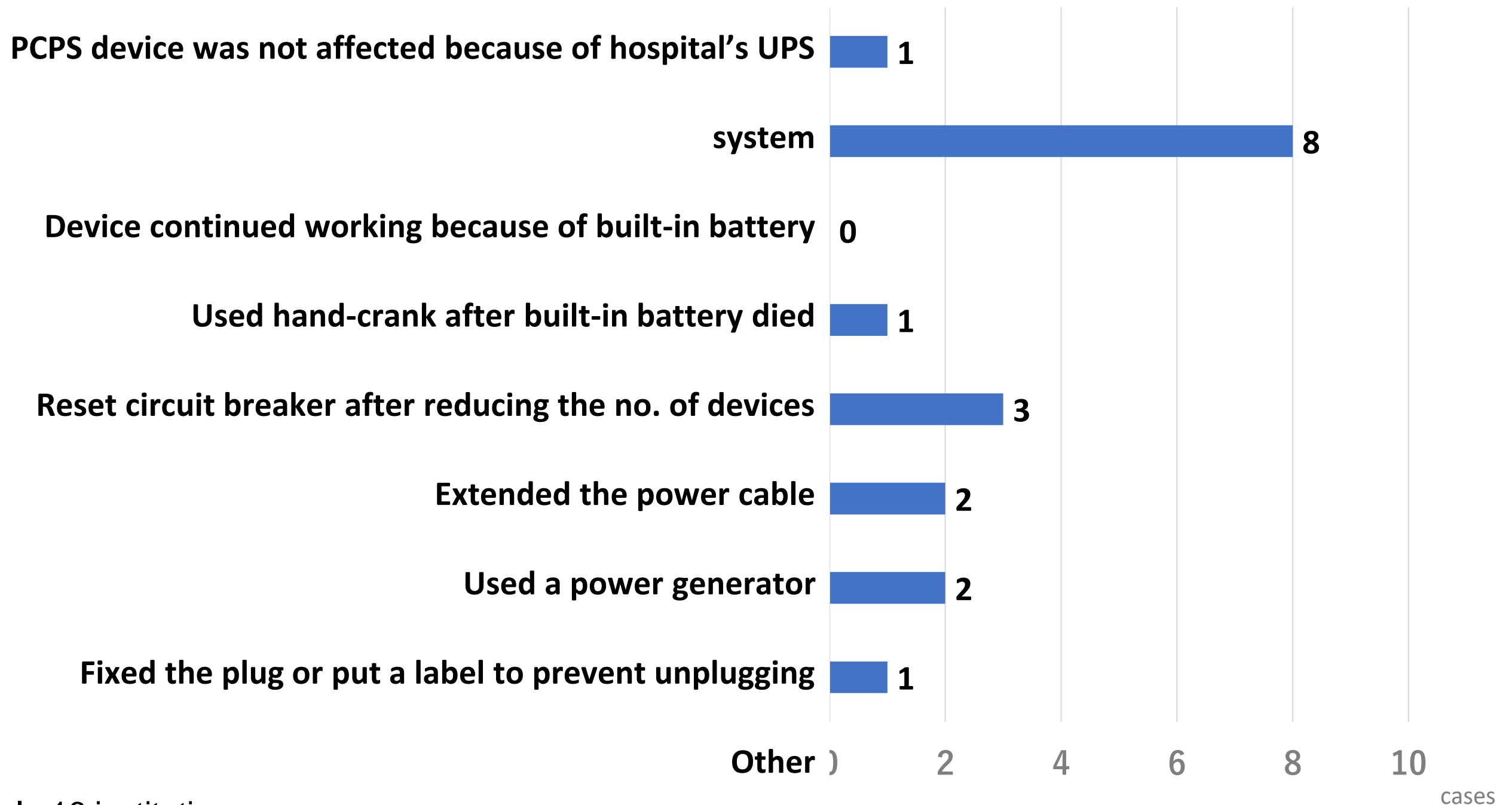
# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



In 16 institutions  
(incl. 3 that did not answer the question)

cases

# Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



In 16 institutions  
(incl. 5 that did not answer the question)

# Incidents & Rates of Power Outage/Interruption

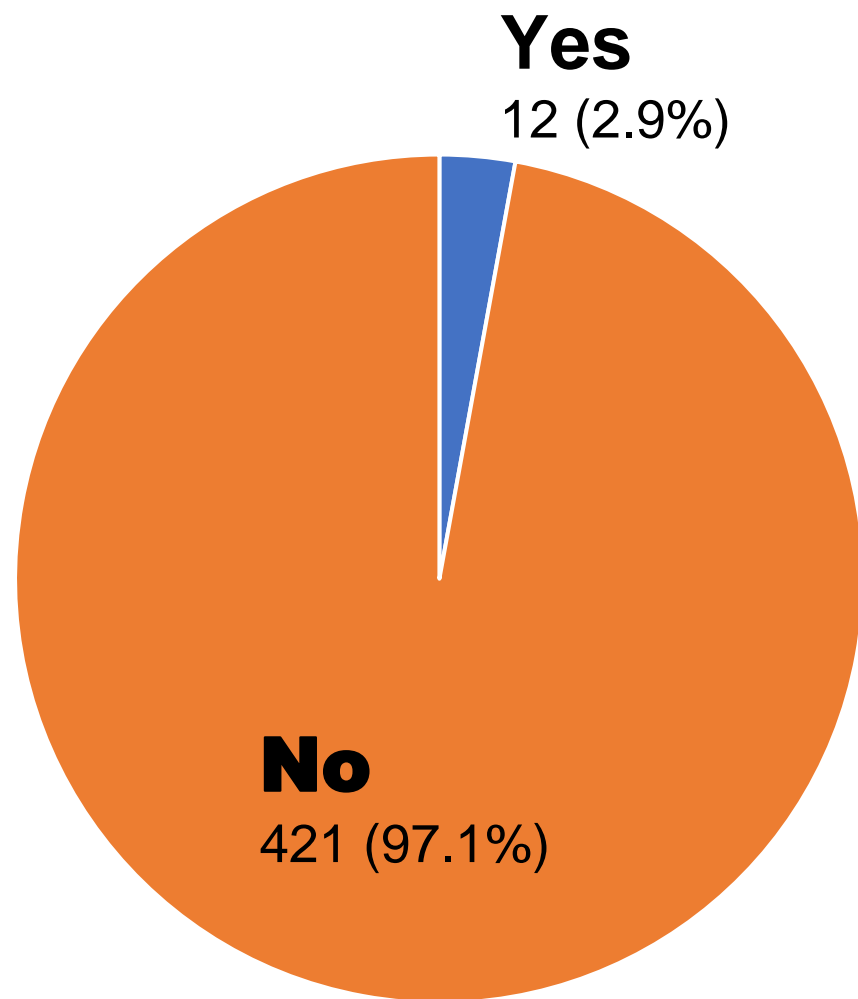
Impact level	2021 Survey		2019 Survey		2017 Survey	
	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	11	0.09%	5	0.04%	8	0.08%
1 – 3a	3	0.03%	9	0.08%	9	0.09%
3b – 5	-	-	1	0.01%	1	0.01%
	No answer: 4 insts.		No answer: 5		No answer: 2	

\*Among 12,179 cases

\*\*Among 11,336 cases

\*\*\*Among 10,445 cases

# Did you experience an Interruption of Medical Gas Supply?



Impact level	No. of cases	Frequency*
1 – 3a	11	0.09%
3b – 5	3	0.03%

No answer: 3 inst.

\*Among 12,179 CPS cases occurring during the 2-year period.

n = 421 (no answer: 3 insts.)

# Incidents & Rates of Medical Gas Supply Interruption

Impact level	2021 Survey		2019 Survey		2017 Survey	
	No. of cases	Frequency*	No. of cases	Frequency**	No. of cases	Frequency***
0	—	—	—	—	—	—
1 – 3a	11	0.09%	5	0.04%	2	0.02%
3b – 5	3	0.03%	0	0%	0	0%
	No answer: 3 inst.		No answer: 1		No answer: 3	

\*Among 12,179 cases

\*\*Among 11,336 cases

\*\*\*Among 10,445 cases