

# **2023 Questionnaire Survey Report on Incidents, Accidents, and Safety Procedures Related to Cardiopulmonary Bypass and Extracorporeal Membrane Oxygenation**

**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 extracorporeal membrane oxygenation (ECMO) systems.

## **◆Target years**

2021 and 2022

## **Background of the Survey**

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

2010: CPB (2008, 2009)

2011: ECMO (2009, 2010)

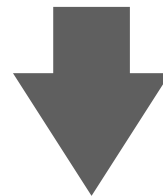
2013: CPB & ECMO (2011, 2012)

2015: CPB & ECMO (2013, 2014)

2017: CPB & ECMO (2015, 2016)

2019: CPB & ECMO (2017, 2018)

2021: CPB & ECMO (2019, 2020)



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

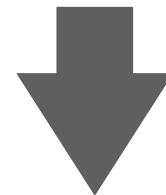
**2023: CPB & ECMO (2021, 2022)**

## **Subjects**

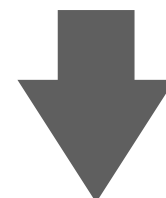
**632 medical institutions with JaSECT members**

## **Responses**

Response rate: 61.2 % (387/632 institutions)



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



Valid response rate: 98.2% (380 institutions)

## Levels of Impact on Patients

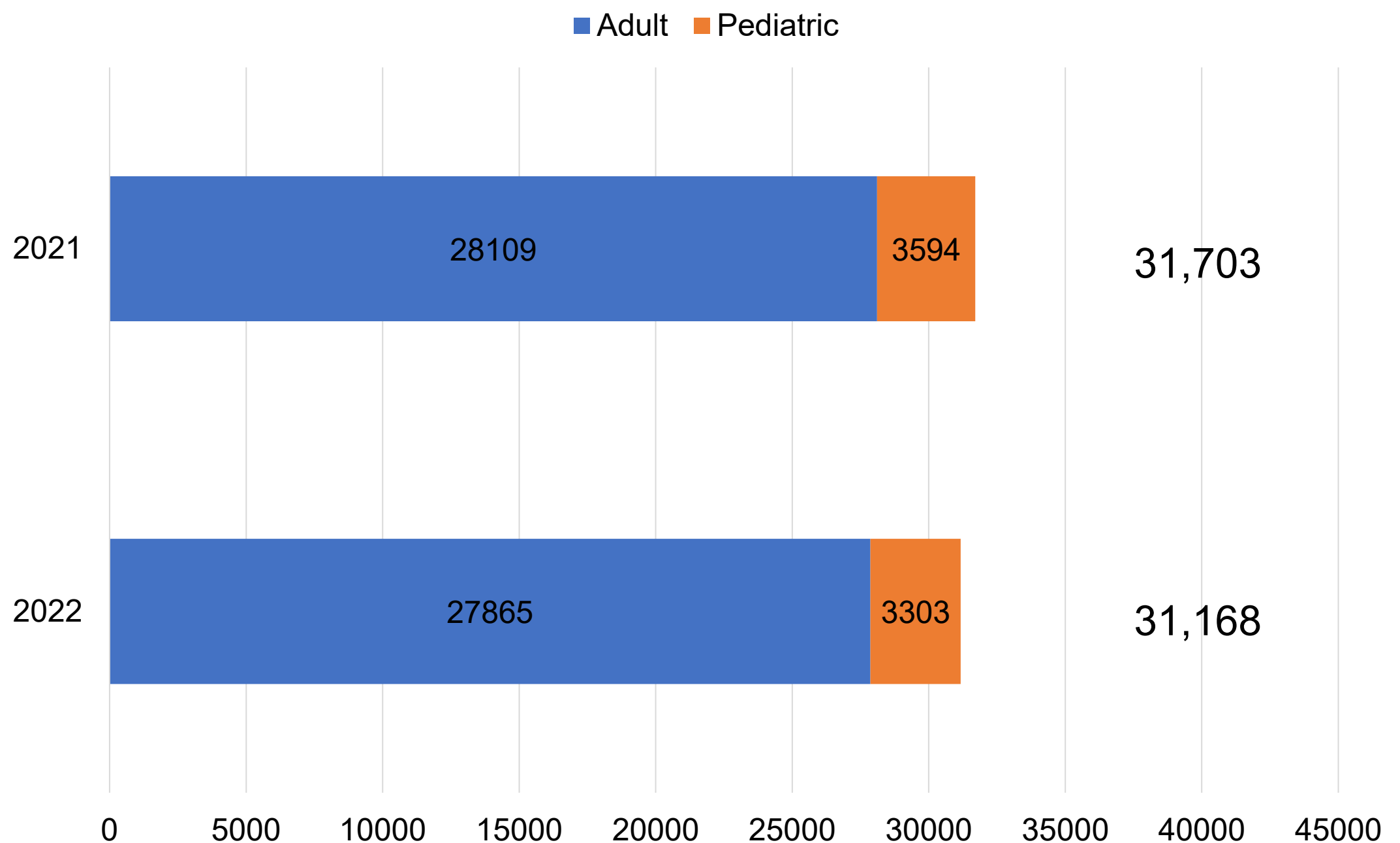
| Level    | Impact on patients  |
|----------|---|
| Level 0  | Errors and/or failures were found in pharmaceuticals and/or medical devices that were not used on patient.                              |
| Level 1  | Errors and/or failures were found in pharmaceuticals and/or medical devices that were 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)**

# Number of CPB cases

Total CPB cases: 62,871 (Adult: 55,974 Pediatric: 6,897)



N=359 insts.

**Cases**

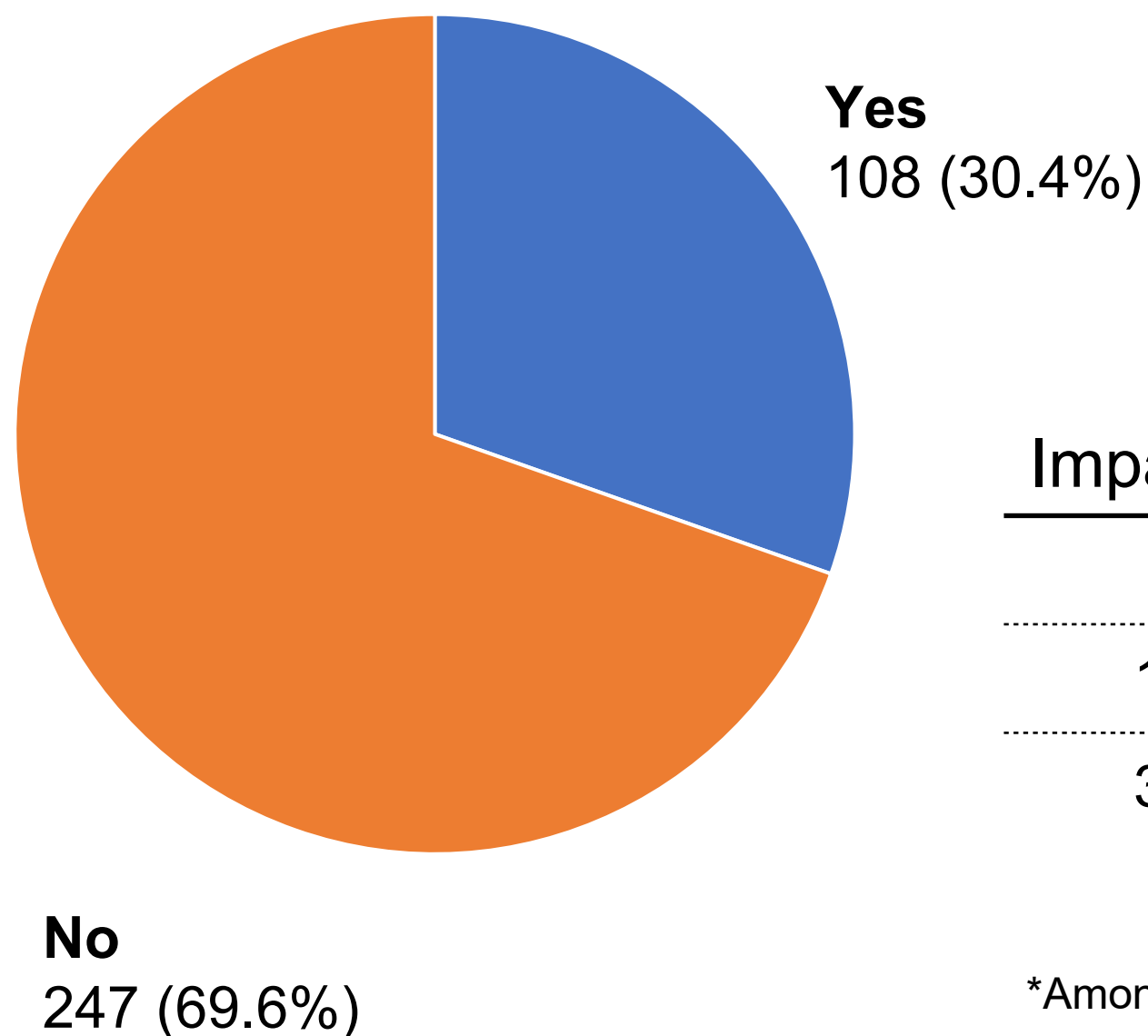
Cardiopulmonary Bypass (CPB)

# CPB-Related Accidents/Incidents & Rates

|                       | 2023 Survey  |              |                | 2021 Survey  |              |                | 2019 Survey  |              |                |
|-----------------------|--------------|--------------|----------------|--------------|--------------|----------------|--------------|--------------|----------------|
|                       | 2021         | 2022         | total          | 2019         | 2020         | total          | 2017         | 2018         | total          |
| CPB cases             | 31,703       | 31,168       | 62,871         | 40,277       | 38,120       | 78,397         | 40,786       | 40,669       | 81,455         |
| Impact level (0)      | 342<br>1.08% | 319<br>1.02% | 661<br>1.06%   | 259<br>0.64% | 284<br>0.75% | 543<br>0.69%   | 379<br>0.93% | 393<br>0.97% | 772<br>0.95%   |
| Impact level (1 – 3a) | 193<br>0.61% | 222<br>0.71% | 415<br>0.66%   | 192<br>0.48% | 245<br>0.64% | 437<br>0.56%   | 340<br>0.83% | 345<br>0.85% | 685<br>0.84%   |
| Impact level (3b – 5) | 17<br>0.06%  | 20<br>0.06%  | 37<br>0.06%    | 11<br>0.03%  | 12<br>0.03%  | 23<br>0.03%    | 16<br>0.04%  | 22<br>0.05%  | 38<br>0.05%    |
| Total                 | 552<br>1.74% | 561<br>1.80% | 1,113<br>1.77% | 462<br>1.15% | 541<br>1.42% | 1,003<br>1.37% | 735<br>1.80% | 760<br>1.87% | 1,495<br>1.84% |



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



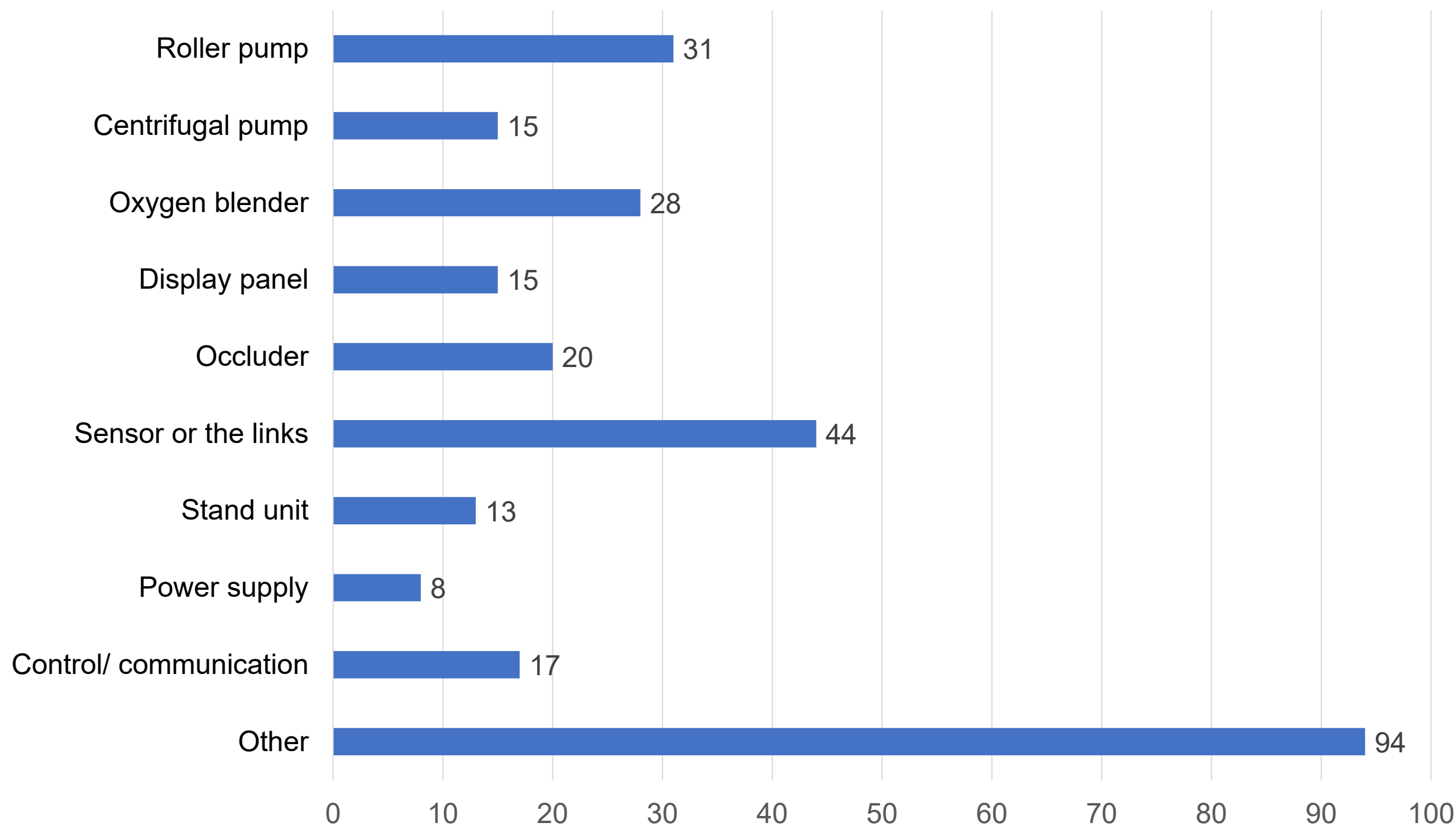
| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 0            | 266          | 0.42%      |
| 1~3a         | 94           | 0.15%      |
| 3b~5         | 9            | 0.01%      |

No answer: 4 insts.

\*Among 62,871 CPB cases occurring during the 2-year period

N=359 (no answer: 4 insts.)

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

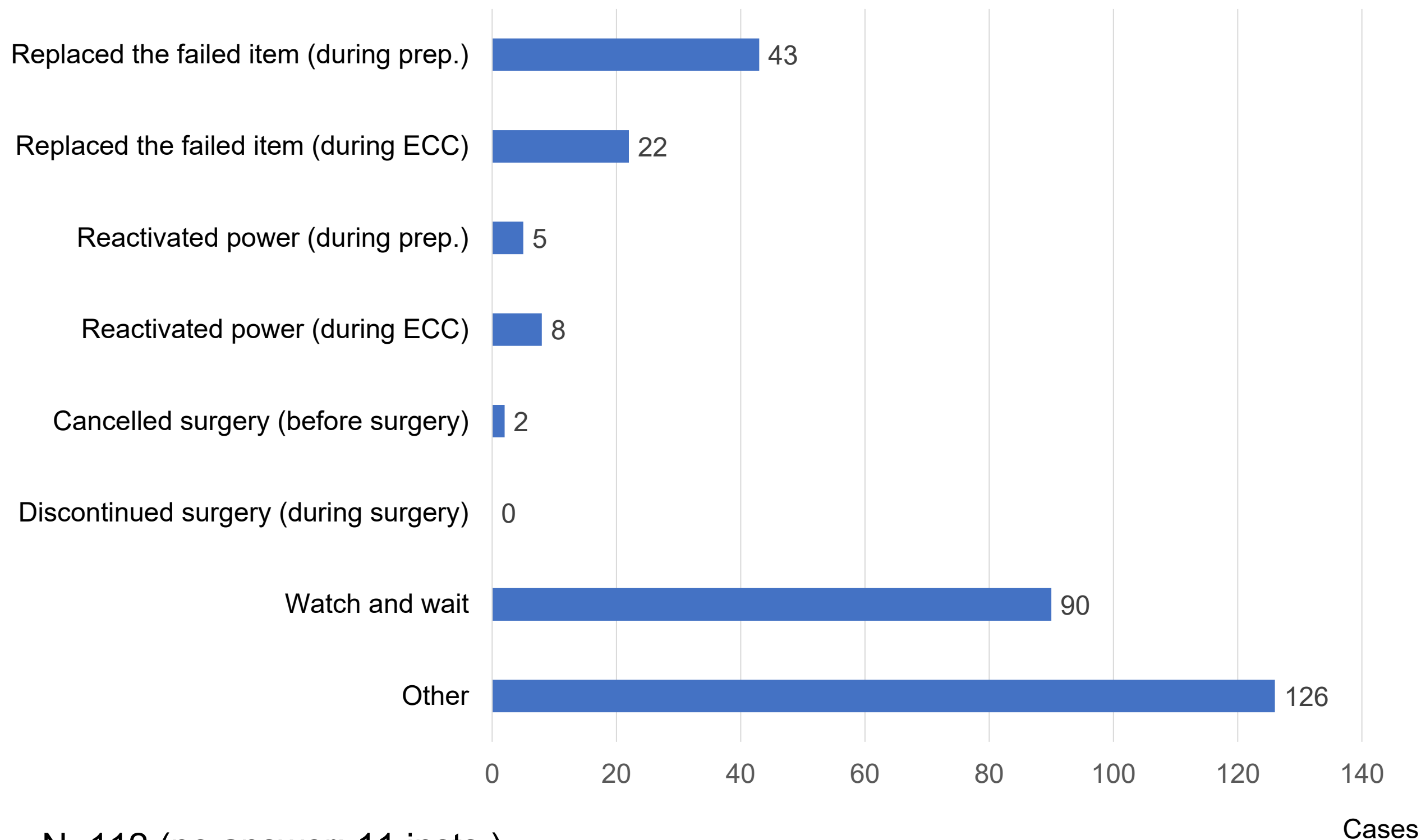


N=112 (no answer: 13 insts.)

Cases

Cardiopulmonary Bypass (CPB)

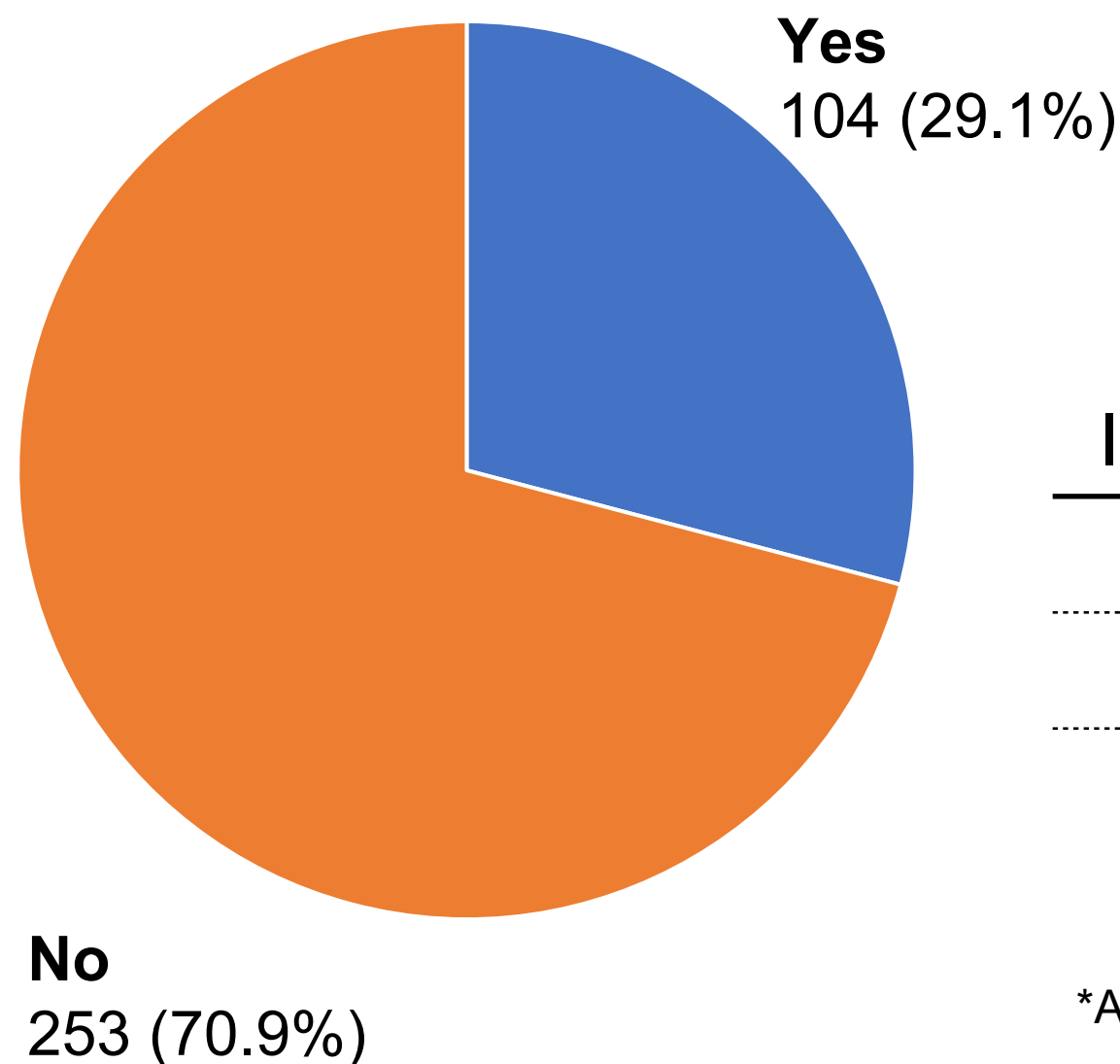
## Which of the following actions did you take in response to the accident/incident and how many times? (Please choose all that apply.)



# CPB Device-Related Incidents & Rates

| 2023 Survey          |              |            | 2021 Survey           |             | 2019 Survey            |              |
|----------------------|--------------|------------|-----------------------|-------------|------------------------|--------------|
| Impact level         | No. of cases | Frequency* | No. of cases          | Frequency** | No. of cases           | Frequency*** |
| 0                    | 266          | 0.42%      | 172                   | 0.22%       | 199                    | 0.24%        |
| 1 – 3a               | 94           | 0.15%      | 112                   | 0.14%       | 117                    | 0.14%        |
| 3b – 5               | 9            | 0.01%      | 6                     | 0.01%       | 6                      | 0.01%        |
| No answer: 4 insts.  |              |            | No answer: 11 insts.  |             | No answer: 18 insts.   |              |
| * Among 62,871 cases |              |            | ** Among 78,397 cases |             | *** Among 81,455 cases |              |

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



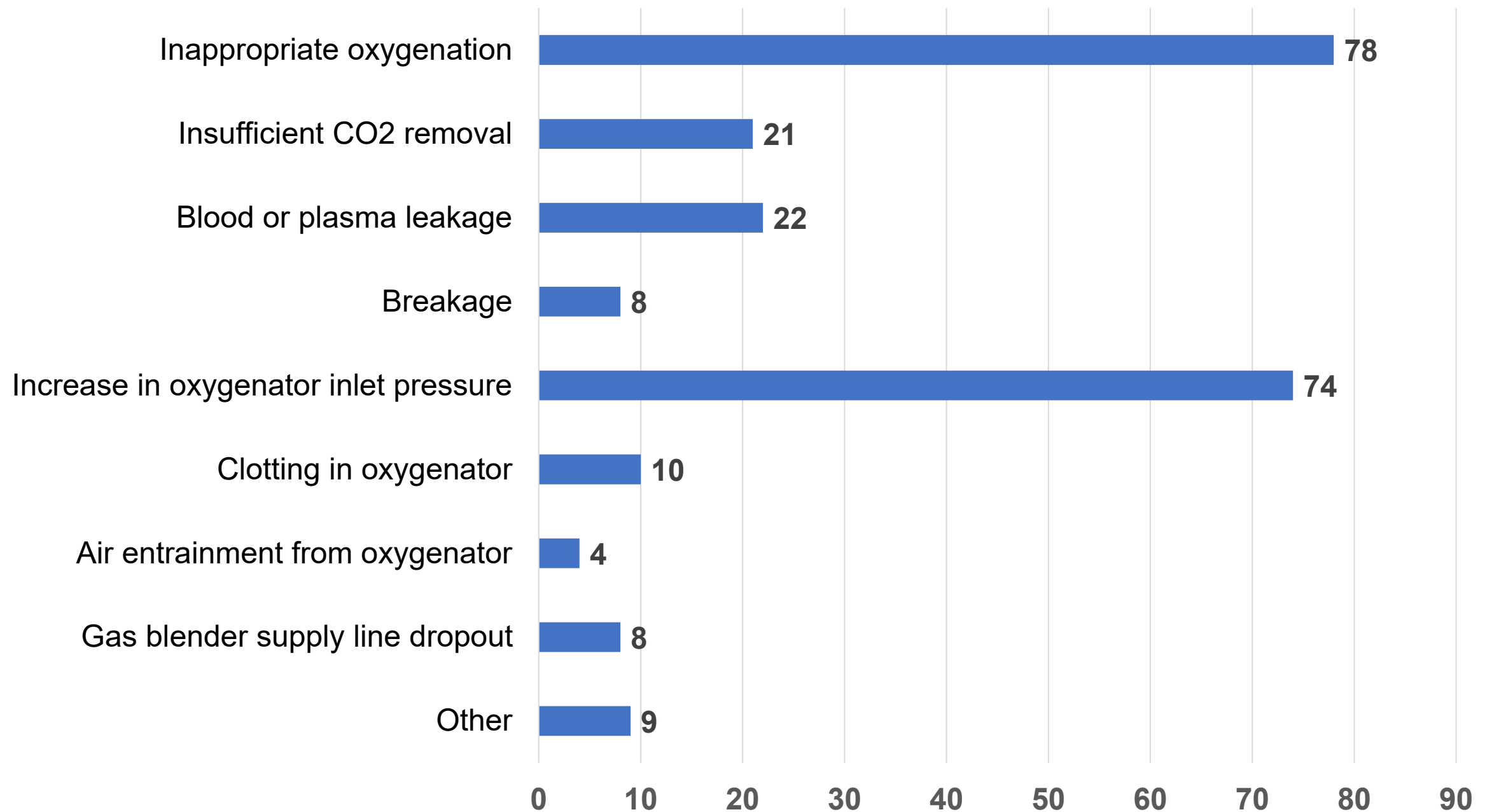
| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 0            | 84           | 0.13%      |
| 1~3a         | 109          | 0.17%      |
| 3b~5         | 9            | 0.01%      |

No answer: 4 insts.

\*Among 62,871 CPB cases occurring during the 2-year period

N=359 (no answer: 2 insts.)

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

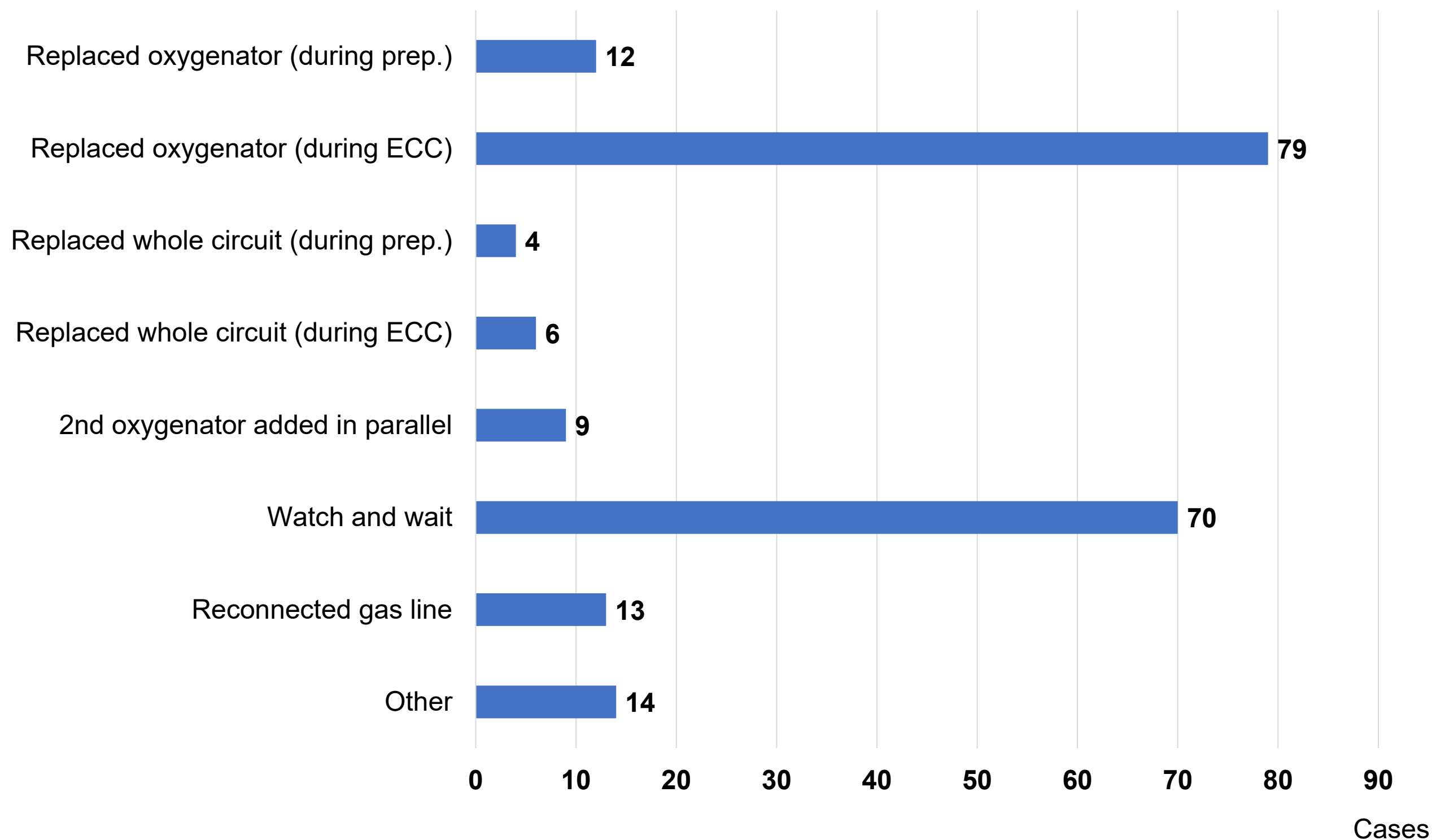


Cases

N=106 (no answer: 4 insts.)

Cardiopulmonary Bypass (CPB)

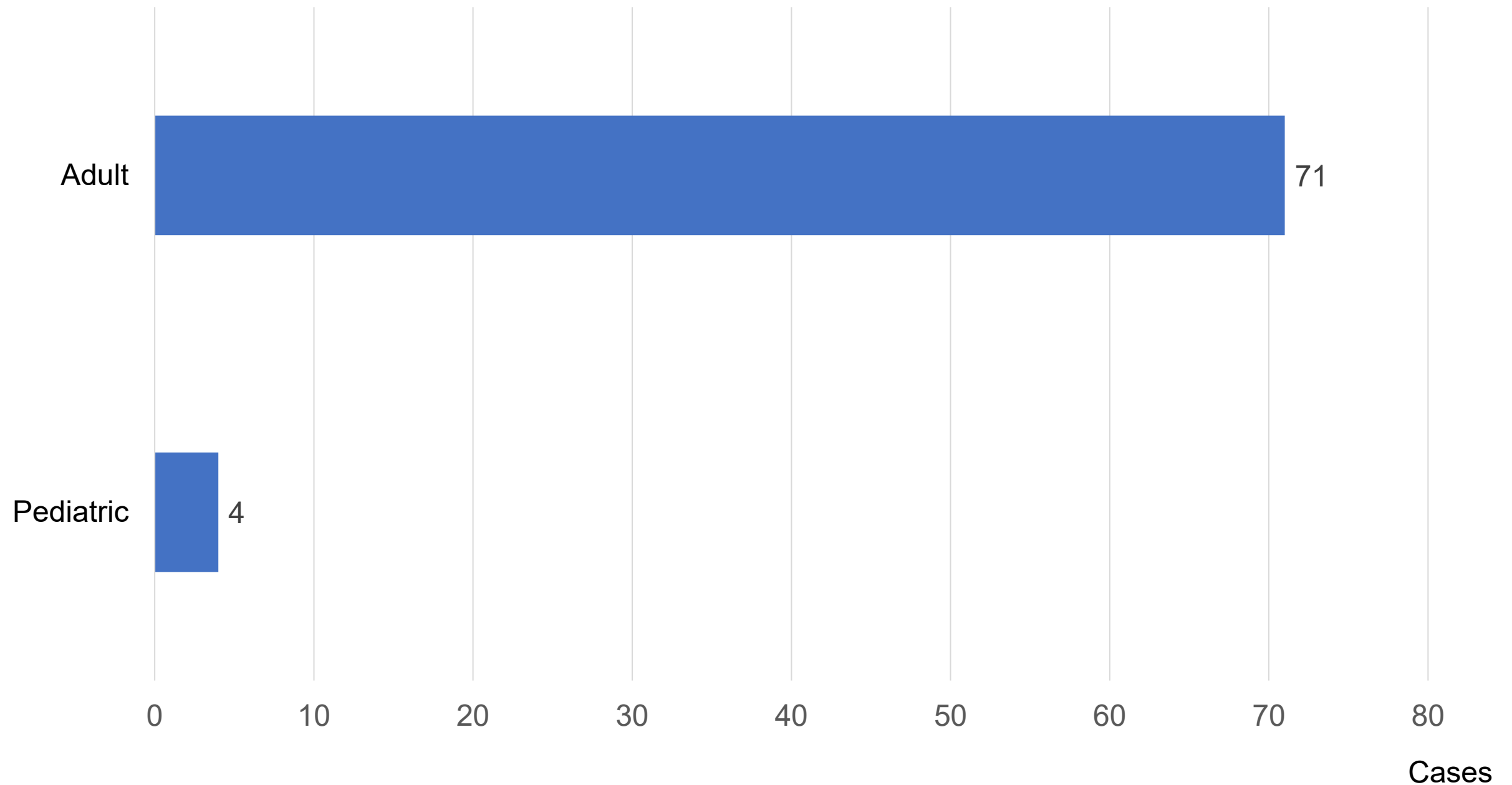
## Which of the following actions did you take in response to the incident/accident? (Please choose all that apply.)



N=106 (no answer: 5 insts.)

# Number of Cases

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



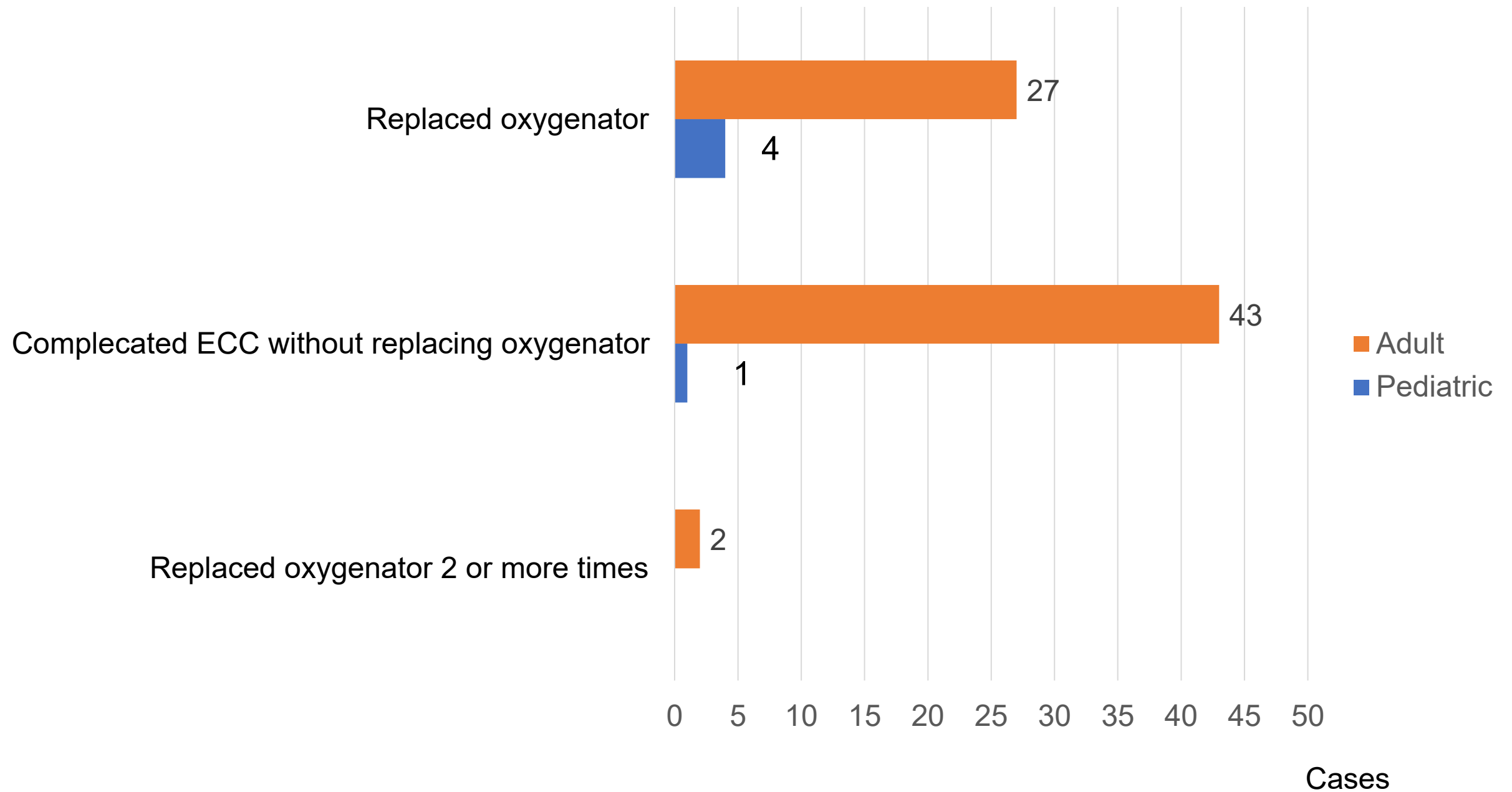
N=60 (no answer: 2 insts.)

Cardiopulmonary Bypass (CPB)



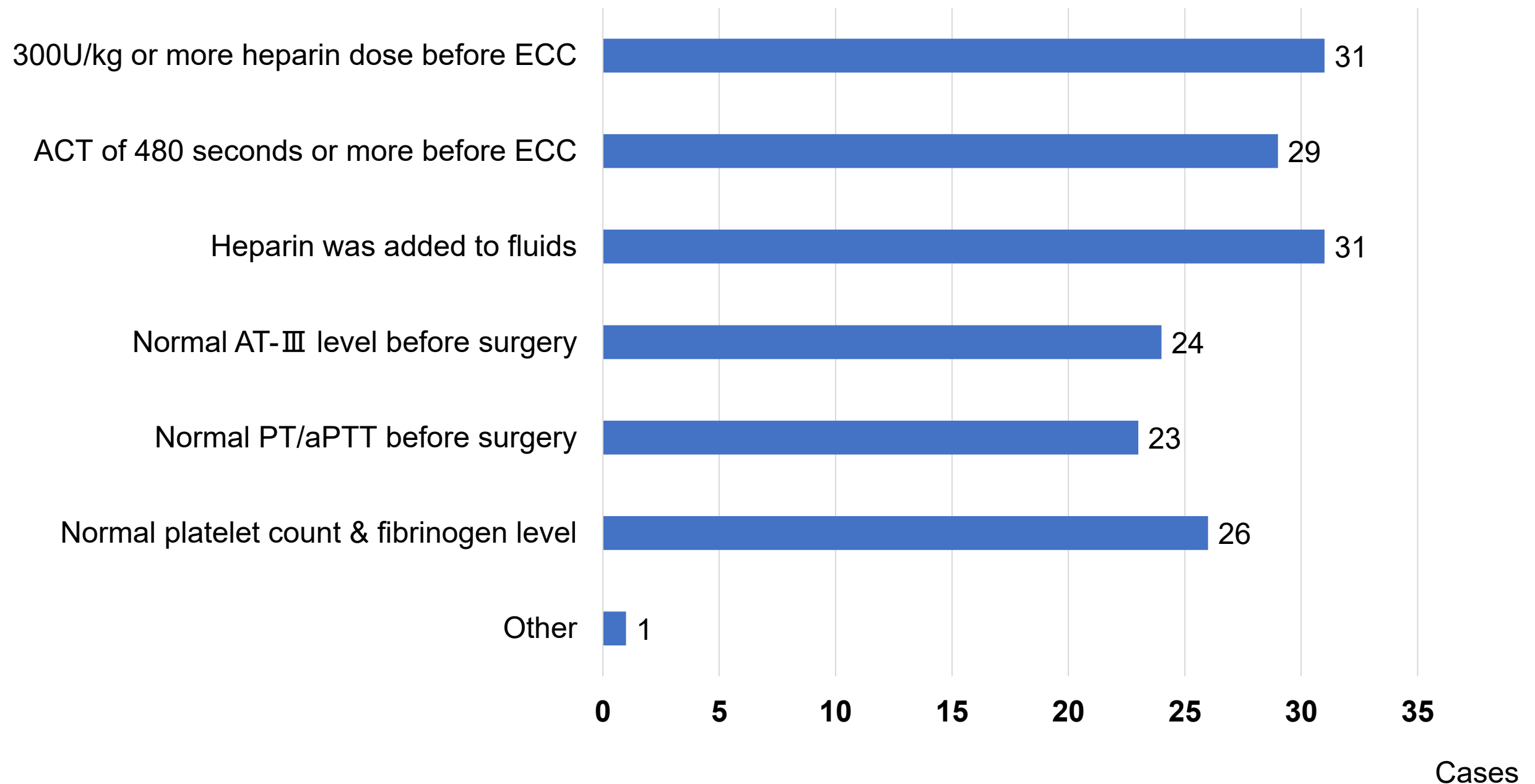
# Did you replace the oxygenator? (Please choose all that apply.)

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



N=62 (no answer: 0 insts.)

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



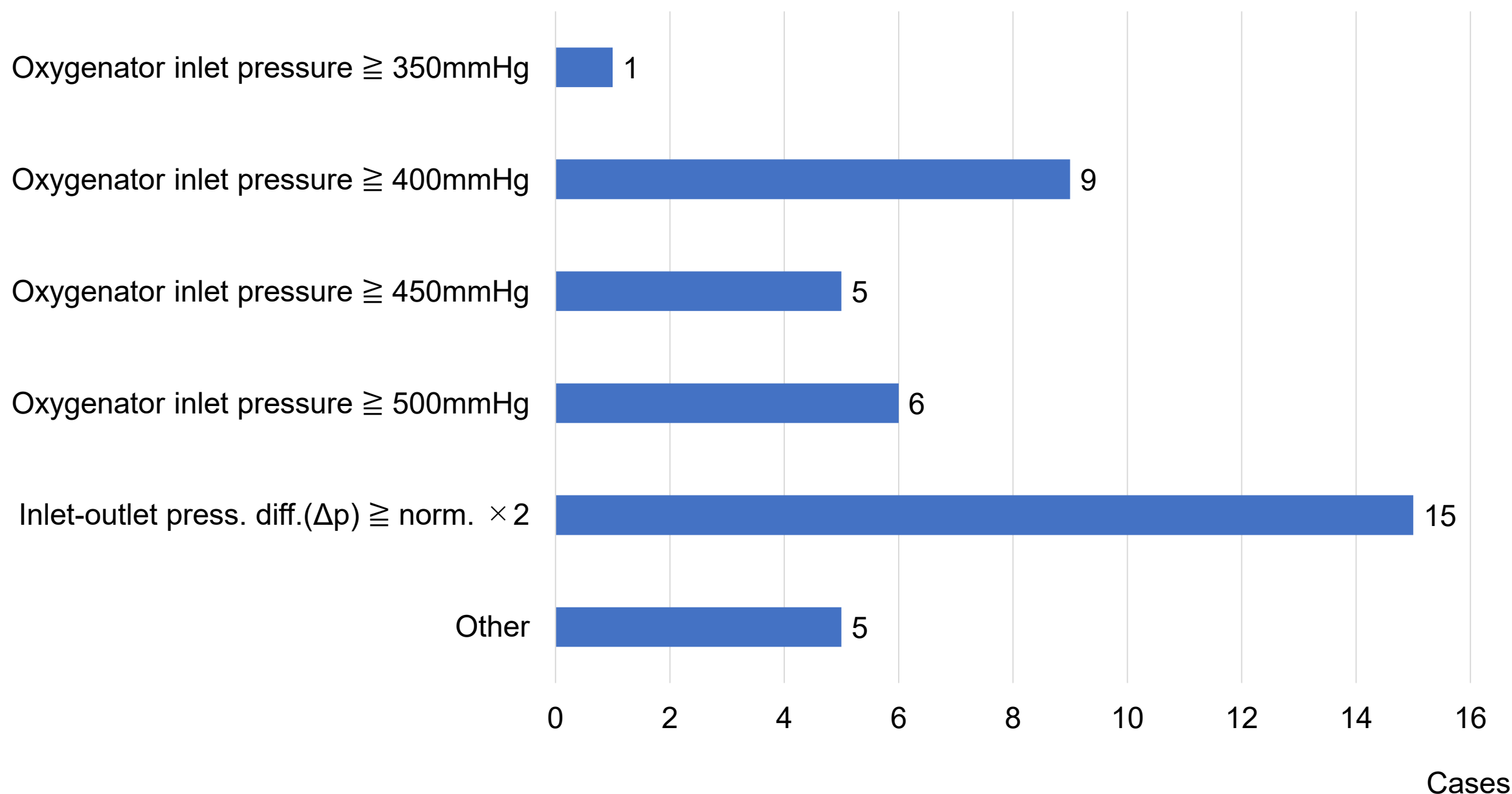
N=26 (no answer: 3 insts.)

Cardiopulmonary Bypass (CPB)

# What was reason for replacing the oxygenator?

(Please choose all that apply.)

(27 institutions that replaced oxygenator 1 or more times)

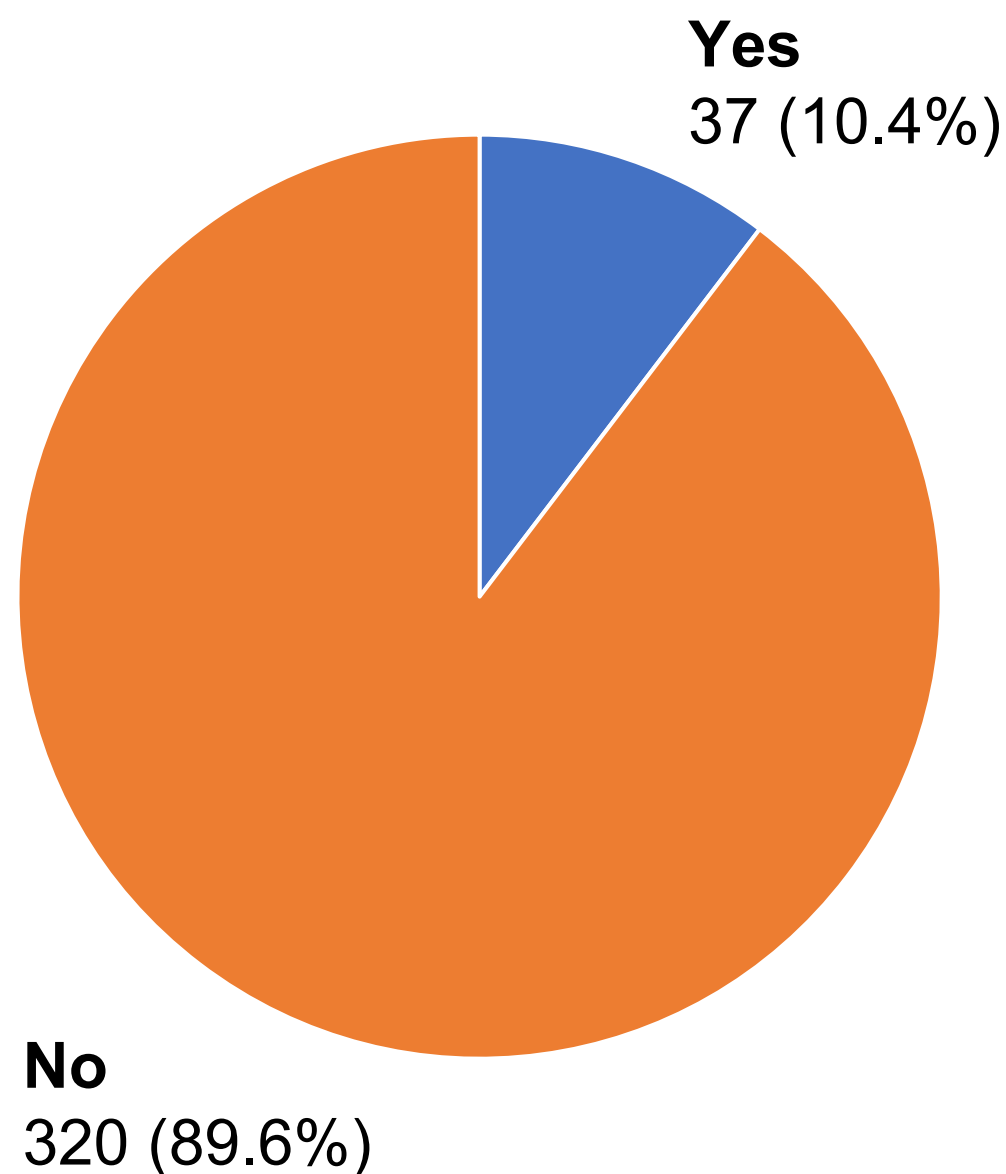


N=26 (no answer: 1 insts.)

# Oxygenator-Related Incidents & Rates

| 2023 Survey          |              |            | 2021 Survey           |             | 2019 Survey           |              |
|----------------------|--------------|------------|-----------------------|-------------|-----------------------|--------------|
| Impact level         | No. of cases | Frequency* | No. of cases          | Frequency** | No. of cases          | Frequency*** |
| 0                    | 84           | 0.13%      | 119                   | 0.15%       | 89                    | 0.11%        |
| 1 – 3a               | 109          | 0.17%      | 106                   | 0.14%       | 120                   | 0.15%        |
| 3b – 5               | 9            | 0.01%      | 4                     | 0.01%       | 12                    | 0.01%        |
| No answer: 4 insts.  |              |            | No answer: 11 insts.  |             | No answer: 11 insts   |              |
| * Among 62,871 cases |              |            | ** Among 78,397 cases |             | ***Among 81,455 cases |              |

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



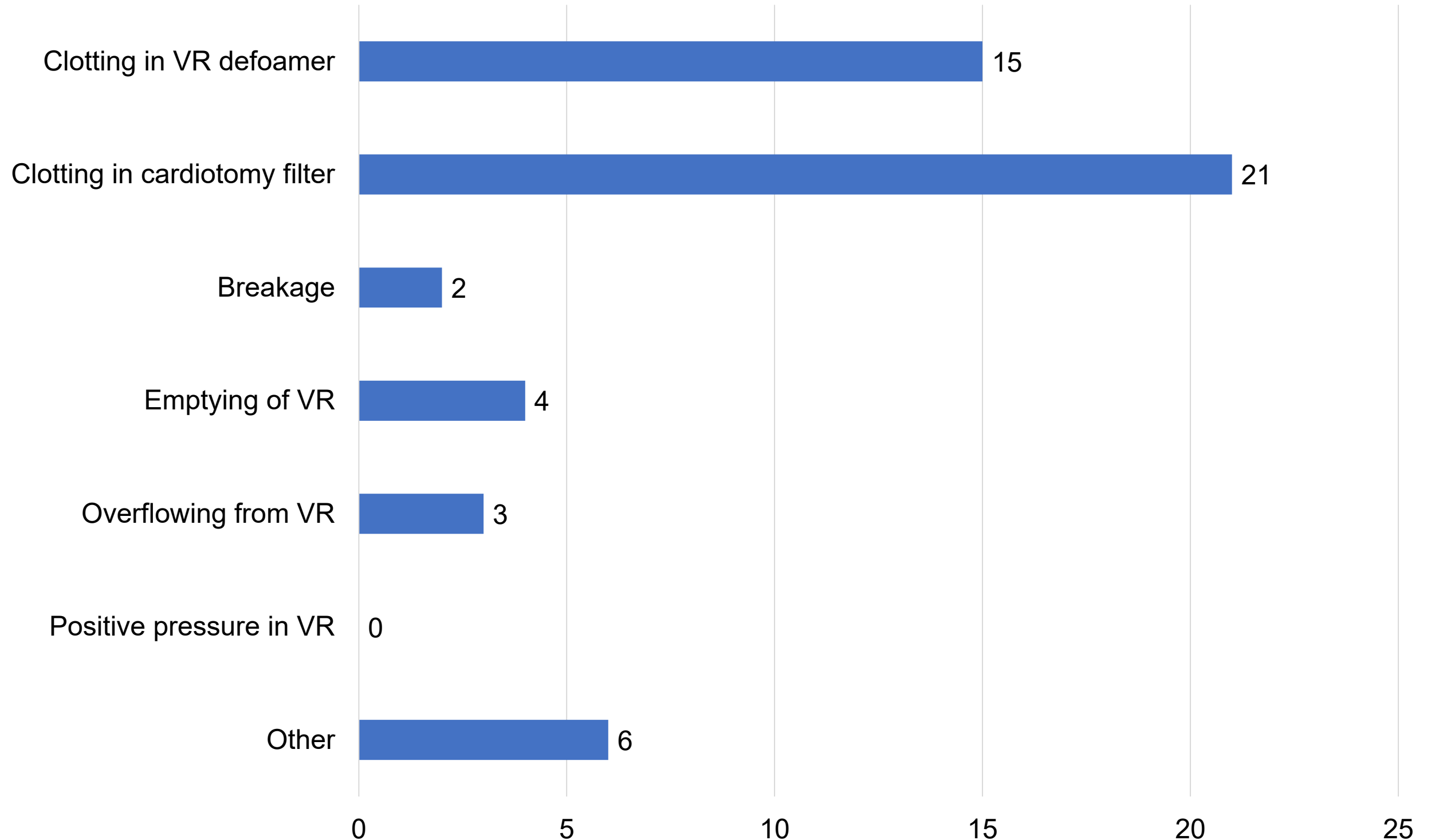
N=359 (no answer: 2 insts.)

| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 0            | 16           | 0.03%      |
| 1~3a         | 29           | 0.05%      |
| 3b~5         | 3            | < 0.01%    |

No answer: 5 insts.

\*Among 62,871 CPB cases occurring during the 2-year period

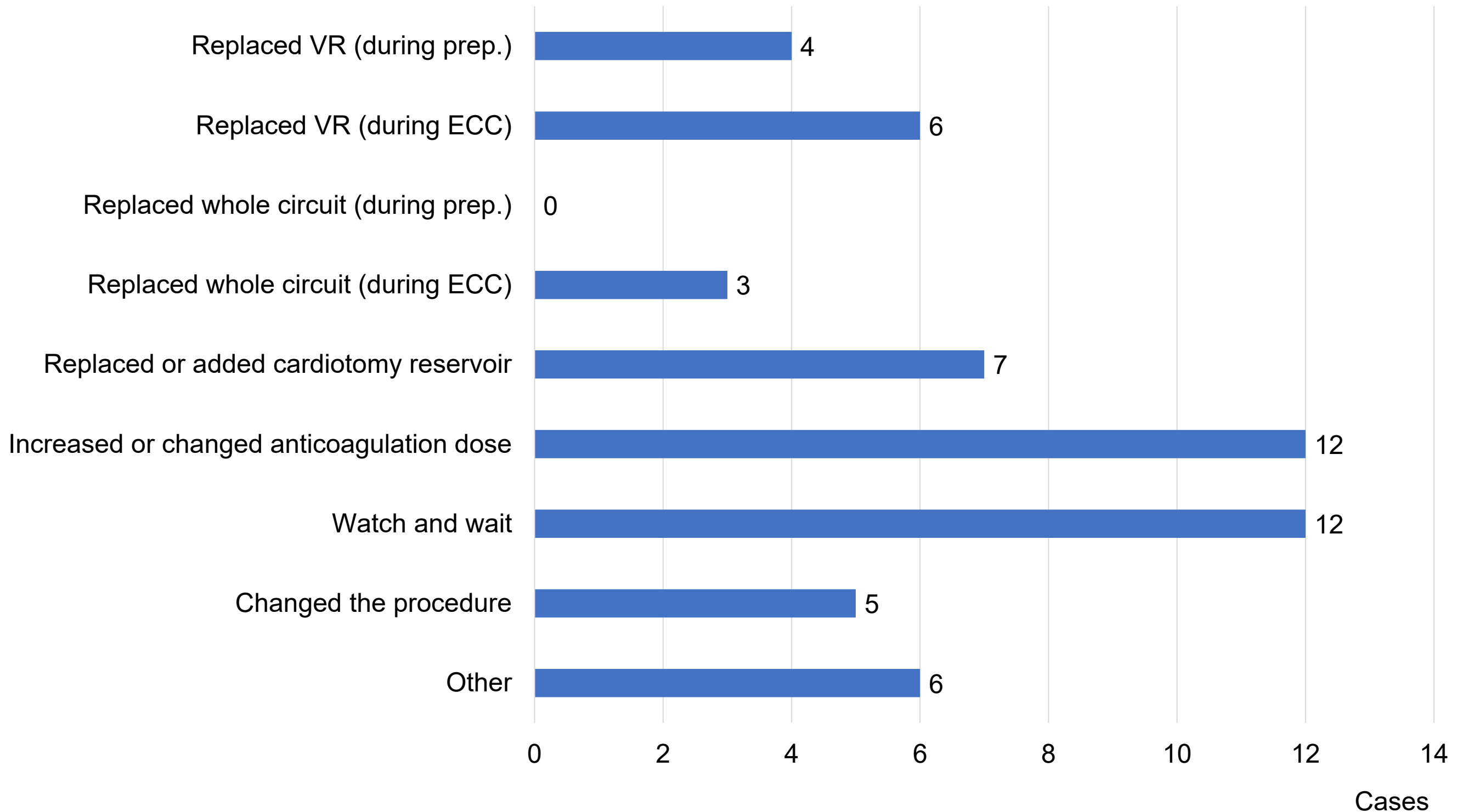
# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



N=39 (no answer: 2 insts.)

Cases  
Cardiopulmonary Bypass (CPB)

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



N=39 (no answer: 3 insts.)

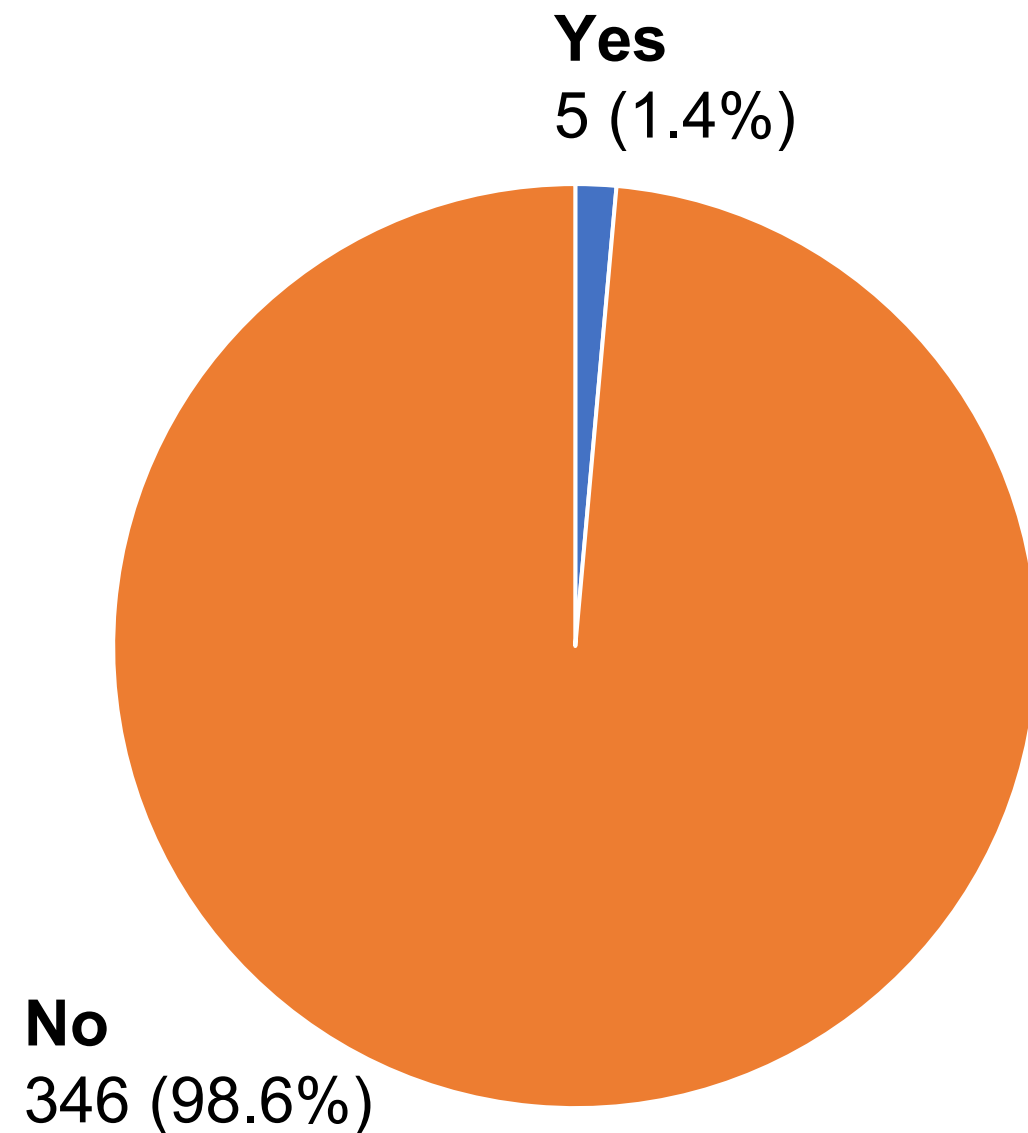
Cardiopulmonary Bypass (CPB)

# Venous-Reservoir-Related Incidents & Rates

| 2023 Survey          |              |            | 2021 Survey           |             | 2019 Survey            |              |
|----------------------|--------------|------------|-----------------------|-------------|------------------------|--------------|
| Impact level         | No. of cases | Frequency* | No. of cases          | Frequency** | No. of cases           | Frequency*** |
| 0                    | 16           | 0.03%      | 30                    | 0.04%       | 46                     | 0.06%        |
| 1 – 3a               | 29           | 0.05%      | 21                    | 0.03%       | 36                     | 0.04%        |
| 3b – 5               | 3            | < 0.01%    | 0                     | 0.00%       | 4                      | < 0.01%      |
| No answer: 33 insts. |              |            | No answer: 33 insts.  |             | No answer: 14 insts.   |              |
| * Among 62,871 cases |              |            | ** Among 78,397 cases |             | *** Among 81,455 cases |              |



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



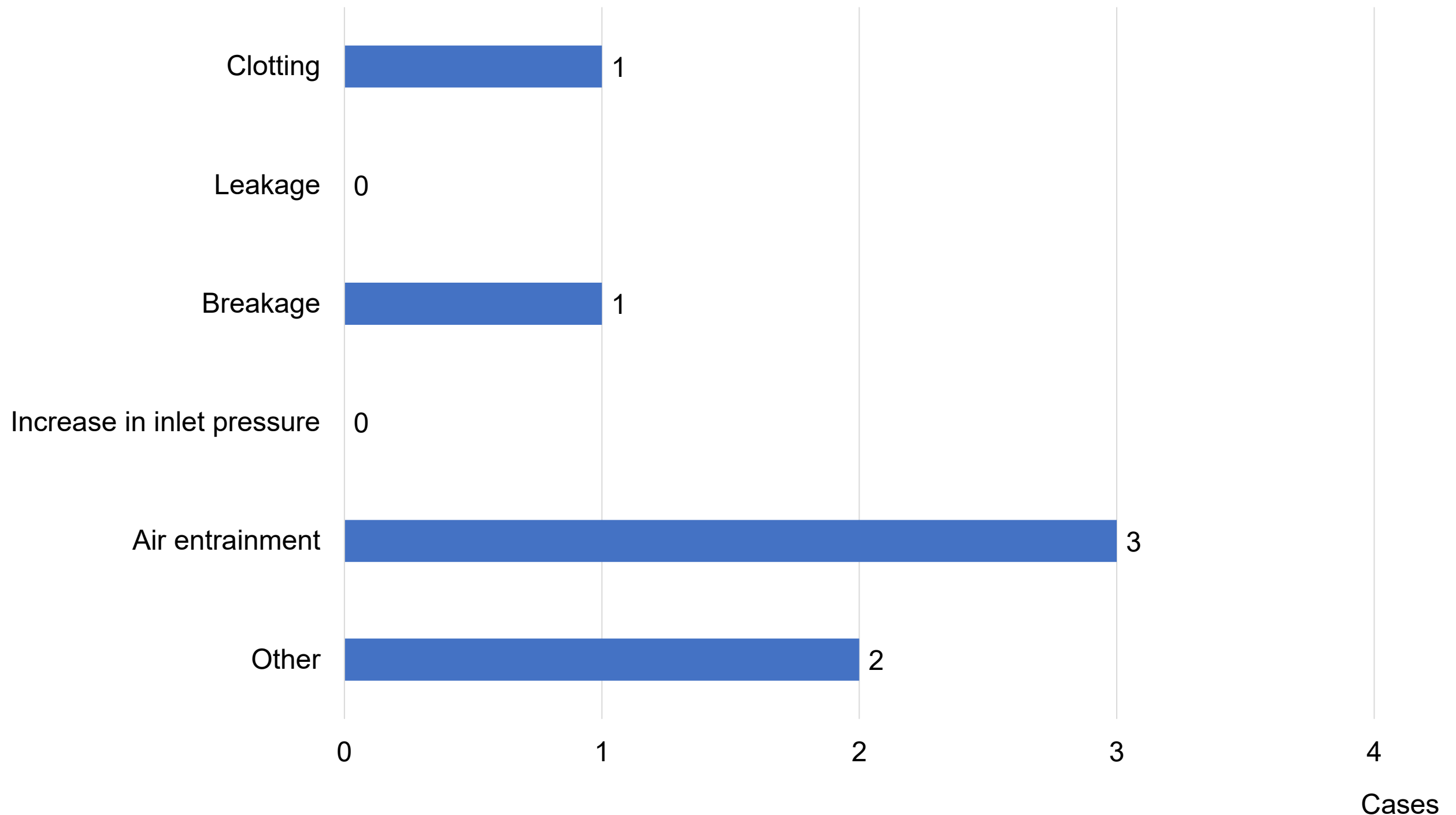
| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 0            | 6            | < 0.01%    |
| 1~3a         | 1            | < 0.01%    |
| 3b~5         | 0            | 0%         |

No answer: 8 insts

\*Among 62,871 CPB cases occurring during the 2-year period

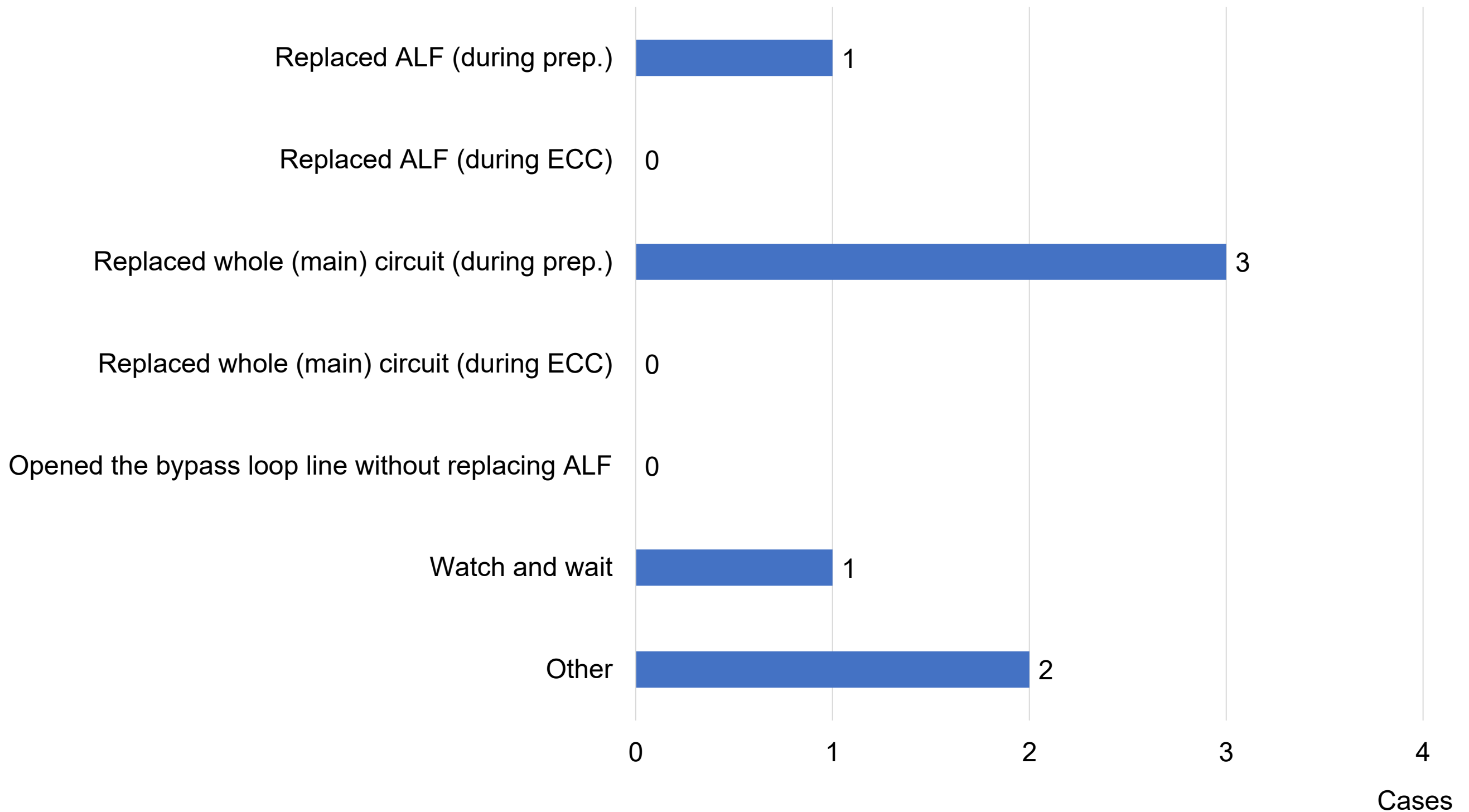
N=359 (no answer: 8 insts.)

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



N=13 (no answer: 8 insts.)

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

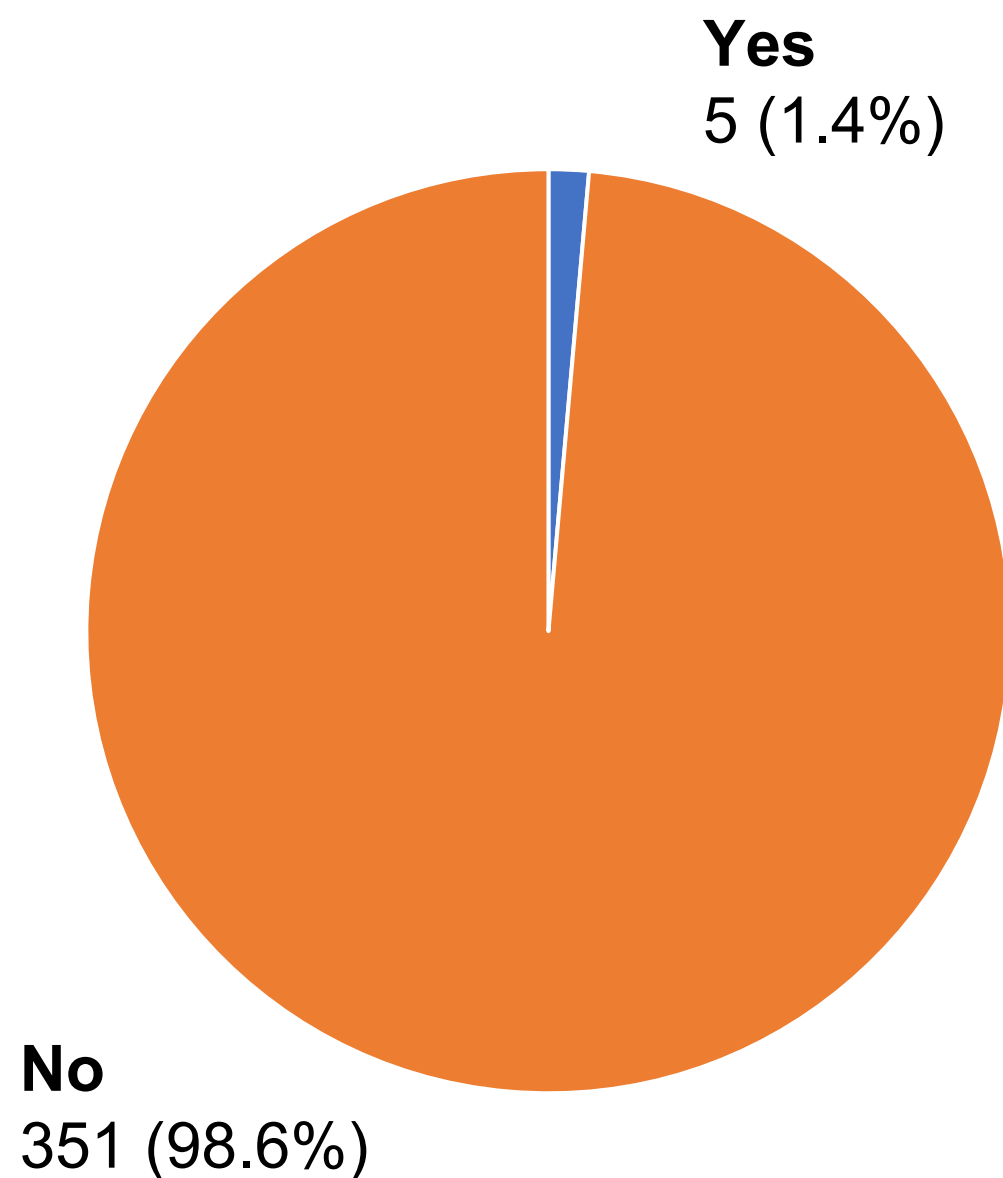


N=13 (no answer: 8 insts.)

# Arterial Line Filter-Related Incidents & Rates

| 2023 Survey         |              |            | 2021 Survey           |             | 2019 Survey            |              |
|---------------------|--------------|------------|-----------------------|-------------|------------------------|--------------|
| Impact level        | No. of cases | Frequency* | No. of cases          | Frequency** | No. of cases           | Frequency*** |
| 0                   | 6            | <0.01%     | 5                     | <0.01%      | 6                      | <0.01%       |
| 1 – 3a              | 1            | <0.01%     | 1                     | <0.01%      | 3                      | <0.01%       |
| 3b – 5              | 0            | 0%         | 0                     | 0%          | 0                      | 0%           |
| No answer: 8 insts. |              |            | No answer: 32 insts.  |             | No answer: 13 insts.   |              |
| *Among 62,871 cases |              |            | ** Among 78,397 cases |             | *** Among 81,455 cases |              |

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



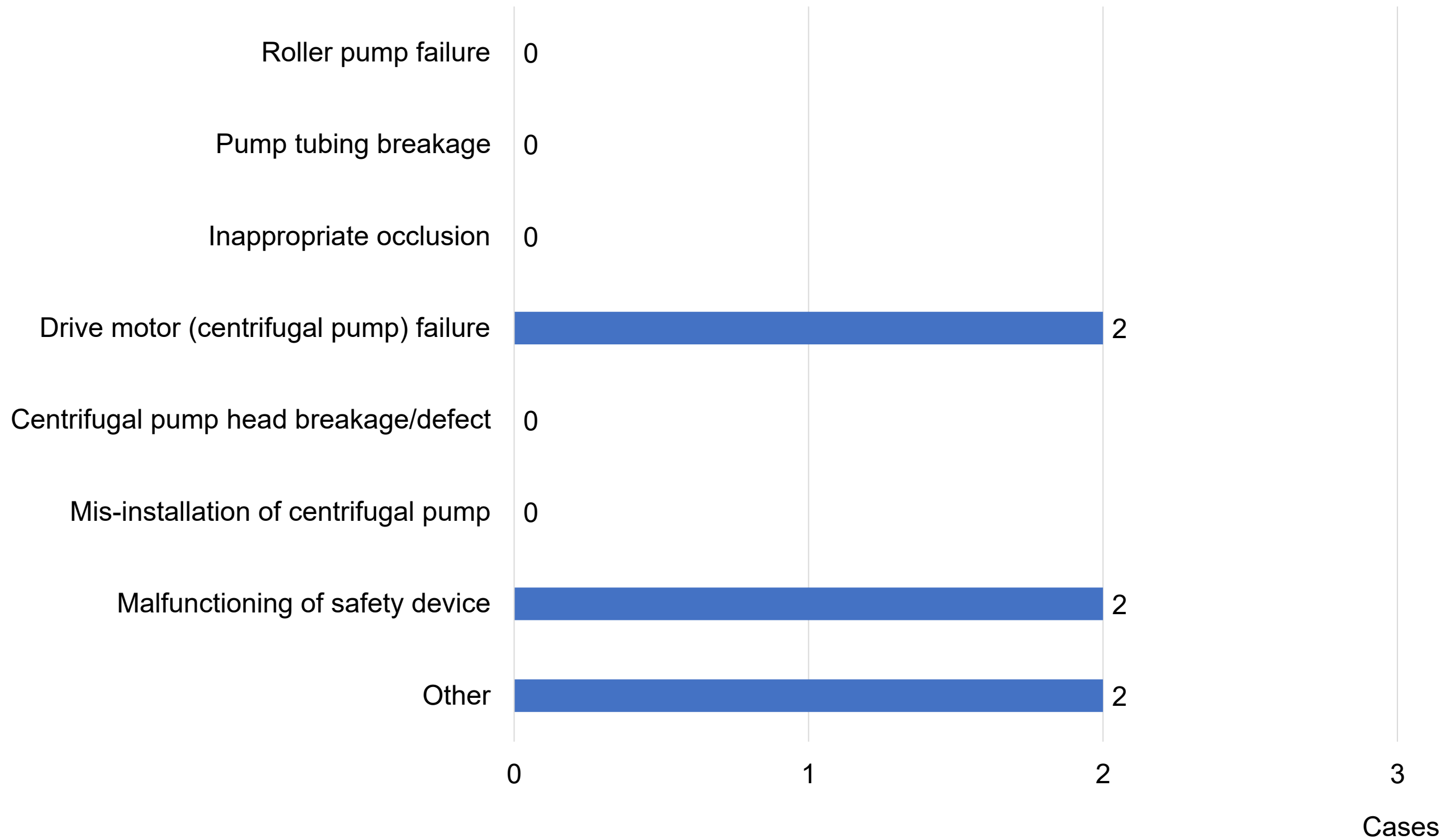
| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 0            | 3            | < 0.01%    |
| 1~3a         | 2            | < 0.01%    |
| 3b~5         | 1            | < 0.01%    |

No answer: 3 insts.

\*Among 62,871 CPB cases occurring during the 2-year period

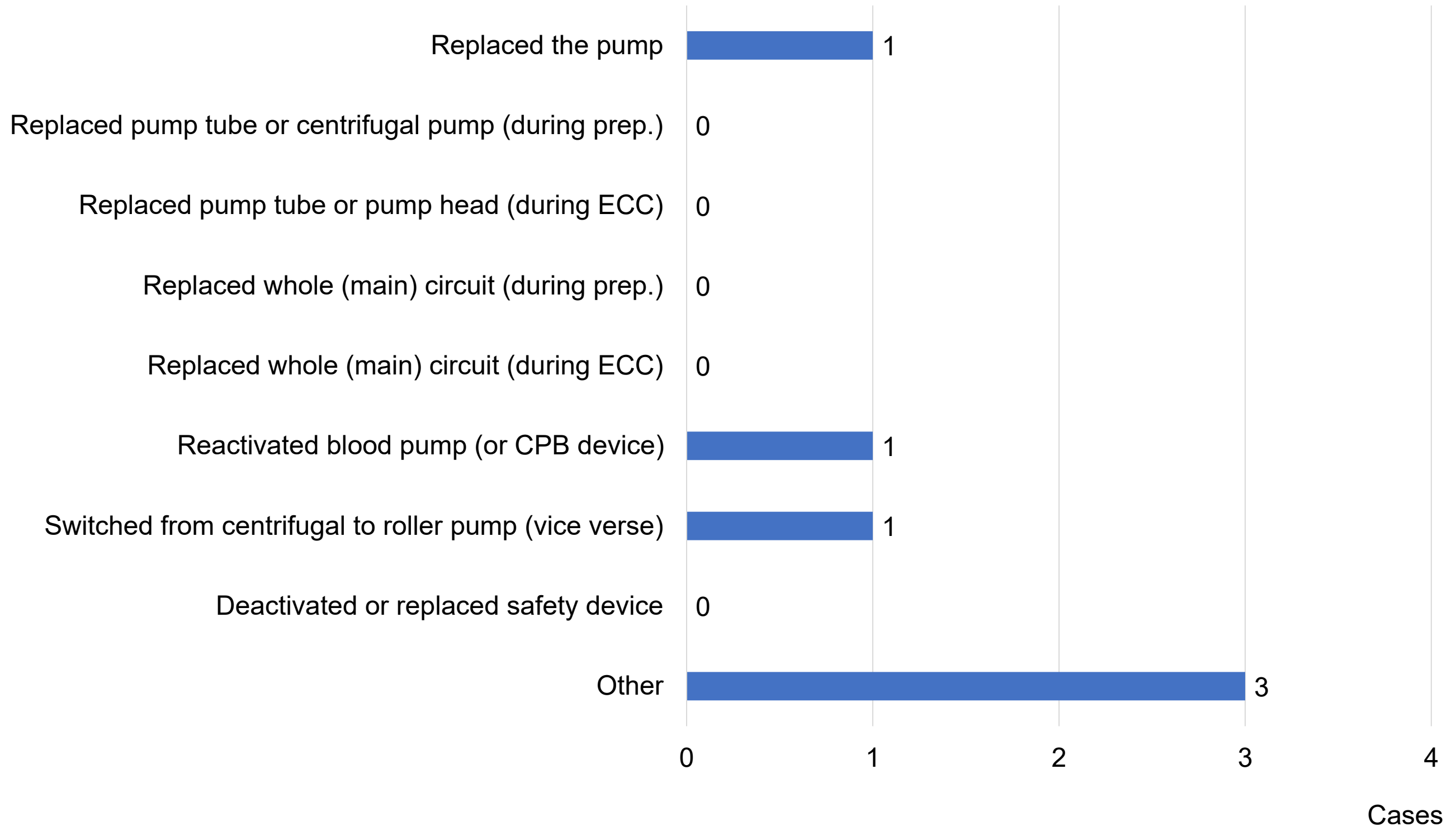
N=359 (no answer: 3 insts.)

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



N=8 (no answer: 3 insts.)

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



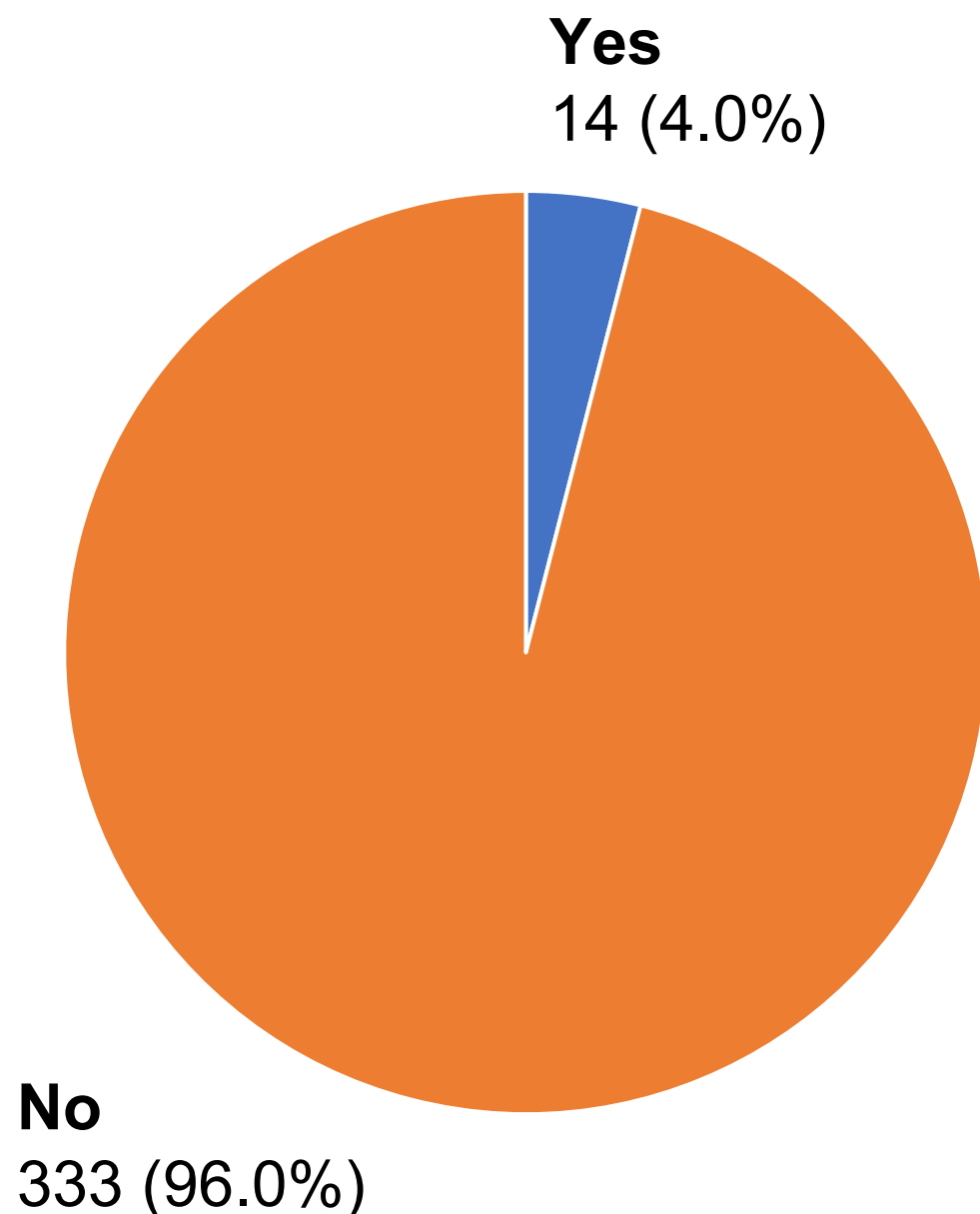
N=8 (no answer: 3 insts.)

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

| 2023 Survey          |              |            | 2021 Survey           |             | 2019 Survey            |              |
|----------------------|--------------|------------|-----------------------|-------------|------------------------|--------------|
| Impact level         | No. of cases | Frequency* | No. of cases          | Frequency** | No. of cases           | Frequency*** |
| 0                    | 3            | < 0.01%    | 7                     | < 0.01%     | 7                      | < 0.01%      |
| 1~3a                 | 2            | < 0.01%    | 8                     | < 0.01%     | 7                      | < 0.01%      |
| 3b~5                 | 1            | < 0.01%    | 0                     | 0%          | 0                      | 0%           |
| No answer: 3 insts.  |              |            | No answer: 8 insts.   |             | No answer: 7 insts.    |              |
| * Among 62,871 cases |              |            | ** Among 78,397 cases |             | *** Among 81,455 cases |              |



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



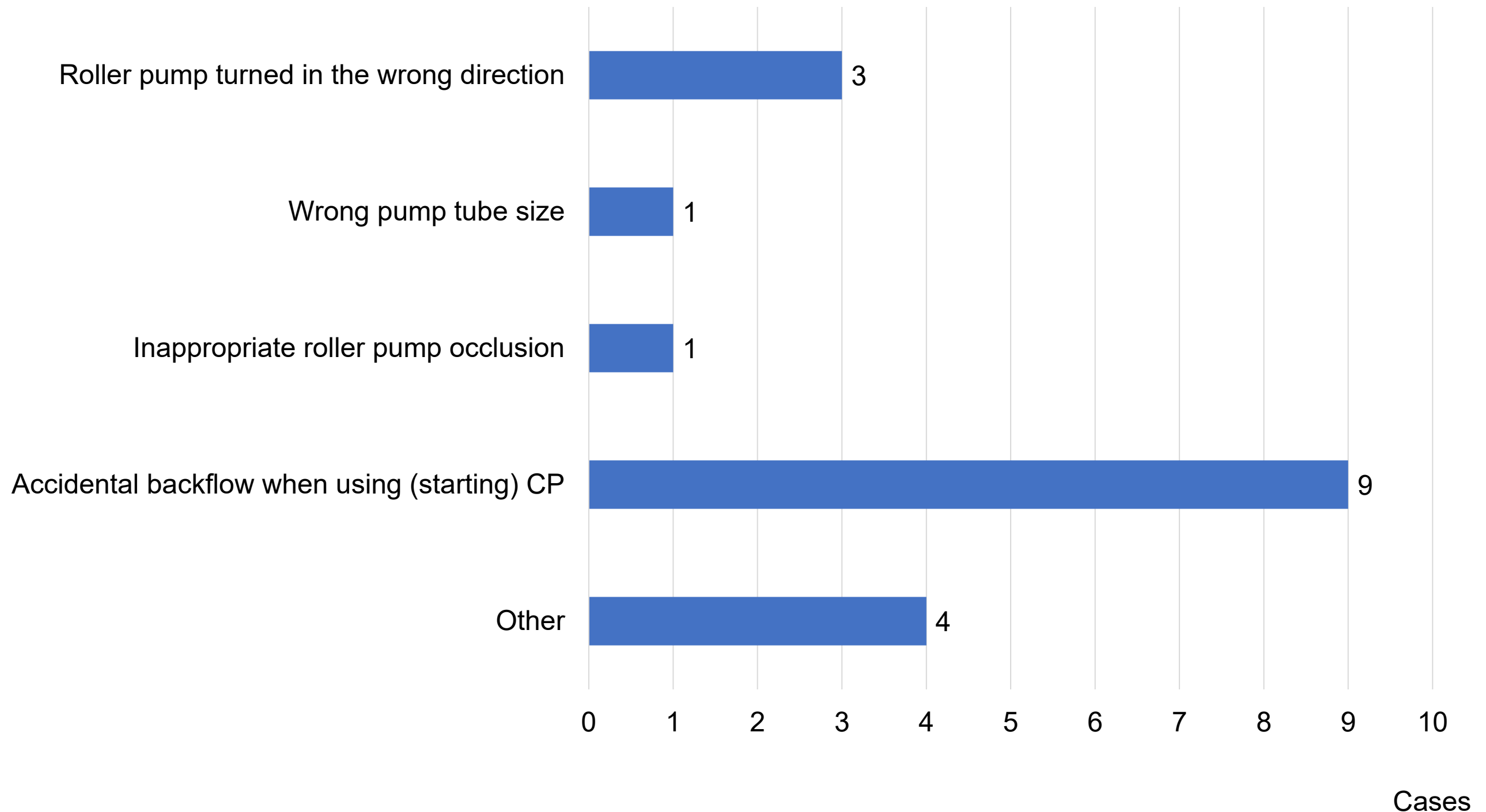
N=359 (no answer: 12 insts.)

| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 0            | 11           | 0.02%      |
| 1~3a         | 6            | <0.01%     |
| 3b~5         | 1            | <0.01%     |

No answer: 12 insts.

\*Among 62,871 CPB cases occurring during the 2-year period

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



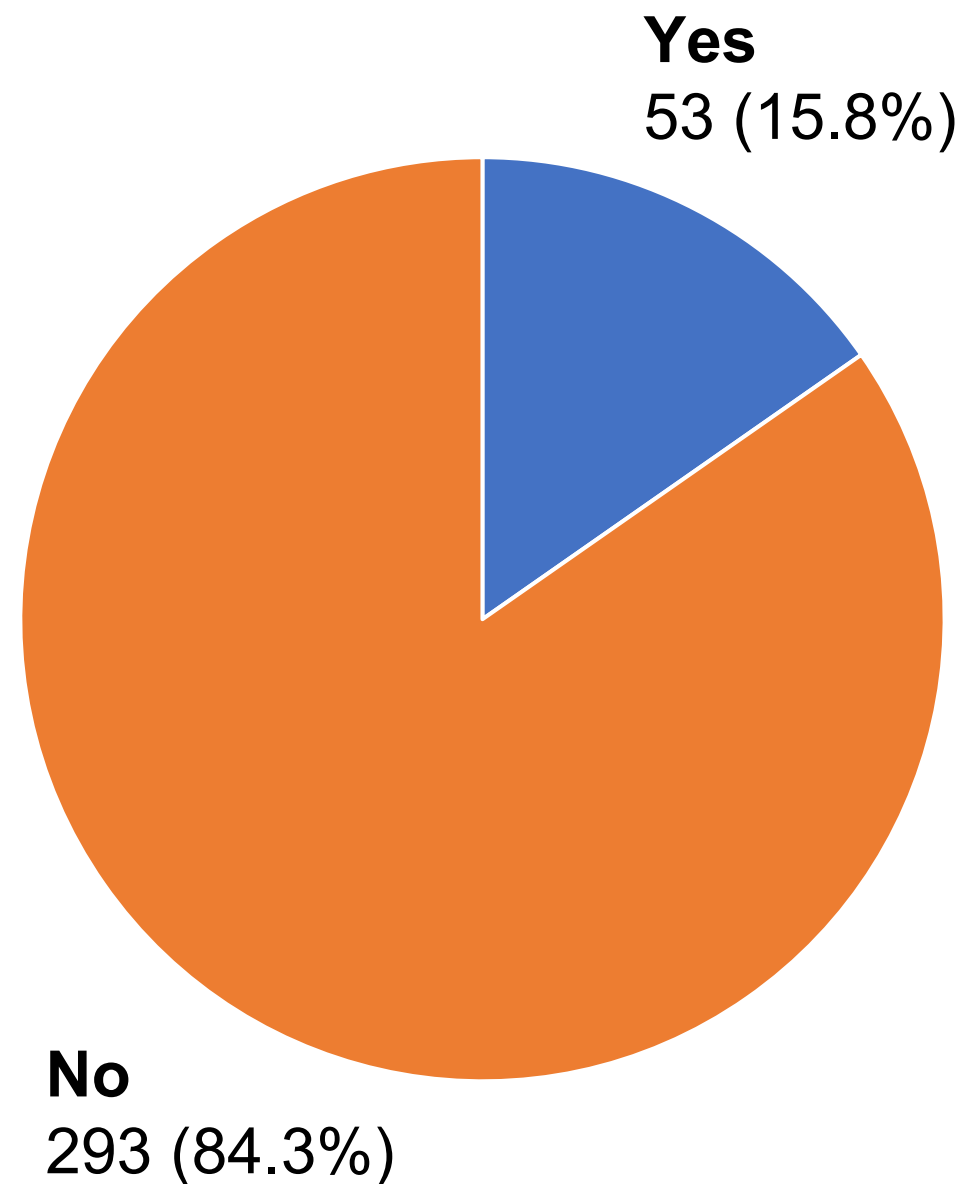
N=26 (no answer: 12 insts.)

Cardiopulmonary Bypass (CPB)

# Blood Pump Mishandling Incidents & Rates

| 2023 Survey          |              |            | 2021 Survey           |             | 2019 Survey            |              |
|----------------------|--------------|------------|-----------------------|-------------|------------------------|--------------|
| Impact level         | No. of cases | Frequency* | No. of cases          | Frequency** | No. of cases           | Frequency*** |
| 0                    | 11           | 0.02%      | 14                    | 0.02%       | 12                     | 0.01%        |
| 1~3a                 | 6            | < 0.01%    | 9                     | 0.01%       | 39                     | 0.05%        |
| 3b~5                 | 1            | < 0.01%    | 0                     | 0%          | 0                      | 0%           |
| No answer: 12 insts. |              |            | No answer: 17 insts.  |             | No answer: 23 insts.   |              |
| * Among 62,871 cases |              |            | ** Among 78,397 cases |             | *** Among 81,455 cases |              |

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



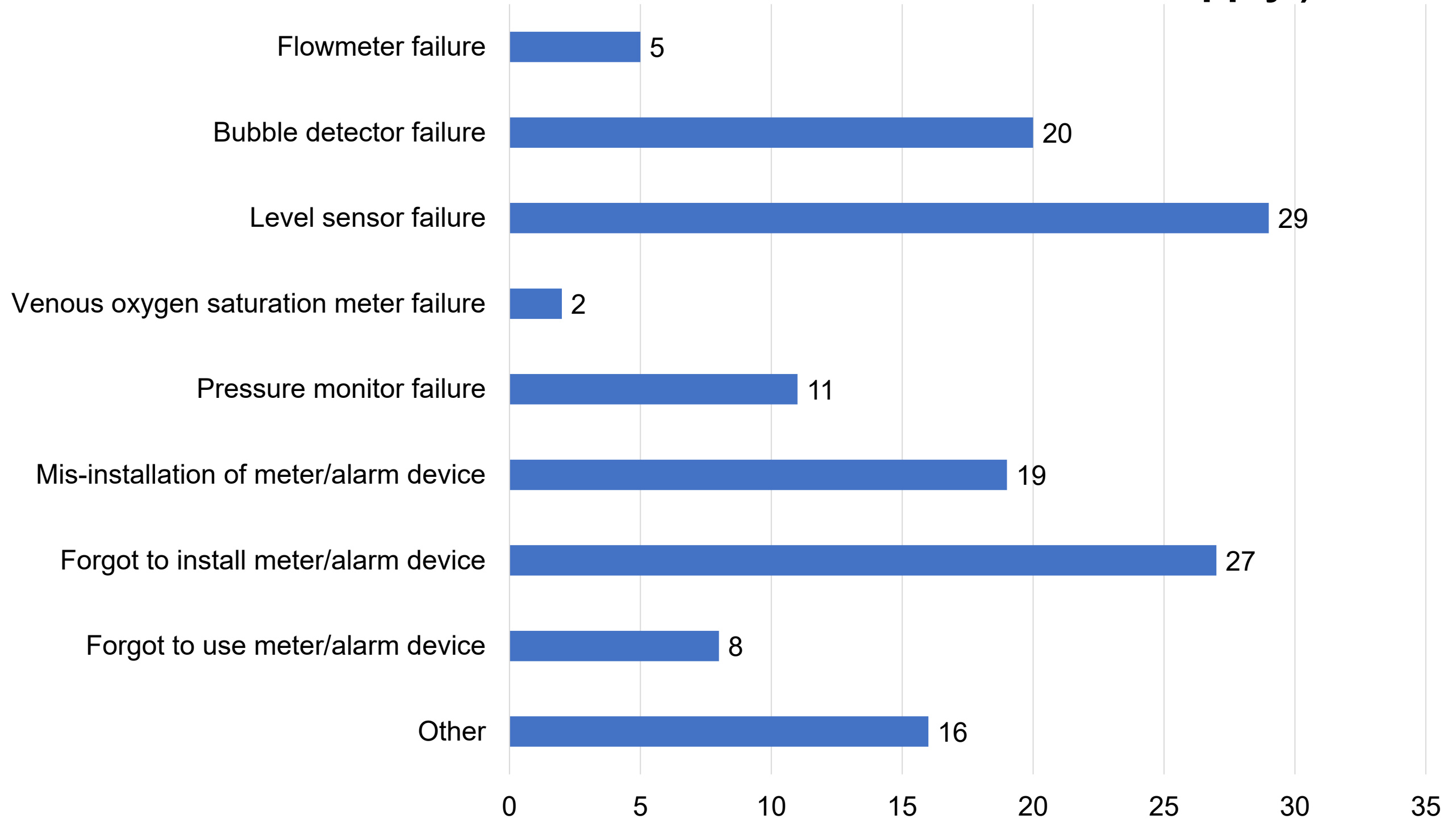
| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 0            | 104          | 0.17%      |
| 1~3a         | 12           | 0.02%      |
| 3b~5         | 0            | 0%         |

No answer: 13 insts.

\*Among 62,871 CPB cases occurring during the 2-year period

N=359 (no answer: 13 insts.)

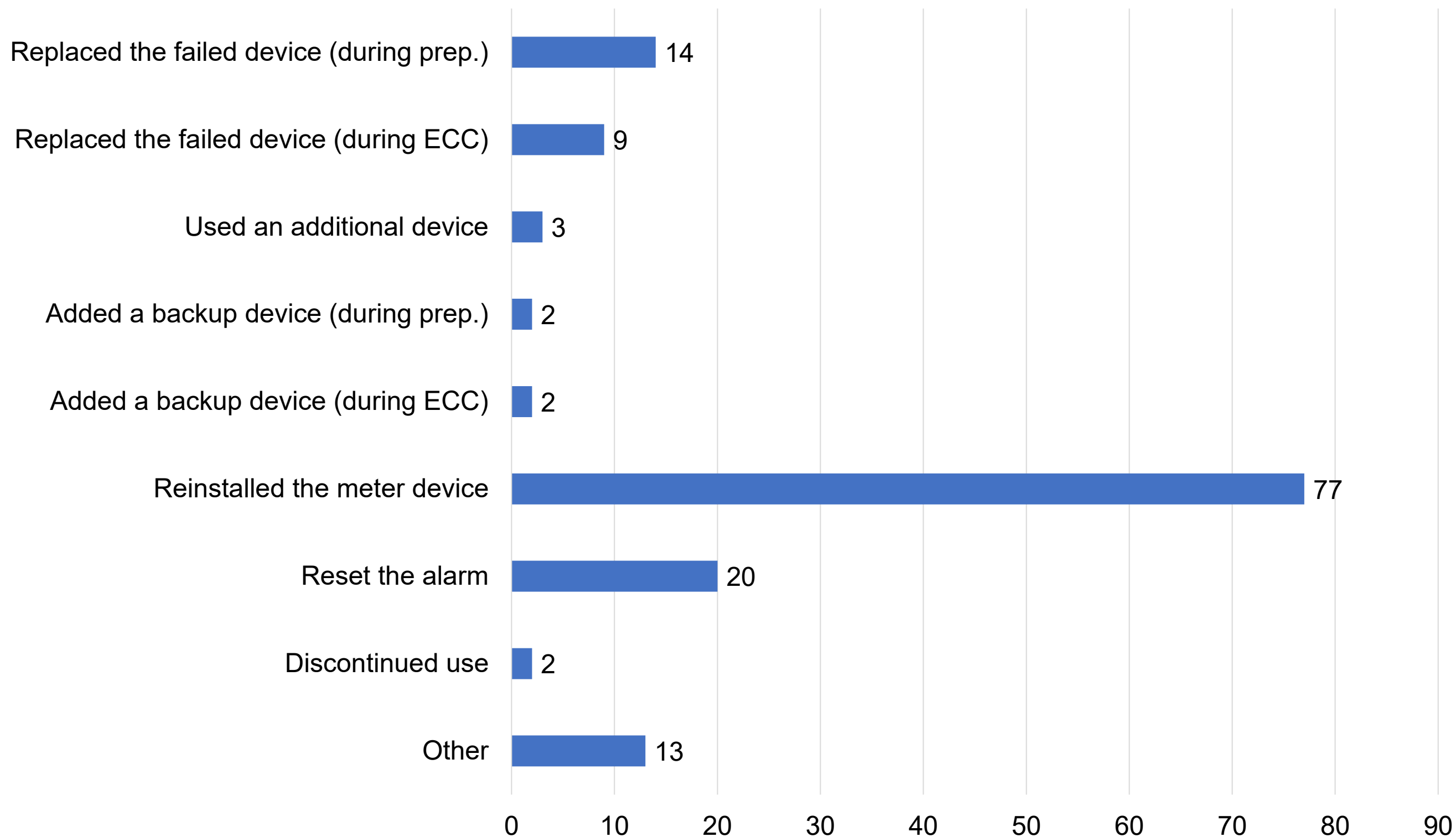
# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



N=66 (no answer: 13 insts.)

Cases  
Cardiopulmonary Bypass (CPB)

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

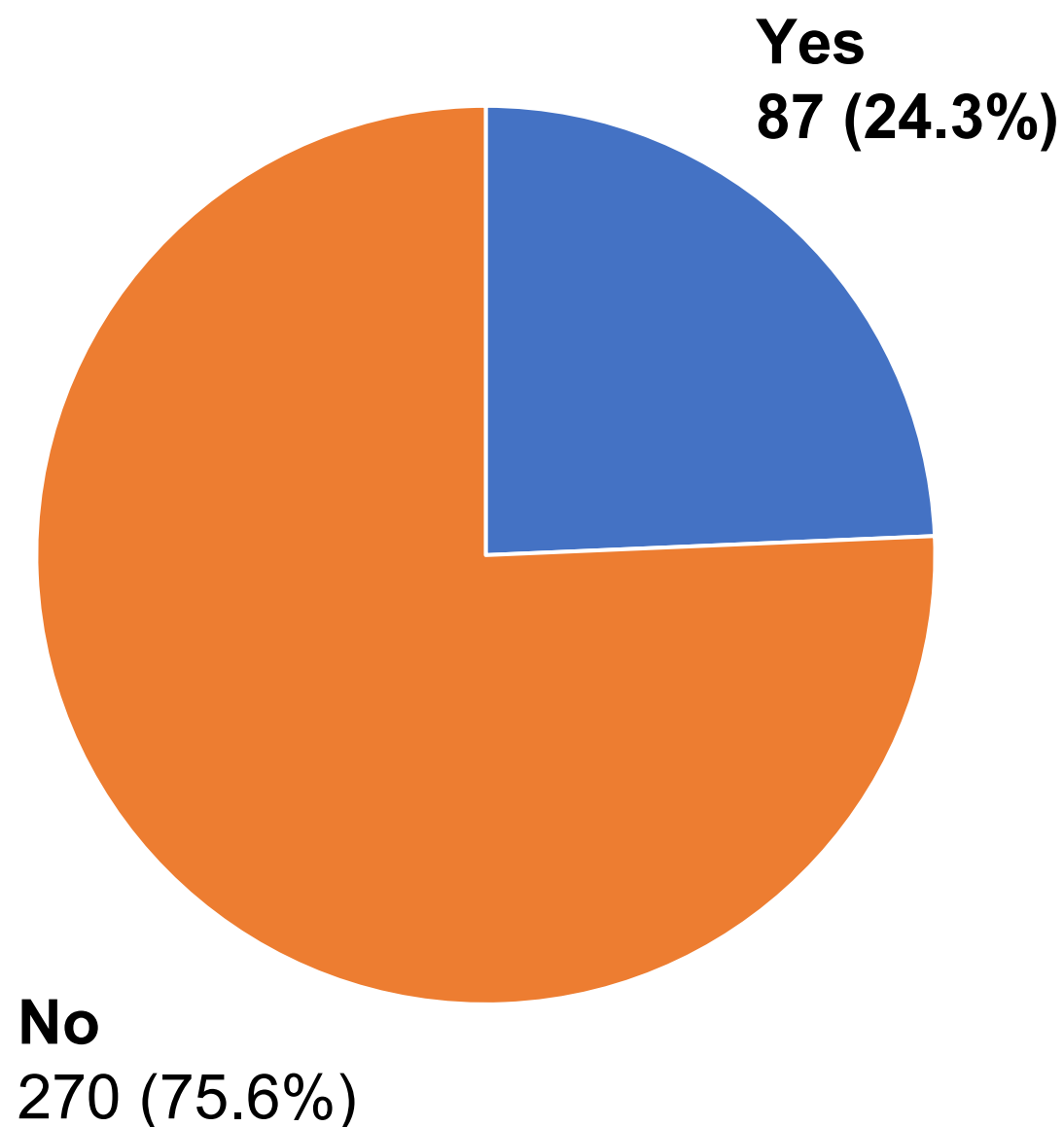


N=66 (no answer: 13 insts.)

# Meter/Alarm-Related Incidents & Rates

| 2023 Survey          |              |            | 2021 Survey           |             | 2019 Survey            |              |
|----------------------|--------------|------------|-----------------------|-------------|------------------------|--------------|
| Impact level         | No. of cases | Frequency* | No. of cases          | Frequency** | No. of cases           | Frequency*** |
| 0                    | 104          | 0.17%      | 120                   | 0.15%       | 134                    | 0.16%        |
| 1~3a                 | 12           | 0.02%      | 25                    | 0.03%       | 26                     | 0.03%        |
| 3b~5                 | 0            | 0%         | 0                     | 0%          | 0                      | 0%           |
| No answer: 13 insts. |              |            | No answer: 9 insts.   |             | No answer: 20          |              |
| * Among 62,871 cases |              |            | ** Among 78,397 cases |             | *** Among 81,455 cases |              |

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



| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 0            | 109          | 0.17%      |
| 1~3a         | 62           | 0.09%      |
| 3b~5         | 2            | < 0.01%    |

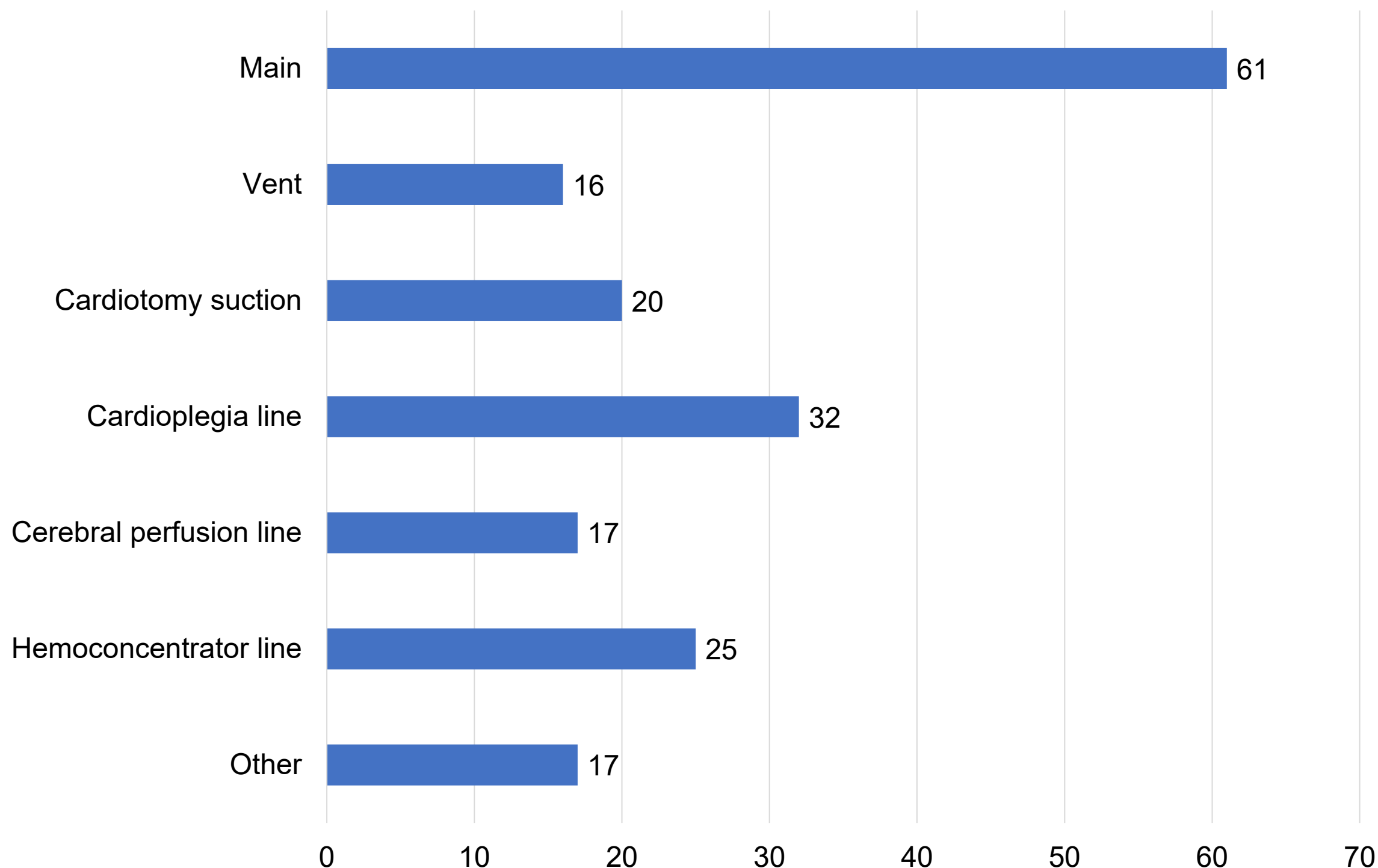
No answer: 8 insts.

\*Among 62,871 CPB cases occurring during the 2-year period

N=359 (no answer: 2 insts.)



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

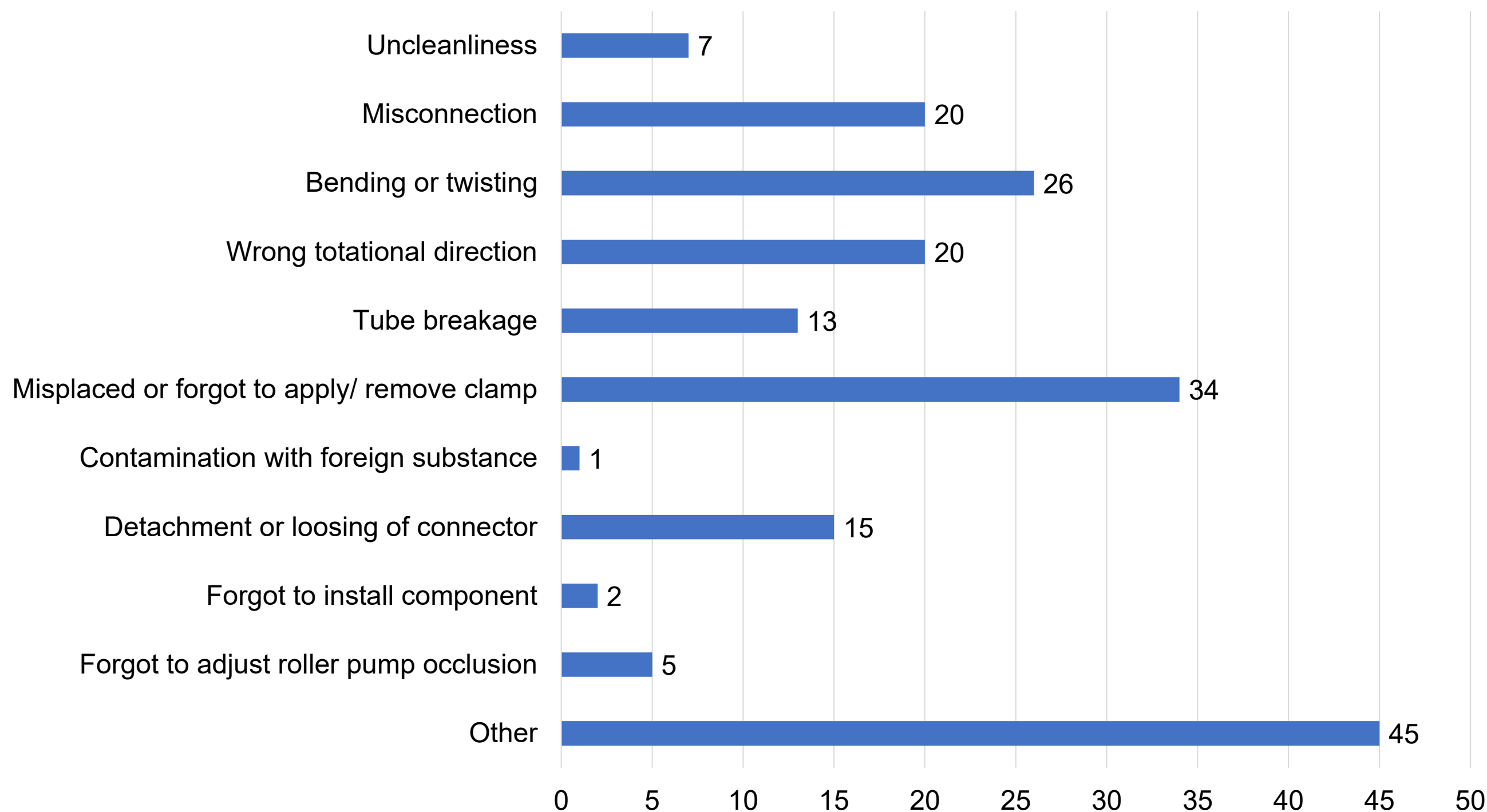


N=89 (no answer: 4 insts.)

Cases

Cardiopulmonary Bypass (CPB)

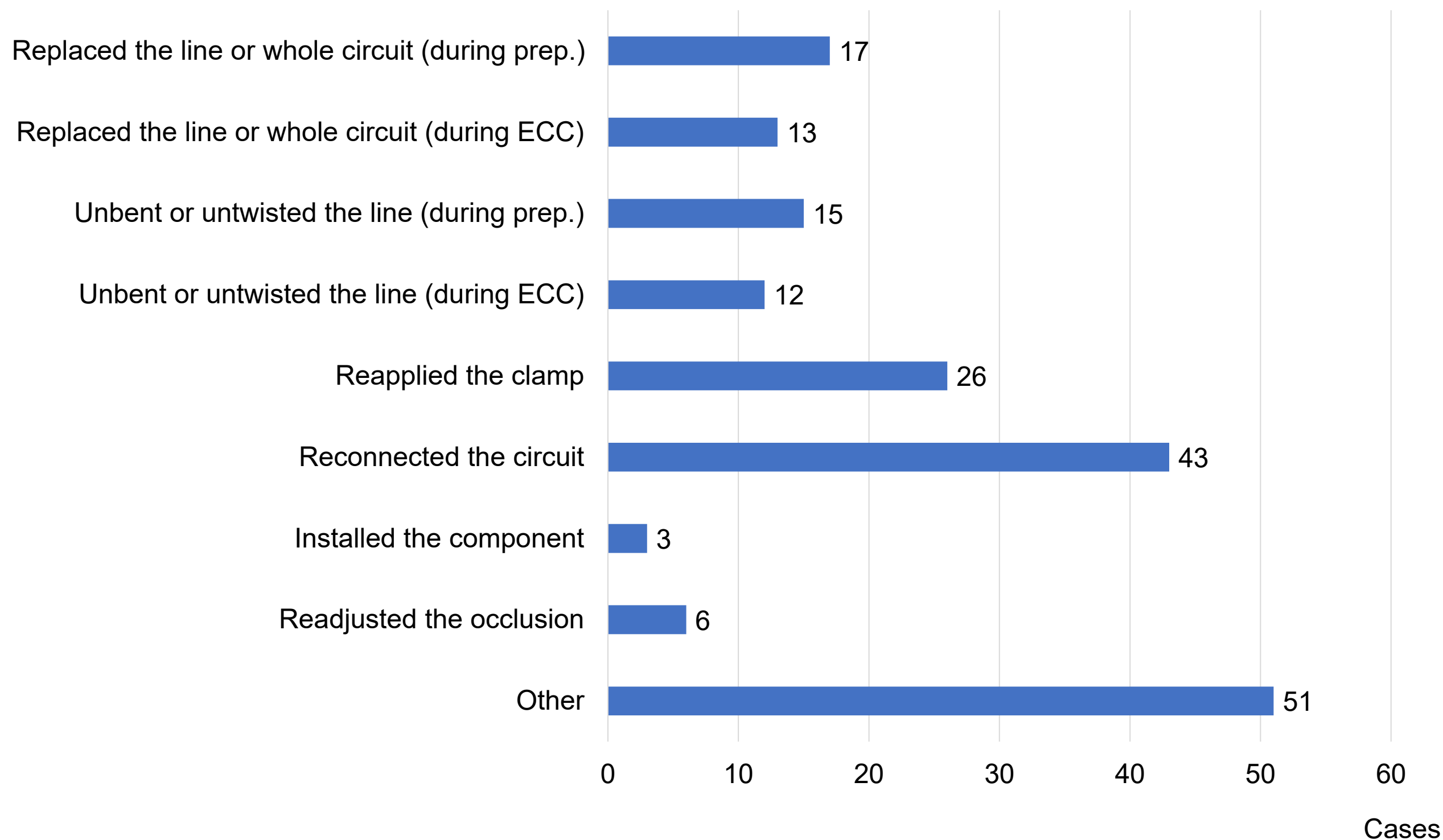
## Which of the following causes was responsible for the accident/incident and how many times? (Please choose all that apply.)



N=89 (no answer: 5 insts.)

Cases  
Cardiopulmonary Bypass (CPB)

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



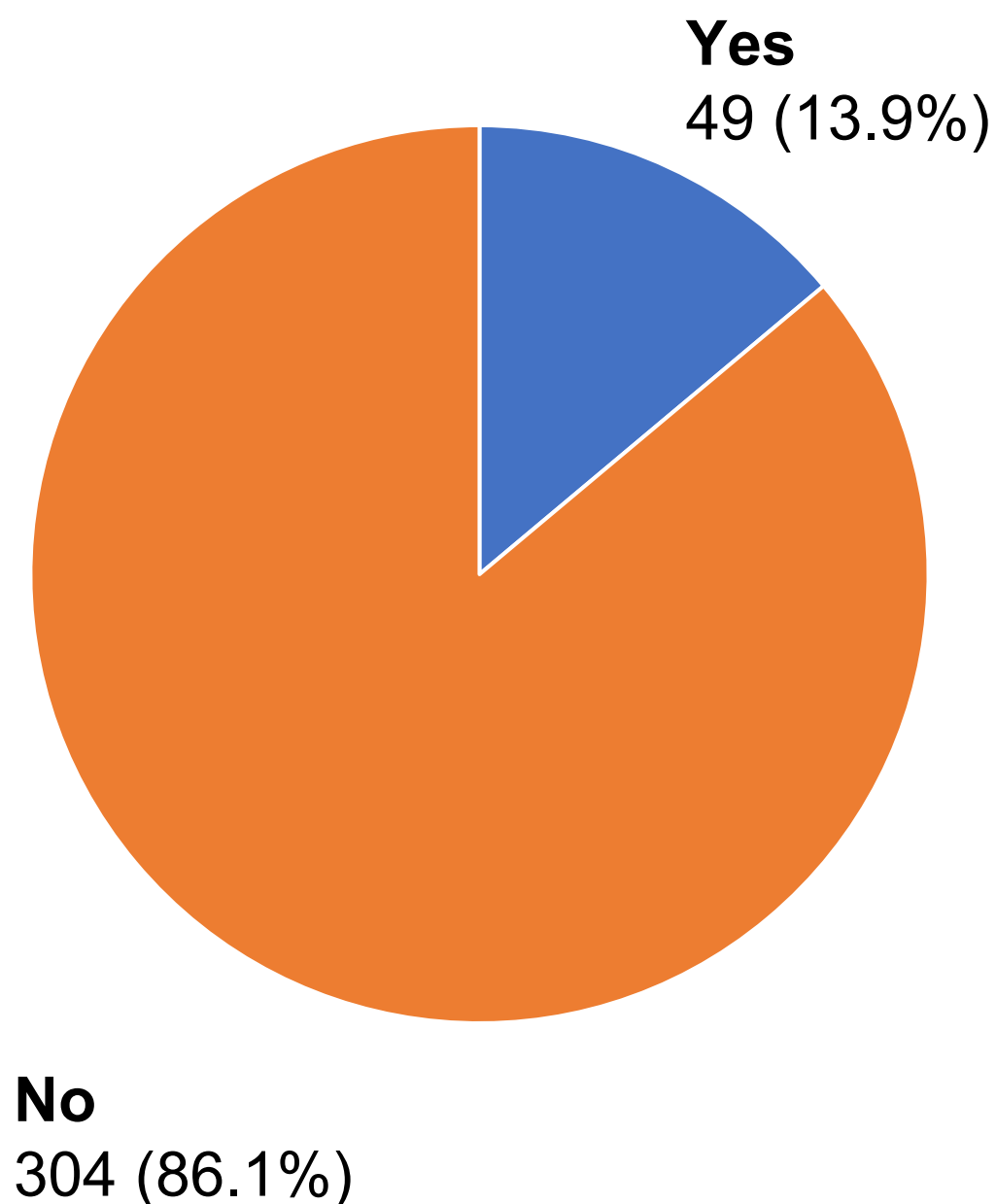
N=89 (no answer: 5 insts.)

Cardiopulmonary Bypass (CPB)

# CPB-Circuitry-Related Incidents & Rates

| 2023 Survey          |              |            | 2021 Survey           |             | 2019 Survey            |              |
|----------------------|--------------|------------|-----------------------|-------------|------------------------|--------------|
| Impact level         | No. of cases | Frequency* | No. of cases          | Frequency** | No. of cases           | Frequency*** |
| 0                    | 109          | 0.17%      | 152                   | 0.19%       | 145                    | 0.18%        |
| 1~3a                 | 62           | 0.09%      | 71                    | 0.09%       | 110                    | 0.14%        |
| 3b~5                 | 0            | 0%         | 0                     | 0%          | 2                      | <0.01%       |
| No answer: 18 insts. |              |            | No answer: 13 insts.  |             | No answer: 18 insts.   |              |
| * Among 62,871 cases |              |            | ** Among 78,397 cases |             | *** Among 81,455 cases |              |

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



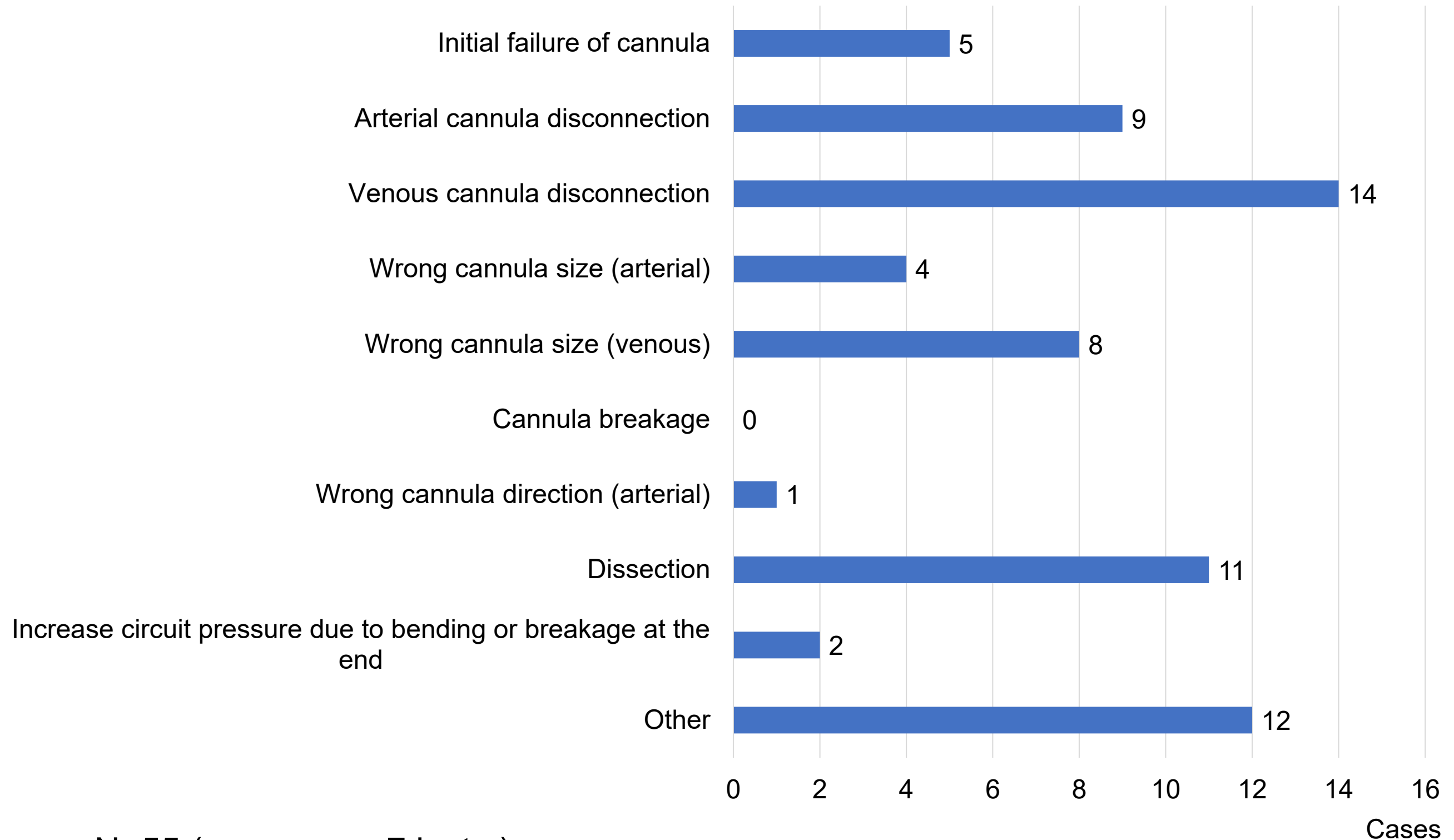
N=359 (no answer: 6 insts.)

| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 0            | 19           | 0.03%      |
| 1~3a         | 33           | 0.05%      |
| 3b~5         | 5            | < 0.01%    |

No answer: 12 insts.

\*Among 62,871 CPB cases occurring during the 2-year period

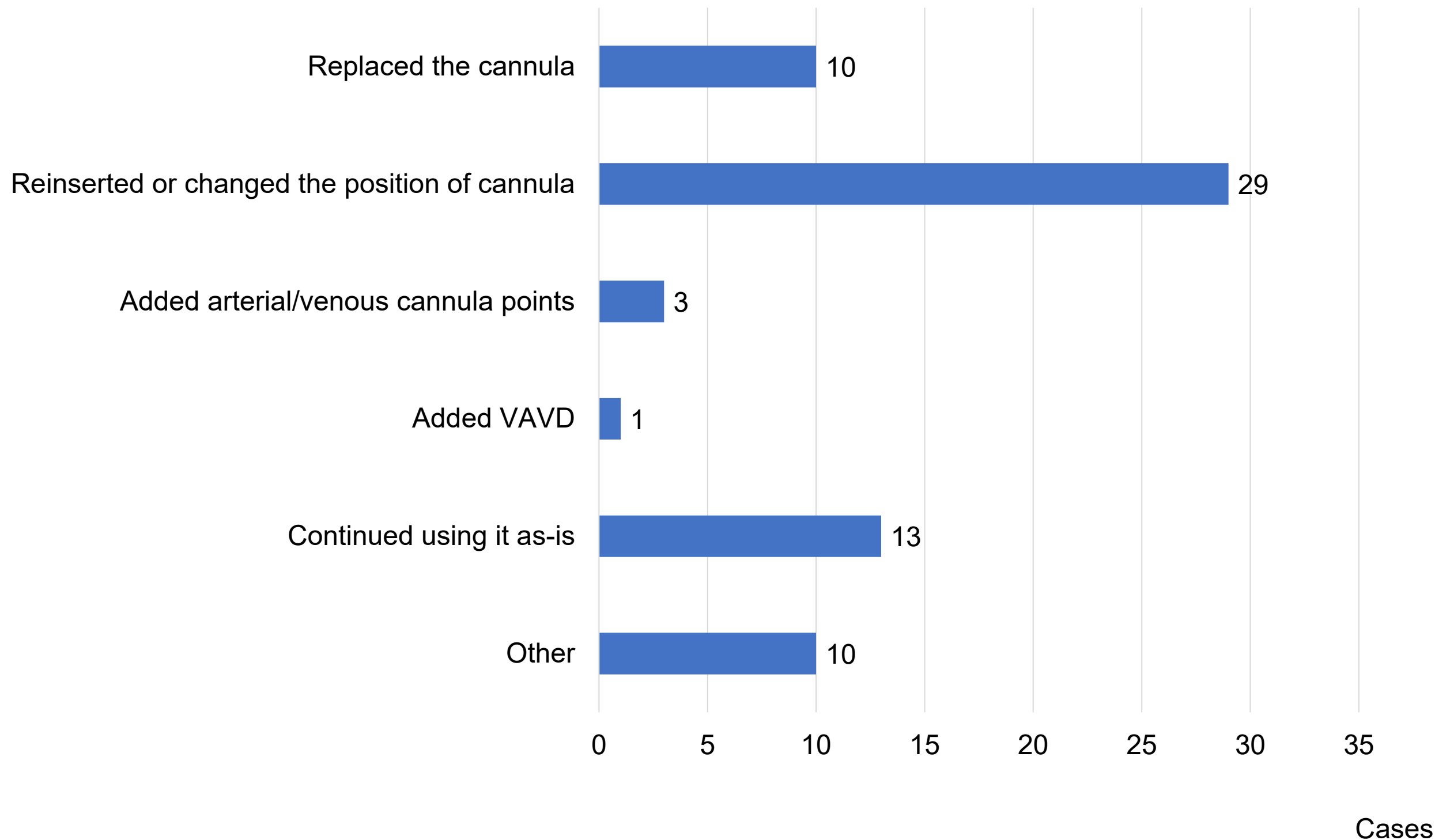
# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



N=55 (no answer: 7 insts.)

Cardiopulmonary Bypass (CPB)

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



N=55 (no answer: 7 insts.)

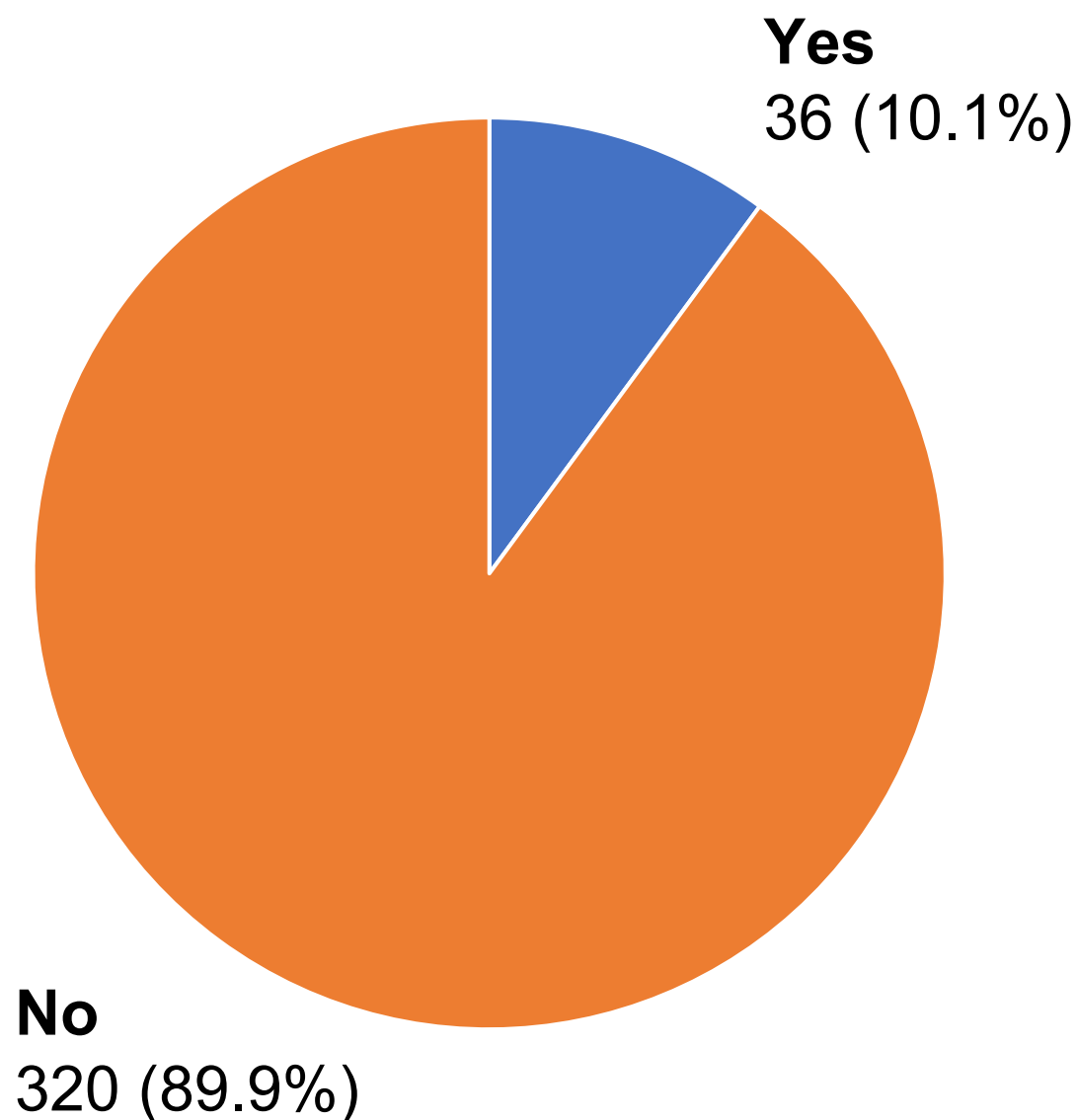
Cardiopulmonary Bypass (CPB)

# Cannula-Related Incidents & Rates

| 2023 Survey          |              |            | 2021 Survey           |             | 2019 Survey            |              |
|----------------------|--------------|------------|-----------------------|-------------|------------------------|--------------|
| Impact level         | No. of cases | Frequency* | No. of cases          | Frequency** | No. of cases           | Frequency*** |
| 0                    | 19           | 0.03%      | 48                    | 0.06%       | 41                     | 0.05%        |
| 1~3a                 | 33           | 0.05%      | 49                    | 0.06%       | 92                     | 0.11%        |
| 3b~5                 | 5            | < 0.01%    | 11                    | 0.01%       | 16                     | 0.02%        |
| No answer: 12 insts. |              |            | No answer: 10 insts.  |             | No answer: 14 insts.   |              |
| * Among 62,871 cases |              |            | ** Among 78,397 cases |             | *** Among 81,455 cases |              |



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



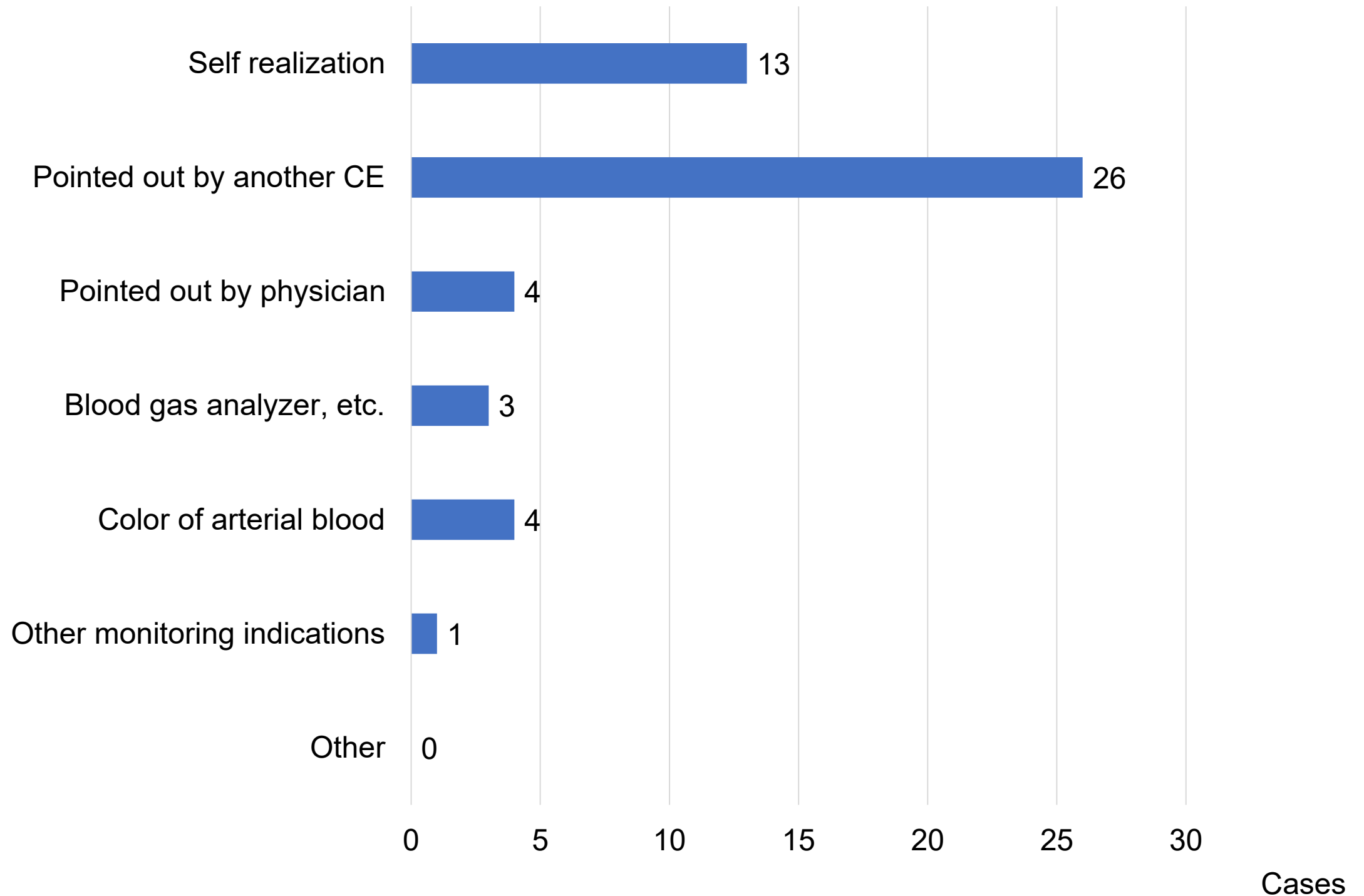
| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 0            | 23           | 0.04%      |
| 1~3a         | 25           | 0.04%      |
| 3b~5         | 0            | 0%         |

No answer: 3 insts.

\*Among 62,871 CPB cases occurring during the 2-year period

N=359 (no answer: 3 insts.)

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

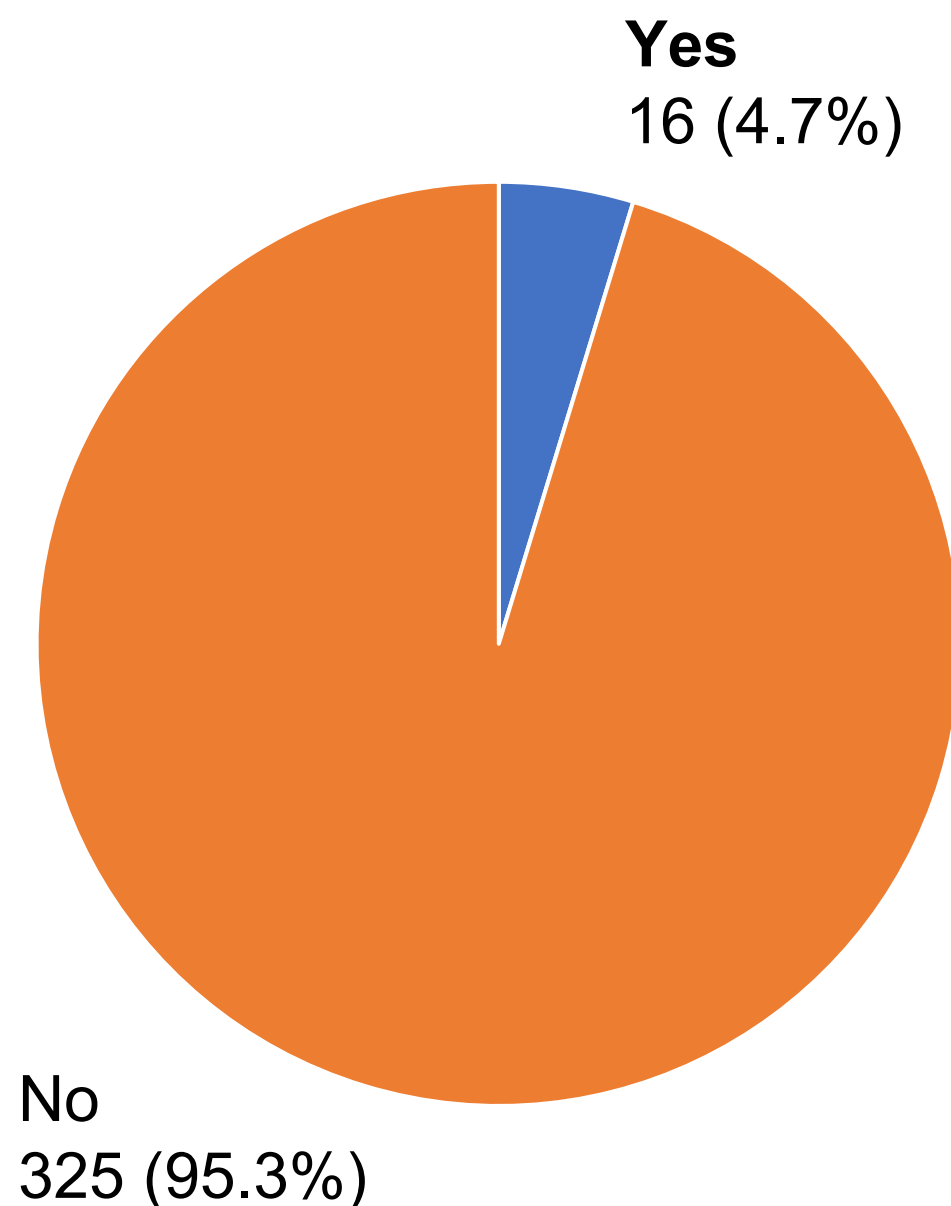


N=39 (no answer: 3 insts.)

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

| 2023 Survey          |              |            | 2021 Survey           |             | 2019 Survey            |              |
|----------------------|--------------|------------|-----------------------|-------------|------------------------|--------------|
| Impact level         | No. of cases | Frequency* | No. of cases          | Frequency** | No. of cases           | Frequency*** |
| 0                    | 23           | 0.04%      | 38                    | 0.05%       | 44                     | 0.06%        |
| 1~3a                 | 25           | 0.04%      | 32                    | 0.04%       | 34                     | 0.04%        |
| 3b~5                 | 0            | 0%         | 0                     | 0%          | 0                      | 0%           |
| No answer: 3 insts.  |              |            | No answer: 9 insts.   |             | No answer: 8 insts.    |              |
| * Among 62,871 cases |              |            | ** Among 78,397 cases |             | *** Among 81,455 cases |              |

# Did you experience an Inadvertent Air Entering the Bloodstream?



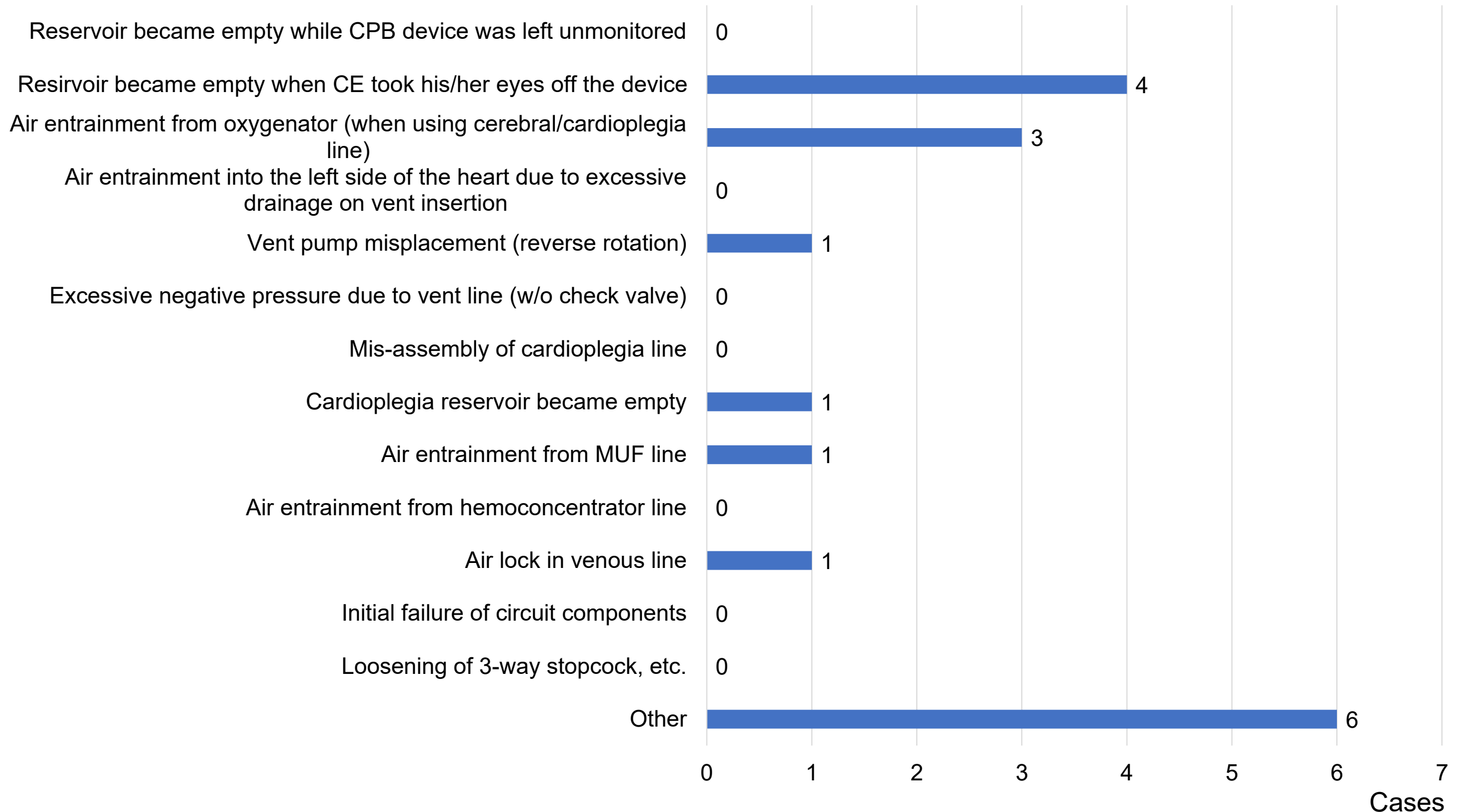
| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 1~3a         | 15           | 0.02%      |
| 3b~5         | 3            | <0.01%     |

No answer: 19 insts.

\*Among 62,871 CPB cases occurring during the 2-year period

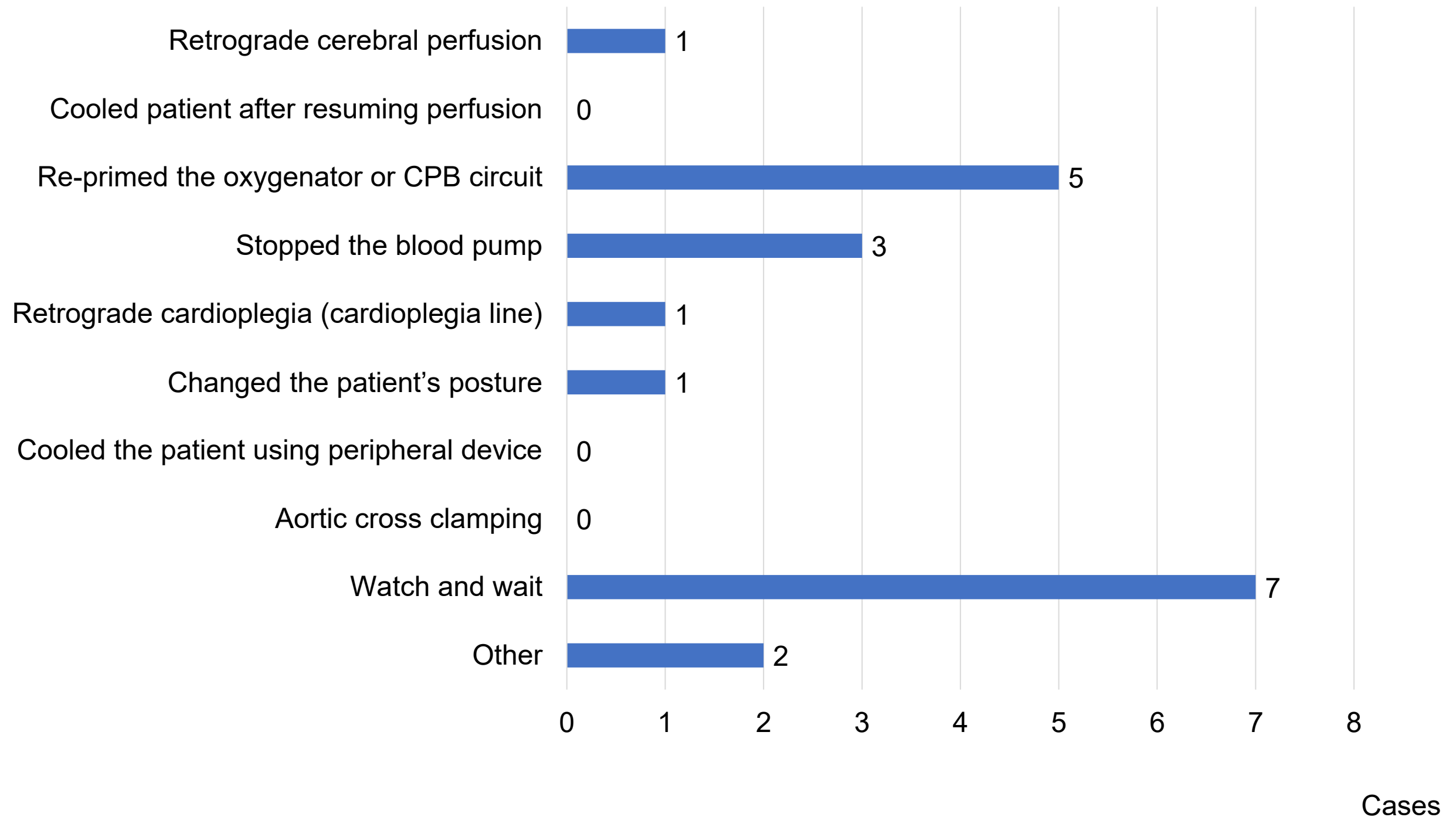
N=359 (no answer: 18 insts.)

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



N=34 (no answer: 20 insts.)

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



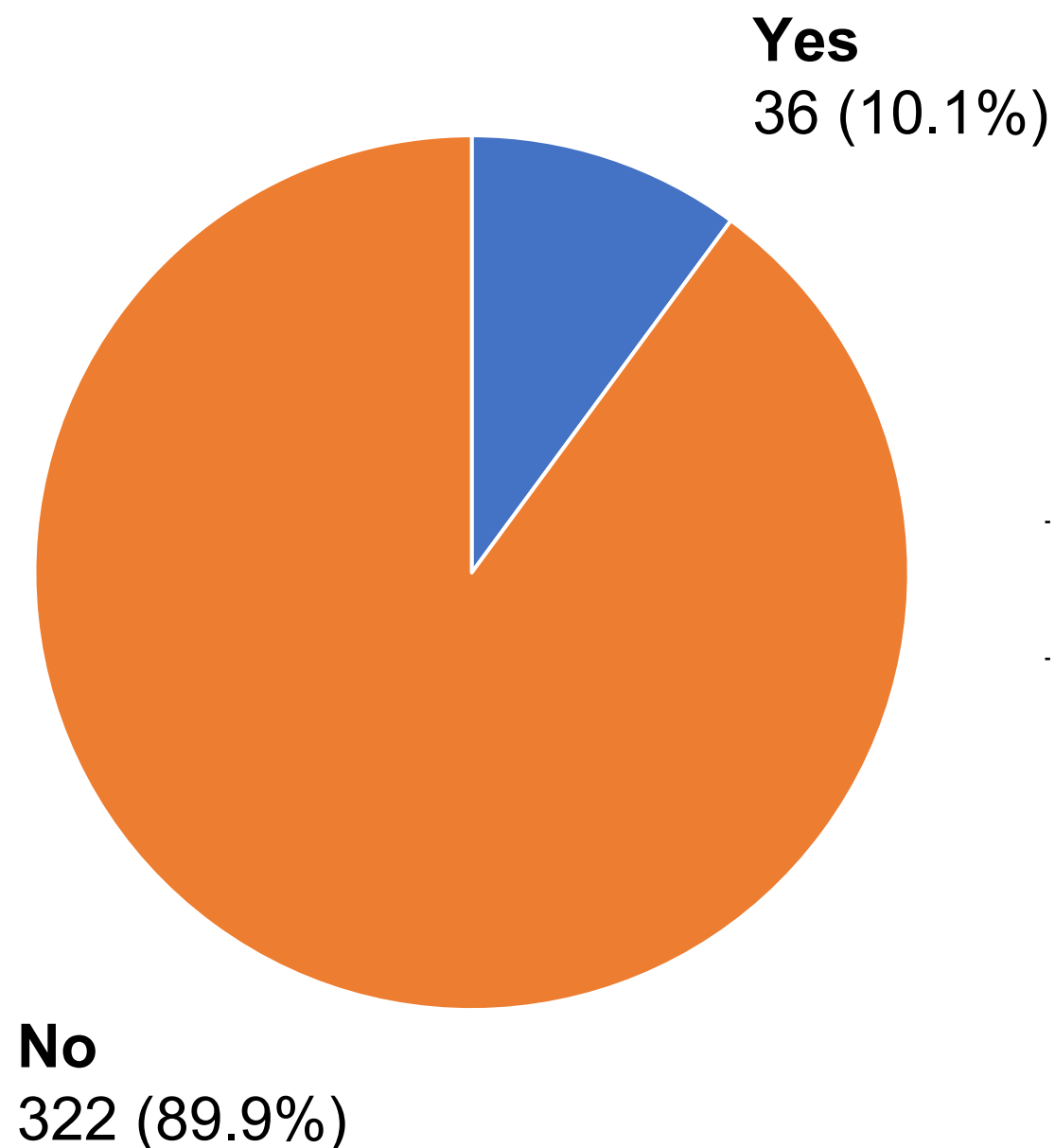
N=34 (no answer: 20 insts.)

Cardiopulmonary Bypass (CPB)

# Incidents & Rates of Inadvertent Air Entering

| 2023 Survey          |              |            | 2021 Survey           |             | 2019 Survey            |              |
|----------------------|--------------|------------|-----------------------|-------------|------------------------|--------------|
| Impact level         | No. of cases | Frequency* | No. of cases          | Frequency** | No. of cases           | Frequency*** |
| 0                    | —            | —          | —                     | —           | —                      | —            |
| 1~3a                 | 15           | 0.02%      | 28                    | 0.04%       | 17                     | 0.02%        |
| 3b~5                 | 3            | < 0.01%    | 3                     | < 0.01%     | 2                      | < 0.01%      |
| No answer: 19 insts. |              |            | No answer: 26 insts.  |             | No answer: 26 insts.   |              |
| * Among 62,871 cases |              |            | ** Among 78,397 cases |             | *** Among 81,455 cases |              |

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



N=359 (no answer: 1 insts.)

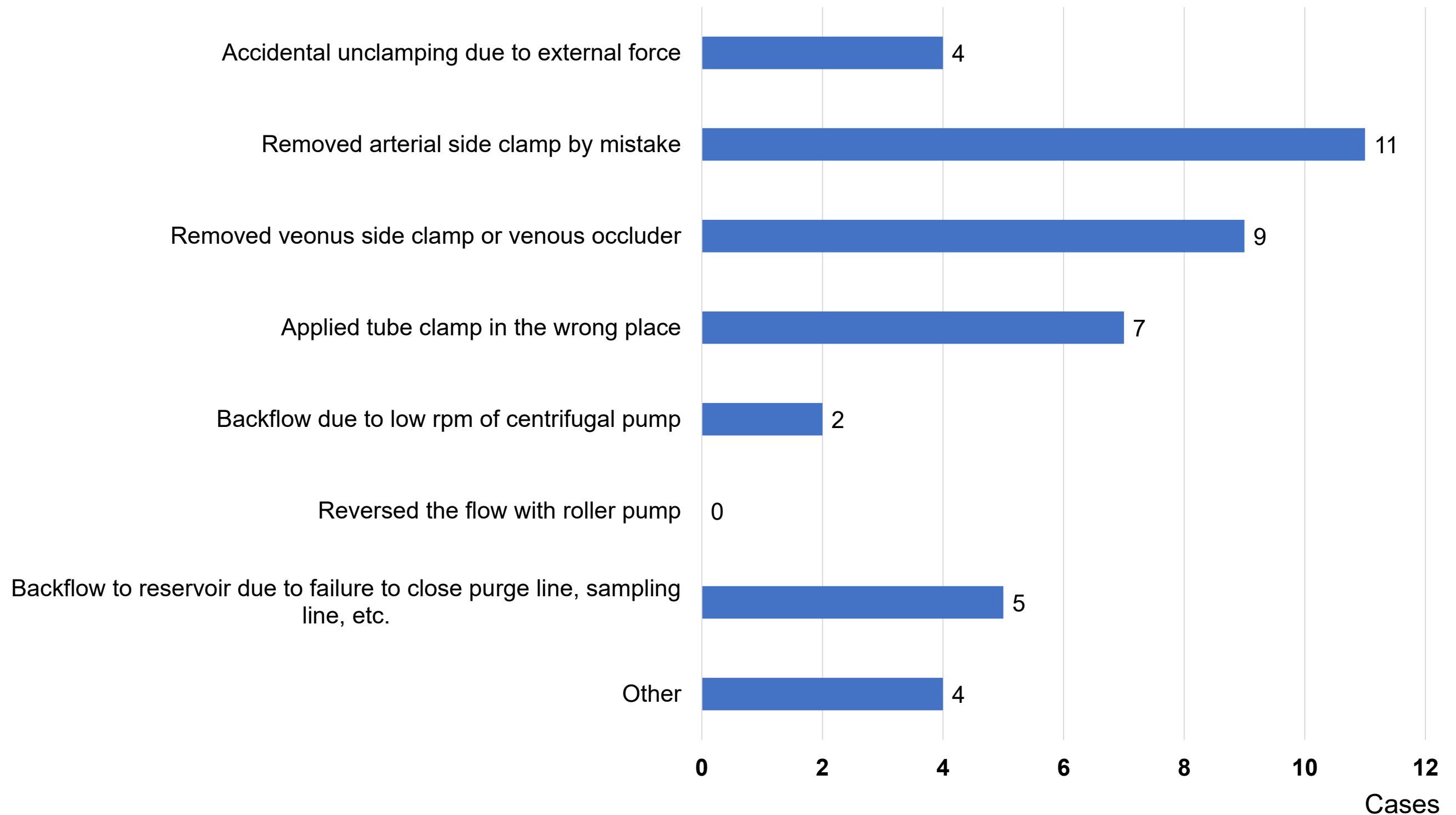
| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 1~3a         | 35           | 0.06%      |
| 3b~5         | 5            | < 0.01%    |

No answer: 5 insts.

\*Among 62,871 CPB cases occurring during the 2-year period

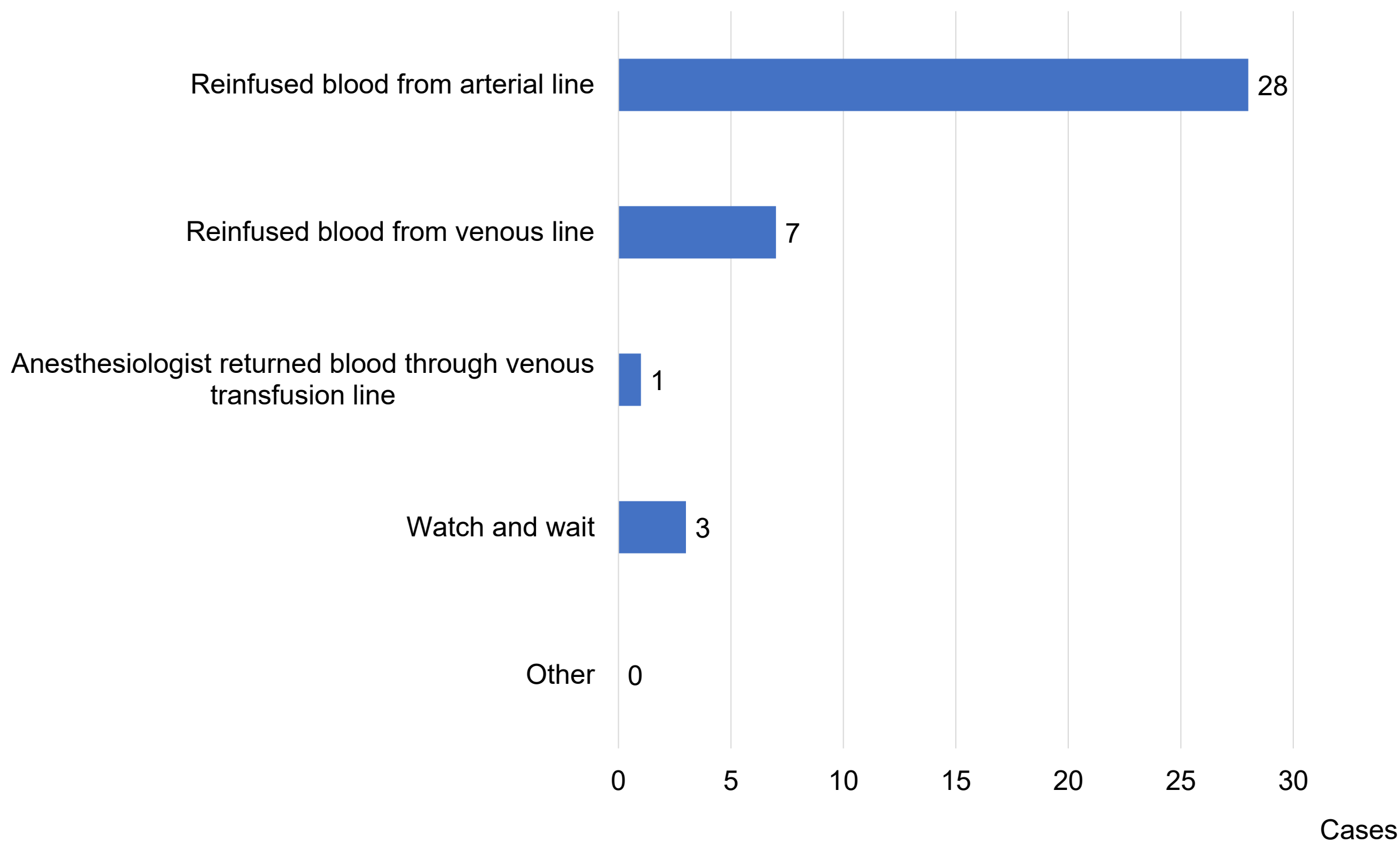


# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



N=37 (no answer: 3 insts.)

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



N=37 (no answer: 6 insts.)

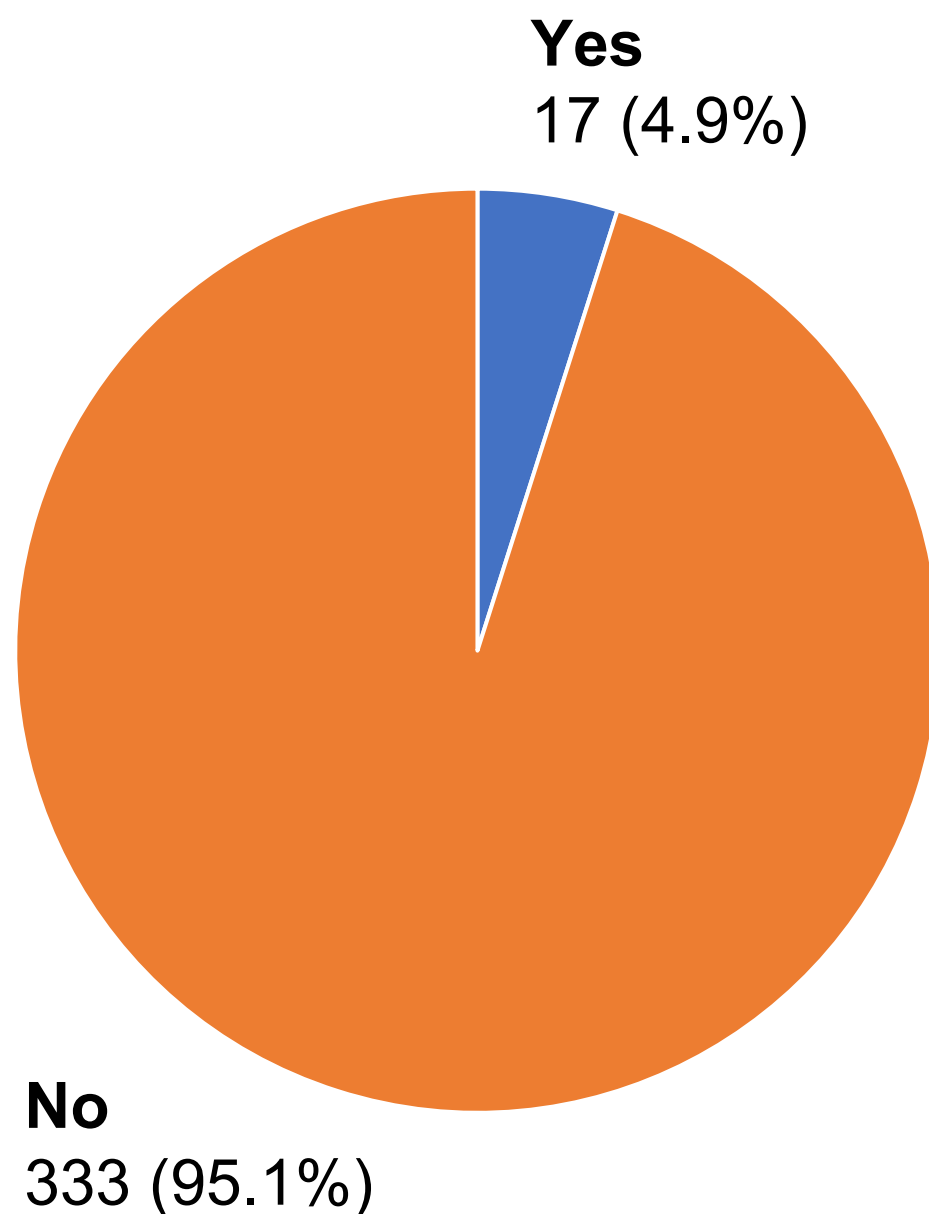
Cardiopulmonary Bypass (CPB)

# Incidents & Rates of Unexpected Blood Drainage after ECC

| 2023 Survey          |              |            | 2021 Survey           |             | 2019 Survey            |              |
|----------------------|--------------|------------|-----------------------|-------------|------------------------|--------------|
| Impact level         | No. of cases | Frequency* | No. of cases          | Frequency** | No. of cases           | Frequency*** |
| 0                    | —            | —          | —                     | —           | —                      | —            |
| 1~3a                 | 35           | 0.06%      | 42                    | 0.05%       | 65                     | 0.08%        |
| 3b~5                 | 5            | < 0.01%    | 2                     | < 0.01%     | 4                      | < 0.01%      |
| No answer: insts.    |              |            | No answer: 6 insts.   |             | No answer: 4 insts.    |              |
| * Among 62,871 cases |              |            | ** Among 78,397 cases |             | *** Among 81,455 cases |              |

# Did you experience a Medication Error?

(excluding errors in cardioplegia)



N=359 (no answer: 9 insts.)

| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 0            | 8            | 0.01%      |
| 1~3a         | 20           | 0.03%      |
| 3b~5         | 0            | 0%         |

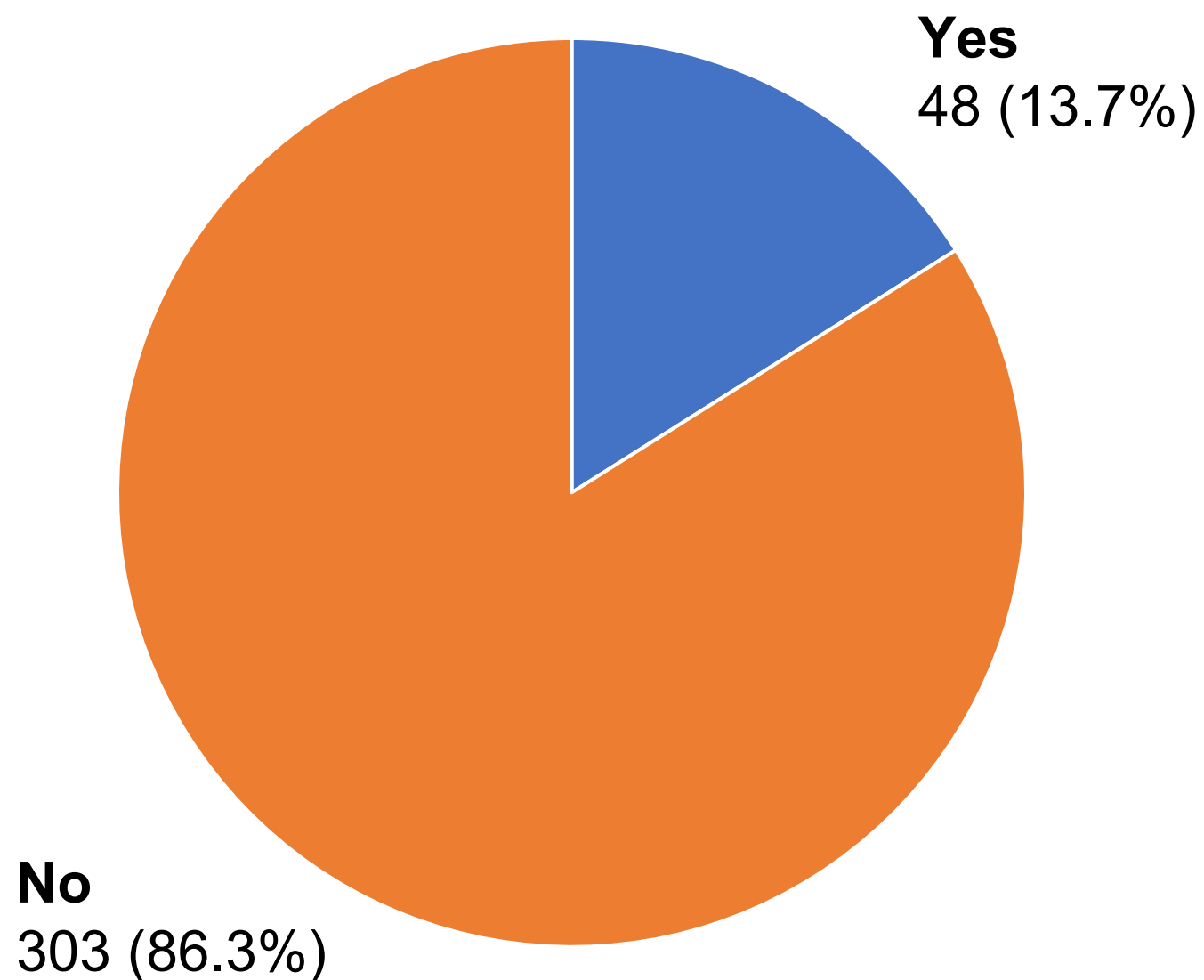
No answer: 9 insts.

\*Among 62,871 CPB cases occurring during the 2-year period

# Incidents & Rates of Medication Errors

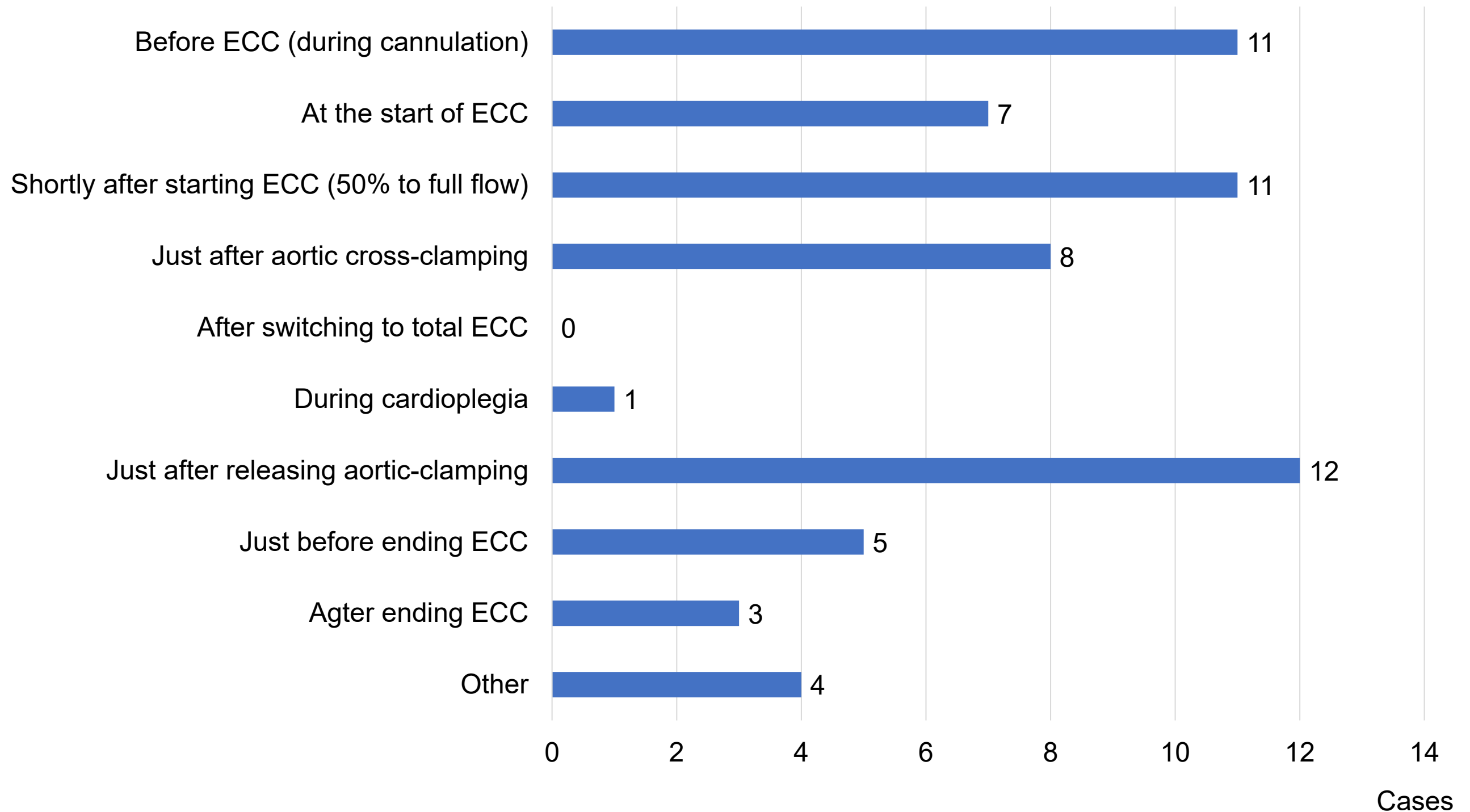
| 2023 Survey          |              |            | 2021 Survey           |             | 2019 Survey            |              |
|----------------------|--------------|------------|-----------------------|-------------|------------------------|--------------|
| Impact level         | No. of cases | Frequency* | No. of cases          | Frequency** | No. of cases           | Frequency*** |
| 0                    | 8            | 0.01%      | 1                     | 0.01%       | 8                      | 0.01%        |
| 1~3a                 | 20           | 0.03%      | 19                    | 0.02%       | 19                     | 0.02%        |
| 3b~5                 | 0            | 0%         | 0                     | 0%          | 0                      | 0%           |
| No answer: 9 insts.  |              |            | No answer: 10 insts.  |             | No answer: 14 insts.   |              |
| * Among 62,871 cases |              |            | ** Among 78,397 cases |             | *** Among 81,455 cases |              |

# Did you experience an Intraoperative Dissection?



N=359 (no answer: 8 insts.)

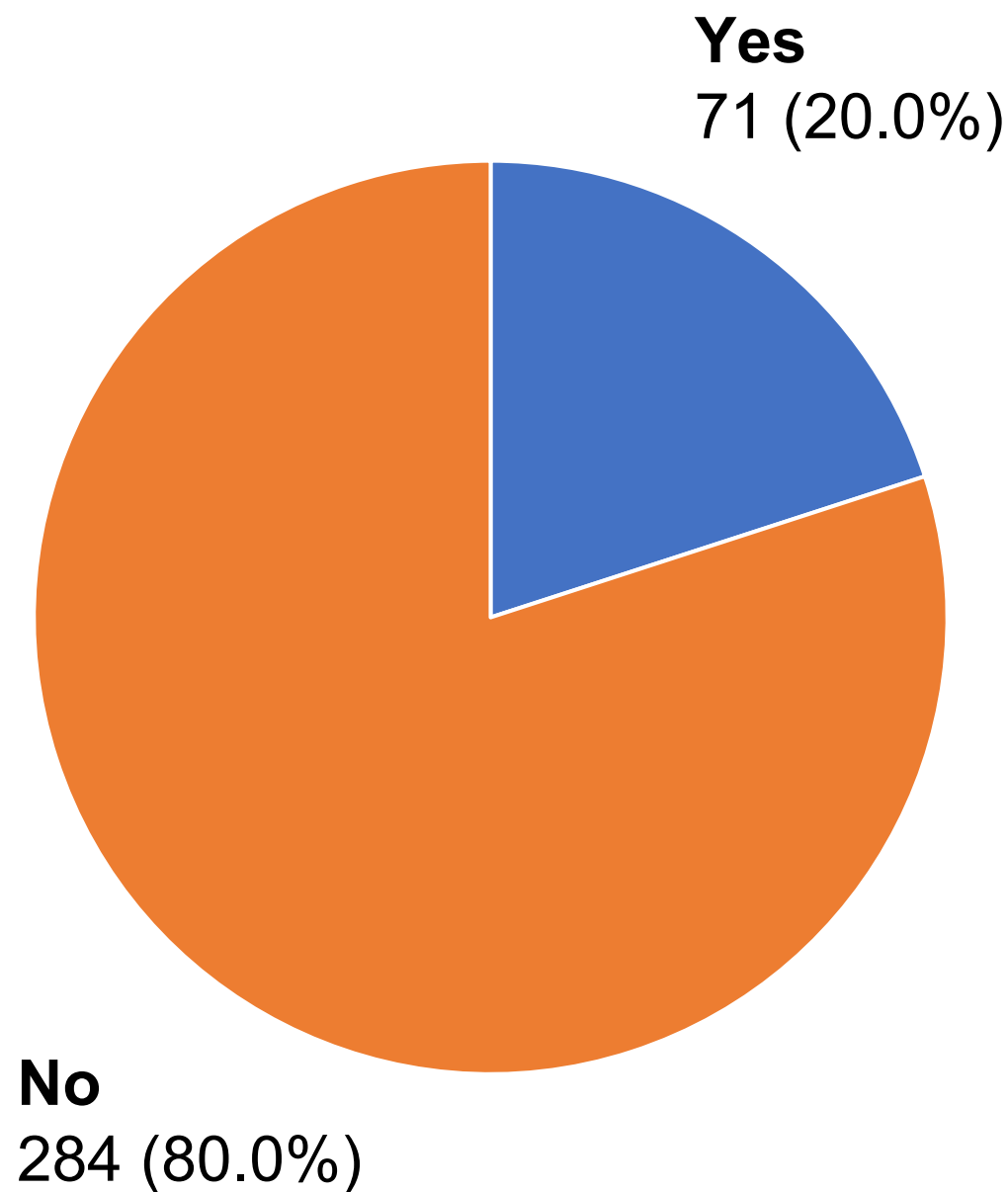
# When did you notice it? (Please choose all that apply.)



N=56 (no answer: 8 insts.)

Cardiopulmonary Bypass (CPB)

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



| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 0            | 79           | 0.13%      |
| 1~3a         | 40           | 0.06%      |
| 3b~5         | 2            | < 0.01%    |

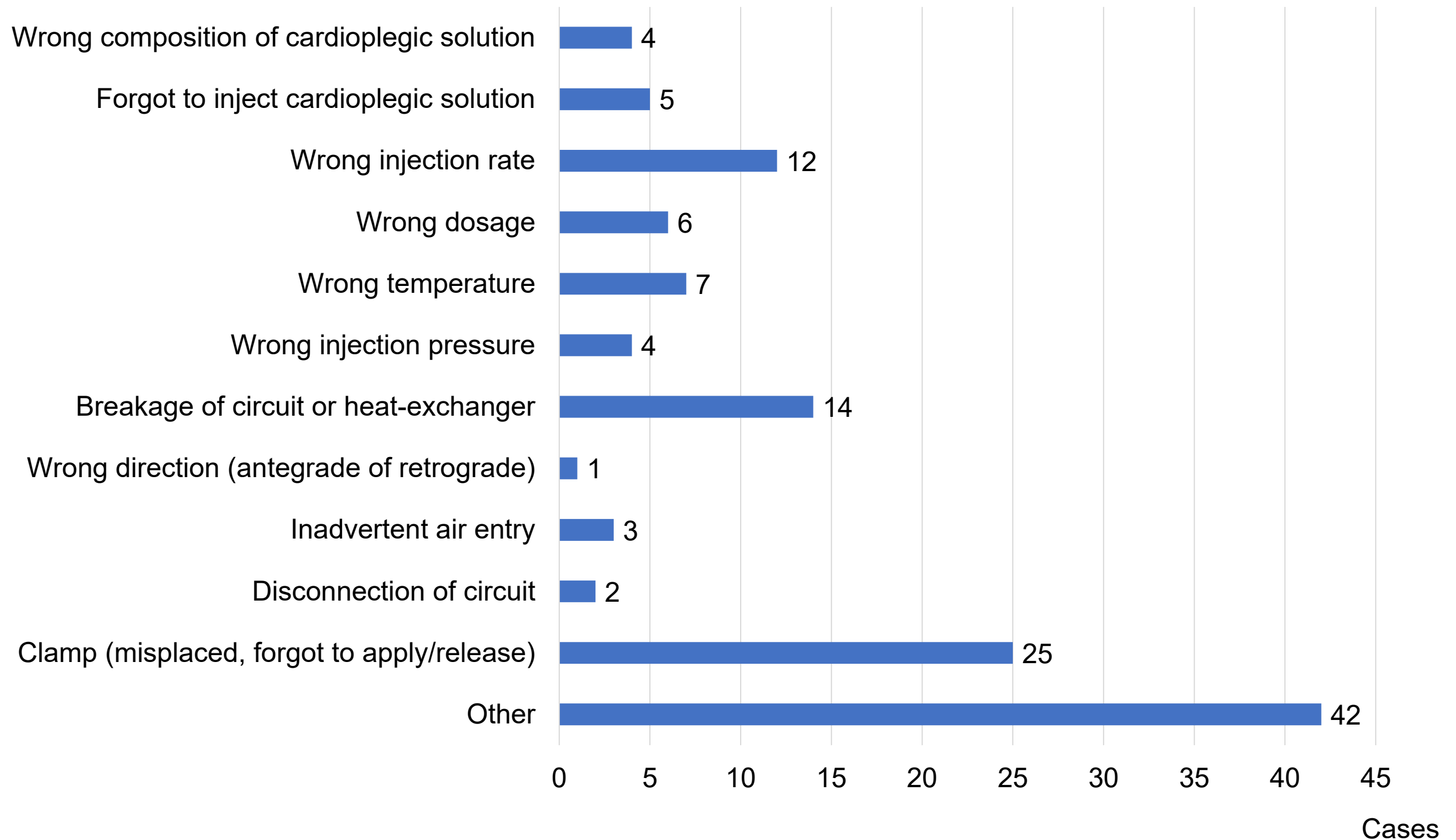
No answer: 7 insts.

\*Among 62,871 CPB cases occurring during the 2-year period

N=359 (no answer: 4 insts.)



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



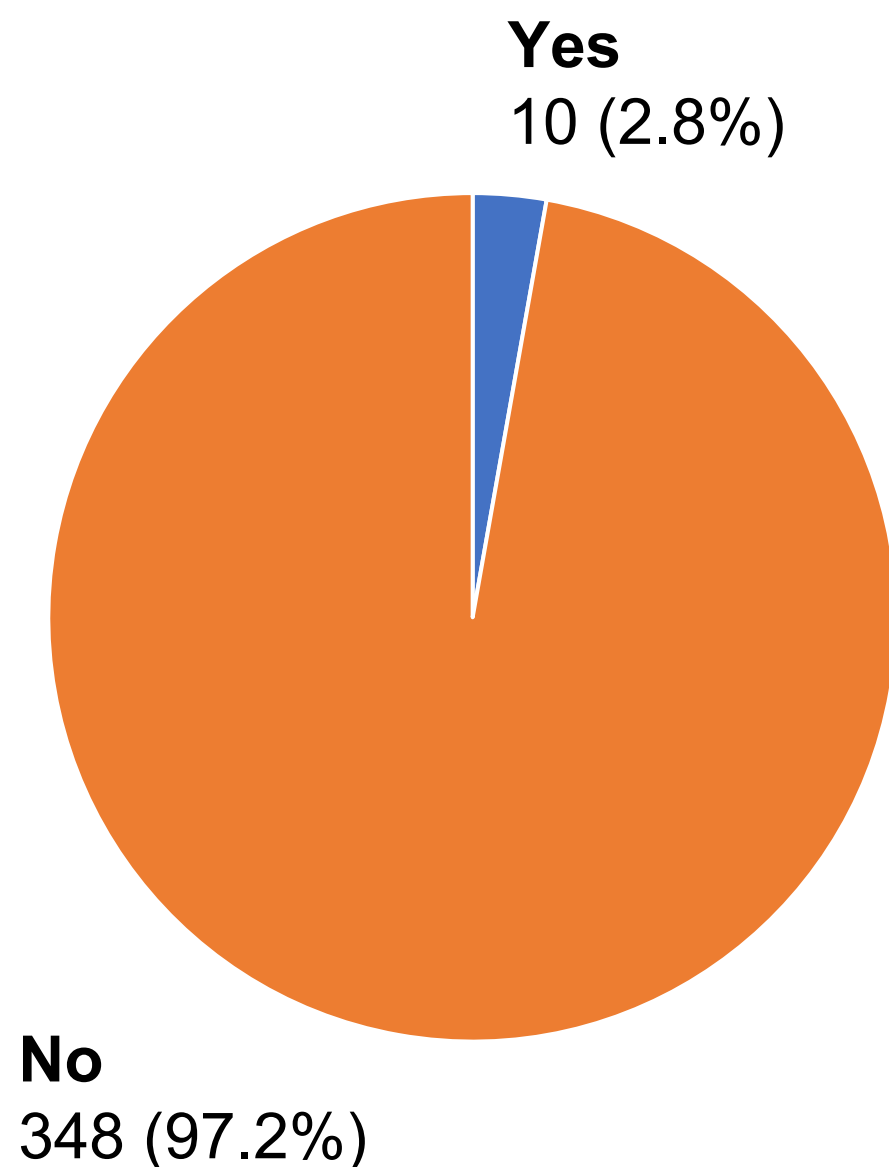
N=75 (no answer: 5 insts.)

Cardiopulmonary Bypass (CPB)

# Cardioplegia-Related Incidents & Rates

| 2023 Survey          |              |            | 2021 Survey           |             | 2019 Survey            |              |
|----------------------|--------------|------------|-----------------------|-------------|------------------------|--------------|
| Impact level         | No. of cases | Frequency* | No. of cases          | Frequency** | No. of cases           | Frequency*** |
| 0                    | 79           | 0.13%      | 95                    | 0.12%       | 136                    | 0.17%        |
| 1~3a                 | 40           | 0.06%      | 87                    | 0.11%       | 114                    | 0.14%        |
| 3b~5                 | 2            | <0.01%     | 2                     | <0.01%      | 2                      | <0.01%       |
| No answer: 7 insts.  |              |            | No answer: 16 insts.  |             | No answer: 10 insts.   |              |
| * Among 62,871 cases |              |            | ** Among 78,397 cases |             | *** Among 81,455 cases |              |

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



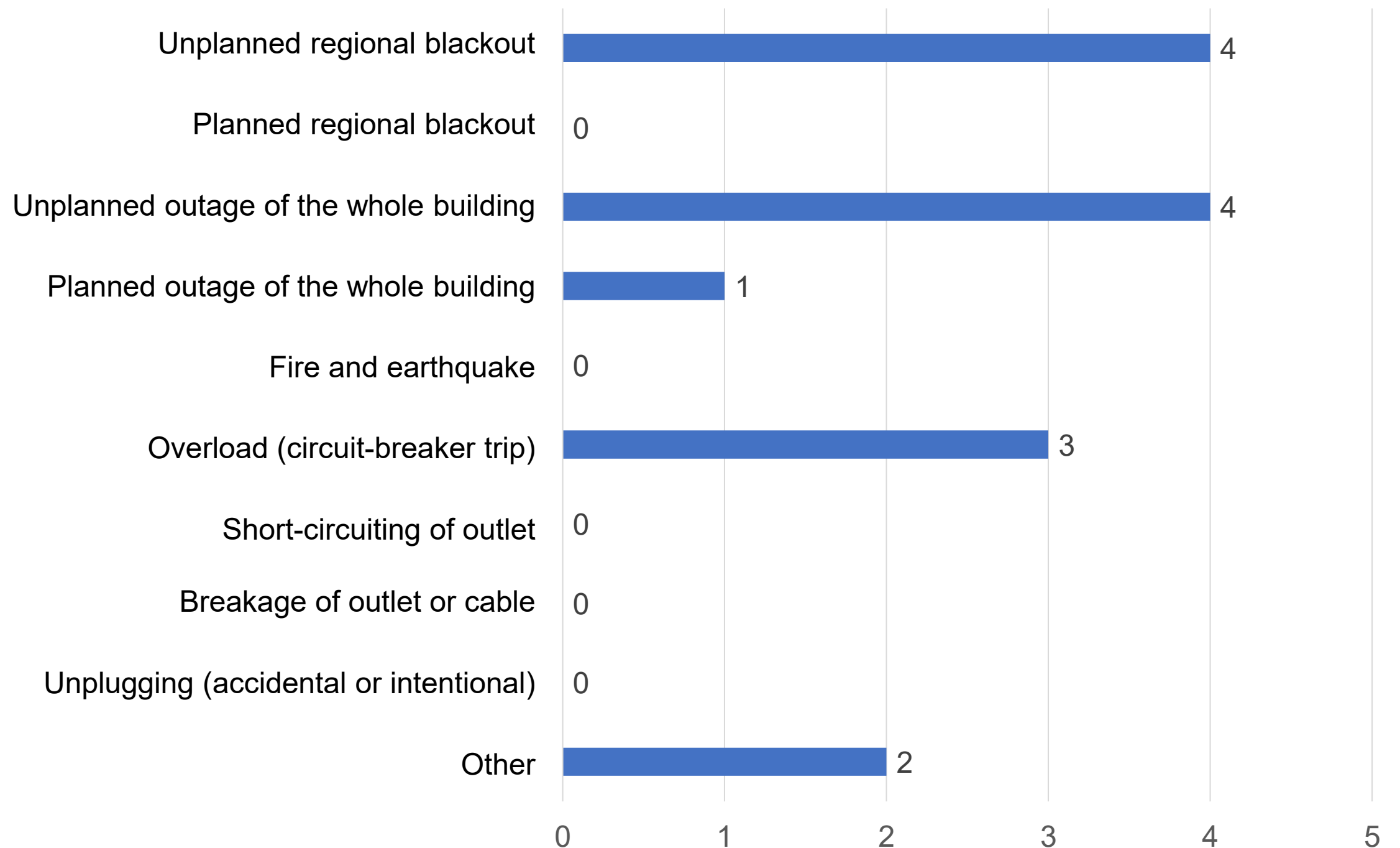
| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 0            | 7            | 0.01%      |
| 1~3a         | 4            | <0.01%     |
| 3b~5         | 0            | 0%         |

No answer: 1 insts.

\*Among 62,871 CPB cases occurring during the 2-year period

N=359 (no answer: 1 insts.)

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

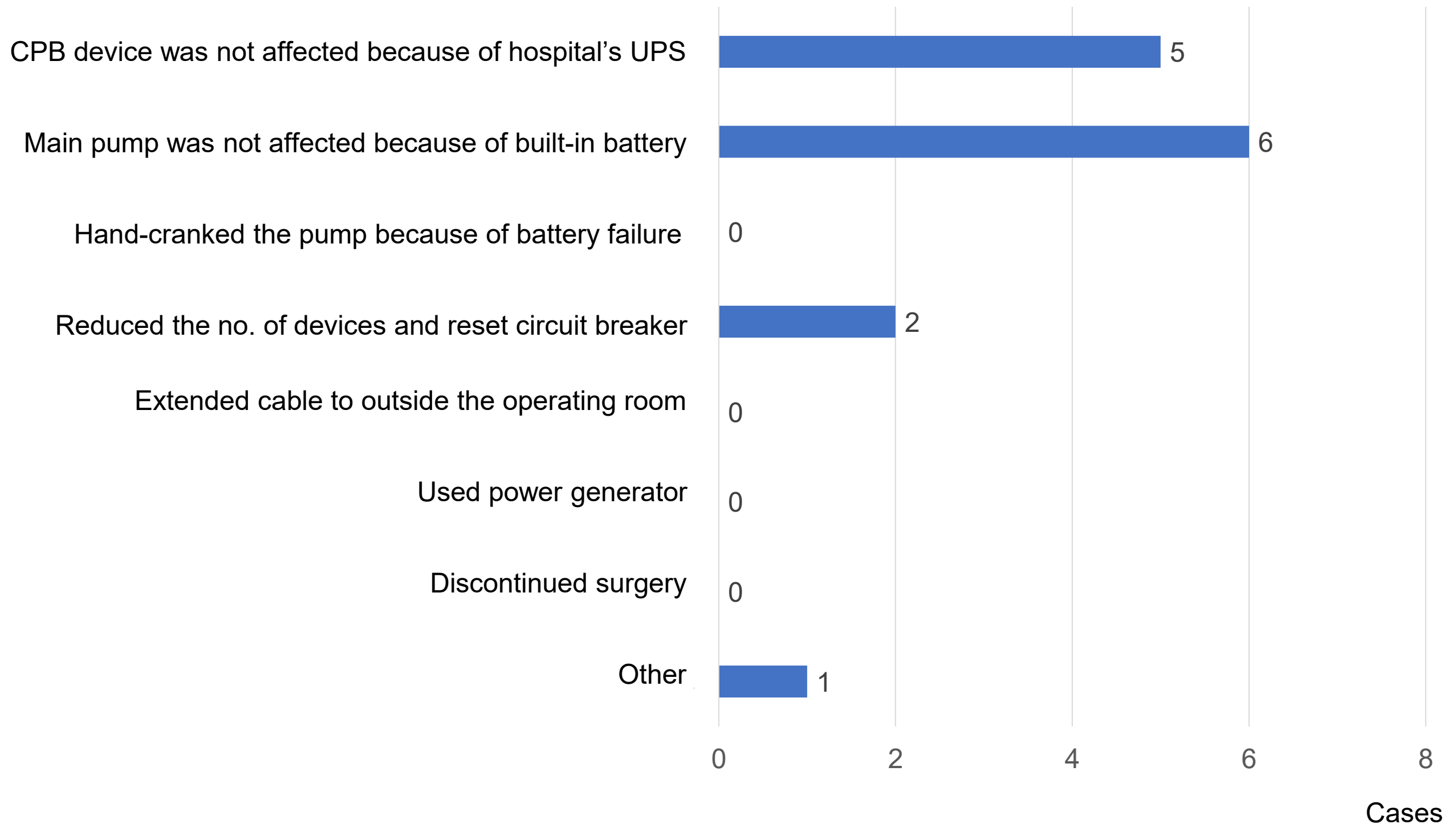


Cases

N=11 (no answer: 2 insts.)

Cardiopulmonary Bypass (CPB)

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

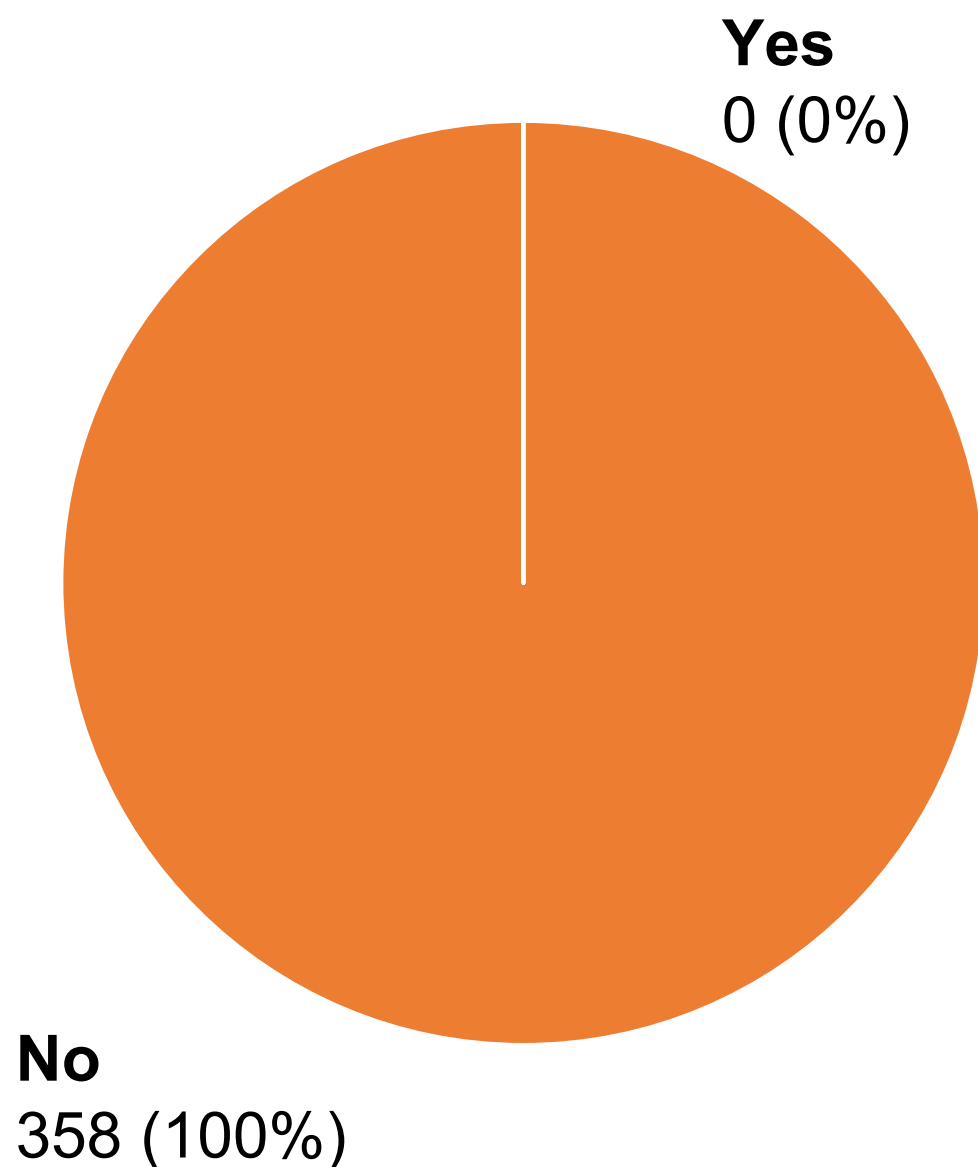


N=11 (no answer: 3 insts.)

# Incidents & Rates related to Power Interruption/Outage

| 2023 Survey          |              |            | 2021 Survey           |             | 2019 Survey            |              |
|----------------------|--------------|------------|-----------------------|-------------|------------------------|--------------|
| Impact level         | No. of cases | Frequency* | No. of cases          | Frequency** | No. of cases           | Frequency*** |
| 0                    | 7            | 0.01%      | 6                     | < 0.01%     | 11                     | 0.01%        |
| 1~3a                 | 4            | < 0.01%    | 3                     | < 0.01%     | 5                      | 0.01%        |
| 3b~5                 | 0            | 0%         | 0                     | 0%          | 0                      | 0%           |
| No answer: 1 insts.  |              |            | No answer: 6 insts.   |             | No answer: 2 insts.    |              |
| * Among 62,871 cases |              |            | ** Among 78,397 cases |             | *** Among 81,455 cases |              |

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



| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 1~3a         | 0            | 0%         |
| 3b~5         | 0            | 0%         |

No answer: 1 insts.

\*Among 62,871 CPB cases occurring during the 2-year period

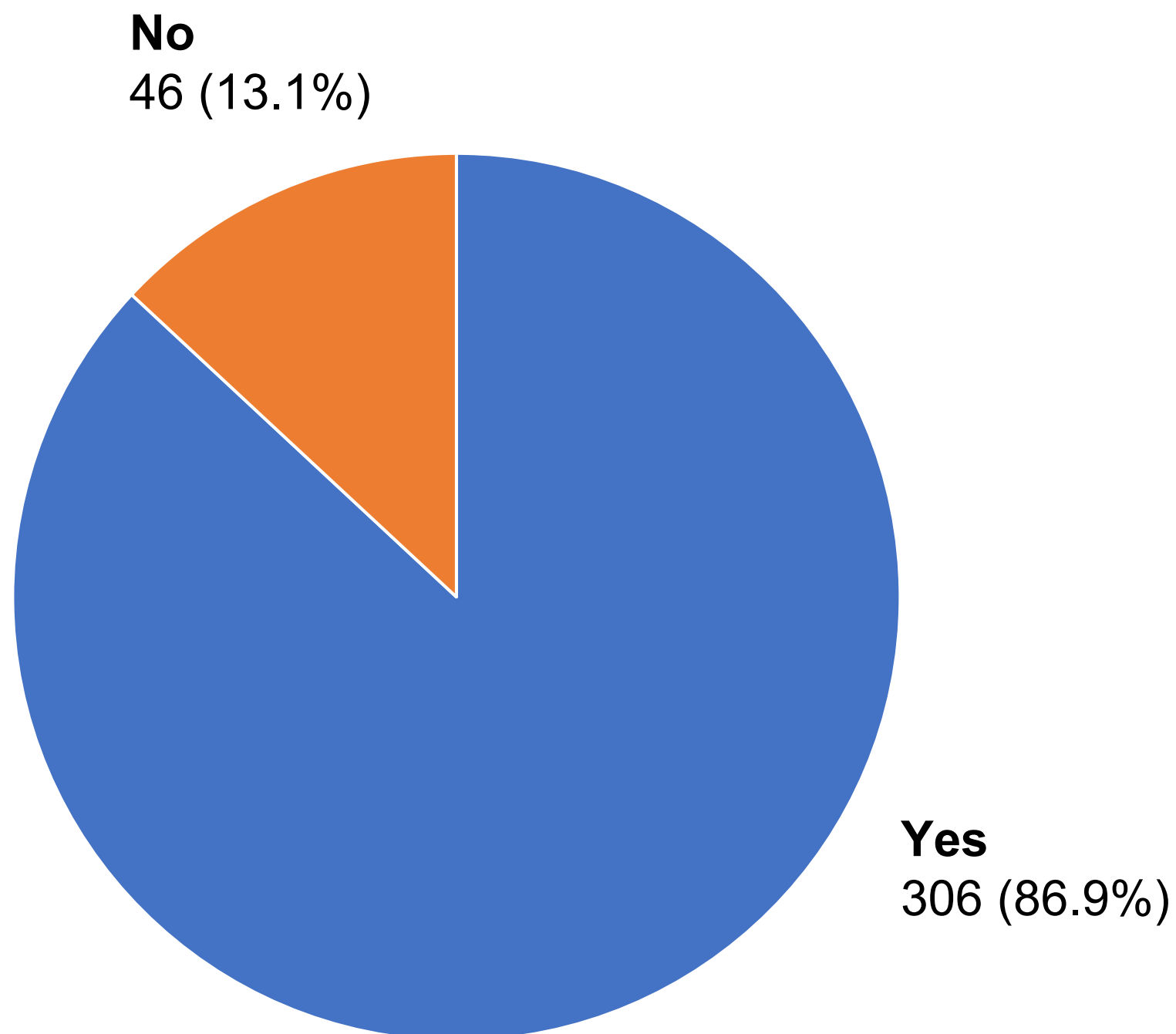
N=359 (no answer: 1 insts.)

# Incidents & Rates related to Medical Gas Supply Interruption

| 2023 Survey          |              |            | 2021 Survey           |             | 2019 Survey            |              |
|----------------------|--------------|------------|-----------------------|-------------|------------------------|--------------|
| Impact level         | No. of cases | Frequency* | No. of cases          | Frequency** | No. of cases           | Frequency*** |
| 0                    | -            | -          | -                     | -           | -                      | -            |
| 1~3a                 | 0            | 0%         | 1                     | < 0.01%     | 1                      | < 0.01%      |
| 3b~5                 | 0            | 0%         | 0                     | 0%          | 0                      | 0%           |
| No answer: 1 insts.  |              |            | No answer: 5 insts.   |             | No answer: 2 insts.    |              |
| * Among 62,871 cases |              |            | ** Among 78,397 cases |             | *** Among 81,455 cases |              |

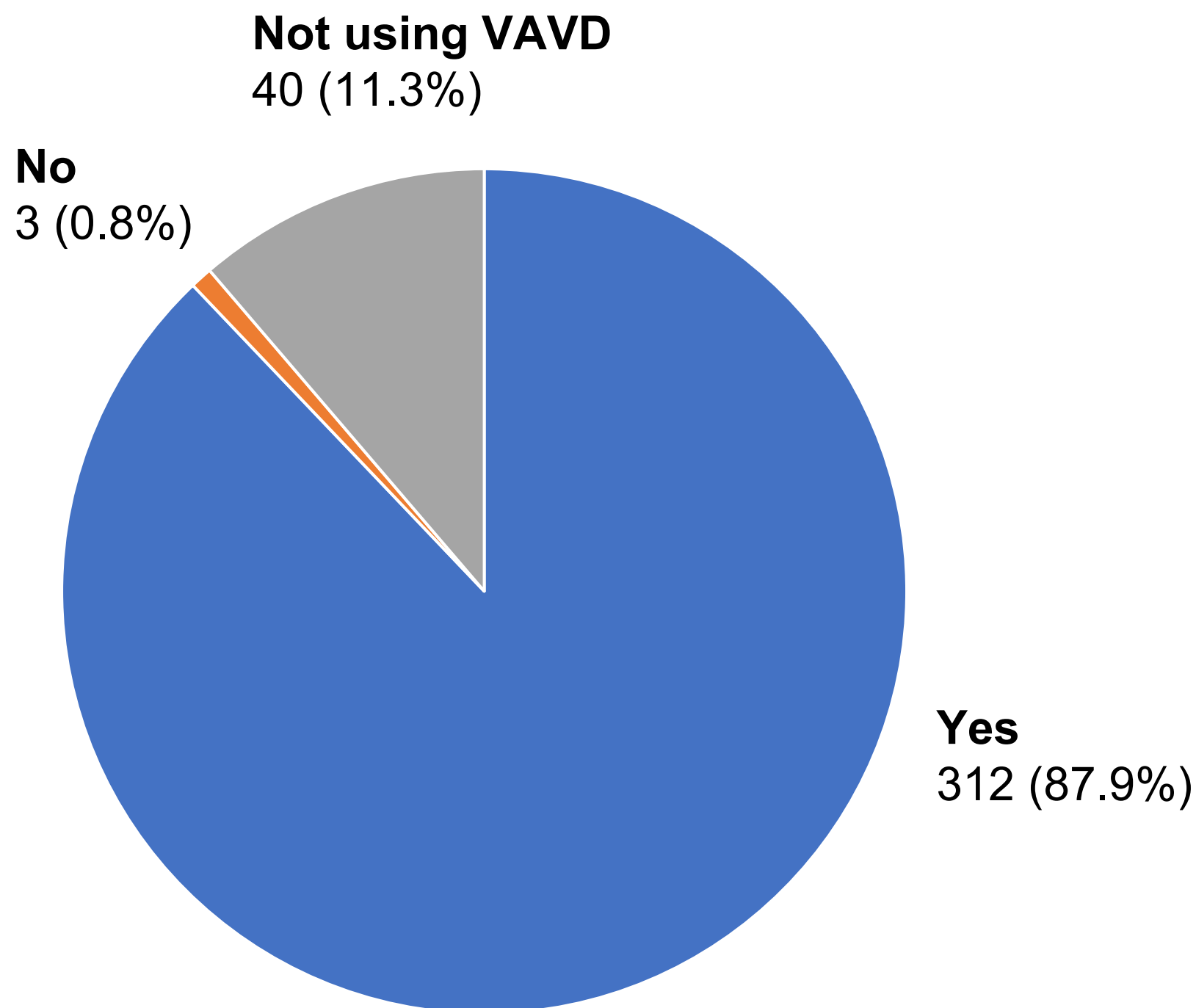


# Do you have an emergency kit in place?



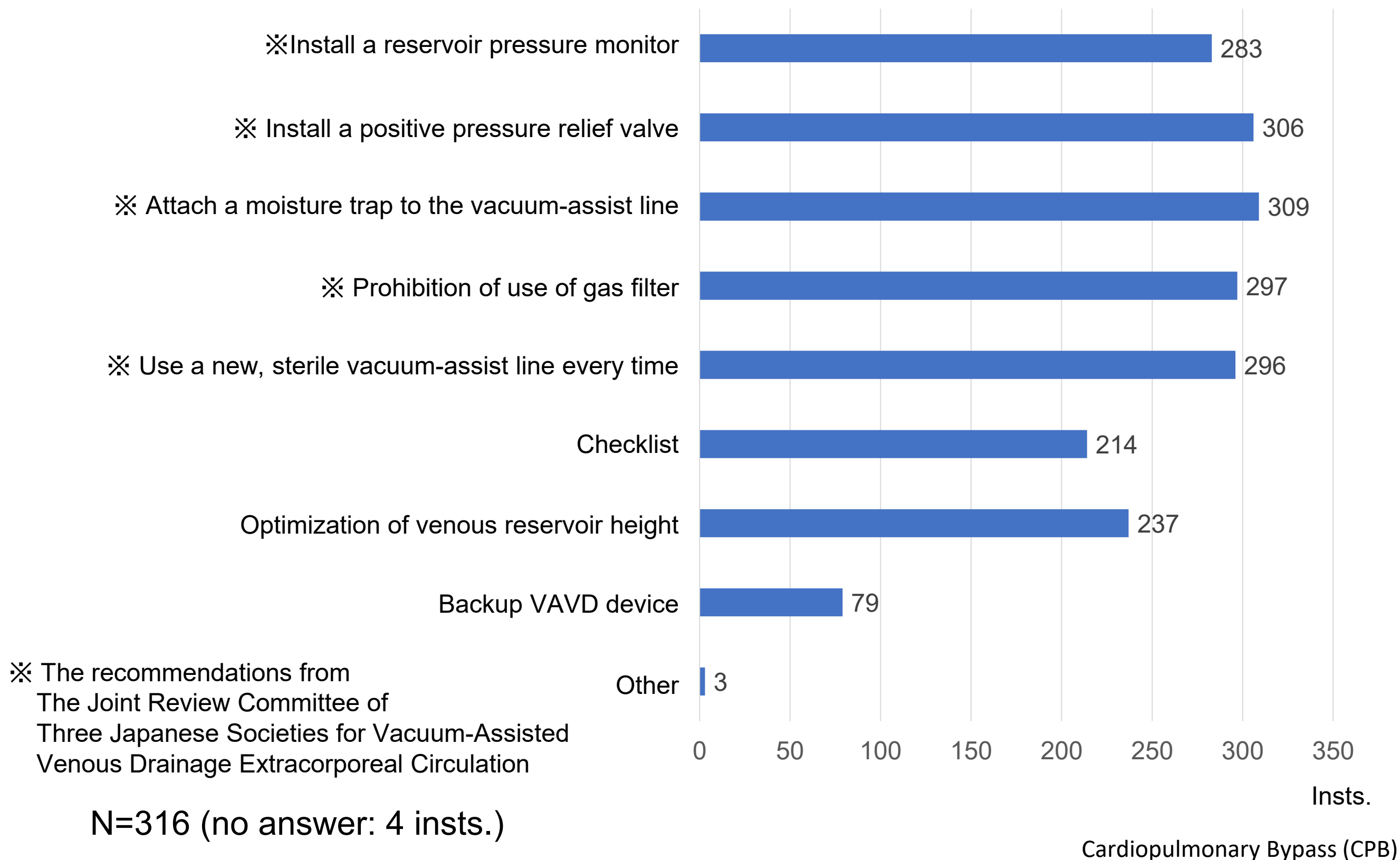
N=359 (no answer: 7 insts.)

# Do you take safety measures when using VAVD?



N=359 (no answer: 4 insts.)

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



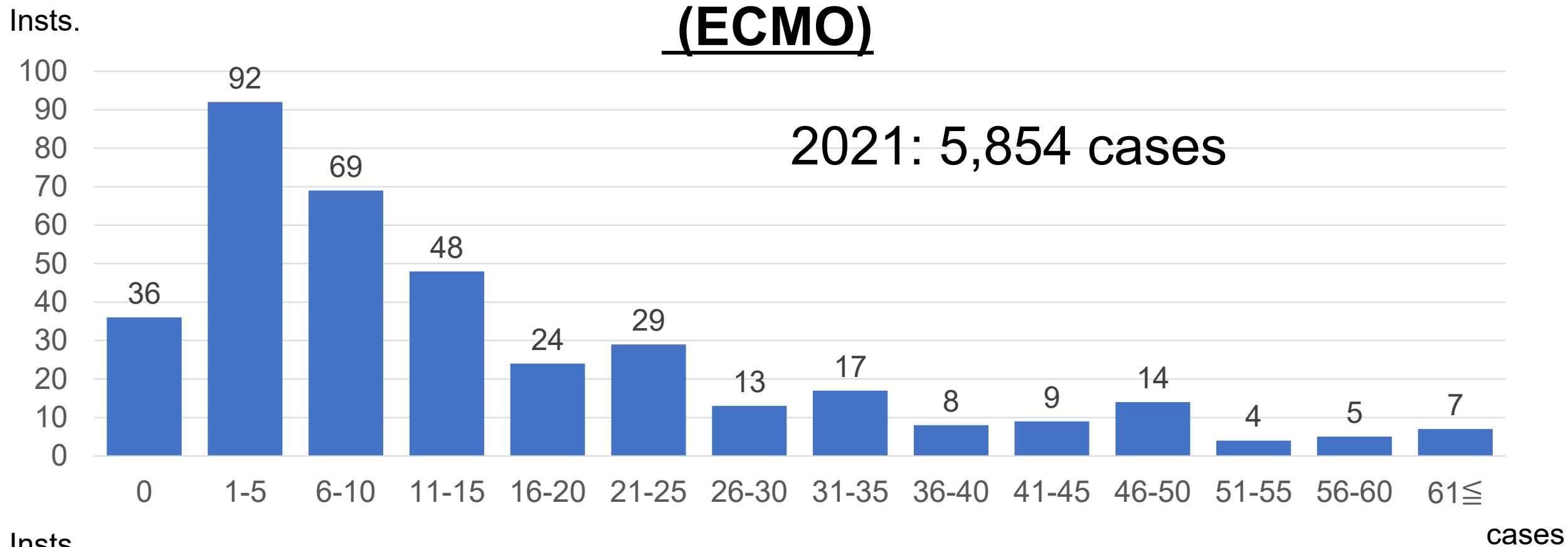
# **Aggregation Results**

## **Extracorporeal Membrane Oxygenation (ECMO)**

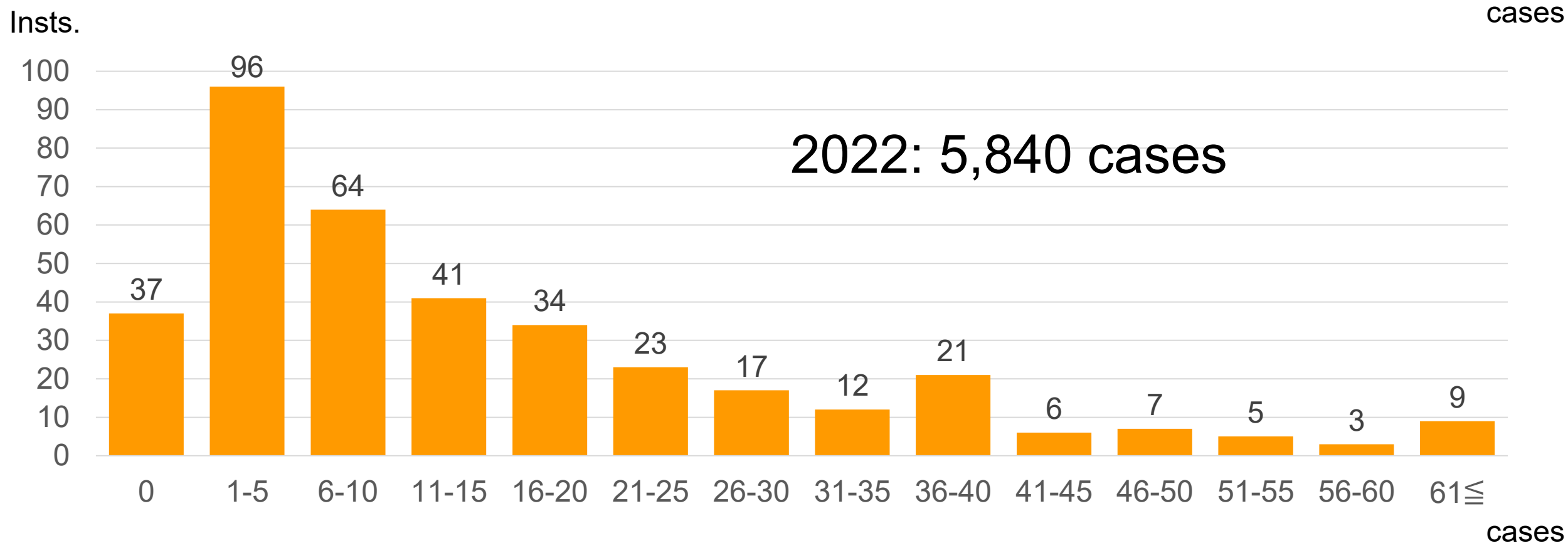
# Distribution of Cases with Extracorporeal Membrane Oxygenation

(ECMO)

2021: 5,854 cases



2022: 5,840 cases

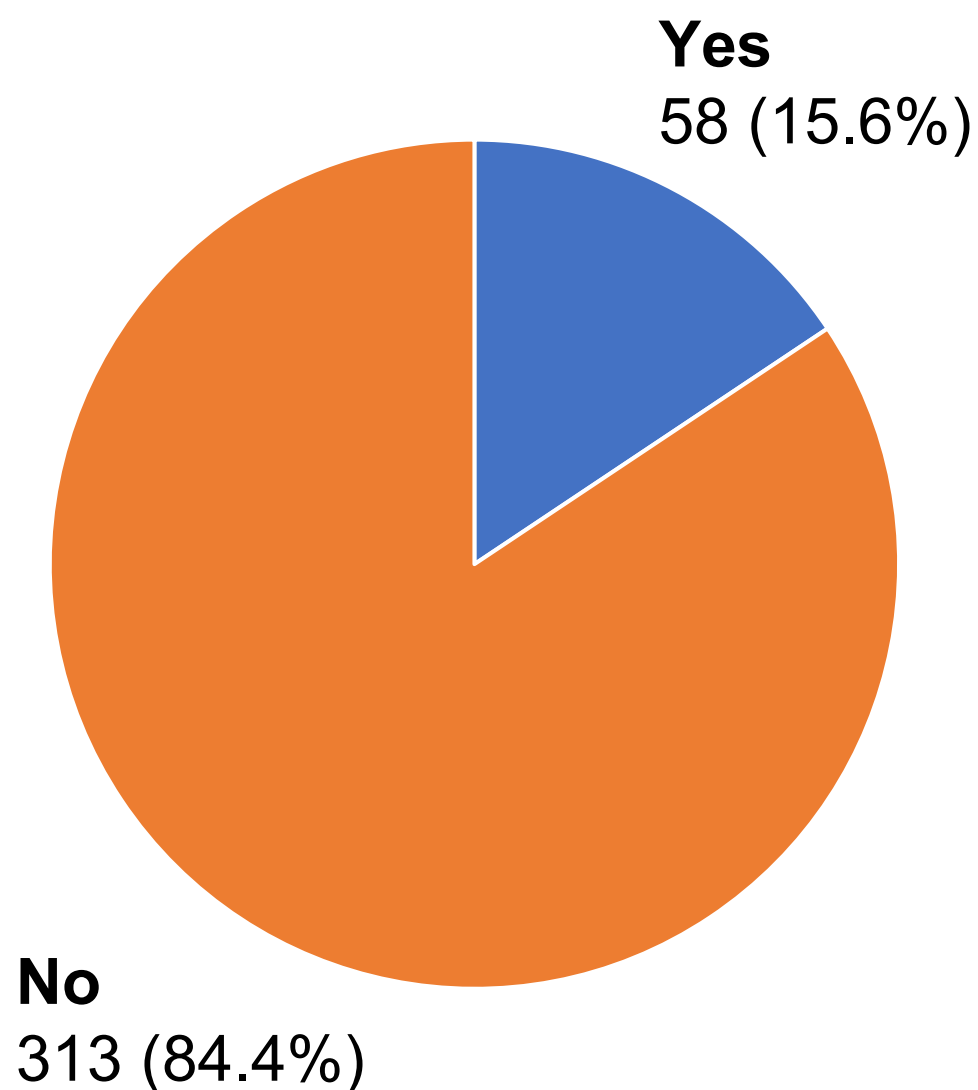


Extracorporeal Membrane Oxygenation (ECMO)

## ECMO-Related Incidents/Accidents & Rates

|                       | 2023 Survey  |              |              | 2021 Survey  |              |              | 2019 Survey  |              |              |
|-----------------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|
|                       | 2021         | 2022         | total        | 2019         | 2020         | total        | 2017         | 2018         | total        |
| ECMO cases            | 5,840        | 5,854        | 11,694       | 6,230        | 5,949        | 12,179       | 5,811        | 5,525        | 11,336       |
| Impact level (0)      | 79<br>0.68%  | 73<br>0.62%  | 152<br>1.30% | 55<br>0.88%  | 59<br>0.99%  | 114<br>0.94% | 58<br>1.00%  | 57<br>1.03%  | 115<br>1.01% |
| Impact level (1 – 3a) | 144<br>1.23% | 164<br>1.40% | 308<br>2.63% | 119<br>1.91% | 105<br>1.77% | 224<br>1.84% | 161<br>2.77% | 128<br>2.32% | 289<br>2.55% |
| Impact level (3b – 5) | 27<br>0.23%  | 27<br>0.23%  | 54<br>0.46%  | 24<br>0.39%  | 22<br>0.37%  | 46<br>0.38%  | 27<br>0.46%  | 23<br>0.42%  | 50<br>0.44%  |
| Total                 | 250<br>4.28% | 264<br>4.51% | 514<br>4.40% | 198<br>3.18% | 186<br>3.13% | 384<br>3.15% | 246<br>4.23% | 208<br>3.76% | 454<br>4.00% |

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



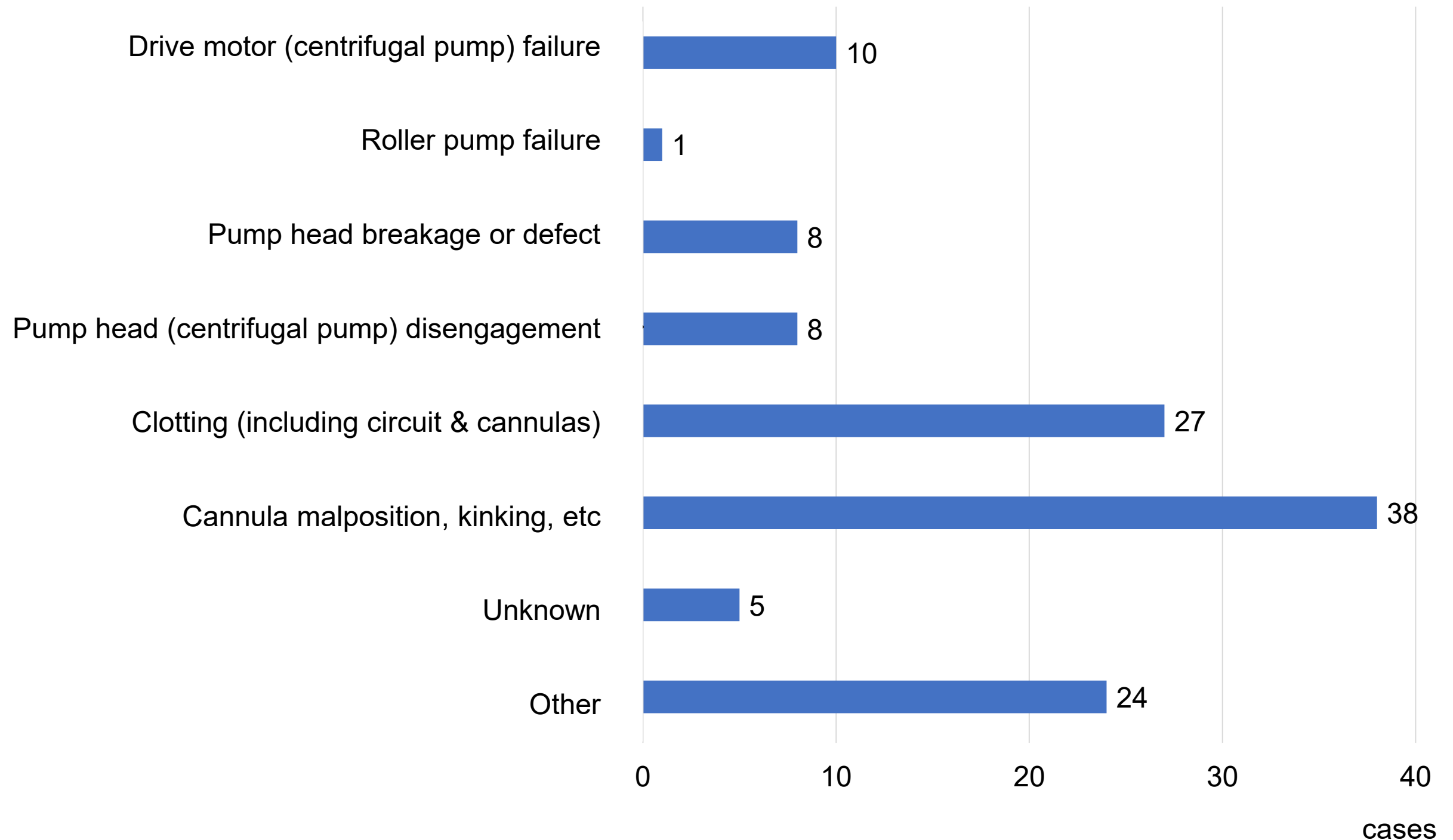
| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 1~3a         | 74           | 0.63%      |
| 3b~5         | 31           | 0.27%      |

No answer: 9 insts.

\*Among 11,694 CPS cases occurring during the 2-year period

N=375 (no answer: 4 insts.)

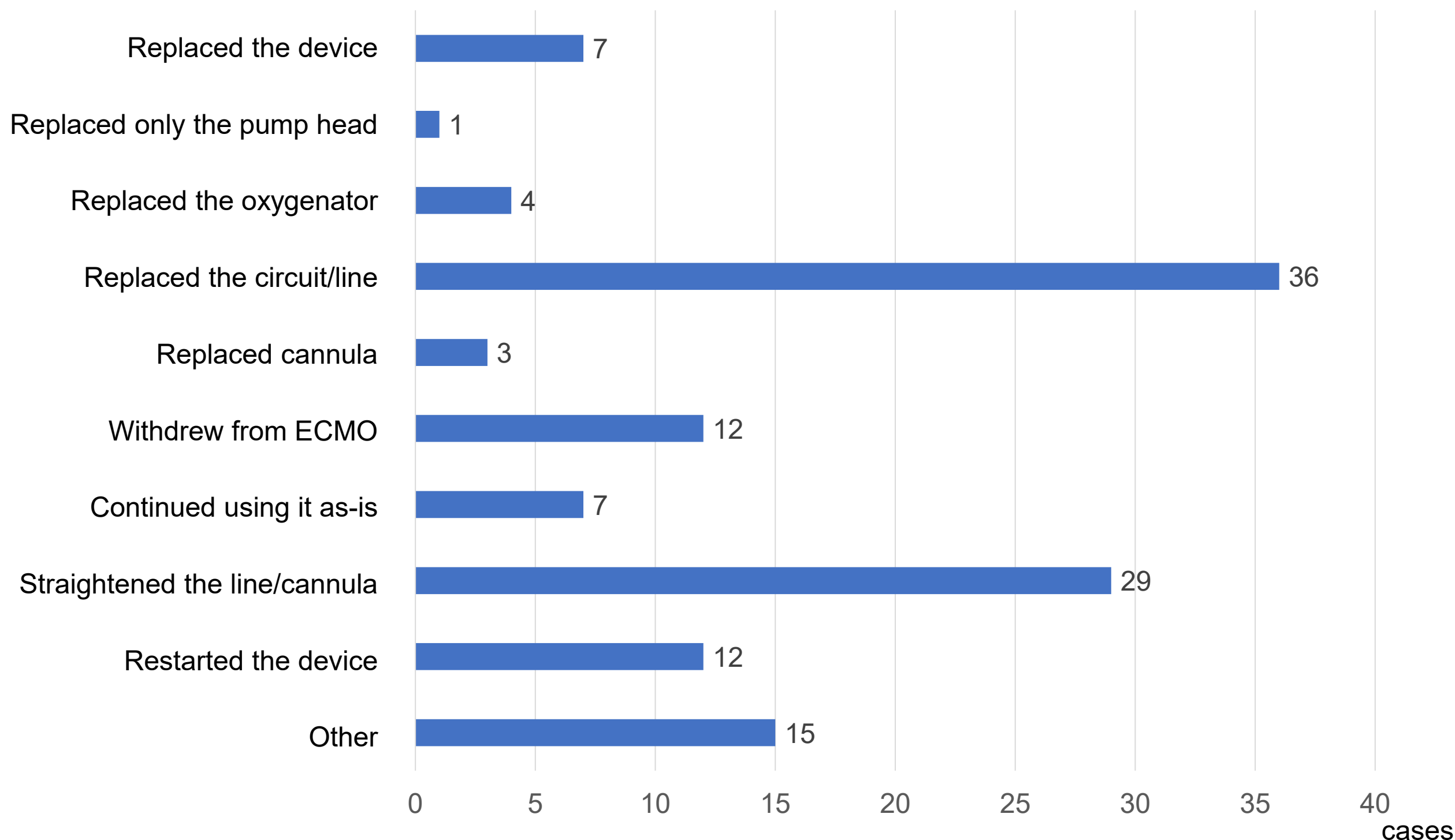
# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



N=62 (no answer: 5 insts.)



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



N=62 (no answer: 5 insts.)

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

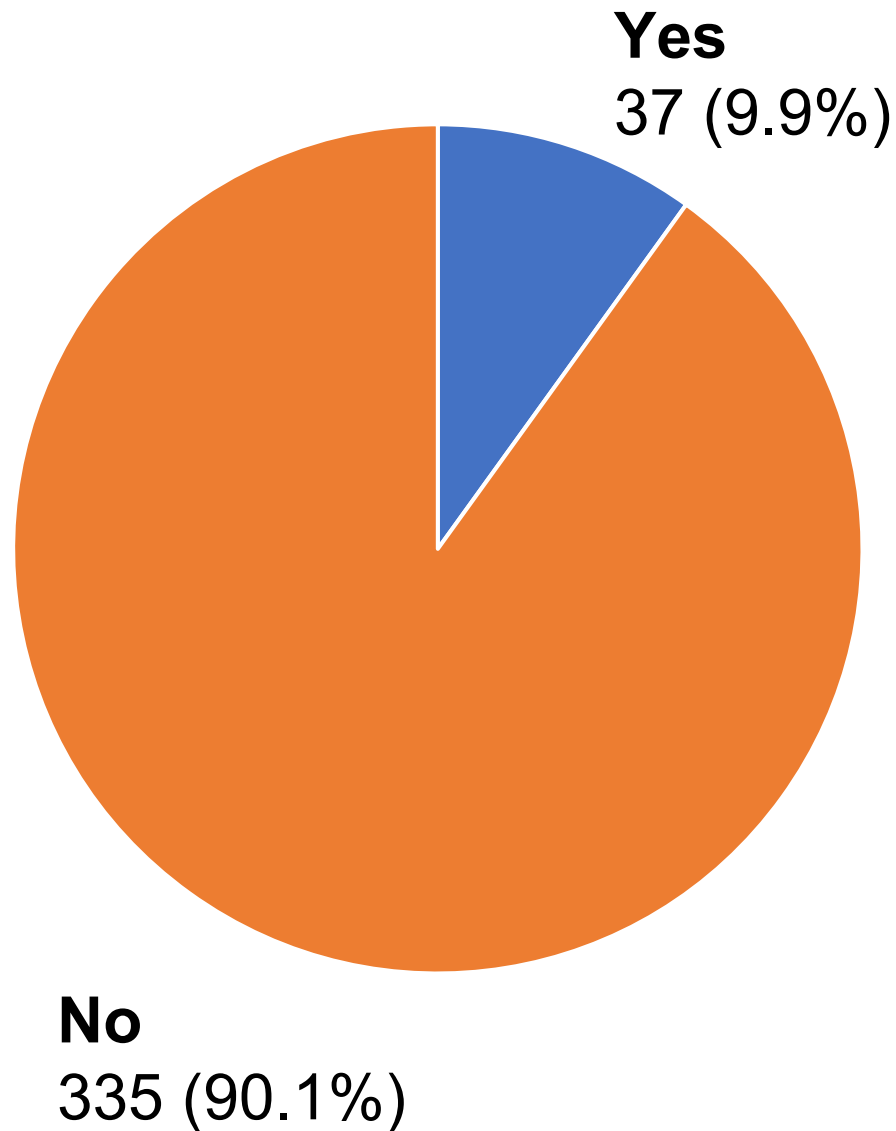
| 2023 Survey         |              |            | 2021 Survey         |             | 2019 Survey         |              |
|---------------------|--------------|------------|---------------------|-------------|---------------------|--------------|
| Impact level        | No. of cases | Frequency* | No. of cases        | Frequency** | No. of cases        | Frequency*** |
| 0                   | —            | —          | —                   | —           | —                   | —            |
| 1~3a                | 74           | 0.63%      | 133                 | 1.09%       | 69                  | 0.61%        |
| 3b~5                | 31           | 0.27%      | 16                  | 0.13%       | 8                   | 0.07%        |
| No answer: 9 insts. |              |            | No answer: 9 insts. |             | No answer: 9 insts. |              |

\* Among 11,694 cases

\*\* Among 12,179 cases

\*\*\* Among 11,336 cases

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



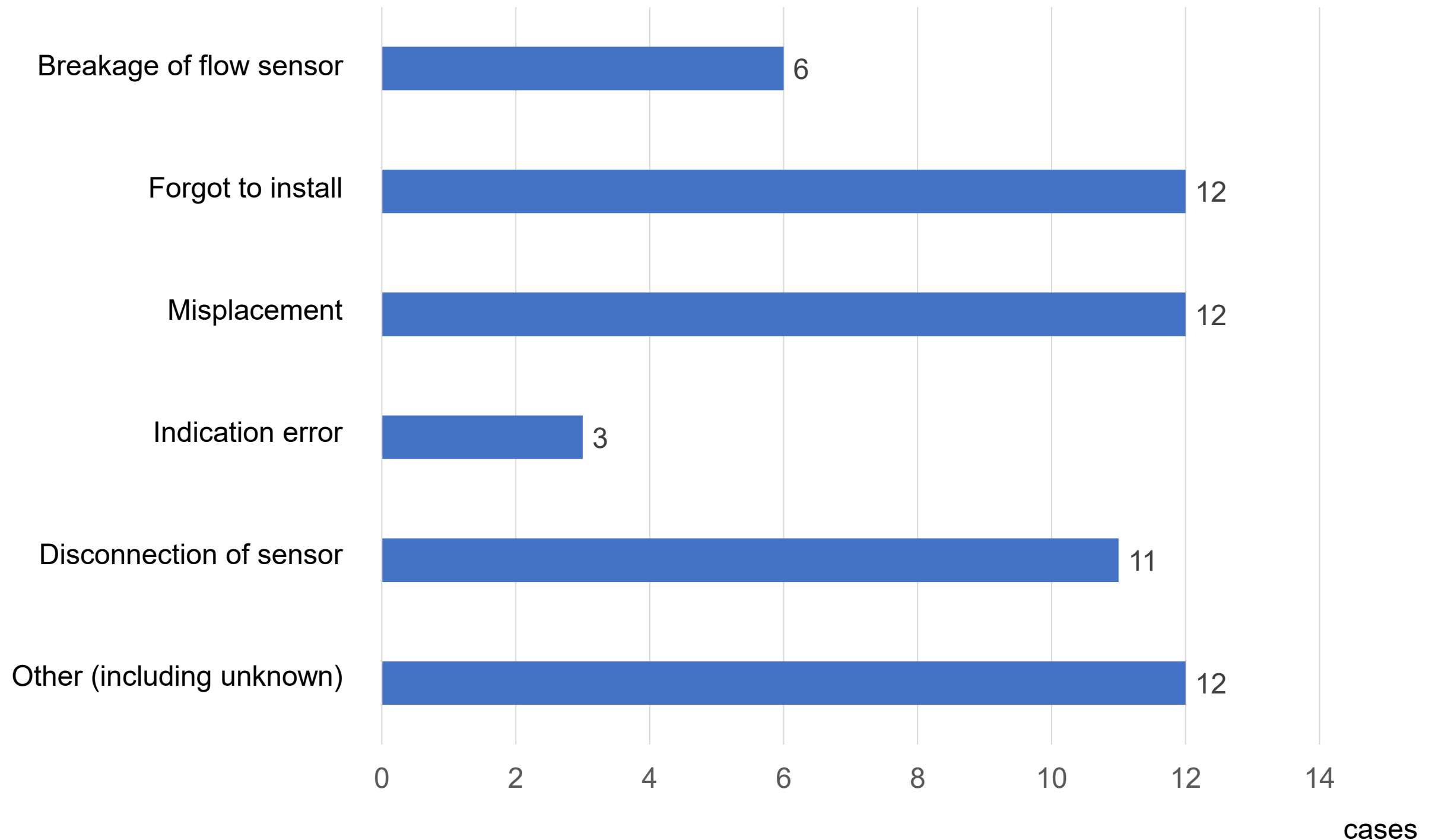
| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 0            | 33           | 0.28%      |
| 1~3a         | 11           | 0.09%      |
| 3b~5         | 0            | 0%         |

No answer: 3 insts.

\*Among 11,694 CPS cases occurring during the 2-year period

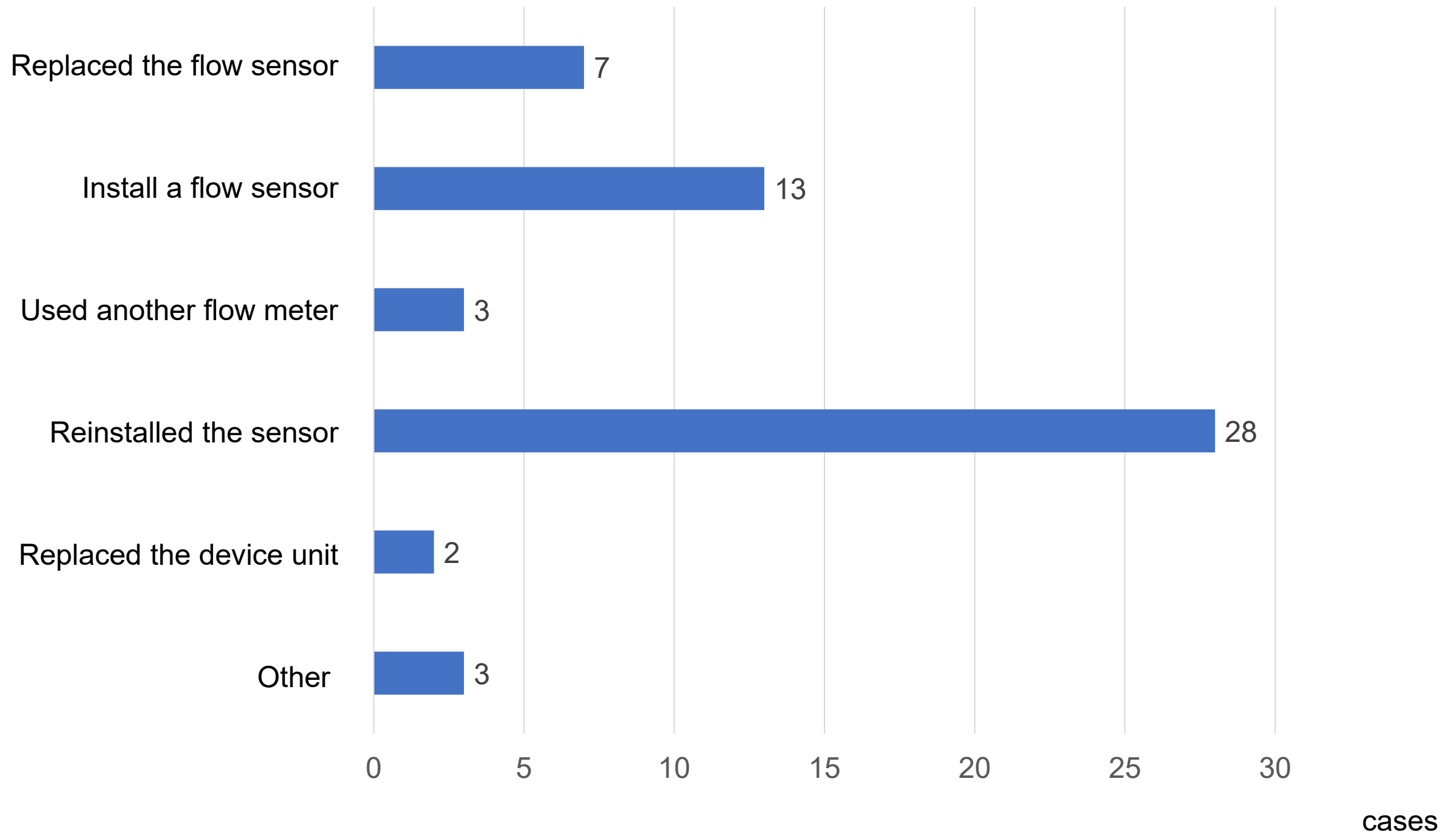
N=375 (no answer: 3 insts.)

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



N=40 (no answer: 5 insts.)

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



N=40 (no answer: 5 insts.)

# Incidents & Rates of Related to Flow Sensor

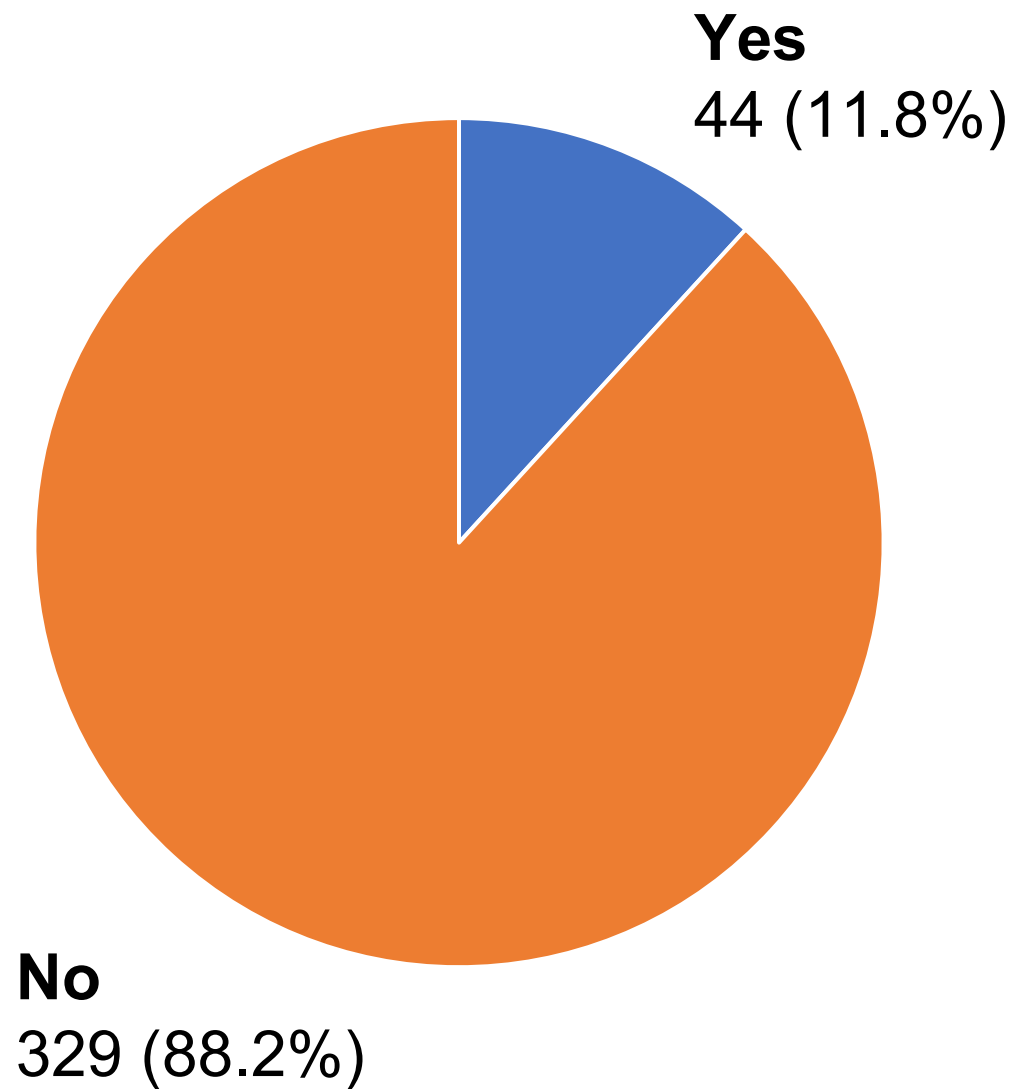
| 2023 Survey         |              |            | 2021 Survey         |             | 2019 Survey         |              |
|---------------------|--------------|------------|---------------------|-------------|---------------------|--------------|
| Impact level        | No. of cases | Frequency* | No. of cases        | Frequency** | No. of cases        | Frequency*** |
| 0                   | 33           | 0.28%      | 65                  | 0.53%       | 53                  | 0.47%        |
| 1~3a                | 11           | 0.09%      | 14                  | 0.12%       | 34                  | 0.30%        |
| 3b~5                | 0            | 0%         | 1                   | 0.01%       | 1                   | 0.01%        |
| No answer: 3 insts. |              |            | No answer: 6 insts. |             | No answer: 6 insts. |              |

\* Among 11,694 cases

\*\* Among 12,179 cases

\*\*\* Among 11,336 cases

# Did you experience Air Entering into the Circuit?



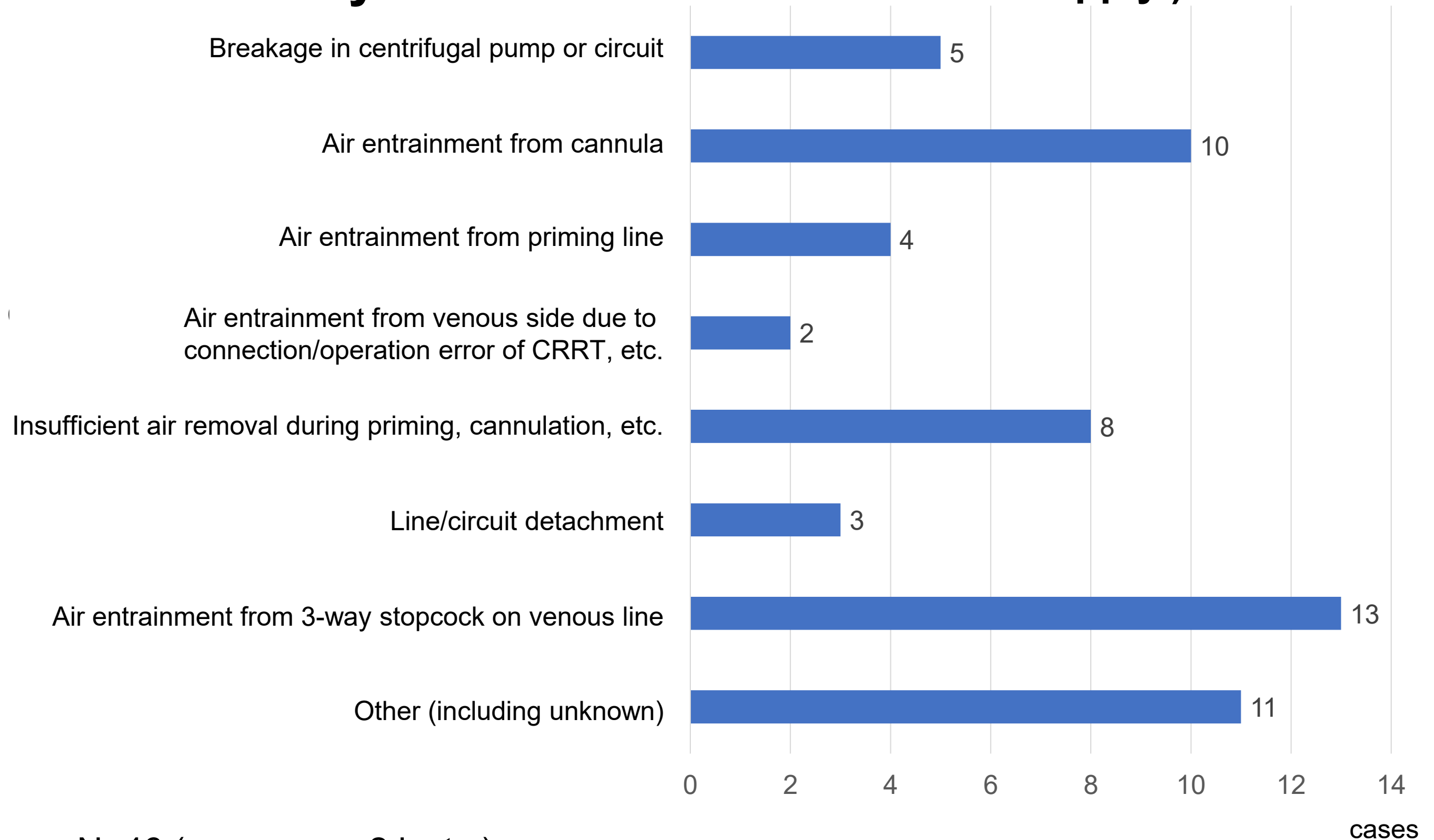
| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 1~3a         | 43           | 0.37%      |
| 3b~5         | 7            | 0.06%      |

No answer: 7 insts.

\*Among 11,694 CPS cases occurring during the 2-year period

N=375 (no answer: 2 insts.)

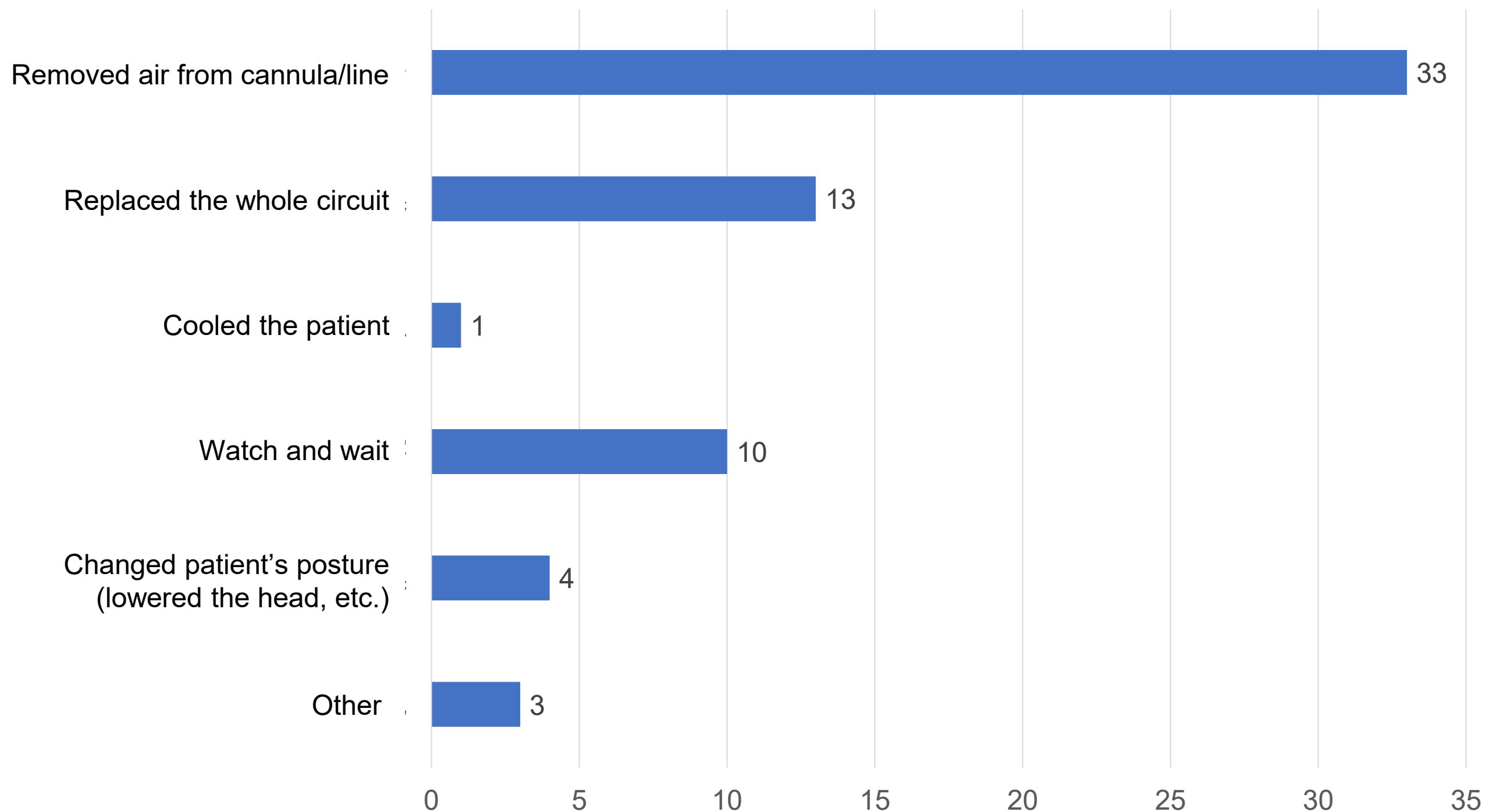
# Which of the following caused the air entering and how many times? (Please choose all that apply.)



N=46 (no answer: 2 insts.)



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



N=46 (no answer: 2 insts.)

cases

# Incidents & Rates of Air Entering into Circuit

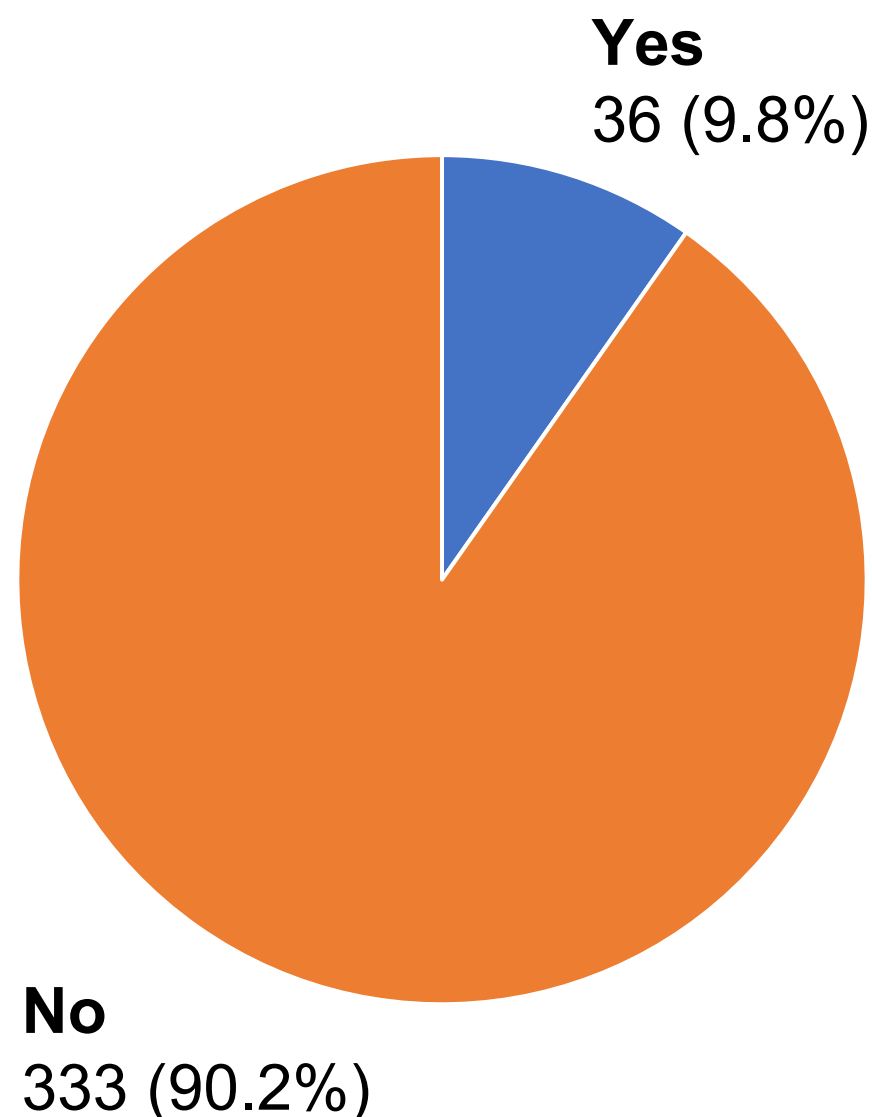
| 2023 Survey         |              |            | 2021 Survey         |             | 2019 Survey         |              |
|---------------------|--------------|------------|---------------------|-------------|---------------------|--------------|
| Impact level        | No. of cases | Frequency* | No. of cases        | Frequency** | No. of cases        | Frequency*** |
| 0                   | -            | -          | -                   | -           | -                   | -            |
| 1~3a                | 43           | 0.37%      | 55                  | 0.45%       | 54                  | 0.48%        |
| 3b~5                | 7            | 0.06%      | 11                  | 0.09%       | 7                   | 0.06%        |
| No answer: 7 insts. |              |            | No answer: 5 insts. |             | No answer: 5 insts. |              |

\* Among 11,694 cases

\*\* Among 12,179 cases

\*\*\* Among 11,336 cases

# Did you experience Unexpected Bleeding from the Circuit?



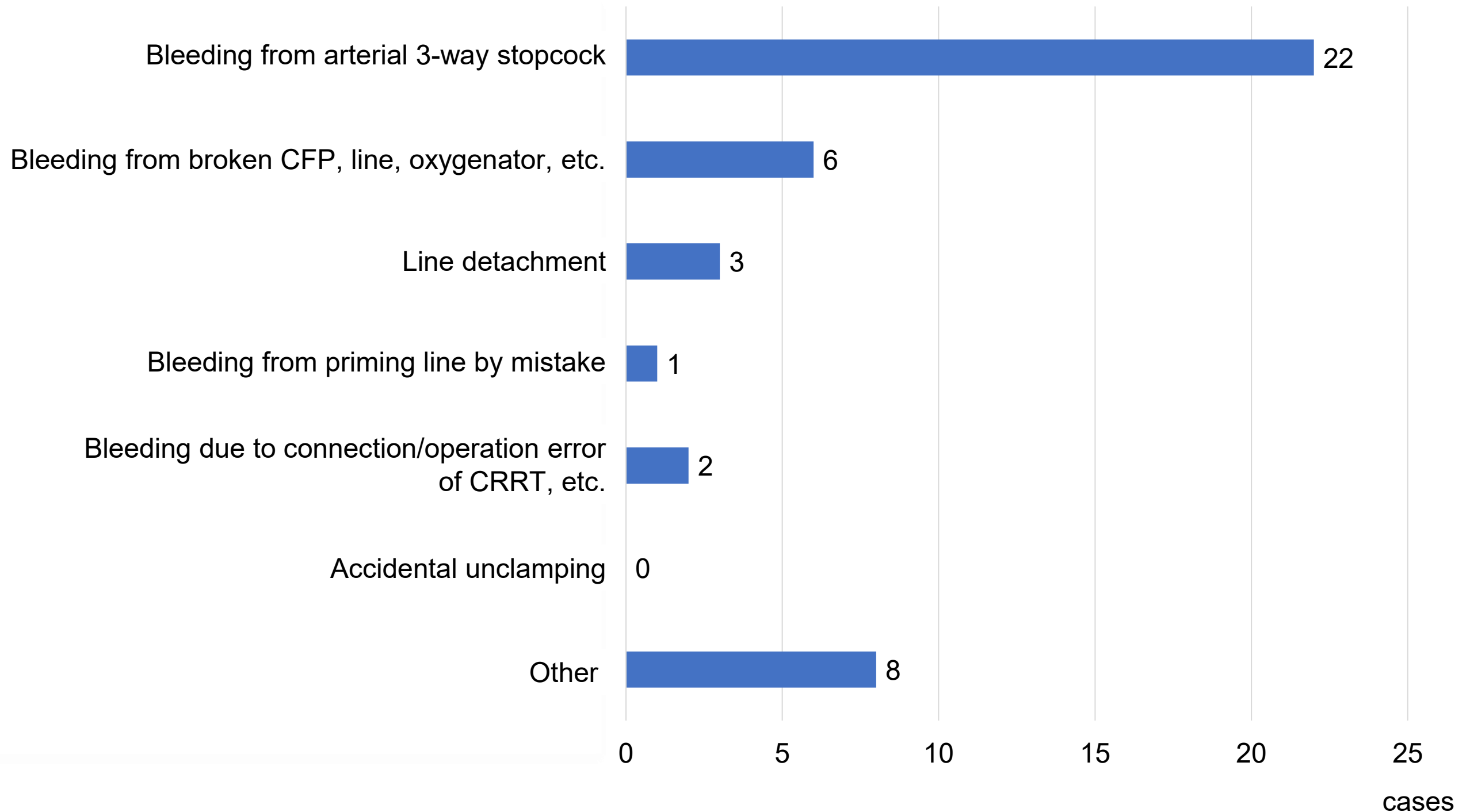
| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 1~3a         | 32           | 0.27%      |
| 3b~5         | 7            | 0.06%      |

No answer: 7 insts.

\*Among 11,694 CPS cases occurring during the 2-year period

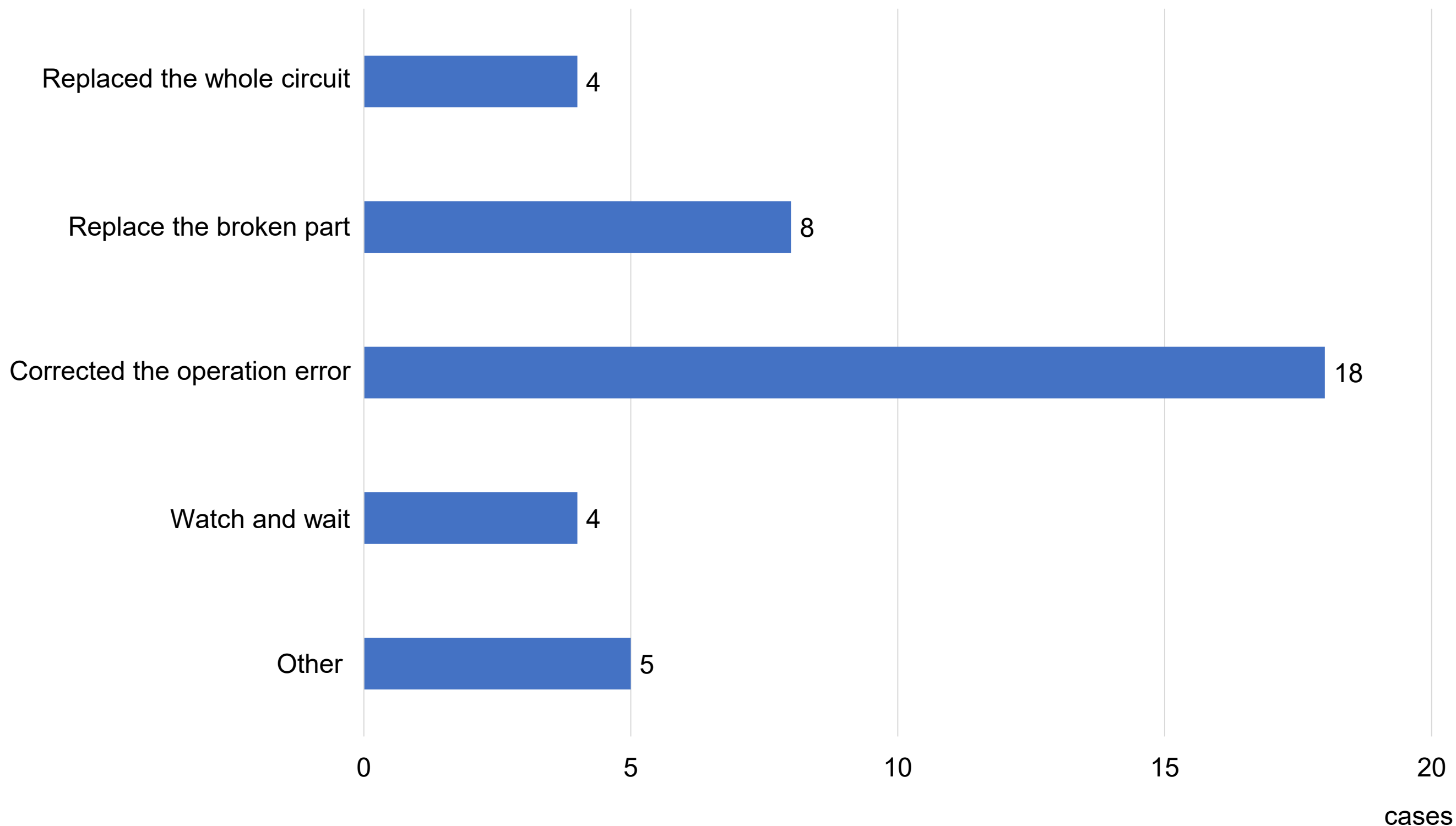
N=375 (no answer: 6 insts.)

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



N=42 (no answer: 7 insts.)

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



N=42 (no answer: 7 insts.)

# Incidents & Rates of Unexpected Bleeding from Circuit

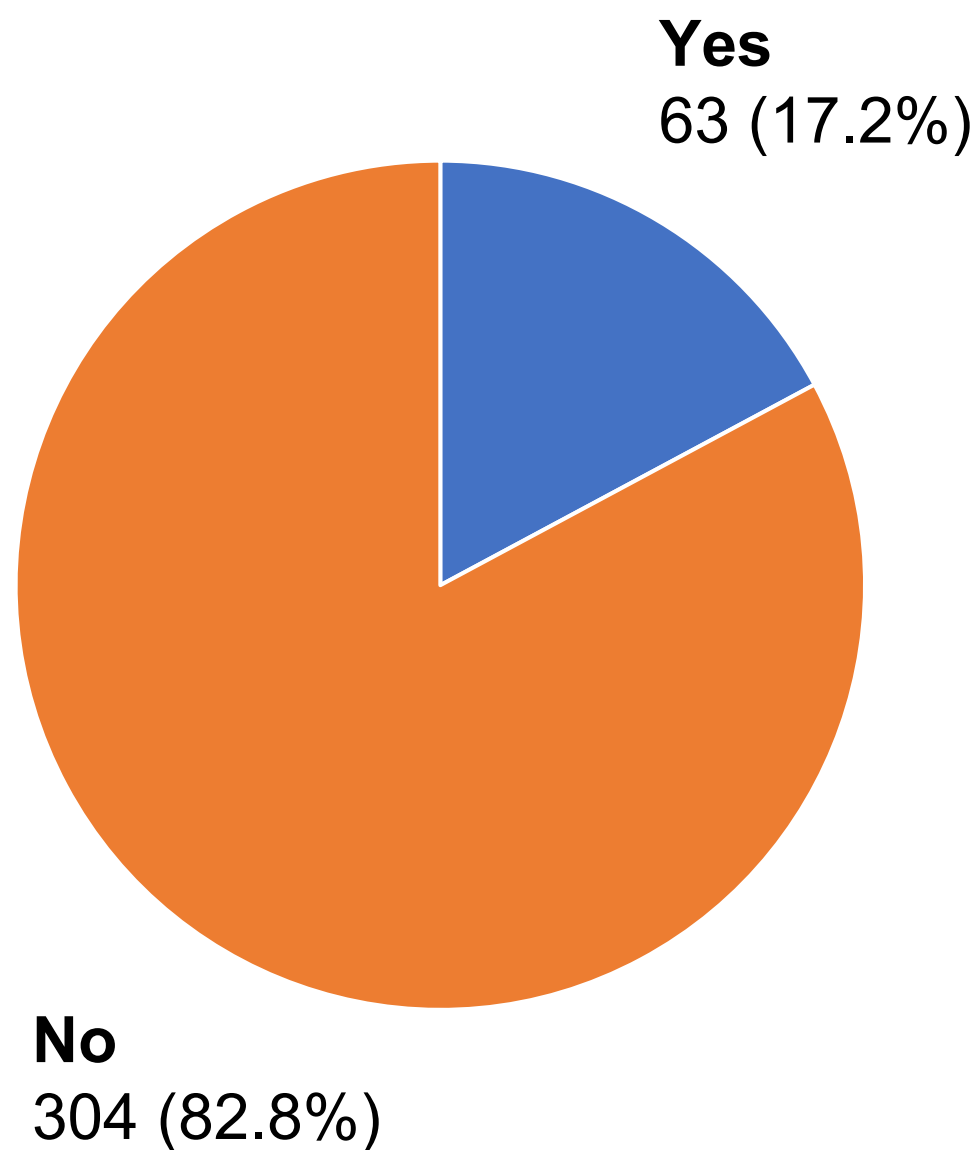
| 2023 Survey         |              |            | 2021 Survey         |             | 2019 Survey         |              |
|---------------------|--------------|------------|---------------------|-------------|---------------------|--------------|
| Impact level        | No. of cases | Frequency* | No. of cases        | Frequency** | No. of cases        | Frequency*** |
| 0                   | -            | -          | -                   | -           | -                   | -            |
| 1~3a                | 32           | 0.27%      | 63                  | 0.52%       | 56                  | 0.49%        |
| 3b~5                | 7            | 0.06%      | 6                   | 0.05%       | 2                   | 0.02%        |
| No answer: 7 insts. |              |            | No answer: 6 insts. |             | No answer: 8 insts. |              |

\* Among 11,694 cases

\*\* Among 12,179 cases

\*\*\* Among 11,336 cases

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



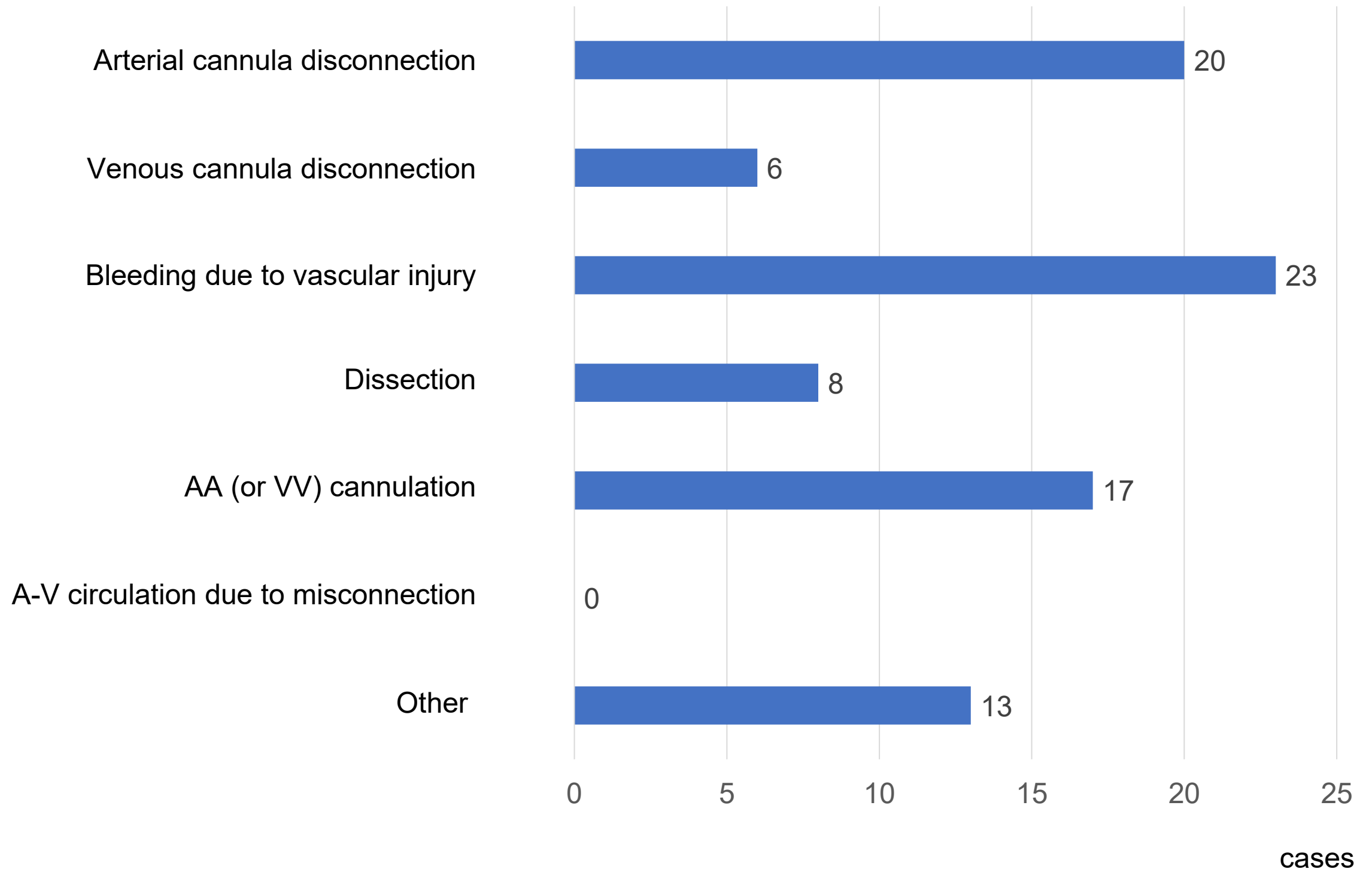
| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 0            | 8            | 0.07%      |
| 1~3a         | 45           | 0.38%      |
| 3b~5         | 27           | 0.23%      |

No answer: 5 insts.

\*Among 11,694 CPS cases occurring during the 2-year period

N=375 (no answer: 8 insts.)

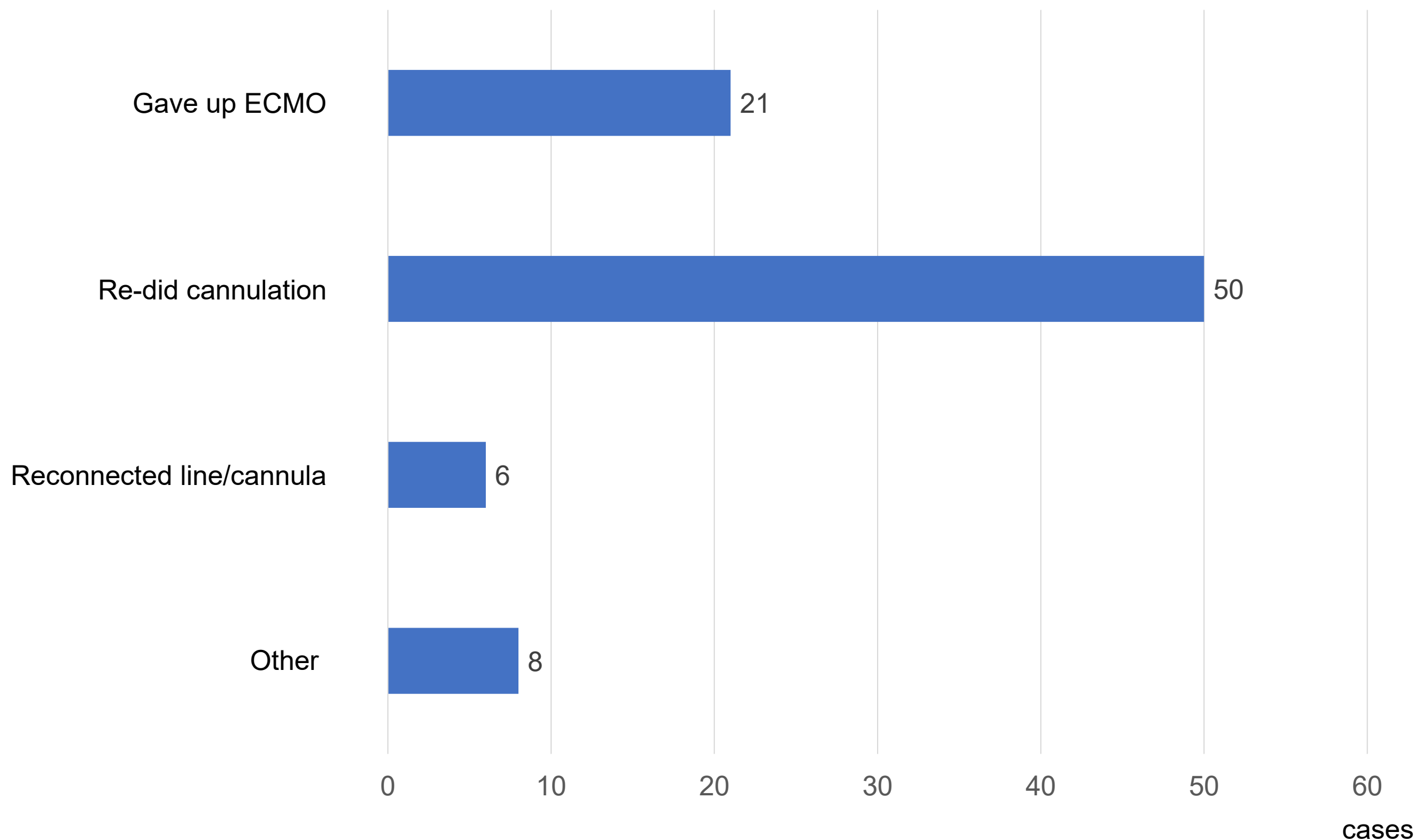
# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



N=71 (no answer: 3 insts.)



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



N=71 (no answer: 5 insts.)

# Incidents & Rates Related to Cannulation

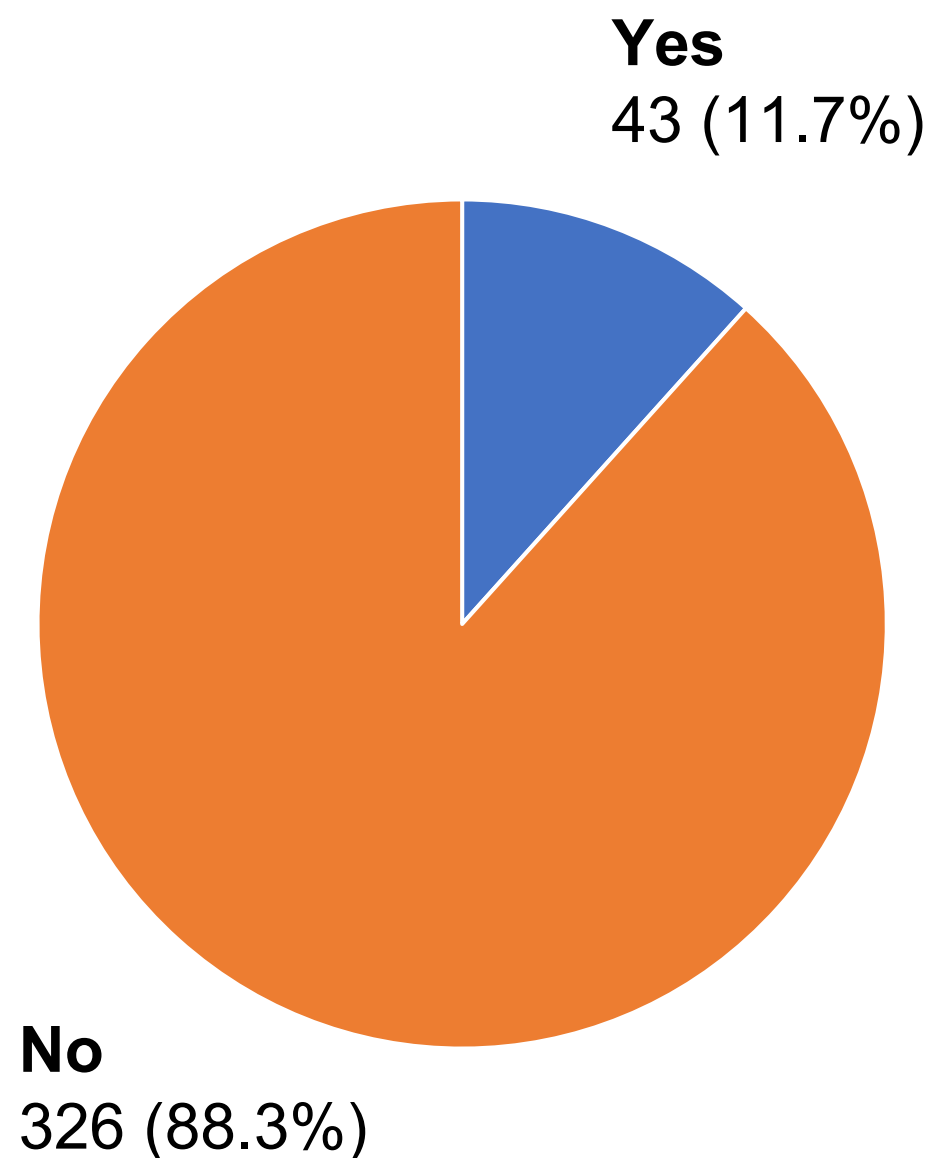
| 2023 Survey         |              |            | 2021 Survey         |             | 2019 Survey         |              |
|---------------------|--------------|------------|---------------------|-------------|---------------------|--------------|
| Impact level        | No. of cases | Frequency* | No. of cases        | Frequency** | No. of cases        | Frequency*** |
| 0                   | 8            | 0.07%      | 11                  | 0.09%       | 16                  | 0.14%        |
| 1~3a                | 45           | 0.38%      | 71                  | 0.58%       | 74                  | 0.65%        |
| 3b~5                | 27           | 0.23%      | 51                  | 0.42%       | 40                  | 0.35%        |
| No answer: 9 insts. |              |            | No answer: 9 insts. |             | No answer: 9 insts. |              |

\* Among 11,694 cases

\*\* Among 12,179 cases

\*\*\* Among 11,336 cases

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



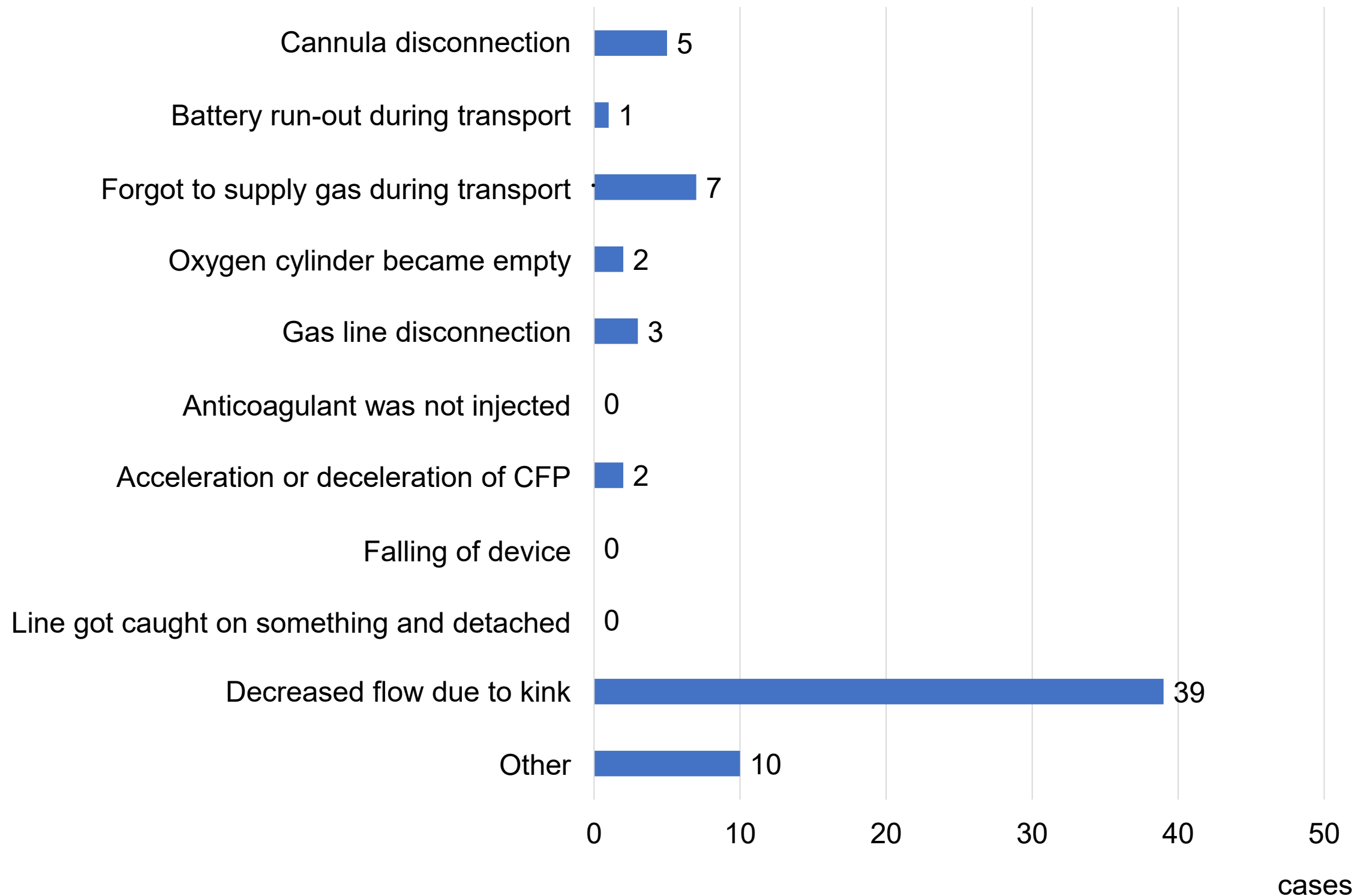
N=375 (no answer: 6 insts.)

| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 1~3a         | 62           | 0.53%      |
| 3b~5         | 5            | 0.04%      |

No answer: 8 insts.

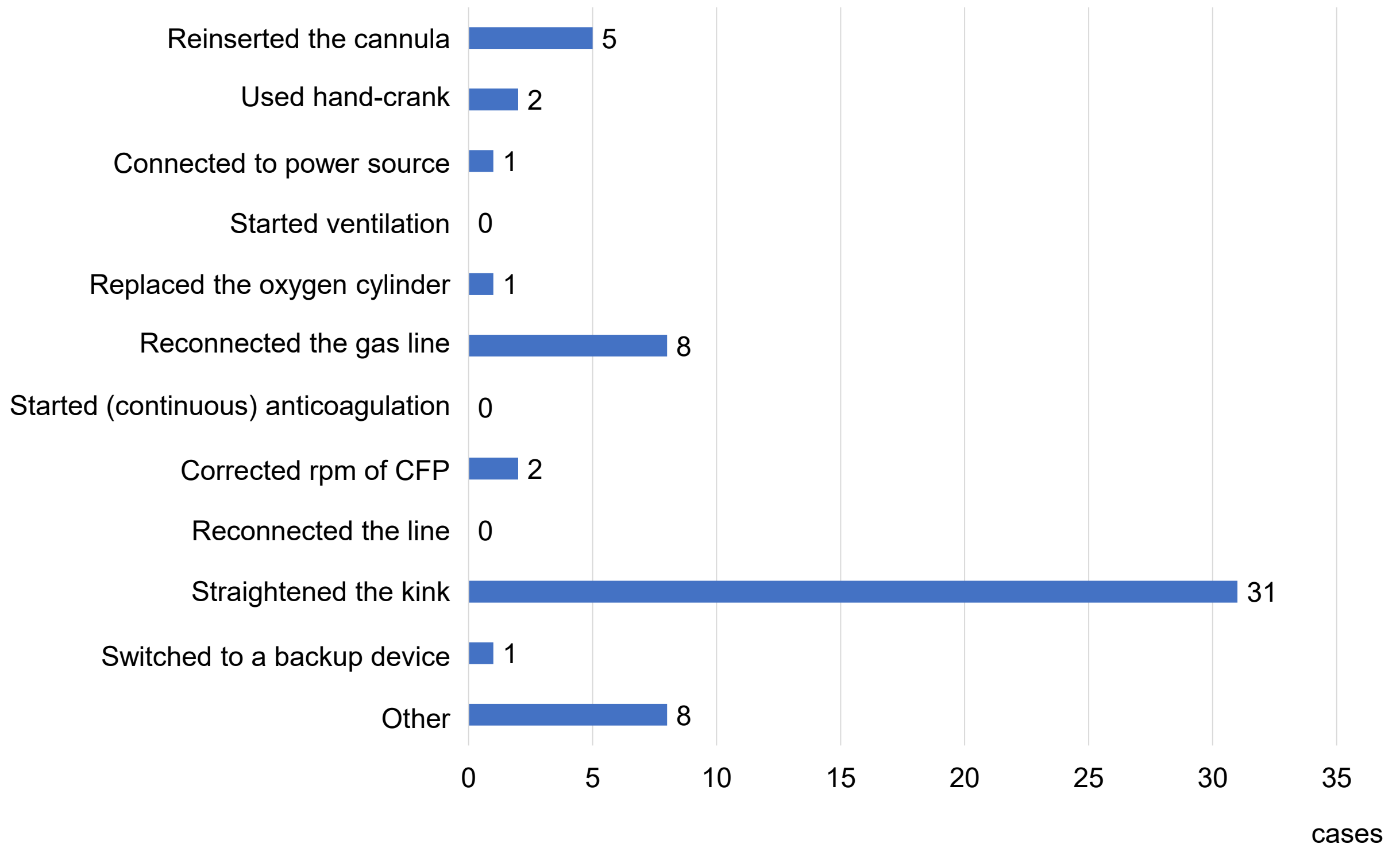
\*Among 11,694 CPS cases occurring during the 2-year period

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



N=49 (no answer: 6 insts.)

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



N=49 (no answer: 10 insts.)

# Incidents & Rates Related to Transport or Destination

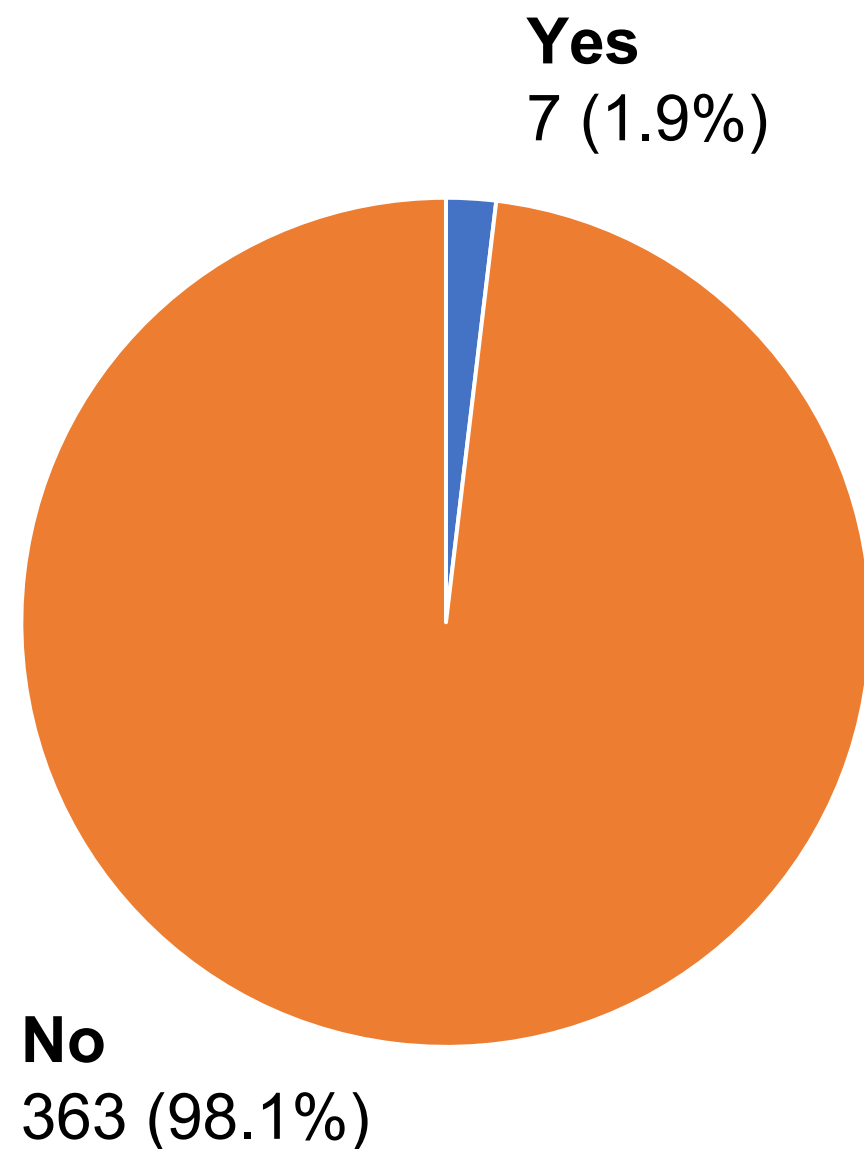
| 2023 Survey         |              |            | 2021 Survey         |             | 2019 Survey         |              |
|---------------------|--------------|------------|---------------------|-------------|---------------------|--------------|
| Impact level        | No. of cases | Frequency* | No. of cases        | Frequency** | No. of cases        | Frequency*** |
| 0                   | -            | -          | -                   | -           | -                   | -            |
| 1~3a                | 62           | 0.53%      | 82                  | 0.67%       | 92                  | 0.81%        |
| 3b~5                | 5            | 0.04%      | 4                   | 0.03%       | 5                   | 0.04%        |
| No answer: 8 insts. |              |            | No answer: 7 insts. |             | No answer: 3 insts. |              |

\* Among 11,694 cases

\*\* Among 12,179 cases

\*\*\* Among 11,336 cases

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



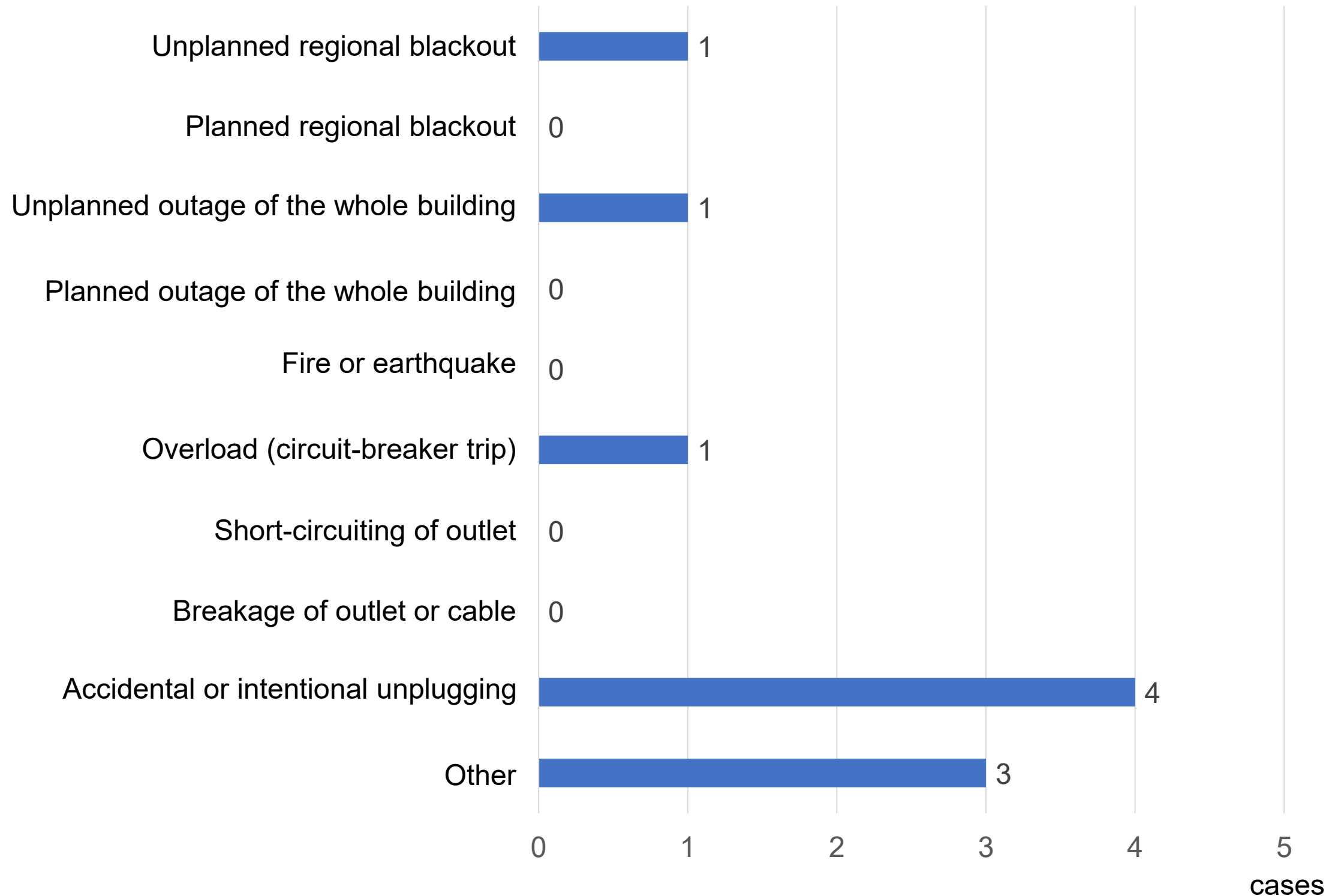
| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 0            | 3            | 0.03%      |
| 1~3a         | 6            | 0.05%      |
| 3b~5         | 0            | 0%         |

No answer: 5 insts.

\*Among 11,694 CPS cases occurring during the 2-year period

N=375 (no answer: 5 insts.)

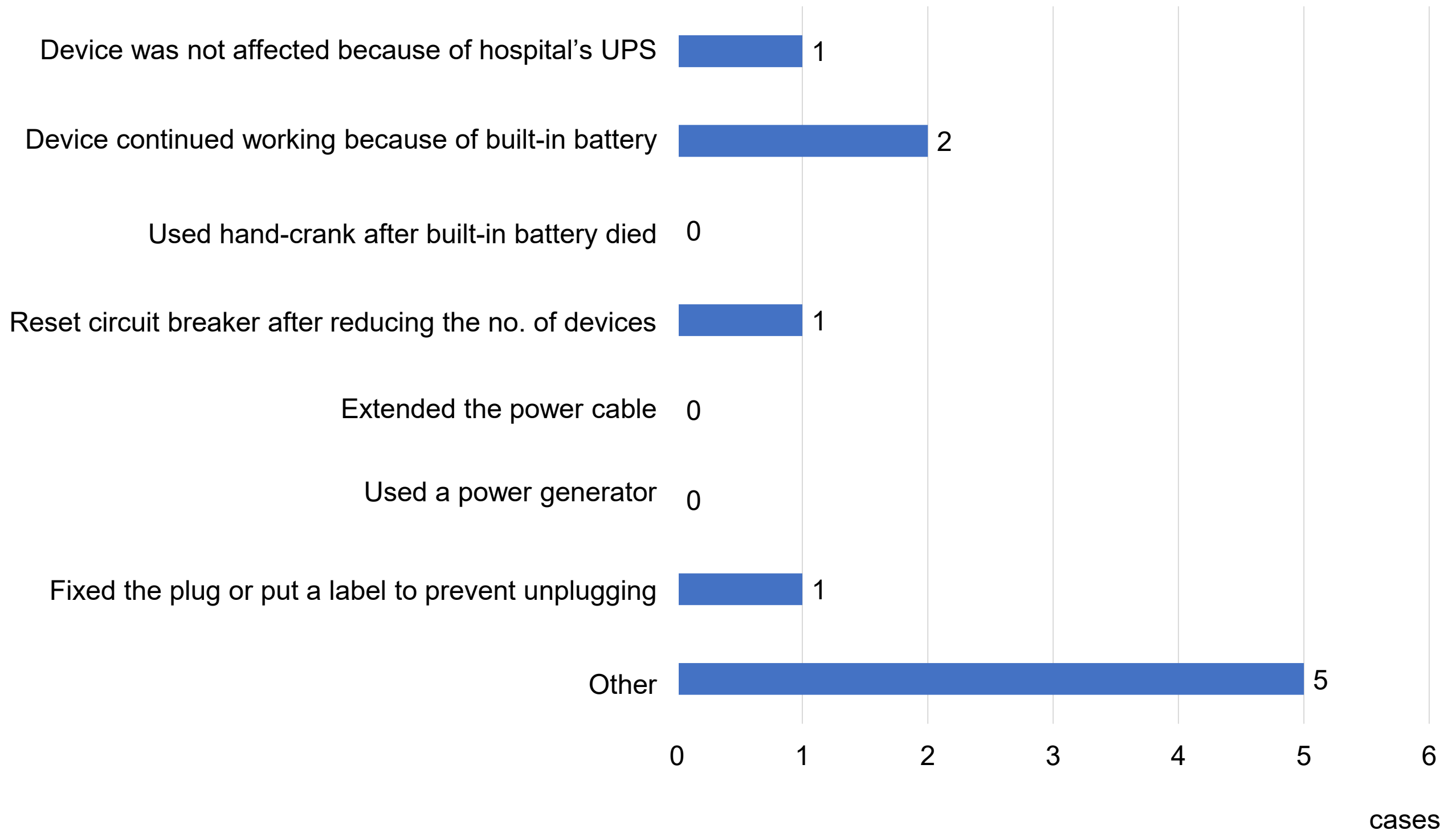
# How many times did you experience the following incidents/accidents? (Please choose all that apply.)



N=12 (no answer: 4 insts.)



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



N=49 (no answer: 5 insts.)

# Incidents & Rates of Power Outage/Interruption

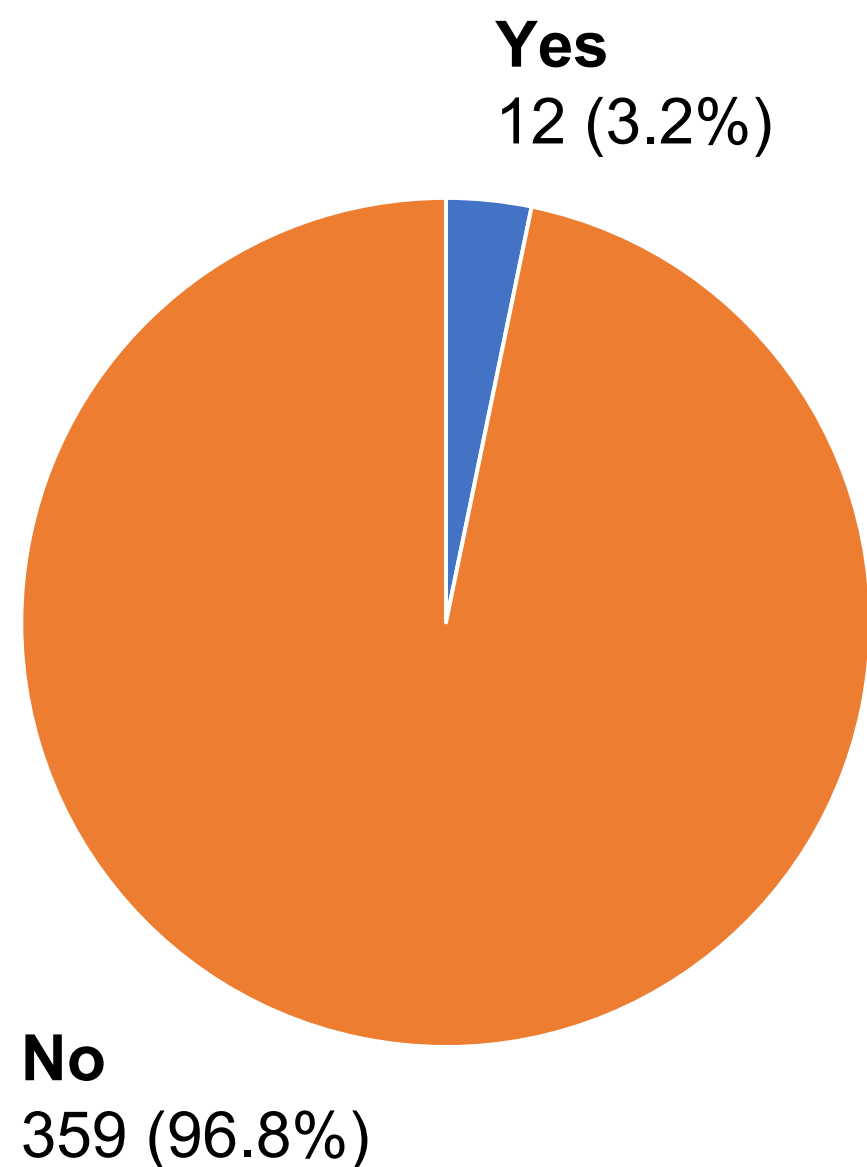
| 2023 Survey         |              |            | 2021 Survey         |             | 2019 Survey         |              |
|---------------------|--------------|------------|---------------------|-------------|---------------------|--------------|
| Impact level        | No. of cases | Frequency* | No. of cases        | Frequency** | No. of cases        | Frequency*** |
| 0                   | 3            | 0.03%      | 11                  | 0.09%       | 5                   | 0.04%        |
| 1~3a                | 6            | 0.05%      | 3                   | 0.03%       | 9                   | 0.08%        |
| 3b~5                | -            | -          | -                   | -           | 1                   | 0.01%        |
| No answer: 5 insts. |              |            | No answer: 4 insts. |             | No answer: 5 insts. |              |

\* Among 11,694 cases

\*\* Among 12,179 cases

\*\*\* Among 11,336 cases

# Did you experience an Interruption of Medical Gas Supply?



| Impact level | No. of cases | Frequency* |
|--------------|--------------|------------|
| 1~3a         | 10           | 0.09%      |
| 3b~5         | 1            | < 0.01%    |

No answer: 5 insts.

\*Among 11,694 CPS cases occurring during the 2-year period

N=375 (no answer: 4 insts.)

# Incidents & Rates of Medical Gas Supply Interruption

| 2023 Survey         |              |            | 2021 Survey         |             | 2019 Survey         |              |
|---------------------|--------------|------------|---------------------|-------------|---------------------|--------------|
| Impact level        | No. of cases | Frequency* | No. of cases        | Frequency** | No. of cases        | Frequency*** |
| 0                   | —            | —          | —                   | —           | —                   | —            |
| 1~3a                | 10           | 0.09%      | 11                  | 0.09%       | 5                   | 0.04%        |
| 3b~5                | 1            | <0.01%     | 3                   | 0.03%       | 0                   | 0%           |
| No answer: 5 insts. |              |            | No answer: 3 insts. |             | No answer: 1 insts. |              |

\* Among 11,694 cases

\*\* Among 12,179 cases

\*\*\* Among 11,336 cases