

# Adverse Reaction Reports Australia and New Zealand

180,809

Expected Reactions

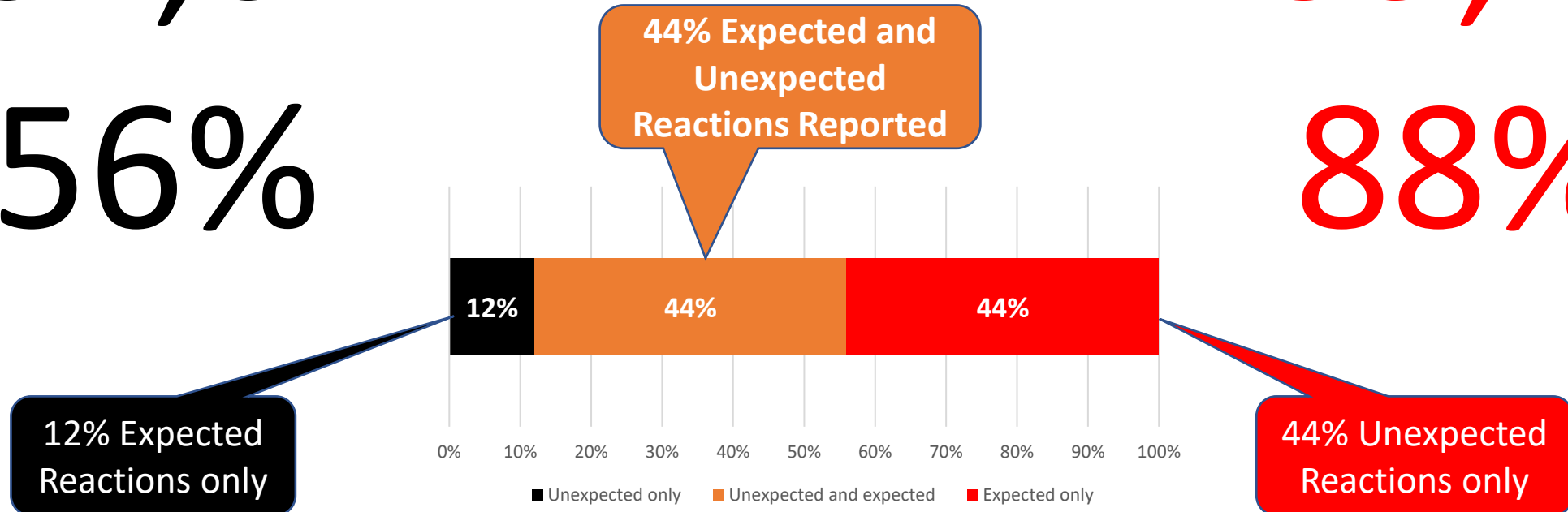
Unexpected Reactions

102,041

159,459

56%

88%



*\*Each Report can have multiple reactions: 3.44 on average*

*As each Adverse Event Report may list multiple reactions, percentages may add to more than 100%.*

# Expected Reactions

# 102,041

# 56%

<b>TOTAL EXPECTED REACTIONS</b>	<b>102,041</b>	<b>56%</b>
<i>Neurological – Headache</i>	<i>50,558</i>	<i>28%</i>
<i>Injection site</i>	<i>37,112</i>	<i>21%</i>
<b>COMMON RESPONSE (ex Vertigo)</b>	<b>47,247</b>	<b>26%</b>
Fatigue	21,399	12%
Lethargy	27,993	15%
<b>MUSCLES/ SKELETON</b>	<b>26,421</b>	<b>15%</b>
Muscular/ tendon	21,439	12%
Musculoskeletal/ joint	5,430	3%
Fracture	74	0%
<b>TEMPERATURE</b>	<b>41,069</b>	<b>23%</b>
Temperature change	36,182	20%
Sweating/ flushes	7,429	4%
Dehydration	551	0%
<b>PAIN/ SWELLING (general)</b>	<b>20,055</b>	<b>11%</b>
Pain	15,504	9%
Swelling	4,933	3%

# Unexpected Reactions

# 159,459

# 88%

**TOTAL UNEXPECTED REACTIONS 159,459 88%**

<b>FLIGHT RISK - UNEXPECTED</b>	<b>102,040</b>	<b>56%</b>
<b>THORACIC/CARDIAC PULMONARY</b>	<b>39,760</b>	<b>22%</b>
Breathing (RESP)	17,883	10%
<b>CLOTS/ BRUISING/ BLOOD</b>	<b>7,481</b>	<b>4%</b>
<b>CENTRAL NERVOUS SYSTEM</b>	<b>3,293</b>	<b>2%</b>
<b>CONSCIOUSNESS/ NEUROLOGICAL (ex headache)</b>	<b>46,138</b>	<b>26%</b>
Vertigo	30,909	17%
<b>HEARING/ VISION</b>	<b>8,226</b>	<b>5%</b>
<b>UNRESPONSIVE</b>	<b>102</b>	<b>0%</b>

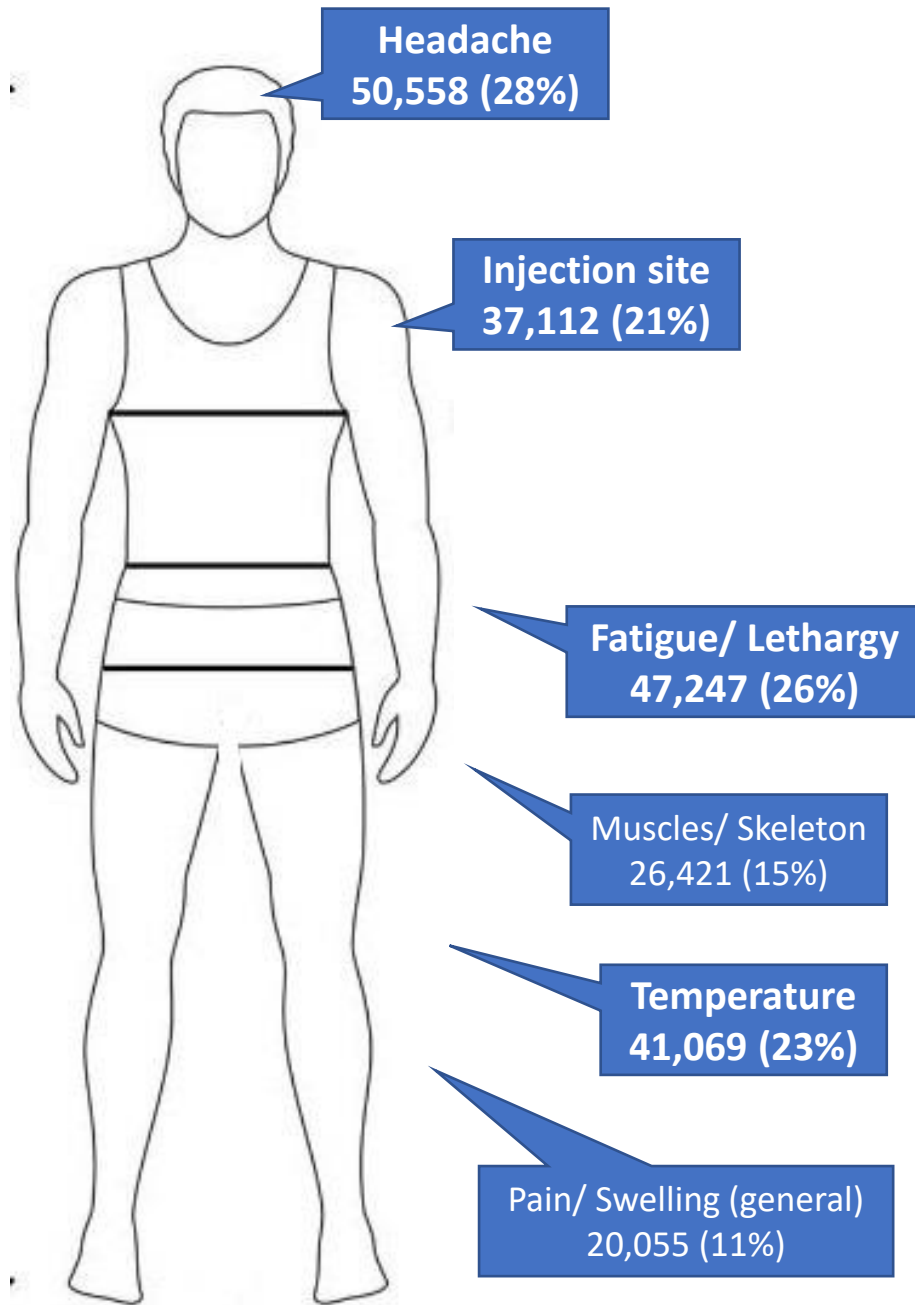
<b>OTHER UNEXPECTED REACTIONS</b>	<b>106,564</b>	<b>59%</b>
<b>RESPIRATORY TRACT</b>	<b>18,647</b>	<b>12%</b>
<b>GASTROINTESTINAL DISORDERS</b>	<b>46,547</b>	<b>26%</b>
<b>REPRODUCTIVE</b>	<b>5,457</b>	<b>3%</b>
<b>URINARY TRACT</b>	<b>1,167</b>	<b>1%</b>
<b>ORGANS/ GLANDS</b>	<b>2,728</b>	<b>2%</b>
<b>EXTREMITIES</b>	<b>8,923</b>	<b>5%</b>
<b>SKIN</b>	<b>20,782</b>	<b>11%</b>
<b>FACE/ EYES/ EARS/ MOUTH/ NOSE (ex Vision, hearing)</b>	<b>12,436</b>	<b>7%</b>
<b>AUTOIMMUNE SYMPTOMS</b>	<b>15,911</b>	<b>9%</b>
<b>HOMEOSTATIS - BLOOD</b>	<b>5,453</b>	<b>3%</b>
<b>INFECTION</b>	<b>2,861</b>	<b>2%</b>
<b>PAIN/ SWELLING (ex general)</b>	<b>896</b>	<b>0%</b>
<b>REACTION (ex injection site)</b>	<b>5,331</b>	<b>3%</b>

*Each Report is counted once per category consequently total percentage may be lower than the total sub-categories.*

# Expected Reactions

# 102,041

# 56%

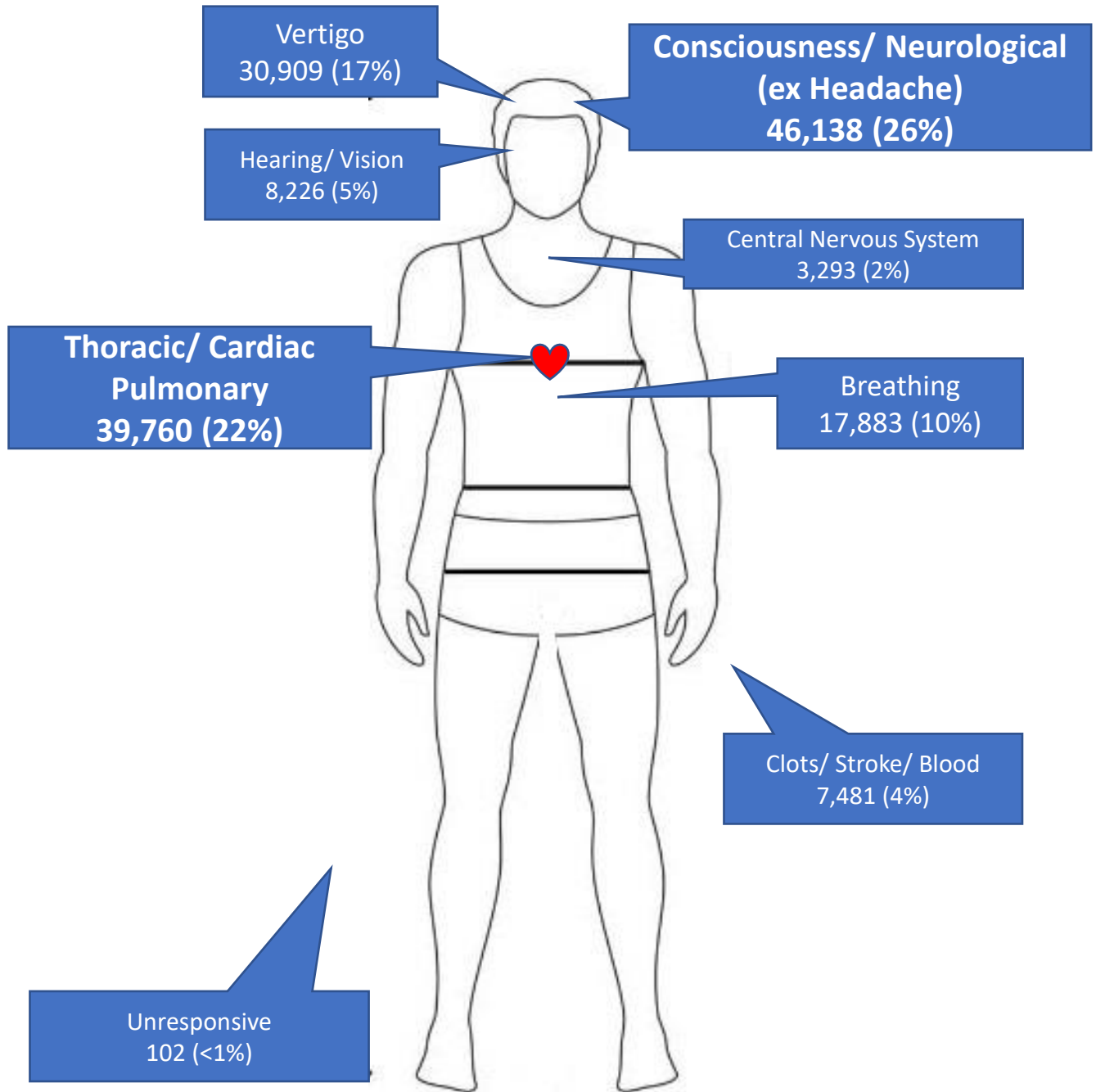


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# Flight Risk Reactions - Unexpected 102,040 56%

<b>FLIGHT RISK - UNEXPECTED</b>	<b>102,040</b>	<b>56%</b>
<b>THORACIC/CARDIAC PULMONARY</b>	<b>39,760</b>	<b>22%</b>
Breathing (RESP)	17,883	10%
<b>CLOTS/ BRUISING/ BLOOD</b>	<b>7,481</b>	<b>4%</b>
<b>CENTRAL NERVOUS SYSTEM</b>	<b>3,293</b>	<b>2%</b>
<b>CONSCIOUSNESS/ NEUROLOGICAL (ex headache)</b>	<b>46,138</b>	<b>26%</b>
Vertigo	30,909	17%
<b>HEARING/ VISION</b>	<b>8,226</b>	<b>5%</b>
<b>UNRESPONSIVE</b>	<b>102</b>	<b>0%</b>

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Unexpected Reactions  
159,459  
88%

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# Flight Risk Reactions

- Unexpected

102,040

56%

Unexpected Reactions

159,459

88%

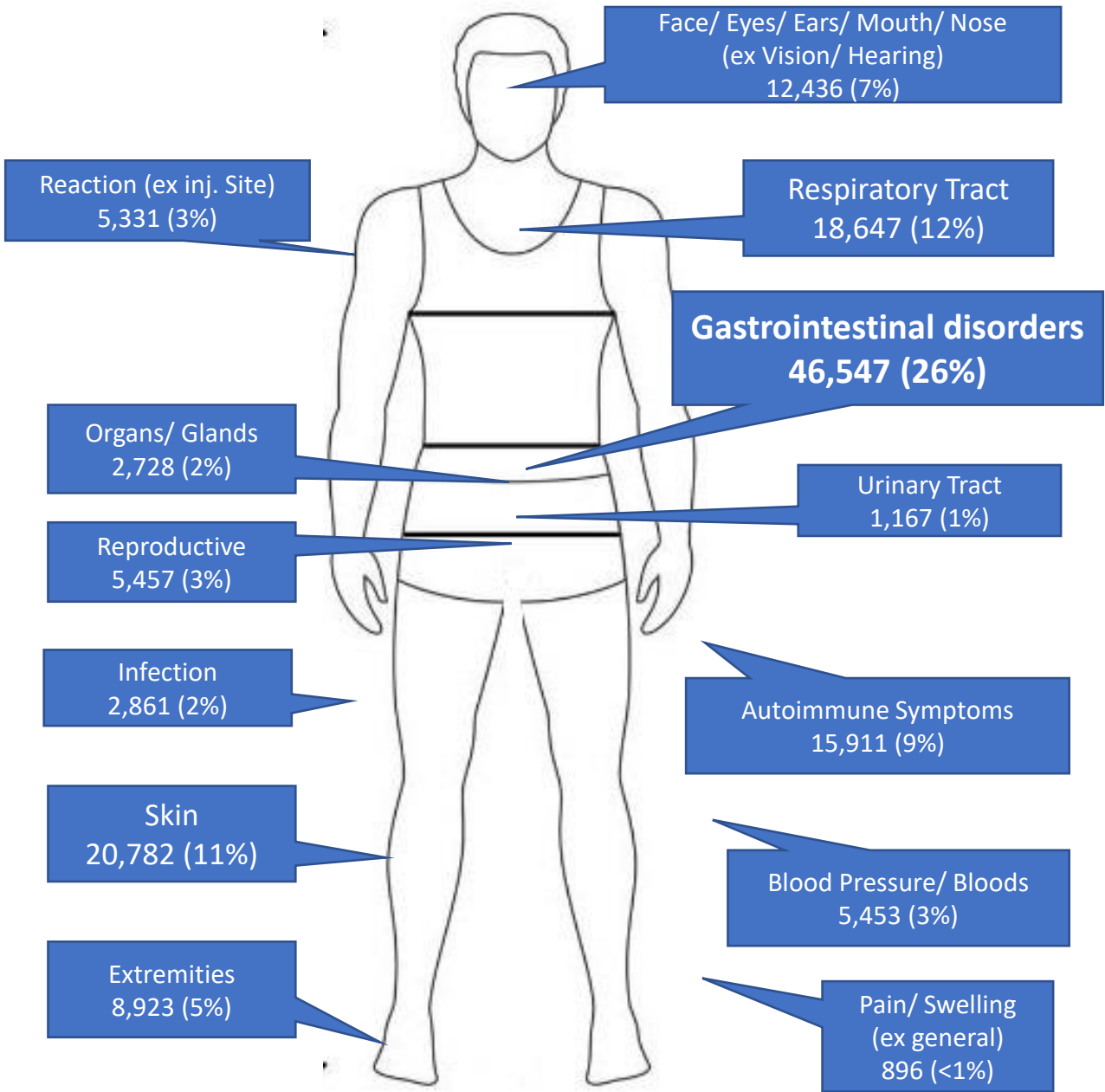
<b>TOTAL CARDIAC/ BREATHING/ CLOTTING/ SPINAL</b>	<b>54,039</b>	<b>30%</b>
<b>THORACIC/CARDIAC PULMONARY AND BREATHING</b>	<b>45,852</b>	<b>25%</b>
<b><u>THORACIC/CARDIAC PULMONARY</u></b>	<b><u>39,760</u></b>	<b><u>22%</u></b>
<b>CORONARY SYMPTOMS</b>	<b>17,788</b>	<b>10%</b>
Coronary Symptoms - Arrythmias	11,120	6%
Coronary Symptoms - Blockages	59	0%
Coronary Symptoms - Bradycardia	370	0%
Coronary Symptoms - Infection	4	0%
Coronary Symptoms - Ischaemia	541	0%
Coronary Symptoms - Muscle damage	110	0%
Coronary Symptoms - Other	2,145	1%
Coronary Symptoms - Tachycardia	5,699	3%
<b>OTHER THORACIC/CARDIAC PULMONARY</b>	<b>30,707</b>	<b>17%</b>
Cardiac arrest	195	0%
Cardiac disorders	849	0%
Coronary Inflammatory disorders	5,346	3%
Coronary Vavular Disorders	33	0%
Thoracic/ Cardiac Pulmonary Symptoms	27,488	15%
<b>(RESP) Breathing</b>	<b>17,883</b>	<b>10%</b>
<b><u>CLOTS/ BRUISING/ BLOOD</u></b>	<b><u>7,481</u></b>	<b><u>4%</u></b>
Bruising	1,340	1%
Clots	111	0%
Haemorrhage/ coagulopathy	171	0%
Pulmonary embolism	1,656	1%
Stroke	1,238	1%
Thrombosis	3,661	2%
Vascular	437	0%
<b><u>CENTRAL NERVOUS SYSTEM</u></b>	<b><u>3,293</u></b>	<b><u>2%</u></b>
Spinal Cord Procedures	8	0%
Spinal Disorders	69	0%
Spinal Infections	75	0%
Spinal Symptoms	3,158	2%

<b>CONSC/ NEURO/ VERTIGO/ HEARING/ VISION</b>	<b>67,479</b>	<b>37%</b>
<b>CONSC/ NEURO/ VERTIGO</b>	<b>64,323</b>	<b>36%</b>
<b><u>CONSCIOUSNESS/ NEUROLOGICAL (ex headache)</u></b>	<b><u>46,138</u></b>	<b><u>26%</u></b>
<b>CONSCIOUSNESS</b>	<b>20,327</b>	<b>11%</b>
Change	1,333	1%
Mental impairment	9,860	5%
Mood	7,242	4%
Sensitivity	1,544	1%
Sleep	3,025	2%
<b>NEUROLOGICAL (ex headache)</b>	<b>2,204</b>	<b>1%</b>
Nerve/ neurological	534	0%
Neurological - Facial	1,437	1%
Neurological - Infection	41	0%
Neurological - Injury	177	0%
Neurological - Obstructions	25	0%
Neurological - Tumour	22	0%
<b>OTHER NEUROLOGICAL</b>	<b>31,379</b>	<b>17%</b>
Autoimmune/ Neurlogical disease	444	0%
Balance/ consciousness	10,751	6%
Numbness	14,879	8%
Paralysis	239	0%
Seizure	6,281	3%
Speech	999	1%
Taste	2,305	1%
<b>Vertigo</b>	<b>30,909</b>	<b>17%</b>
<b><u>HEARING/ VISION</u></b>	<b><u>8,226</u></b>	<b><u>5%</u></b>
Deafness	2,511	1%
Vision	5,979	3%
<b><u>UNRESPONSIVE</u></b>	<b><u>102</u></b>	<b><u>0%</u></b>
Death	9	0%
Unresponsive	93	0%

# Other Unexpected Reactions

## 106,564

### 59%



OTHER UNEXPECTED REACTIONS	106,564	59%
RESPIRATORY TRACT	18,647	12%
GASTROINTESTINAL DISORDERS	46,547	26%
REPRODUCTIVE	5,457	3%
URINARY TRACT	1,167	1%
ORGANS/ GLANDS	2,728	2%
EXTREMITIES	8,923	5%
SKIN	20,782	11%
FACE/ EYES/ EARS/ MOUTH/ NOSE (ex Vision, hearing)	12,436	7%
AUTOIMMUNE SYMPTOMS	15,911	9%
HOMEOSTATIS - BLOOD	5,453	3%
INFECTON	2,861	2%
PAIN/ SWELLING (ex general)	896	0%
REACTION (ex injection site)	5,331	3%

0% = < 0.5%

**Unexpected Reactions**  
**159,459**  
**88%**

As each Adverse Event Report may list multiple reactions, percentages may add to more than 100%.

Each Report is counted once per category consequently total percentage may be lower than the total sub-categories.

<b>RESPIRATORY TRACT</b>	<b>18,647</b>	<b>12%</b>
<b>RESPIRATORY TRACT INFECTIONS</b>	<b>13,965</b>	<b>8%</b>
Covid-19	309	0%
Lower Respiratory Tract Infections	967	1%
Upper Respiratory Tract Infections	12,782	7%
<b>RESPIRATORY TRACT ISSUES</b>	<b>2,298</b>	<b>1%</b>
Lower Respiratory Tract Issues	2,156	1%
Upper Respiratory Tract Issues	151	0%
<b>(RESP TRACT SYMPTOMS) Cough</b>	<b>3,300</b>	<b>2%</b>
<b>GASTROINTESTINAL DISORDERS</b>	<b>46,547</b>	<b>26%</b>
GIT Infection/ inflammation	925	1%
GIT Symptoms	40,501	22%
GIT Vascular/ Haemorrhagic	371	0%
Lower GIT	249	0%
Throat - Upper GIT	7,267	4%
Weight increase/ hunger	80	0%
<b>REPRODUCTIVE</b>	<b>5,457</b>	<b>3%</b>
Abortion	358	0%
Menstrual disorder	4,275	2%
Pregnancy/ birth defects	281	0%
Reproductive disorders	202	0%
Reproductive infections	100	0%
Reproductive symptoms	432	0%
<b>URINARY TRACT</b>	<b>1,167</b>	<b>1%</b>
Bladder/ Urinary Tract Symptoms	737	0%
Urinary Tract Bleeding	230	0%
Urinary Tract Disorders	15	0%
Urinary Tract Infections	253	0%
<b>ORGANS/ GLANDS</b>	<b>2,728</b>	<b>2%</b>
Breast	645	0%
Kidney	640	0%
Liver	746	0%
Other organ/ glands	793	0%
<b>EXTREMITIES</b>	<b>8,923</b>	<b>5%</b>
Limb/ peripheral	8,903	5%
Nails	29	0%

# Other Unexpected Reactions

106,564

59%

<b>SKIN</b>	<b>20,782</b>	<b>11%</b>
Allergic rash	4,442	2%
Burning - skin	1,314	1%
Cellulitis	397	0%
Pallor	2,073	1%
Rash	13,797	8%
Skin	1,473	1%

## Unexpected Reactions

159,459

88%

<b>FACE/ EYES/ EARS</b>	<b>12,436</b>	<b>7%</b>
<b>EARS (ex Deafness)</b>	<b>1,068</b>	<b>1%</b>
<b>EYES (ex Vision)</b>	<b>3,317</b>	<b>2%</b>
<b>FACE</b>	<b>2,072</b>	<b>1%</b>
Facial - rash	534	0%
Facial - Swelling/ injury	1,175	1%
Jaw	402	0%
<b>MOUTH</b>	<b>4,390</b>	<b>2%</b>
Dental	156	0%
Mouth	4,259	2%
<b>NOSE</b>	<b>2,965</b>	<b>2%</b>
Nasal	2,033	1%
Nose bleed	971	1%
<b>AUTOIMMUNE SYMPTOMS</b>	<b>15,911</b>	<b>9%</b>
Lymph node	12,522	7%
Pre-existing	2,091	1%
White blood cell/ platelet	1,469	1%
<b>HOMEOSTATIS - BLOOD</b>	<b>5,453</b>	<b>3%</b>
Blood pressure	4,494	2%
Diabetic/ glucose	376	0%
Other - blood/ hormone	673	0%
<b>INFECTION</b>	<b>2,861</b>	<b>2%</b>
Herpes	2,033	1%
Infections/ bacteria/ viral	847	0%
<b>PAIN/ SWELLING (ex general)</b>	<b>896</b>	<b>0%</b>
Arthritis	593	0%
Fluid	58	0%
Mass/ cyst	246	0%
<b>REACTION (ex injection site)</b>	<b>5,331</b>	<b>3%</b>
Adverse event unspecified	937	1%
Allergy	66	0%
Anaphalactic	1,716	1%
Drug reaction	287	0%
Error	2,225	1%
Ineffective	79	0%
Recall phenomenon	10	0%
Treatment/ investigation required	47	0%

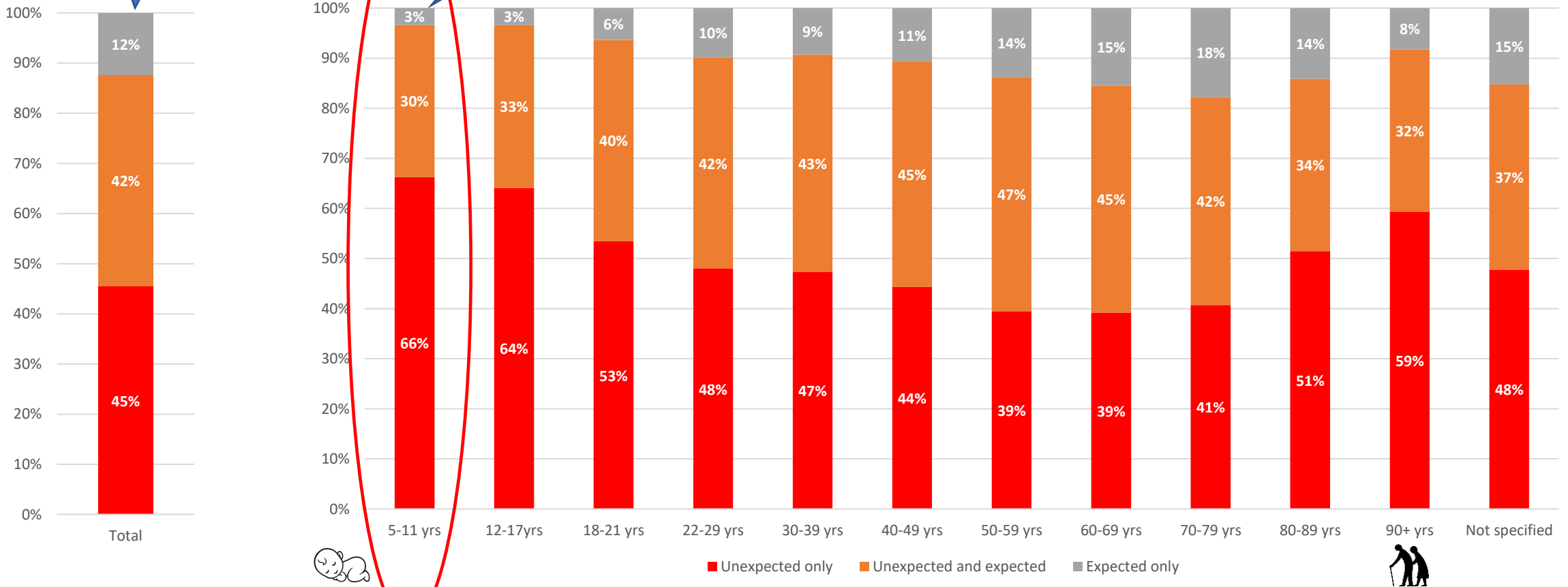
# Australian Results By Age



In Australia only 12% of Adverse Events reports had 'Expected' Reactions only

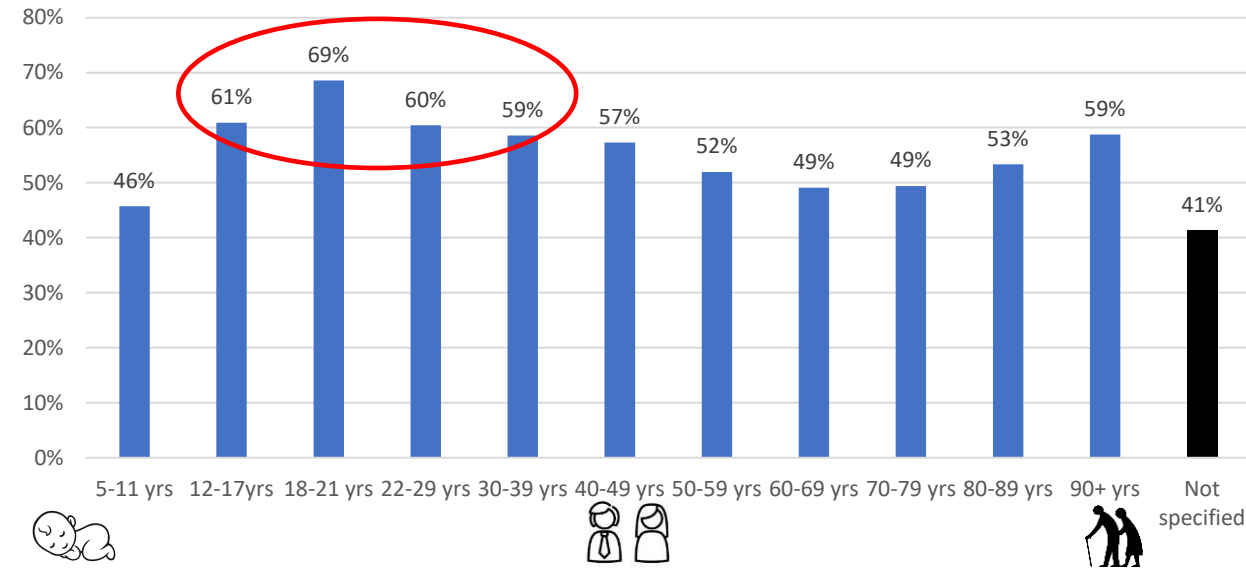
Only 3% reported 'Expected' Reactions only

Reaction by Age - Australia



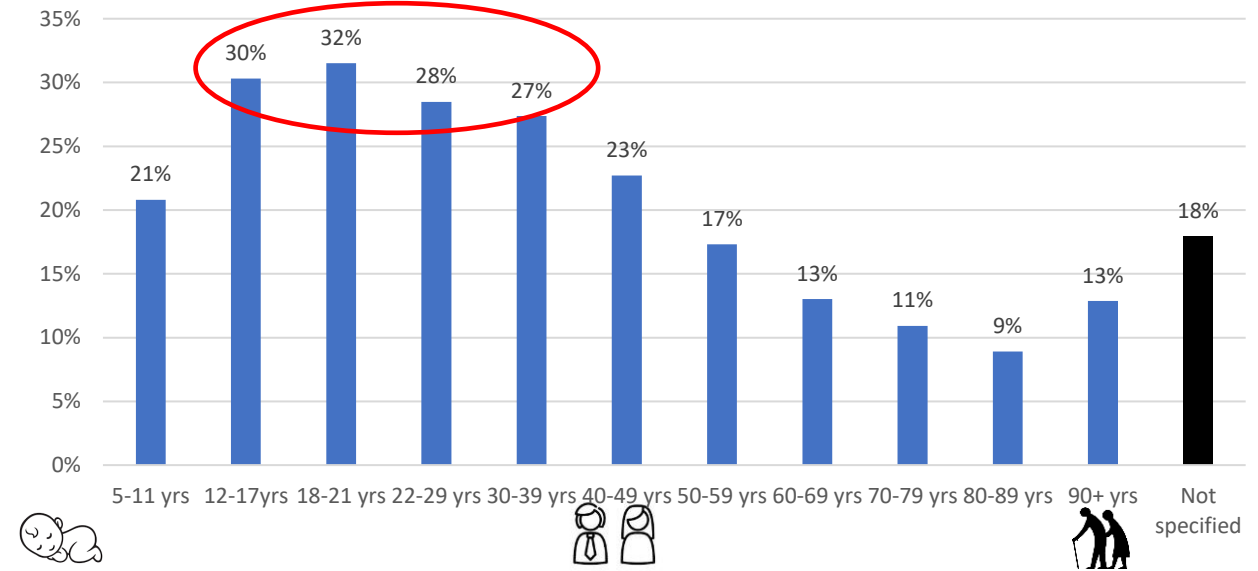
# Flight Risk Reactions - Unexpected

## FLIGHT RISK

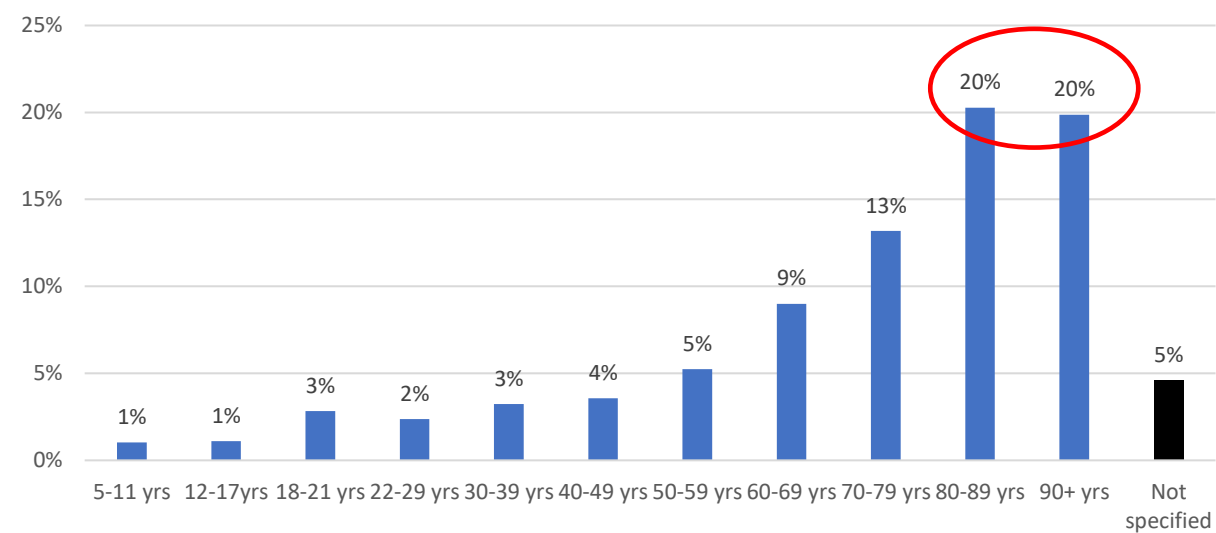
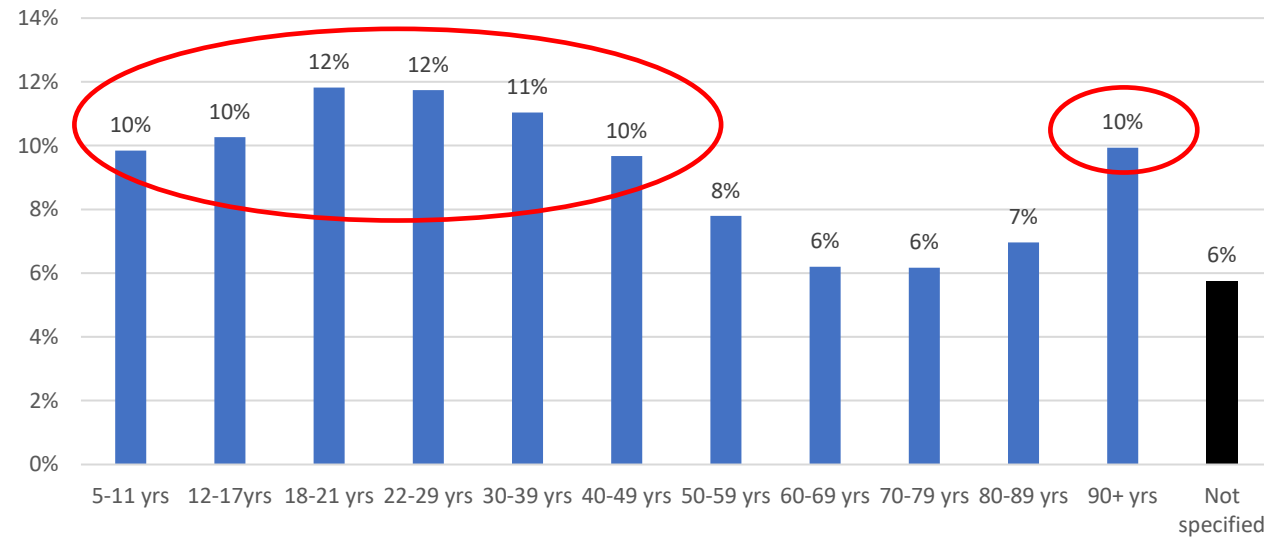


(RESP) Breathing

## THORACIC/CARDIAC PULMONARY

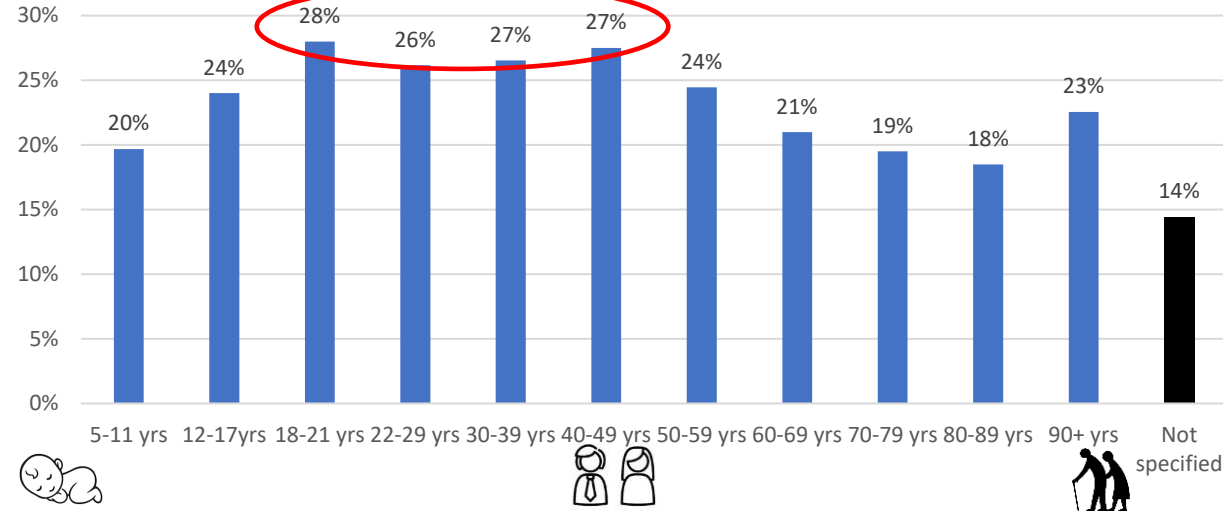


CLOTS/ BRUISING/ BLOOD

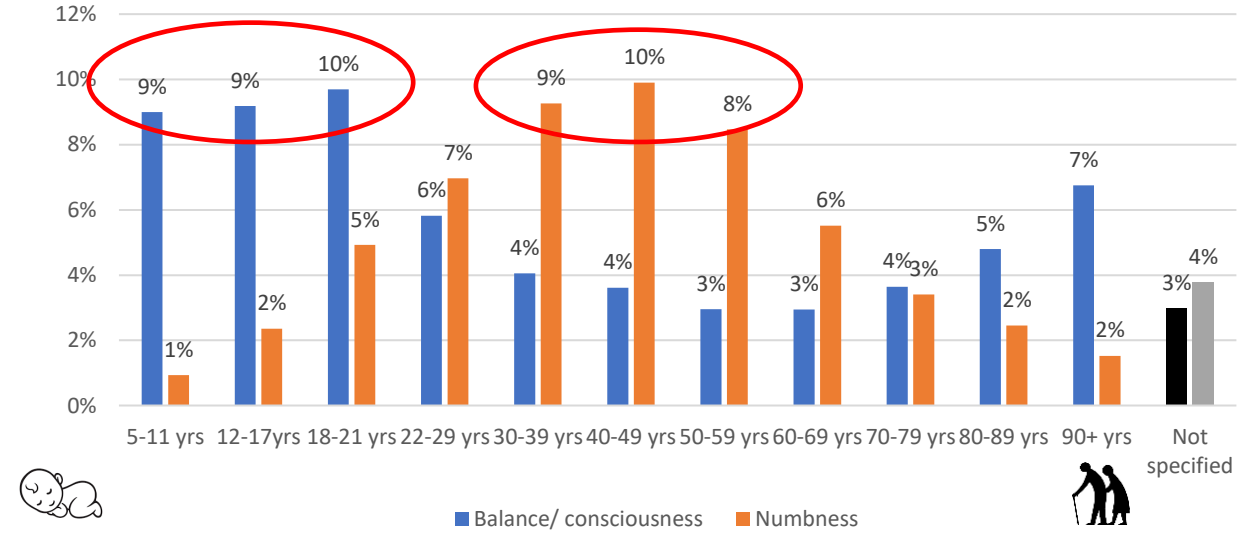


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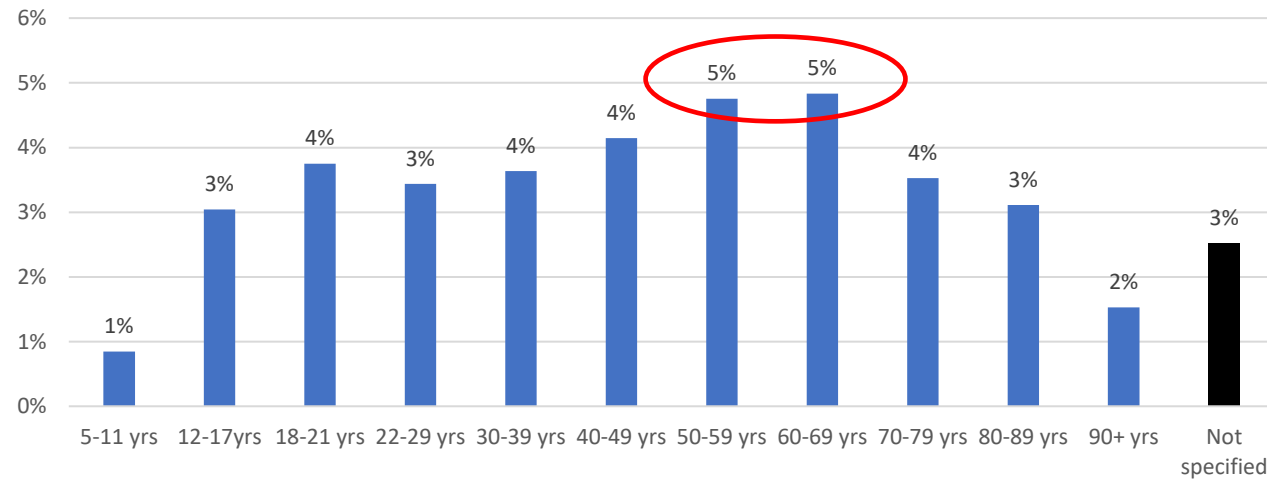
CONSCIOUSNESS/ NEUROLOGICAL (ex headache)



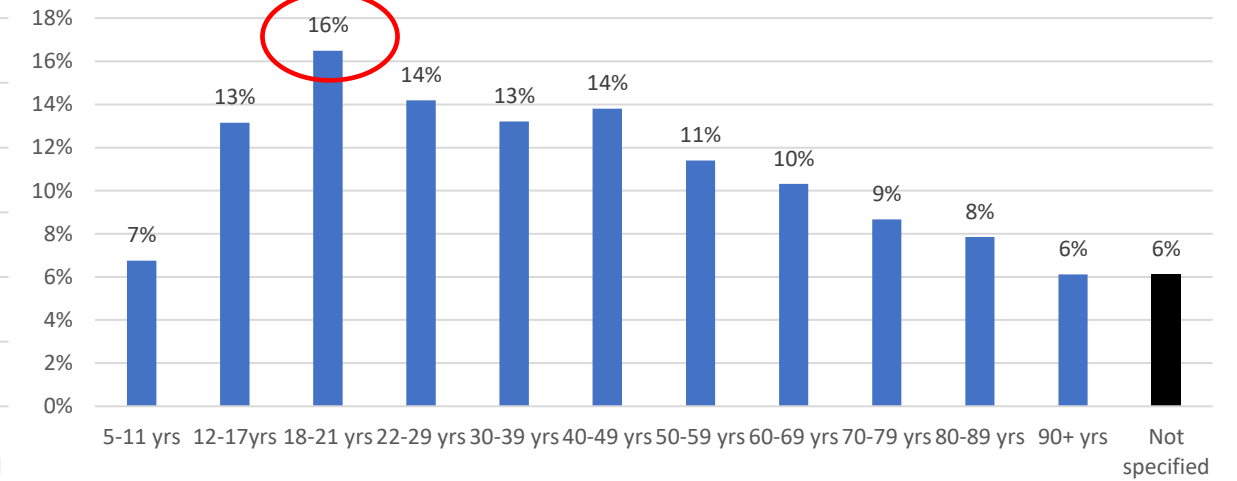
Balance/ consciousness and Numbness



HEARING/ VISION

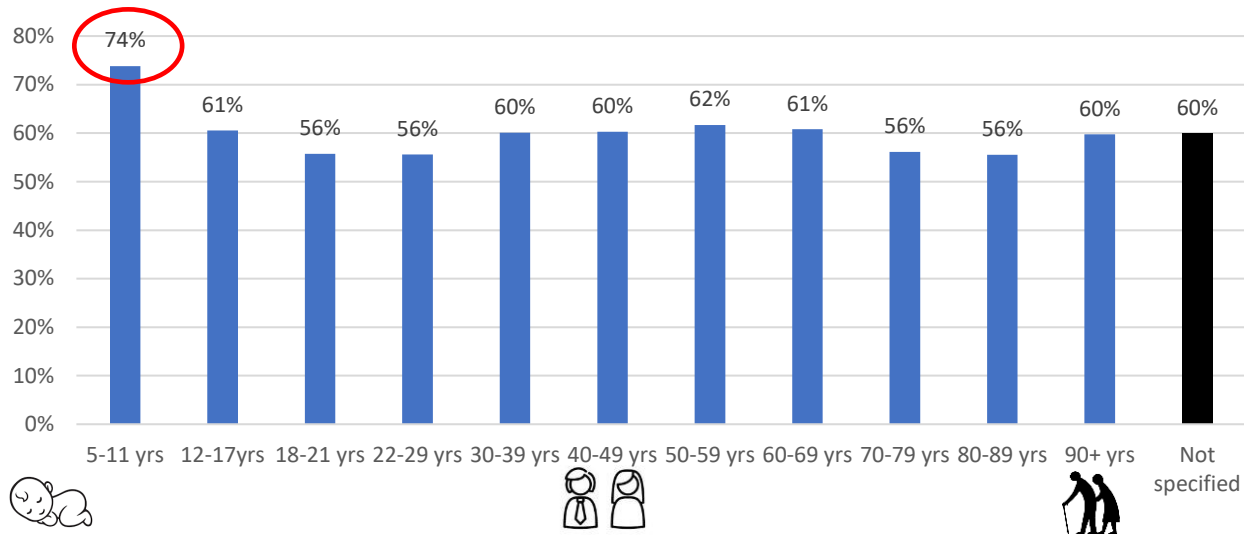


Vertigo

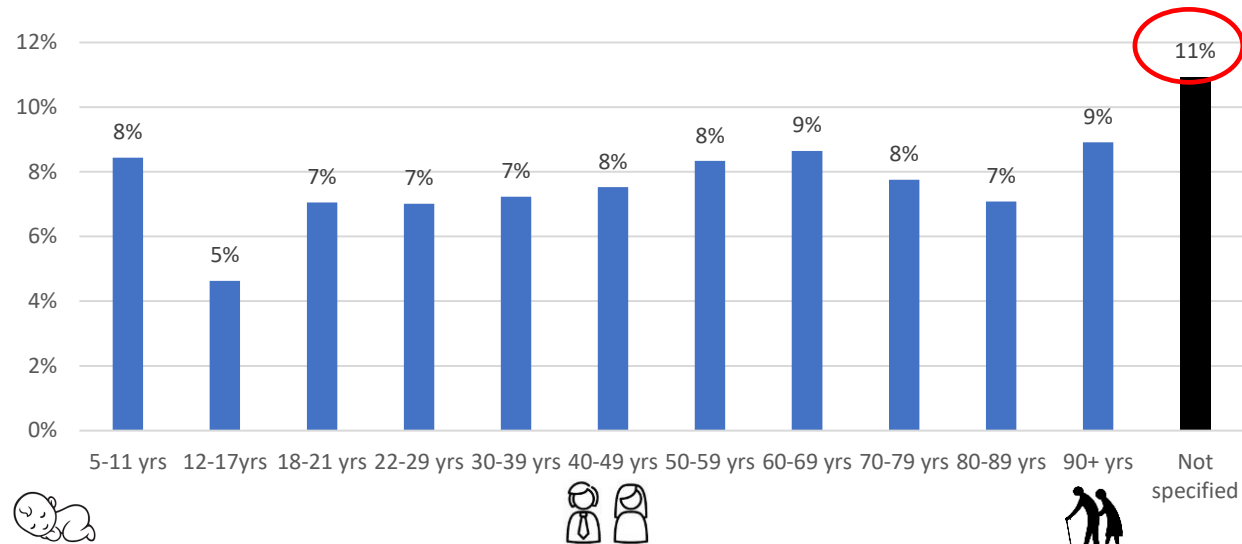


# Other Unexpected Reactions

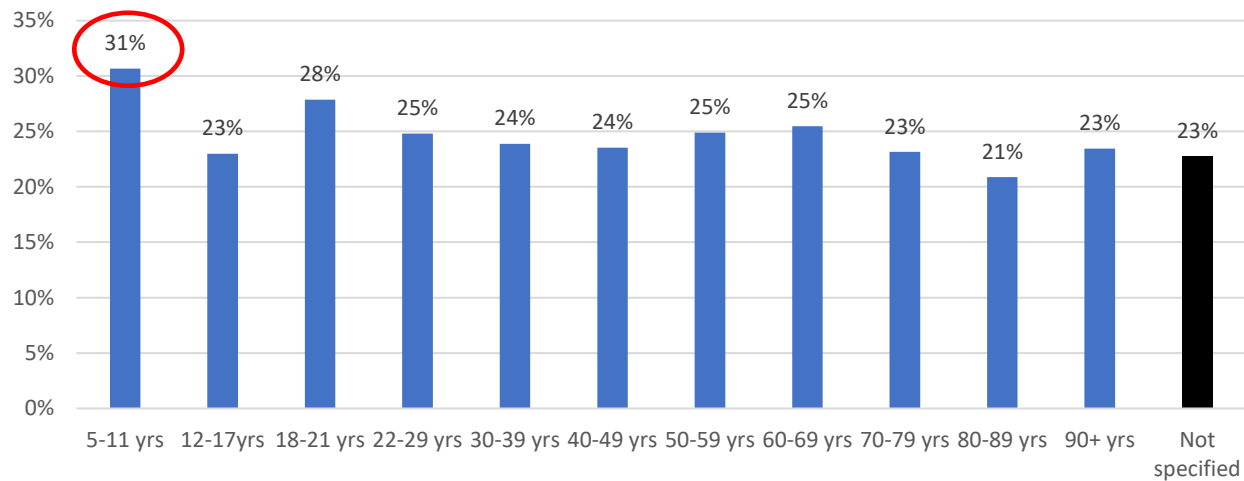
## OTHER UNEXPECTED REACTIONS



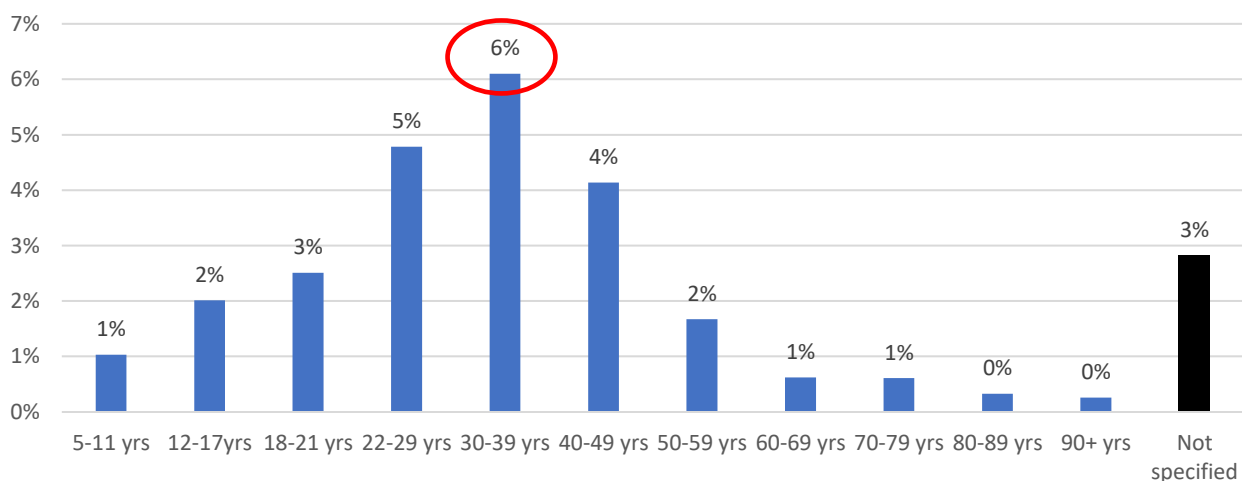
## RESPIRATORY TRACT



## GASTROINTESTINAL DISORDERS

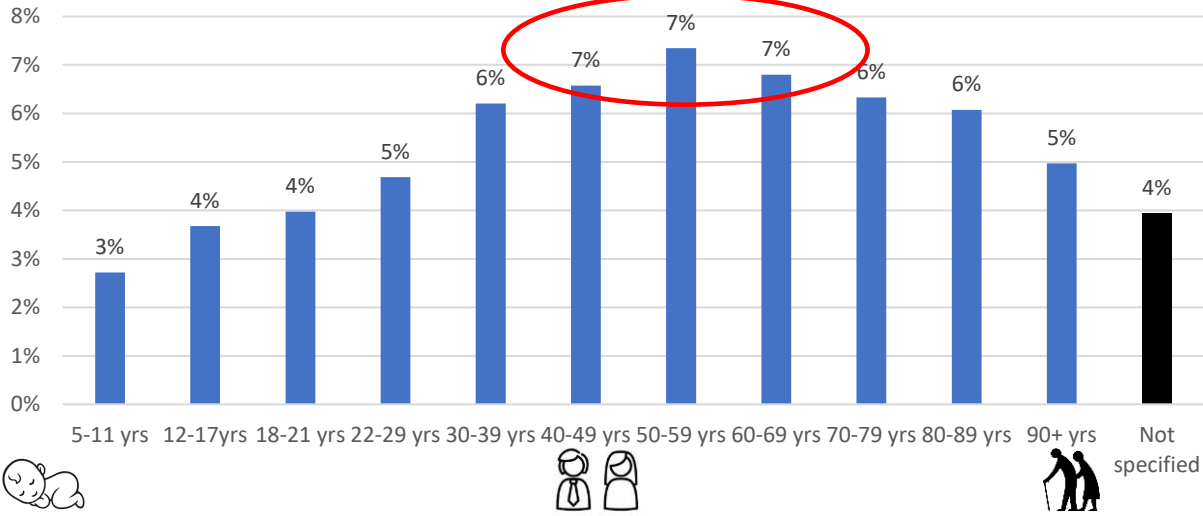


## REPRODUCTIVE

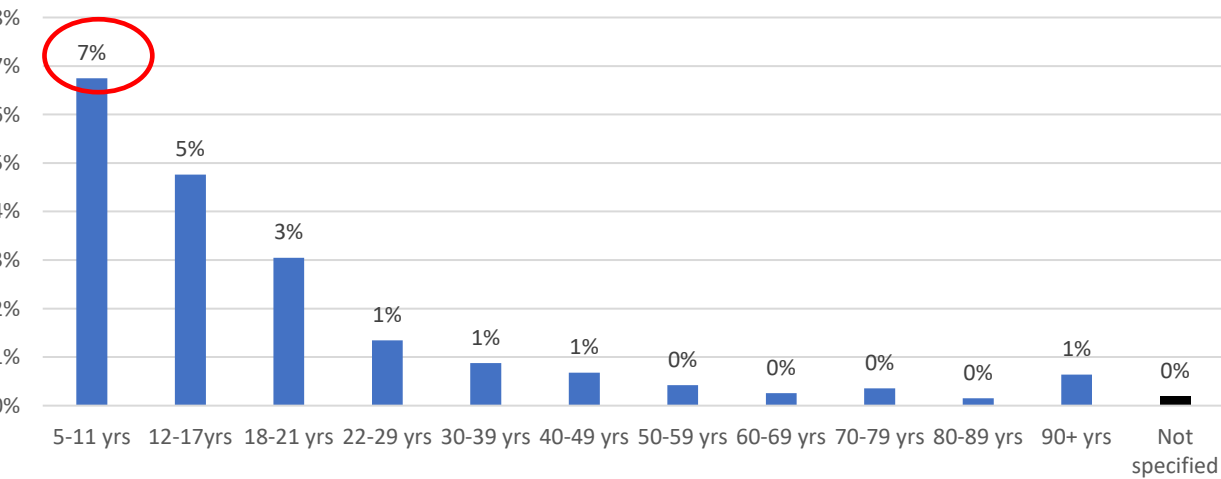


# Other Unexpected Reactions

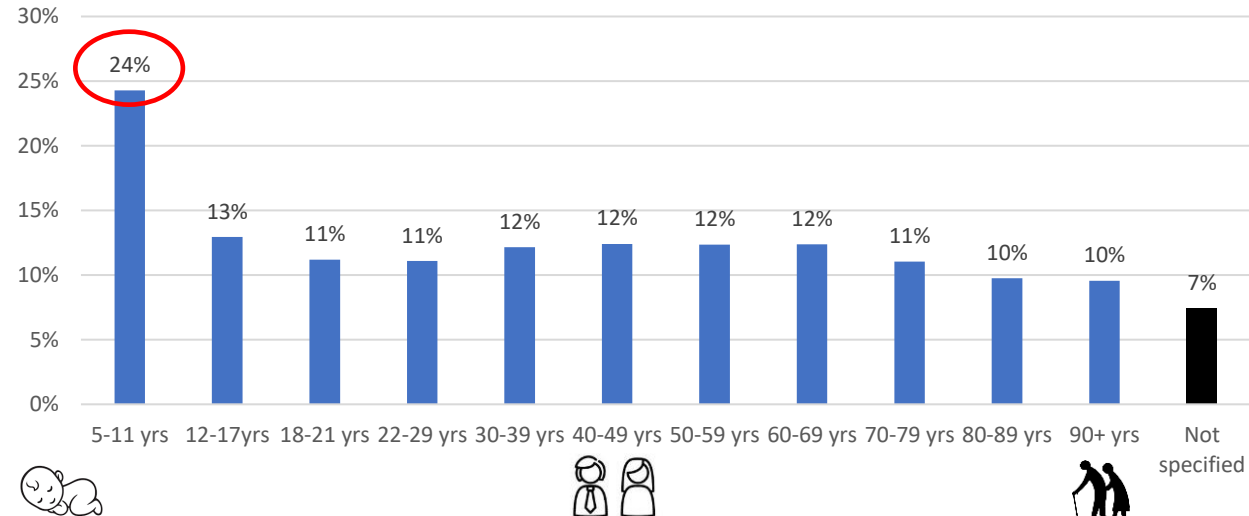
## EXTREMITIES



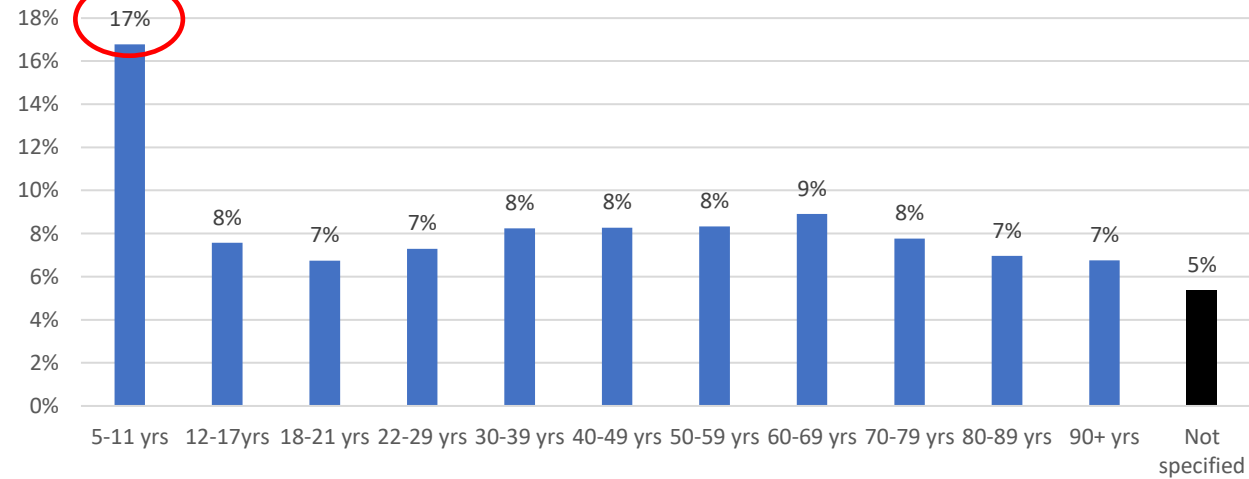
## Pallor



## SKIN

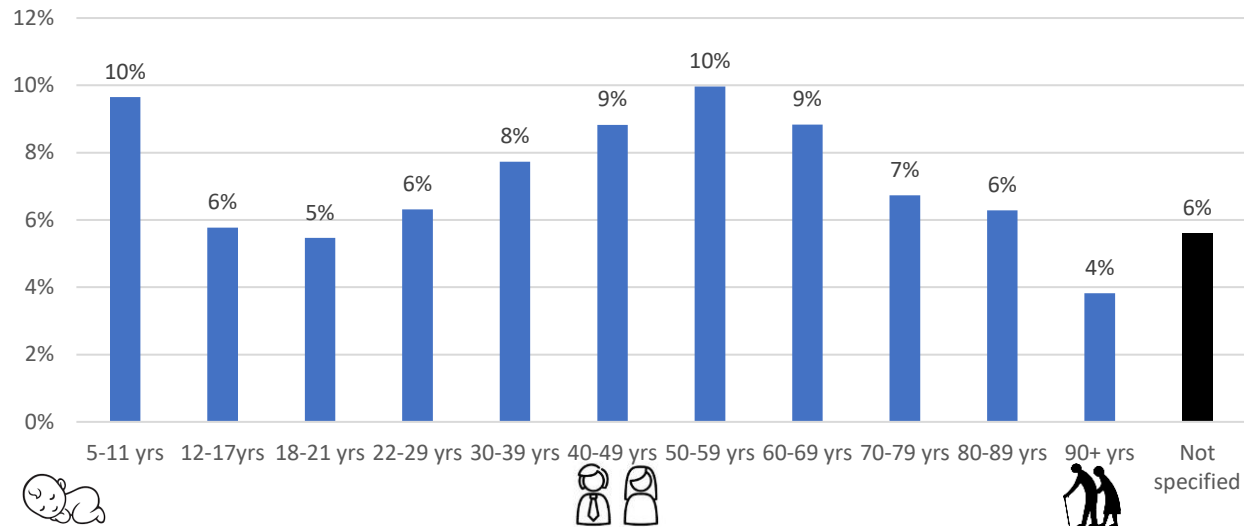


## Rash

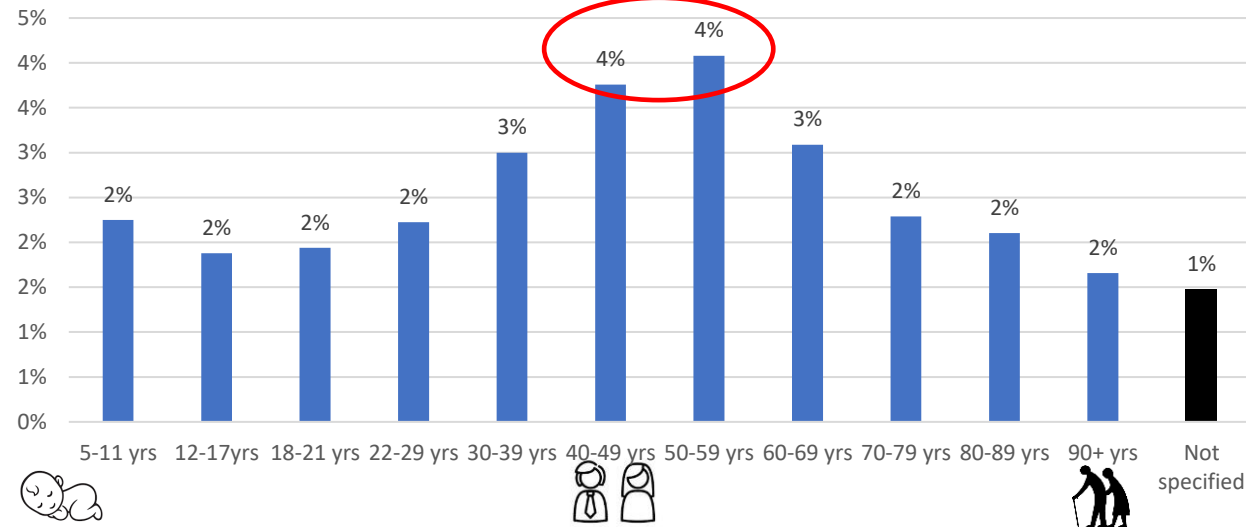


# Other Unexpected Reactions

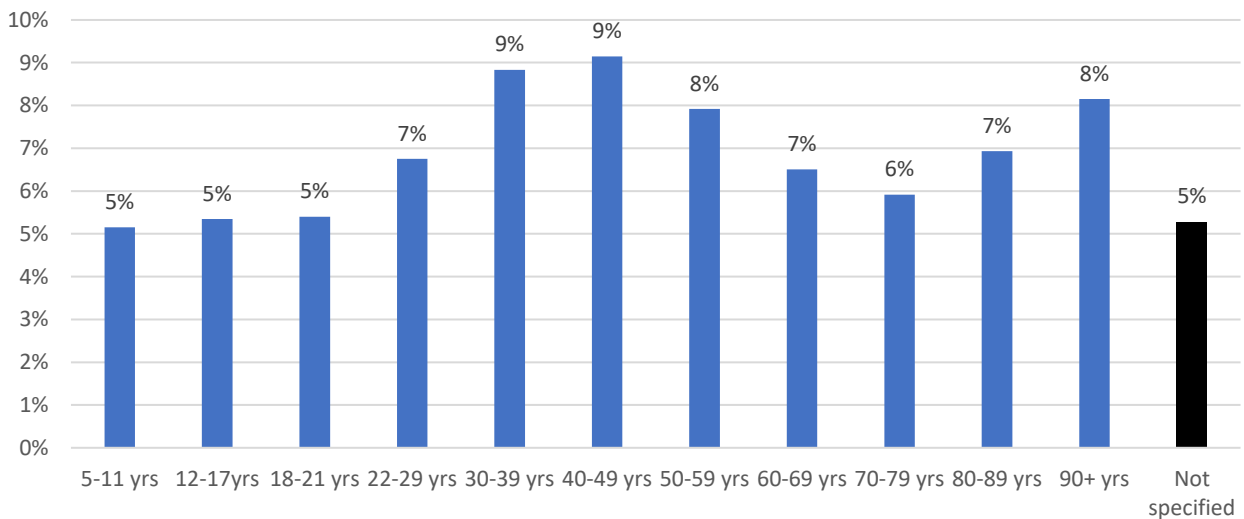
## FACE/ EYES/ EARS



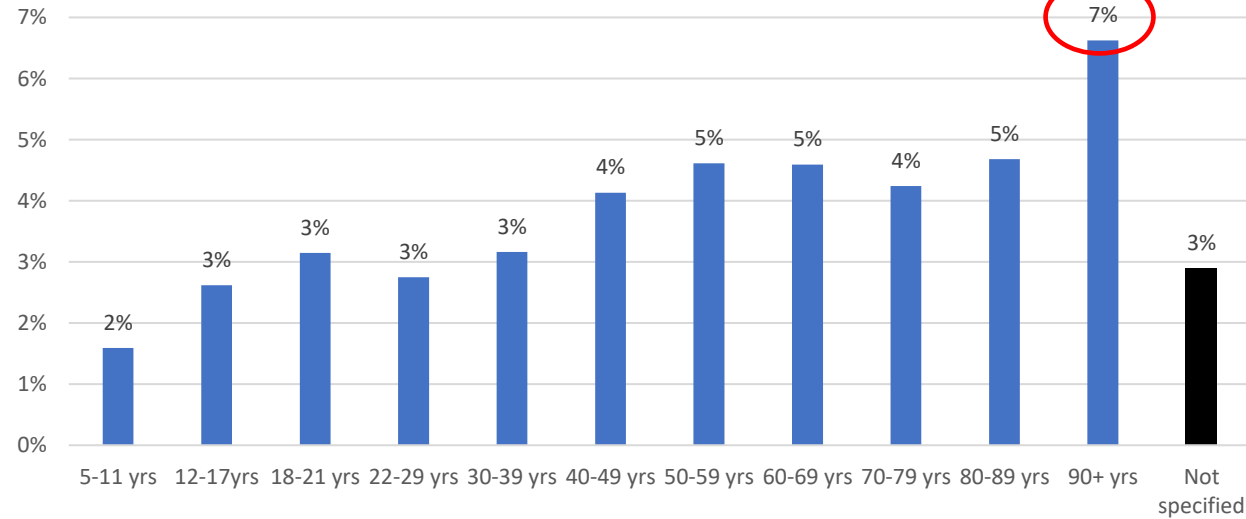
## MOUTH



## AUTOIMMUNE SYMPTOMS

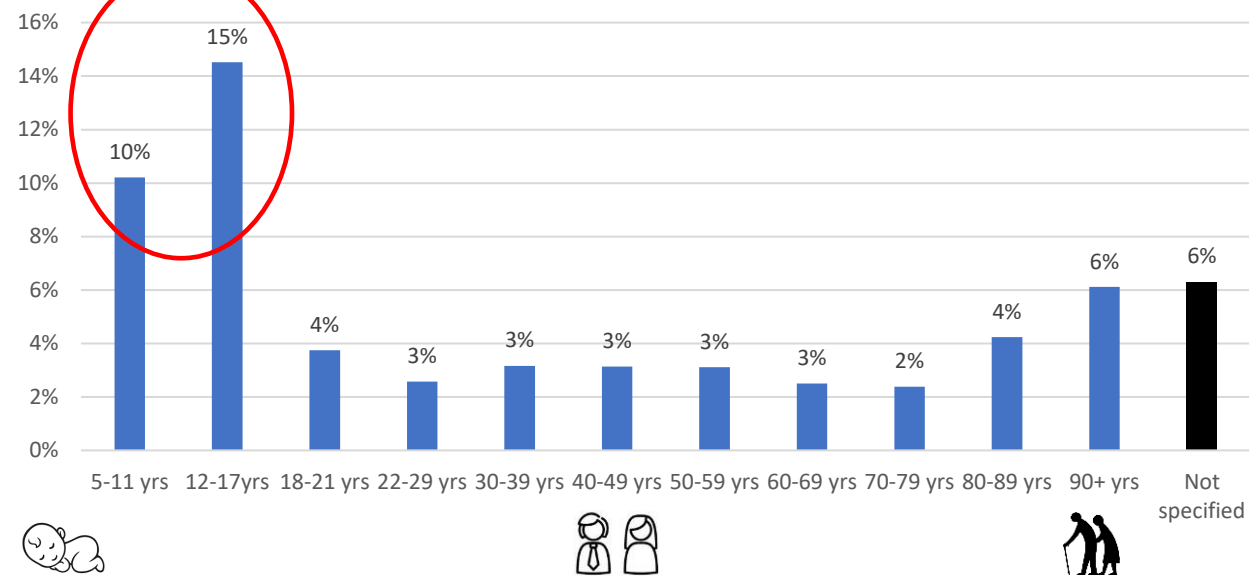


## BLOOD PRESSURE/ BLOODS

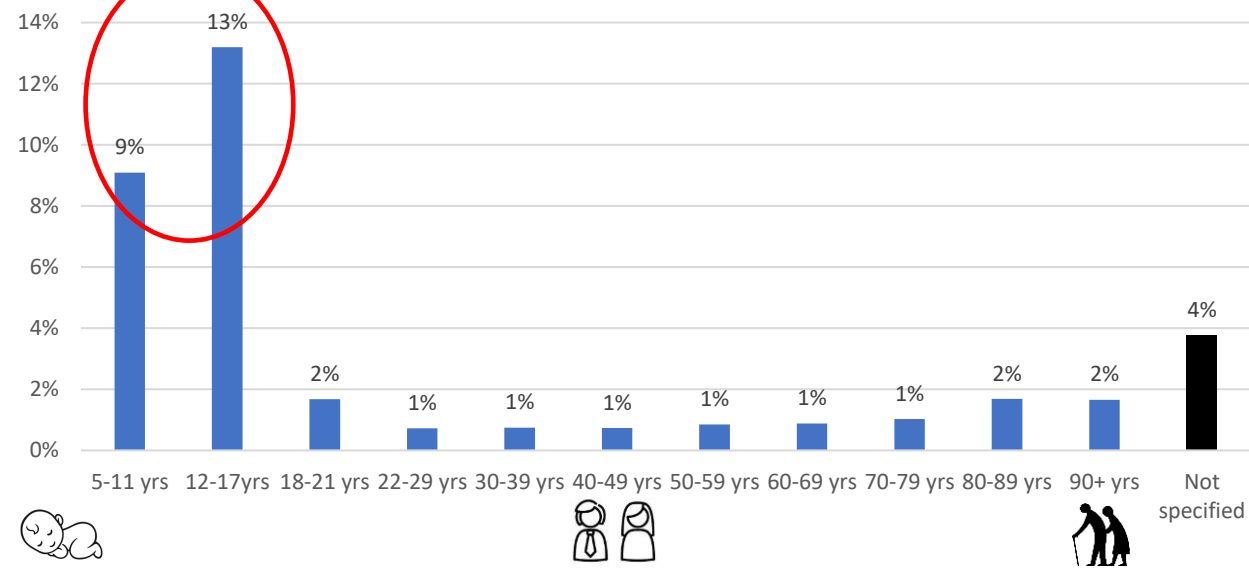


# Other Unexpected Reactions

REACTION (ex injection site)

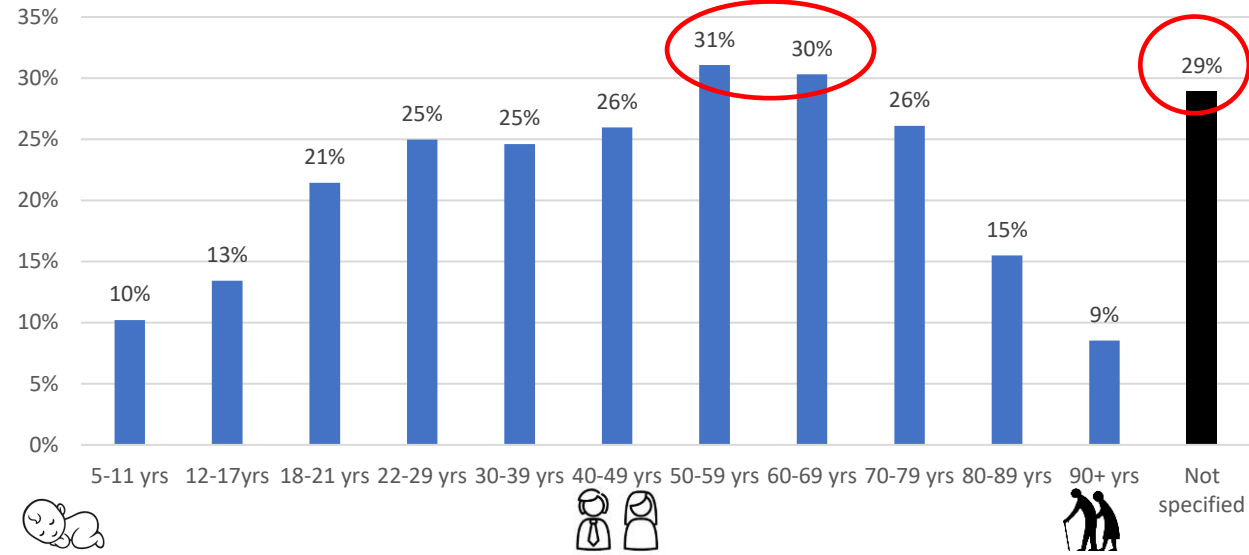


Error

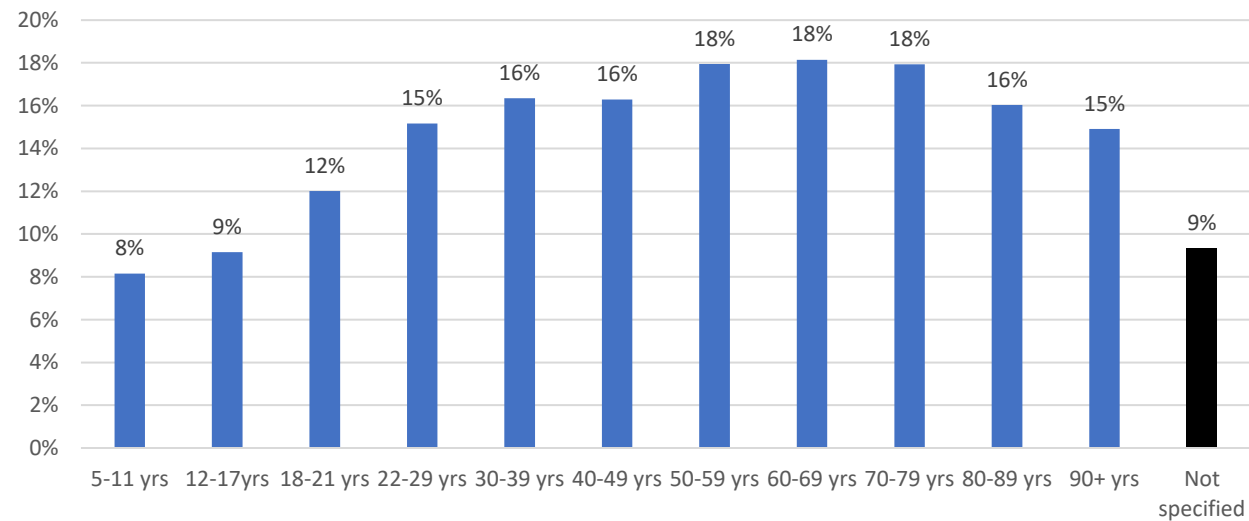


# Expected Reactions

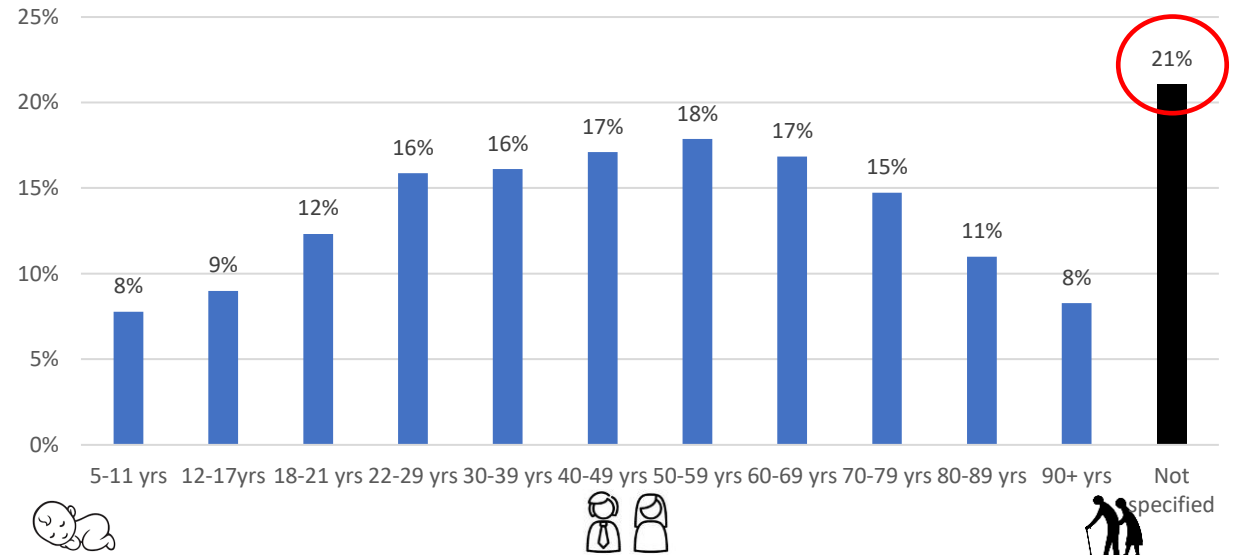
(CONSC) Neurological - Headache



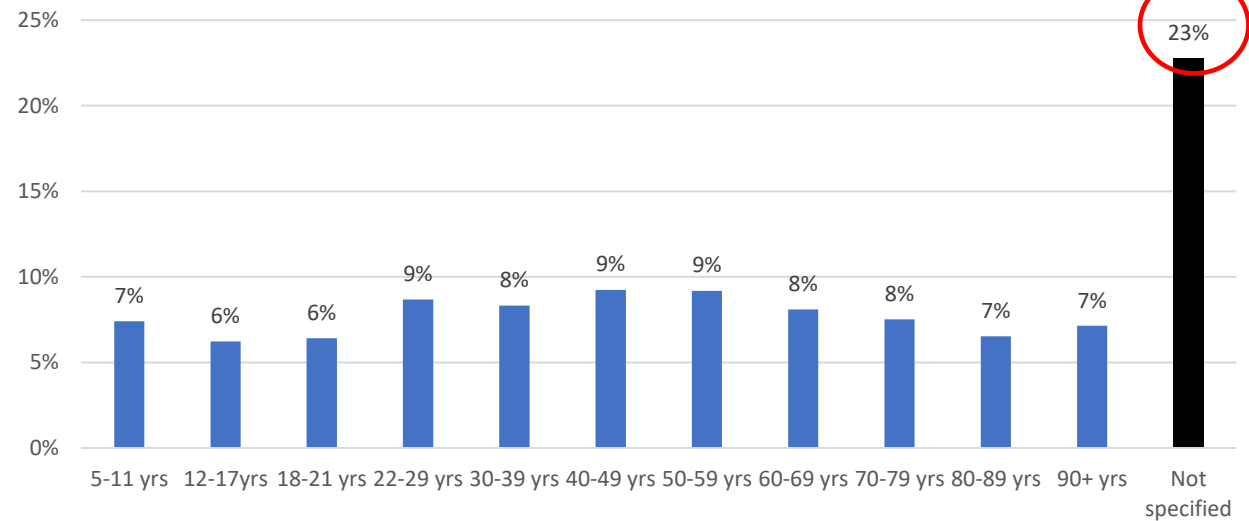
Fatigue



(REACT) Injection site



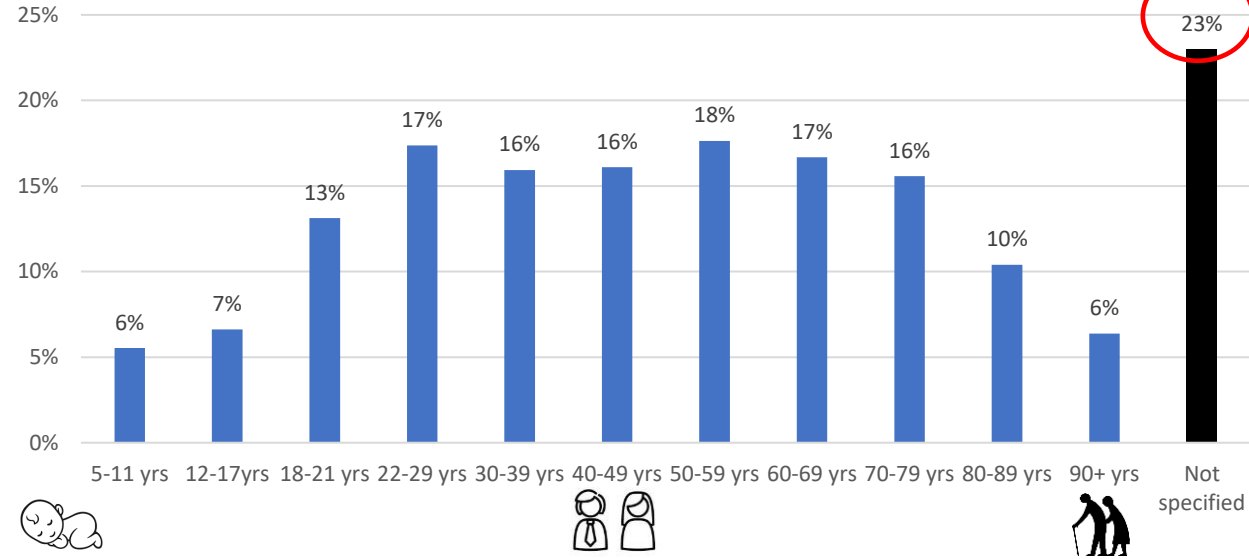
Lethargy



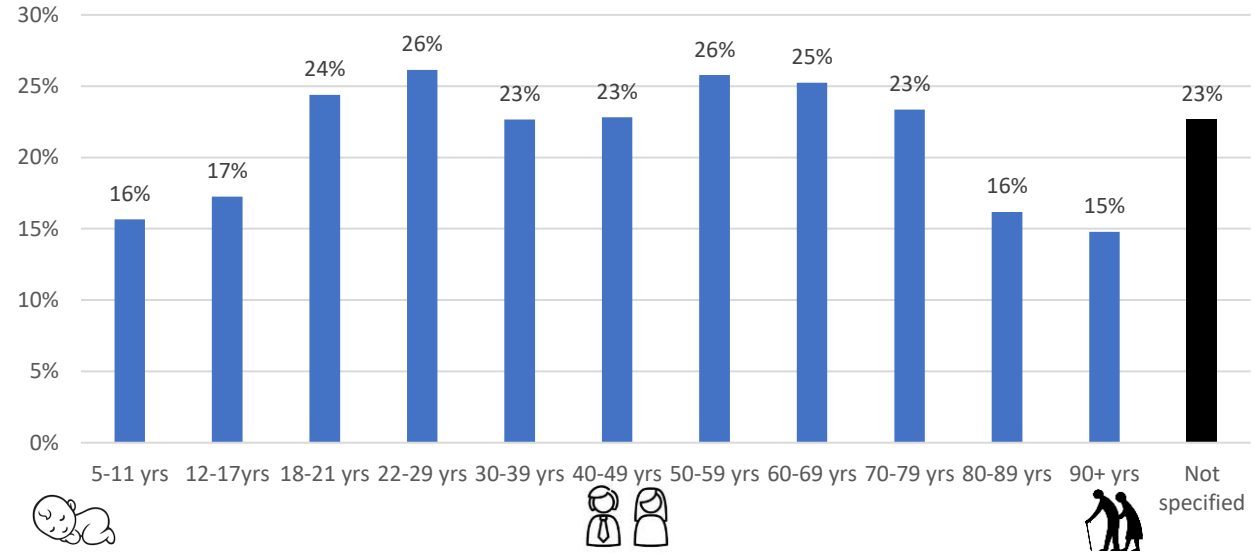


# Expected Reactions

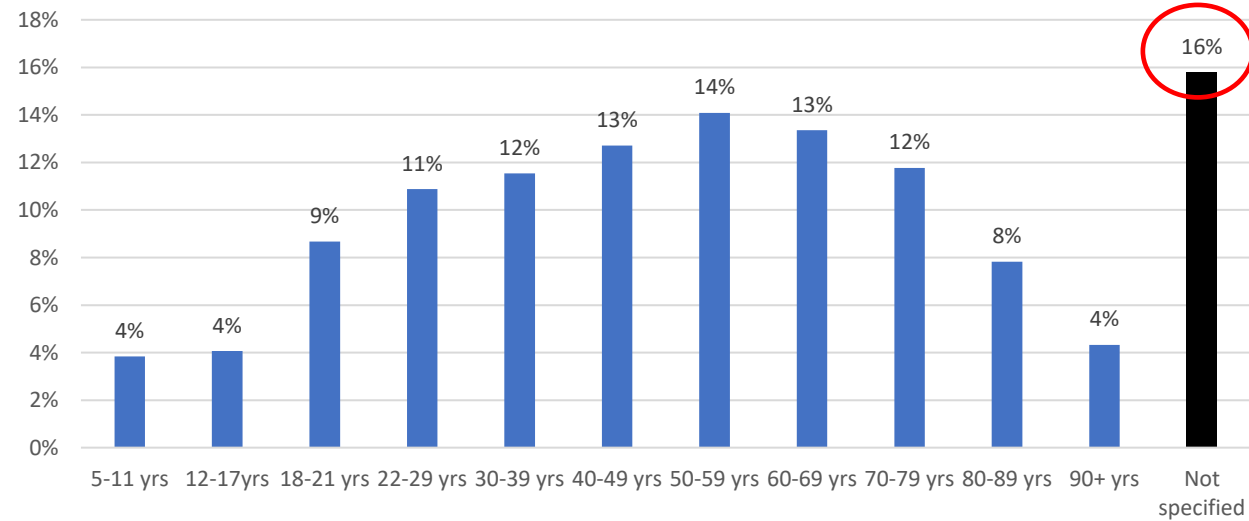
## MUSCLES/ SKELETON



## TEMPERATURE

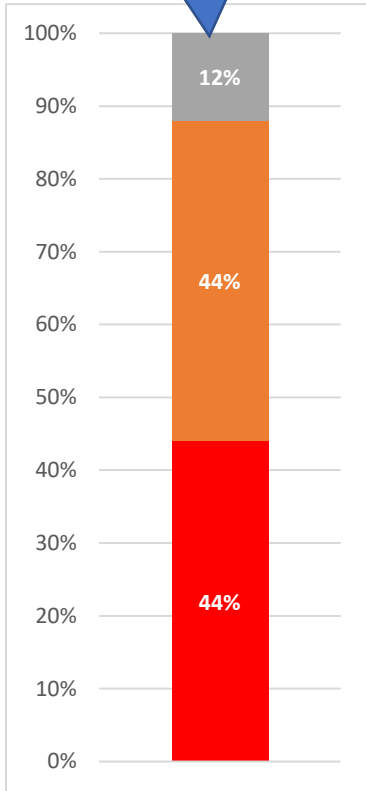


## PAIN/ SWELLING (general)

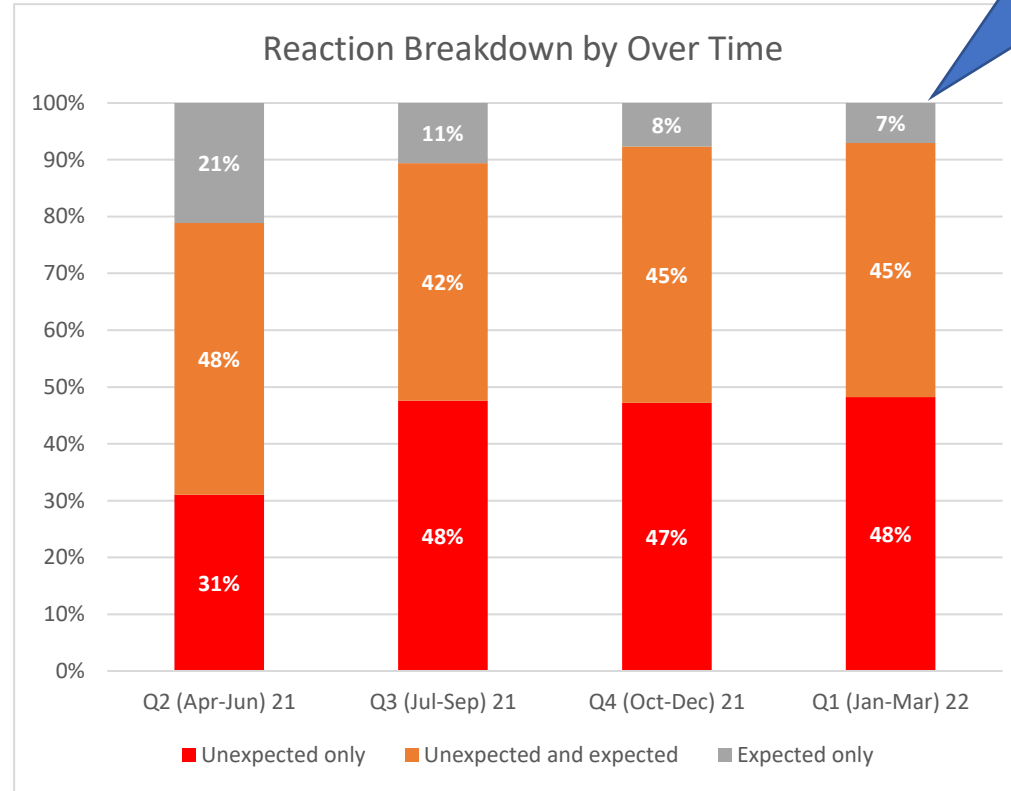


# Australia and New Zealand Over Time

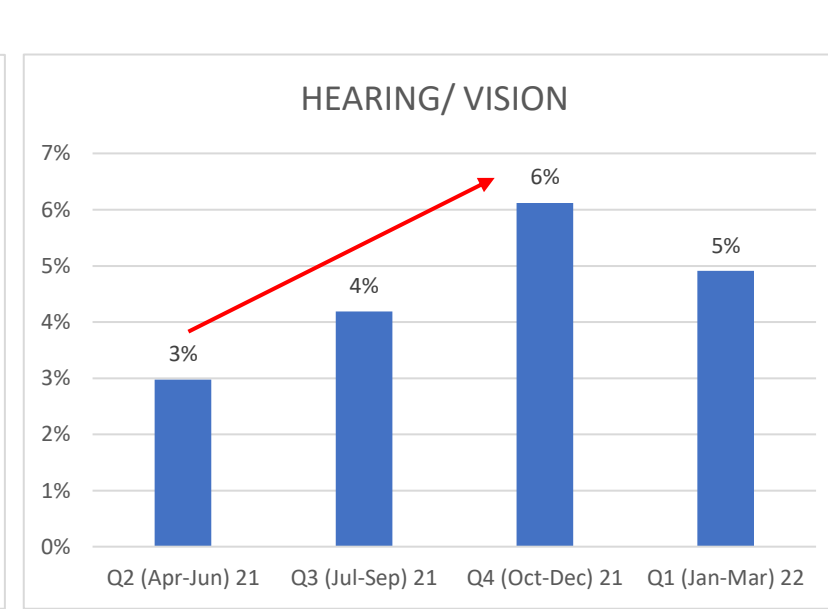
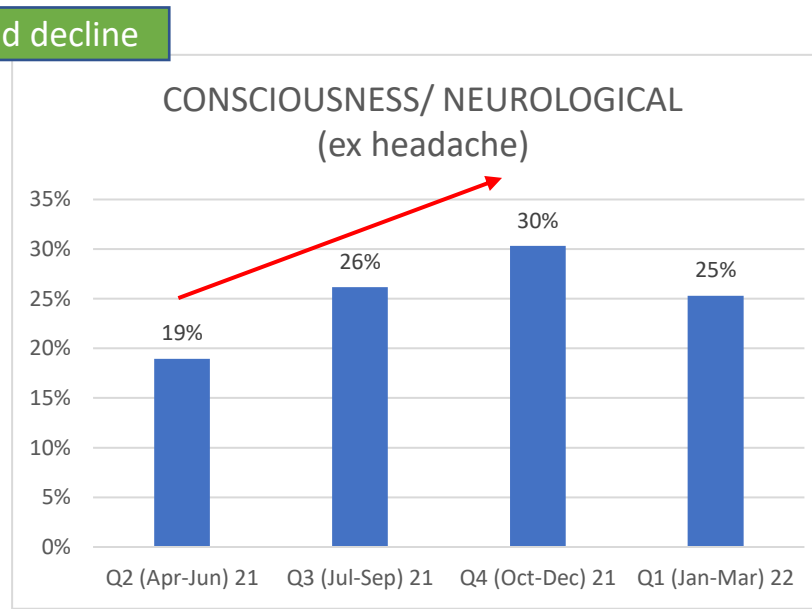
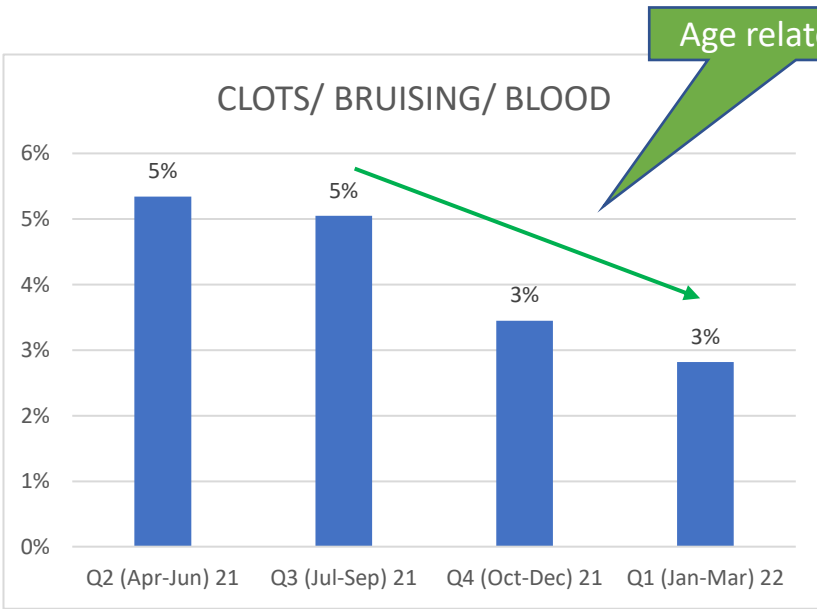
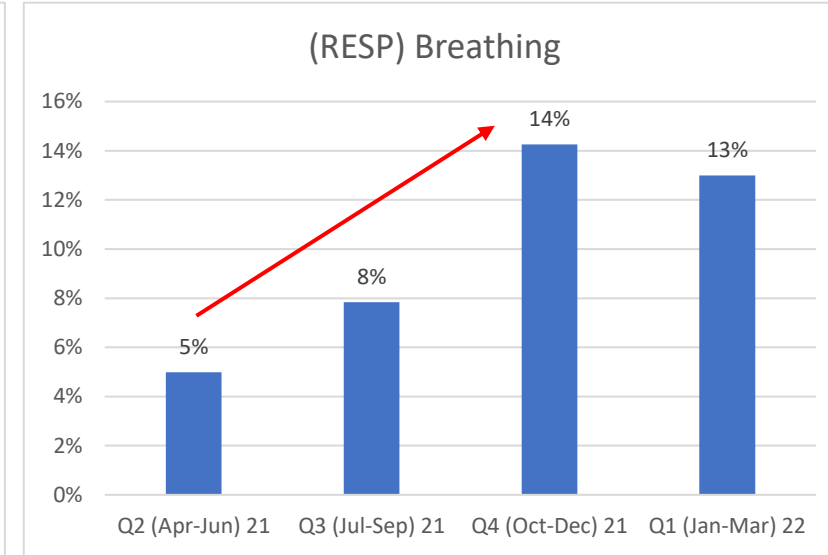
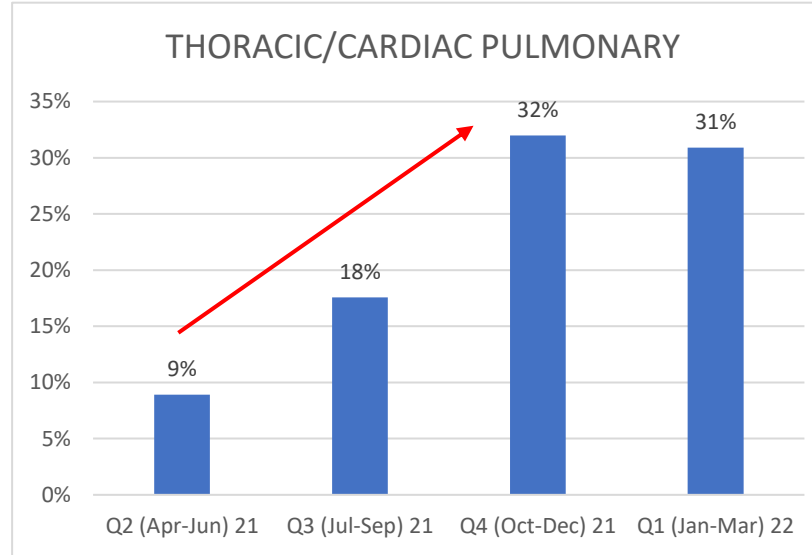
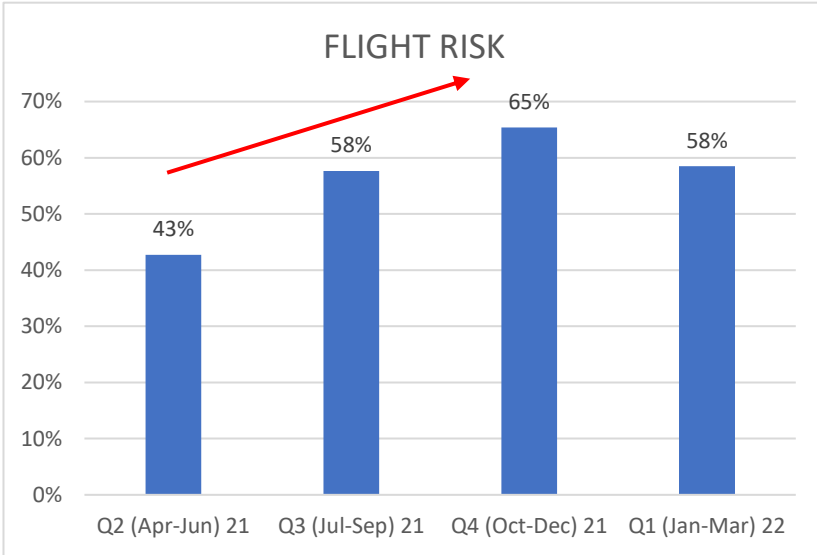
Across Australia and New Zealand  
12% of Adverse Events reports  
had 'Expected' Reactions only



Reports of 'Expected' Reactions only  
declined from 21% in Apr-Jun 21 to  
7% in Jan-Mar 22

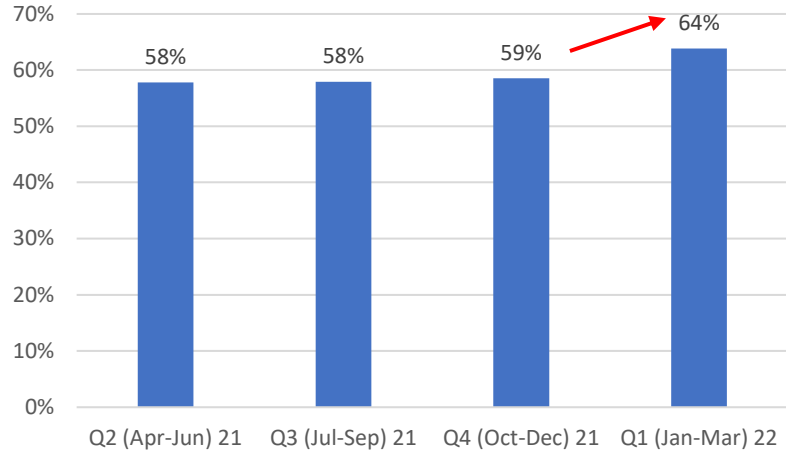


# Flight Risk Reactions - Unexpected

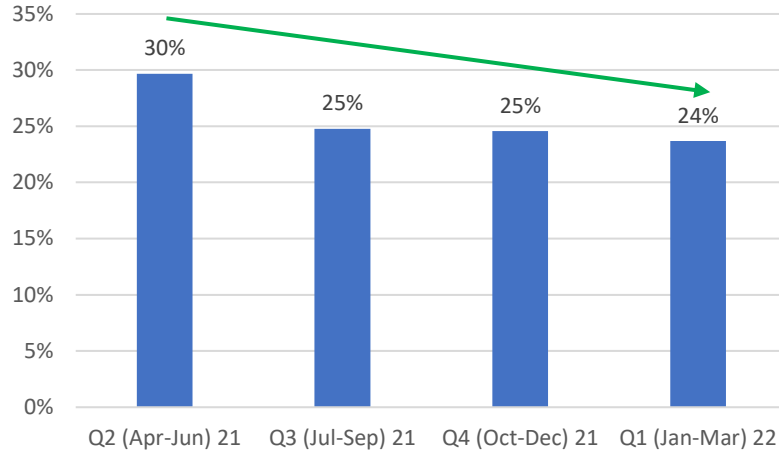


# Other Unexpected Reactions

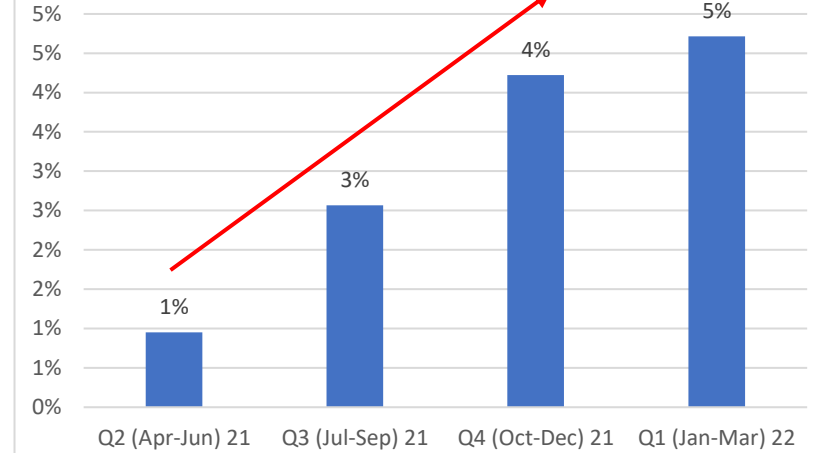
## OTHER UNEXPECTED REACTIONS



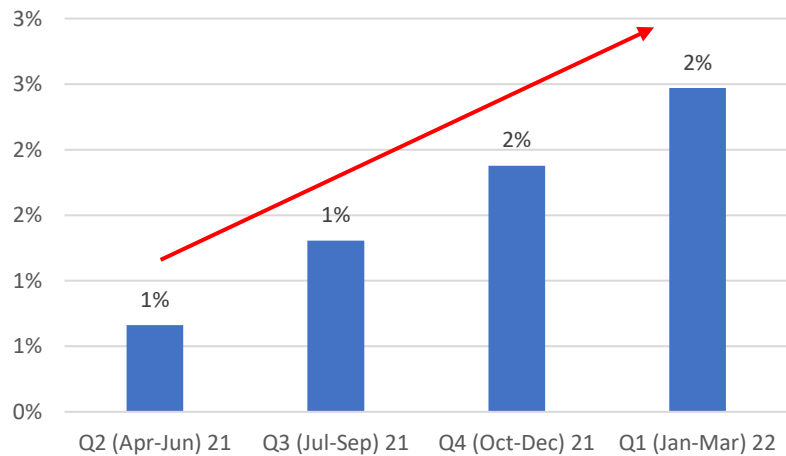
## GASTROINTESTINAL DISORDERS



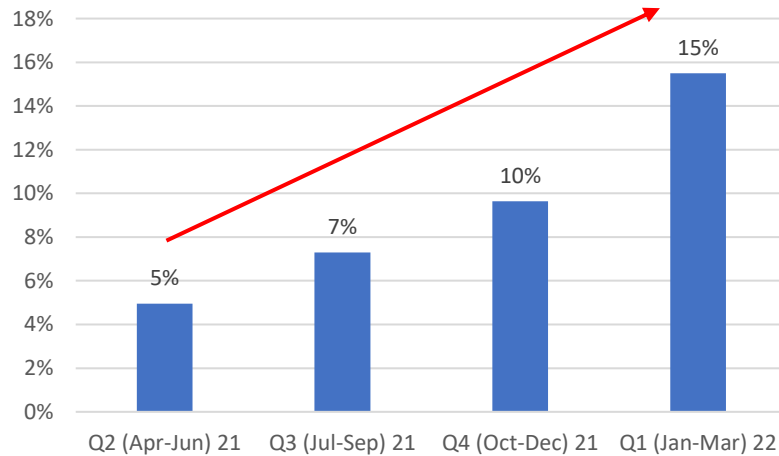
## REPRODUCTIVE



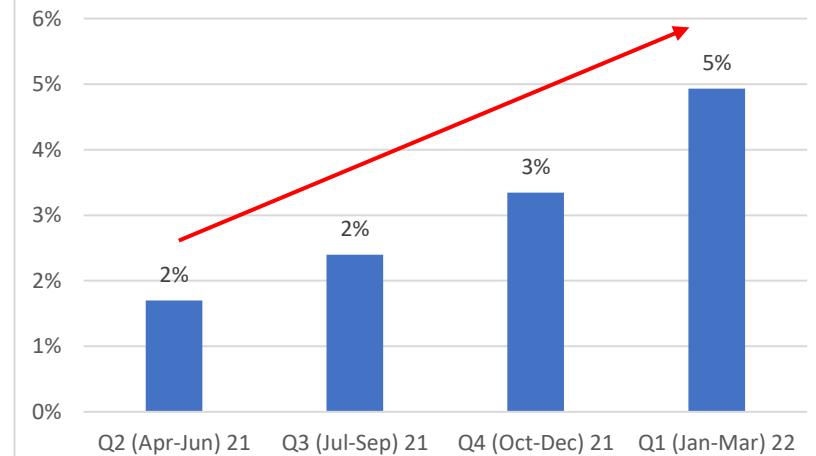
## ORGANS/ GLANDS



## AUTOIMMUNE SYMPTOMS

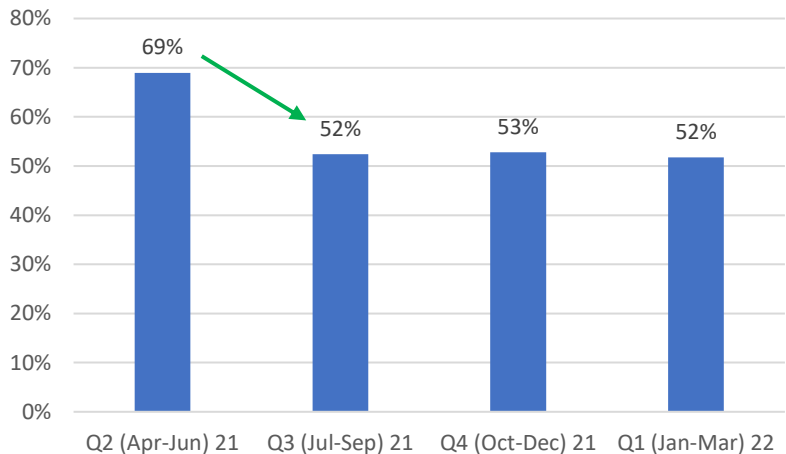


## REACTION (ex injection site)

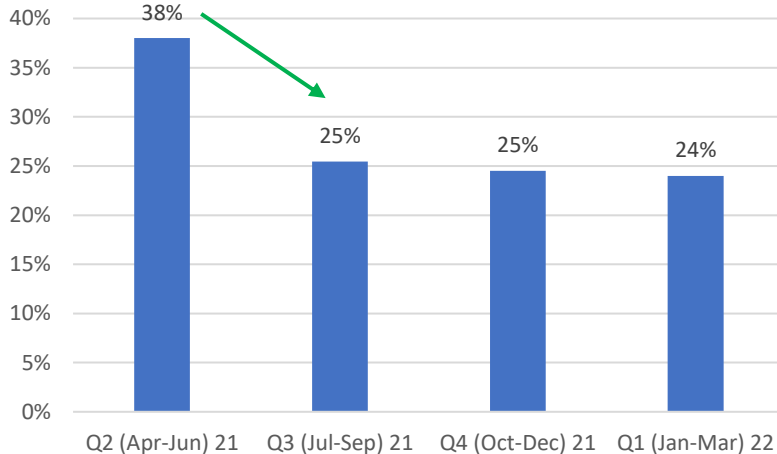


# Expected Reactions

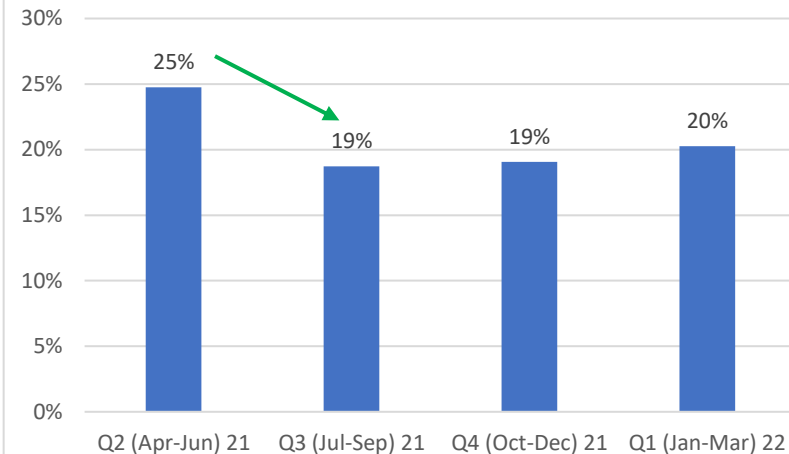
## EXPECTED REACTIONS



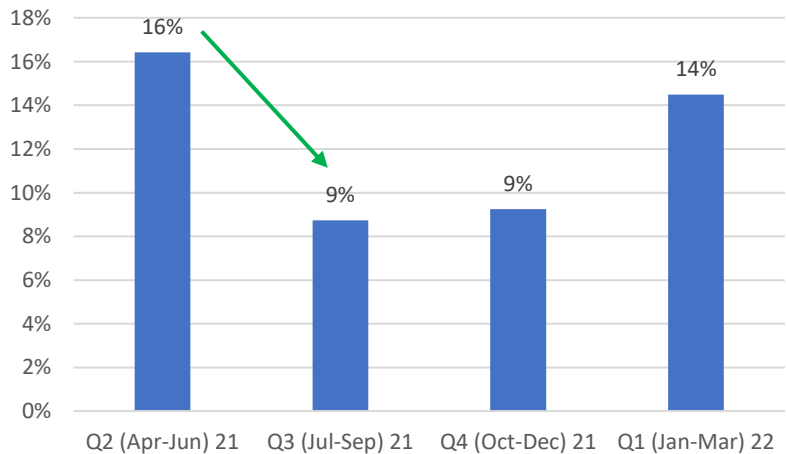
## (CONSC) Neurological - Headache



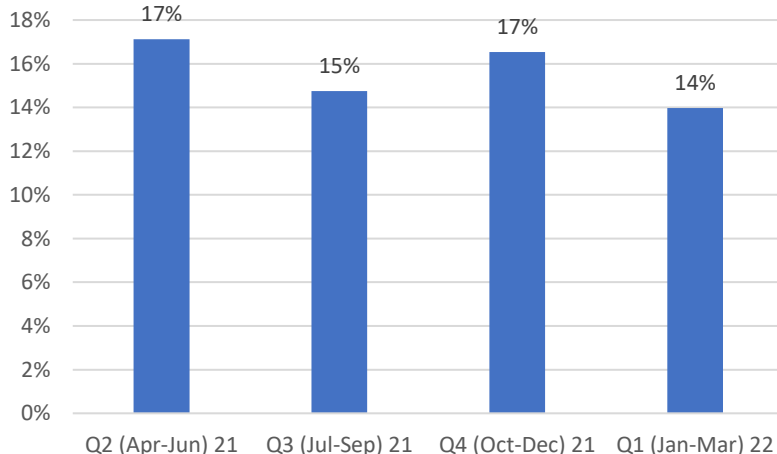
## (REACT) Injection site



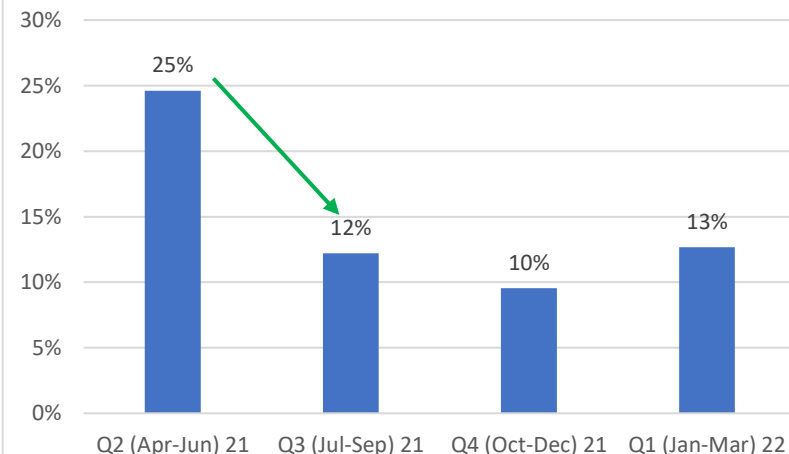
## Fatigue



## Lethargy

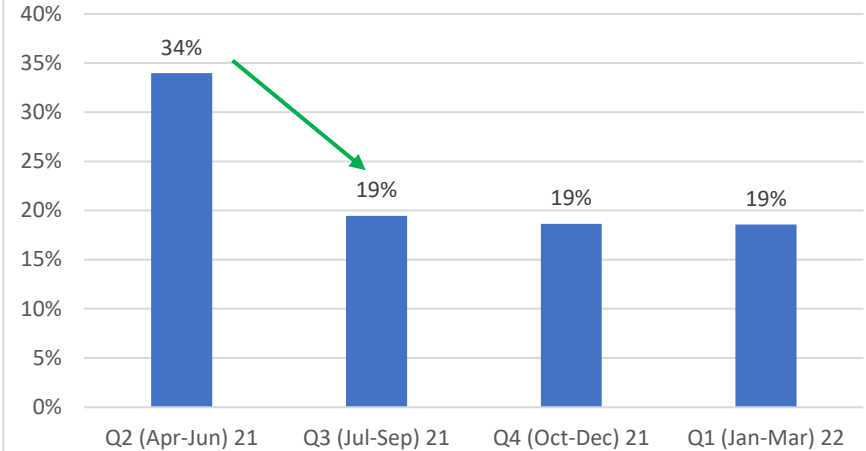


## MUSCLES/ SKELETON

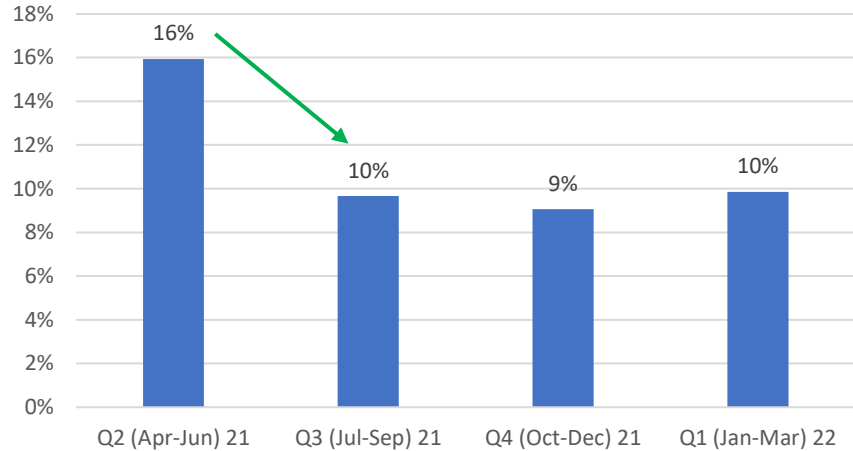


# Expected Reactions

TEMPERATURE



PAIN/ SWELLING (general)

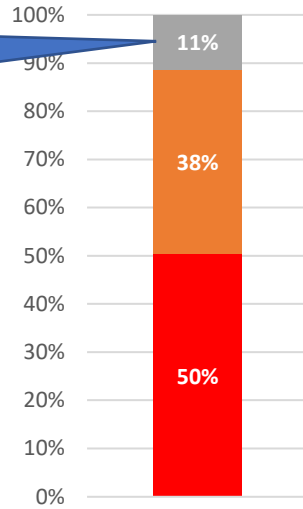


Australia and  
New Zealand  
By Age and Gender

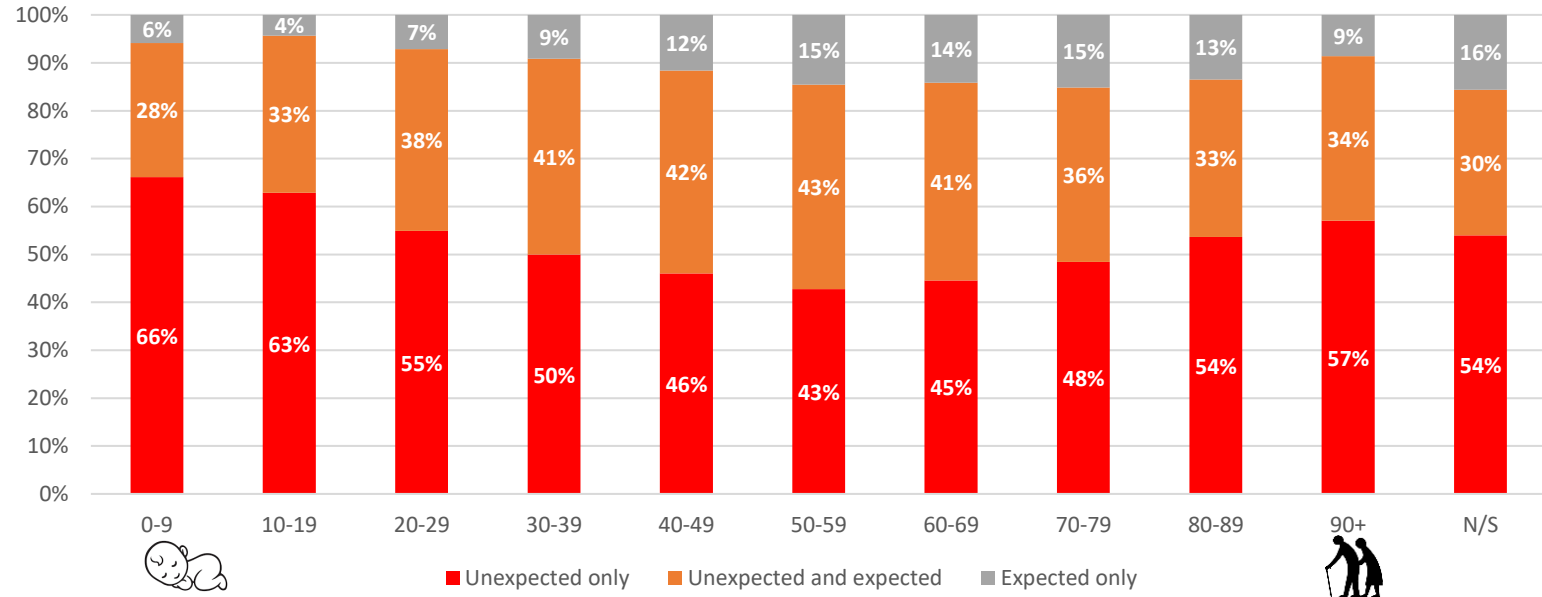


11% of Males reported ONLY an 'Expected' Reaction

### Male Reactions

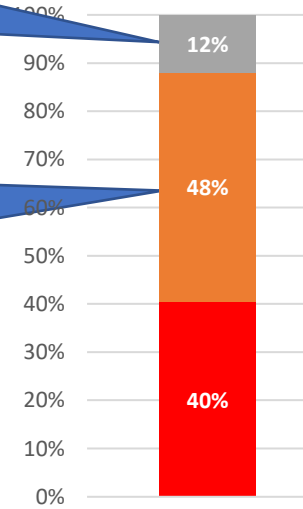


### Male Reactions Reported by Age

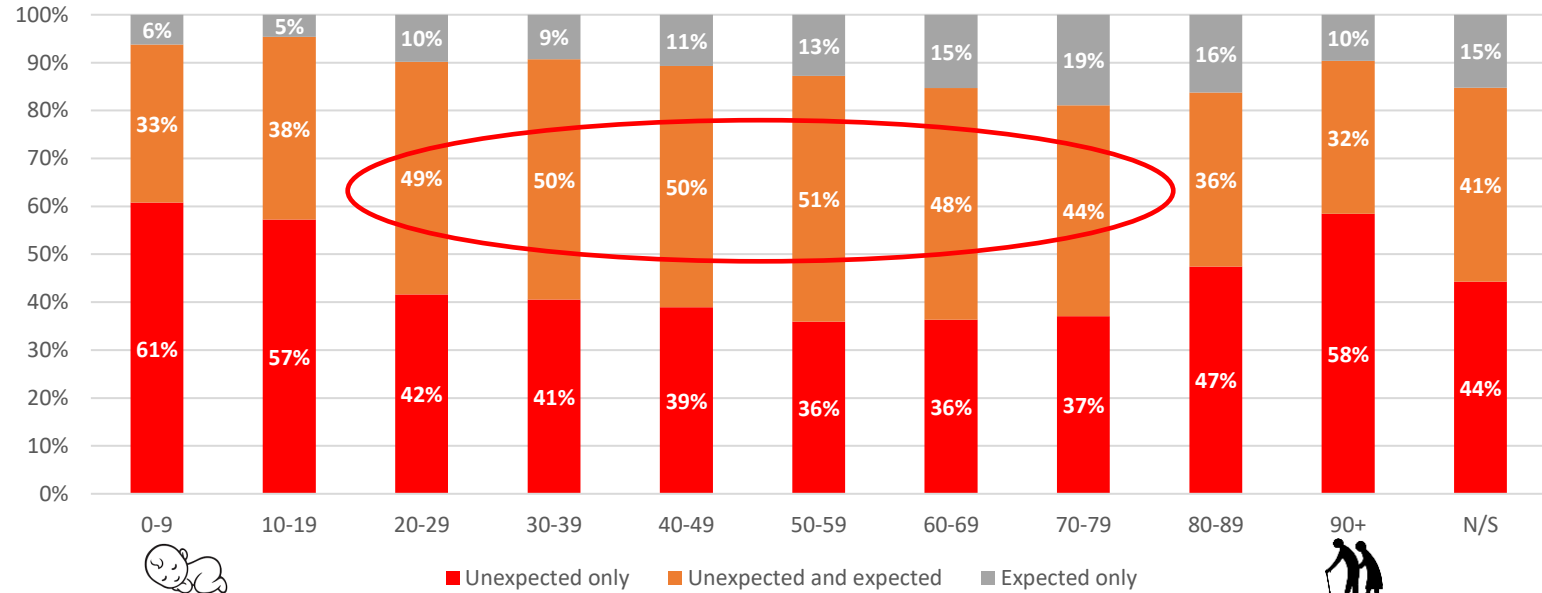


Similarly, 12% of Females reported ONLY an 'Expected' Reaction

### Female Reactions



### Female Reactions Reported by Age

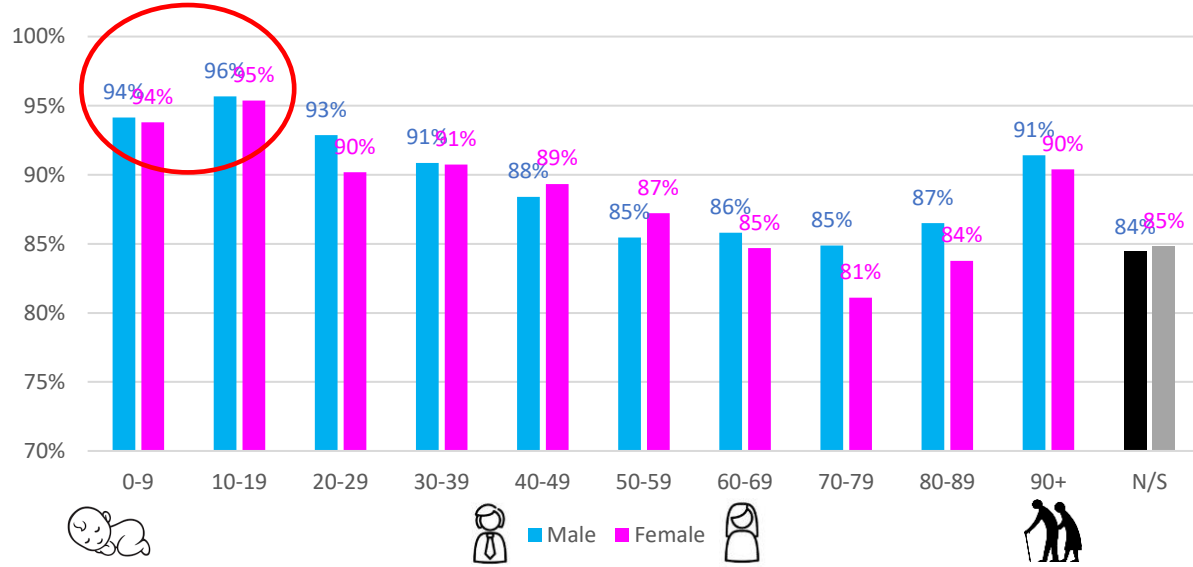


Females were more likely than Males to report both an 'Unexpected' and 'Expected' reaction

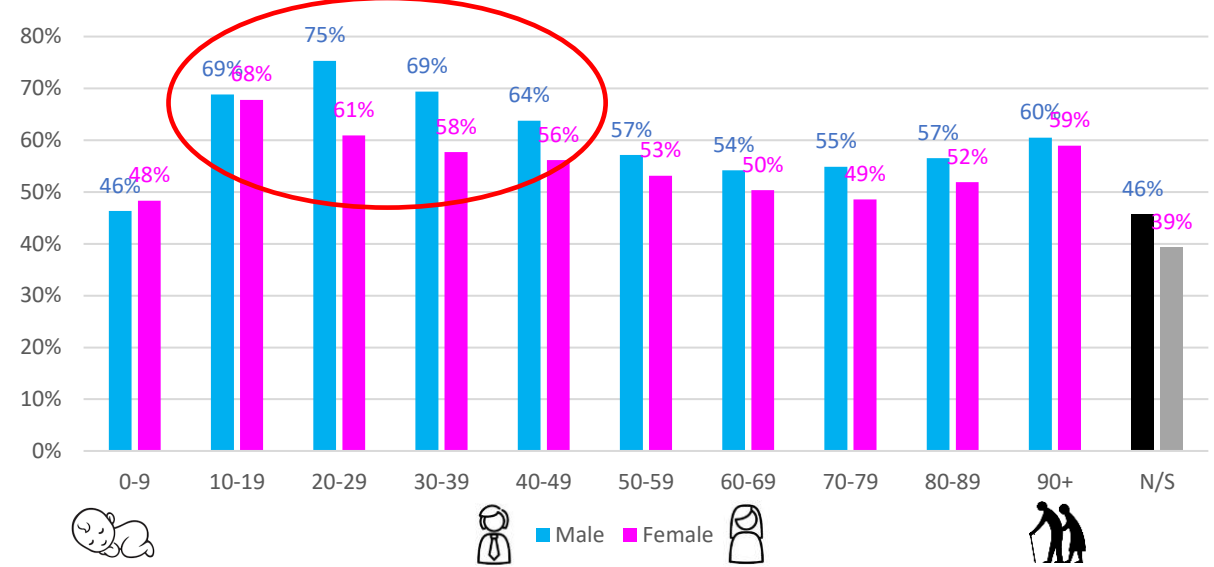
Males reported 3.0 reactions  
Females reported 3.6 reactions

# Flight Risk Reactions - Unexpected

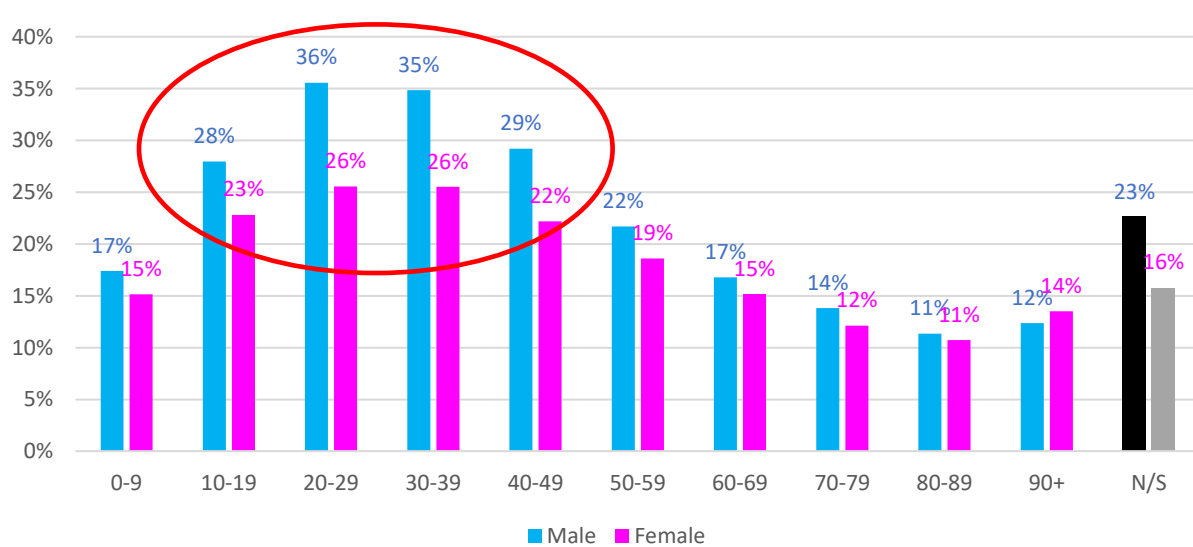
## UNEXPECTED REACTIONS



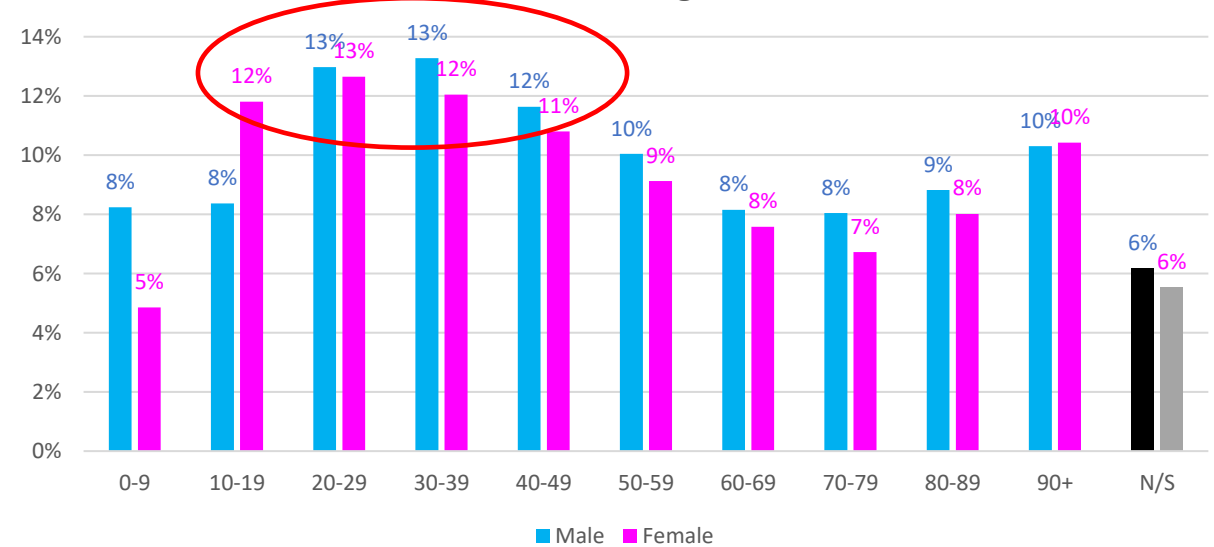
## FLIGHT RISK REACTIONS



## THORACIC/ CARDIAC PULMONARY

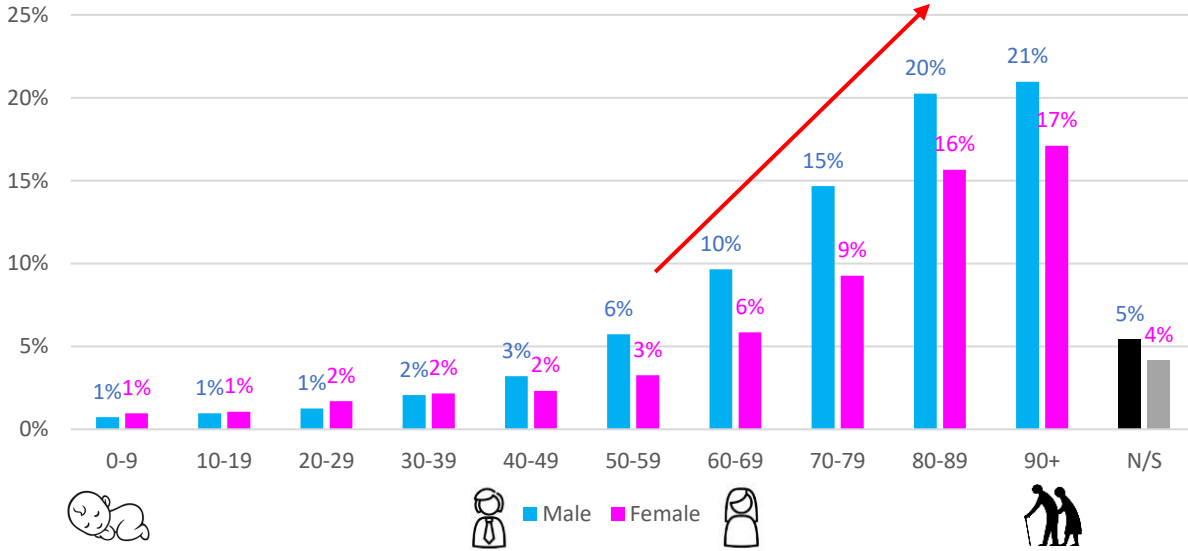


## Breathing

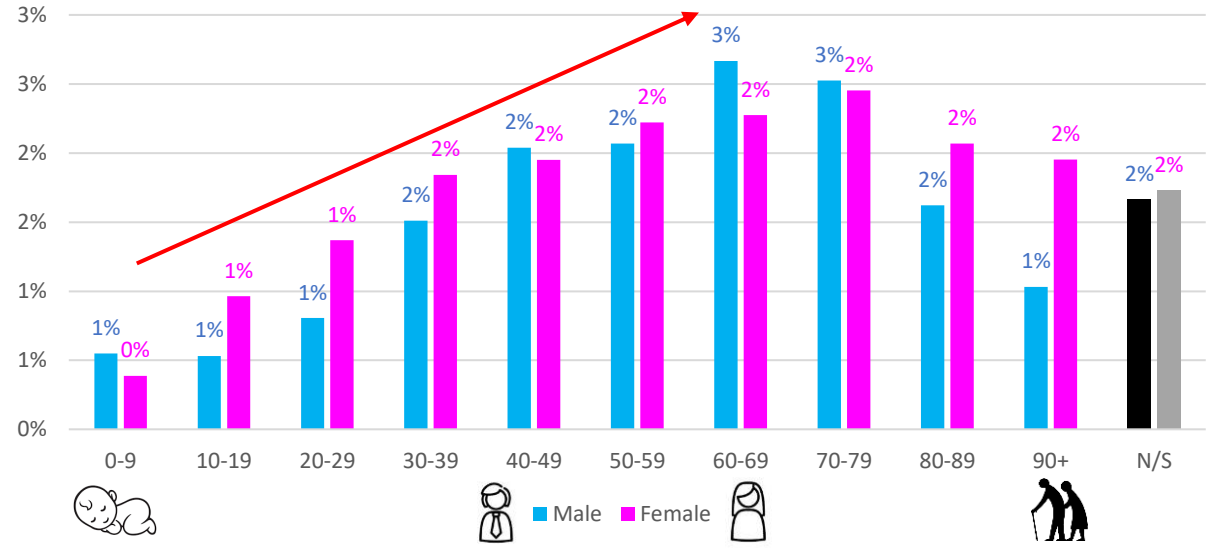


# Flight Risk Reactions - Unexpected

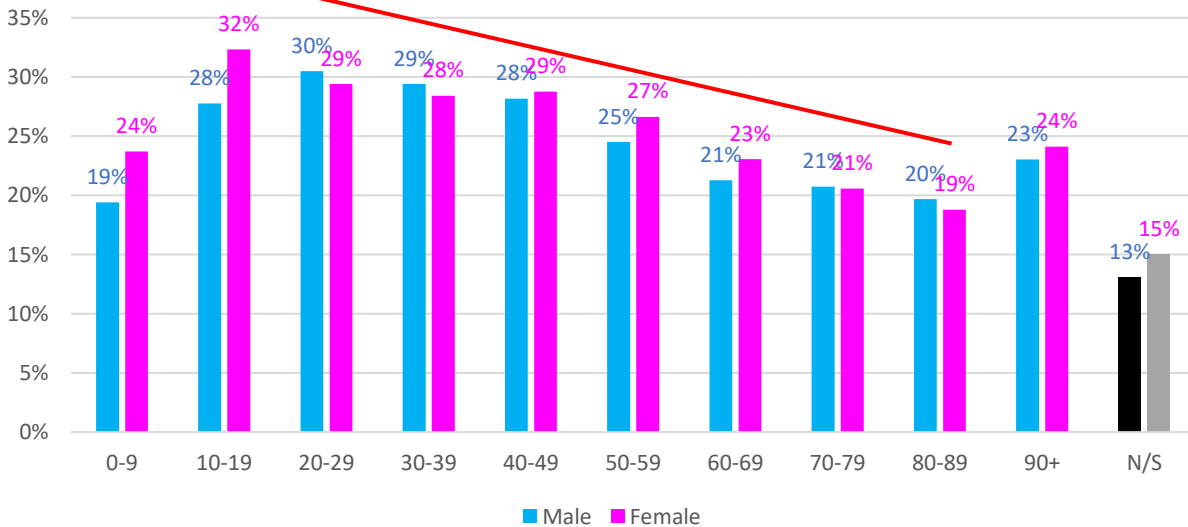
## CLOTS/ STROKE/ BLOOD



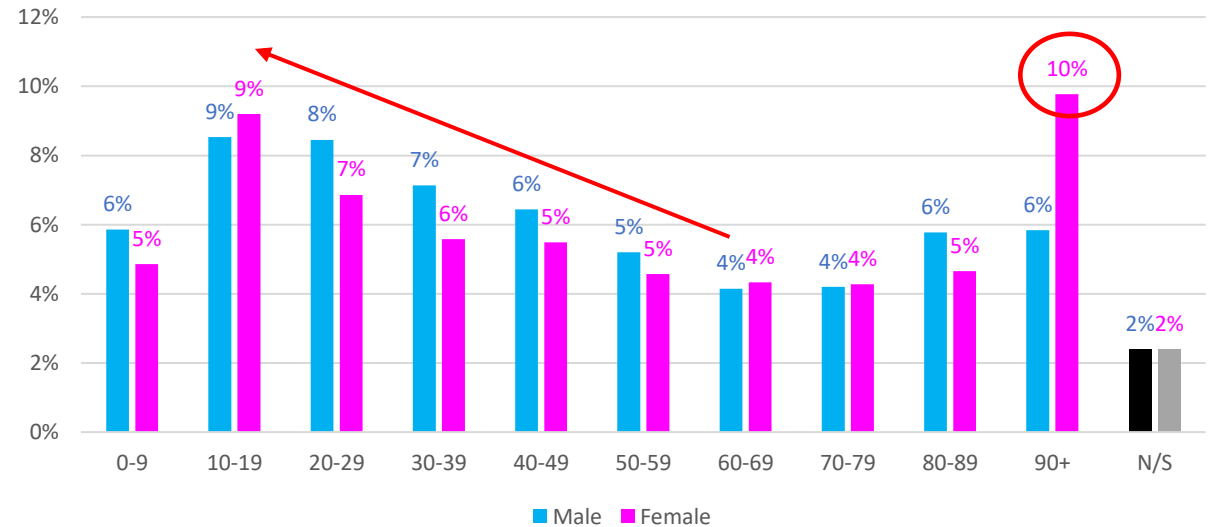
## CENTRAL NERVOUS SYSTEM (Spine)



## CONSCIOUSNESS/ NEUROLOGICAL (ex Headache)

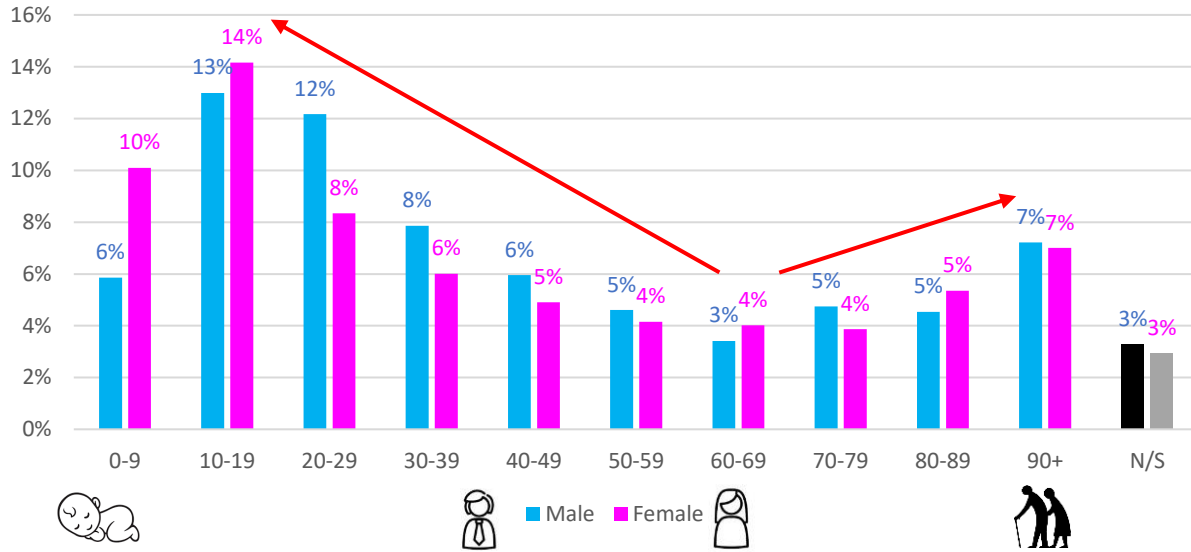


## Mental Impairment

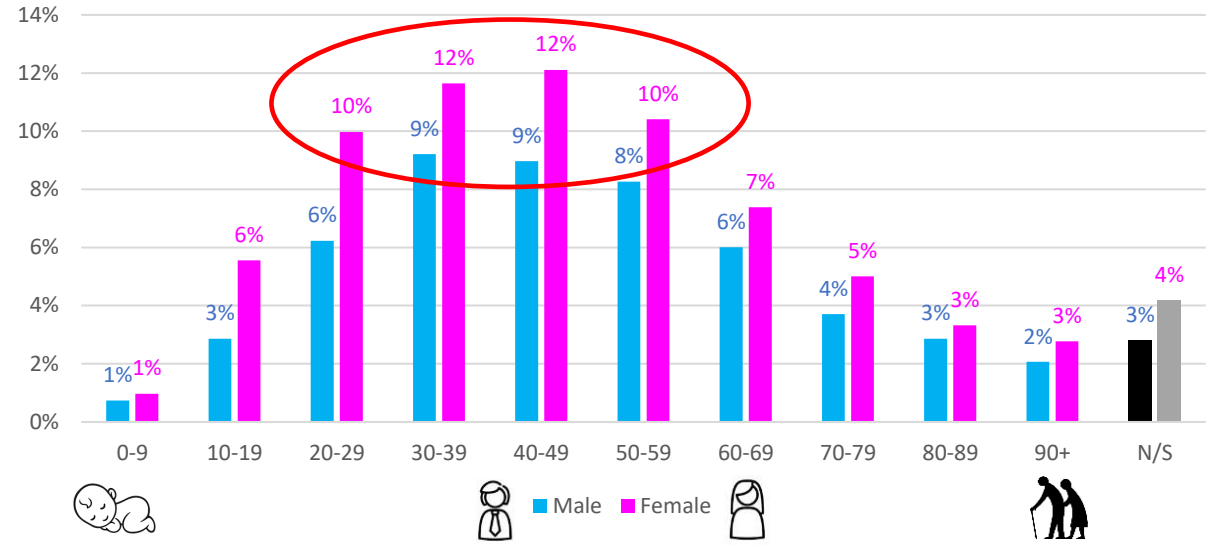


# Flight Risk Reactions - Unexpected

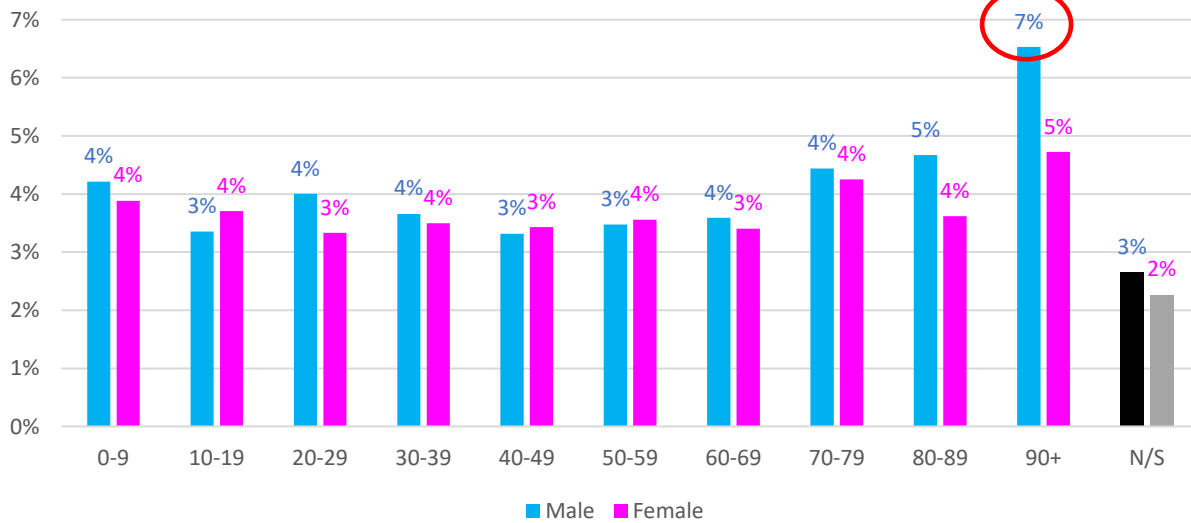
## Balance/ consciousness



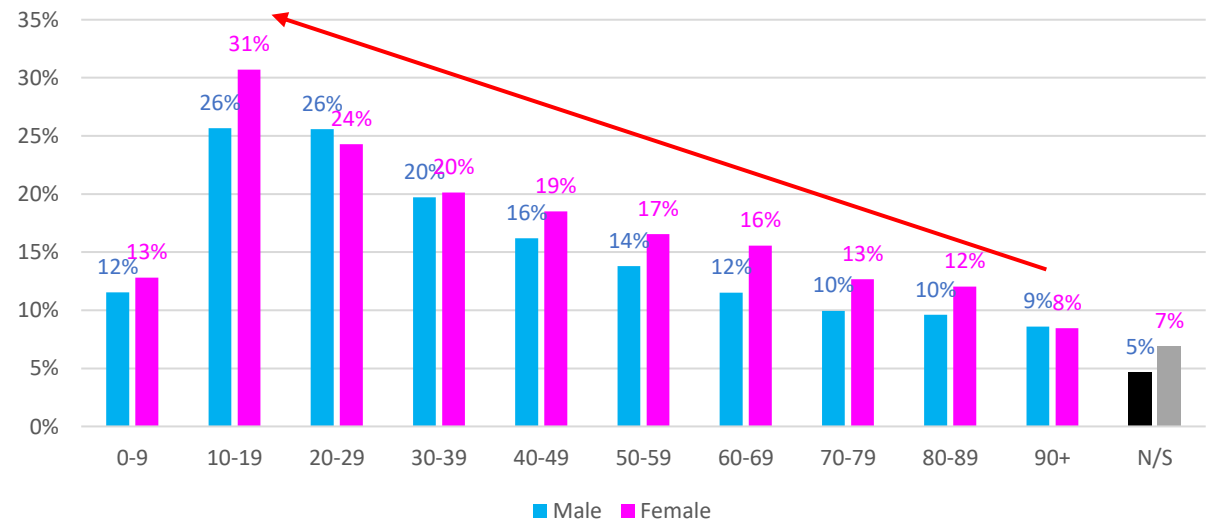
## Numbness



## Seizure

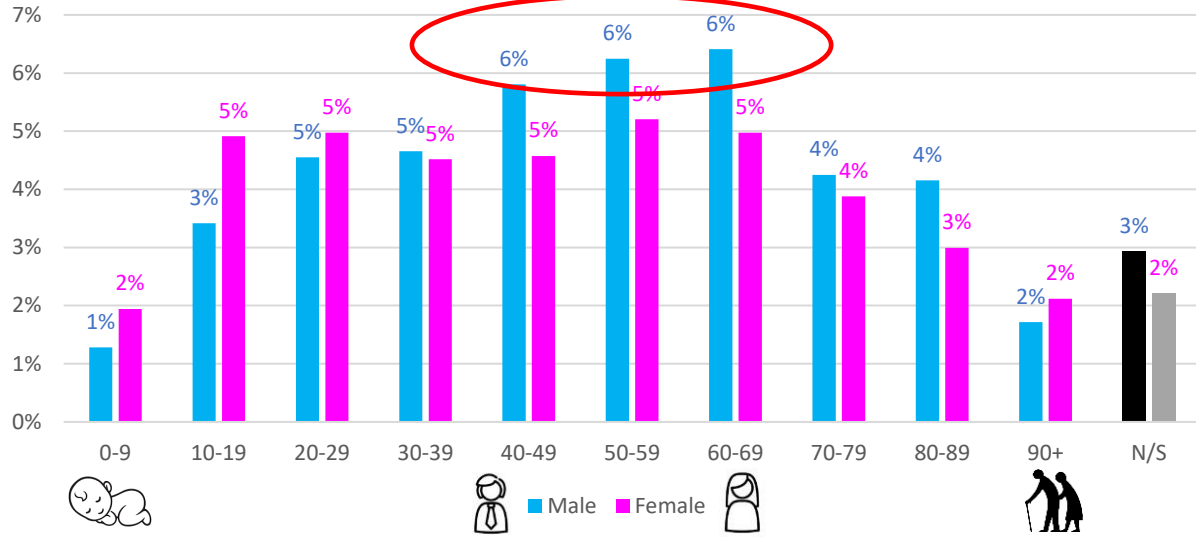


## Vertigo

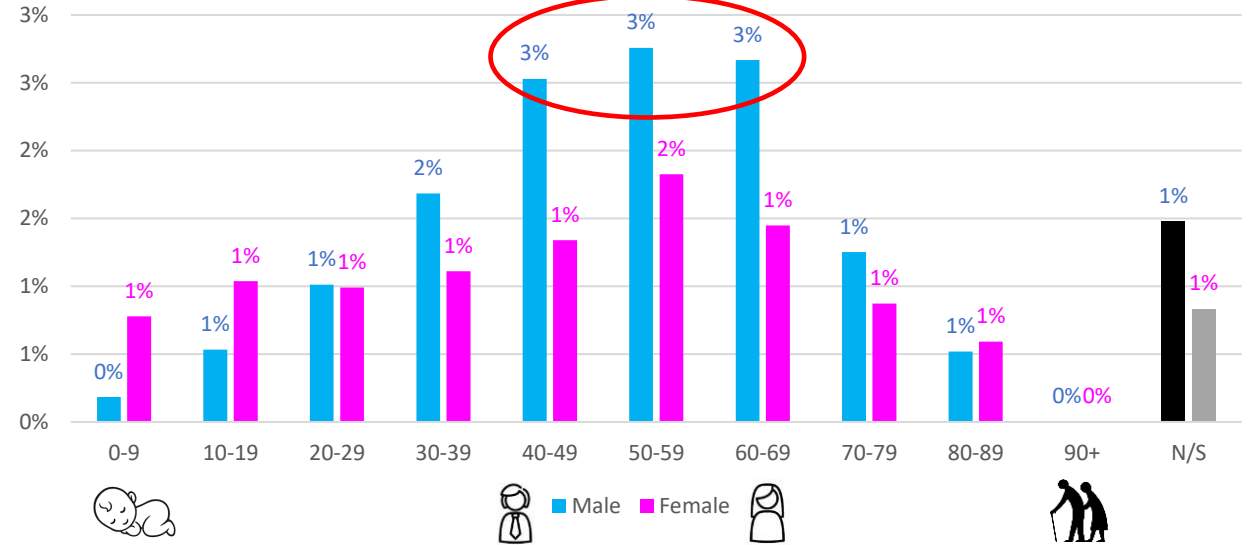


# Flight Risk Reactions - Unexpected

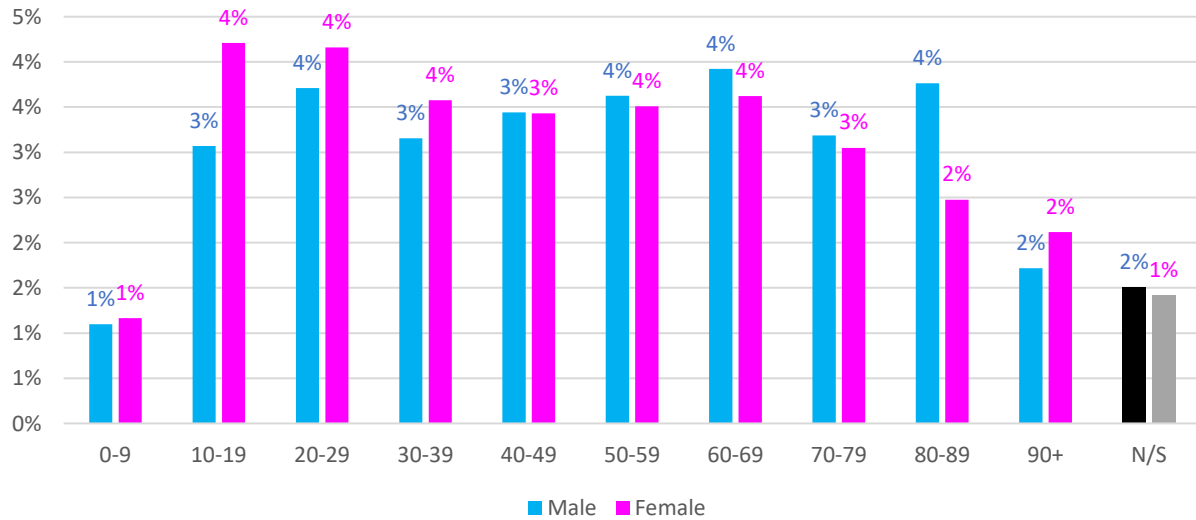
## HEARING/ VISION



## Deafness

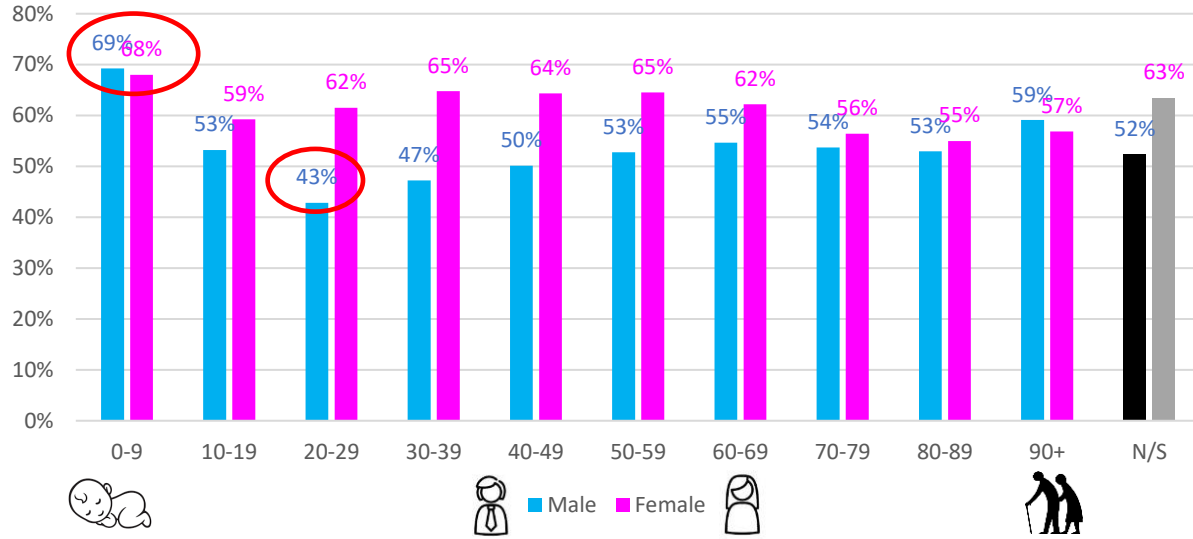


## Vision

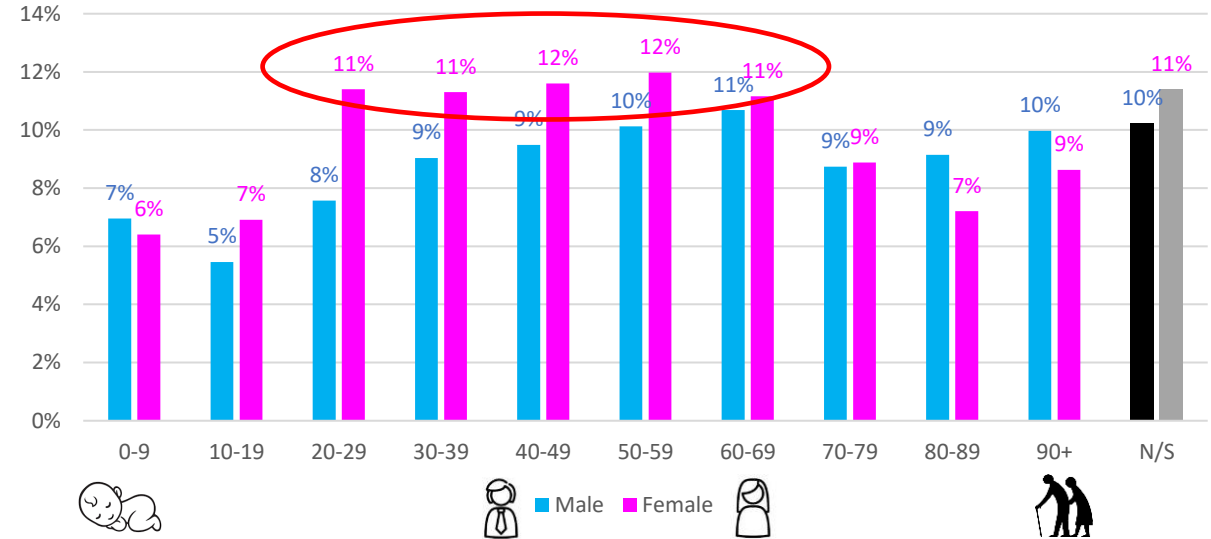


# Other Unexpected Reactions

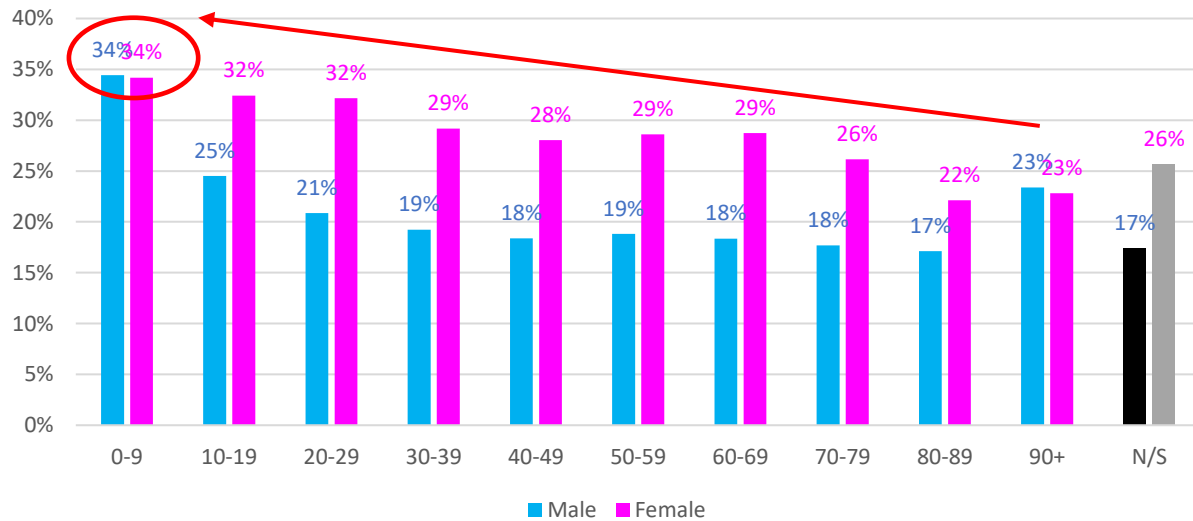
## OTHER UNEXPECTED REACTIONS



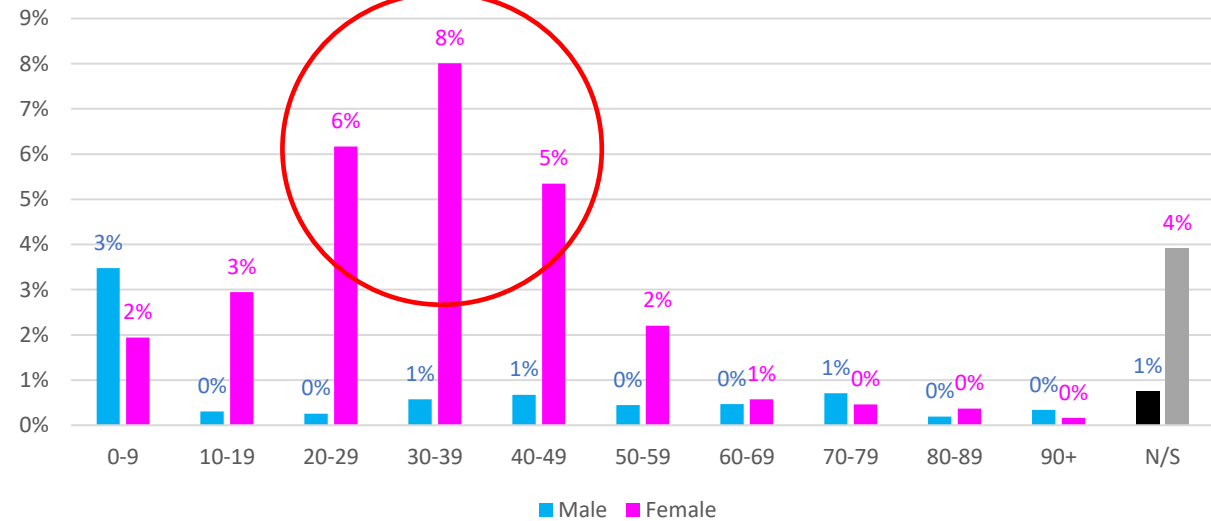
## RESPIRATORY TRACT



## GASTROINTESTINAL DISORDERS

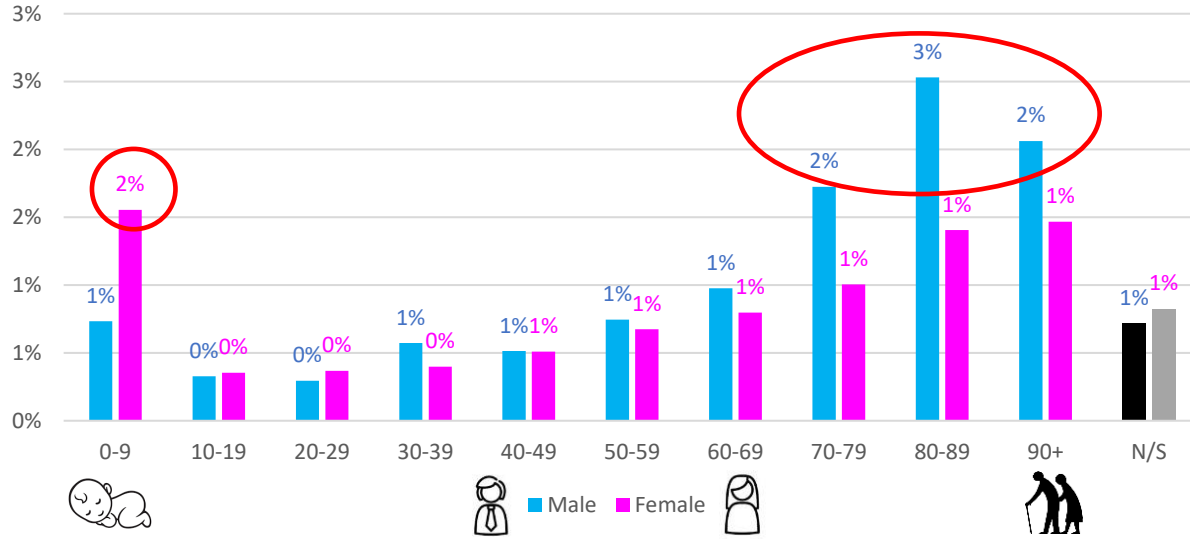


## REPRODUCTIVE

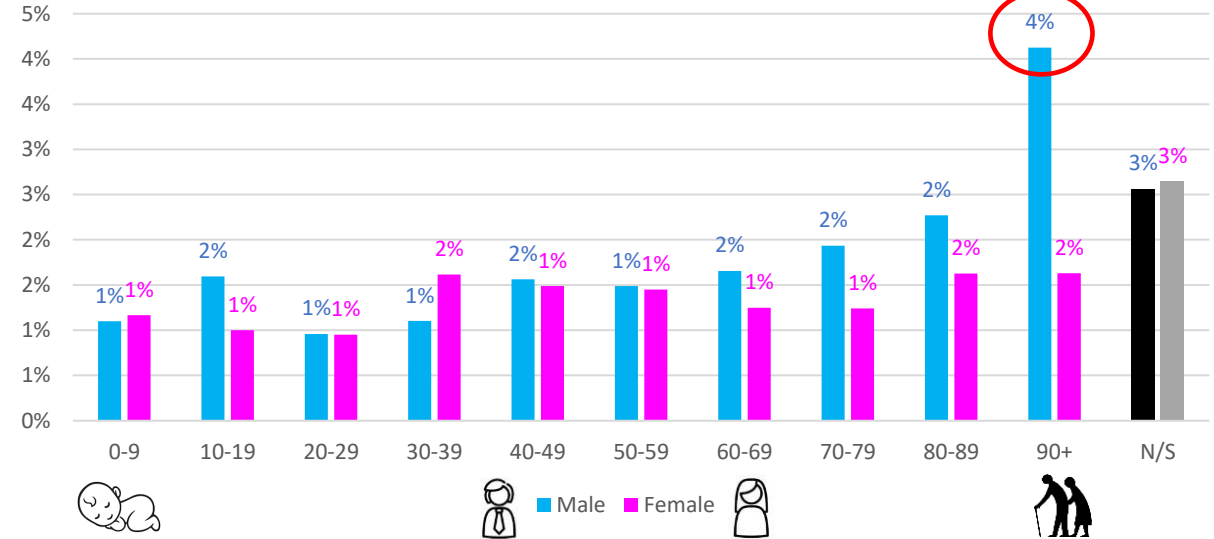


# Other Unexpected Reactions

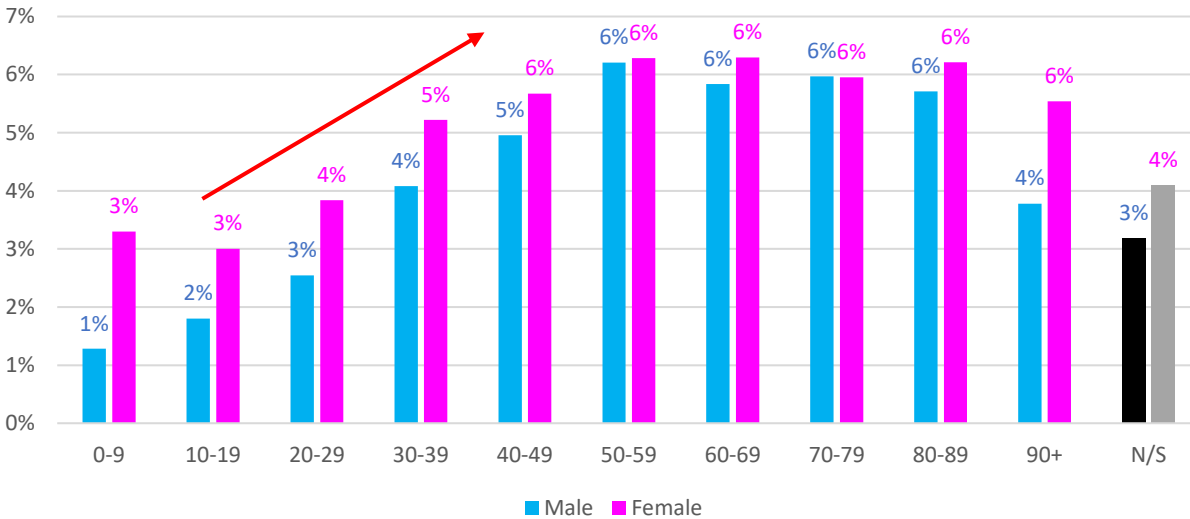
## URINARY TRACT



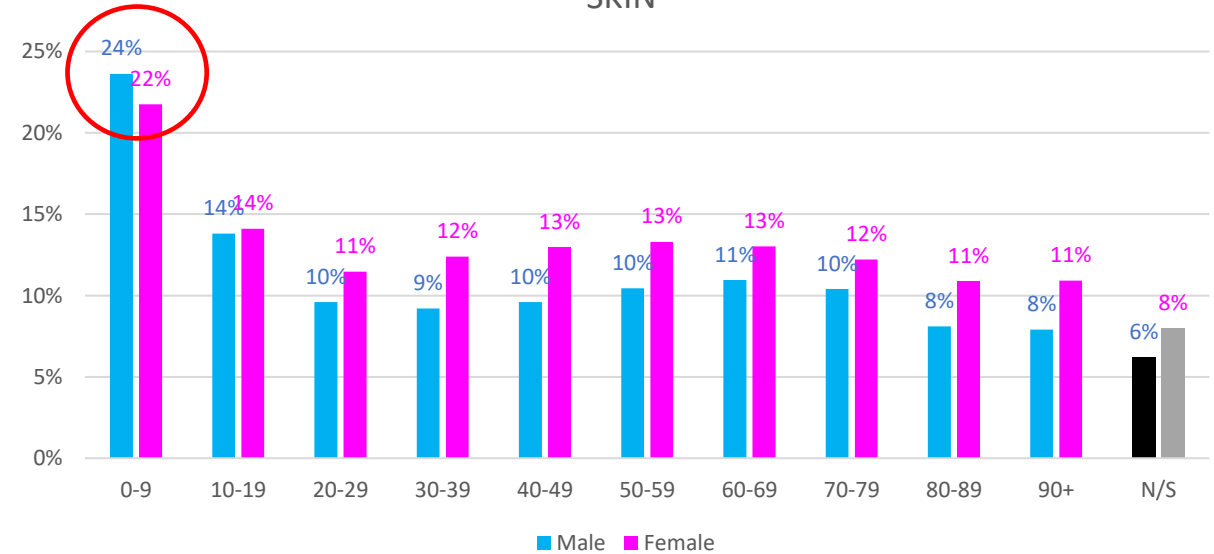
## ORGANS/ GLANDS



## EXTREMITIES

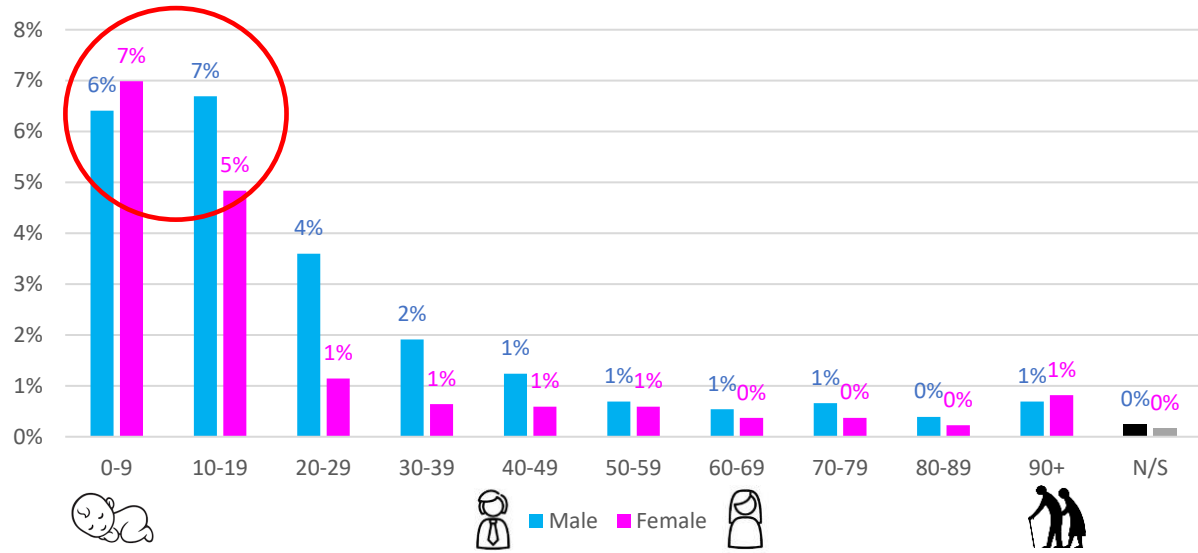


## SKIN

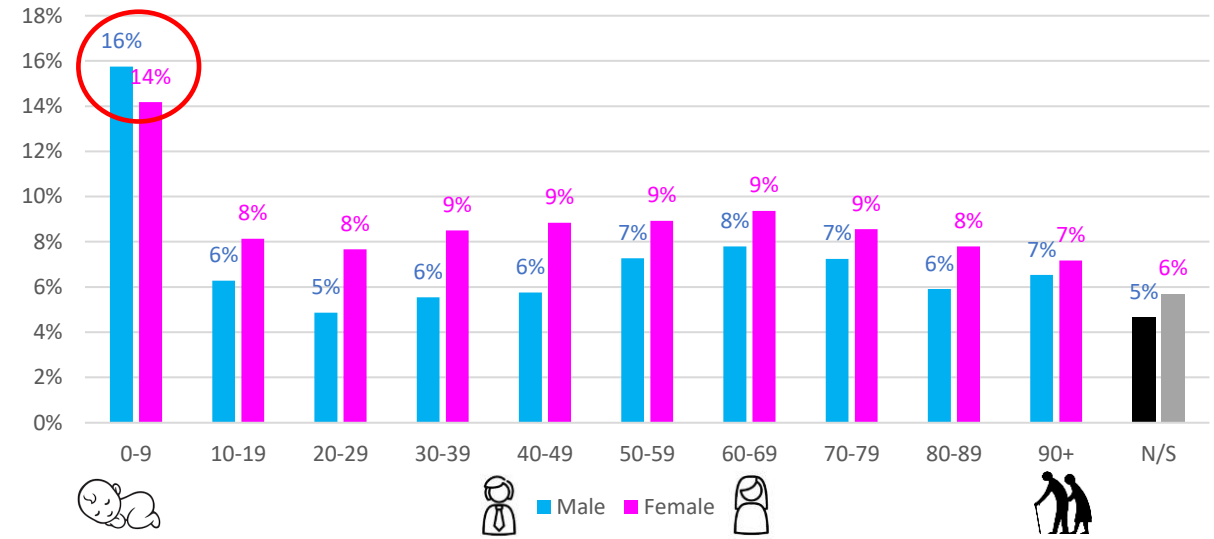


# Other Unexpected Reactions

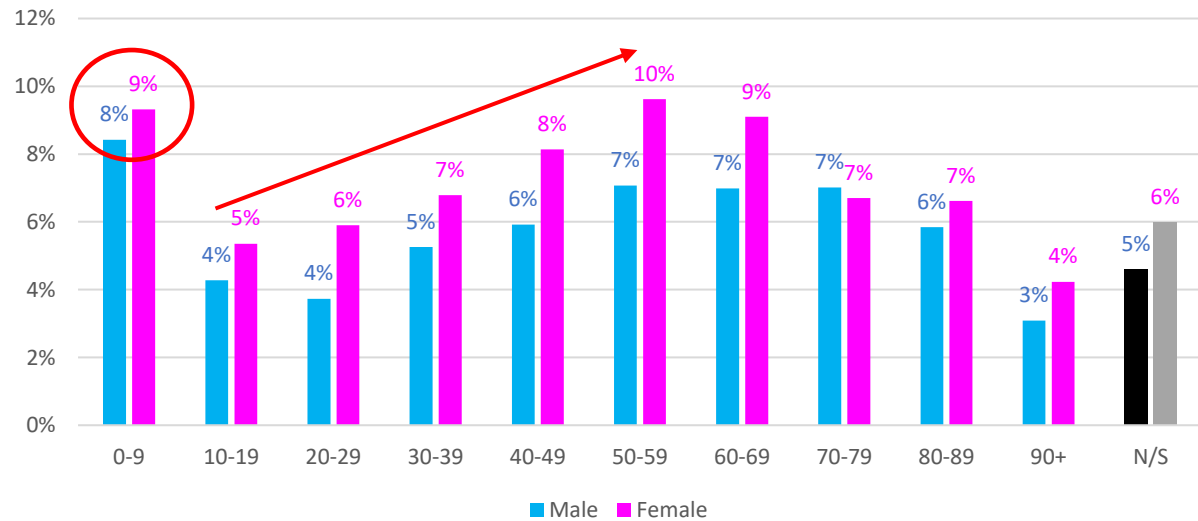
## Pallor



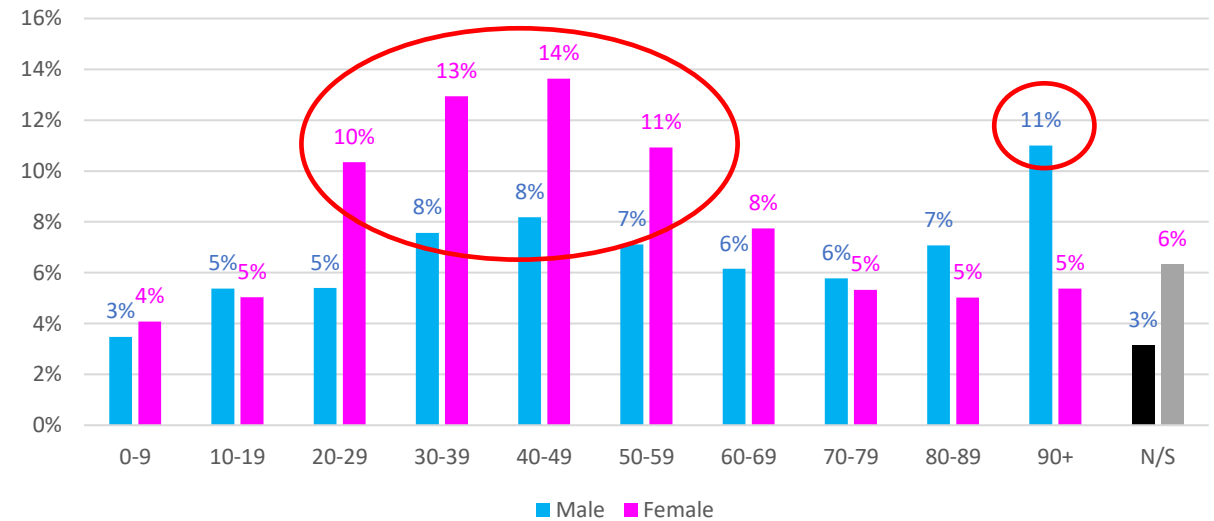
## Rash



## FACE/ EYES/ EARS/ MOUTH/ NOSE



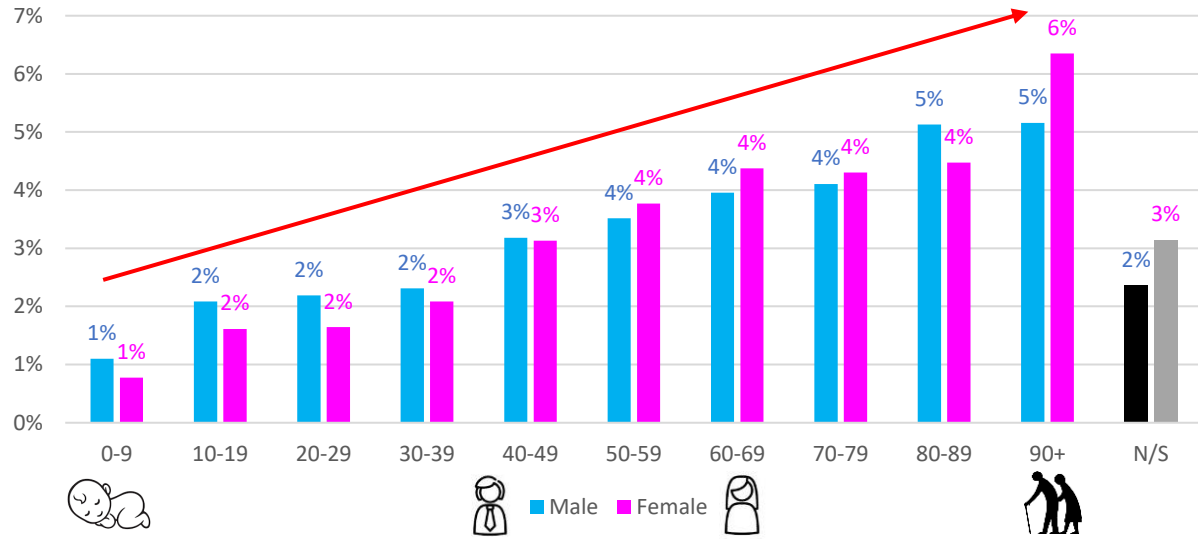
## AUTOIMMUNE SYMPTOMS



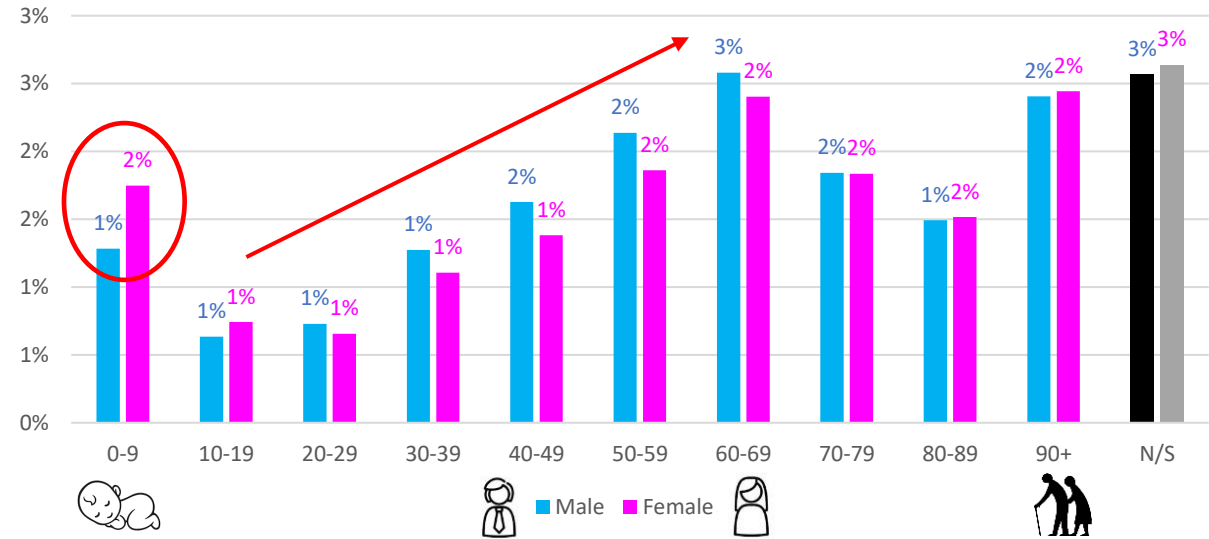


# Other Unexpected Reactions

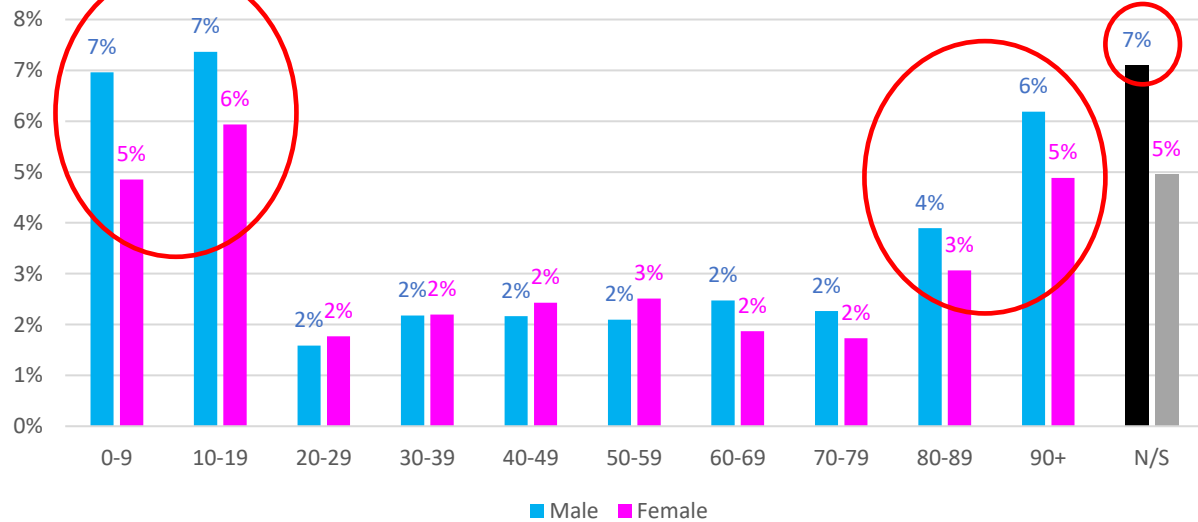
## BLOOD PRESSURE/ BLOODS



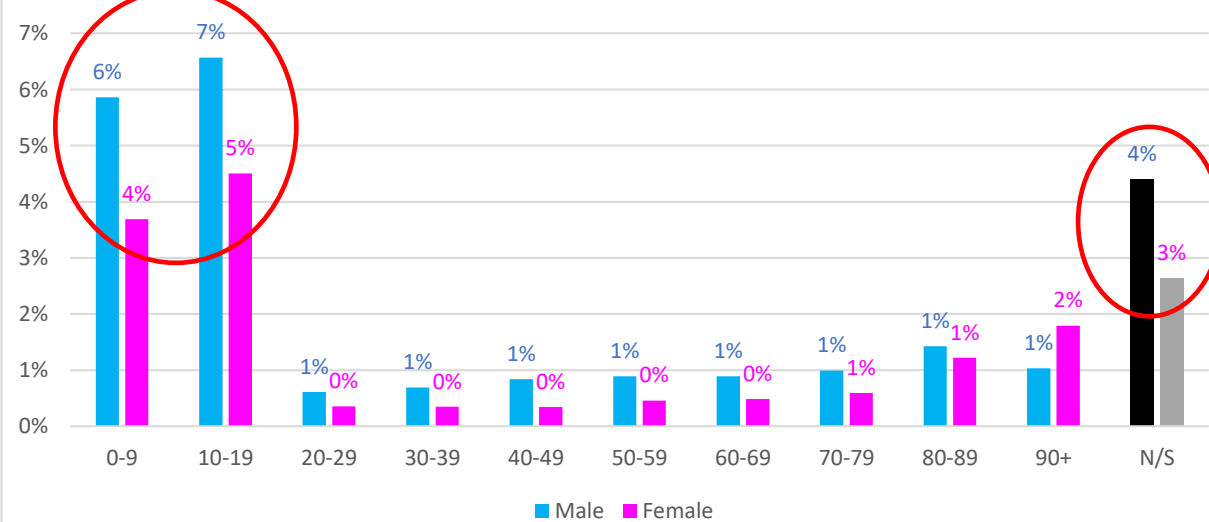
## INFECTION



## REACTION (ex Injection Site)



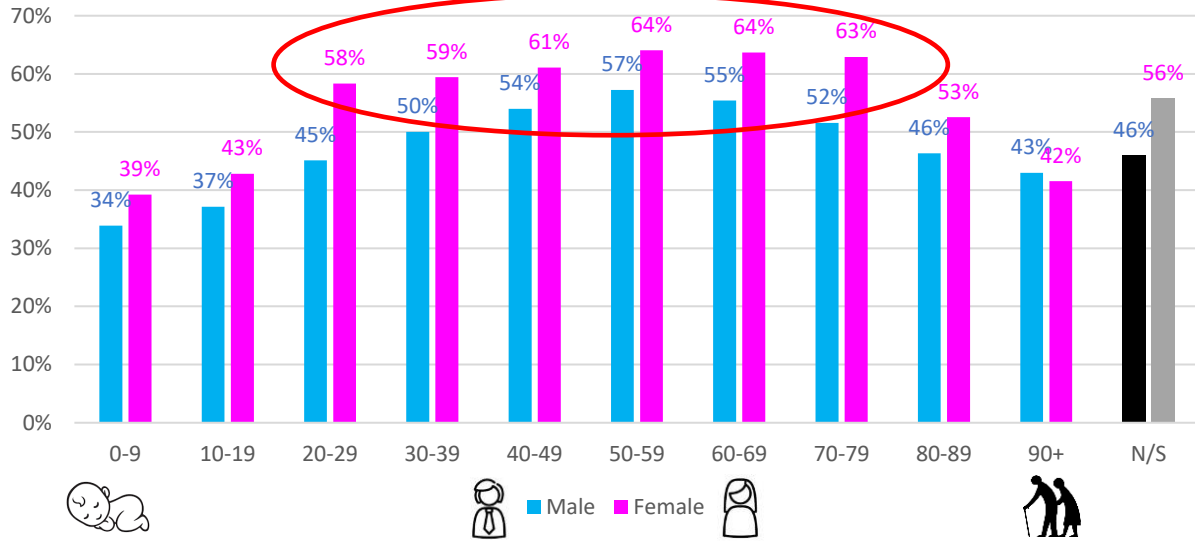
## Error (injection administration)



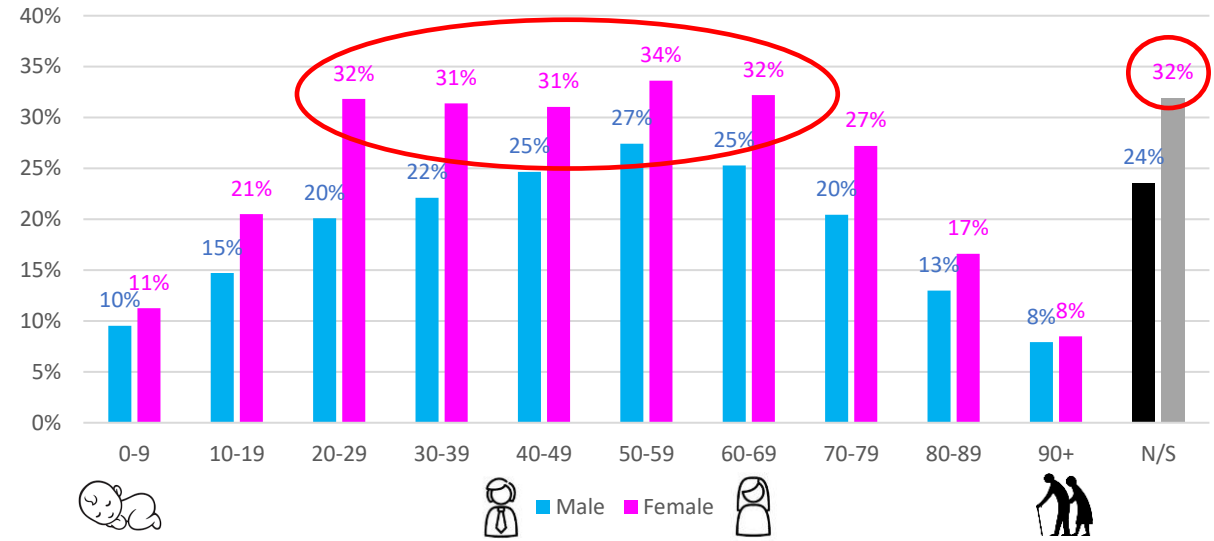
0% = < 0.5%

# Expected Reactions

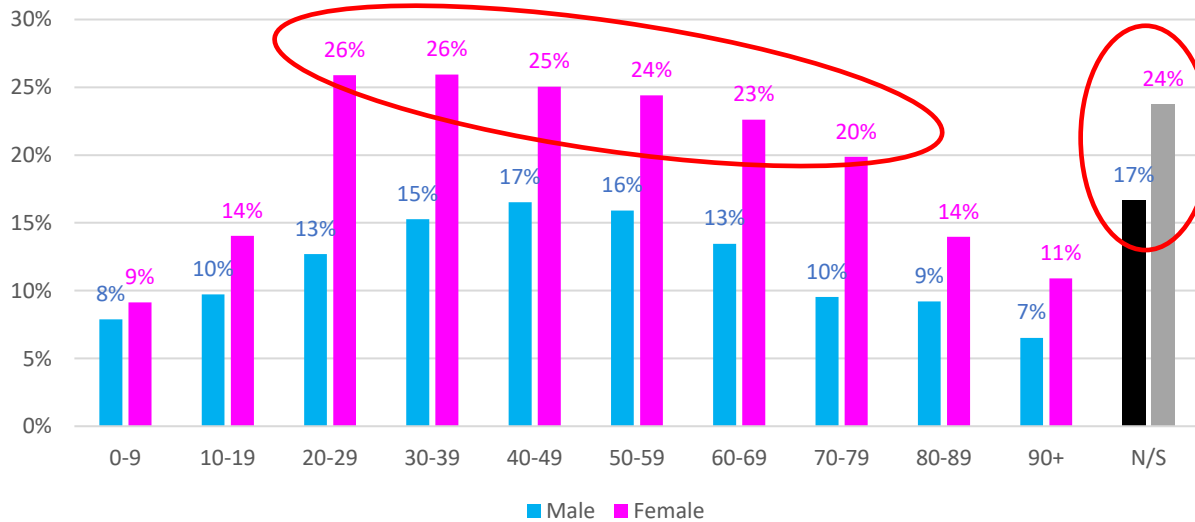
## EXPECTED REACTIONS



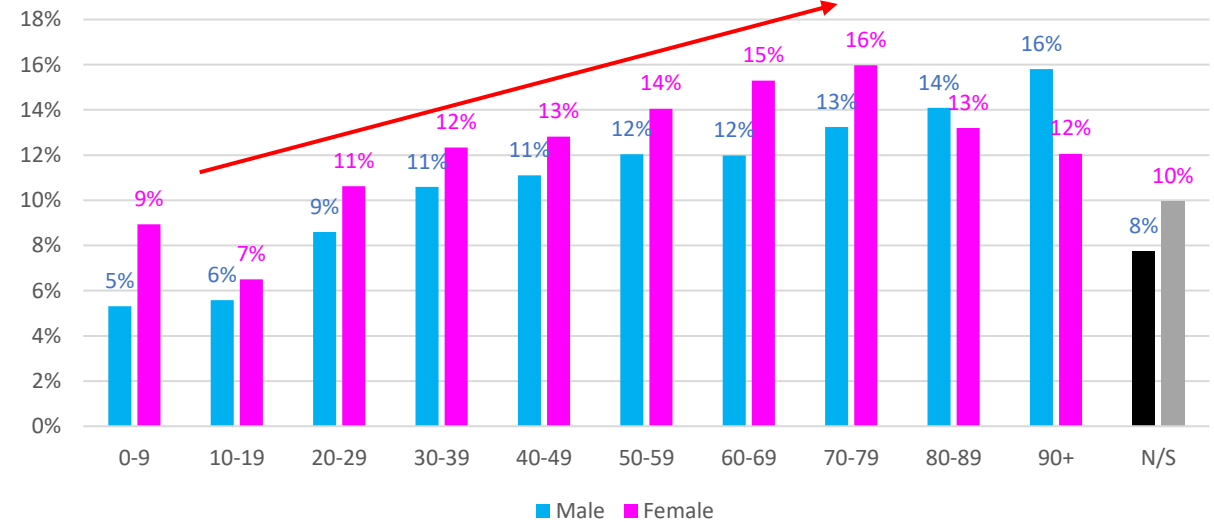
## Neurological - Headache



## Injection Site

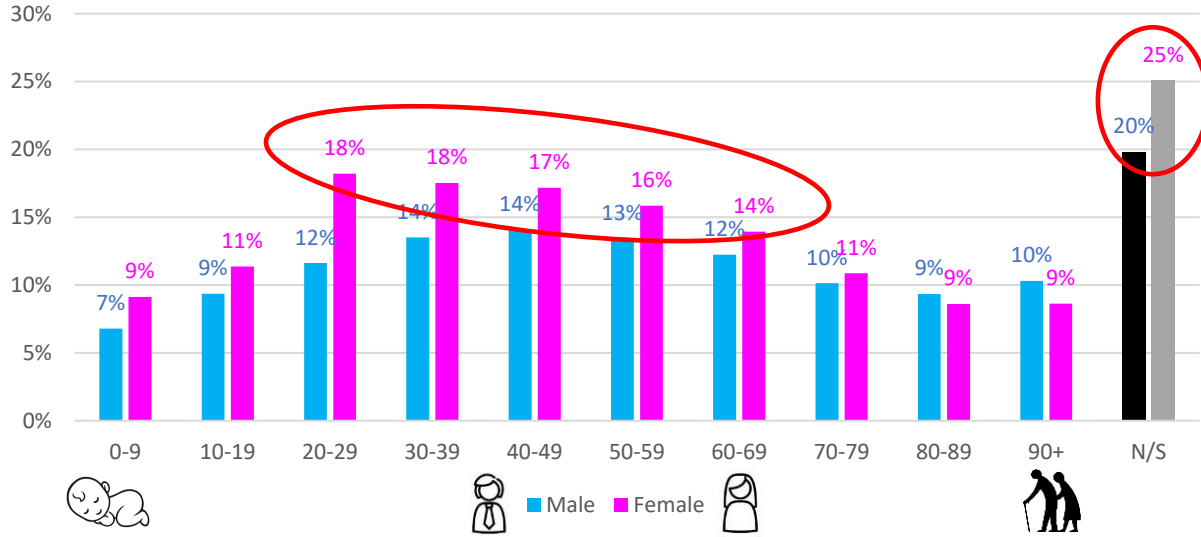


## Fatigue

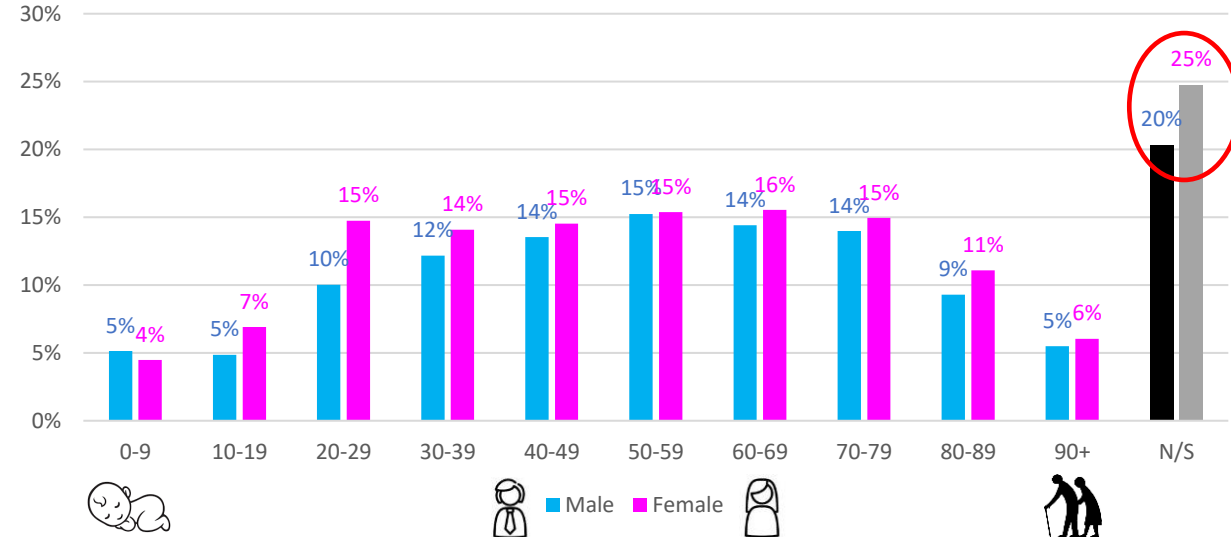


# Expected Reactions

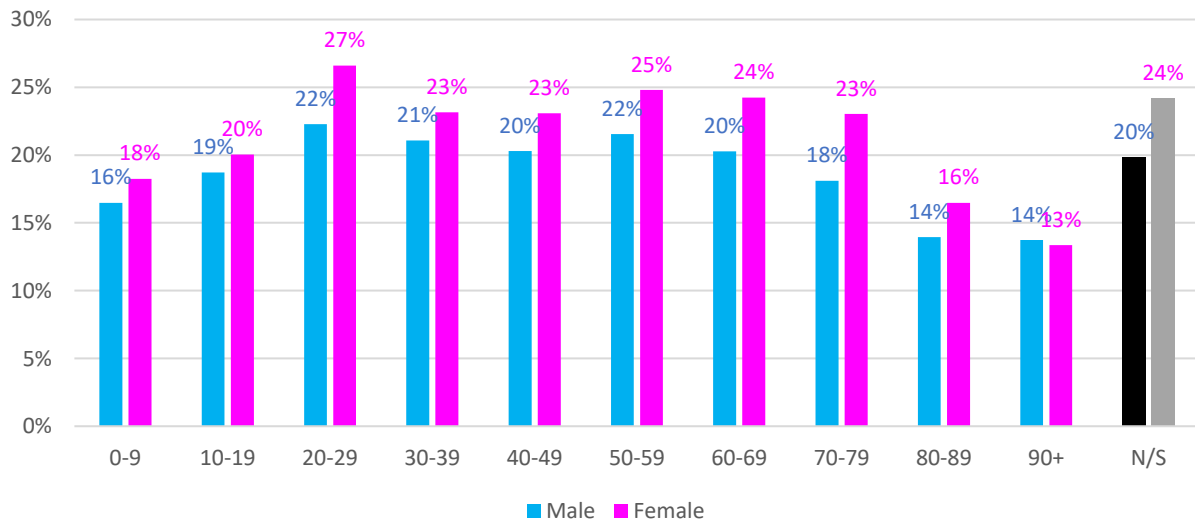
## Lethargy



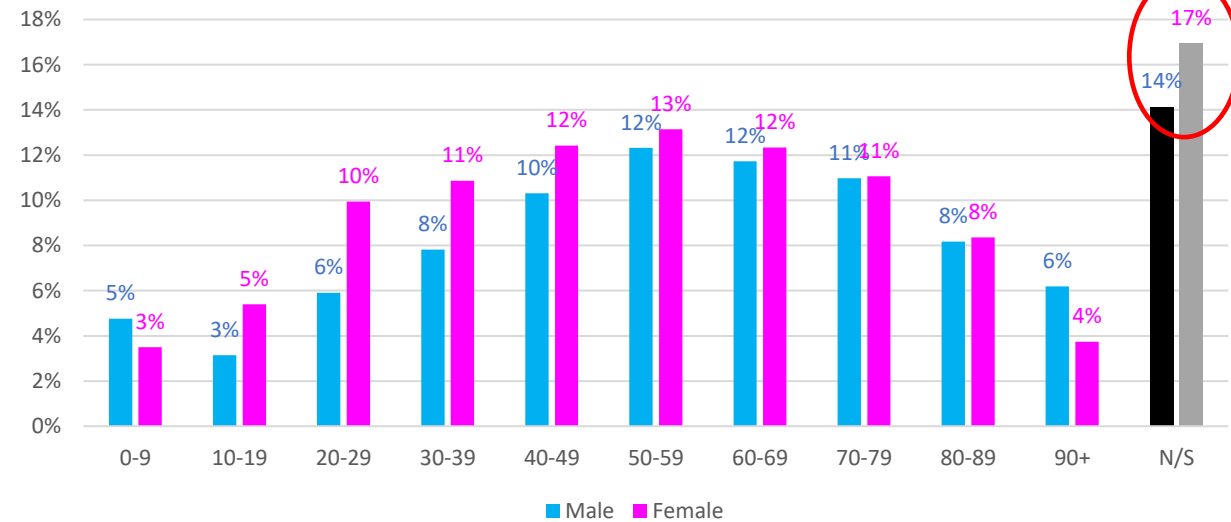
## MUSCLES/ SKELETON



## TEMPERATURE



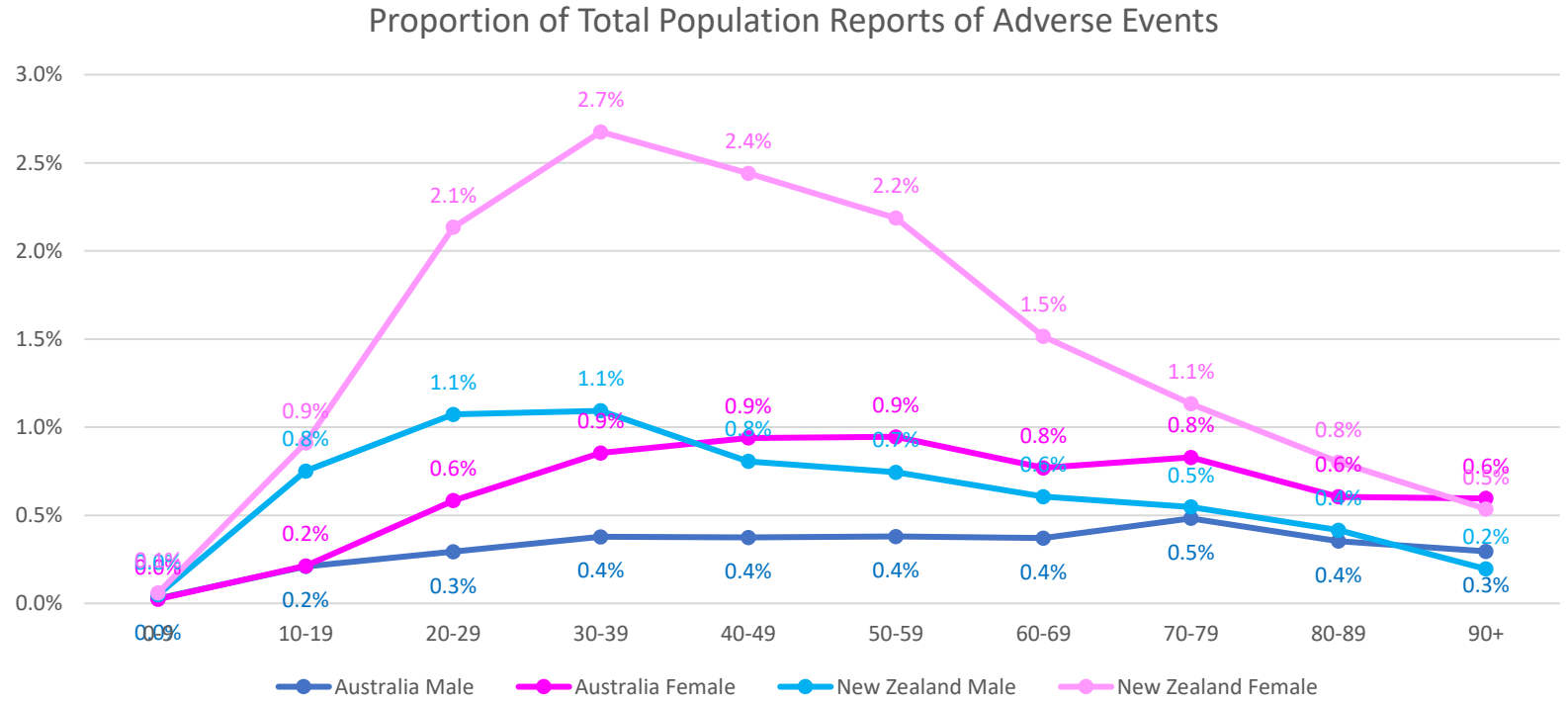
## PAIN/ SWELLING (general)



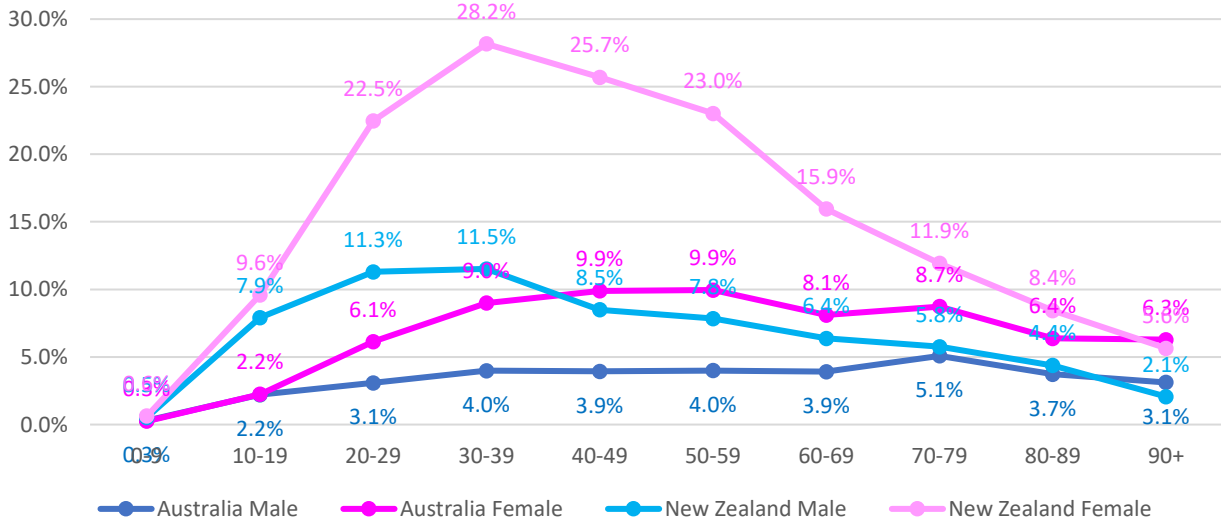
# Adverse Reaction Reports by Population

Australia	
Total Adverse Events Reports	122,580
~ Population	26,000,000

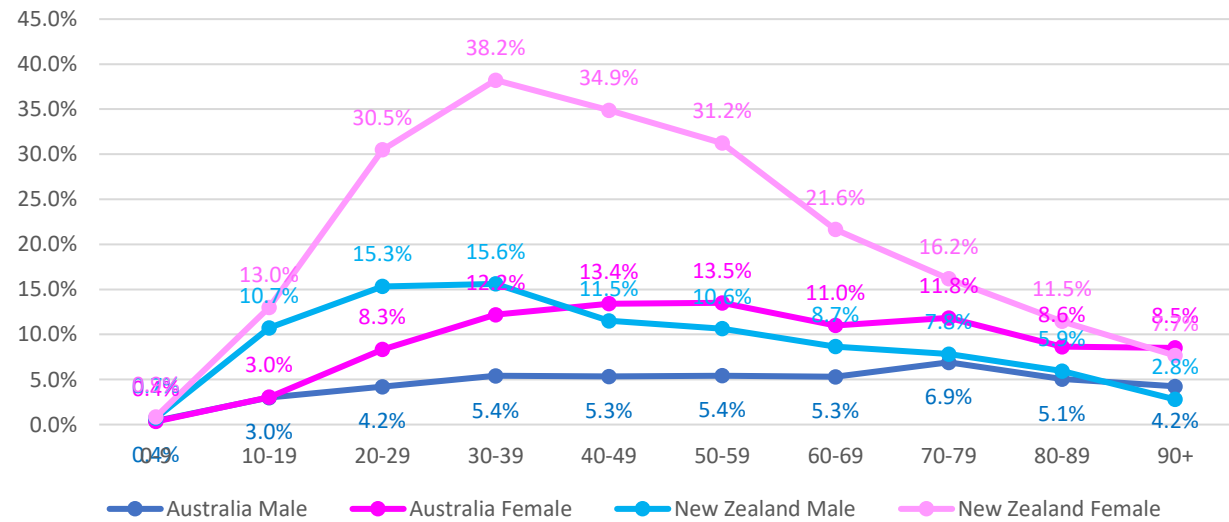
New Zealand	
Total Adverse Events Reports	58,229
~ Population	4,900,000



Proportion of Total Population Reports of Adverse Events  
Reporting rate = 10% Covid-19 Vaccination rate = 95%



Proportion of Total Population Reports of Adverse Events  
Reporting rate = 10% Covid-19 Vaccination rate = 70%

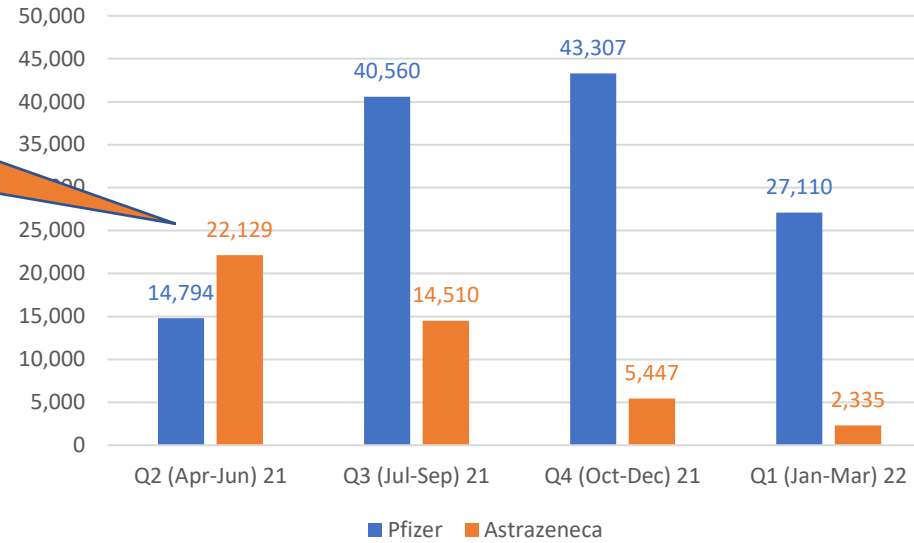


Pfizer

Vs

Astrazeneca

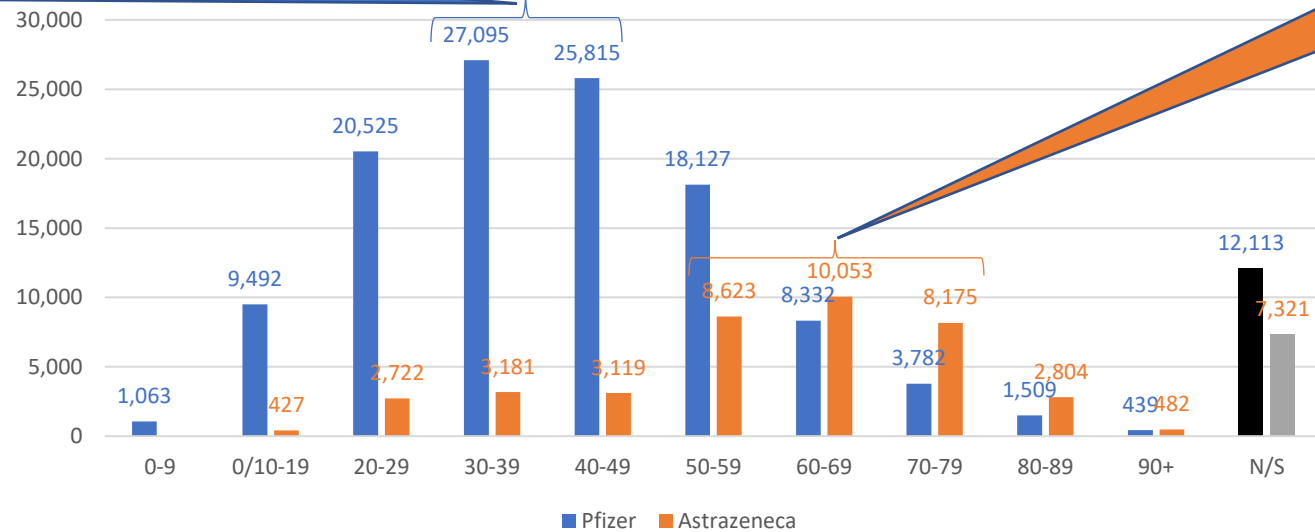
### Reports for Covid-19 Medicines Over Time



Half (50%) of reports related to AstraZeneca were made from Apr-Jun 2021.

41% of reports related to Pfizer were made by 30-49 year olds (27% of population)

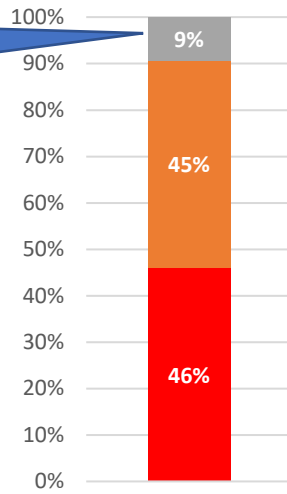
### Reports for Covid-19 Medicines by Age



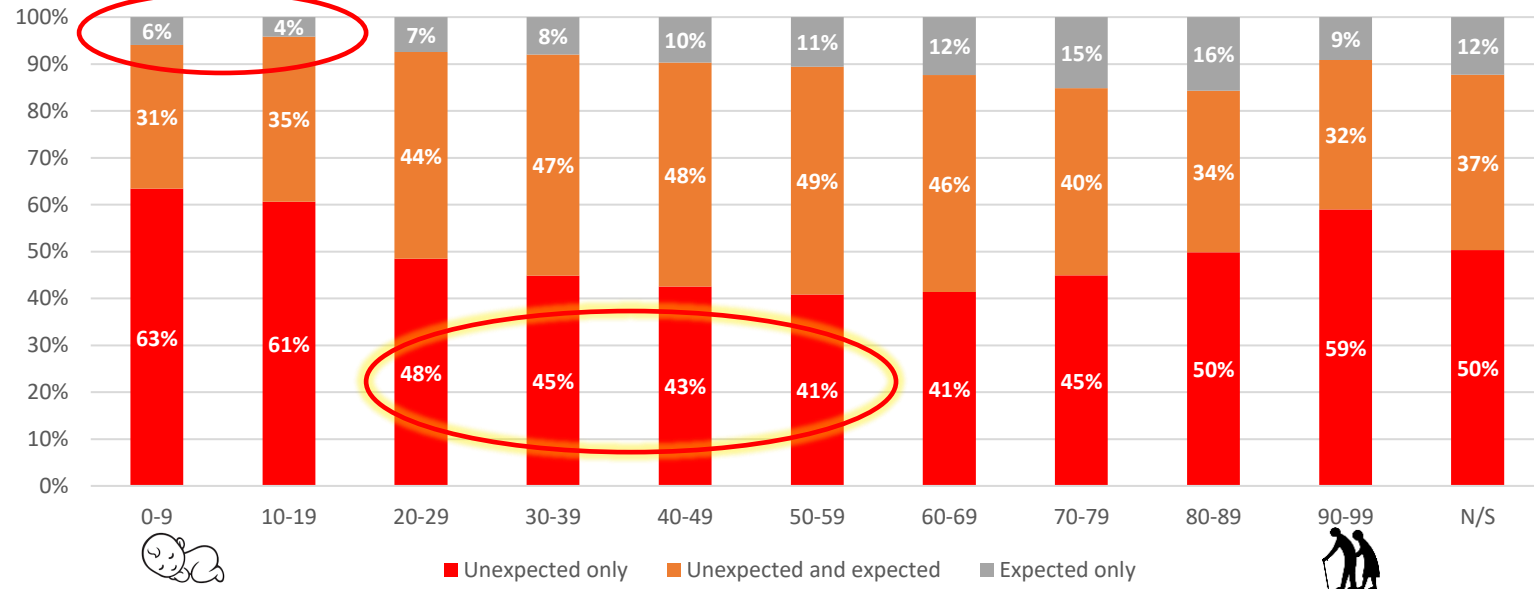
Over half (57%) of reports related to AstraZeneca were made by 50-79 year olds (30% of population)

9% of Reaction Reports for Pfizer reported ONLY an 'Expected' Reaction

Pfizer Reactions

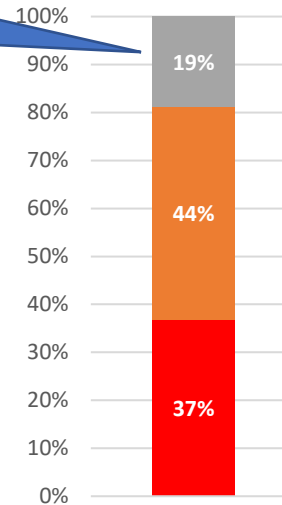


Pfizer Reactions Reported by Age

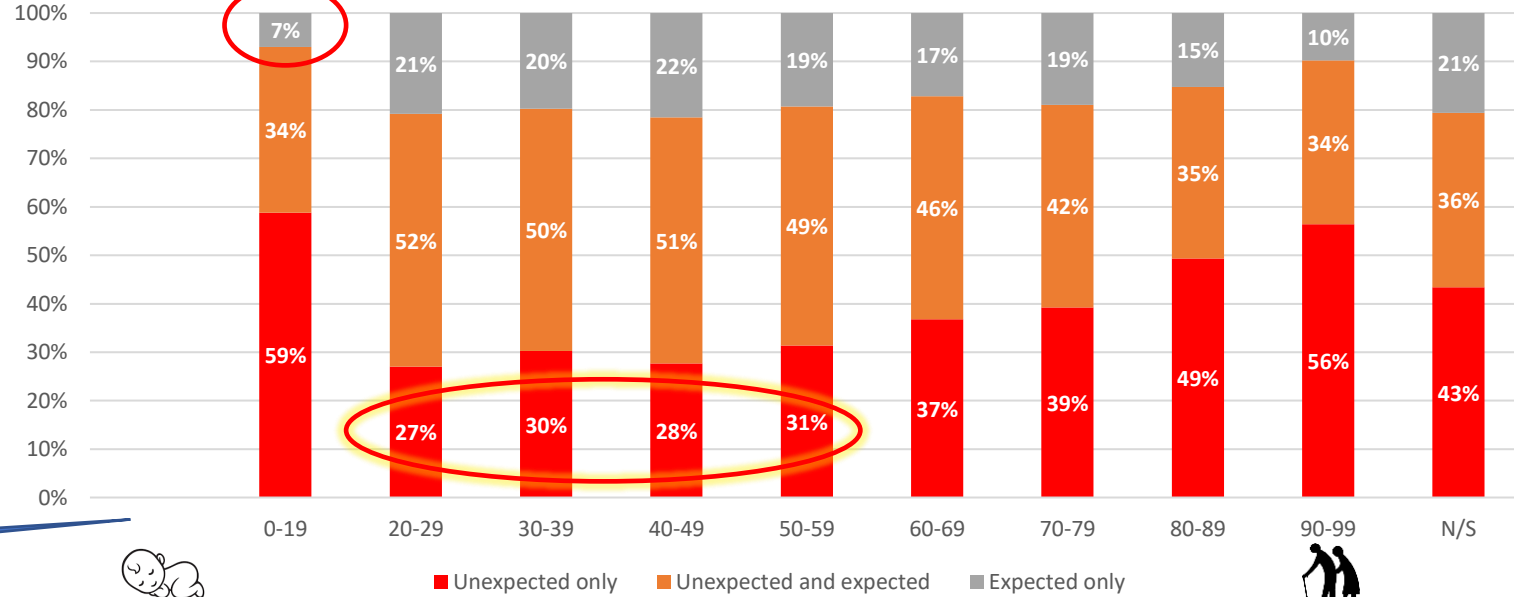


19% of Reaction Reports for AstraZeneca reported ONLY an 'Expected' Reaction

Astra Reactions



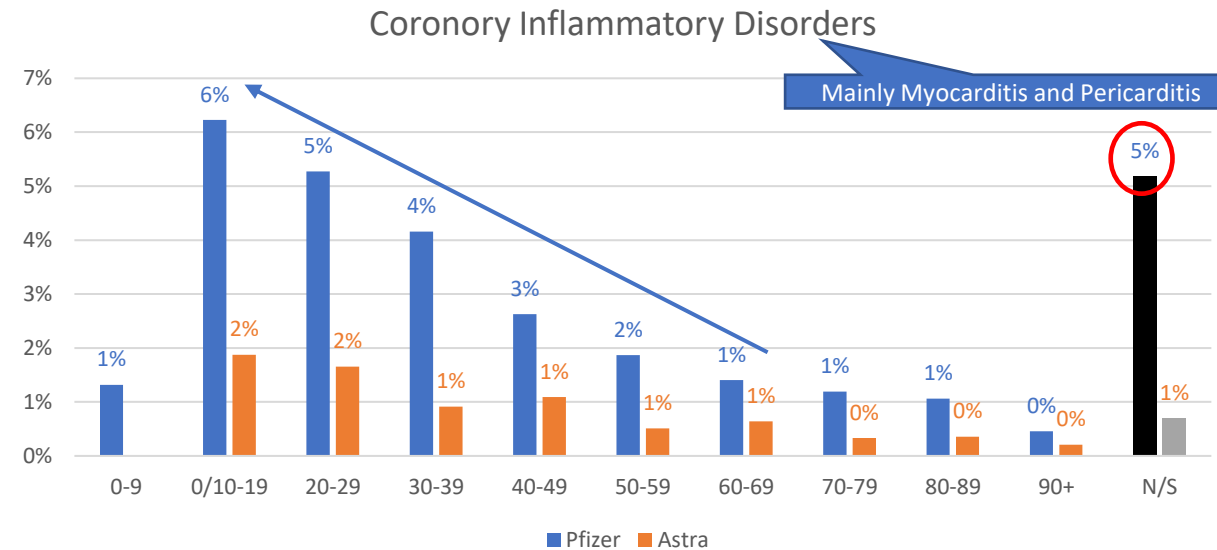
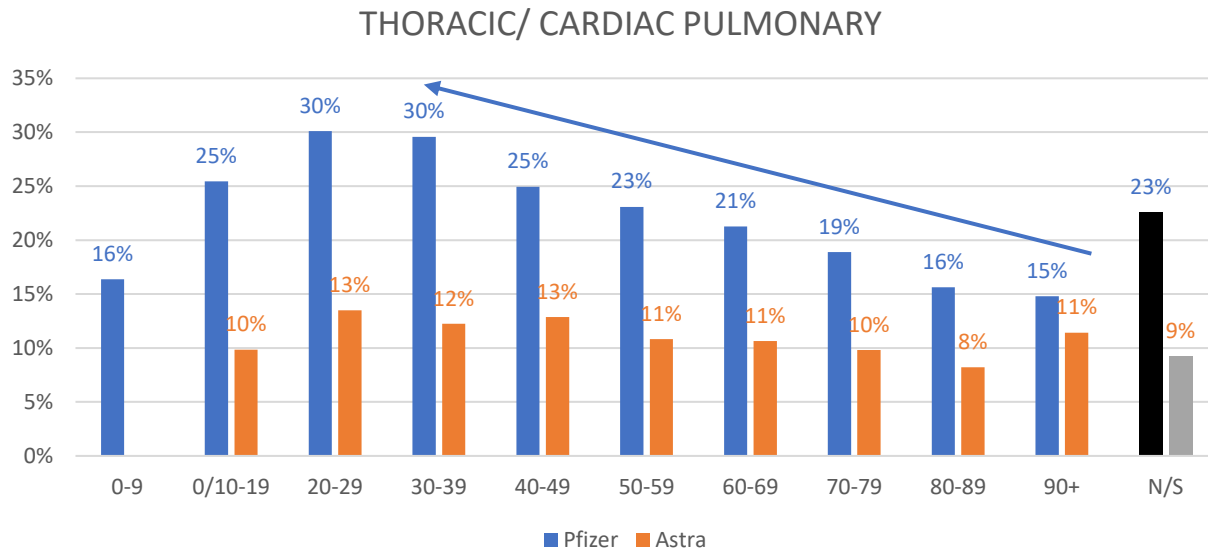
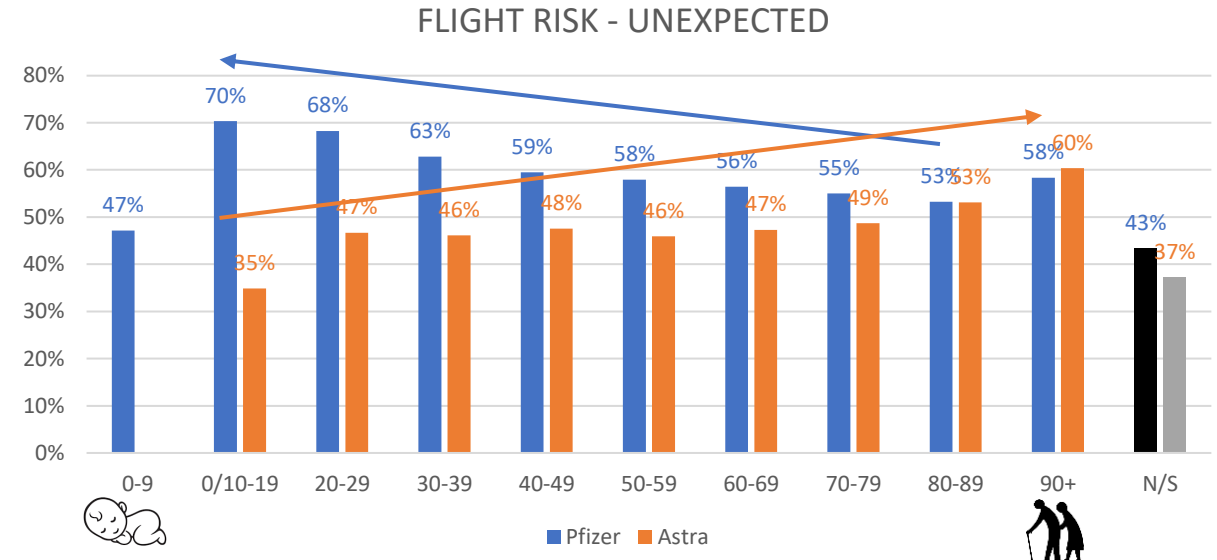
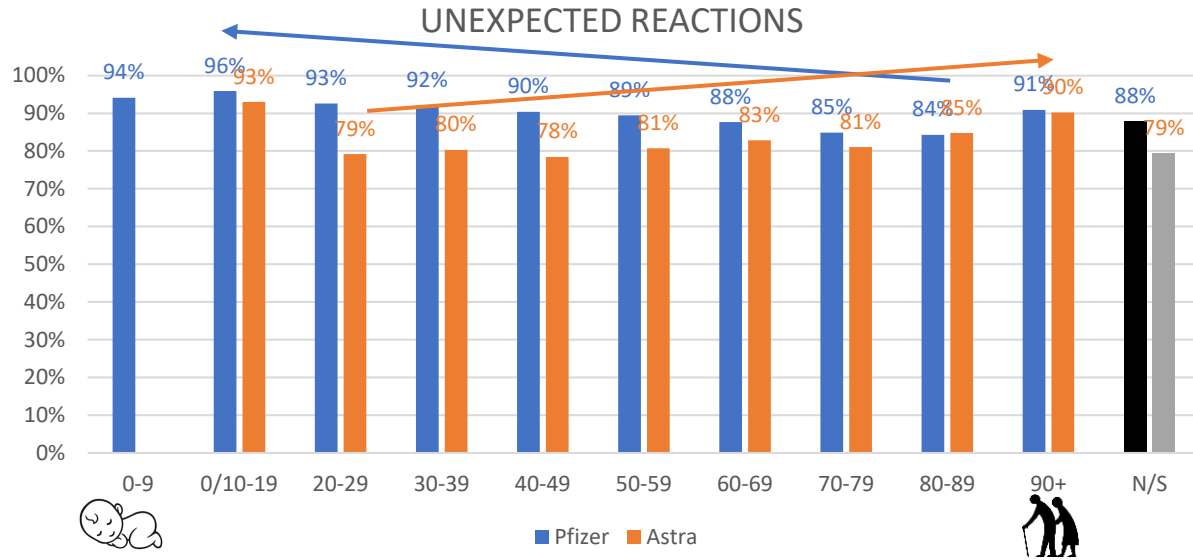
Astrazeneca Reactions Reported by Age



0-9 years grouped with 10-19 years for AstraZeneca, due to low numbers

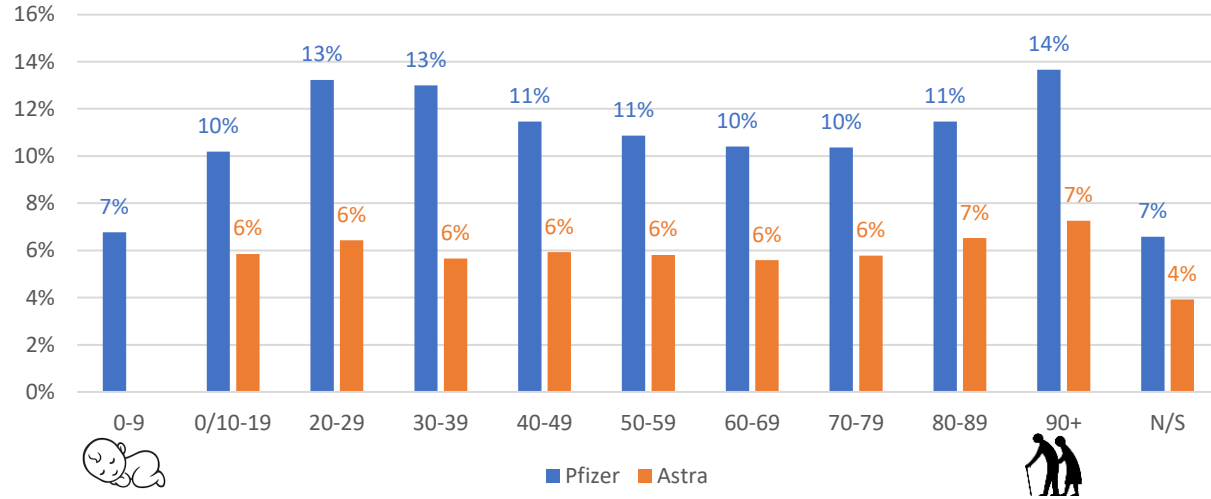


# Flight Risk Reactions - Unexpected

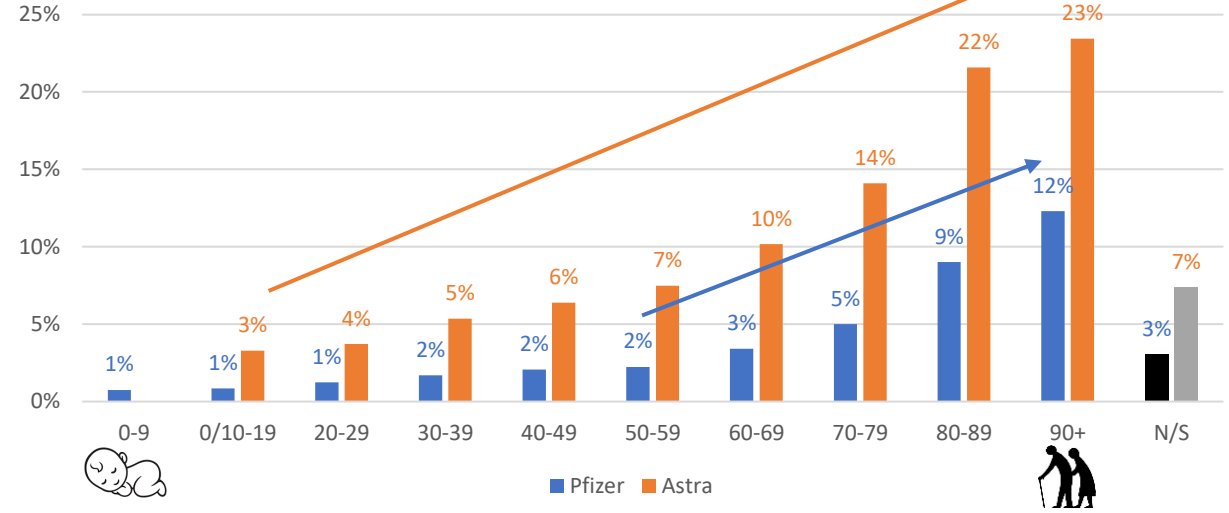


# Flight Risk Reactions - Unexpected

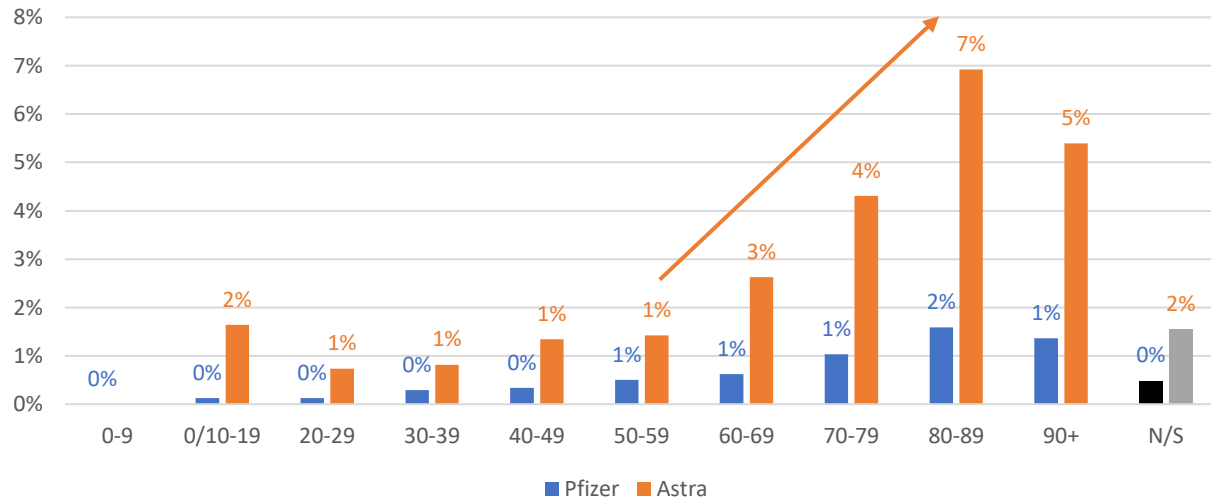
## Breathing (RESP)



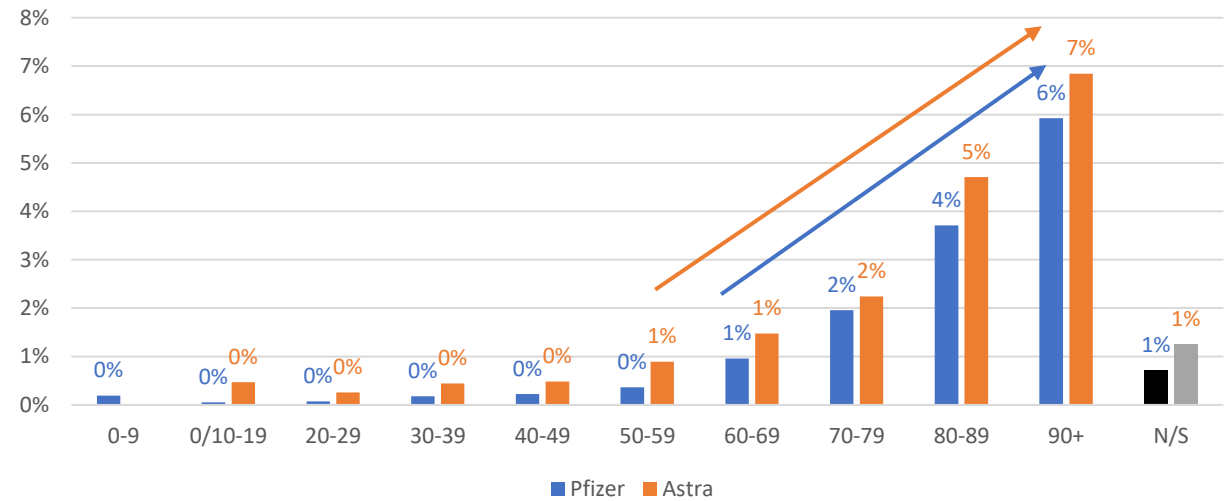
## CLOTS/ STROKE/ BLOOD



## Pulmonary embolism

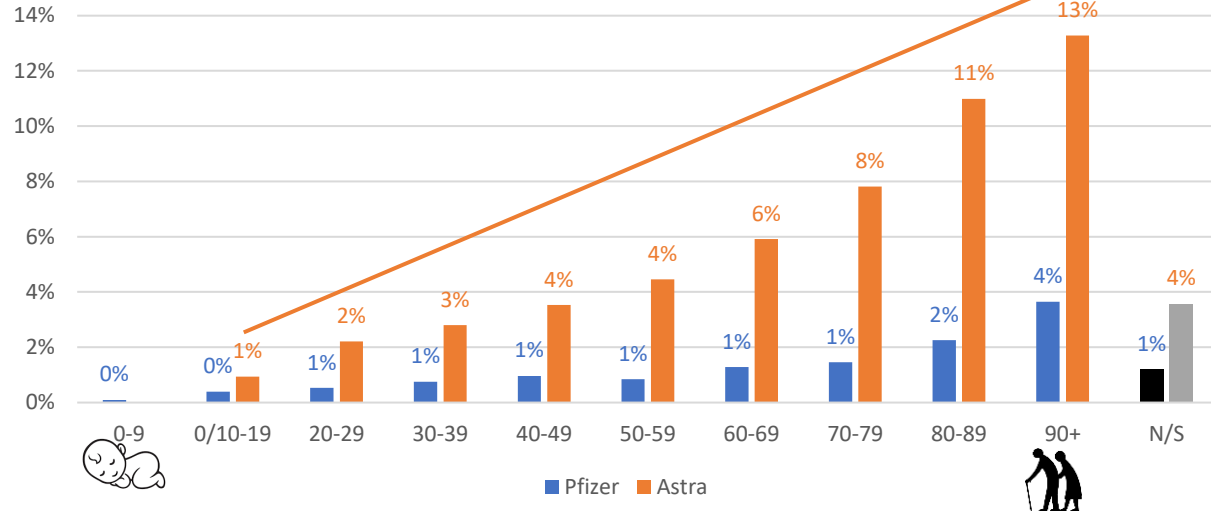


## Stroke

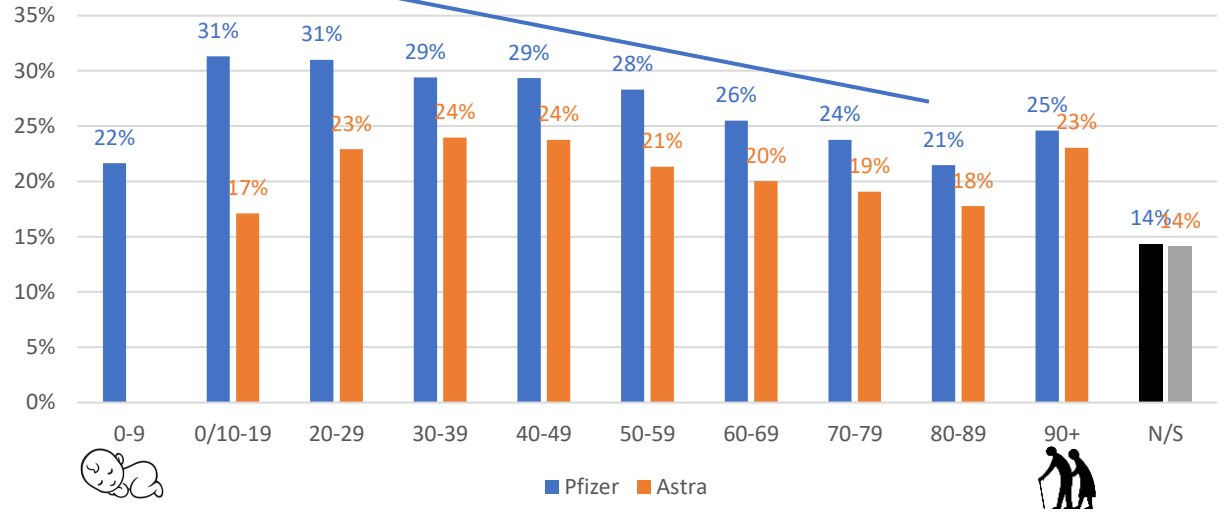


# Flight Risk Reactions - Unexpected

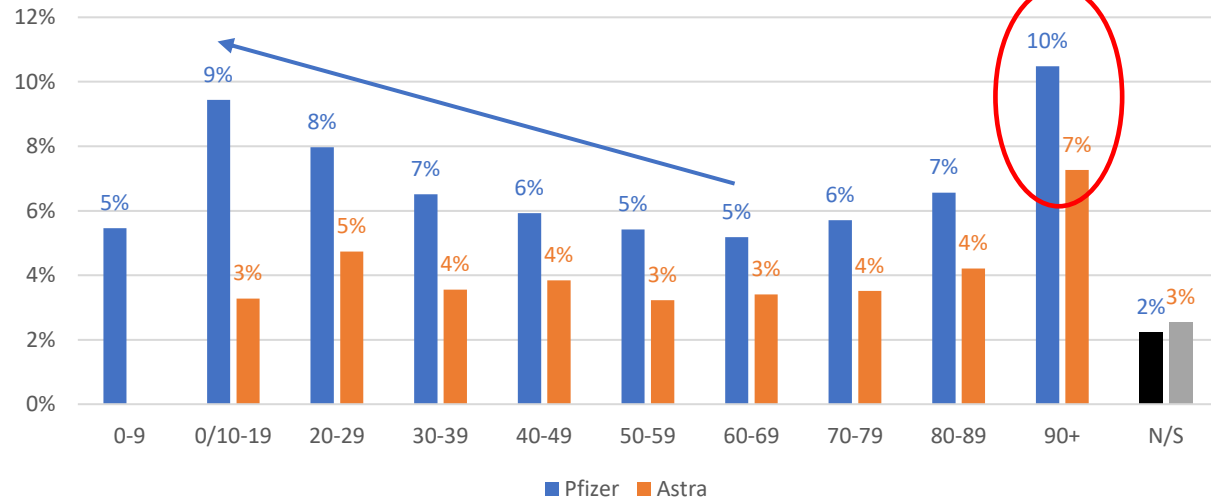
## Thrombosis



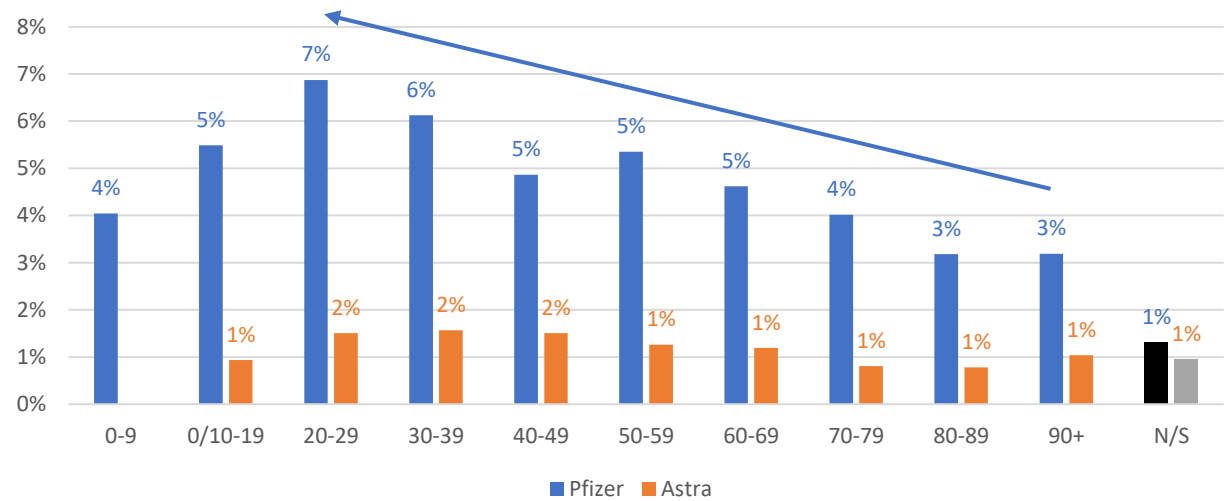
## CONSCIOUSNESS/ NEUROLOGICAL (ex Headache)



## Mental Impairment

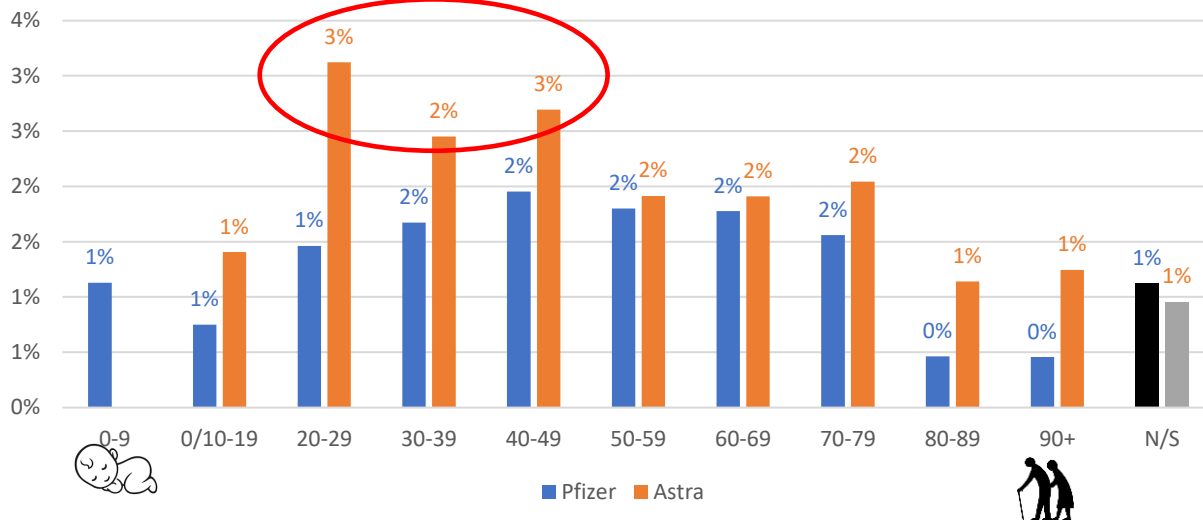


## Mood

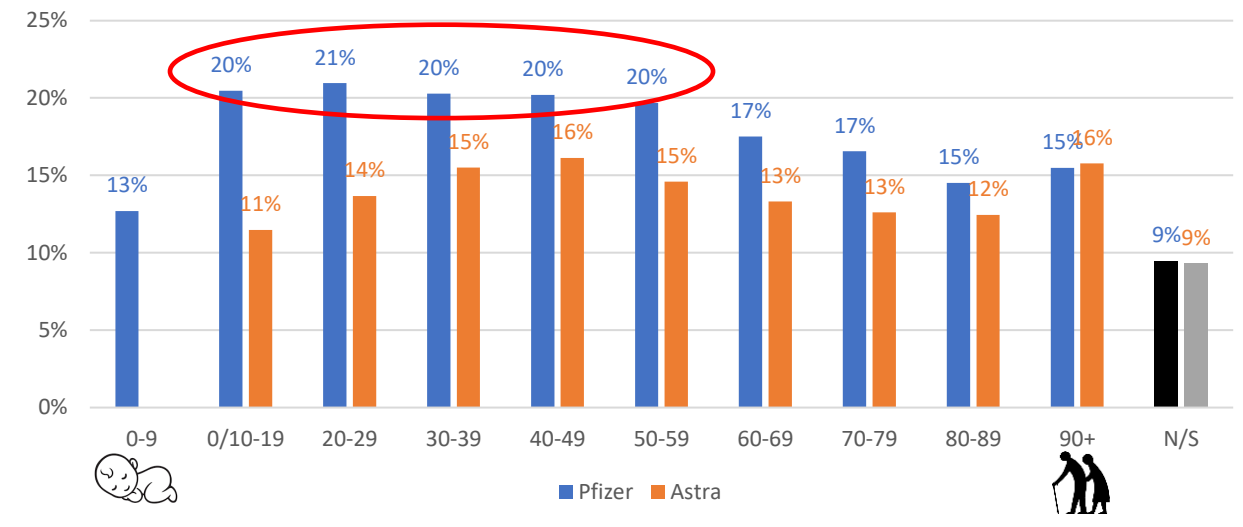


# Flight Risk Reactions - Unexpected

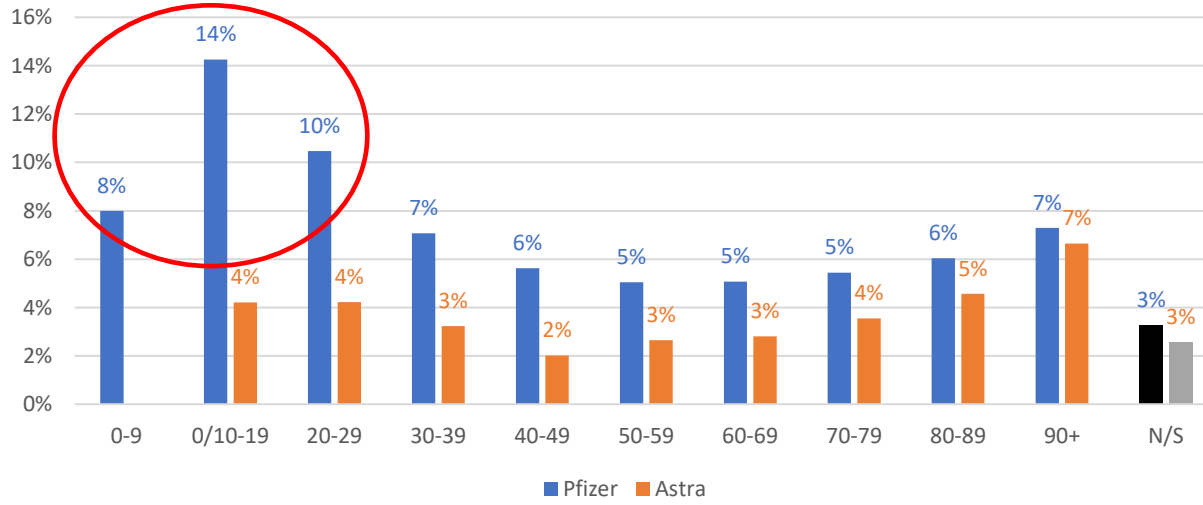
## Sleep



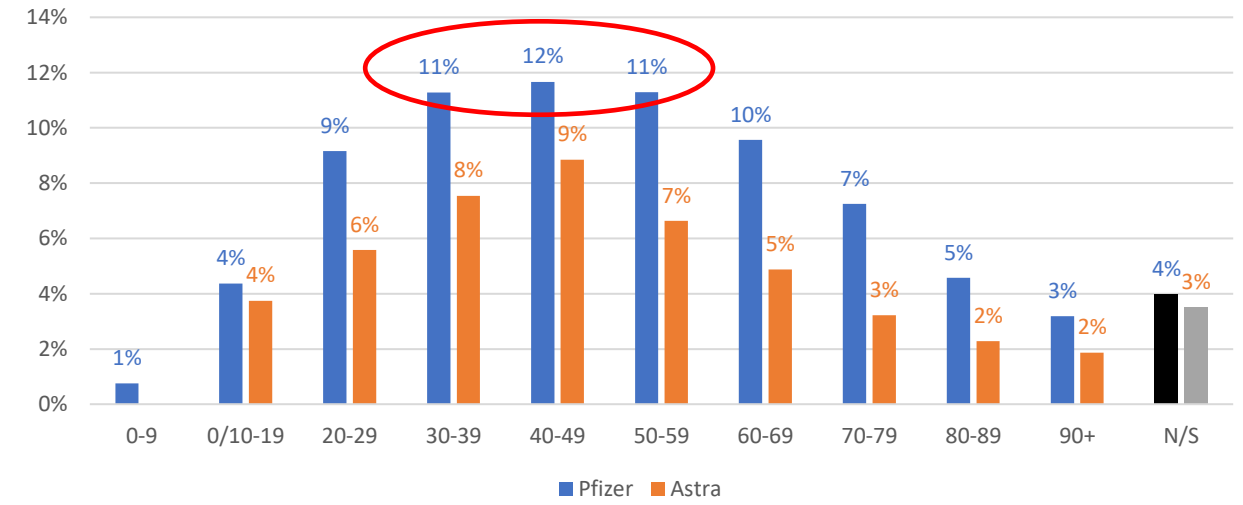
## OTHER NEUROLOGICAL



## Balance/ Consciousness

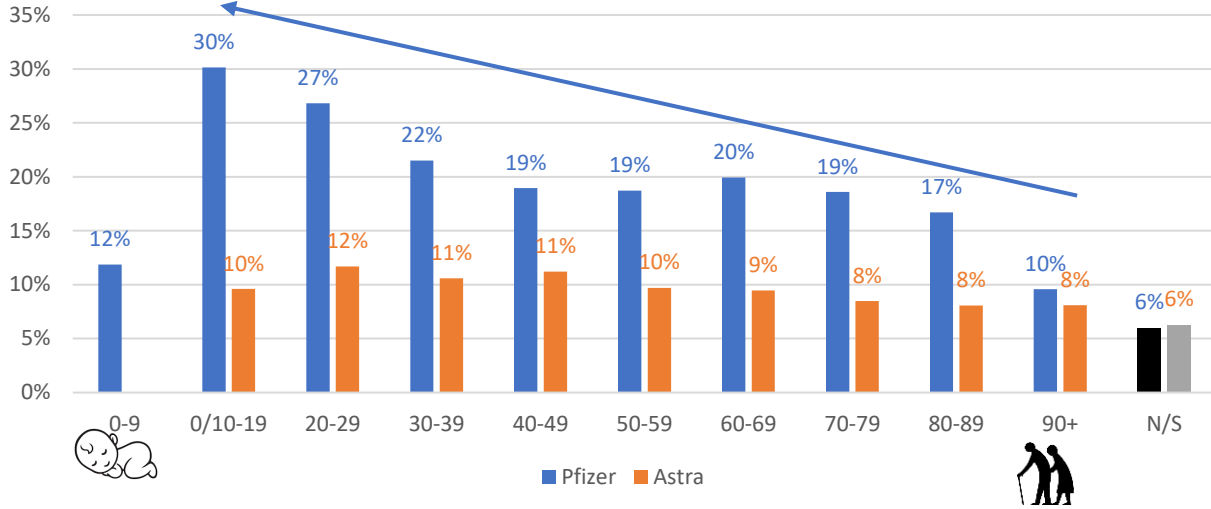


## Numbness

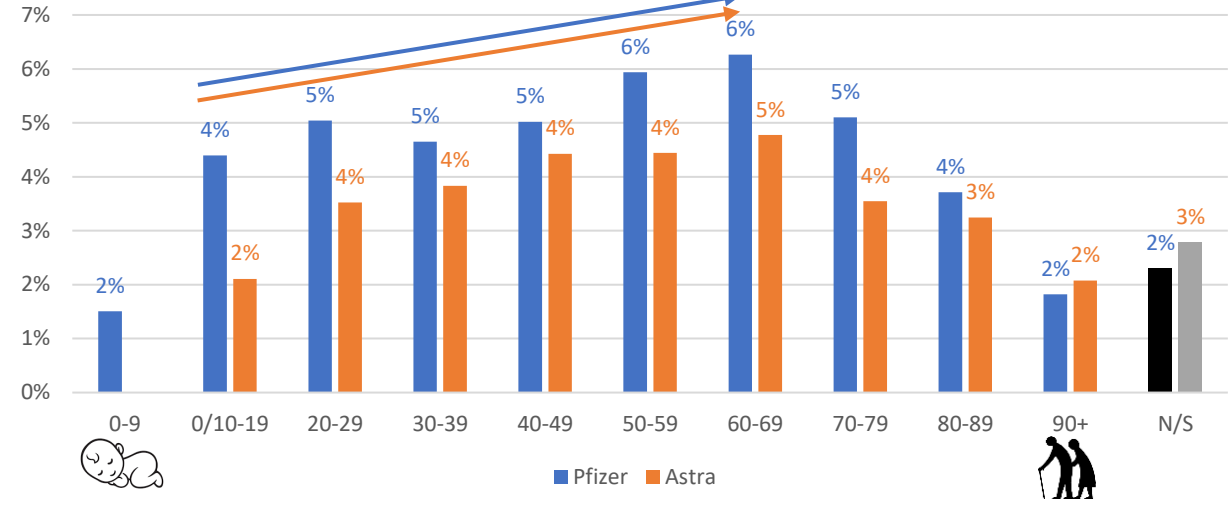


# Flight Risk Reactions - Unexpected

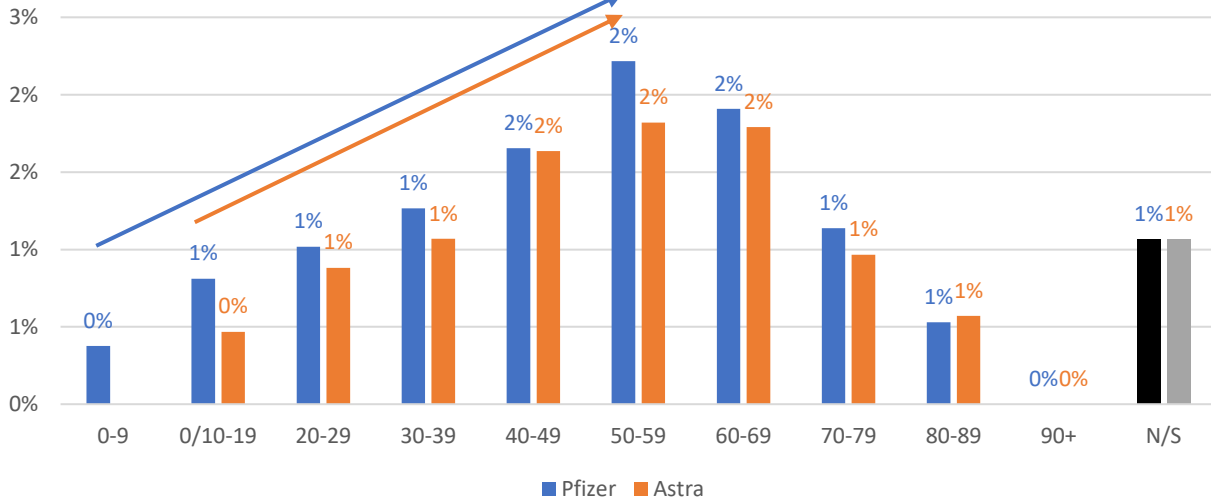
## Vertigo



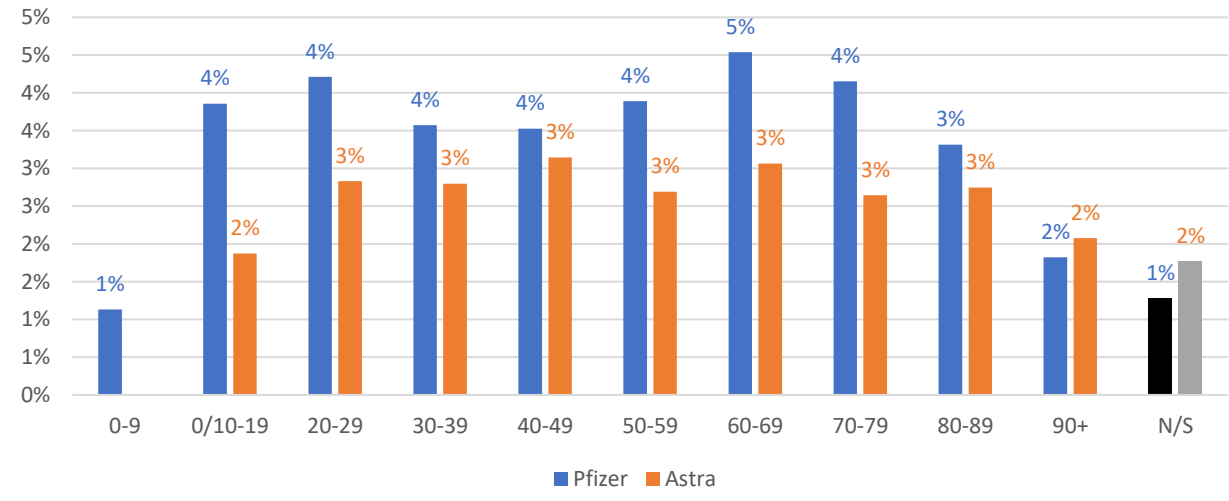
## HEARING/ VISION



## Deafness

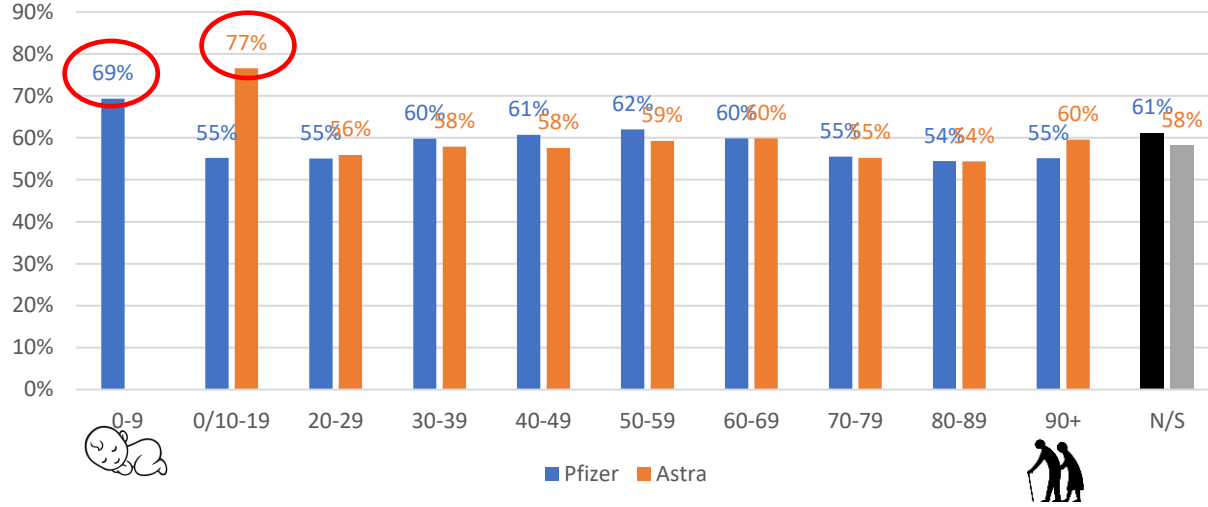


## Vision

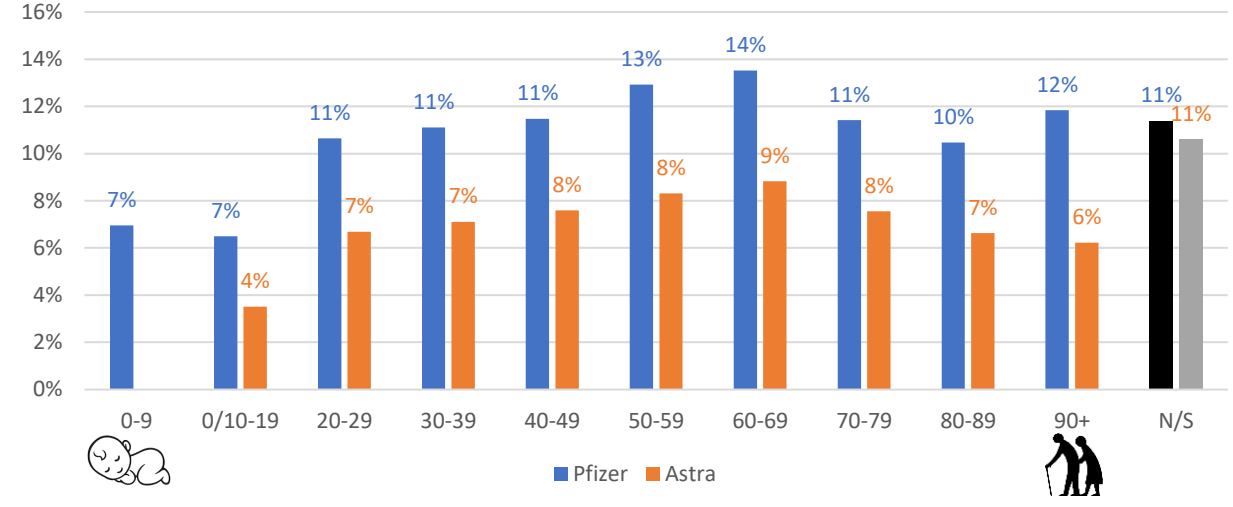


# Other Unexpected Reactions

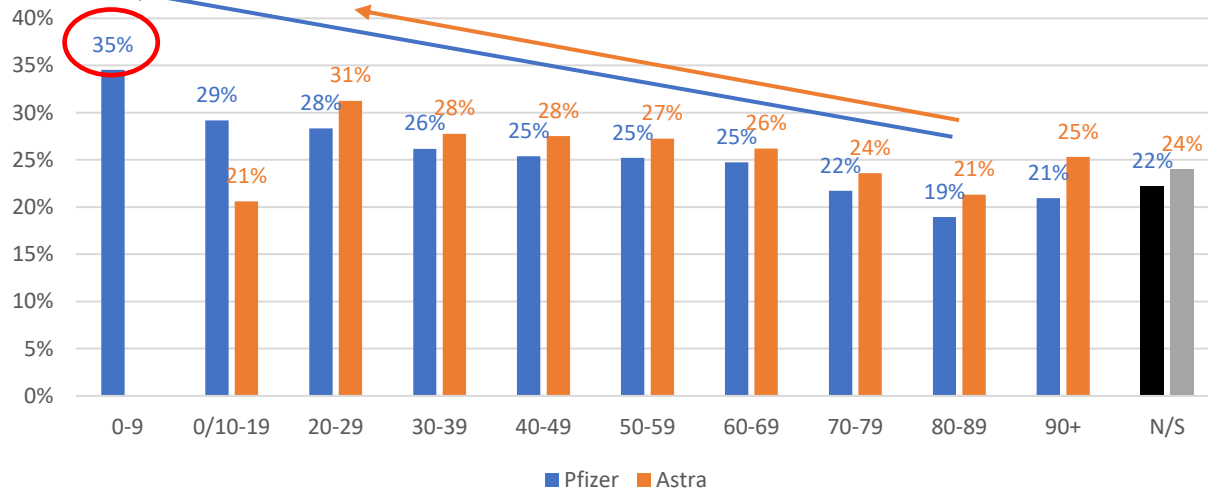
## OTHER UNEXPECTED REACTIONS



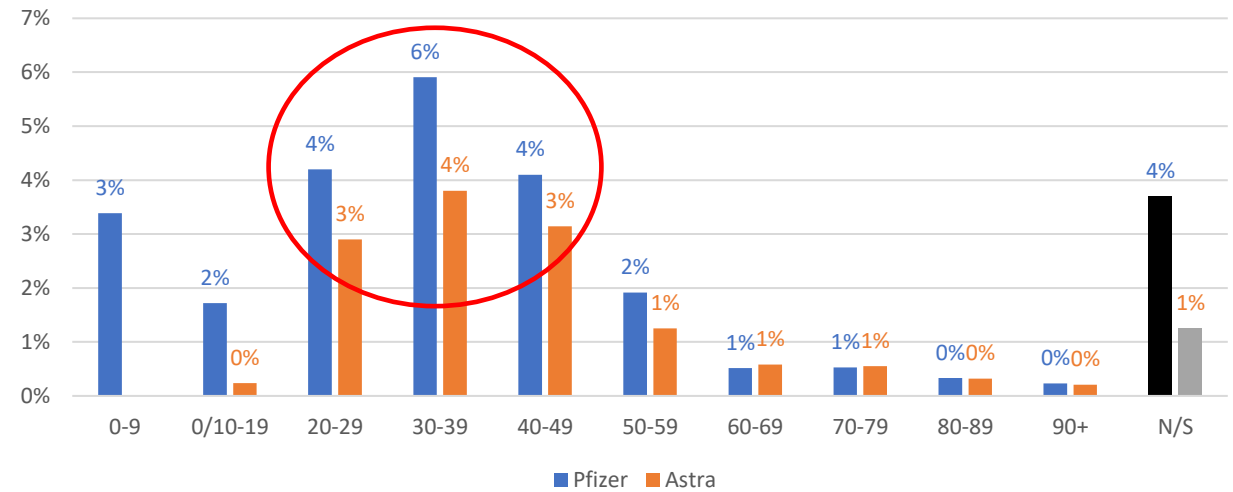
## RESPIRATORY TRACT (ex Breathing)



## GASTROINTESTINAL DISORDERS

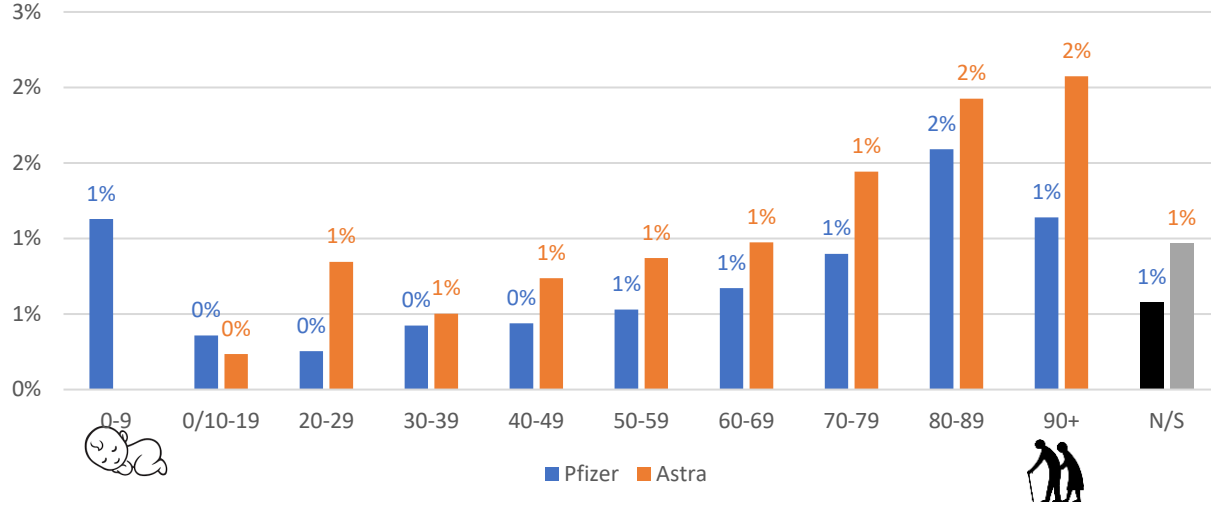


## REPRODUCTIVE

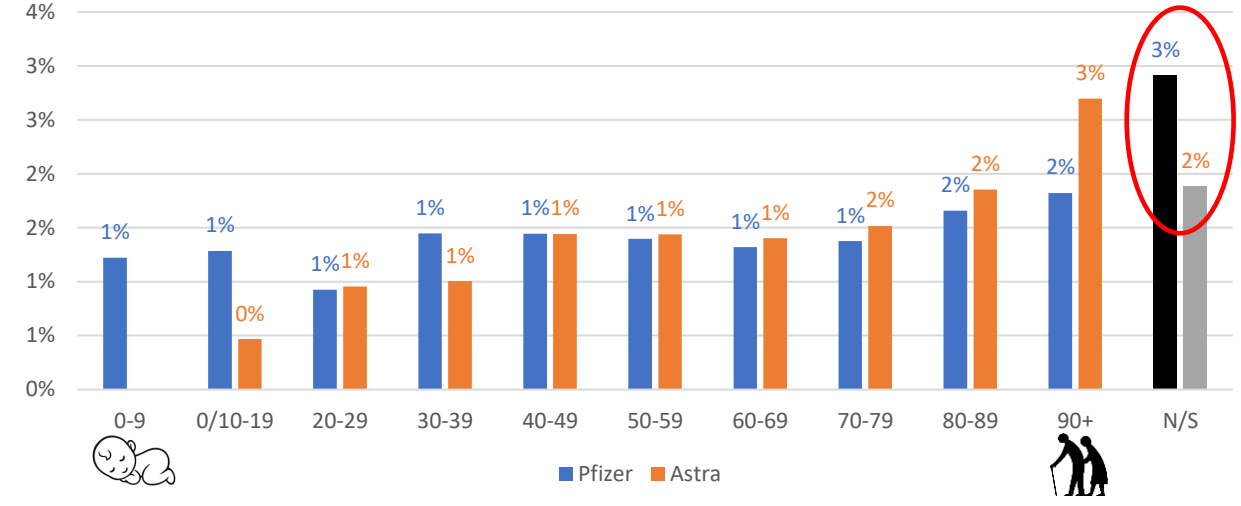


# Other Unexpected Reactions

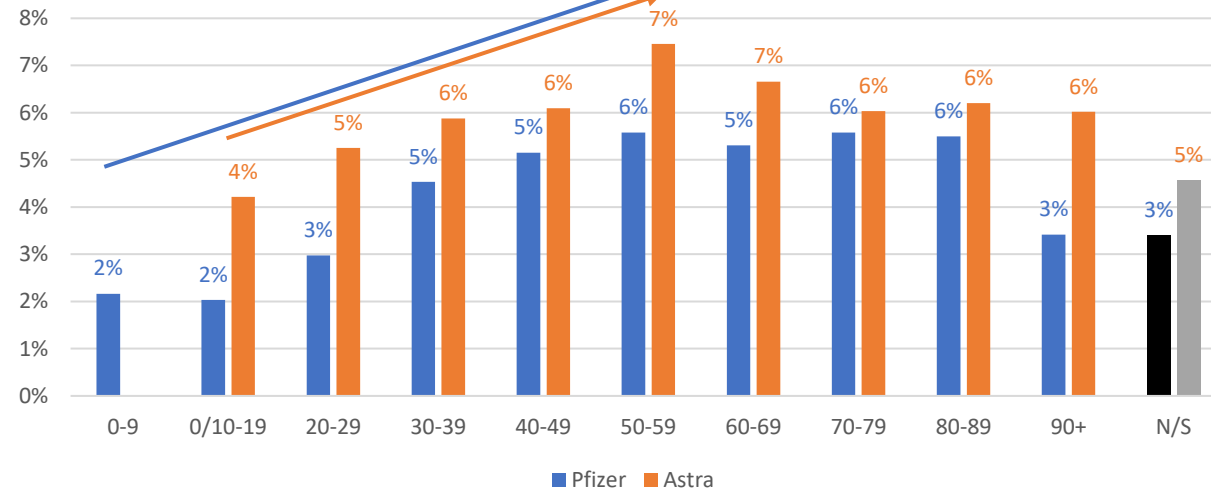
## URINARY TRACT



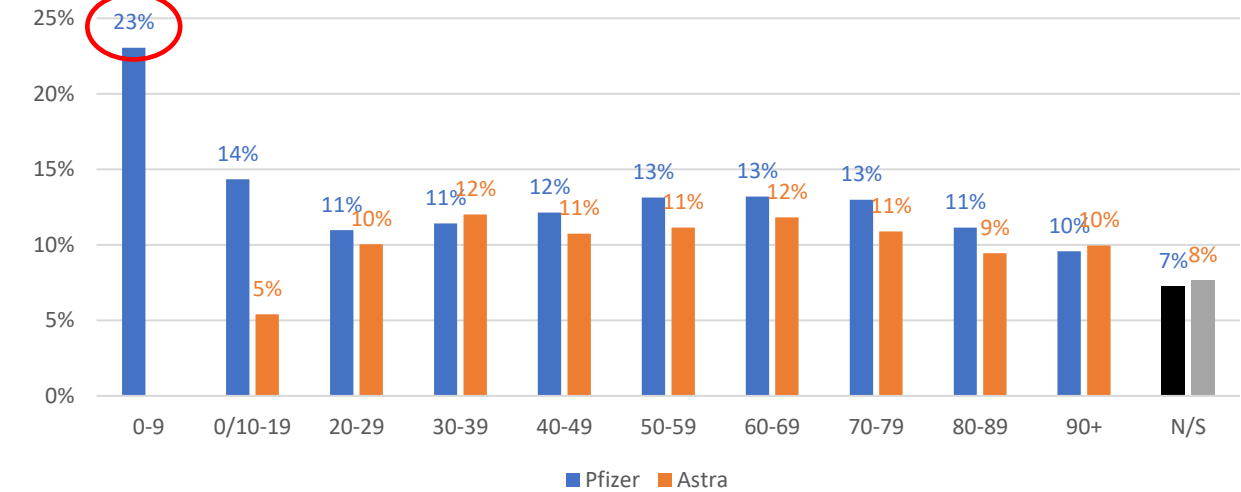
## ORGANS/ GLANDS



## EXTREMITIES

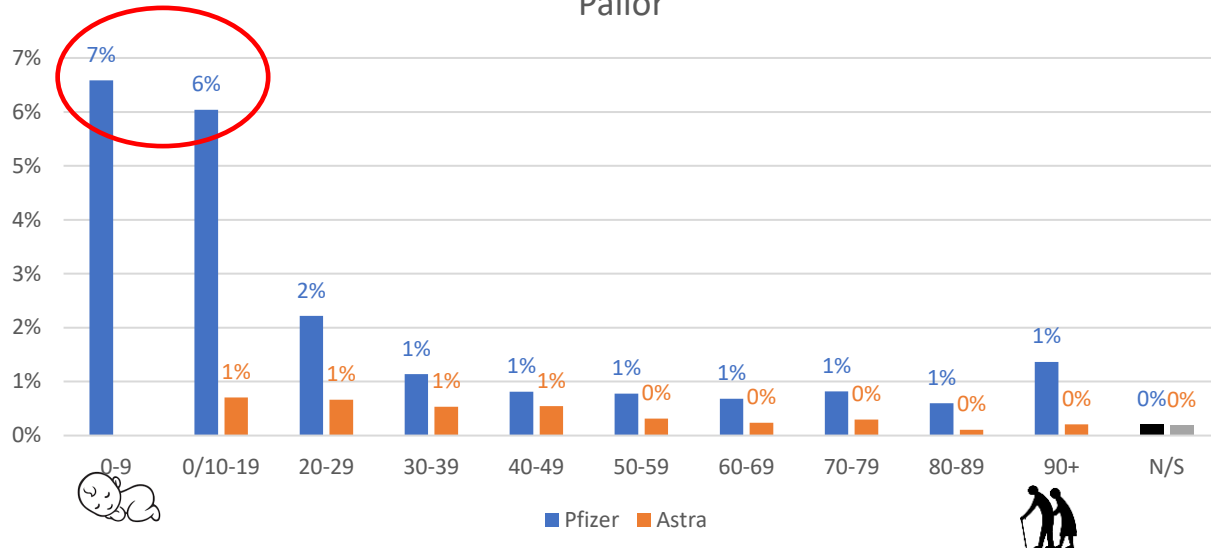


## SKIN

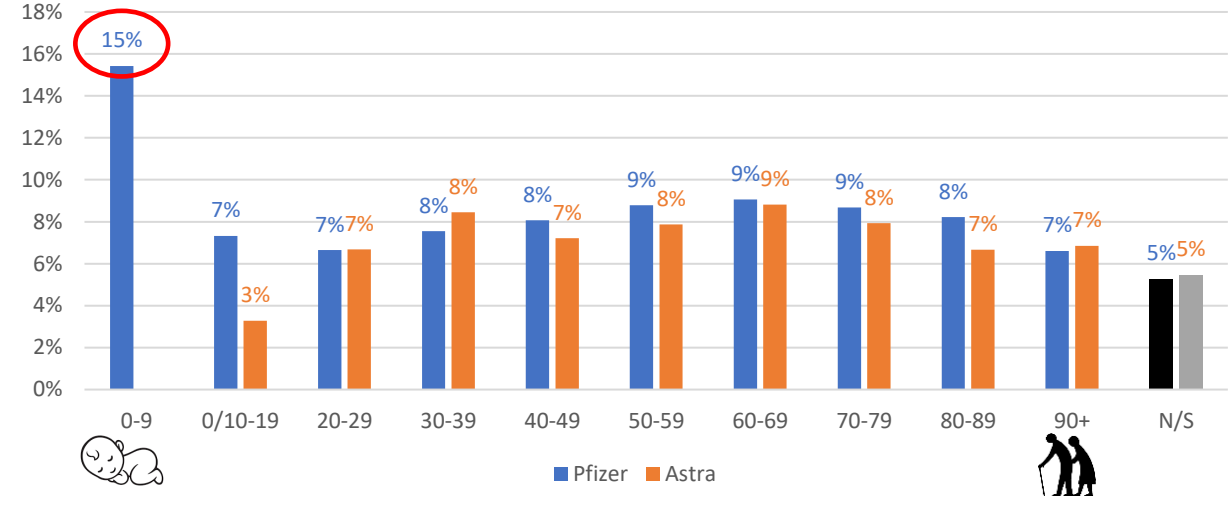


# Other Unexpected Reactions

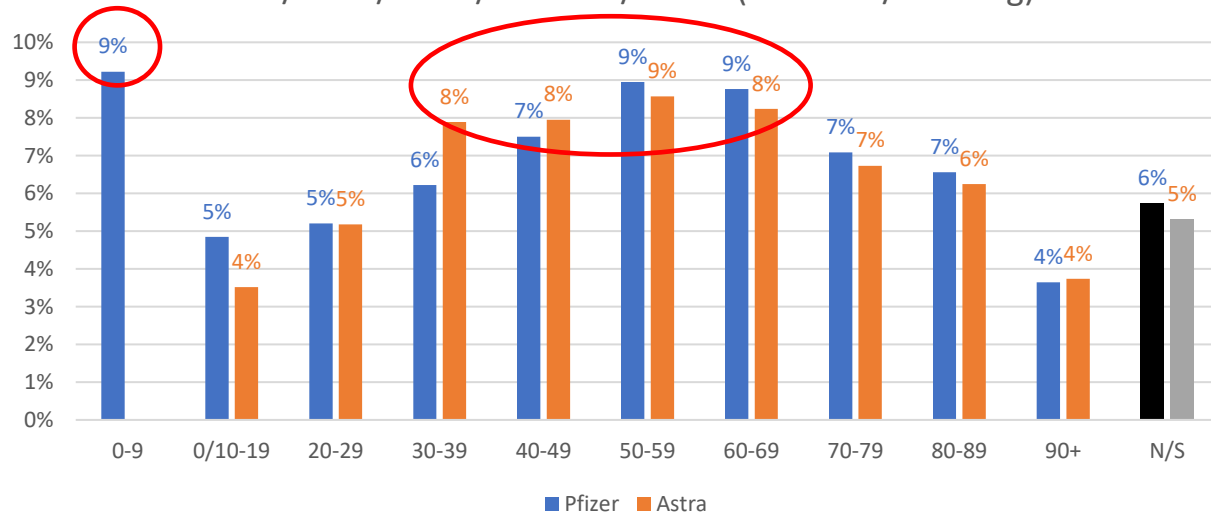
Pallor



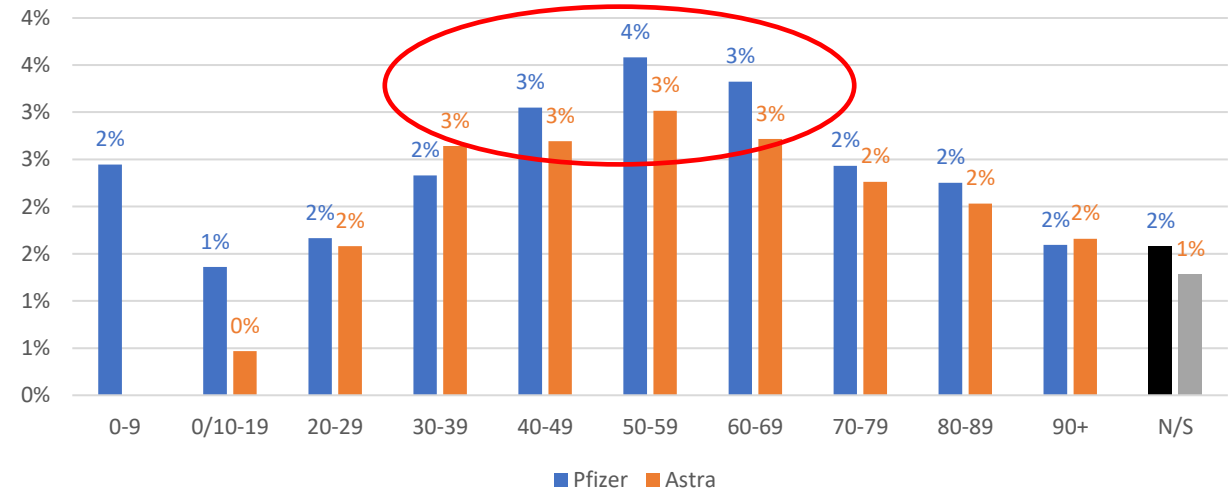
Rash



FACE/ EYES/ EARS/ MOUTH/ NOSE (ex Vision/ Hearing)



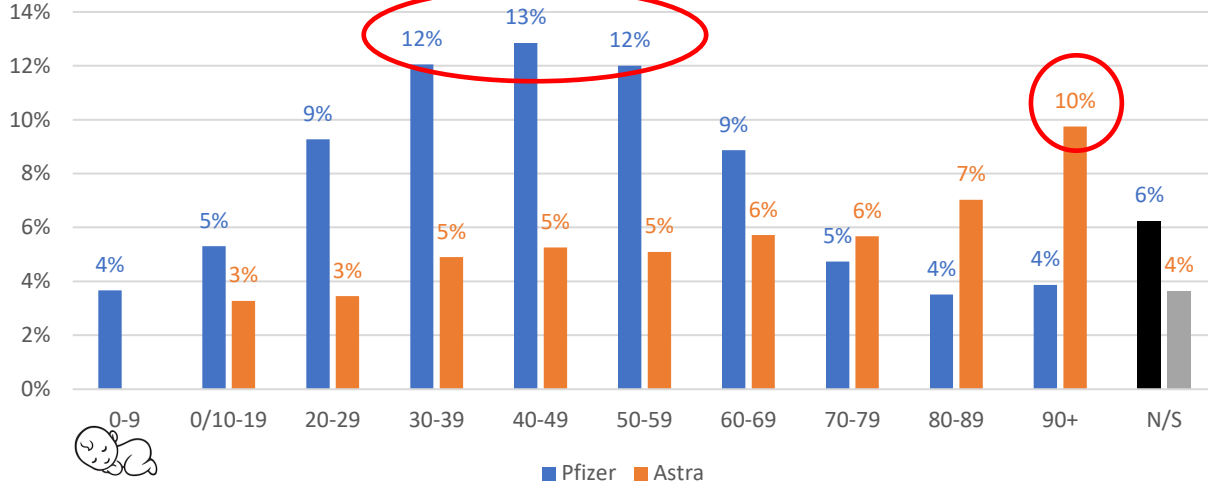
Mouth



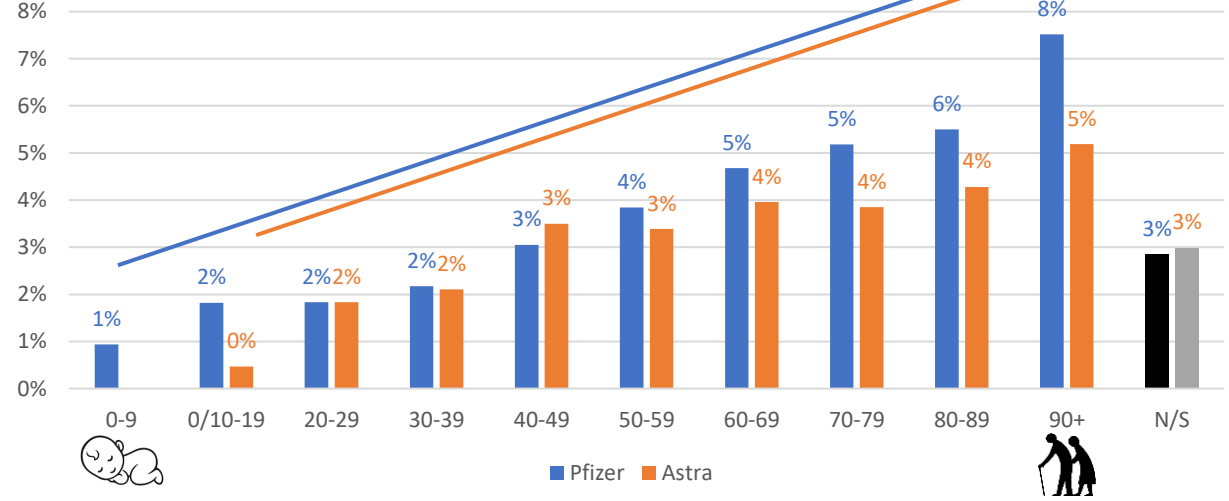


# Other Unexpected Reactions

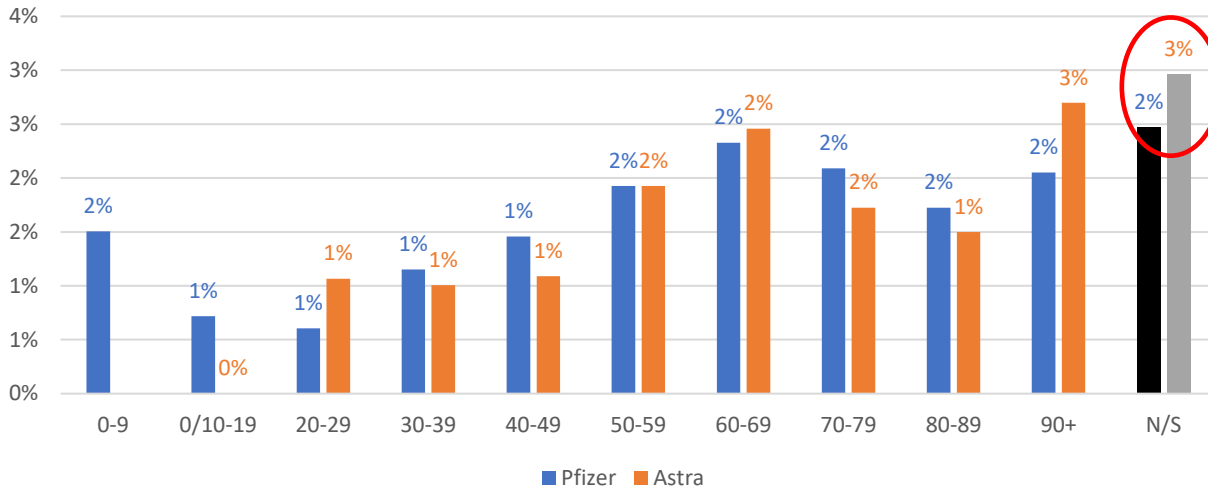
## AUTOIMMUNE SYMPTOMS



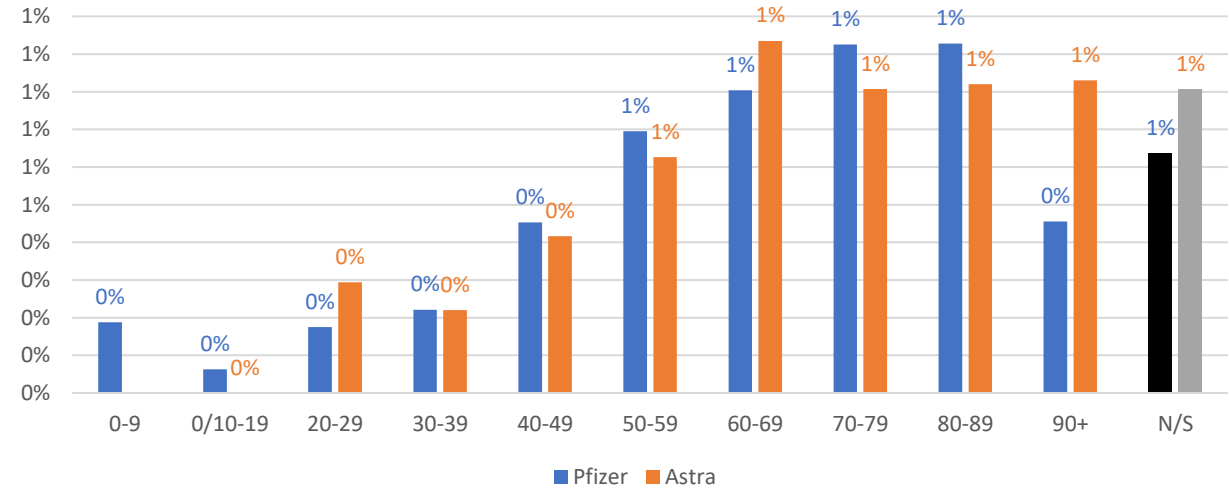
## BLOOD PRESSURE/ BLOODS



## INFECTION



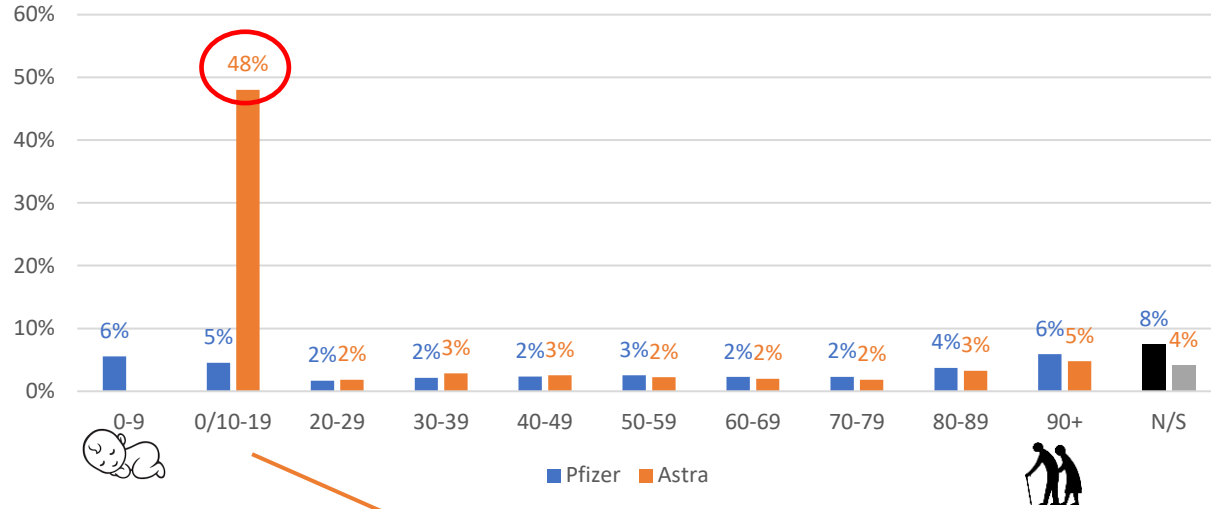
## PAIN/ SWELLING (ex general)



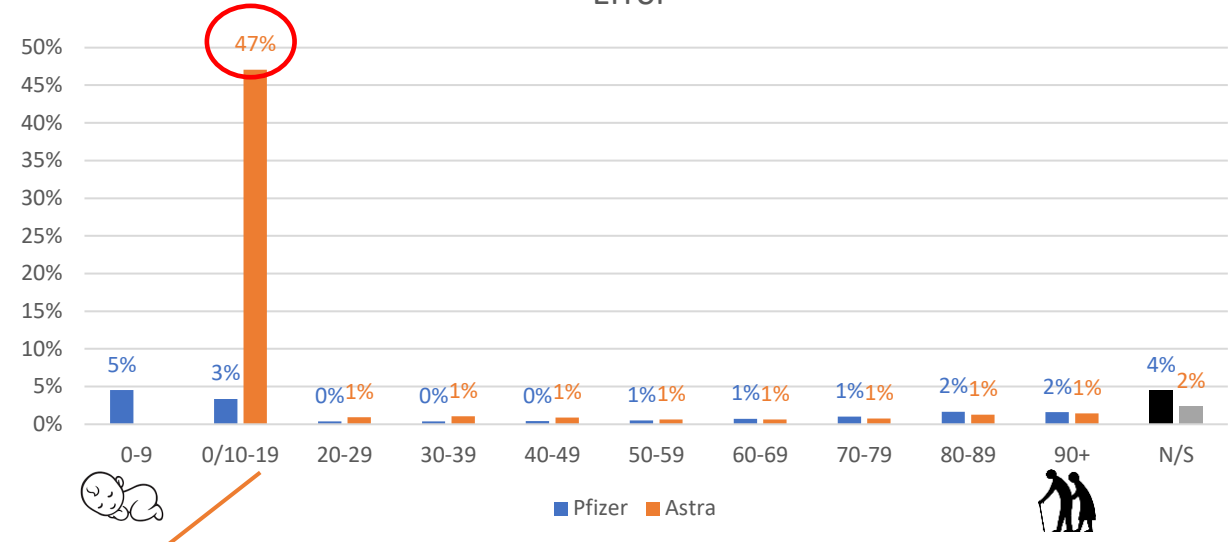
0% = < 0.5%

# Other Unexpected Reactions

REACTION (ex injection site)



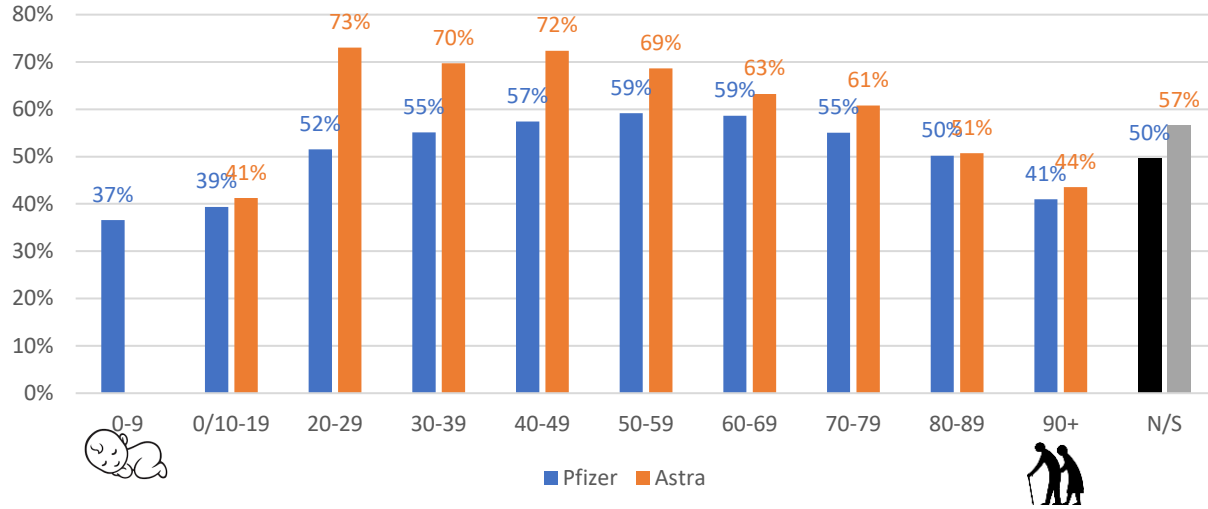
Error



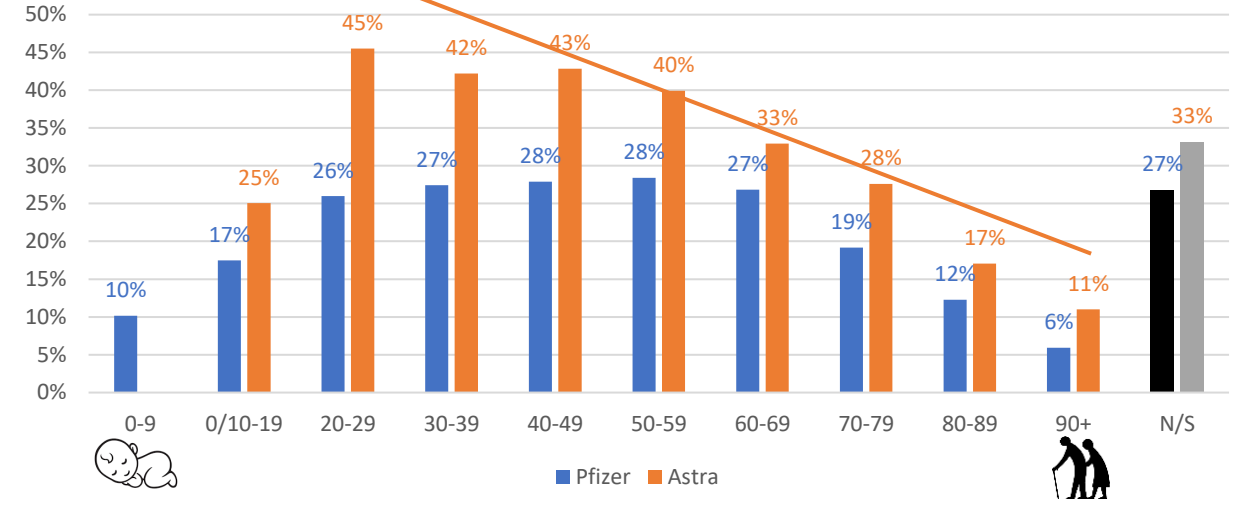
ASTRAZENECA	0-19	0-9	10-19
Cases	427	16	411
<b>REACTION (ex injection site)</b>	<b>205</b> → <b>48%</b>	<b>4</b>	<b>201</b> → <b>49%</b>
<b>Error</b>	<b>201</b> → <b>47%</b>	<b>3</b>	<b>198</b> → <b>48%</b>
Device connection issue	1	0	1
Incorrect dose administered	1	0	1
Medication error	11	0	11
Product administered to patient of inappropriate age	87	2	85
Syringe issue	1	0	1
Vaccination error	171	2	169
Wrong drug administered	1	0	1
Wrong product administered	47	1	46

# Expected Reactions

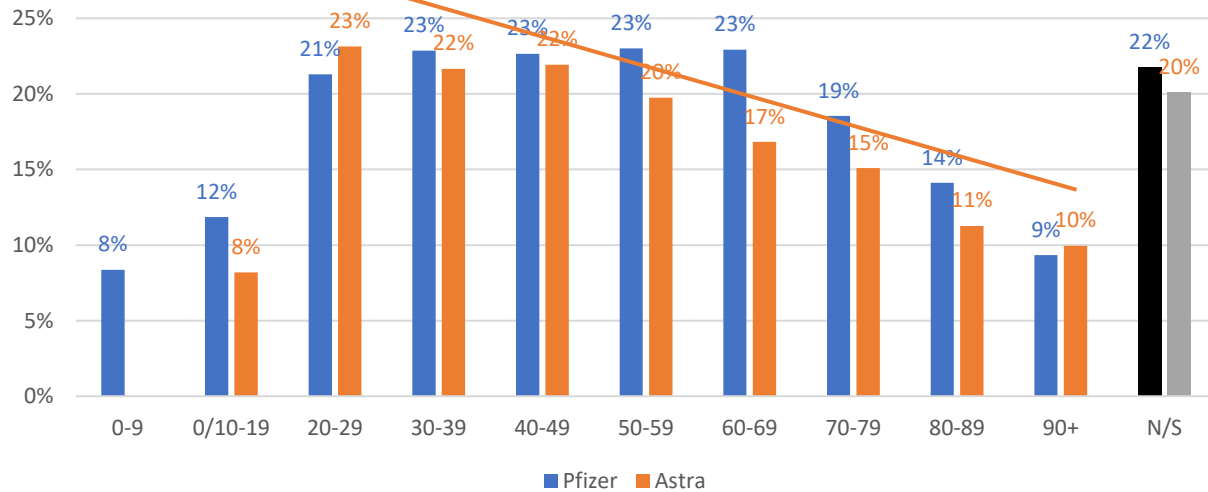
## EXPECTED REACTIONS



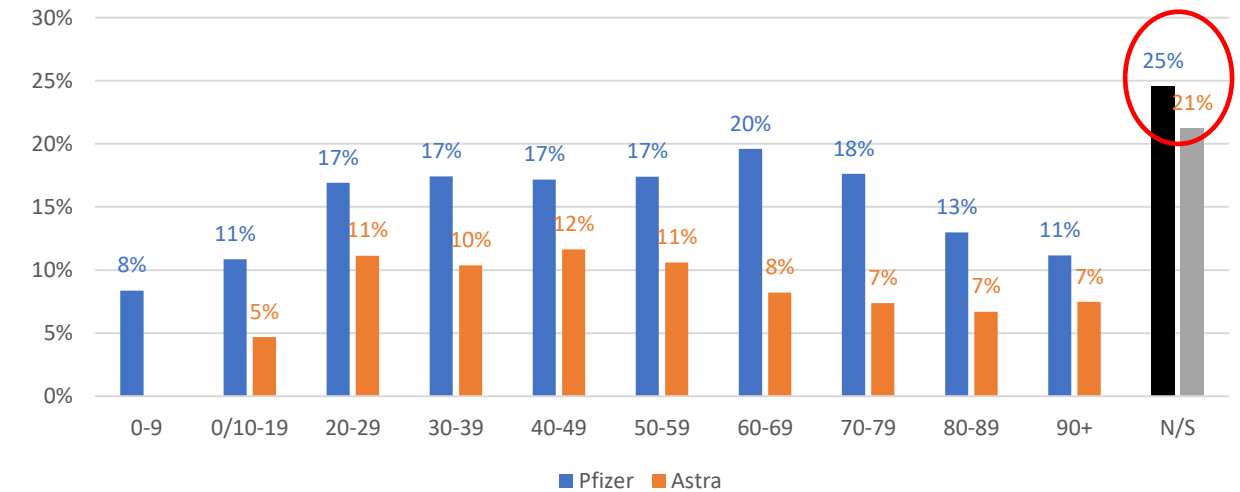
## Headache



## Injection site

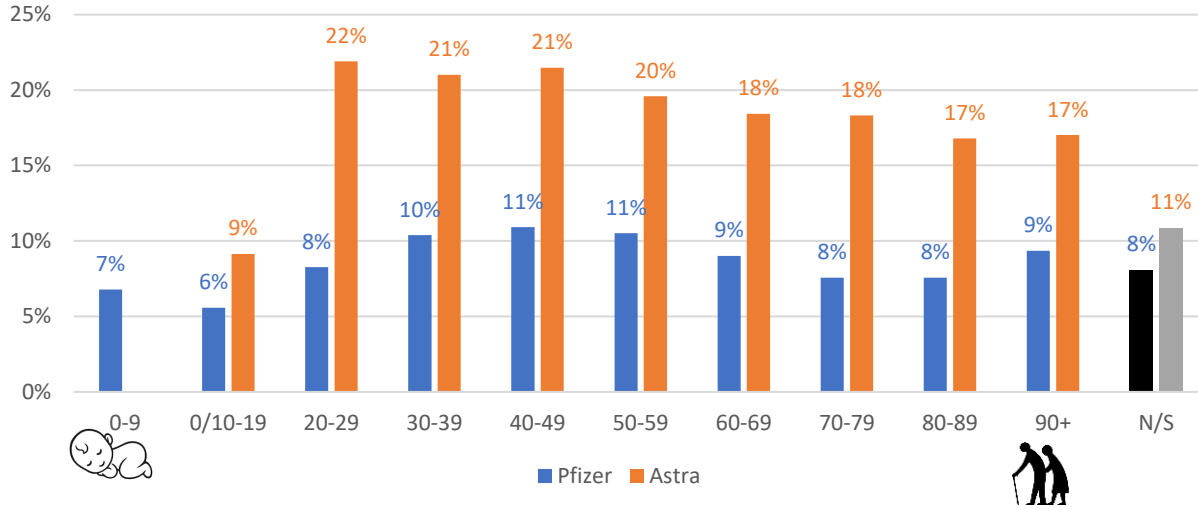


## Lethargy

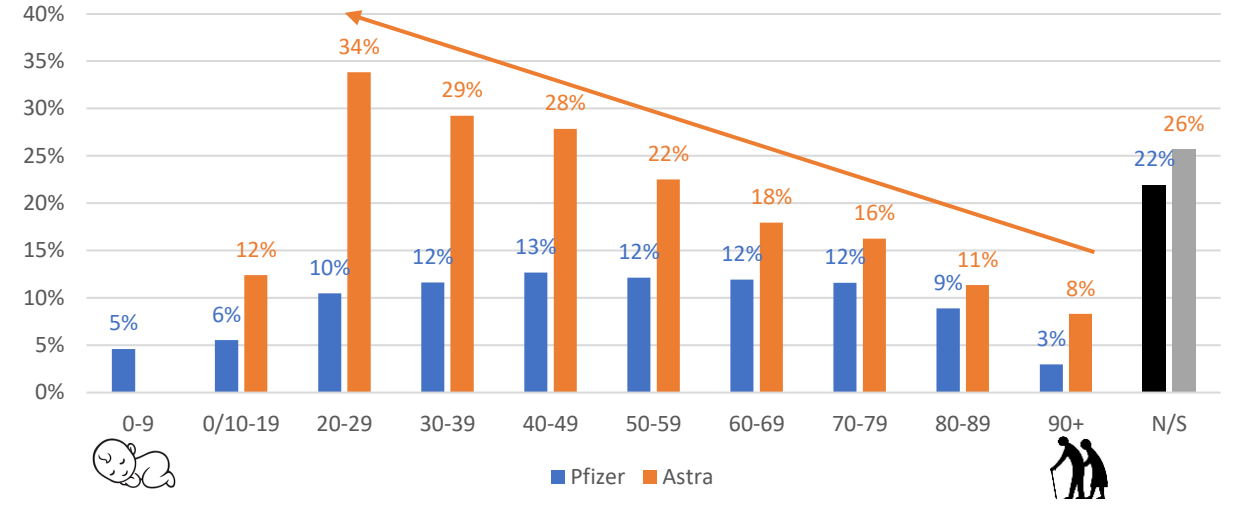


# Expected Reactions

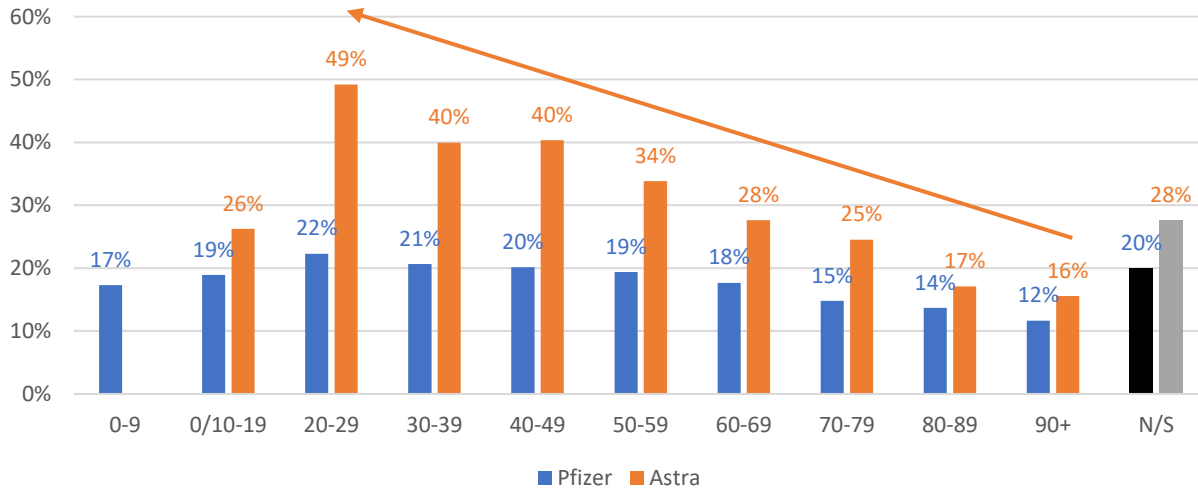
## Fatigue



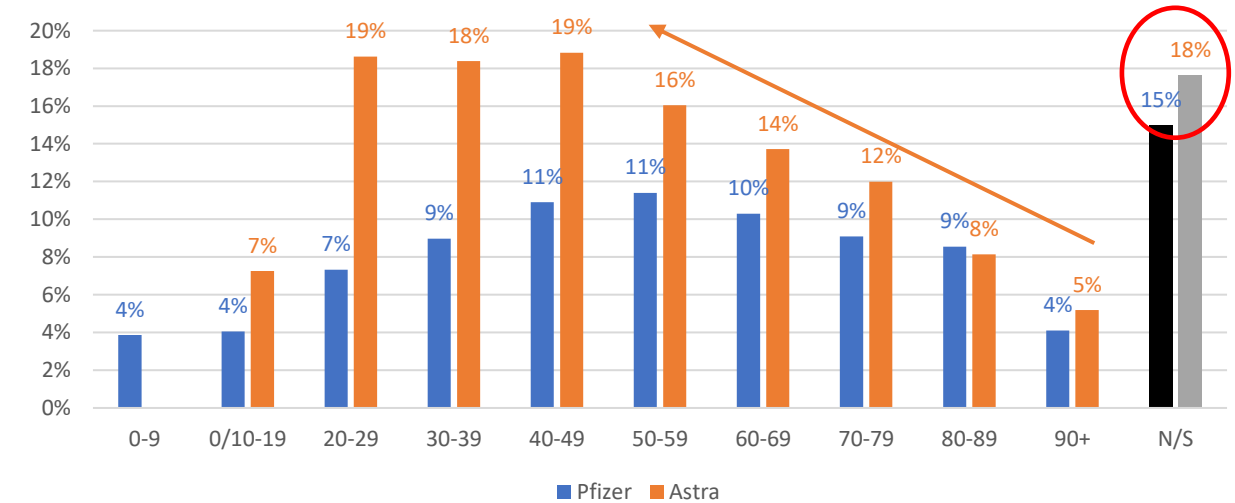
## MUSCLES/ SKELETON



## TEMPERATURE



## PAIN/ SWELLING (general)



Australia  
5-11 year old  
Reactions  
Complete List

Medical class - groups	Total		5-11 yrs	
Cases	122,580		1,067	
<b>TOTAL UNEXPECTED REACTIONS</b>	<b>107,423</b>	<b>87.6%</b>	<b>1,031</b>	<b>96.6%</b>
<b>TOTAL FLIGHT RISK</b>	<b>65,068</b>	<b>53.1%</b>	<b>488</b>	<b>45.7%</b>
<b>TOTAL CARDIAC/ BREATHING/ CLOTTING/ SPINAL</b>	<b>36,459</b>	<b>29.7%</b>	<b>273</b>	<b>25.6%</b>
<b>THORACIC/CARDIAC PULMONARY AND BREATHING</b>	<b>28,959</b>	<b>23.6%</b>	<b>258</b>	<b>24.2%</b>
<b>THORACIC/CARDIAC PULMONARY</b>	<b>25,028</b>	<b>20.4%</b>	<b>222</b>	<b>20.8%</b>
<b>CORONARY SYMPTOMS</b>	<b>11,951</b>	<b>9.7%</b>	<b>81</b>	<b>7.6%</b>
<b>Coronary Symptoms - Arrhythmias</b>	<b>6,612</b>	<b>5.4%</b>	<b>41</b>	<b>3.8%</b>
Arrhythmia	236	0.2%	2	0.2%
Bundle branch block right	23	0.0%	1	0.1%
Heart rate irregular	343	0.3%	4	0.4%
Palpitations	5,426	4.4%	35	3.3%
Sinus arrhythmia	13	0.0%	2	0.2%
<b>Coronary Symptoms - Bradycardia</b>	<b>283</b>	<b>0.2%</b>	<b>2</b>	<b>0.2%</b>
Heart rate decreased	66	0.1%	1	0.1%
Sinus bradycardia	21	0.0%	1	0.1%
<b>Coronary Symptoms - Ischaemia</b>	<b>463</b>	<b>0.4%</b>	<b>1</b>	<b>0.1%</b>
Myocardial infarction	308	0.3%	1	0.1%
<b>Coronary Symptoms - Other</b>	<b>2,073</b>	<b>1.7%</b>	<b>32</b>	<b>3.0%</b>
Cardiac discomfort	34	0.0%	1	0.1%
Cardiac murmur	26	0.0%	2	0.2%
Echocardiogram	161	0.1%	1	0.1%
Echocardiogram normal	26	0.0%	2	0.2%
Electrocardiogram	302	0.2%	7	0.7%
Electrocardiogram abnormal	458	0.4%	11	1.0%
Electrocardiogram normal	64	0.1%	2	0.2%
Electrocardiogram ST segment elevation	150	0.1%	2	0.2%
Sinus rhythm	16	0.0%	1	0.1%
Troponin	218	0.2%	8	0.7%
Troponin I	57	0.0%	1	0.1%
Troponin increased	722	0.6%	6	0.6%
<b>Coronary Symptoms - Tachycardia</b>	<b>3,942</b>	<b>3.2%</b>	<b>27</b>	<b>2.5%</b>
Atrial tachycardia	16	0.0%	1	0.1%
Heart rate increased	1,209	1.0%	6	0.6%
Sinus tachycardia	97	0.1%	2	0.2%
Tachycardia	2,500	2.0%	18	1.7%

Medical class - groups	Total		5-11 yrs	
Cases	122,580		1,067	
<b>OTHER THORACIC/CARDIAC PULMONARY</b>	<b>18,437</b>	<b>15.0%</b>	<b>196</b>	<b>18.4%</b>
<b>Cardiac arrest</b>	<b>171</b>	<b>0.1%</b>	<b>3</b>	<b>0.3%</b>
Cardiac arrest	126	0.1%	2	0.2%
Coronary artery aneurysm	1	0.0%	1	0.1%
<b>Cardiac disorders</b>	<b>779</b>	<b>0.6%</b>	<b>1</b>	<b>0.1%</b>
Cardiomegaly	53	0.0%	1	0.1%
<b>Coronary Inflammatory disorders</b>	<b>4,660</b>	<b>3.8%</b>	<b>27</b>	<b>2.5%</b>
Carditis	126	0.1%	2	0.2%
Myocarditis	1,403	1.1%	7	0.7%
Myopericarditis	69	0.1%	2	0.2%
Pericarditis	3,223	2.6%	17	1.6%
<b>Thoracic/ Cardiac Pulmonary Symptoms</b>	<b>15,399</b>	<b>12.6%</b>	<b>188</b>	<b>17.6%</b>
Chest discomfort	4,269	3.5%	35	3.3%
Chest pain	12,368	10.1%	170	15.9%
Chest X-ray abnormal	11	0.0%	1	0.1%
Chest X-ray normal	19	0.0%	1	0.1%
<b>(RESP) Breathing</b>	<b>10,430</b>	<b>8.5%</b>	<b>105</b>	<b>9.8%</b>
Dyspnoea	9,737	7.9%	95	8.9%
Dyspnoea exertional	135	0.1%	3	0.3%
Oxygen saturation decreased	88	0.1%	1	0.1%
Painful respiration	40	0.0%	3	0.3%
Respiratory rate increased	47	0.0%	3	0.3%
Tachypnoea	80	0.1%	1	0.1%
Wheezing	421	0.3%	6	0.6%

Medical class - groups	Total		5-11 yrs	
Cases	122,580		1,067	
<b>CONSC/ NEURO/ VERTIGO/ HEARING/ VISION</b>	<b>39,401</b>	<b>32.1%</b>	<b>267</b>	<b>25.0%</b>
<b>CONSC/ NEURO/ VERTIGO</b>	<b>37,146</b>	<b>30.3%</b>	<b>263</b>	<b>24.6%</b>
<b>CONSCIOUSNESS/ NEUROLOGICAL (ex headache)</b>	<b>28,034</b>	<b>22.9%</b>	<b>210</b>	<b>19.7%</b>
<b>CONSCIOUSNESS</b>	<b>11,220</b>	<b>9.2%</b>	<b>81</b>	<b>7.6%</b>
<b>Change</b>	<b>1,201</b>	<b>1.0%</b>	<b>2</b>	<b>0.2%</b>
Feeling abnormal	1,168	1.0%	2	0.2%
<b>Mental impairment</b>	<b>5,570</b>	<b>4.5%</b>	<b>46</b>	<b>4.3%</b>
Attention deficit hyperactivity disorder	1	0.0%	1	0.1%
Confusional state	1,192	1.0%	2	0.2%
Delirium	133	0.1%	2	0.2%
Disorientation	304	0.2%	6	0.6%
Presyncope	2,864	2.3%	35	3.3%
<b>Mood</b>	<b>2,085</b>	<b>1.7%</b>	<b>18</b>	<b>1.7%</b>
Anxiety	1,041	0.8%	11	1.0%
Crying	28	0.0%	2	0.2%
Irritability	83	0.1%	4	0.4%
Mood altered	66	0.1%	1	0.1%
<b>Sensitivity</b>	<b>1,382</b>	<b>1.1%</b>	<b>10</b>	<b>0.9%</b>
Hypersensitivity	777	0.6%	6	0.6%
Photophobia	486	0.4%	4	0.4%
<b>Sleep</b>	<b>2,182</b>	<b>1.8%</b>	<b>7</b>	<b>0.7%</b>
Insomnia	1,599	1.3%	1	0.1%
Nightmare	54	0.0%	1	0.1%
Sleep disorder	297	0.2%	5	0.5%
Sleep terror	7	0.0%	1	0.1%
<b>NEUROLOGICAL (ex headache)</b>	<b>1,870</b>	<b>1.5%</b>	<b>4</b>	<b>0.4%</b>
<b>Nerve/ neurological</b>	<b>464</b>	<b>0.4%</b>	<b>1</b>	<b>0.1%</b>
Demyelination	98	0.1%	1	0.1%
<b>Neurological - Facial</b>	<b>1,228</b>	<b>1.0%</b>	<b>2</b>	<b>0.2%</b>
Bell's palsy	639	0.5%	2	0.2%
<b>Neurological - Injury</b>	<b>130</b>	<b>0.1%</b>	<b>1</b>	<b>0.1%</b>
Intracranial pressure increased	23	0.0%	1	0.1%
<b>Neurological - Obstructions</b>	<b>25</b>	<b>0.0%</b>	<b>1</b>	<b>0.1%</b>
Electroencephalogram abnormal	3	0.0%	1	0.1%

Medical class - groups	Total		5-11 yrs	
Cases	122,580		1,067	
<b>OTHER NEUROLOGICAL</b>	<b>18,459</b>	<b>15.1%</b>	<b>144</b>	<b>13.5%</b>
<b>Autoimmune/ Neurlogical disease</b>	<b>400</b>	<b>0.3%</b>	<b>4</b>	<b>0.4%</b>
Multisystem inflammatory syndrome in children	7	0.0%	4	0.4%
<b>Balance/ consciousness</b>	<b>4,952</b>	<b>4.0%</b>	<b>96</b>	<b>9.0%</b>
Hypertensive encephalopathy	1	0.0%	1	0.1%
Loss of consciousness	357	0.3%	5	0.5%
Posture abnormal	3	0.0%	1	0.1%
Syncope	3,534	2.9%	89	8.3%
<b>Numbness</b>	<b>8,141</b>	<b>6.6%</b>	<b>10</b>	<b>0.9%</b>
Hypoaesthesia	2,180	1.8%	2	0.2%
Paraesthesia	6,740	5.5%	9	0.8%
<b>Seizure</b>	<b>4,577</b>	<b>3.7%</b>	<b>42</b>	<b>3.9%</b>
Clonic convulsion	7	0.0%	1	0.1%
Dyskinesia	70	0.1%	1	0.1%
Febrile convulsion	19	0.0%	1	0.1%
Gait disturbance	464	0.4%	1	0.1%
Generalised tonic-clonic seizure	65	0.1%	4	0.4%
Muscle spasms	1,078	0.9%	6	0.6%
Muscle twitching	352	0.3%	1	0.1%
Petit mal epilepsy	20	0.0%	1	0.1%
Posterior reversible encephalopathy syndrome	4	0.0%	1	0.1%
Postictal state	6	0.0%	2	0.2%
Seizure	756	0.6%	15	1.4%
Tardive dyskinesia	1	0.0%	1	0.1%
Tonic clonic movements	25	0.0%	1	0.1%
Tonic convulsion	16	0.0%	1	0.1%
Tremor	1,656	1.4%	7	0.7%
<b>Speech</b>	<b>825</b>	<b>0.7%</b>	<b>4</b>	<b>0.4%</b>
Dysphemia	25	0.0%	1	0.1%
Dysphonia	332	0.3%	3	0.3%
<b>Taste</b>	<b>1,802</b>	<b>1.5%</b>	<b>1</b>	<b>0.1%</b>
Taste disorder	375	0.3%	1	0.1%
<b>Vertigo</b>	<b>13,650</b>	<b>11.1%</b>	<b>72</b>	<b>6.7%</b>
Dizziness	12,413	10.1%	69	6.5%
Dizziness postural	41	0.0%	1	0.1%
Vertigo	1,438	1.2%	2	0.2%

Medical class - groups	Total		5-11 yrs	
Cases	122,580		1,067	
<b>CLOTS/ BRUISING/ BLOOD</b>	<b>6,855</b>	<b>5.6%</b>	<b>11</b>	<b>1.0%</b>
<b>Bruising</b>	<b>1,191</b>	<b>1.0%</b>	<b>6</b>	<b>0.6%</b>
Blood blister	47	0.0%	1	0.1%
Contusion	866	0.7%	3	0.3%
Purpura	47	0.0%	2	0.2%
<b>Stroke</b>	<b>1,074</b>	<b>0.9%</b>	<b>3</b>	<b>0.3%</b>
Basal ganglia haemorrhage	6	0.0%	1	0.1%
Cerebrovascular accident	494	0.4%	1	0.1%
Superior sagittal sinus thrombosis	12	0.0%	1	0.1%
<b>Thrombosis</b>	<b>3,487</b>	<b>2.8%</b>	<b>2</b>	<b>0.2%</b>
Fibrin D dimer increased	1,611	1.3%	2	0.2%
<b>CENTRAL NERVOUS SYSTEM</b>	<b>2,925</b>	<b>2.4%</b>	<b>7</b>	<b>0.7%</b>
<b>Spinal Infections</b>	<b>67</b>	<b>0.1%</b>	<b>1</b>	<b>0.1%</b>
Myelitis transverse	35	0.0%	1	0.1%
<b>Spinal Symptoms</b>	<b>2,796</b>	<b>2.3%</b>	<b>6</b>	<b>0.6%</b>
Back pain	1,682	1.4%	1	0.1%
Neck pain	1,152	0.9%	5	0.5%

Medical class - groups	Total		5-11 yrs	
Cases	122,580		1,067	
<b>HEARING/ VISION</b>	<b>4,579</b>	<b>3.7%</b>	<b>9</b>	<b>0.8%</b>
<b>Deafness</b>	<b>1,767</b>	<b>1.4%</b>	<b>2</b>	<b>0.2%</b>
Deafness	152	0.1%	1	0.1%
Tinnitus	1,417	1.2%	1	0.1%
<b>Vision</b>	<b>2,960</b>	<b>2.4%</b>	<b>7</b>	<b>0.7%</b>
Nystagmus	24	0.0%	1	0.1%
Vision blurred	1,793	1.5%	4	0.4%
Visual impairment	689	0.6%	2	0.2%
<b>UNRESPONSIVE</b>	<b>100</b>	<b>0.1%</b>	<b>1</b>	<b>0.1%</b>
<b>Unresponsive</b>	<b>93</b>	<b>0.1%</b>	<b>1</b>	<b>0.1%</b>
Coma scale abnormal	16	0.0%	1	0.1%



Medical class - groups	Total		5-11 yrs	
Cases	122,580		1,067	
<b>OTHER UNEXPECTED REACTIONS</b>	<b>73,078</b>	<b>59.6%</b>	<b>788</b>	<b>73.9%</b>
<b>RESPIRATORY TRACT</b>	<b>9,999</b>	<b>8.2%</b>	<b>90</b>	<b>8.4%</b>
<b>RESPIRATORY TRACT INFECTIONS</b>	<b>5,867</b>	<b>4.8%</b>	<b>46</b>	<b>4.3%</b>
<b>Covid-19</b>	<b>309</b>	<b>0.3%</b>	<b>29</b>	<b>2.7%</b>
Breakthrough COVID-19	2	0.0%	2	0.2%
COVID-19	167	0.1%	11	1.0%
SARS-CoV-2 antibody test positive	22	0.0%	5	0.5%
SARS-CoV-2 test negative	6	0.0%	2	0.2%
SARS-CoV-2 test positive	81	0.1%	9	0.8%
<b>Lower Respiratory Tract Infections</b>	<b>917</b>	<b>0.7%</b>	<b>2</b>	<b>0.2%</b>
Pneumonia	447	0.4%	2	0.2%
<b>Upper Respiratory Tract Infections</b>	<b>4,722</b>	<b>3.9%</b>	<b>15</b>	<b>1.4%</b>
Influenza like illness	3,941	3.2%	11	1.0%
Nasopharyngitis	363	0.3%	1	0.1%
Respiratory tract infection	35	0.0%	2	0.2%
Tonsillitis	121	0.1%	4	0.4%
<b>RESPIRATORY TRACT ISSUES</b>	<b>2,005</b>	<b>1.6%</b>	<b>33</b>	<b>3.1%</b>
<b>Lower Respiratory Tract Issues</b>	<b>1,867</b>	<b>1.5%</b>	<b>26</b>	<b>2.4%</b>
Asthma	320	0.3%	10	0.9%
Chest X-ray	64	0.1%	1	0.1%
Costochondritis	249	0.2%	3	0.3%
Musculoskeletal chest pain	226	0.2%	7	0.7%
Obstructive airways disorder	21	0.0%	1	0.1%
Pleurisy	75	0.1%	1	0.1%
Pleuritic pain	214	0.2%	1	0.1%
Respiratory distress	28	0.0%	1	0.1%
Respiratory symptom	16	0.0%	1	0.1%
<b>Upper Respiratory Tract Issues</b>	<b>146</b>	<b>0.1%</b>	<b>8</b>	<b>0.7%</b>
Croup infectious	15	0.0%	8	0.7%
<b>(RESP TRACT SYMPTOMS) Cough</b>	<b>2,777</b>	<b>2.3%</b>	<b>17</b>	<b>1.6%</b>
Cough	2,562	2.1%	17	1.6%

Medical class - groups	Total		5-11 yrs	
Cases	122,580		1,067	
<b>GASTROINTESTINAL DISORDERS</b>	<b>29,475</b>	<b>24.0%</b>	<b>327</b>	<b>30.6%</b>
<b>GIT Infection/ inflammation</b>	<b>812</b>	<b>0.7%</b>	<b>9</b>	<b>0.8%</b>
Abdominal lymphadenopathy	3	0.0%	1	0.1%
Enterocolitis	1	0.0%	1	0.1%
Flank pain	73	0.1%	2	0.2%
Gastroenteritis	89	0.1%	3	0.3%
Gastrointestinal infection	9	0.0%	1	0.1%
Gastrooesophageal reflux disease	158	0.1%	1	0.1%
<b>GIT Symptoms</b>	<b>25,112</b>	<b>20.5%</b>	<b>294</b>	<b>27.6%</b>
Abdominal discomfort	393	0.3%	10	0.9%
Abdominal distension	262	0.2%	1	0.1%
Abdominal pain	4,875	4.0%	92	8.6%
Abdominal pain lower	70	0.1%	1	0.1%
Abdominal pain upper	1,052	0.9%	18	1.7%
Abnormal faeces	16	0.0%	1	0.1%
Decreased appetite	1,954	1.6%	18	1.7%
Diarrhoea	4,764	3.9%	36	3.4%
Dyspepsia	284	0.2%	2	0.2%
Epigastric discomfort	15	0.0%	1	0.1%
Eructation	55	0.0%	1	0.1%
Frequent bowel movements	29	0.0%	1	0.1%
Nausea	14,409	11.8%	93	8.7%
Retching	155	0.1%	2	0.2%
Vomiting	5,787	4.7%	128	12.0%
<b>GIT Vascular/ Haemorrhagic</b>	<b>306</b>	<b>0.2%</b>	<b>3</b>	<b>0.3%</b>
Haematemesis	43	0.0%	2	0.2%
Rectal haemorrhage	106	0.1%	1	0.1%
<b>Throat - Upper GIT</b>	<b>4,401</b>	<b>3.6%</b>	<b>44</b>	<b>4.1%</b>
Dysphagia	422	0.3%	2	0.2%
Oesophageal discomfort	2	0.0%	1	0.1%
Oropharyngeal discomfort	309	0.3%	3	0.3%
Oropharyngeal pain	1,763	1.4%	26	2.4%
Pharyngeal paraesthesia	53	0.0%	1	0.1%
Pharyngeal swelling	405	0.3%	1	0.1%
Pharyngitis	94	0.1%	1	0.1%
Throat irritation	568	0.5%	5	0.5%
Throat tightness	786	0.6%	7	0.7%
<b>Weight increase/ hunger</b>	<b>75</b>	<b>0.1%</b>	<b>1</b>	<b>0.1%</b>
Increased appetite	18	0.0%	1	0.1%

Medical class - groups	Total		5-11 yrs	
<i>Cases</i>	<i>122,580</i>		<i>1,067</i>	
<b>REPRODUCTIVE</b>	<b>3,702</b>	<b>3.0%</b>	<b>11</b>	<b>1.0%</b>
<b>Menstrual disorder</b>	<b>2,726</b>	<b>2.2%</b>	<b>6</b>	<b>0.6%</b>
Heavy menstrual bleeding	919	0.7%	1	0.1%
Menstrual disorder	2,259	1.8%	4	0.4%
Oligomenorrhoea	115	0.1%	2	0.2%
Vaginal haemorrhage	180	0.1%	2	0.2%
<b>Reproductive infections</b>	<b>92</b>	<b>0.1%</b>	<b>1</b>	<b>0.1%</b>
Scrotal oedema	2	0.0%	1	0.1%
<b>Reproductive symptoms</b>	<b>360</b>	<b>0.3%</b>	<b>4</b>	<b>0.4%</b>
Scrotal pain	2	0.0%	1	0.1%
Scrotal swelling	6	0.0%	2	0.2%
Testicular pain	44	0.0%	1	0.1%
Testicular swelling	19	0.0%	2	0.2%
<b>URINARY TRACT</b>	<b>1,020</b>	<b>0.8%</b>	<b>14</b>	<b>1.3%</b>
<b>Bladder/ Urinary Tract Symptoms</b>	<b>642</b>	<b>0.5%</b>	<b>10</b>	<b>0.9%</b>
Blood urea increased	6	0.0%	1	0.1%
Dysuria	71	0.1%	2	0.2%
Pollakiuria	137	0.1%	3	0.3%
Polyuria	31	0.0%	1	0.1%
Urinary incontinence	94	0.1%	3	0.3%
<b>Urinary Tract Bleeding</b>	<b>199</b>	<b>0.2%</b>	<b>4</b>	<b>0.4%</b>
Haematuria	100	0.1%	4	0.4%
<b>Urinary Tract Infections</b>	<b>226</b>	<b>0.2%</b>	<b>1</b>	<b>0.1%</b>
Urinary tract infection	197	0.2%	1	0.1%
<b>ORGANS/ GLANDS</b>	<b>2,453</b>	<b>2.0%</b>	<b>19</b>	<b>1.8%</b>
<b>Kidney</b>	<b>605</b>	<b>0.5%</b>	<b>3</b>	<b>0.3%</b>
Henoch-Schonlein purpura	11	0.0%	1	0.1%
IgA nephropathy	13	0.0%	2	0.2%
Protein urine present	2	0.0%	1	0.1%
<b>Liver</b>	<b>675</b>	<b>0.6%</b>	<b>5</b>	<b>0.5%</b>
Aspartate aminotransferase increased	3	0.0%	1	0.1%
C-reactive protein increased	323	0.3%	4	0.4%
<b>Other organ/ glands</b>	<b>750</b>	<b>0.6%</b>	<b>11</b>	<b>1.0%</b>
Appendicitis	217	0.2%	7	0.7%
Basedow's disease	34	0.0%	1	0.1%
Goitre	7	0.0%	1	0.1%
Lipase increased	11	0.0%	1	0.1%
Splenomegaly	23	0.0%	1	0.1%

Medical class - groups	Total		5-11 yrs	
<i>Cases</i>	<i>122,580</i>		<i>1,067</i>	
<b>EXTREMITIES</b>	<b>7,130</b>	<b>5.8%</b>	<b>29</b>	<b>2.7%</b>
<b>Limb/ peripheral</b>	<b>7,114</b>	<b>5.8%</b>	<b>29</b>	<b>2.7%</b>
Axillary pain	425	0.3%	4	0.4%
Chillblains	54	0.0%	1	0.1%
Limb discomfort	565	0.5%	1	0.1%
Limb injury	9	0.0%	1	0.1%
Pain in extremity	4,917	4.0%	19	1.8%
Peripheral swelling	1,053	0.9%	4	0.4%
<b>SKIN</b>	<b>13,859</b>	<b>11.3%</b>	<b>259</b>	<b>24.3%</b>
<b>Allergic rash</b>	<b>2,240</b>	<b>1.8%</b>	<b>20</b>	<b>1.9%</b>
Pruritus	2,213	1.8%	20	1.9%
<b>Burning - skin</b>	<b>1,098</b>	<b>0.9%</b>	<b>1</b>	<b>0.1%</b>
Skin warm	18	0.0%	1	0.1%
<b>Pallor</b>	<b>989</b>	<b>0.8%</b>	<b>72</b>	<b>6.7%</b>
Pallor	989	0.8%	72	6.7%
<b>Rash</b>	<b>9,443</b>	<b>7.7%</b>	<b>179</b>	<b>16.8%</b>
Eczema	69	0.1%	1	0.1%
Erythema	614	0.5%	7	0.7%
Erythema multiforme	28	0.0%	2	0.2%
Kawasaki's disease	5	0.0%	4	0.4%
Pityriasis rosea	45	0.0%	1	0.1%
Psoriasis	34	0.0%	2	0.2%
Rash	5,233	4.3%	69	6.5%
Rash erythematous	246	0.2%	9	0.8%
Rash papular	75	0.1%	4	0.4%
Rash pruritic	819	0.7%	23	2.2%
Rash vesicular	73	0.1%	3	0.3%
Urticaria	2,202	1.8%	64	6.0%
<b>Skin</b>	<b>1,190</b>	<b>1.0%</b>	<b>11</b>	<b>1.0%</b>
Alopecia	81	0.1%	1	0.1%
Cutaneous vasculitis	18	0.0%	1	0.1%
Cyanosis	77	0.1%	4	0.4%
Dermatitis	53	0.0%	1	0.1%
Molluscum contagiosum	2	0.0%	1	0.1%
Pain of skin	88	0.1%	1	0.1%
Skin discolouration	119	0.1%	1	0.1%
Yellow skin	7	0.0%	1	0.1%

Medical class - groups	Total		5-11 yrs	
<i>Cases</i>	<i>122,580</i>		<i>1,067</i>	
<b>FACE/ EYES/ EARS</b>	<b>9,355</b>	<b>7.6%</b>	<b>103</b>	<b>9.7%</b>
<b>EARS (ex Deafness)</b>	<b>866</b>	<b>0.7%</b>	<b>4</b>	<b>0.4%</b>
Ear infection	90	0.1%	2	0.2%
Ear pain	411	0.3%	1	0.1%
Ear swelling	26	0.0%	1	0.1%
<b>EYES (ex Vision)</b>	<b>2,268</b>	<b>1.9%</b>	<b>35</b>	<b>3.3%</b>
Conjunctival hyperaemia	5	0.0%	2	0.2%
Conjunctivitis	57	0.0%	3	0.3%
Corneal reflex decreased	1	0.0%	1	0.1%
Erythromelalgia	5	0.0%	1	0.1%
Excessive eye blinking	2	0.0%	1	0.1%
Eye irritation	96	0.1%	1	0.1%
Eye movement disorder	24	0.0%	1	0.1%
Eye pain	555	0.5%	2	0.2%
Eye pruritus	130	0.1%	2	0.2%
Eye swelling	235	0.2%	12	1.1%
Eyelid oedema	19	0.0%	1	0.1%
Glassy eyes	5	0.0%	1	0.1%
Lacrimation increased	113	0.1%	1	0.1%
Mydriasis	16	0.0%	1	0.1%
Ocular hyperaemia	189	0.2%	7	0.7%
Periorbital oedema	33	0.0%	1	0.1%
Periorbital swelling	87	0.1%	3	0.3%
Sensation of foreign body	56	0.0%	2	0.2%
Swelling of eyelid	68	0.1%	1	0.1%
<b>FACE</b>	<b>1,254</b>	<b>1.0%</b>	<b>24</b>	<b>2.2%</b>
<b>Facial - rash</b>	<b>225</b>	<b>0.2%</b>	<b>10</b>	<b>0.9%</b>
Rash macular	110	0.1%	5	0.5%
Rash maculo-papular	95	0.1%	5	0.5%
<b>Facial - Swelling/ injury</b>	<b>723</b>	<b>0.6%</b>	<b>11</b>	<b>1.0%</b>
Swelling face	589	0.5%	11	1.0%
<b>Jaw</b>	<b>326</b>	<b>0.3%</b>	<b>3</b>	<b>0.3%</b>
Pain in jaw	285	0.2%	2	0.2%
Trismus	28	0.0%	1	0.1%

Medical class - groups	Total		5-11 yrs	
<i>Cases</i>	<i>122,580</i>		<i>1,067</i>	
<b>MOUTH</b>	<b>3,447</b>	<b>2.8%</b>	<b>24</b>	<b>2.2%</b>
<b>Mouth</b>	<b>3,345</b>	<b>2.7%</b>	<b>24</b>	<b>2.2%</b>
Chapped lips	7	0.0%	1	0.1%
Cheilitis	9	0.0%	1	0.1%
Lip discolouration	5	0.0%	1	0.1%
Lip dry	14	0.0%	1	0.1%
Lip swelling	610	0.5%	9	0.8%
Lip ulceration	9	0.0%	1	0.1%
Mouth ulceration	229	0.2%	2	0.2%
Oral candidiasis	21	0.0%	1	0.1%
Oral disorder	6	0.0%	1	0.1%
Oral pruritus	19	0.0%	3	0.3%
Paraesthesia oral	984	0.8%	1	0.1%
Perioral dermatitis	3	0.0%	1	0.1%
Swollen tongue	658	0.5%	1	0.1%
Tongue discomfort	43	0.0%	2	0.2%
Tongue dry	5	0.0%	1	0.1%
Tongue pruritus	18	0.0%	2	0.2%
<b>NOSE</b>	<b>2,444</b>	<b>2.0%</b>	<b>28</b>	<b>2.6%</b>
<b>Nasal</b>	<b>1,698</b>	<b>1.4%</b>	<b>17</b>	<b>1.6%</b>
Nasal congestion	324	0.3%	3	0.3%
Nasal discomfort	20	0.0%	1	0.1%
Rhinorrhoea	777	0.6%	11	1.0%
Sinusitis	252	0.2%	1	0.1%
Sneezing	138	0.1%	5	0.5%
<b>Nose bleed</b>	<b>780</b>	<b>0.6%</b>	<b>11</b>	<b>1.0%</b>
Epistaxis	780	0.6%	11	1.0%

Medical class - groups	Total		5-11 yrs	
<i>Cases</i>	<i>122,580</i>		<i>1,067</i>	
<b>AUTOIMMUNE SYMPTOMS</b>	<b>8,838</b>	<b>7.2%</b>	<b>55</b>	<b>5.2%</b>
<b>Lymph node</b>	<b>5,502</b>	<b>4.5%</b>	<b>31</b>	<b>2.9%</b>
Axillary mass	46	0.0%	1	0.1%
Lymph node pain	249	0.2%	1	0.1%
Lymphadenitis	63	0.1%	4	0.4%
Lymphadenopathy	5,136	4.2%	24	2.2%
Lymphadenopathy mediastinal	3	0.0%	1	0.1%
<b>Pre-existing</b>	<b>2,091</b>	<b>1.7%</b>	<b>16</b>	<b>1.5%</b>
Concomitant disease aggravated	1,907	1.6%	16	1.5%
<b>White blood cell/ platelet</b>	<b>1,414</b>	<b>1.2%</b>	<b>8</b>	<b>0.7%</b>
Haemoglobin decreased	30	0.0%	1	0.1%
Inflammatory marker increased	35	0.0%	2	0.2%
Lymphopenia	19	0.0%	2	0.2%
Thrombocytopenia	797	0.7%	3	0.3%
White blood cell count increased	56	0.0%	1	0.1%
<b>HOMEOSTATIS - BLOOD</b>	<b>4,557</b>	<b>3.7%</b>	<b>17</b>	<b>1.6%</b>
<b>Blood pressure</b>	<b>3,686</b>	<b>3.0%</b>	<b>7</b>	<b>0.7%</b>
Blood pressure increased	852	0.7%	1	0.1%
Blood pressure measurement	18	0.0%	1	0.1%
Hypotension	625	0.5%	5	0.5%
<b>Diabetic/ glucose</b>	<b>326</b>	<b>0.3%</b>	<b>5</b>	<b>0.5%</b>
Blood glucose abnormal	10	0.0%	1	0.1%
Blood glucose increased	99	0.1%	1	0.1%
Diabetes mellitus	25	0.0%	1	0.1%
Diabetic ketoacidosis	17	0.0%	3	0.3%
Type 1 diabetes mellitus	16	0.0%	2	0.2%
<b>Other - blood/ hormone</b>	<b>631</b>	<b>0.5%</b>	<b>5</b>	<b>0.5%</b>
Blood creatine increased	10	0.0%	1	0.1%
C-reactive protein	45	0.0%	1	0.1%
Hypothyroidism	20	0.0%	1	0.1%
Red blood cell count decreased	9	0.0%	1	0.1%
Red blood cell sedimentation rate	1	0.0%	1	0.1%
Red blood cell sedimentation rate increased	47	0.0%	1	0.1%
Serum ferritin increased	11	0.0%	1	0.1%

Medical class - groups	Total		5-11 yrs	
<i>Cases</i>	<i>122,580</i>		<i>1,067</i>	
<b>INFECTION</b>	<b>2,390</b>	<b>1.9%</b>	<b>21</b>	<b>2.0%</b>
<b>Herpes</b>	<b>1,620</b>	<b>1.3%</b>	<b>14</b>	<b>1.3%</b>
Herpes zoster	1,304	1.1%	7	0.7%
Oral herpes	160	0.1%	2	0.2%
Varicella	16	0.0%	5	0.5%
<b>Infections/ bacteria/ viral</b>	<b>788</b>	<b>0.6%</b>	<b>7</b>	<b>0.7%</b>
Inflammation	270	0.2%	2	0.2%
Neutrophilia	11	0.0%	1	0.1%
Secretion discharge	14	0.0%	1	0.1%
Staphylococcal bacteraemia	4	0.0%	1	0.1%
Staphylococcal infection	22	0.0%	1	0.1%
Staphylococcus test positive	2	0.0%	1	0.1%
Streptococcus test	1	0.0%	1	0.1%
Viral infection	128	0.1%	1	0.1%
<b>PAIN/ SWELLING (ex general)</b>	<b>713</b>	<b>0.6%</b>	<b>3</b>	<b>0.3%</b>
<b>Arthritis</b>	<b>428</b>	<b>0.3%</b>	<b>1</b>	<b>0.1%</b>
Epidemic polyarthritis	2	0.0%	1	0.1%
<b>Mass/ cyst</b>	<b>228</b>	<b>0.2%</b>	<b>2</b>	<b>0.2%</b>
Chest wall mass	2	0.0%	1	0.1%
Empyema	4	0.0%	1	0.1%

Medical class - groups	Total		5-11 yrs	
<i>Cases</i>	122,580		1,067	
<b>REACTION (ex injection site)</b>	<b>4,860</b>	<b>4.0%</b>	<b>109</b>	<b>10.2%</b>
<b>Adverse event unspecified</b>	<b>937</b>	<b>0.8%</b>	<b>5</b>	<b>0.5%</b>
Adverse event following immunisation	829	0.7%	5	0.5%
<b>Allergy</b>	<b>53</b>	<b>0.0%</b>	<b>1</b>	<b>0.1%</b>
Food allergy	10	0.0%	1	0.1%
<b>Anaphalactic</b>	<b>1,291</b>	<b>1.1%</b>	<b>1</b>	<b>0.1%</b>
Anaphylactic reaction	1,246	1.0%	1	0.1%
<b>Drug reaction</b>	<b>261</b>	<b>0.2%</b>	<b>4</b>	<b>0.4%</b>
Sepsis	106	0.1%	1	0.1%
Serum sickness	2	0.0%	1	0.1%
Vaccine breakthrough infection	41	0.0%	2	0.2%
<b>Error</b>	<b>2,217</b>	<b>1.8%</b>	<b>97</b>	<b>9.1%</b>
Expired product administered	280	0.2%	6	0.6%
Inappropriate schedule of product administration	159	0.1%	3	0.3%
Incorrect dosage administered	16	0.0%	3	0.3%
Incorrect dose administered	140	0.1%	18	1.7%
Multiple use of single-use product	2	0.0%	1	0.1%
Product administered to patient of inappropriate age	334	0.3%	36	3.4%
Product preparation issue	21	0.0%	5	0.5%
Underdose	57	0.0%	4	0.4%
Vaccination error	1,799	1.5%	92	8.6%
Wrong product administered	197	0.2%	11	1.0%
<b>Ineffective</b>	<b>79</b>	<b>0.1%</b>	<b>1</b>	<b>0.1%</b>
Drug ineffective	43	0.0%	1	0.1%
No adverse event	54	0.0%	1	0.1%

Medical class - groups	Total		5-11 yrs	
<i>Cases</i>	122,580		1,067	
<b>TOTAL EXPECTED REACTIONS</b>	<b>66,859</b>	<b>54.5%</b>	<b>360</b>	<b>33.7%</b>
<b>(CONSC) Neurological - Headache</b>	<b>32,288</b>	<b>26.3%</b>	<b>109</b>	<b>10.2%</b>
Head discomfort	300	0.2%	1	0.1%
Headache	30,477	24.9%	106	9.9%
Migraine	1,783	1.5%	3	0.3%
<b>(REACT) Injection site</b>	<b>20,470</b>	<b>16.7%</b>	<b>83</b>	<b>7.8%</b>
Administration site irritation	1	0.0%	1	0.1%
Extensive swelling of vaccinated limb	188	0.2%	1	0.1%
Injection site erythema	416	0.3%	1	0.1%
Injection site pain	5,204	4.2%	24	2.2%
Injection site rash	316	0.3%	4	0.4%
Injection site reaction	12,542	10.2%	52	4.9%
Injection site swelling	811	0.7%	1	0.1%
Vaccination site reaction	77	0.1%	1	0.1%
<b>COMMON RESPONSE (ex Vertigo)</b>	<b>30,297</b>	<b>24.7%</b>	<b>155</b>	<b>14.5%</b>
<b>Fatigue</b>	<b>18,638</b>	<b>15.2%</b>	<b>87</b>	<b>8.2%</b>
Asthenia	1,535	1.3%	4	0.4%
Fatigue	14,667	12.0%	46	4.3%
Malaise	4,032	3.3%	40	3.7%
<b>Lethargy</b>	<b>13,154</b>	<b>10.7%</b>	<b>79</b>	<b>7.4%</b>
Exercise tolerance decreased	103	0.1%	1	0.1%
Lethargy	11,884	9.7%	75	7.0%
Listless	15	0.0%	1	0.1%
Muscular weakness	874	0.7%	1	0.1%
Somnolence	392	0.3%	3	0.3%

Medical class - groups	Total		5-11 yrs	
<i>Cases</i>	122,580		1,067	
<b>PAIN/ SWELLING (general)</b>	<b>15,240</b>	<b>12.4%</b>	<b>41</b>	<b>3.8%</b>
<b>Pain</b>	<b>14,079</b>	<b>11.5%</b>	<b>32</b>	<b>3.0%</b>
Arthralgia	11,965	9.8%	25	2.3%
Pain	2,258	1.8%	8	0.7%
<b>Swelling</b>	<b>1,404</b>	<b>1.1%</b>	<b>10</b>	<b>0.9%</b>
Angioedema	540	0.4%	9	0.8%
Swelling	747	0.6%	1	0.1%
<i>Total reactions mentioned</i>	<i>398,293</i>	<i>3.2</i>	<i>2,837</i>	<i>2.7</i>

Medical class - groups	Total		5-11 yrs	
<i>Cases</i>	122,580		1,067	
<b>MUSCLES/ SKELETON</b>	<b>20,695</b>	<b>16.9%</b>	<b>59</b>	<b>5.5%</b>
<b>Fracture</b>	<b>70</b>	<b>0.1%</b>	<b>2</b>	<b>0.2%</b>
Ankle fracture	7	0.0%	1	0.1%
Radius fracture	1	0.0%	1	0.1%
<b>Muscular/ tendon</b>	<b>19,295</b>	<b>15.7%</b>	<b>47</b>	<b>4.4%</b>
Hypotonia	12	0.0%	2	0.2%
Muscle fatigue	43	0.0%	1	0.1%
Myalgia	18,841	15.4%	44	4.1%
<b>Musculoskeletal/ joint</b>	<b>1,690</b>	<b>1.4%</b>	<b>10</b>	<b>0.9%</b>
Joint instability	2	0.0%	1	0.1%
Joint swelling	321	0.3%	1	0.1%
Musculoskeletal discomfort	95	0.1%	1	0.1%
Musculoskeletal pain	99	0.1%	1	0.1%
Musculoskeletal stiffness	628	0.5%	3	0.3%
Osteomyelitis	2	0.0%	1	0.1%
Synovitis	13	0.0%	2	0.2%
<b>TEMPERATURE</b>	<b>28,676</b>	<b>23.4%</b>	<b>167</b>	<b>15.7%</b>
<b>Dehydration</b>	<b>446</b>	<b>0.4%</b>	<b>4</b>	<b>0.4%</b>
Dehydration	178	0.1%	1	0.1%
Polydipsia	19	0.0%	1	0.1%
Thirst	245	0.2%	3	0.3%
<b>Sweating/ flushes</b>	<b>5,274</b>	<b>4.3%</b>	<b>46</b>	<b>4.3%</b>
Cold sweat	920	0.8%	20	1.9%
Flushing	849	0.7%	5	0.5%
Hyperhidrosis	2,771	2.3%	20	1.9%
Night sweats	290	0.2%	1	0.1%
<b>Temperature change</b>	<b>25,071</b>	<b>20.5%</b>	<b>128</b>	<b>12.0%</b>
Chills	10,443	8.5%	8	0.7%
Feeling cold	522	0.4%	2	0.2%
Feeling hot	1,111	0.9%	11	1.0%
Feeling of body temperature change	368	0.3%	1	0.1%
Pyrexia	16,772	13.7%	109	10.2%
Temperature regulation disorder	10	0.0%	1	0.1%