

TGA – adverse events reports

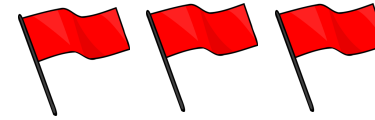
- **Scientific / Marketing** approach

Kim Burgess

- B. App Sci: Scientific Information Services (majors: Numerical / Programming)
- 29 years running Market Research business
 - Community Consultation / Customer & Member Satisfaction
 - Data collection, analysis and reporting: for management decision making
 - Data analyst/ database programming/ customised and automated reporting
 - Text analytics/ Coding
 - Field manager/ Data collection/ Observations/ Surveys
 - Data mapping, matching (linking of customer data to survey data)
 - Design of methodology
 - Development of presentations – for audience
 - Sub-contract to industry/ ‘trouble-shooter’

2020

- Overseas data = governments and universities



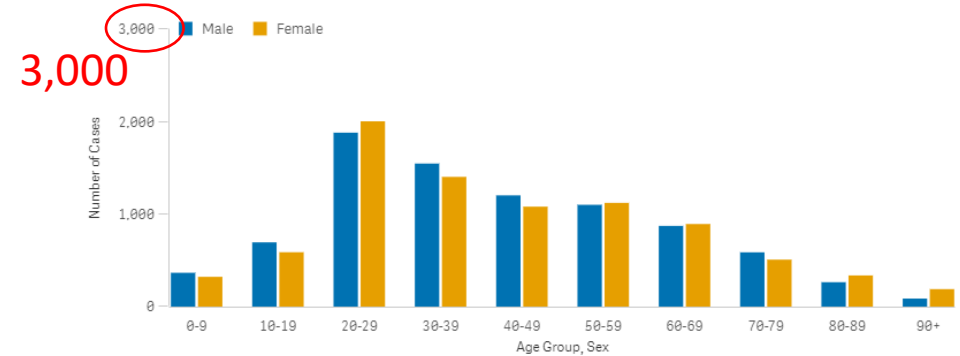
“Cases” and PCR tests



COVID-19 cases by age group and sex

This graph shows the number of confirmed COVID-19 cases for males and females by age group since 22 January 2020.

Source: NNDSS data 1/8/2020



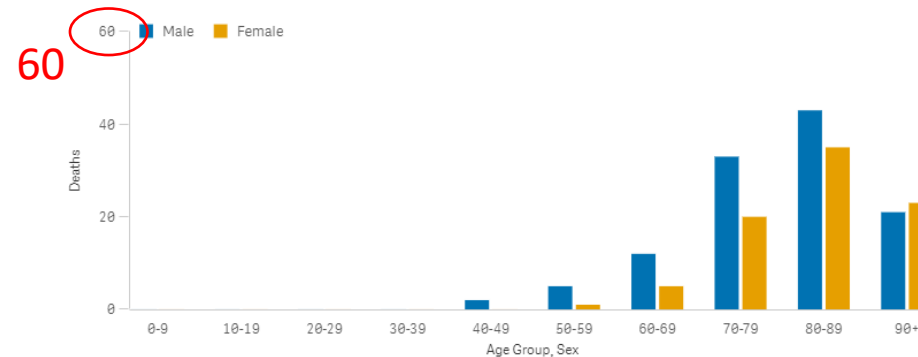
Note that the chart does not include cases where age or sex are unknown

COVID-19 deaths by age group and sex

WITH covid

This graph shows the number of COVID-19 deaths for males and females by age group since 22 January 2020.

Source: NNDSS data 01/08/2020



Note that the chart does not include cases where age or sex are unknown

“Trust the Science”



- Science censored – one information source
- New scientific methods / Pandemic plans ignored

Data Collection

- PCR tests
- Sign-in protocols / Covid app/ QR coding
- 5 km restriction/ work permits/ travel permits
- Surveillance – cameras/ police/ on-line surveillance

Covid live database – (cases and deaths)

- Age
- Gender
- Postcode
- Melbourne LGA
- Aged-care residents (*moved, then removed*)

Covid “CASES”:

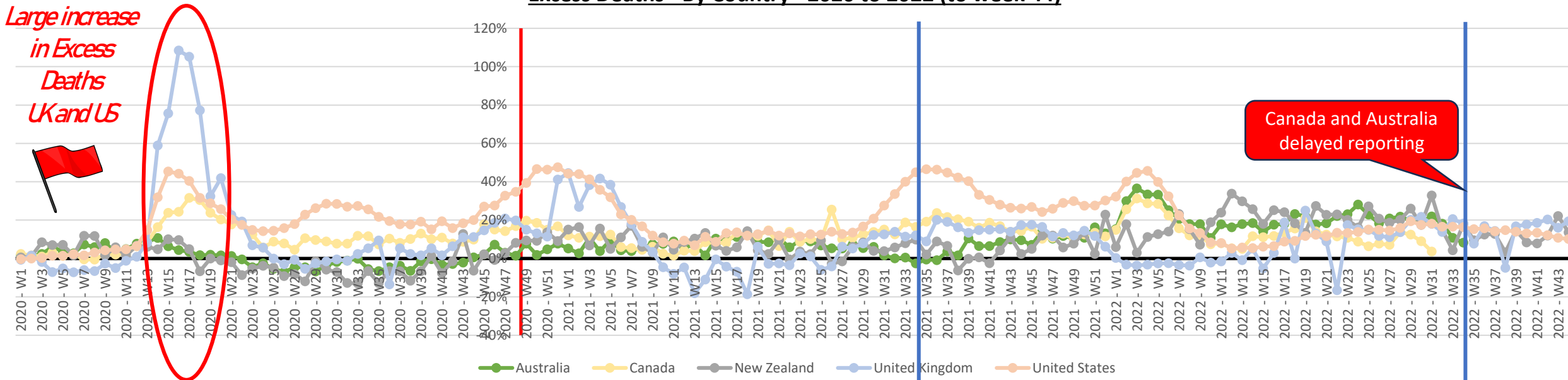
From Covidlive.com.au for Melbourne LGAs

- “Hot spots”
- “Cool spots”

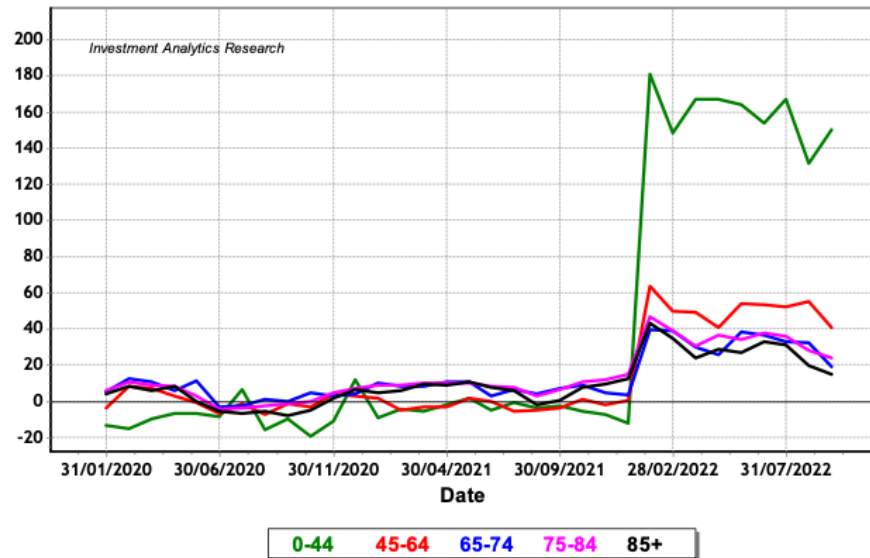


Greater Melbourne			
Average age	37	↑↓	
English only at home	62%	↑↓	
Overseas born	34%	↑↓	
4+ person per household	28%	↑↓	
Single person household	23%	↑↓	
Population density per hectare	4.4	↑↓	
Sales workers, machinery operators and drivers, labourers	23%	↑↓	
Increase in population from 2016 to 2020	11%	↑↓	

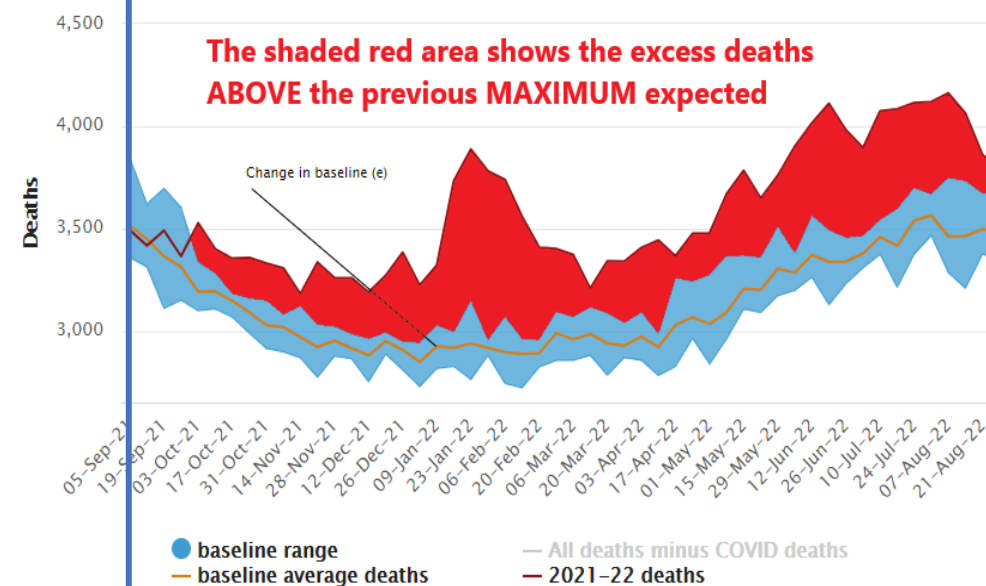
Excess Deaths - By Country - 2020 to 2022 (to week 44)



Australian Monthly % Excess Mortality Based 2015-19 By Age Groups



All deaths, with and without COVID-19, Australia, 30 August 2021 - 28 August 2022 vs baseline benchmarks



Govt reports: Data Source: <https://www.tga.gov.au/database-adverse-event-notifications-daen>

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

[Further information about the medicine summary](#)

[Information on printing search results](#)

Sort by:

Number of cases - highest first


[Print version of this report](#)

MedDRA system organ class	MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary.	Number of cases	Number of cases with a single suspected medicine	Number of cases where death was a reported outcome
Nervous system disorders	Headache	663	650	1
General disorders and administration site conditions	Fatigue	403	396	0
General disorders and administration site conditions	Chest pain	364	354	2
Nervous system disorders	Dizziness	300	295	1
General disorders and administration site conditions	Pyrexia	299	293	1
Gastrointestinal disorders	Nausea	293	286	1
Respiratory, thoracic and mediastinal disorders	Dyspnoea	284	272	1
Musculoskeletal and connective tissue disorders	Myalgia	280	274	0
Cardiac disorders	Pericarditis	237	226	0
Nervous system	Paraesthesia	234	231	0

Downloaded Complete Data Set for Analysis

"Death was a reported outcome" is not available in the "List of reports"

Medicine summary

List of reports

List of reports

Further information about the list of reports

Information on printing search results

Sort by: Report date - earliest first

Print version of this report

Case number	Report entry date	Age (yrs)	Gender	Medicines reported as being taken	MedDRA reaction terms
625168	16/09/2021	40	M	COMIRNATY COVID-19 vaccine (BNT162b2 (mRNA)) - Suspected	Vestibular neuronitis
625176	16/09/2021	45	F	COMIRNATY COVID-19 vaccine (BNT162b2 (mRNA)) - Suspected	- Anxiety - Headache - Palpitations - Paraesthesia
625182	16/09/2021	37	F	COMIRNATY COVID-19 vaccine (BNT162b2 (mRNA)) - Suspected	- Chills - Headache - Hyperhidrosis
625190	16/09/2021	76	F	COMIRNATY COVID-19 vaccine (BNT162b2 (mRNA)) - Suspected	- Headache - Hypoglycaemia - Nausea
625203	16/09/2021	27	M	COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected	- Myocarditis - Pericarditis
625235	16/09/2021	84	M	COMIRNATY COVID-19 vaccine (BNT162b2 (mRNA)) - Suspected	Cerebrovascular accident

TGA DAEN (Database of Adverse Events Notifications):

- Monitor approved medications
- Negative adverse events = halt of use and investigation
- **Not designed to collect 'experimental' data**

Reporting to TGA

11. Medicine and vaccine adverse event reporting

Table 42 Source of notifications of medicine and vaccine adverse reaction for 1 July to 31 December

	2020	2021
	1 July to 31 December	
Accepted cases total	12,340 (96%)	78,544 (96%)
Reports by health professionals (total)	2,445	6,706
Medical practitioners	569	2,850
Pharmacists	1,329	1,434
Nurses	363	1,280
Others	113	328
Unknown	71	814
Patients/consumers	462	19,769
Pharmaceutical companies	7,978	9,514
State and Territory health departments	1,406	42,456
Other source	49	99
Rejected/withdrawn cases	475 (4%)	2,873 (4%)
Total received	12,815	81,417
Average number of reports received weekly	493	3,131
Vaccine reports included in this table	1,727	73,238

Total X 6.4

Pharmacists
X 1

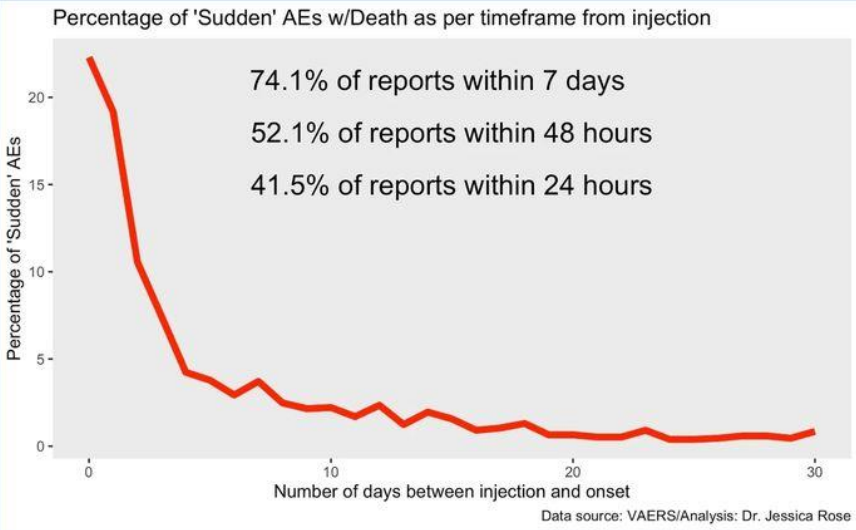
Patient/ consumer
X 42

State & Territory health depts
X 30

Over half ½ (52%) of reports within 2 days (48 hours)

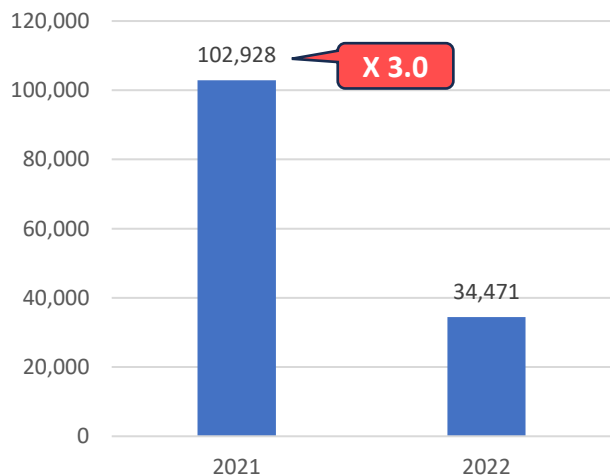
Nearly three quarters ¾ a week (7 days)

And for the subset of people of died:

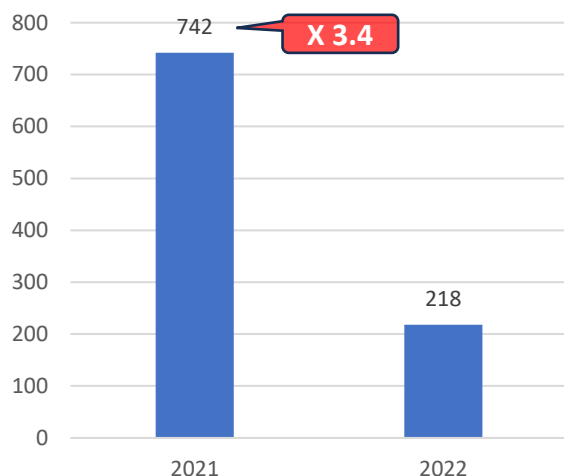


2021 Reporting rates :

Reports

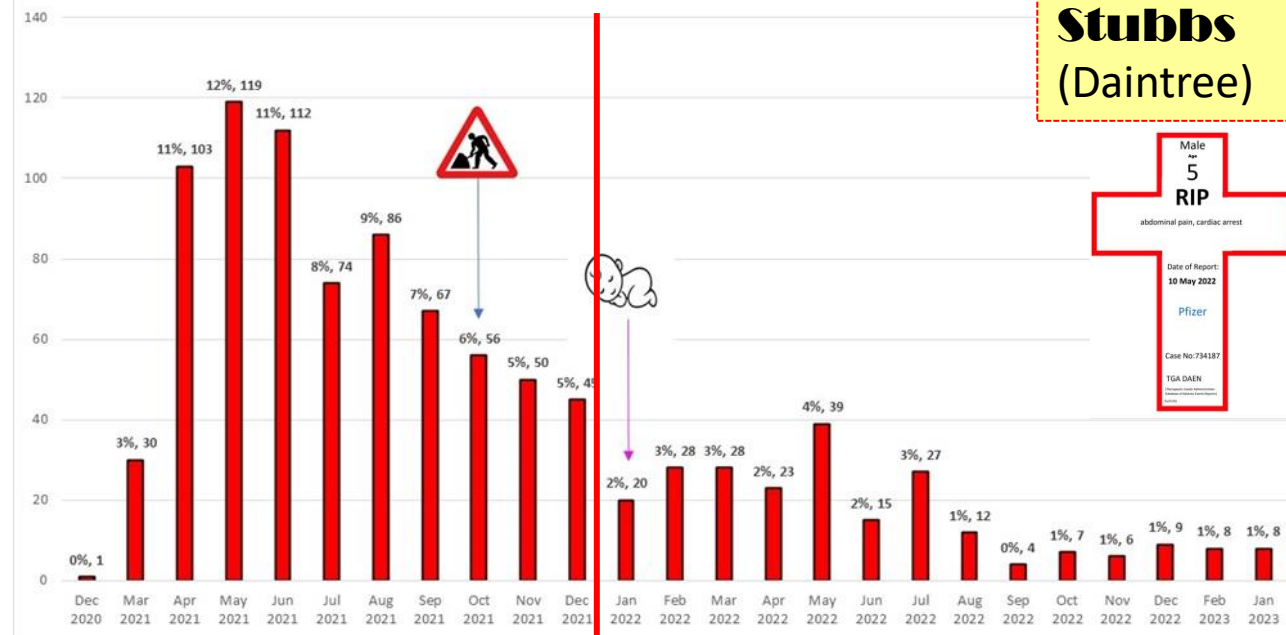


Deaths



TGA Reports of Death (Covid-19 medicines) by Month

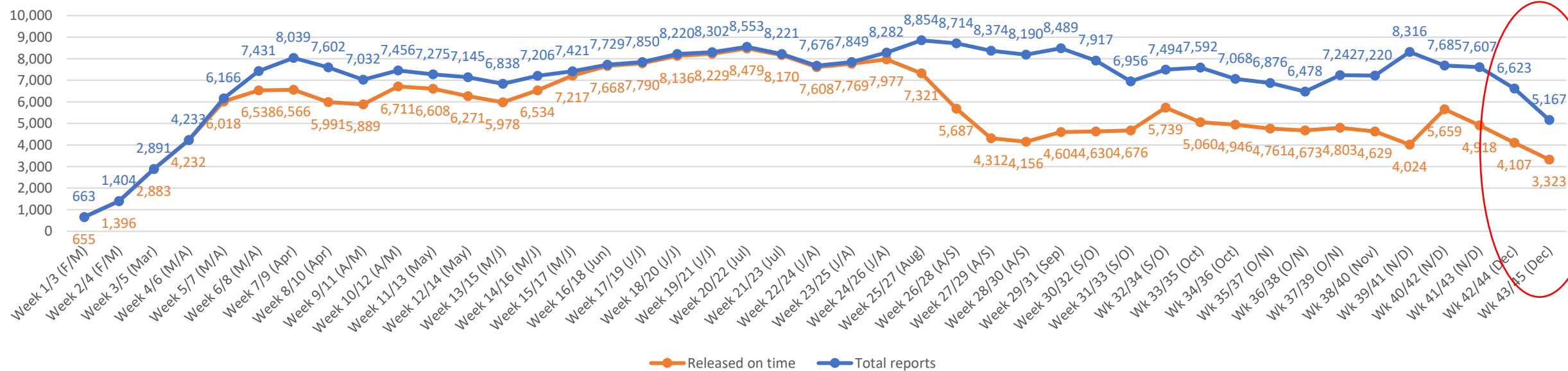
"The Crosses"



Michelle Stubbs
(Daintree)



TGA adverse events reports for 'covid' medicines



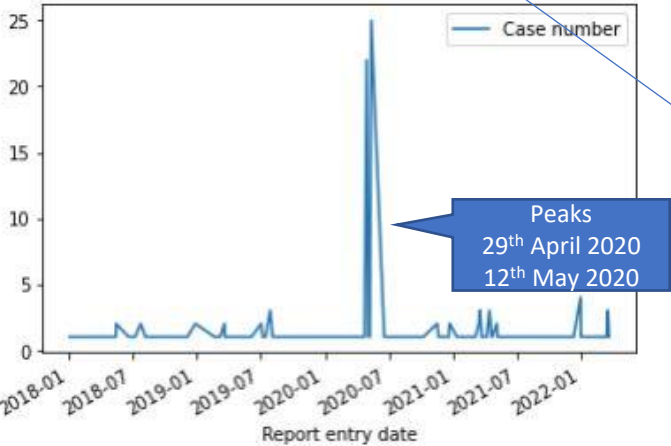
Treatments NOT recommended for Covid 19*

Blake Downward (Adelaide)

Analysis of TGA DAEN (1/1/2018 – 31/3/2022)

Hydroxychloroquine

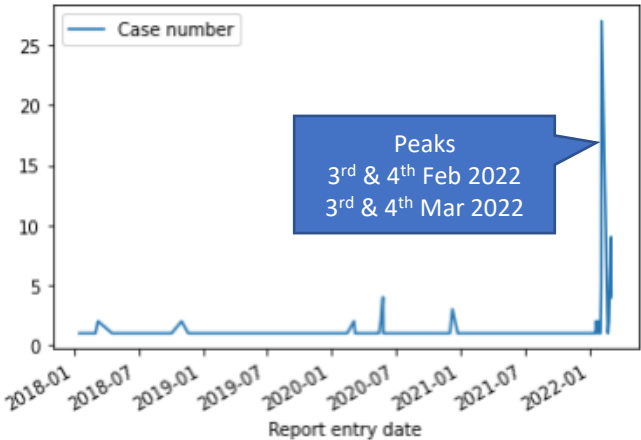
199 cases total – 48 suspect



- Ivermectin
- Doxycycline
- Zinc
- Hydroxychloroquine

Doxycycline

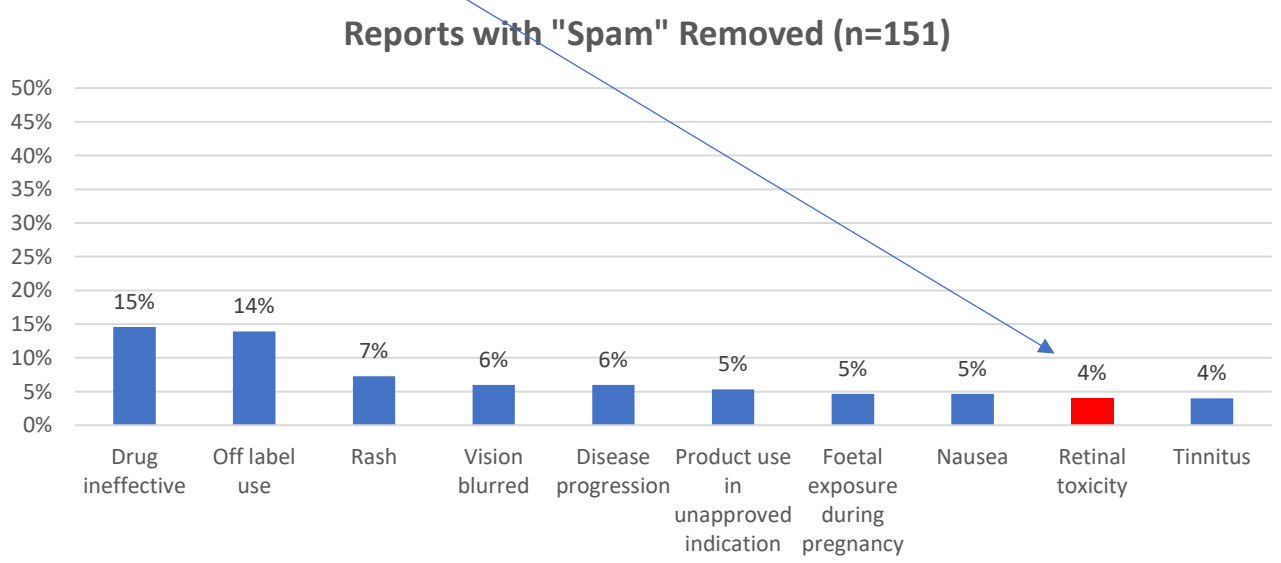
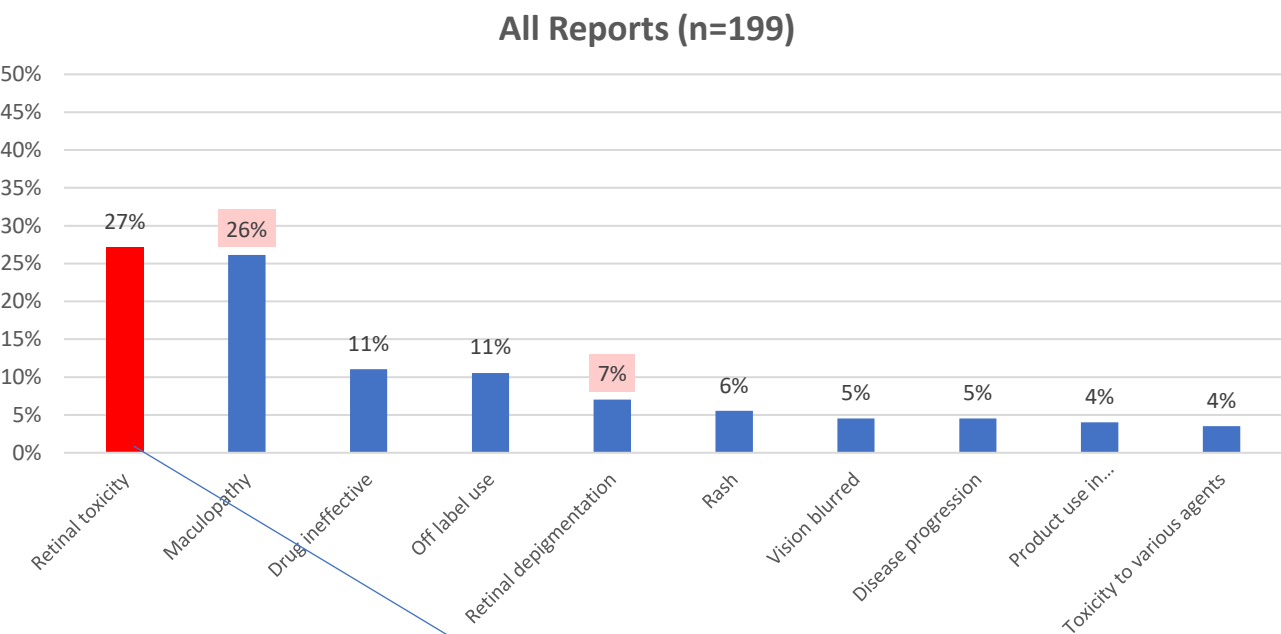
162 cases total – 49 suspect



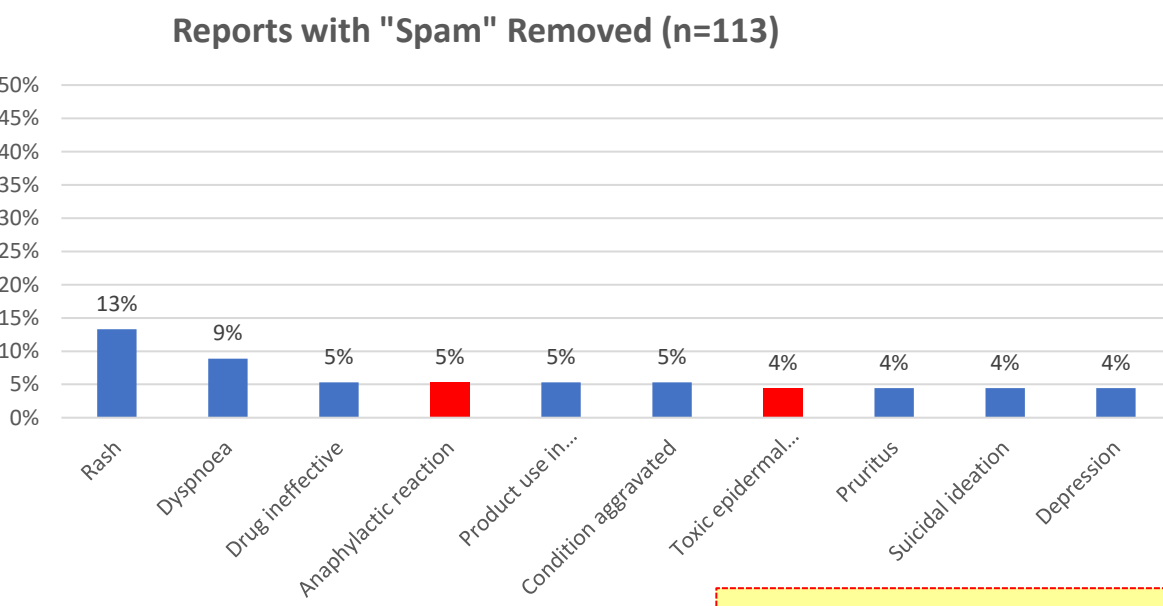
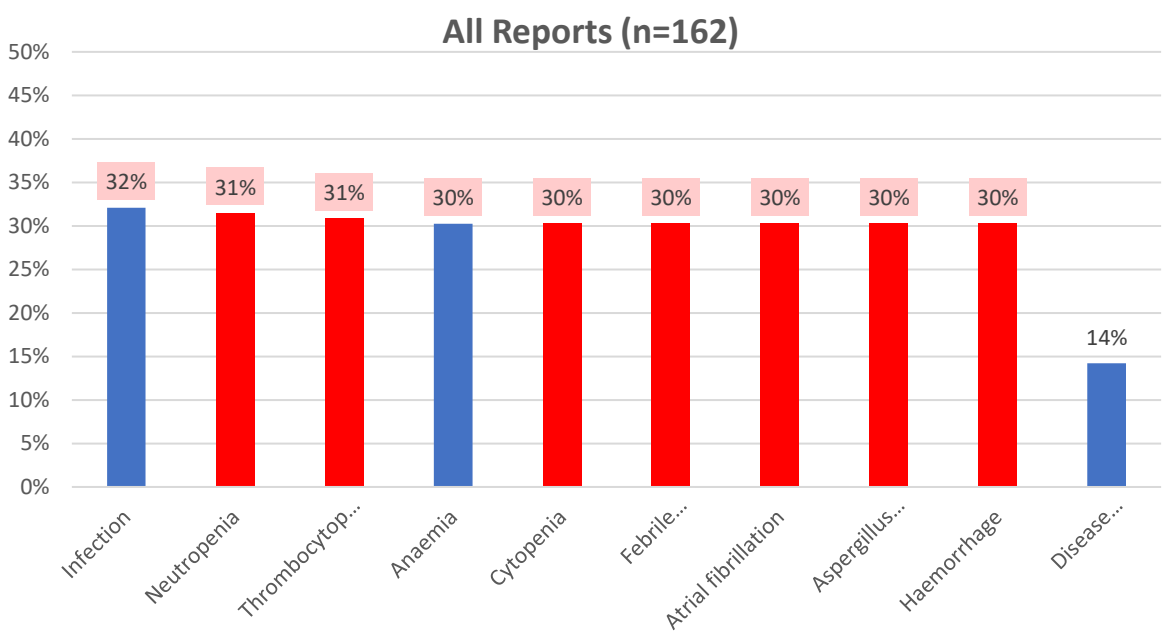
Case number	Report entry date	Age (yrs)	Gender	MedDRA reaction terms
494129	29/04/2020	53	F	[Maculopathy, Retinal toxicity]
494130	29/04/2020	63	F	[Maculopathy, Retinal depigmentation, Retinal toxicity]
494140	29/04/2020	55	F	[Maculopathy, Retinal depigmentation, Retinal toxicity]
494142	29/04/2020	69	F	[Maculopathy, Retinal toxicity]
494132	29/04/2020	71	F	[Maculopathy, Retinal depigmentation, Retinal toxicity]
494143	29/04/2020	60	F	[Maculopathy, Retinal depigmentation, Retinal toxicity]
494124	29/04/2020	50	F	[Maculopathy, Retinal toxicity]
494125	29/04/2020	55	F	[Maculopathy, Retinal depigmentation, Retinal toxicity]
494126	29/04/2020	88	M	[Maculopathy, Retinal depigmentation, Retinal toxicity]
494134	29/04/2020	57	F	[Maculopathy, Retinal toxicity]
494139	29/04/2020	63	F	[Maculopathy, Retinal toxicity]
495378	12/05/2020	-	-	[Maculopathy, Retinal toxicity]
495386	12/05/2020	-	-	[Maculopathy, Retinal toxicity]
495390	12/05/2020	-	-	[Maculopathy, Retinal toxicity]
495348	12/05/2020	-	-	[Maculopathy, Retinal toxicity]
495364	12/05/2020	-	-	[Maculopathy, Retinal toxicity]
495371	12/05/2020	-	-	[Maculopathy, Retinal toxicity]
495374	12/05/2020	-	-	[Maculopathy, Retinal toxicity]
495363	12/05/2020	-	-	[Maculopathy, Retinal toxicity]
495373	12/05/2020	-	-	[Maculopathy, Retinal toxicity]
495376	12/05/2020	-	-	[Maculopathy, Retinal toxicity]
495365	12/05/2020	-	-	[Maculopathy, Retinal toxicity]

Case number	Report entry date	Age (yrs)	Gender	MedDRA reaction terms
6891763	01/02/2022	-	-	[Anaemia, Aspergillus infection, Atrial fibrillation, Cytopenia, Febrile neutropenia, Haemorrhage, Infection, Neutropenia, Thrombocytopenia]
703845	1/02/2022	-	-	[Anaemia, Aspergillus infection, Atrial fibrillation, Autologous haematopoietic stem cell transplant, Cytopenia, Disease progression, Febrile neutropenia, Haemorrhage, Infection, Neutropenia, Thrombocytopenia]
704945	3/02/2022	-	-	[Anaemia, Aspergillus infection, Atrial fibrillation, Cytopenia, Febrile neutropenia, Haemorrhage, Infection, Neutropenia, Thrombocytopenia]
704943	3/02/2022	-	-	[Anaemia, Aspergillus infection, Atrial fibrillation, Cytopenia, Febrile neutropenia, Haemorrhage, Infection, Neutropenia, Thrombocytopenia]
704946	3/02/2022	-	-	[Anaemia, Aspergillus infection, Atrial fibrillation, Cytopenia, Febrile neutropenia, Haemorrhage, Infection, Neutropenia, Thrombocytopenia]
704948	3/02/2022	-	-	[Anaemia, Aspergillus infection, Aspergillus test, Atrial fibrillation, Cytopenia, Febrile neutropenia, Haemorrhage, Infection, Neutropenia, Thrombocytopenia]
704944	3/02/2022	-	-	[Anaemia, Aspergillus infection, Atrial fibrillation, Cytopenia, Febrile neutropenia, Haemorrhage, Infection, Neutropenia, Thrombocytopenia]
705415	4/02/2022	-	-	[Anaemia, Aspergillus infection, Atrial fibrillation, Cytopenia, Dysphagia, Febrile neutropenia, Haemorrhage, Infection, Neutropenia, Thrombocytopenia]
705443	4/02/2022	-	-	[Anaemia, Aspergillus infection, Atrial fibrillation, Cytopenia, Febrile neutropenia, Haemorrhage, Infection, Neutropenia, Thrombocytopenia]
705458	4/02/2022	-	-	[Anaemia, Aspergillus infection, Atrial fibrillation, Cytopenia, Disease recurrence, Febrile neutropenia, Haemorrhage, Infection, Neutropenia, Thrombocytopenia]
705455	4/02/2022	-	-	[Anaemia, Aspergillus infection, Atrial fibrillation, Cytopenia, Disease progression, Febrile neutropenia, Haemorrhage, Infection, Neutropenia, Thrombocytopenia]
705456	4/02/2022	-	-	[Anaemia, Aspergillus infection, Atrial fibrillation, Cytopenia, Febrile neutropenia, Haemorrhage, Infection, Neutropenia, Poisoning, Thrombocytopenia]
705457	4/02/2022	-	-	[Anaemia, Aspergillus infection, Atrial fibrillation, Cytopenia, Febrile neutropenia, Haemorrhage, Infection, Neutropenia, Poisoning, Thrombocytopenia]
705459	4/02/2022	-	-	[Anaemia, Aspergillus infection, Atrial fibrillation, Cytopenia, Febrile neutropenia, Haemorrhage, Infection, Neutropenia, Thrombocytopenia]
705466	4/02/2022	-	-	[Anaemia, Aspergillus infection, Atrial fibrillation, Cytopenia, Febrile neutropenia, Haemorrhage, Infection, Neutropenia, Thrombocytopenia]
705472	4/02/2022	-	-	[Anaemia, Aspergillus infection, Atrial fibrillation, Cytopenia, Febrile neutropenia, Haemorrhage, Infection, Neutropenia, Thrombocytopenia]

Hydroxychloroquine – Top 10 Reported Reactions



Doxycycline – Top 10 Reported Reactions



Red highlights “important” reactions (TGA)

Analysis of TGA DAEN (1/1/2018 – 31/3/2022)

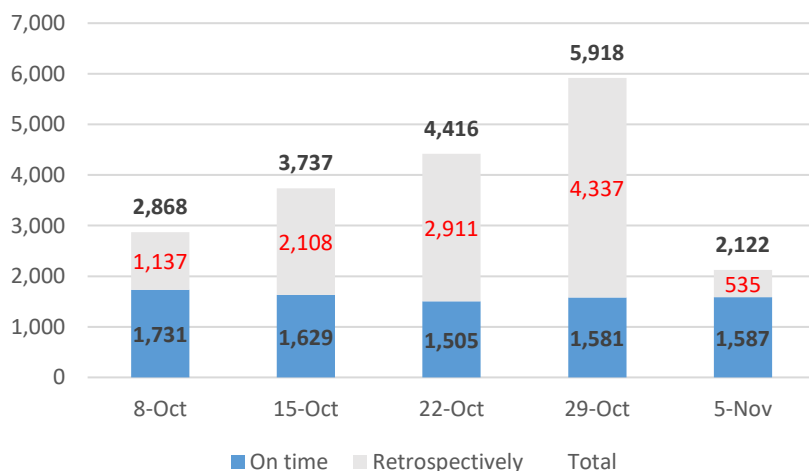
Appear in Top 10 as a result of ‘spam’

Blake Downward

Data manipulation

- “Medicine Summary” does not match “List of reports”
- Some reactions listed under 2 different MedDRA system organ classes
- Delay in release of reports – weekly totals much lower than actual
- Modification and removal reports / “public” vs “shadow” database
- Lack of download options/ live changes/ continued modifications
- No reporting other than “Medicine Summary”
- Lack of detail/ missing data
- *Apparent ‘targeting’ of reports by reaction*

Release of Reports



- “Sudden death” report was **removed**
- “**Death**” was the adverse reaction for 4 cases on **22/4/21** (3 changed to “Adverse event following immunisation” and 1 changed to “Intestinal obstruction”)

MedDRA reaction term (22/10/23)	List of reports	Medicine summary	Change
Guillain-Barre syndrome	176	171	-5

MedDRA reaction term (29/10/23)	List of reports	Medicine Summary	Change
Intermenstrual bleeding	170	108	-62
Swelling of eyelid	27	15	-12
Thrombosis with thrombocytopenia syndrome	145	135	-10
Heavy menstrual bleeding	384	374	-10
Cutaneous vasculitis	10	1	-9
Immune thrombocytopenia	103	94	-9
Incorrect route of product administration	11	3	-8
Death	9	4	-5

MedDRA reaction term (5/11/23)	List of reports	Medicine Summary	Change
Thrombophlebitis superficial	212	72	-140
Metrorrhagia	8	1	-7

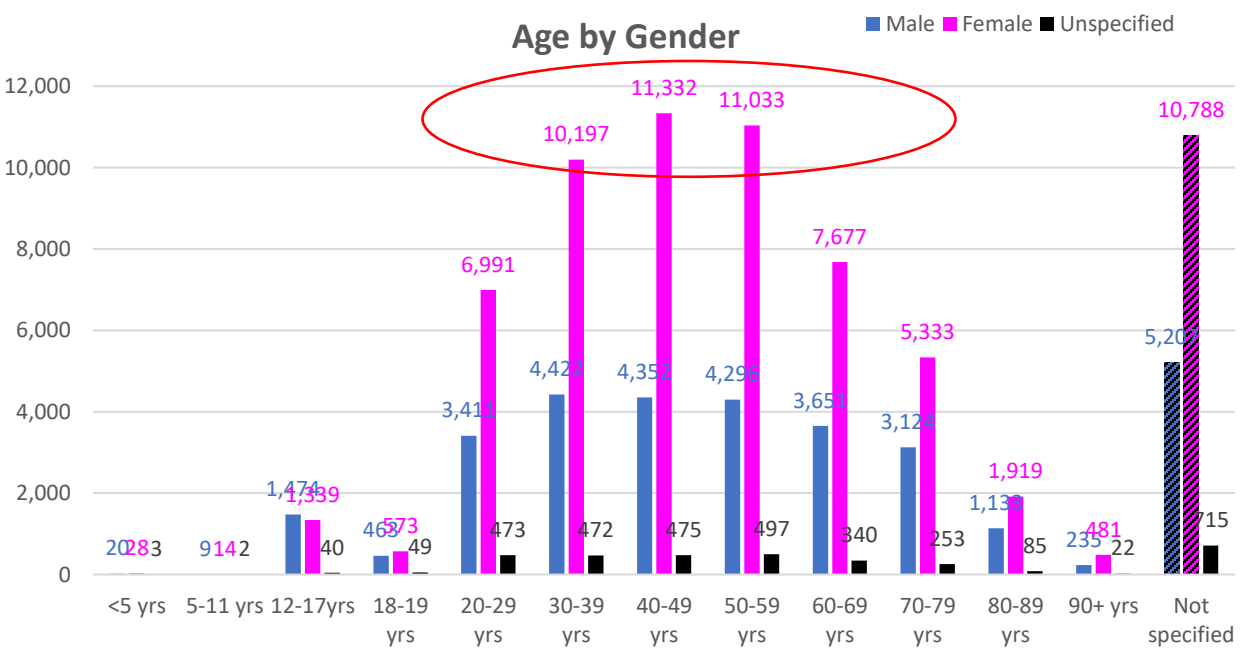
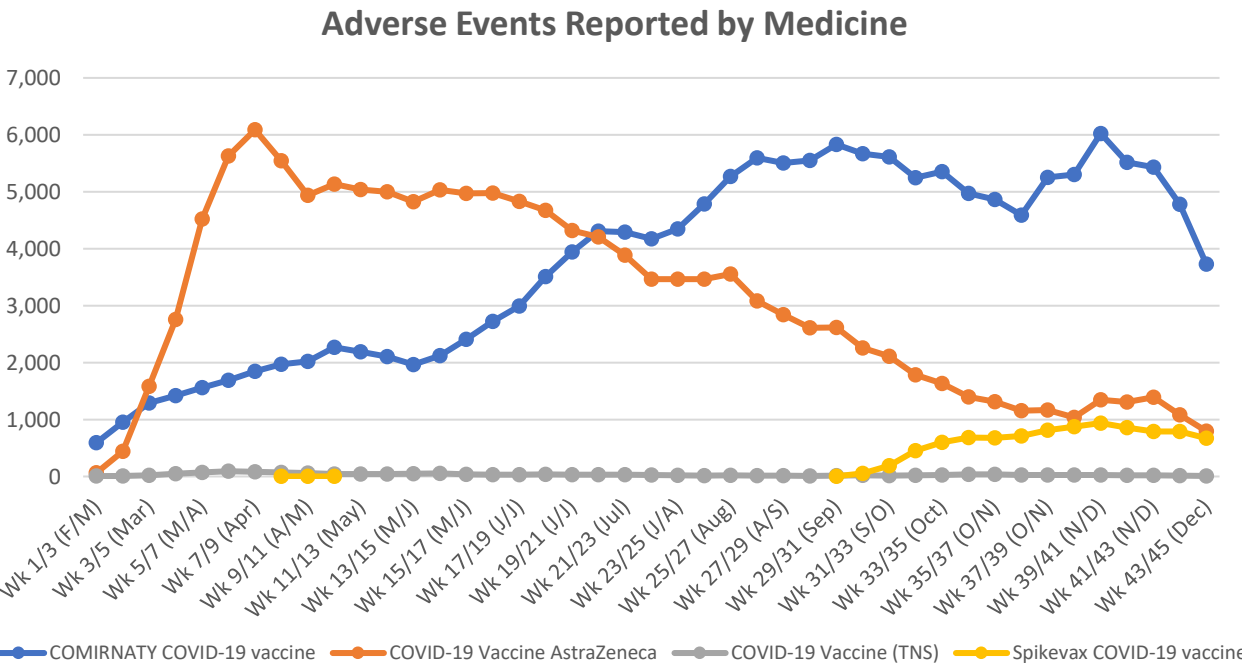
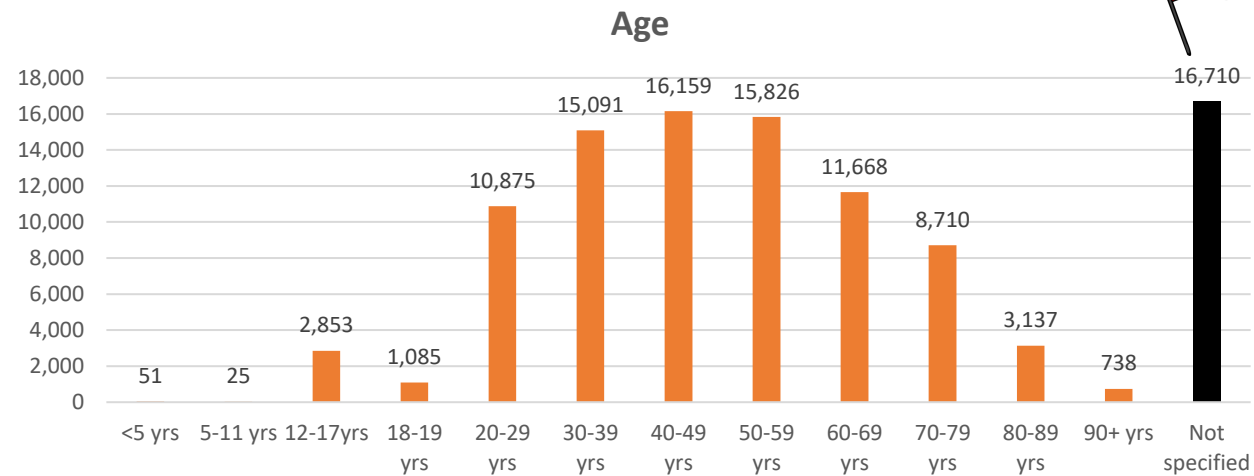
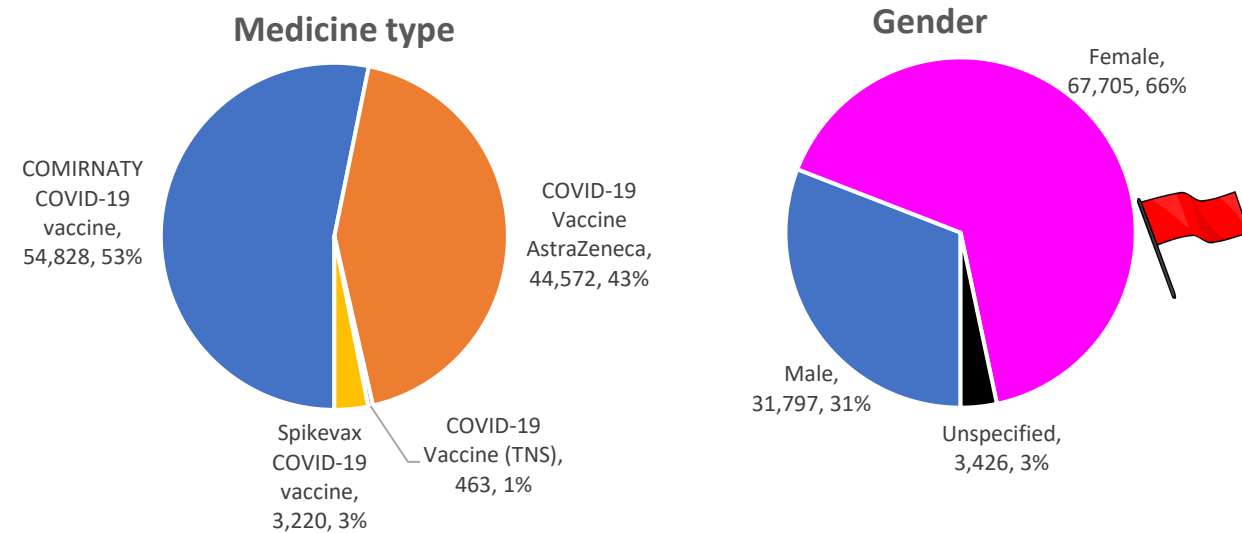
Total Cases Removed	245	19/11
THORACIC/CARDIAC PULMONARY	177	72.24%
Coronary Inflammatory disorders	161	65.71%
Myocarditis	43	17.55%
Pericarditis	127	51.84%

MedDRA reaction term (26/11)	List of reports	Medicine Summary	Change
Guillain-Barre syndrome	193	184	-9
Pulmonary embolism	1,283	1279	-4

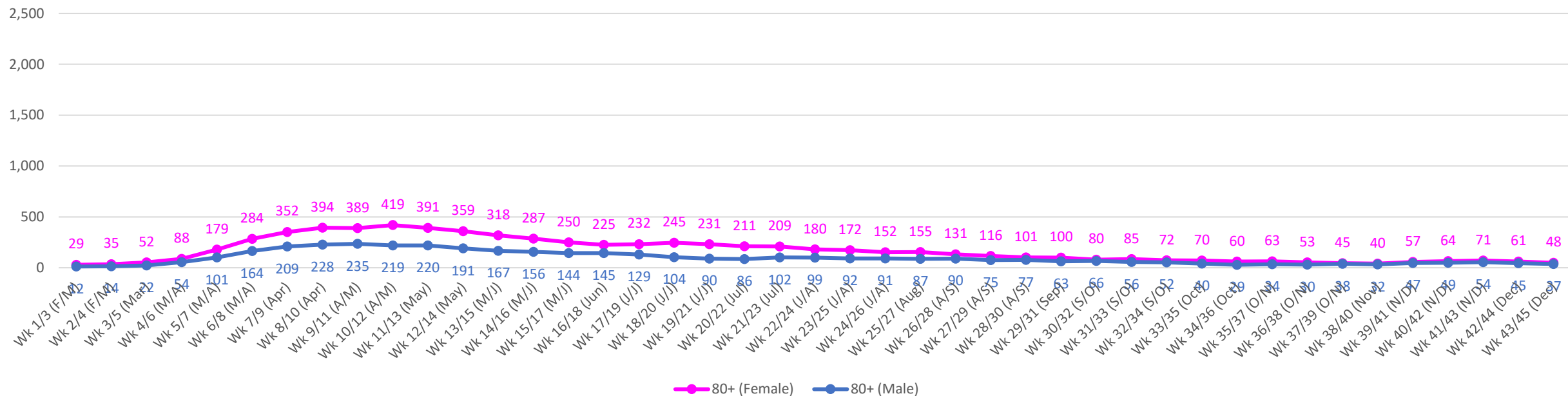
MedDRA reaction term (31/12/23)	List of reports	Medicine Summary	Change
Pericarditis	2,410	2,389	-21
Pulmonary embolism	1,374	1,363	-11
Cerebrovascular accident	412	404	-8
Thrombocytopenia	747	740	-7

MedDRA reaction term (3/12/23)	List of reports	Medicine Summary	Change
Vaccination error	737	730	-7
Expired product administered	99	93	-6
Incorrect route of drug administration	8	2	-6

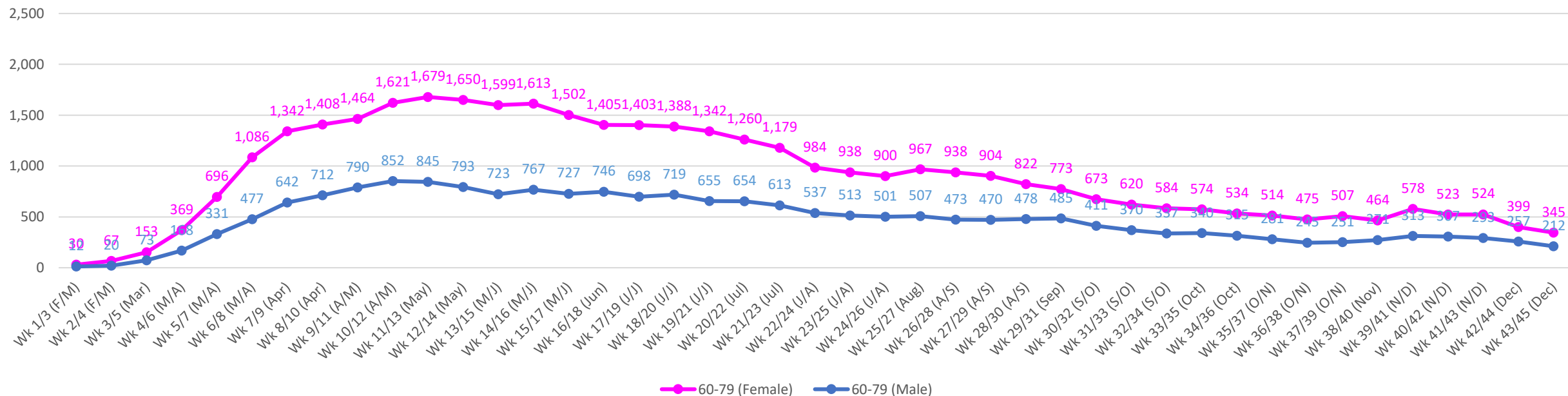
TGA adverse events for 'covid' medicines to 31/12/21:



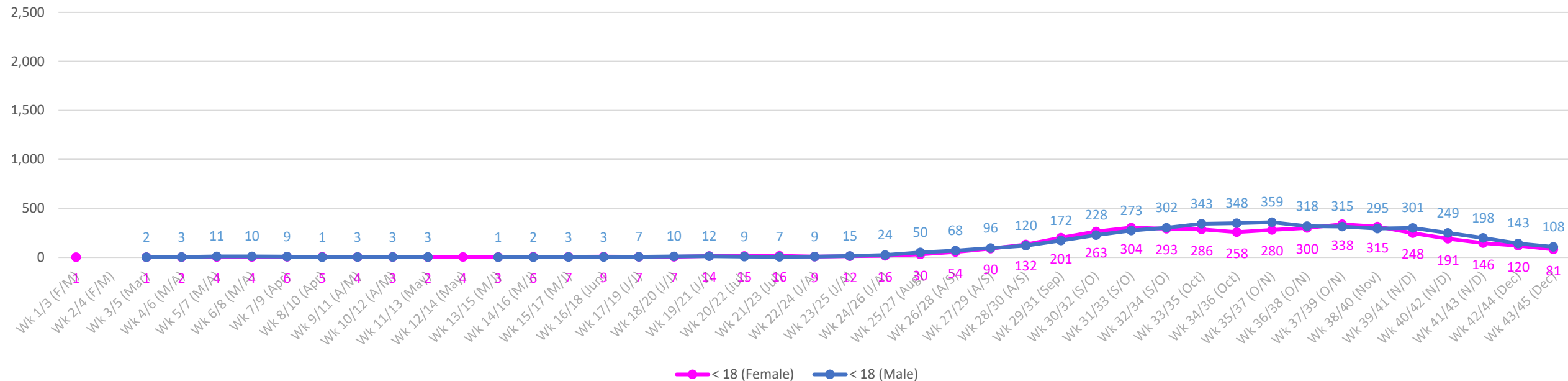
80+ by Gender



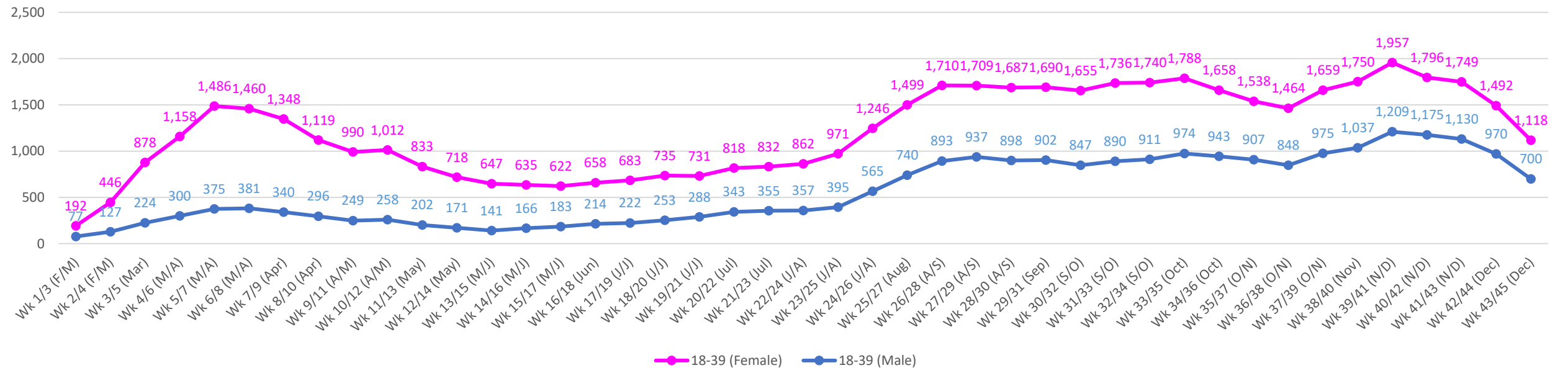
60-79 by Gender



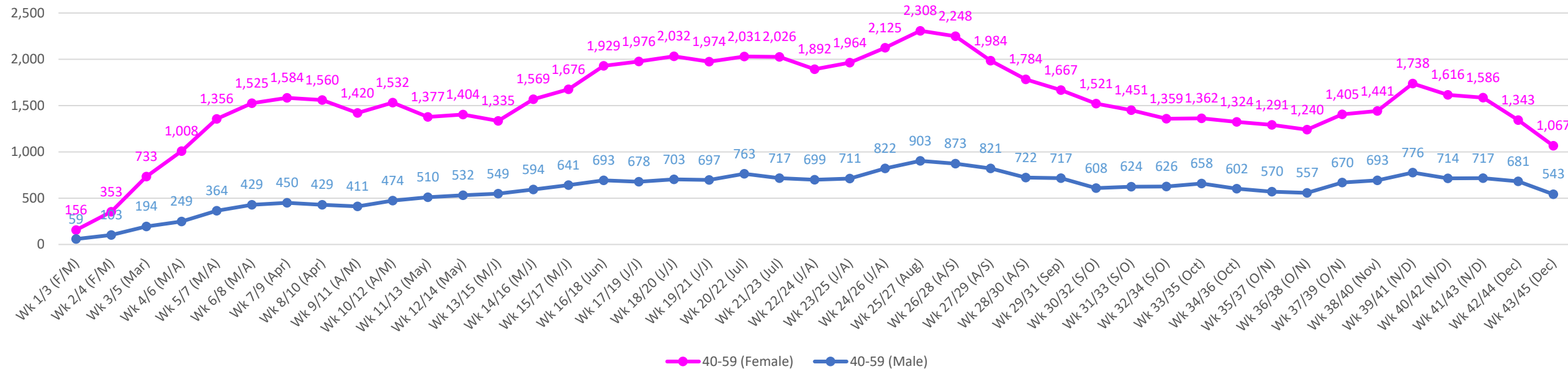
< 18 by Gender



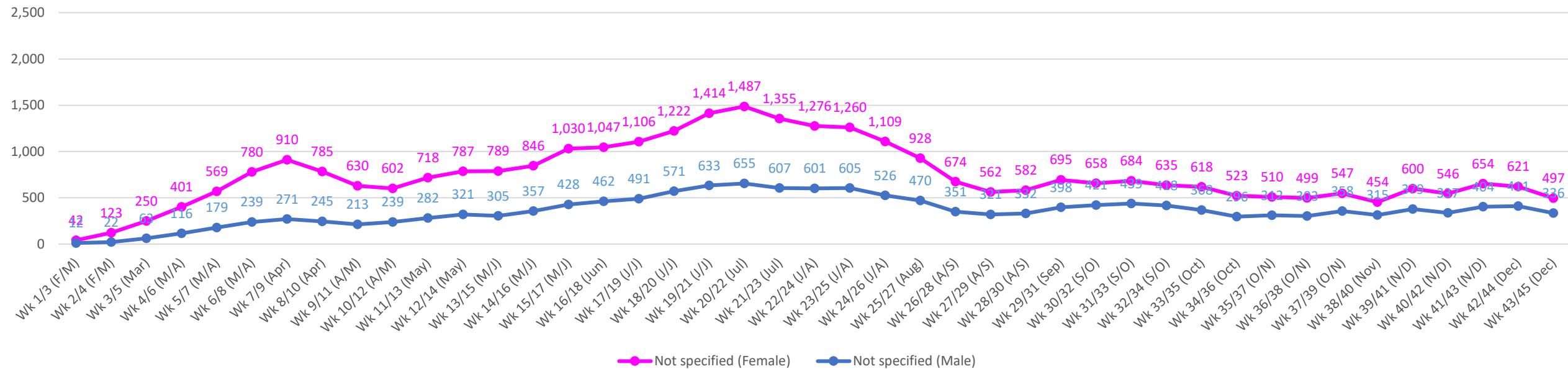
18-39 by Gender



40-59 by Gender



Age Not Specified by Gender



Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

[Further information about the medicine summary](#)

[Information on printing search results](#)

Sort by:

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Print version of this report

MedDRA system organ class	MedDRA reaction term click on a term below to search the MedlinePlus medical dictionary.	Number of cases	Number of cases with a single suspected medicine	Number of cases where death was a reported outcome
Nervous system disorders	Headache	663	650	1
General disorders and administration site conditions	Fatigue	403	396	0
General disorders and administration site conditions	Chest pain	364	354	2
Nervous system disorders	Dizziness	300	295	1
General disorders and administration site conditions	Pyrexia	299	293	1

Govt reporting

Reaction results using TGA MedDRA system organ class (28 classes)

TGA MedDRA system organ class	102,928
General disorders and administration site conditions	53,628
Nervous system disorders	51,906
Musculoskeletal and connective tissue disorders	28,140
Gastrointestinal disorders	24,139
Respiratory, thoracic and mediastinal disorders	15,241
Skin and subcutaneous tissue disorders	13,720
Cardiac disorders	10,421
Vascular disorders	6,695
Investigations	6,424
Blood and lymphatic system disorders	4,903
Infections and infestations	4,749
Psychiatric disorders	4,533
Eye disorders	4,224
Injury, poisoning and procedural complications	3,086
Ear and labyrinth disorders	2,991
Reproductive system and breast disorders	2,465
Metabolism and nutrition disorders	2,173
Immune system disorders	1,865
Renal and urinary disorders	878
Hepatobiliary disorders	241
Pregnancy, puerperium and perinatal conditions	234
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	178
Surgical and medical procedures	153
Endocrine disorders	130
Product issues	122
Social circumstances	93
Congenital, familial and genetic disorders	44

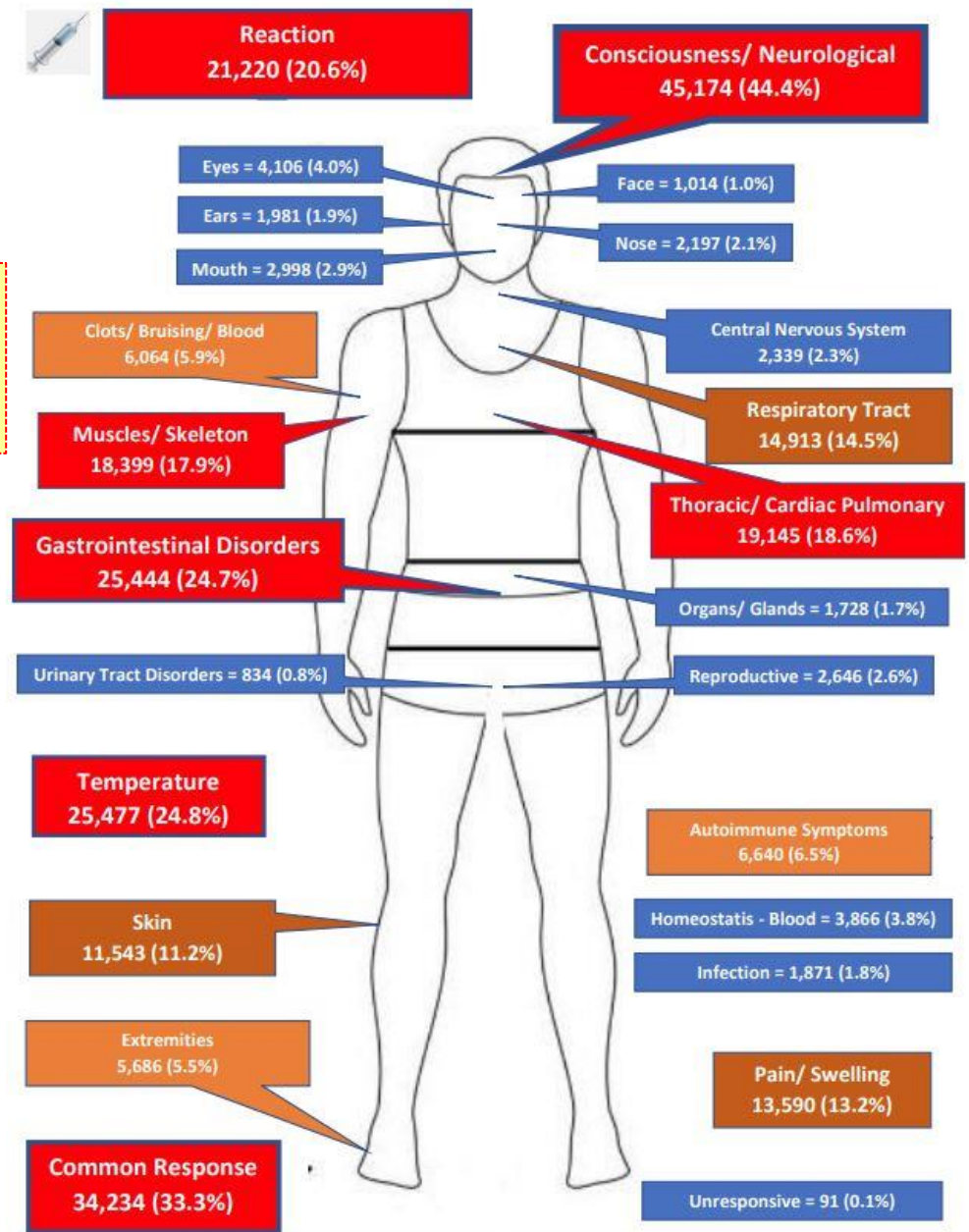
Cardiac disorders	10,421	New categories
Palpitations	3,964	Coronary symptoms – Arrythmias
Pericarditis	2,410	Coronary inflammatory disorders
Tachycardia	1,956	Coronary symptoms - Tachycardia
Myocarditis	1,119	Coronary inflammatory disorders
Atrial fibrillation	281	Coronary symptoms – Arrythmias
Myocardial infarction	218	Coronary symptoms – Ischaemia

General disorders and administration site conditions	53,628	New categories
Pyrexia	14,896	Temperature change
Fatigue	12,468	Fatigue (Common response)
Injection site reaction	11,291	Injection site (Reaction)
Chills	9,772	Temperature change
Chest pain	8,830	Thoracic/ Cardiac Pulmonary Symptoms
Nervous system disorders	51,906	
Headache	27,233	Headache (Neurological)
Dizziness	10,693	Vertigo (Common Response)
Lethargy	10,433	Lethargy (Common Response)
Paraesthesia	5,627	Numbness (Other Neurological)
Musculoskeletal and connective tissue disorders	28,140	
Myalgia	16,946	Muscular/ tendon
Arthralgia	10,446	Pain
Pain in extremity	3,893	Extremities
Back pain	1,351	Spinal symptoms
Gastrointestinal disorders	24,139	
Nausea	12,731	GIT Symptoms
Vomiting	4,774	GIT Symptoms
Abdominal pain	4,111	GIT Symptoms
Diarrhoea	4,078	GIT Symptoms
Paraesthesia oral	904	Mouth
Abdominal pain upper	873	GIT Symptoms
Swollen tongue	565	Mouth
Respiratory, thoracic and mediastinal disorders	15,241	
Dyspnoea	7,532	Breathing
Cough	2,217	Cough
Oropharyngeal pain	1,565	Throat –Upper GIT
Pulmonary embolism	1,375	Pulmonary embolism (Clots/ Bruising/ Blood)
Rhinorrhoea	704	Nose
Skin and subcutaneous tissue disorders	13,720	
Rash	4,542	Rash (Skin)
Hyperhidrosis	2,324	Sweating/ flushes (Temperature)
Pruritus	1,896	Allergic rash (Skin)
Urticaria	1,789	Rash (Skin)
Cold sweat	746	Sweating/ flushes (Temperature)

3,300+
reactions

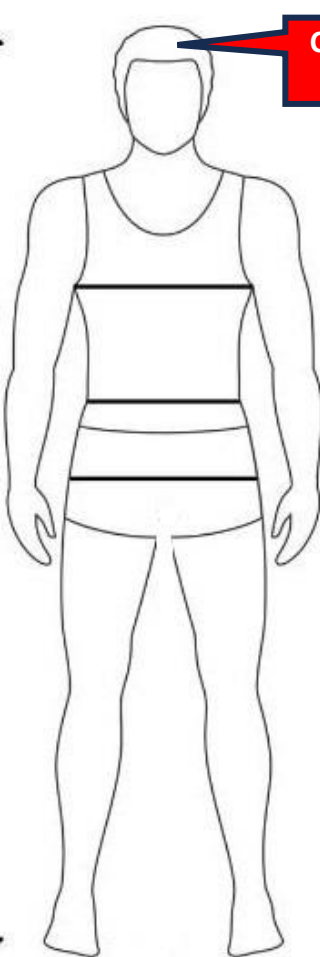
Registered Nurse
- **Teena Santerelli** (Newcastle)
Categorised all reactions into meaningful groups

Grouped into 122 categories



TGA Adverse Events Reports for Covid Medicines: 2021

1/1/21-31/12/21: List of reports analysis n = 102,928



Consciousness/ Neurological
45,174 (44%)

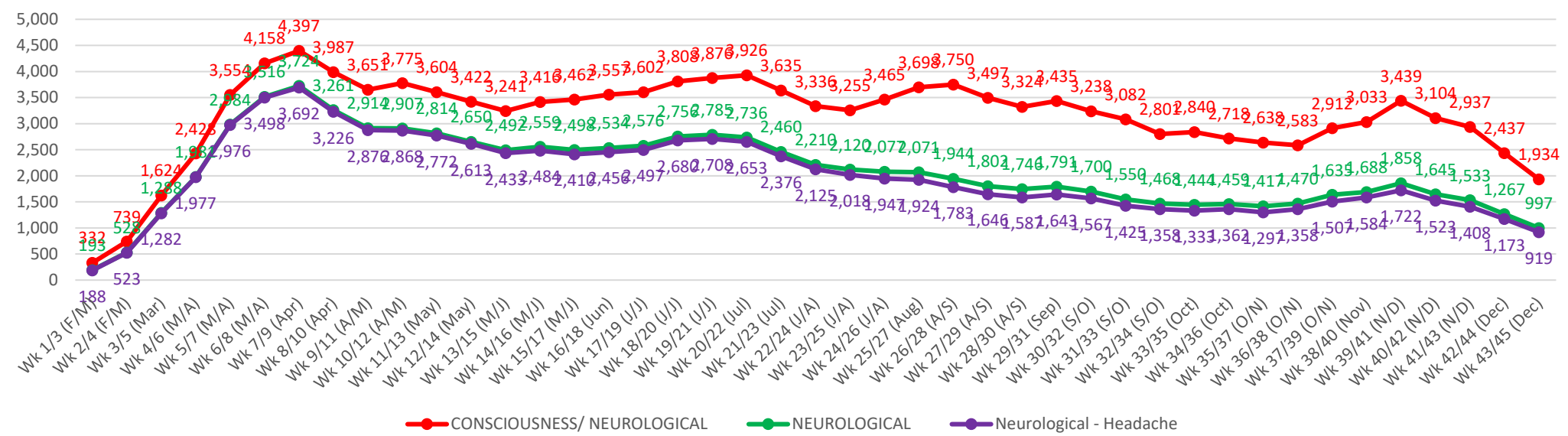
CONSCIOUSNESS/ NEUROLOGICAL	45,714
NEUROLOGICAL	29,929
Neurological - Headache	28,694
Headache	27,273

Headache =
60% of "Consciousness/ Neurological"
26% of ALL REPORTS

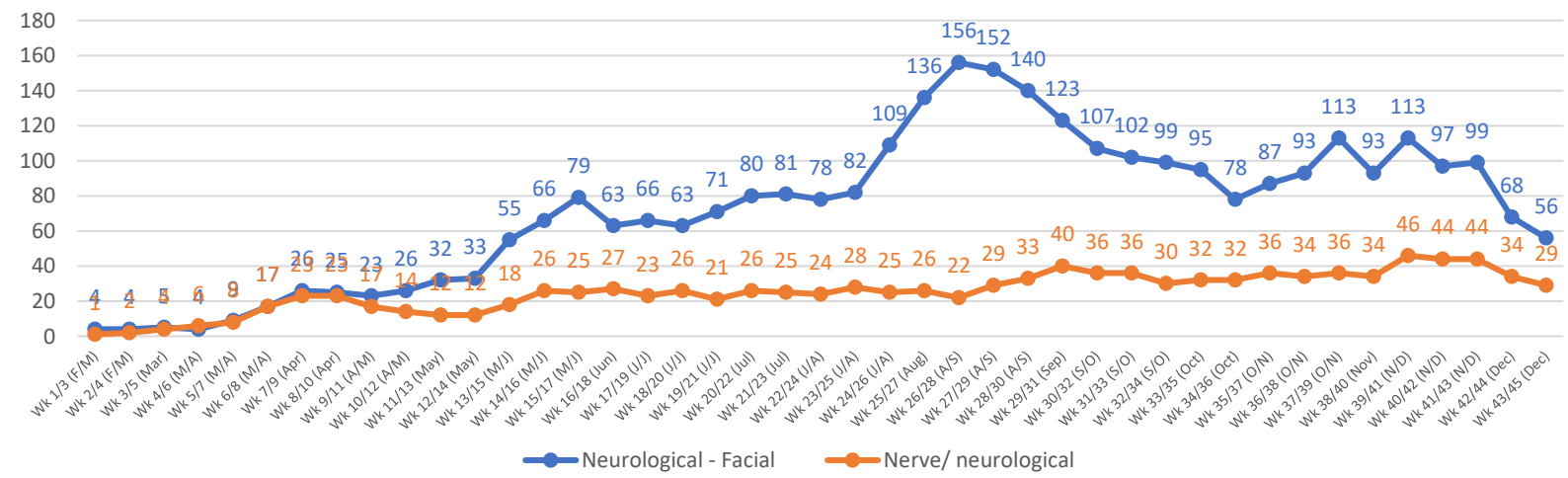


Headache: Early
increase, then
steady decline

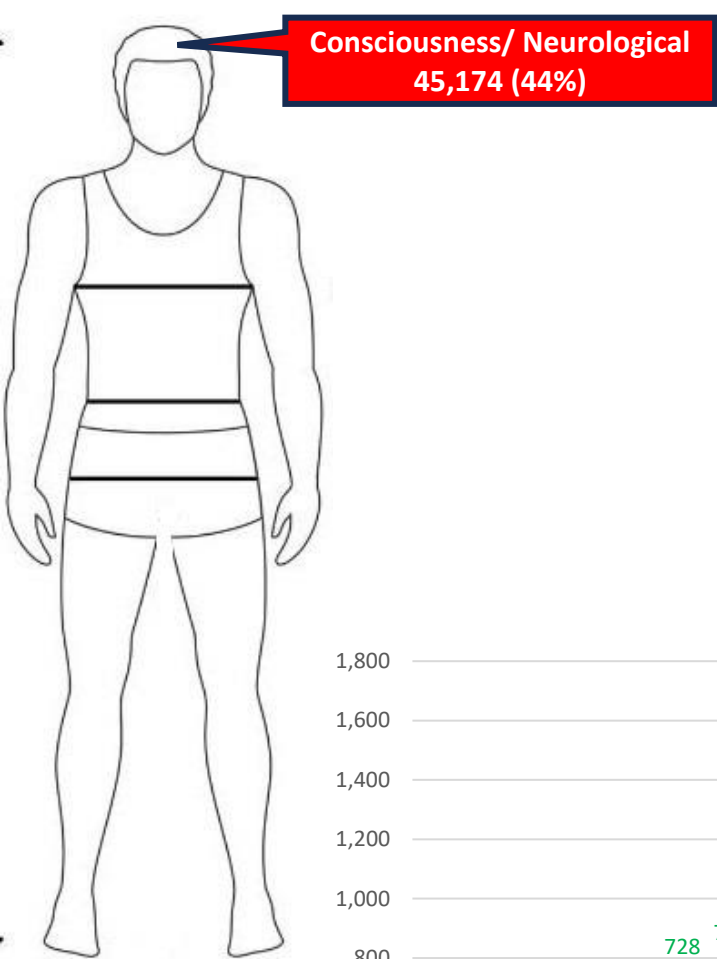
Adverse Reactions Reported for Covid Medicines - Consciousness/ Neurological



Neurological - Facial	1,049
Bell's palsy	530
Facial paralysis	419
Nerve/ neurological	370
Demyelination	93
Electric shock sensation	84
Neurological - Injury	95
Neurological - Infection	23
Encephalitis	17
Neurological - Obstructions	19
Neurological - Tumour	12



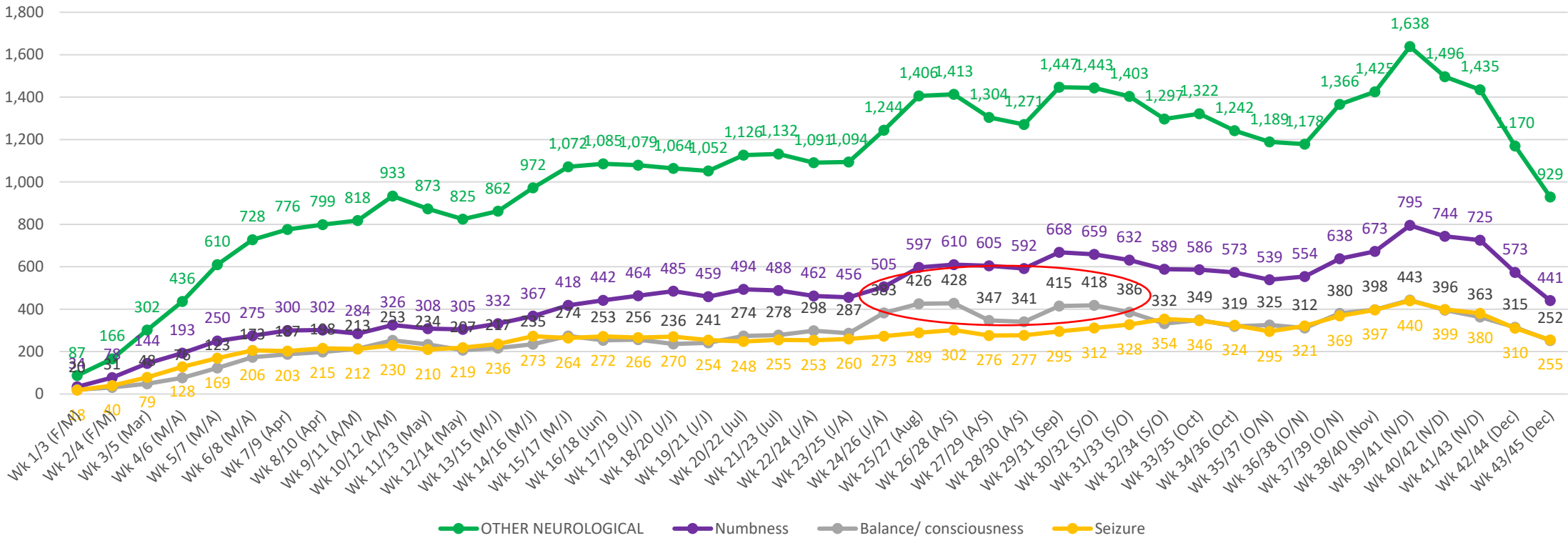
Increase in other
"Neurological"
reactions

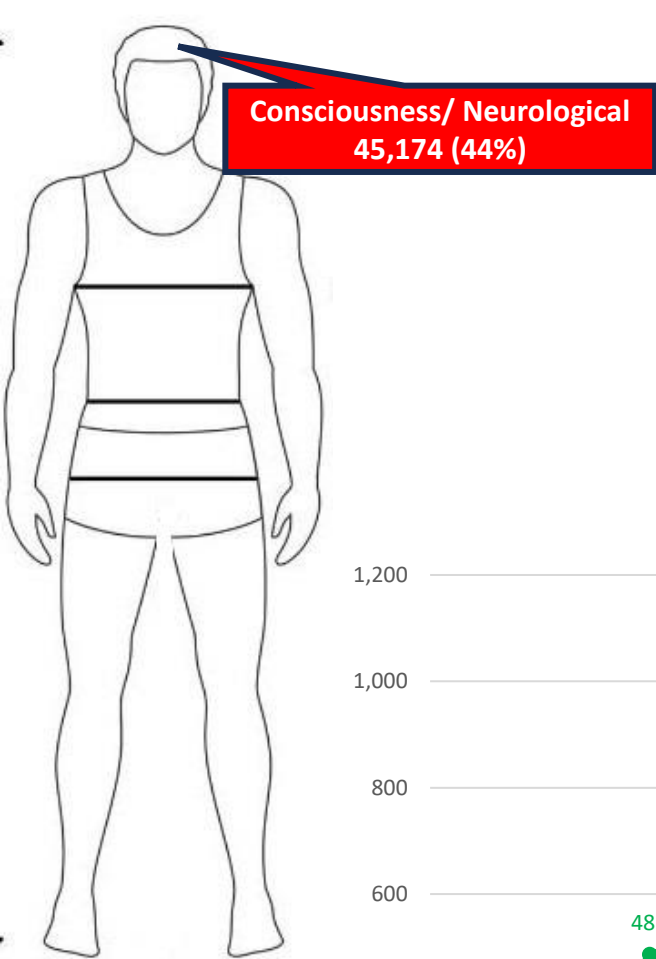


CONSCIOUSNESS/ NEUROLOGICAL	45,714
OTHER NEUROLOGICAL	15,435
Numbness	6,765
Paraesthesia ("pins and needles")	5,627
Balance/ consciousness	4,045
Syncope (loss of consciousness)	2,894
Hypoaesthesia (abnormal sensory response)	1,737
Balance disorder	383
Seizure	3,835
Tremor	1,395
Muscle spasms	890

Taste	1,561
Speech	704
Autoimmune/ Neurlogical disease	327
Guillain-Barre syndrome	227
Multiple sclerosis	22
Paralysis	170

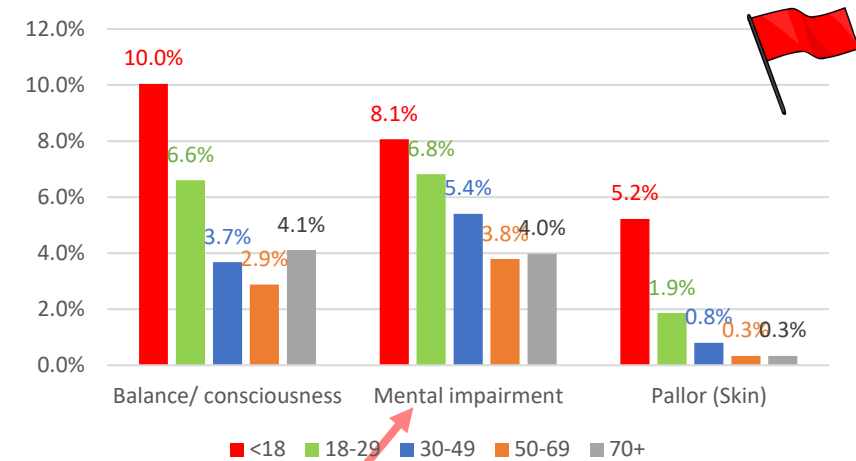
Adverse Reactions Reported for Covid Medicines - Other Neurological



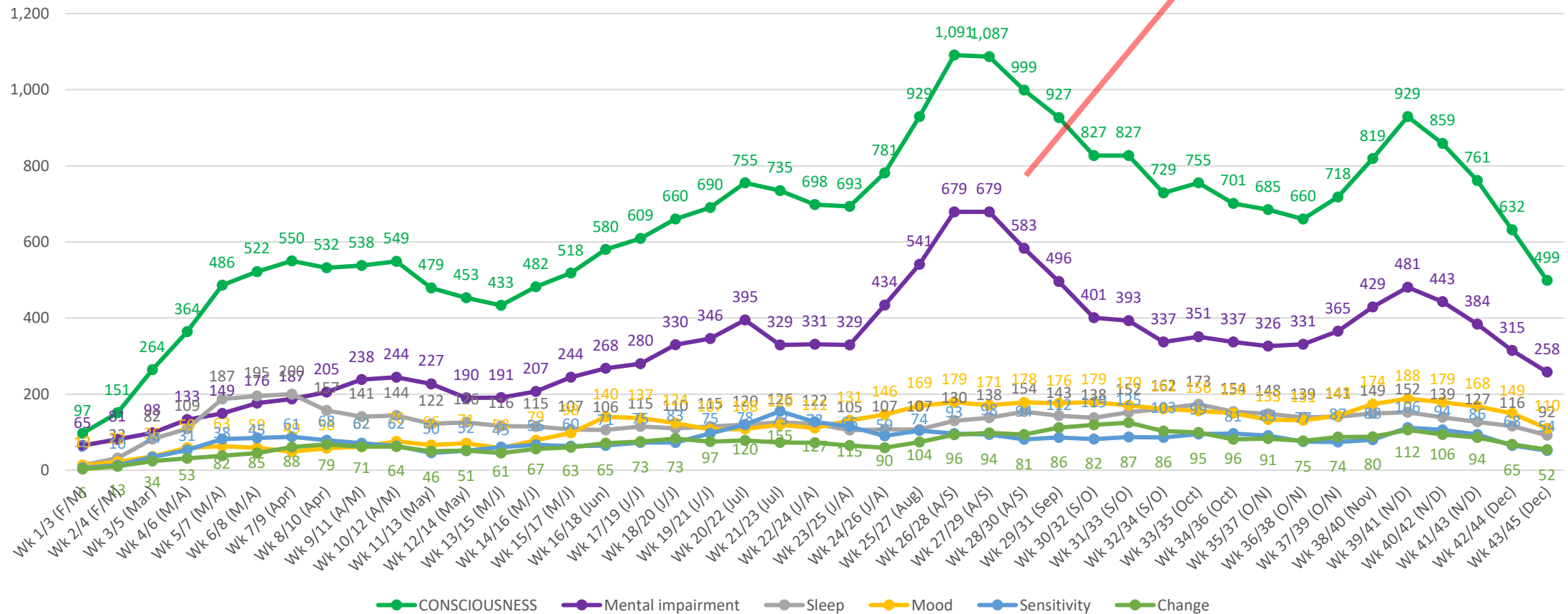


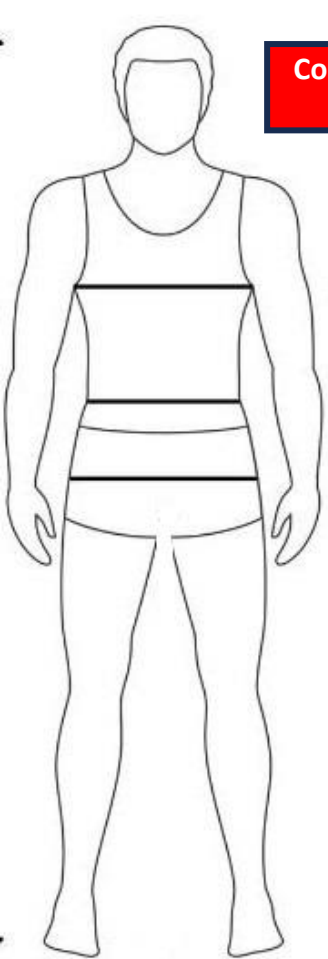
CONSCIOUSNESS/ NEUROLOGICAL	45,714
CONSCIOUSNESS	9,493
Mental impairment	4,685
Presyncope (near fainting)	2,581
Confusional state	870
Sleep	1,864
Insomnia	1,403
Mood	1,712
Anxiety	876
Panic attack	104

Sensitivity	1,161
Hypersensitivity	638
Photophobia	422
Change	1,029
Feeling abnormal	1,004



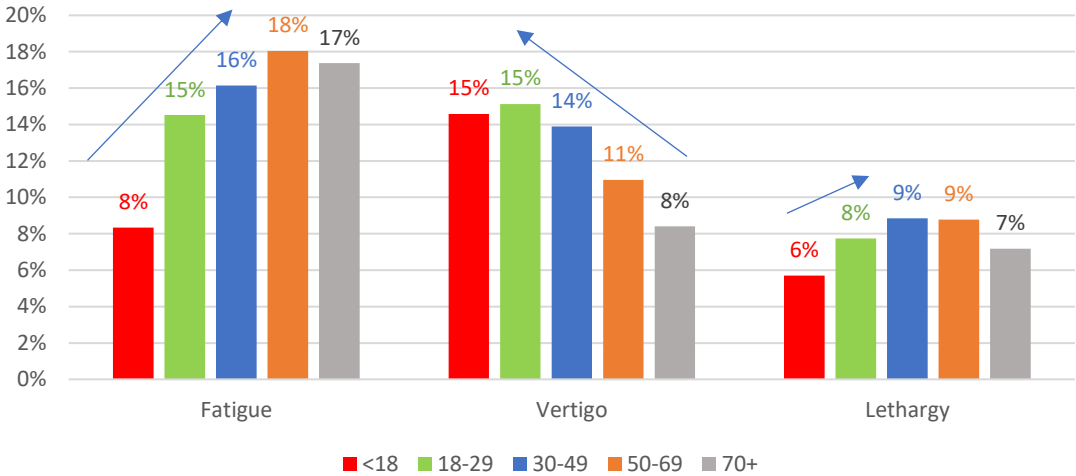
Adverse Reactions Reported for Covid Medicines - Consciousness



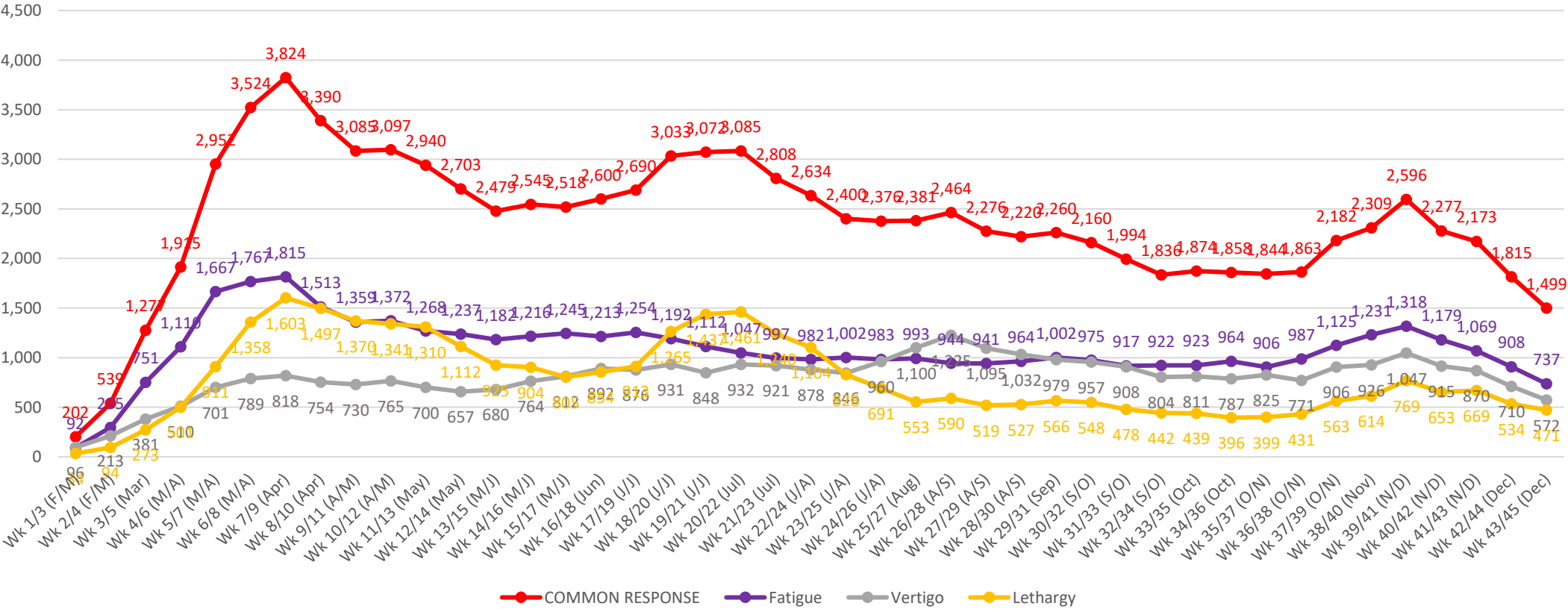


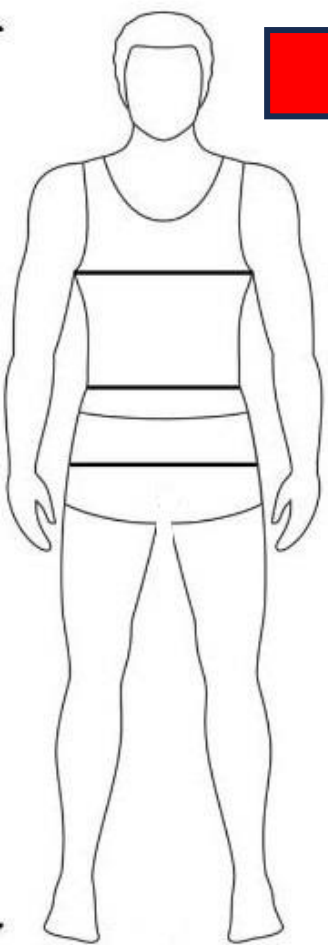
Common Response
34,234 (33%)

COMMON RESPONSE	34,234
Fatigue	15,757
Fatigue	12,468
Malaise	3,359
Vertigo	11,707
Dizziness	10,693
Vertigo	1,169
Lethargy	11,440
Lethargy	10,433



Adverse Reactions Reported for Covid Medicines - Common Response

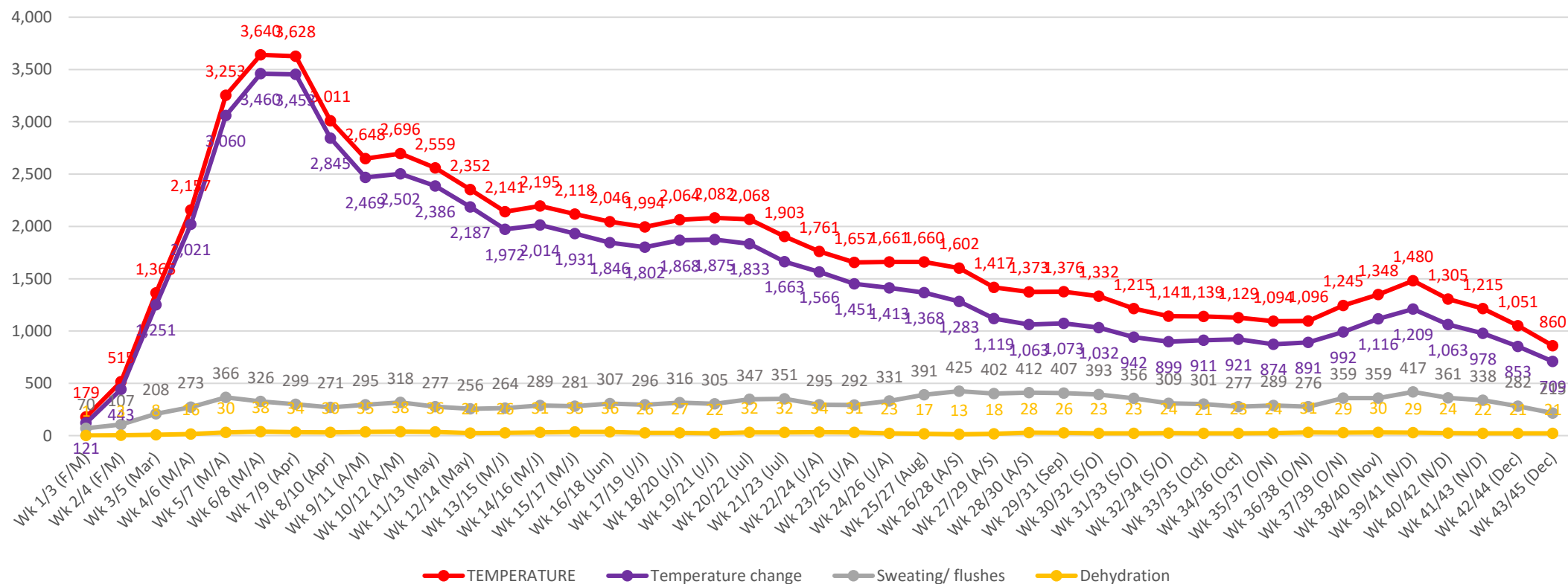


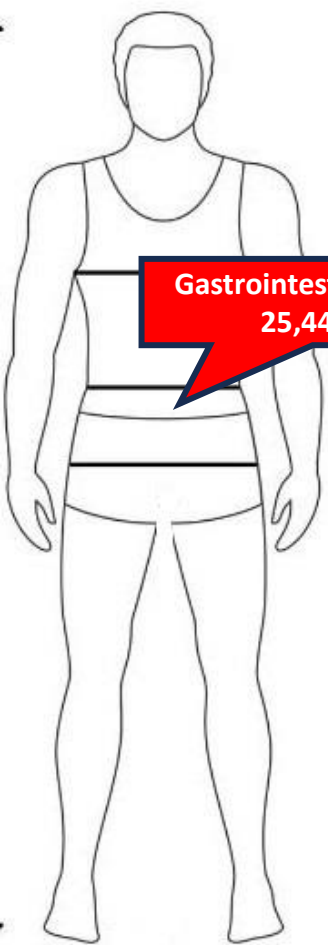


Temperature
25,477 (25%)

TEMPERATURE	25,477
Temperature change	22,414
Pyrexia	14,896
Chills	9,772
Sweating/ flushes	4,502
Hyperhidrosis	2,324
Flushing	785
Cold sweat	746
Dehydration	372
Thirst	212
Dehydration	141

Adverse Reactions Reported for Covid Medicines - Temperature





Gastrointestinal Disorders
25,444 (25%)

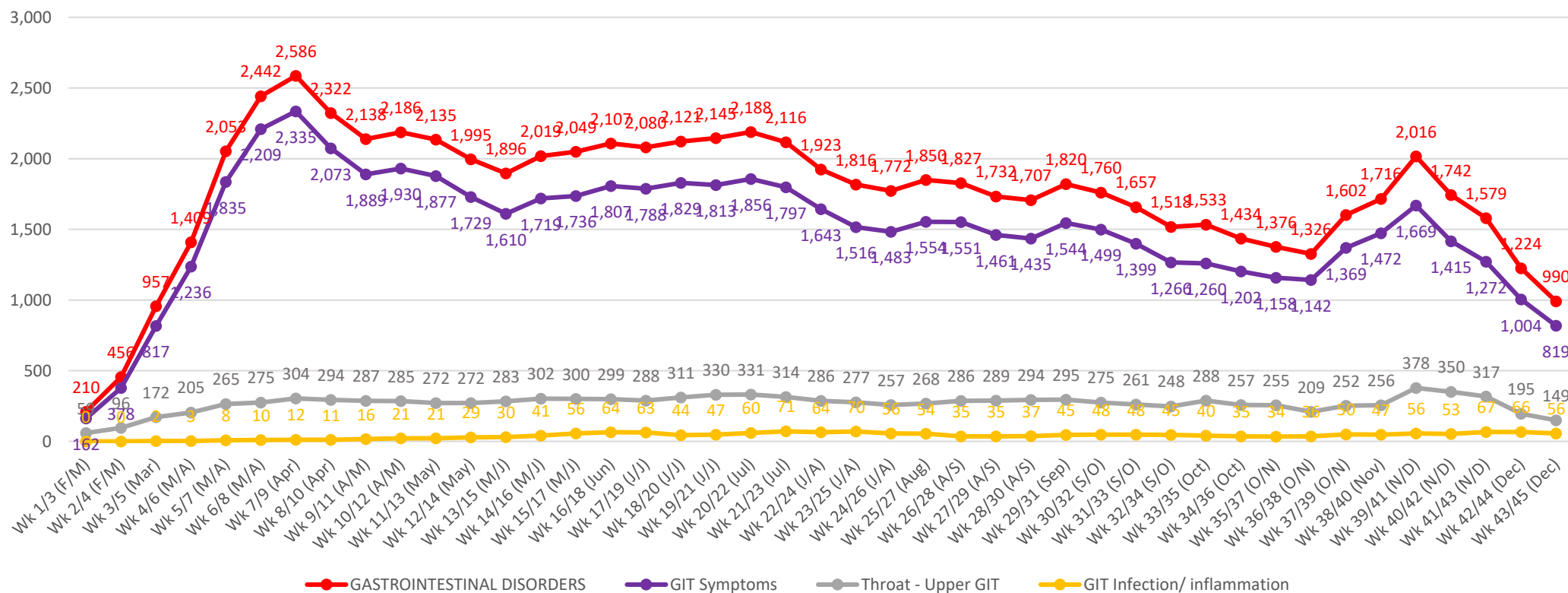
GASTROINTESTINAL DISORDERS	25,444
GIT Symptoms	21,729
Nausea	12,731
Vomiting	4,774
Abdominal pain	4,111
Diarrhoea	4,078
Throat - Upper GIT	3,882
Oropharyngeal pain	1,565
Throat tightness	703
GIT Infection/ inflammation	574
Gastrooesophageal reflux disease	116

Mainly Symptoms

GIT Symptoms =
85% of "Gastrointestinal disorders"

GIT Vascular/ Haemorrhagic	259
Rectal haemorrhage	88
Lower GIT	135
Gastrointestinal disorder	27
Weight increase/ hunger	55
Weight increased	22

Adverse Reactions Reported for Covid Medicines - Gastrointestinal Disorders

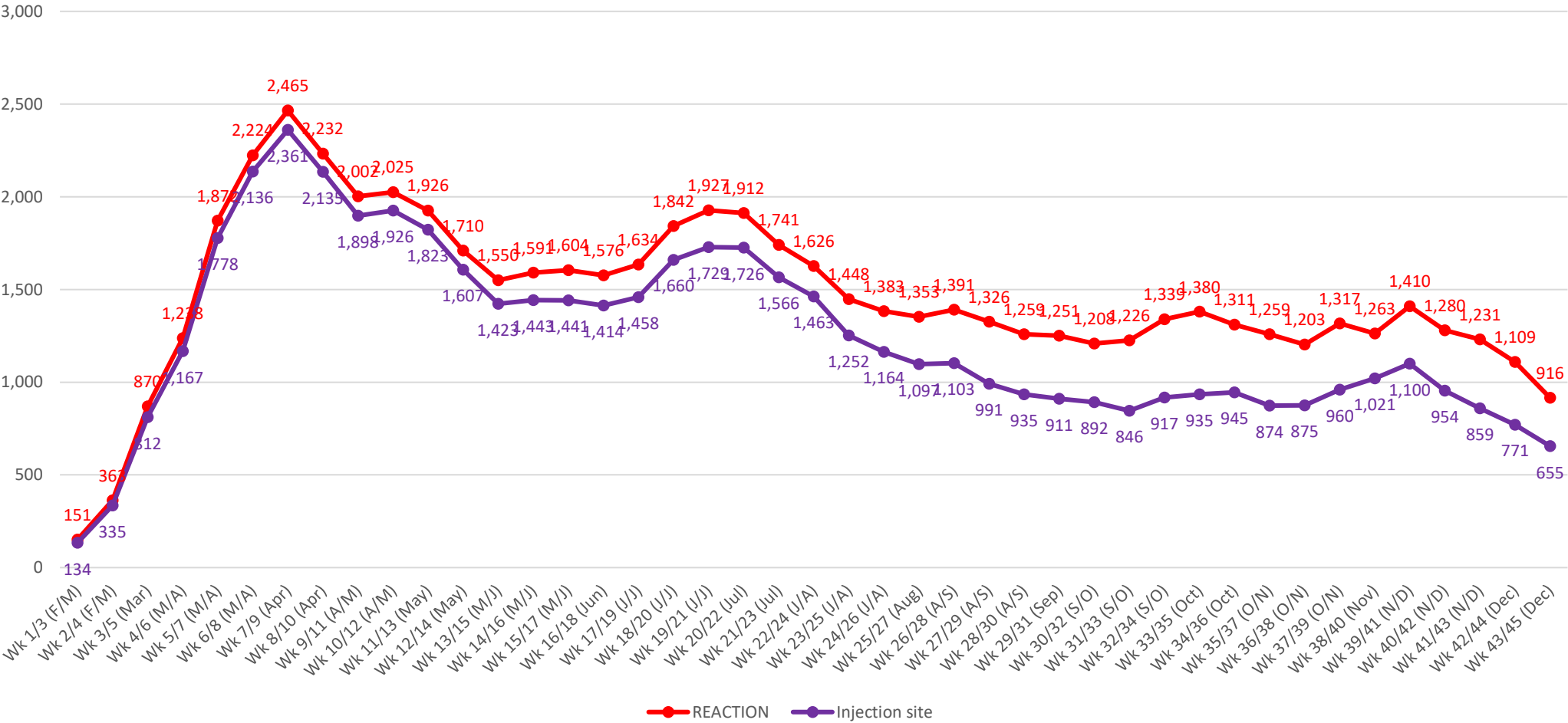


*Large initial increase,
then steady decline.
Decline is due to decline
in "Symptoms"*

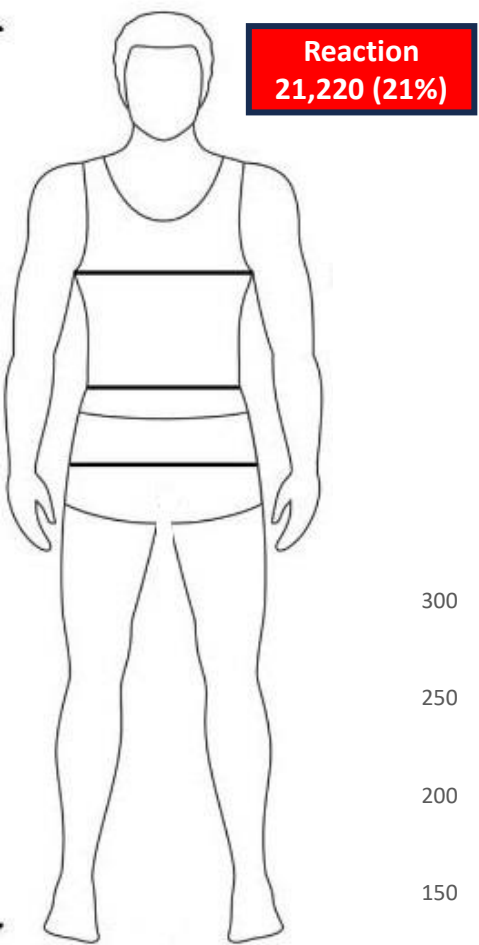


REACTION	21,220
Injection site	18,009
Injection site reaction	11,291
Injection site pain	4,358

Adverse Reactions Reported for Covid Medicines - Reaction



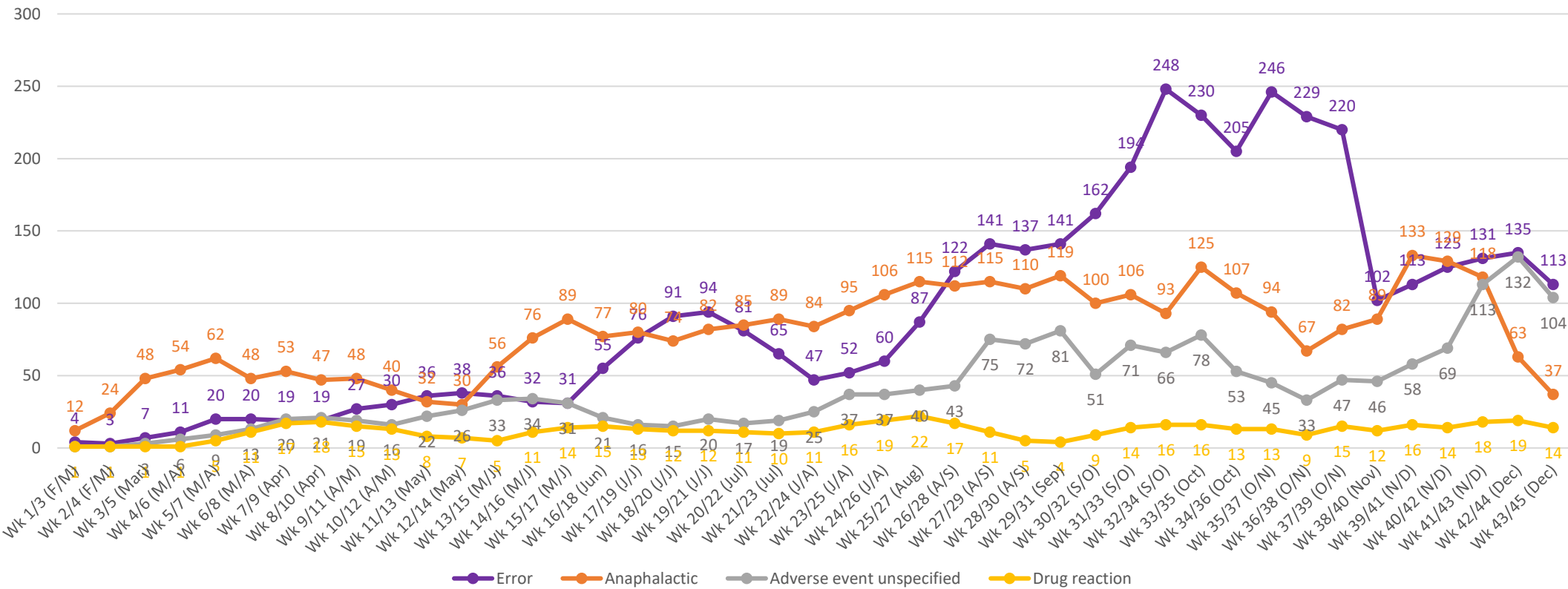
Large initial increase
then steady decline
Decline is due to decline
in "Injection site"



REACTION	21,220
Error	1,377
Vaccination error	1,004
Expired product administered	191
Product administered to patient of inappropriate age	129
Wrong product administered	115
Anaphalactic	1,144
Anaphylactic reaction	1,107
Adverse event unspecified	598
Adverse event following immunisation	516

Drug reaction	172
Sepsis	86
Treatment/ investigation required	42
Hospitalisation	32
Allergy	35
Seasonal allergy	21
Ineffective	14
Drug ineffective	12

Adverse Reactions Reported for Covid Medicines - Reaction



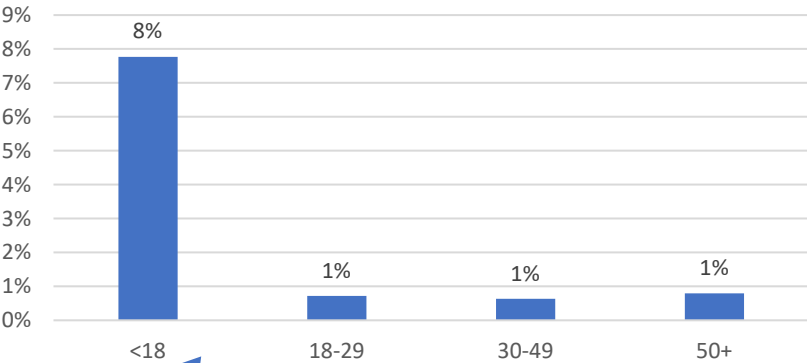
Late increase in
"Error" and "Adverse
Event Unspecified"

REACTION	21,220
Error	1,377
Vaccination error	1,004
Expired product administered	191
Product administered to patient of inappropriate age	129
Wrong product administered	115



Patients under 18 years of age were 8 times more likely to report an “Error” than others

Error (REACTION)



	<18
Error	224
Vaccination error	187
Product administered to patient of inappropriate age	86
Wrong product administered	48
Medication error	11
Expired product administered	4
Inappropriate schedule of product administration	4
Underdose	2
Incorrect dose administered	1
Product administered at inappropriate site	1
Product administration error	1
Wrong drug administered	1

REACTION	21,220
Adverse event unspecified	598
Adverse event following immunisation	516



Most reported reaction where the outcome was death

26% of reports with “Adverse event following immunisation” had an outcome of death

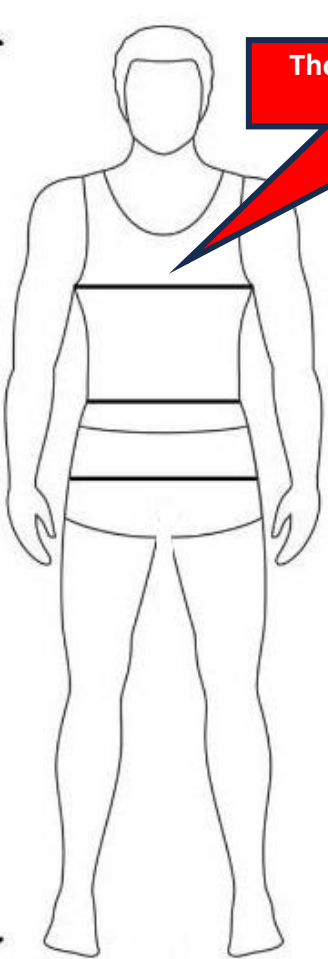
MedDRA system organ class	MedDRA reaction term	Number of cases	Cases with a single suspected medicine	Cases where death was a reported outcome
Injury, poisoning and procedural complications	Adverse event following immunisation	503	493	133
Respiratory, thoracic and mediastinal disorders	Dyspnoea	7,743	7,556	75
Cardiac disorders	Cardiac arrest	118	110	68
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	1,375	1,317	65
Nervous system disorders	Cerebrovascular accident	404	386	58
General disorders and administration site conditions	Concomitant disease progression	82	76	54
Blood and lymphatic system disorders	Thrombocytopenia	753	716	47

Search summary counter

Reports (cases)	Single suspected medicine	Reported deaths
102,761	100,974	747

18% of “Reports deaths” had “Adverse event following immunisation” as a reaction (133 of 747 – see above)

NB: Screenshots were taken in 2023 – therefore some reports have been deleted



Thoracic/ Cardiac Pulmonary
(19%)

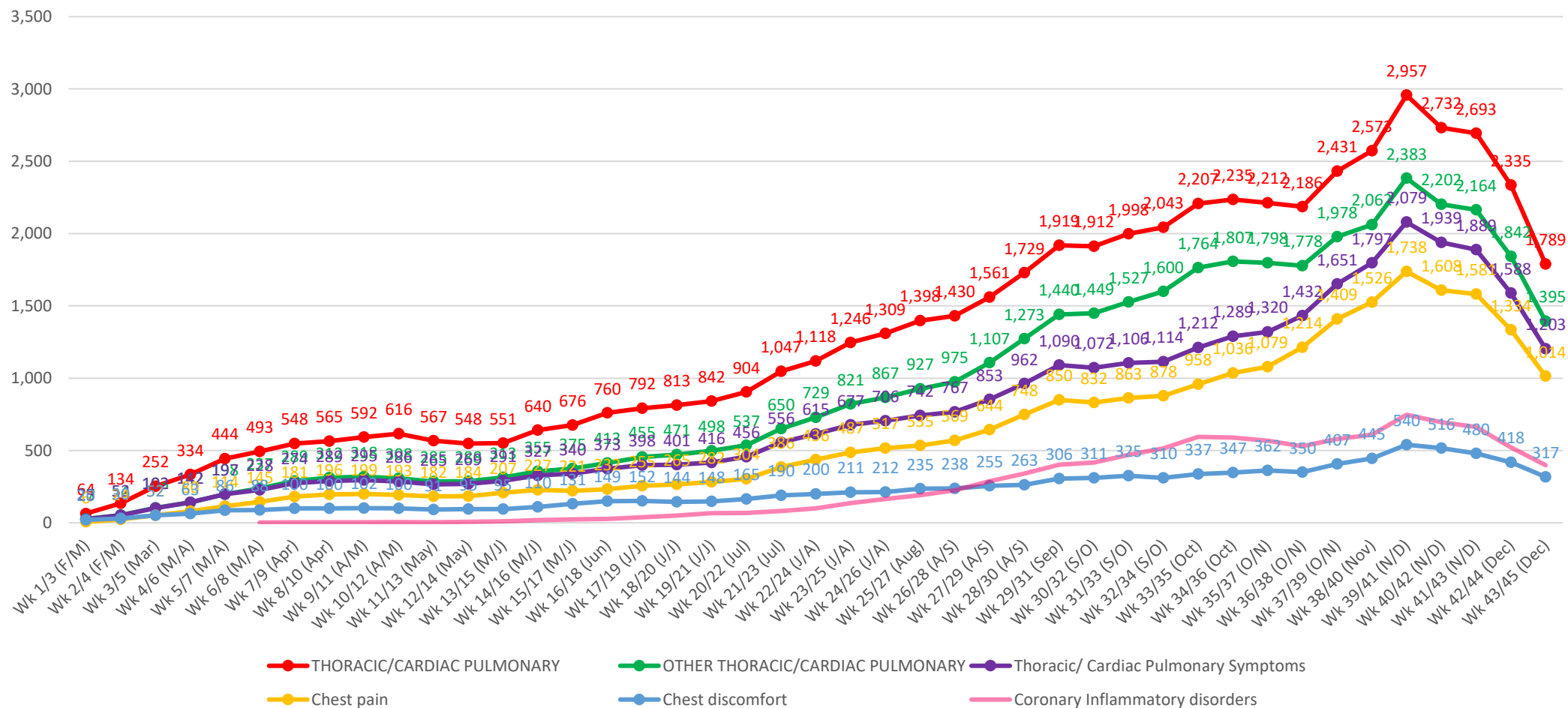
THORACIC/CARDIAC PULMONARY	19,145
OTHER THORACIC/CARDIAC PULMONARY	13,828
Thoracic/ Cardiac Pulmonary Symptoms	11,314
Chest pain	8,830
Chest discomfort	3,285
Coronary Inflammatory disorders	3,476

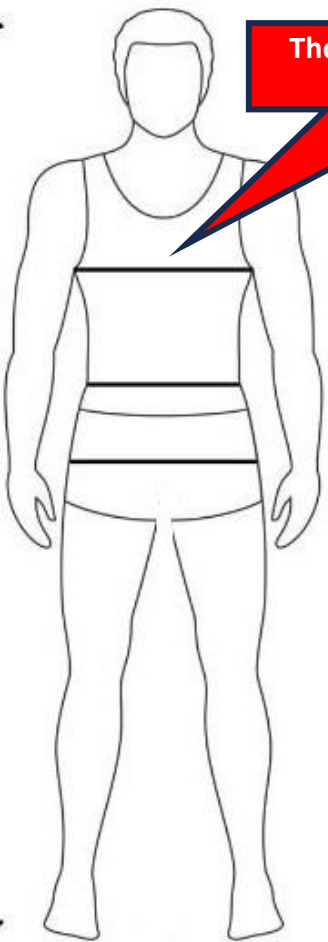
Mainly Symptoms



Thoracic/ Cardiac Pulmonary Symptoms" =
82% of "Other Thoracic/ Cardiac Pulmonary"
11% of ALL REPORTS

Adverse Reactions Reported for Covid Medicines - Thoracic/ Cardiac Pulmonary



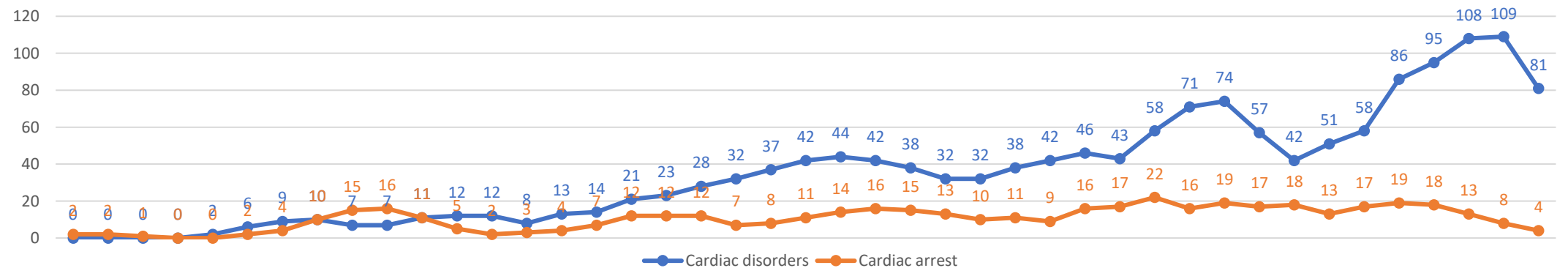
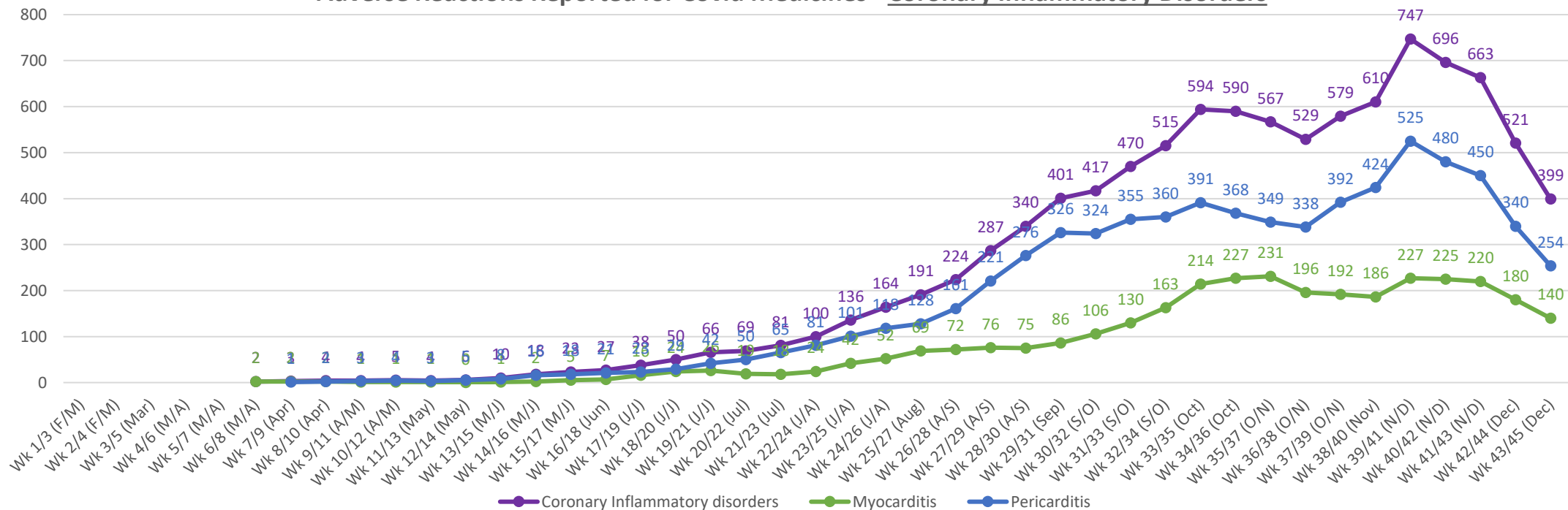


Thoracic/ Cardiac Pulmonary
(19%)

THORACIC/CARDIAC PULMONARY	19,145
OTHER THORACIC/CARDIAC PULMONARY	13,828
Coronary Inflammatory disorders	3,476
Pericarditis	2,410
Myocarditis	1,119

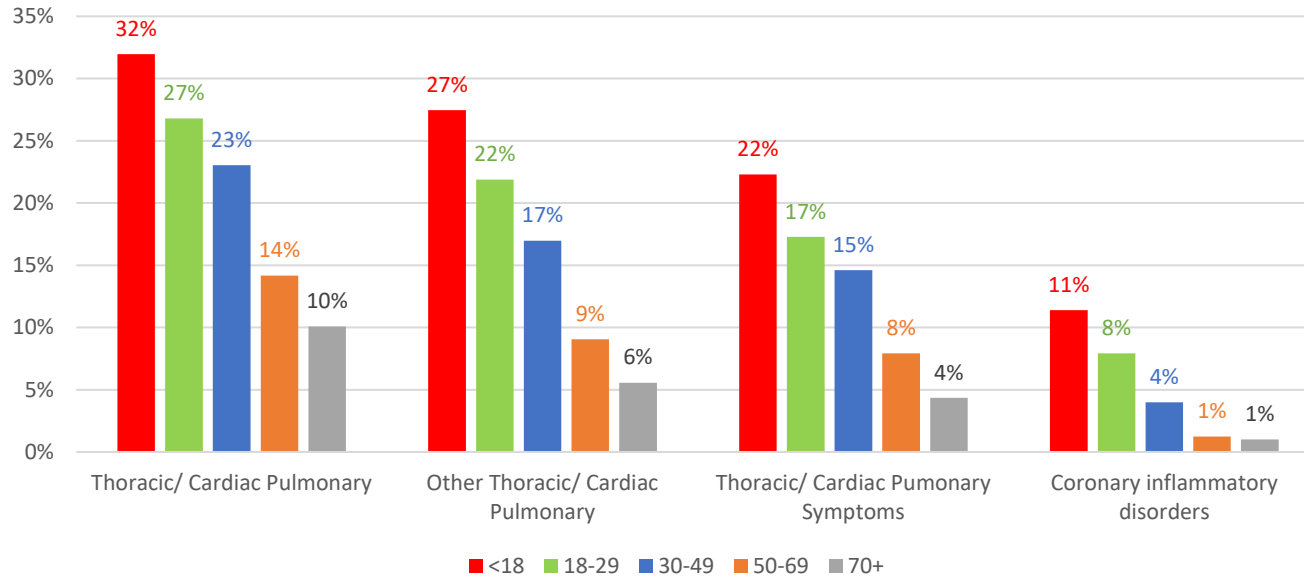
Cardiac disorders	532
Pericardial effusion	162
Cardiac arrest	151
Cardiac arrest (58% resulted in death)	110
Coronary Vavular Disorders	20

Adverse Reactions Reported for Covid Medicines - Coronary Inflammatory Disorders

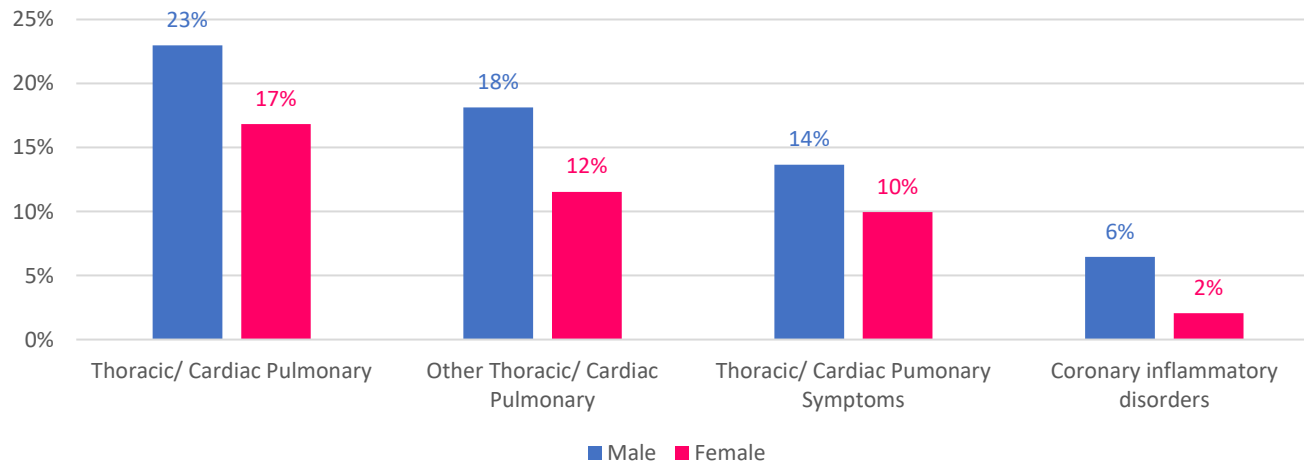


Steady increase,
except Oct decline

Rates of Thoracic/ Cardiac Pulmonary by Age and Gender

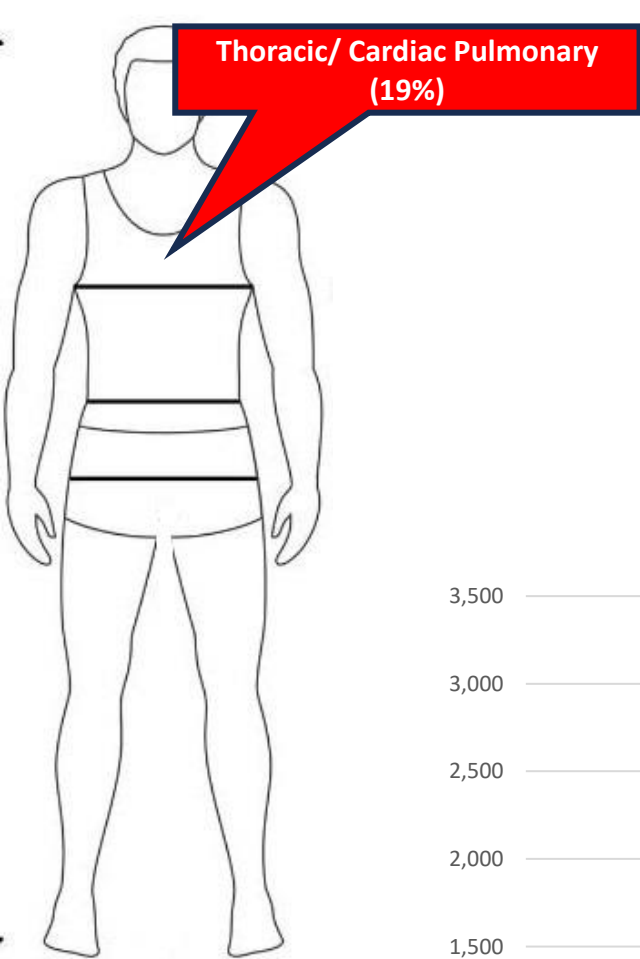


- Under 18 years** reported the higher rates for:
- “Thoracic/ Cardiac Pulmonary” reactions (32%), especially:
 - “Other Thoracic/ Cardiac/ Pulmonary” (27%)
 - “Thoracic/ Cardiac Pulmonary Symptoms” (22%)
 - “Coronary inflammatory disorders” (11%)



- Males** reported the higher rates for:
- “Thoracic/ Cardiac Pulmonary” reactions (23%), especially:
 - “Other Thoracic/ Cardiac/ Pulmonary” (18%)
 - “Thoracic/ Cardiac Pulmonary Symptoms” (14%)
 - “Coronary inflammatory disorders” (6%)

*****Consider reporting rates by Age and Gender when assessing these results***



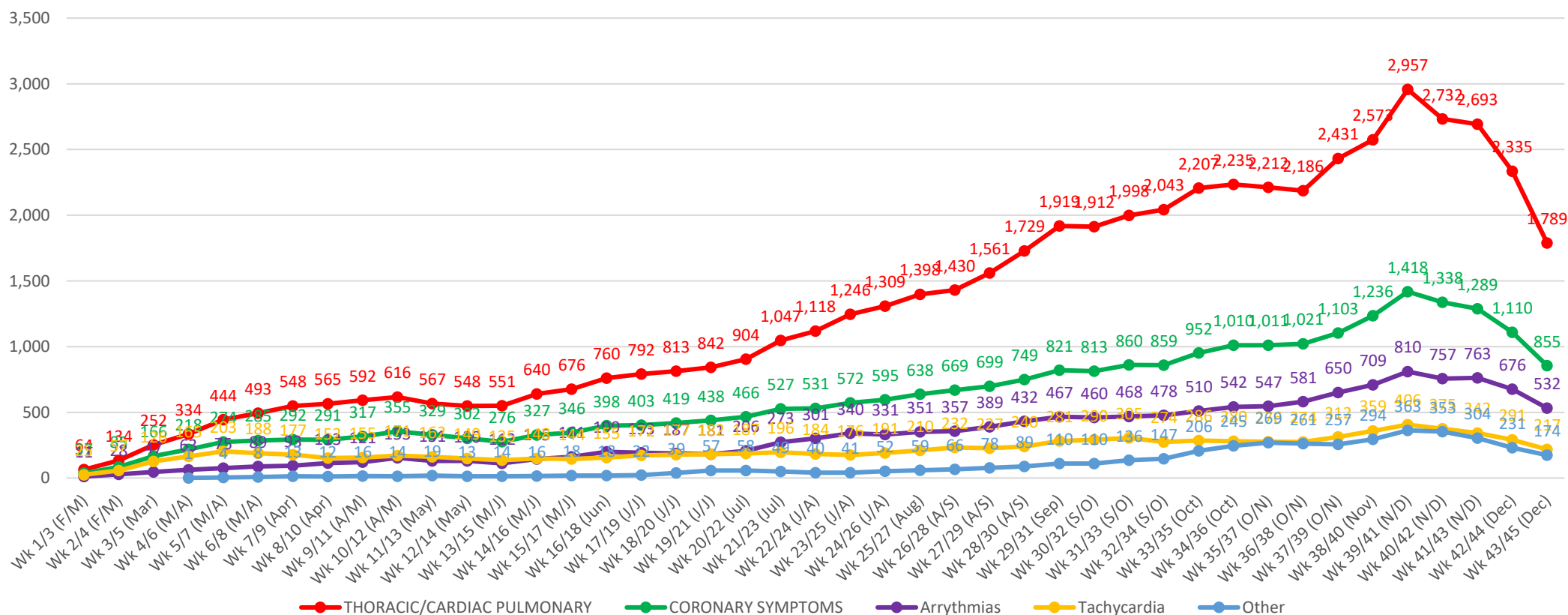
Thoracic/ Cardiac Pulmonary
(19%)

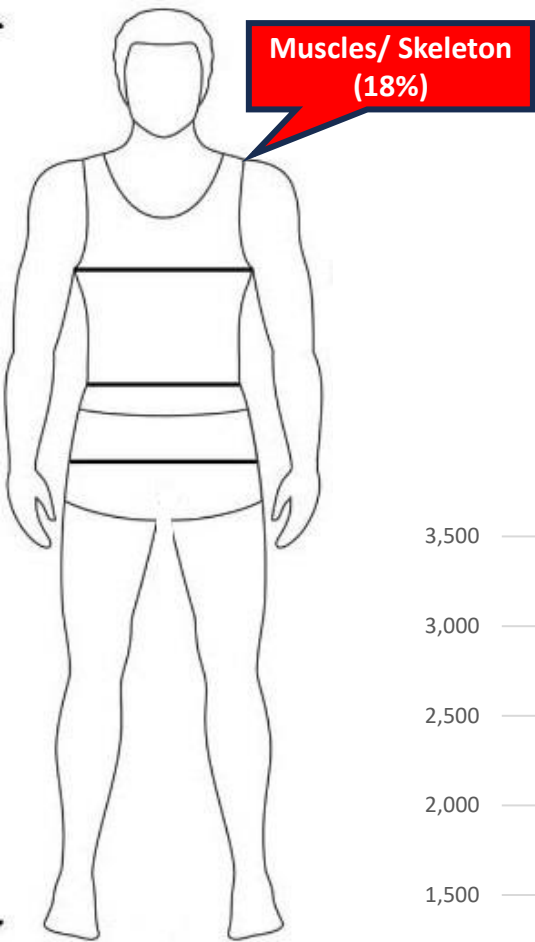
THORACIC/CARDIAC PULMONARY	19,145
CORONARY SYMPTOMS	9,098
Coronary Symptoms - Arrythmias	4,845
Palpitations	3,964
Coronary Symptoms - Tachycardia	3,133
Coronary Symptoms - Other	1,470
Troponin increased	565
Electrocardiogram abnormal	275

Coronary Symptoms - Ischaemia	348
Myocardial infarction (13% resulted in death)	218
Acute myocardial infarction (13% resulted in death)	99
Myocardial ischaemia (68% resulted in death)	23
Coronary Symptoms - Bradycardia	225
Coronary Symptoms - Muscle damage	87
Cardiomyopathy	32
Coronary Symptoms - Blockages	46
Electrocardiogram PR segment depression	17



Adverse Reactions Reported for Covid Medicines - Coronary Symptoms



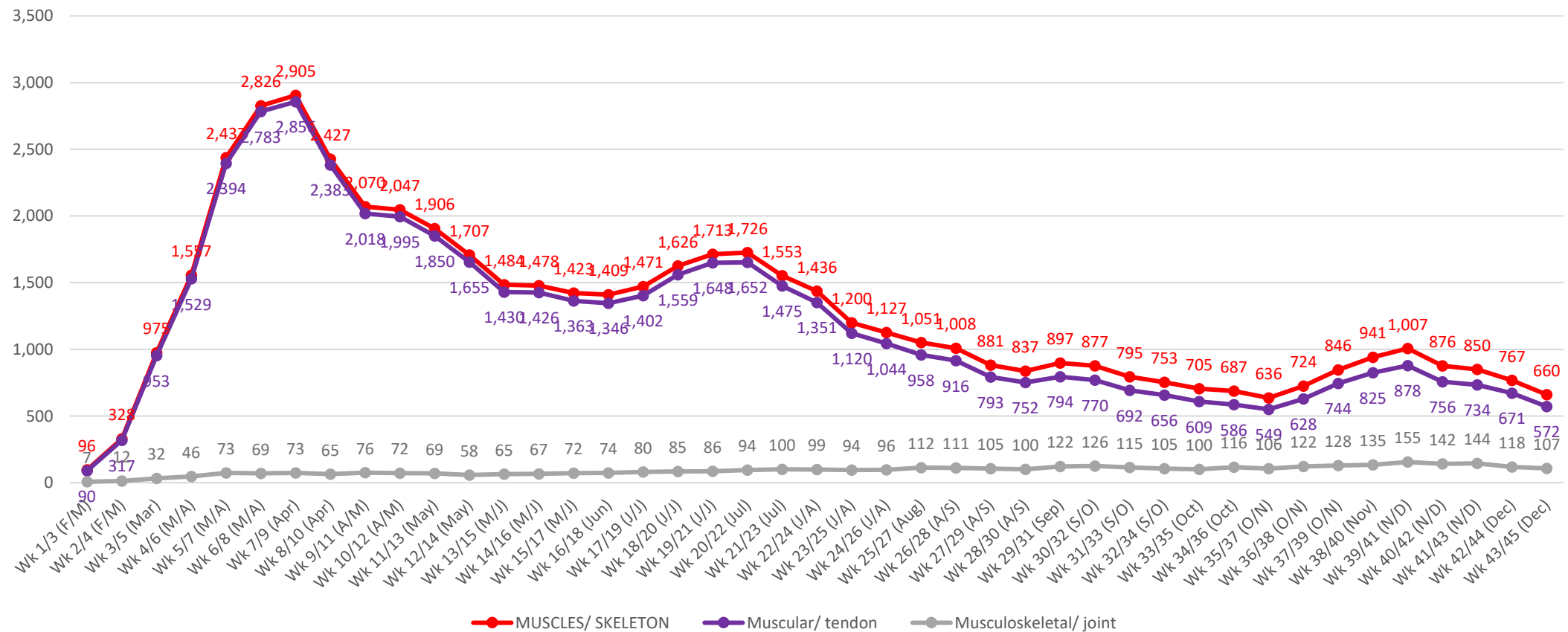


MUSCLES/ SKELETON	18,399
Muscular/ tendon	17,305
Myalgia (muscle aches & pain)	16,946
Muscle tightness	138
Musculoskeletal/ joint	1,342
Joint swelling	256
Bursitis	146
Joint stiffness	112
Fracture	33

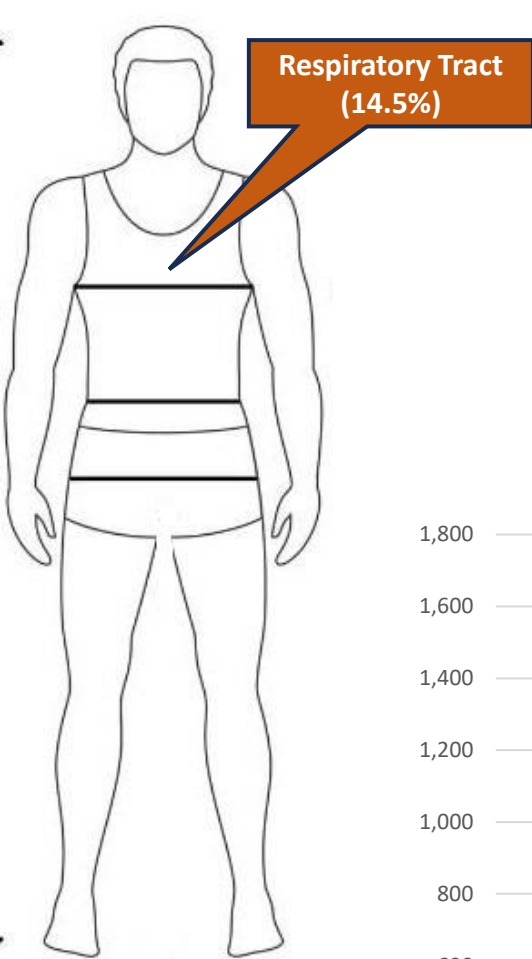


*Reports related to
"Musculoskeletal/
Joint" increasing*

Adverse Reactions Reported for Covid Medicines - Muscles/ Skeleton



*Large initial
increase,
then decline*



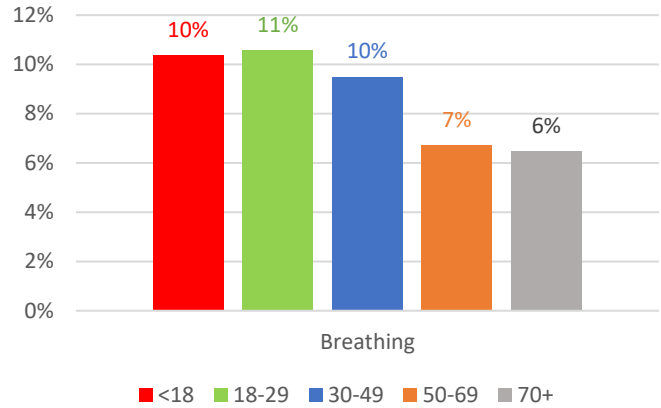
Respiratory Tract
(14.5%)

RESPIRATORY TRACT	14,913
RESPIRATORY TRACT SYMPTOMS	9,741
Breathing	8,103
Dyspnoea	7,532
Cough	2,396
Cough	2,217

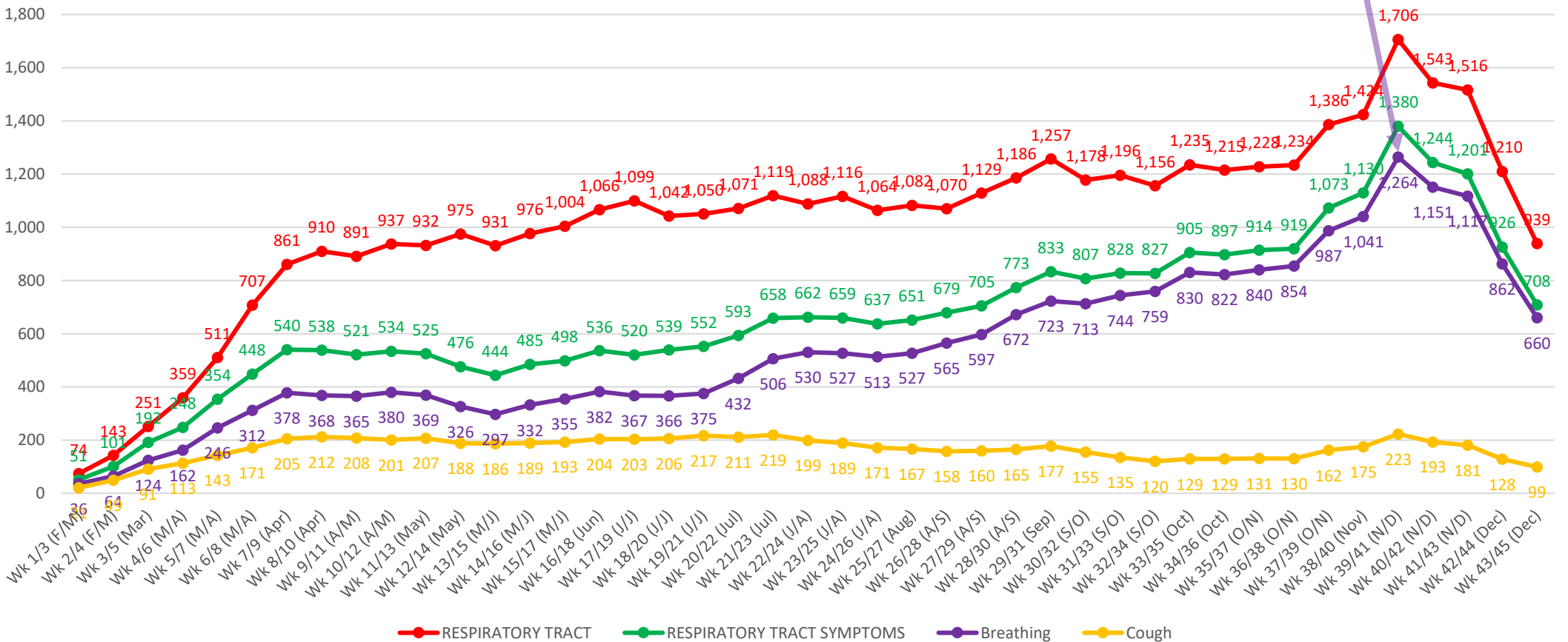
Mainly Symptoms



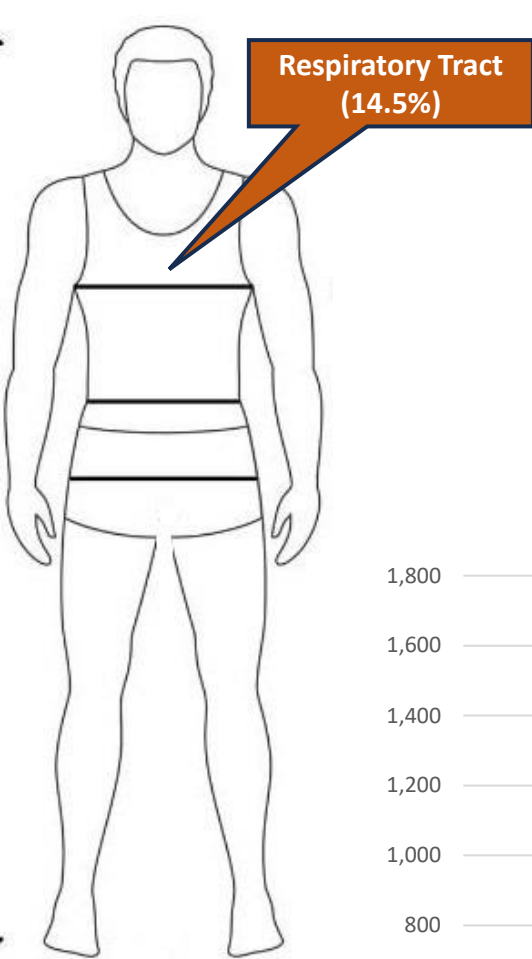
"Breathing" increased most,
particularly in late



Adverse Reactions Reported for Covid Medicines - Respiratory Tract



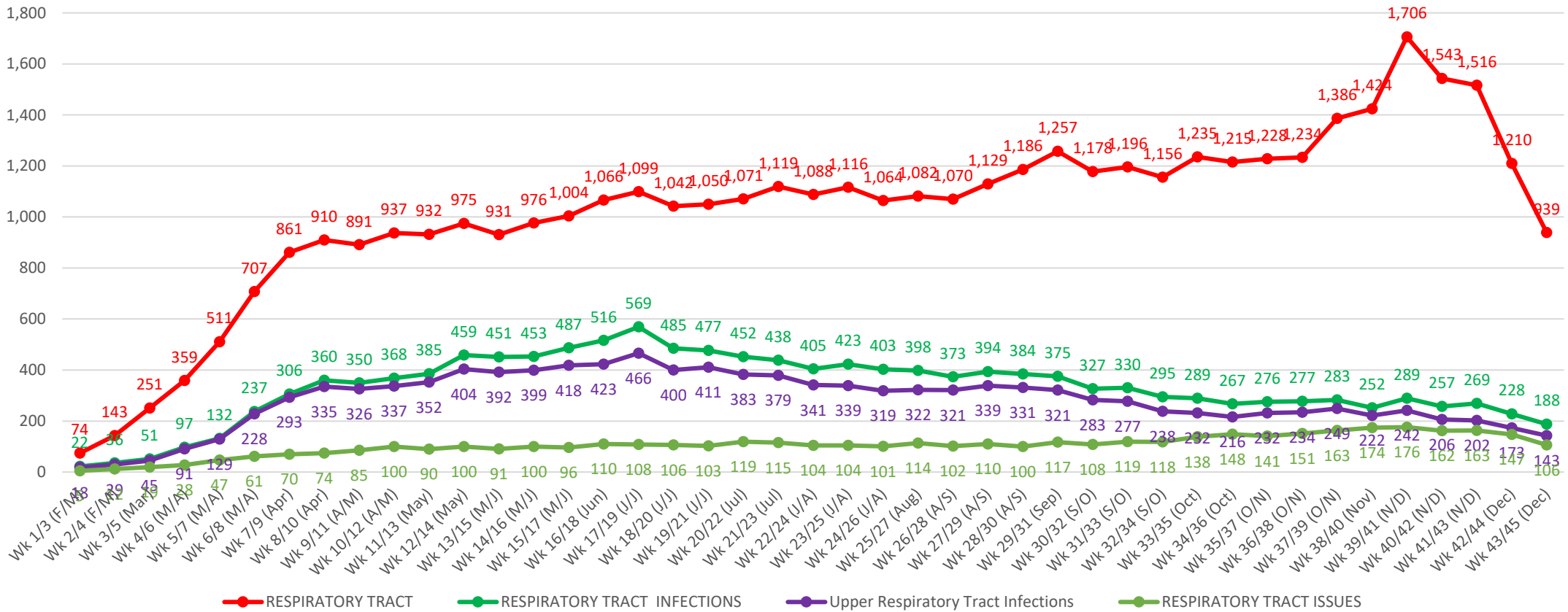
Steady increase,
peaks early and late



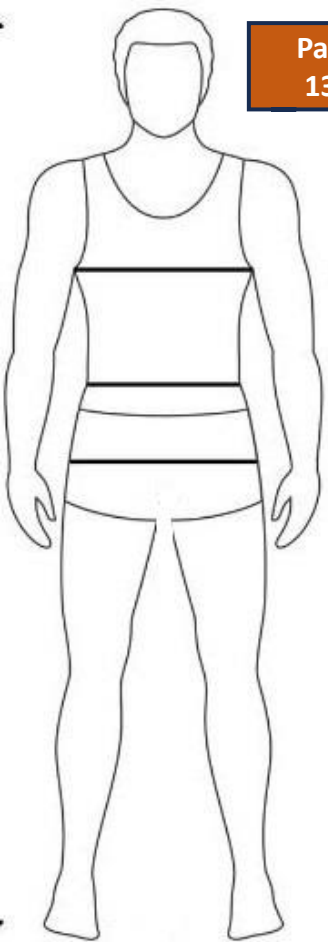
RESPIRATORY TRACT	14,913
RESPIRATORY TRACT INFECTIONS	4,749
Upper Respiratory Tract Infections	4,050
Influenza like illness	3,368
Lower Respiratory Tract Infections	717
Pneumonia (10% resulted in death)	337
Lower respiratory tract infection	287
Covid-19	50

RESPIRATORY TRACT ISSUES	1,523
Lower Respiratory Tract Issues	1,413
Asthma	240
Upper Respiratory Tract Issues	114
Laryngitis	61

Adverse Reactions Reported for Covid Medicines - Respiratory Tract



Early increase due to
"Respiratory Tract
Infections"



Pain/ Swelling
13,590 (13%)

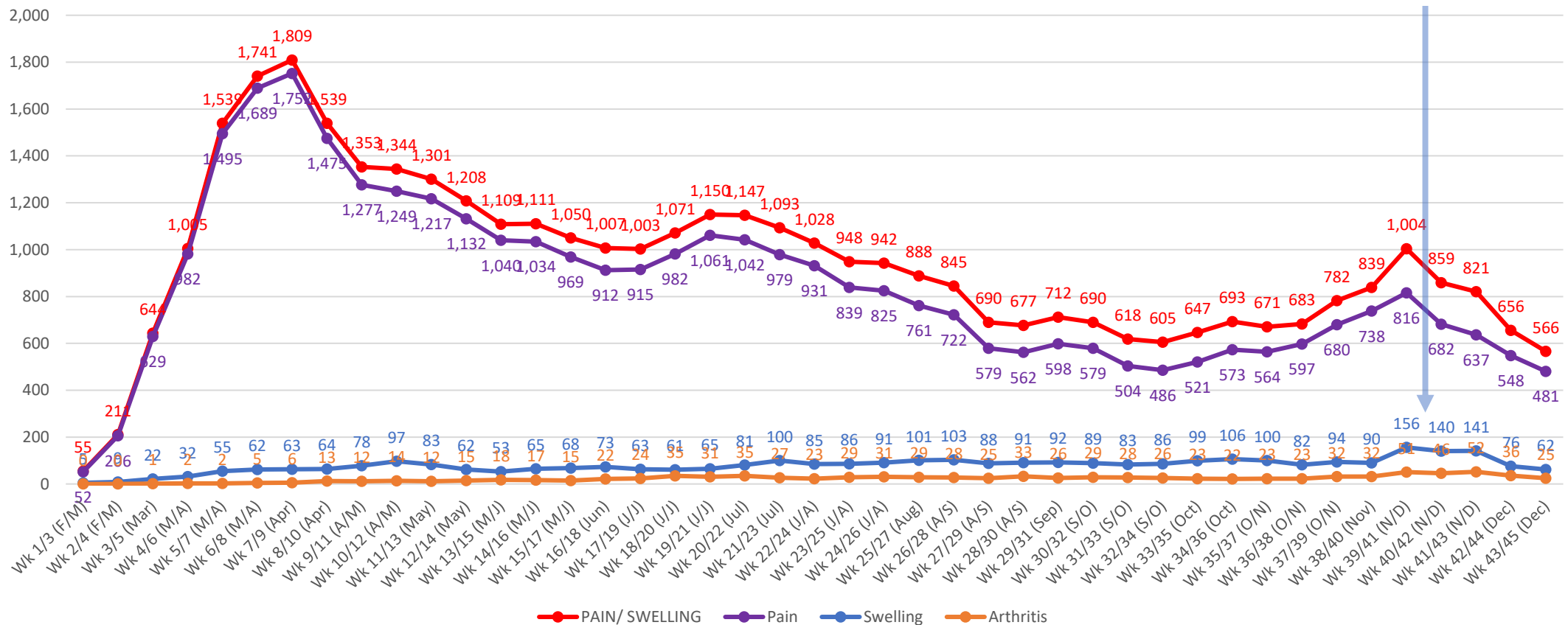
PAIN/ SWELLING	13,590
Pain	12,222
Arthralgia (pain in joint)	10,446
Pain	1,888
Swelling	1,150
Swelling	590
Angioedema (swelling)	471
Arthritis	331
Arthritis	107

Mass/ cyst	146
Fluid	43



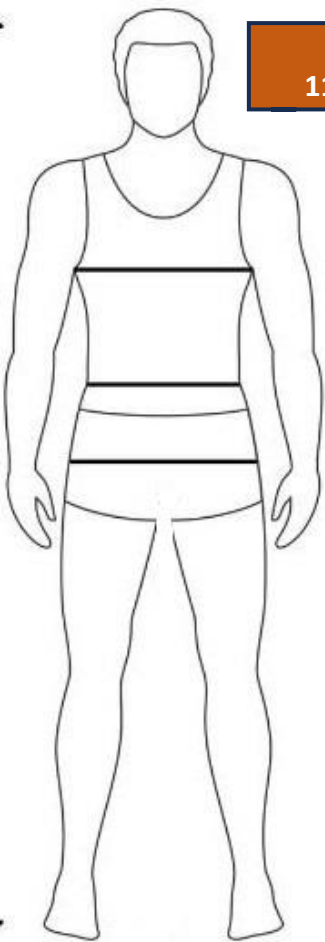
*"Swelling"
and
"Arthritis"
increased*

Adverse Reactions Reported for Covid Medicines - Pain/ Swelling



*Large initial increase,
then decline, due to
"Pain"*





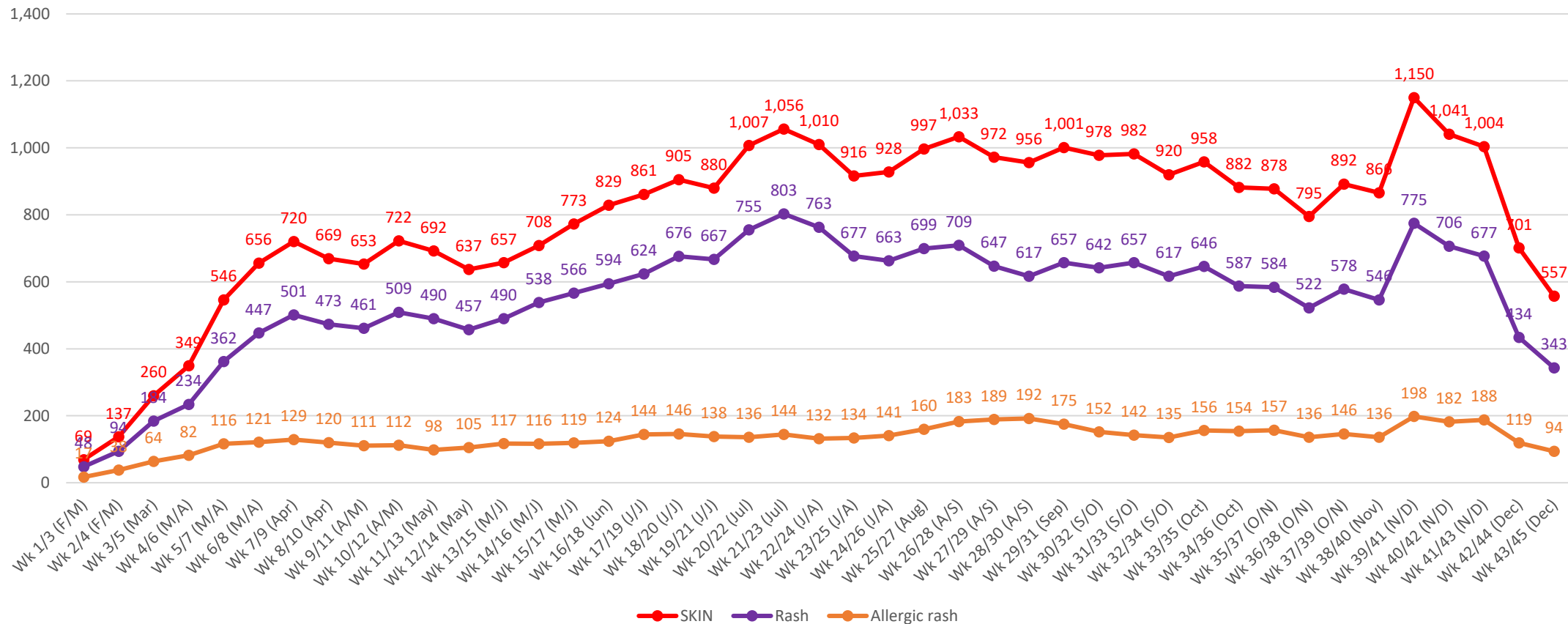
Skin
11,543 (11%)

SKIN	11,543
Rash	7,993
Rash	4,542
Urticaria (hives)	1,789
Allergic rash	1,921
Pruritus (itchiness)	1,896

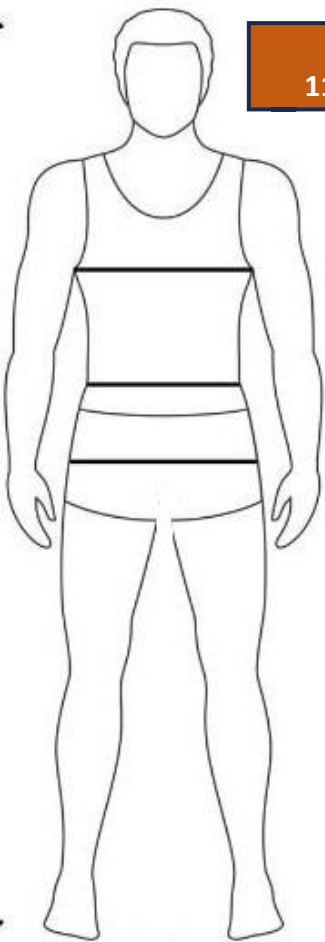
"Rash" =
69% of "Skin"

Skin	885
Skin discolouration	97
Sensitive skin	96
Burning - skin	834
Burning sensation	412
Neuralgia (shooting/ stabbing/ burning sensation)	325
Pallor	795
Cellulitis	290

Adverse Reactions Reported for Covid Medicines - Skin



*Increases,
mainly influenced
by "Rash"*



Skin
11,543 (11%)

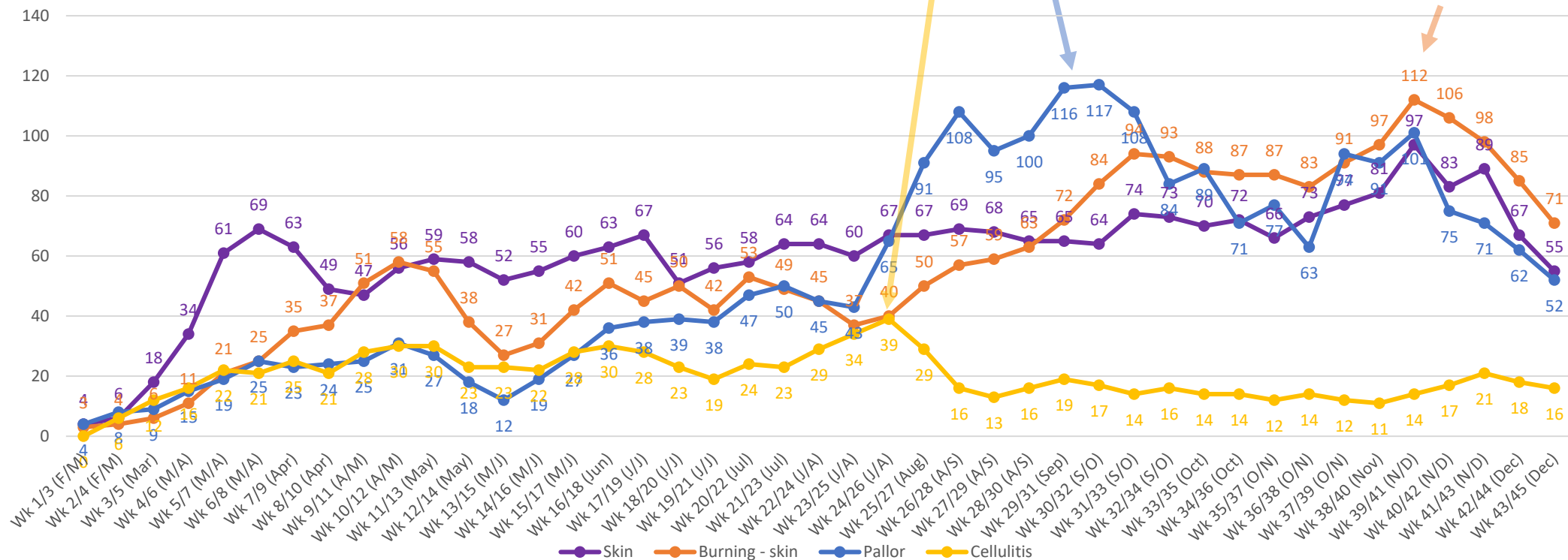
SKIN	11,543
Skin	885
Skin discolouration	97
Sensitive skin	96
Burning - skin	834
Burning sensation	412
Neuralgia (shooting/ stabbing/ burning sensation)	325
Pallor	795
Cellulitis	290

*"Pallor" reported
more by 18*

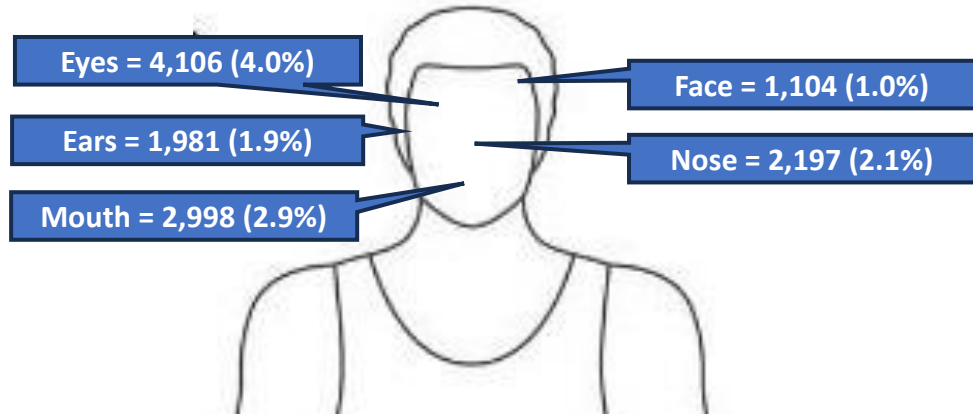
*"Cellulitis" reports declined,
after peaking in August*

*"Burning skin"
increased*

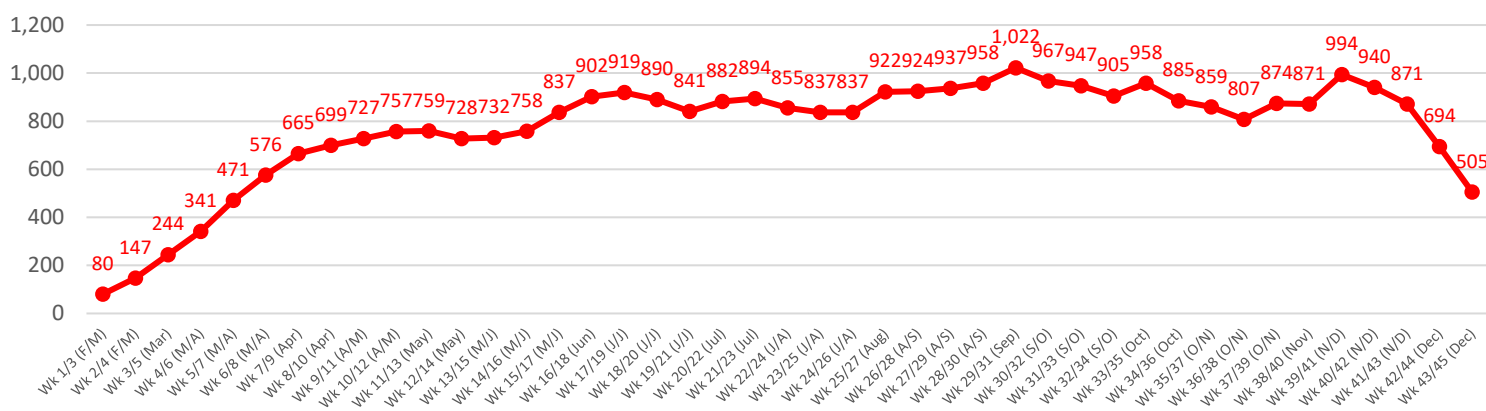
Adverse Reactions Reported for Covid Medicines - Skin



FACE/ EYES/ EARS
11,204 (11%)

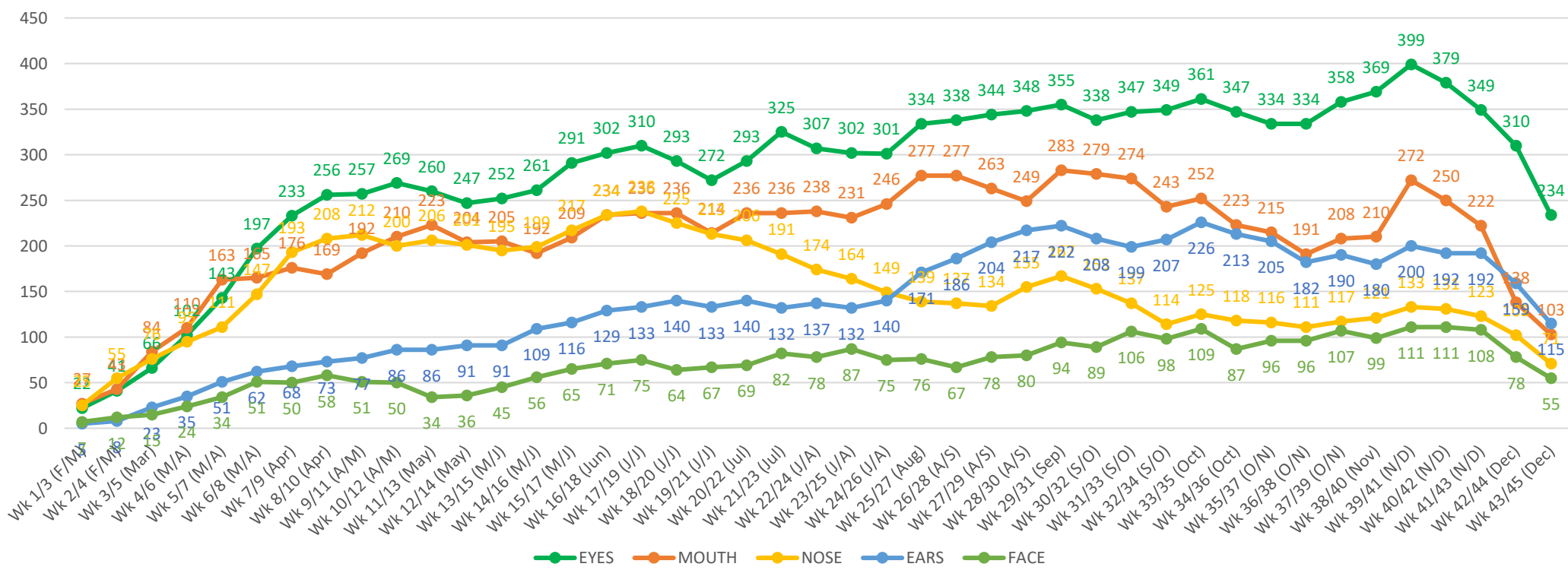


Adverse Reactions Reported for Covid Medicines - Face/ Eyes/ Ears



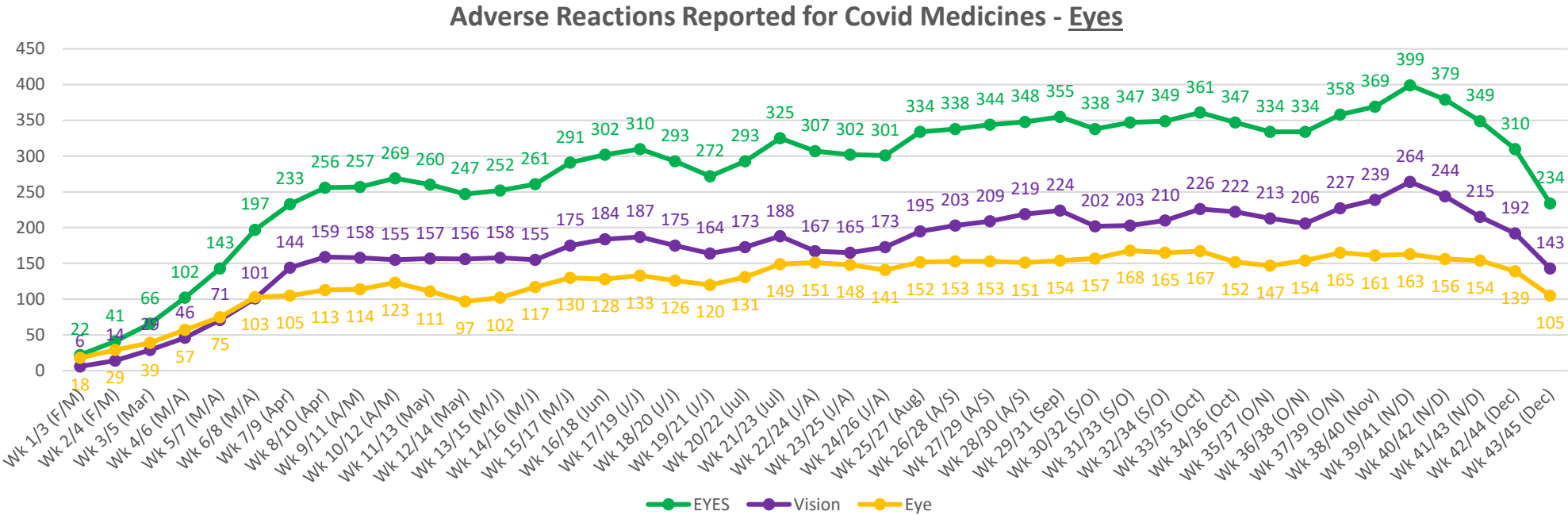
Adverse Reactions Reported for Covid Medicines - Face/ Eyes/ Ears

FACE/ EYES/ EARS	11,204
EYES	4,106
MOUTH	2,998
NOSE	2,197
EARS	1,981
FACE	1,014

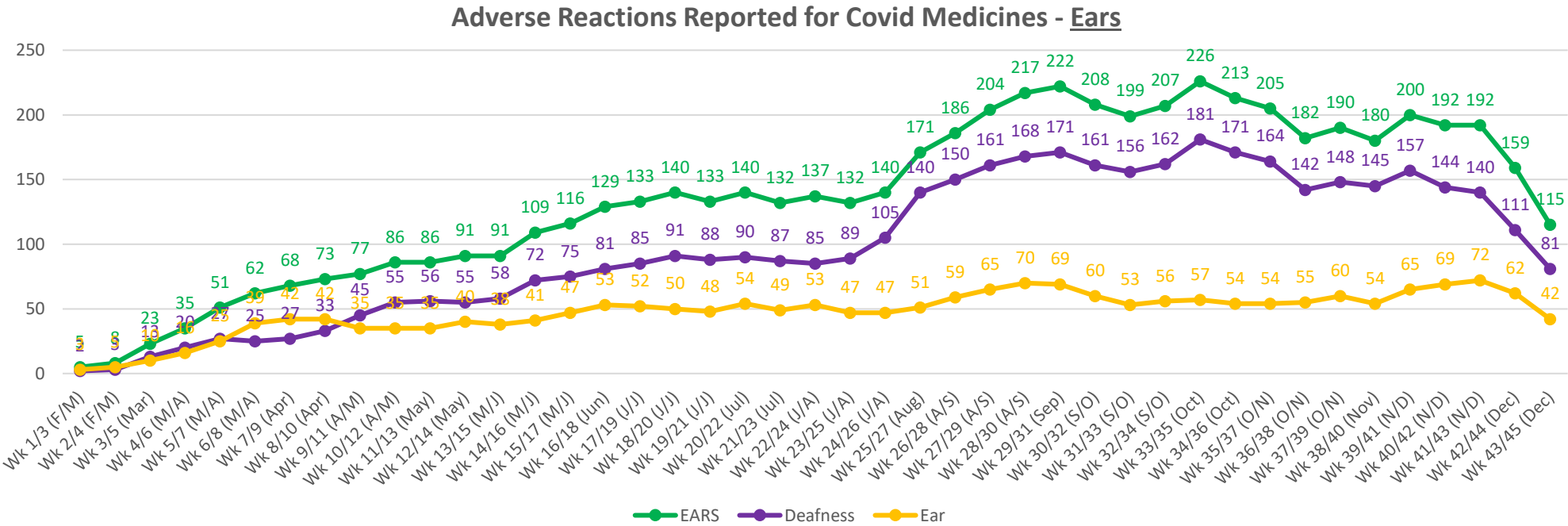



Steady increase

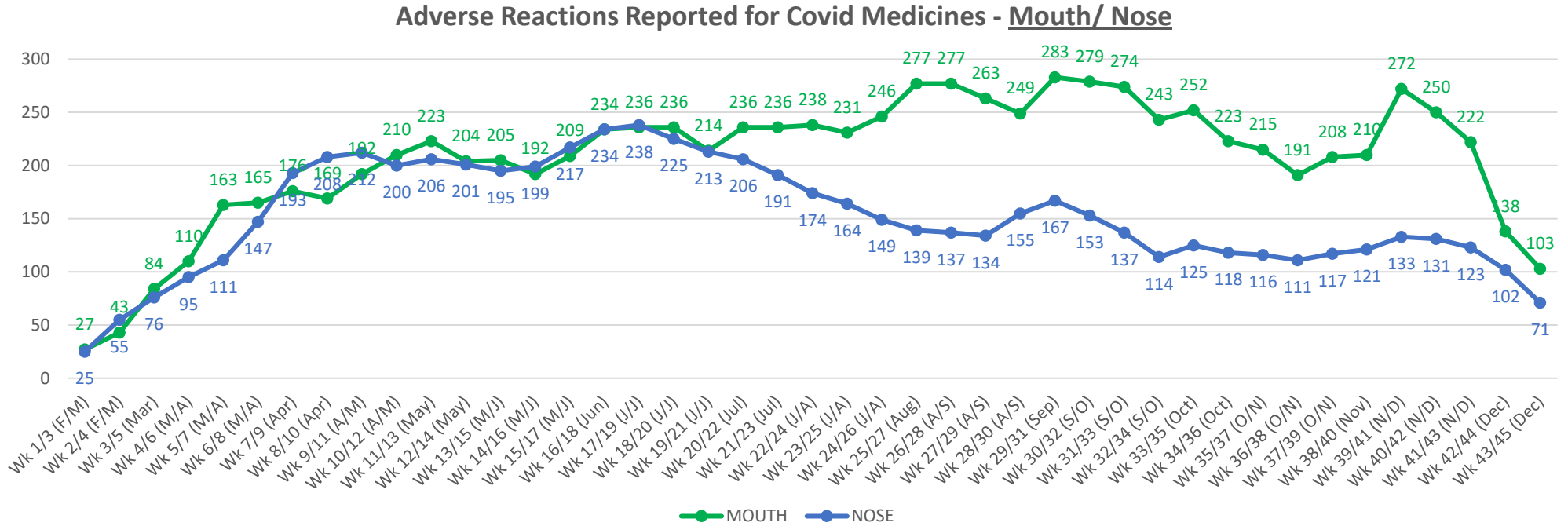
EYES	4,106
Vision	2,477
Vision blurred	1,525
Eye	1,853
Eye pain	466
Eye swelling	188



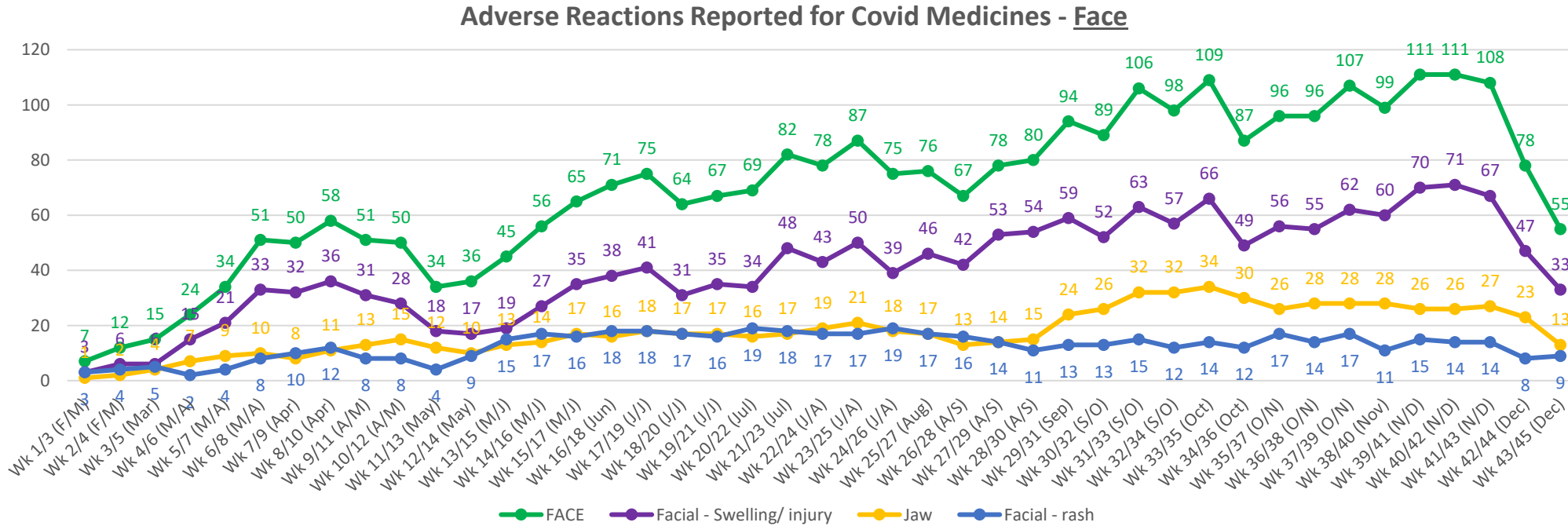
EARS	1,981
Deafness	1,424
Tinnitus	1,152
Ear	687
Ear pain	340

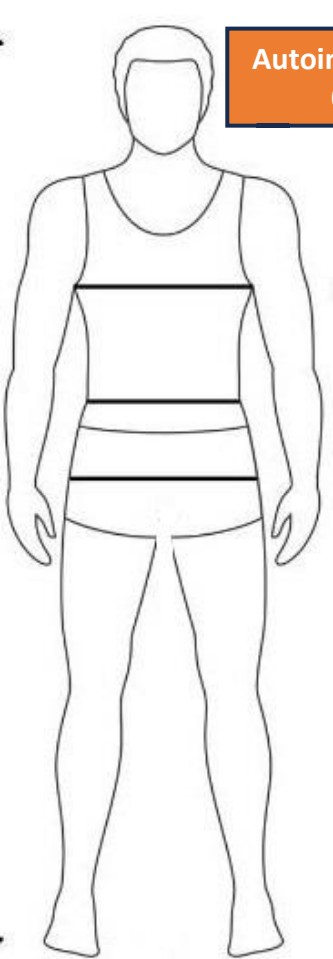


MOUTH	2,998
Paraesthesia oral	904
Swollen tongue	565
Lip swelling	504
Dry mouth	285
NOSE	2,197
Rhinorrhoea (runny nose)	704
Epistaxis (nose bleed)	703



FACE	1,014
Facial - Swelling/ injury	591
Swelling face	488
Jaw	257
Pain in jaw	224
Facial - rash	184
Rash macular	94





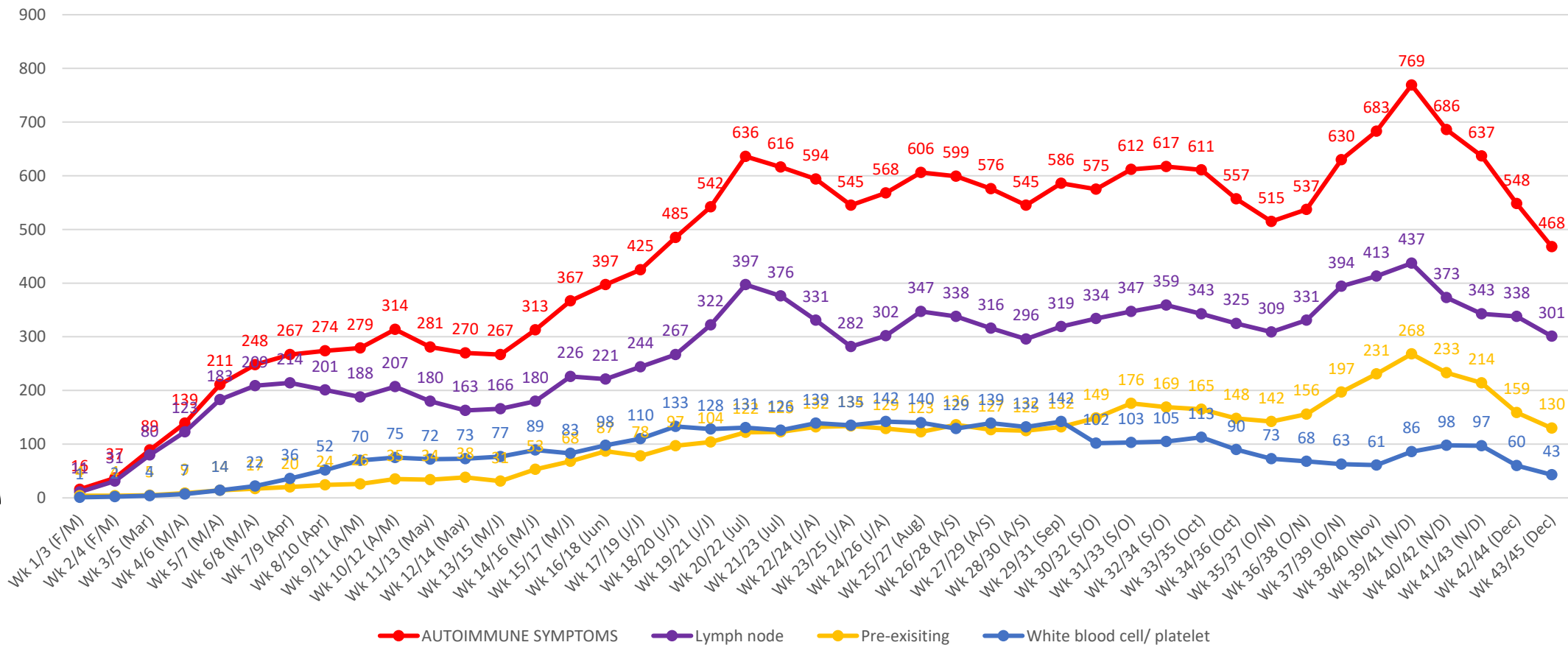
Autoimmune Symptoms
6,640 (6.5%)

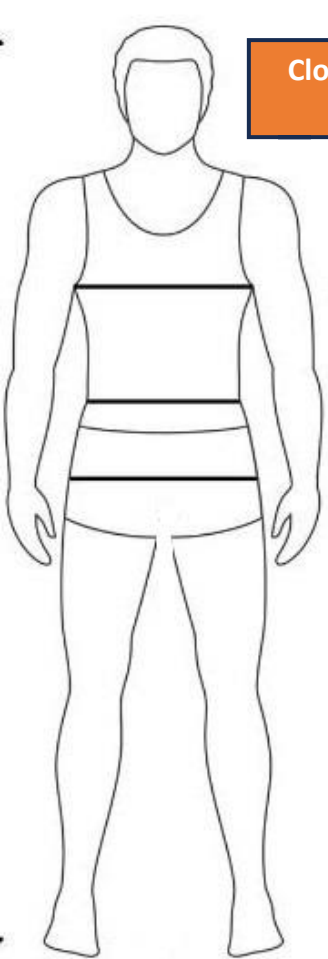
AUTOIMMUNE SYMPTOMS	6,640
Lymph node	3,978
Lymphadenopathy	3,695
Pre-exisiting	1,554
Concomitant disease aggravated	1,402
Concomitant disease progression	75
White blood cell/ platelet	1,230
Thrombocytopenia	750

66% of reports with
“Concomitant disease progression”
had an outcome of death

MedDRA system organ class	MedDRA reaction term	Number of cases	Cases with a single suspected medicine	Cases where death was a reported outcome
General disorders and administration site conditions	Concomitant disease progression	82	76	54

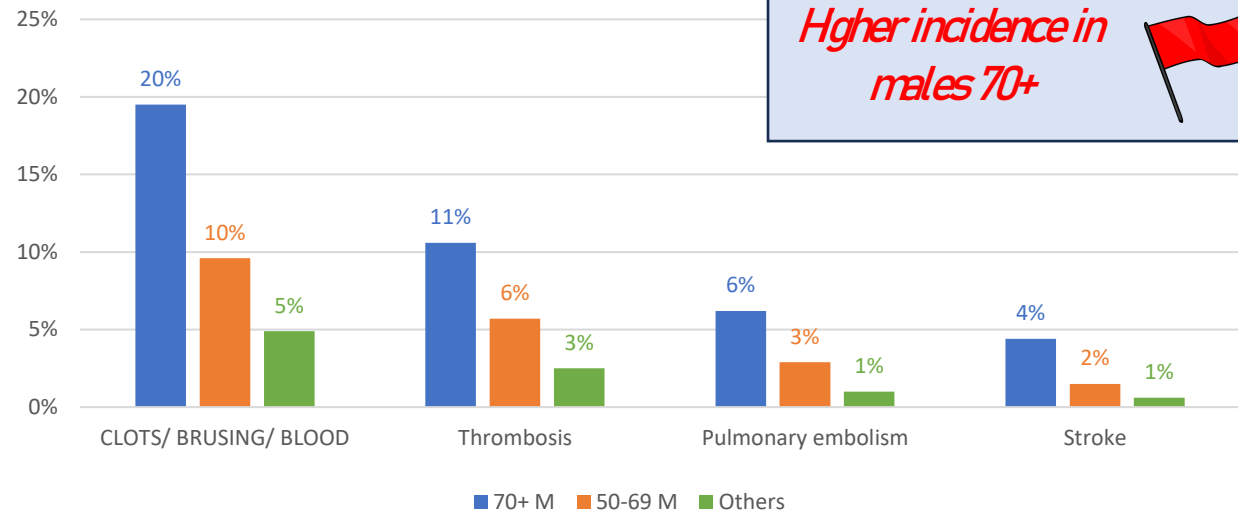
Adverse Reactions Reported for Covid Medicines - Autoimmune Symptoms



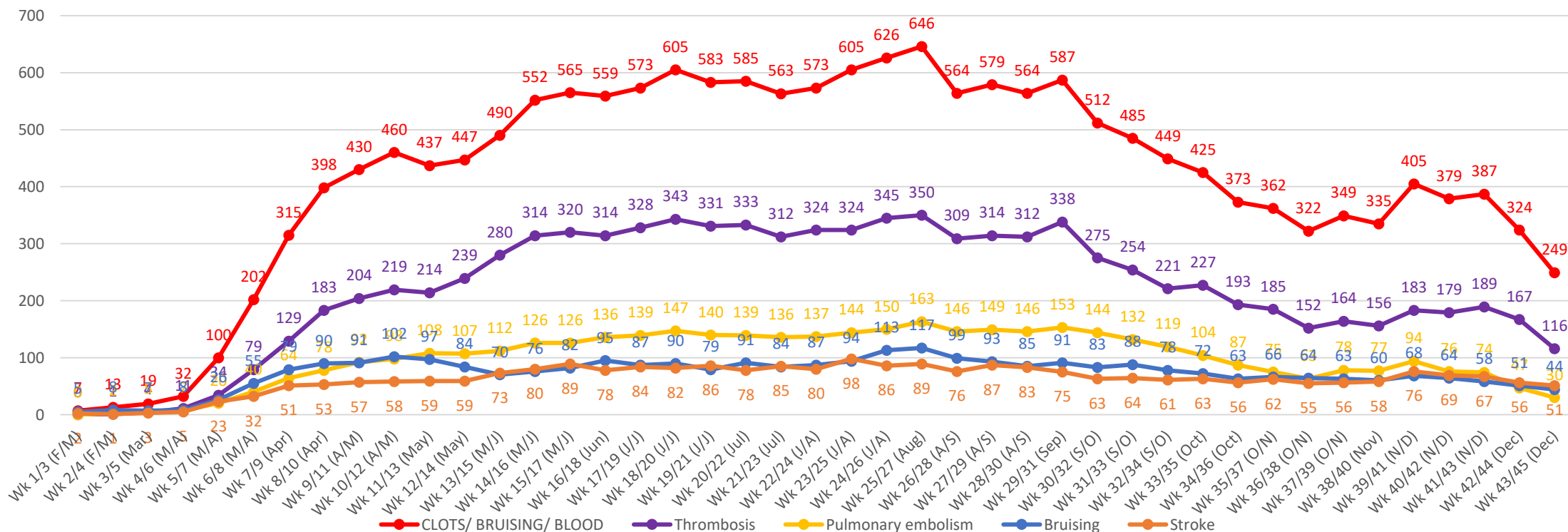


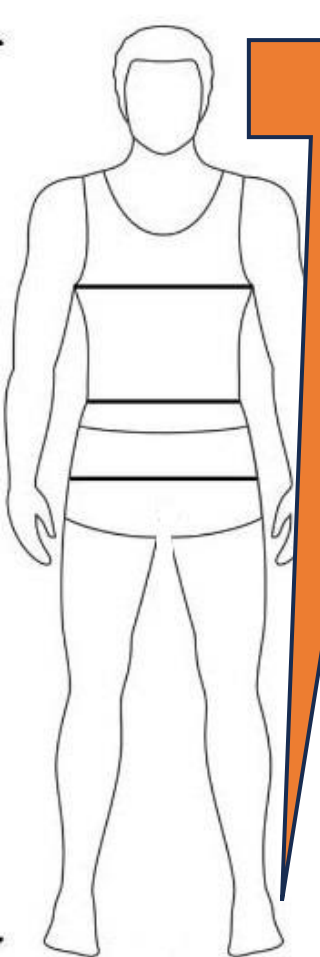
Clots/ Bruising/ Blood
6,064 (6%)

CLOTS/ BRUISING/ BLOOD	6,064
Thrombosis	3,176
Fibrin D dimer increased	1,494
Deep vein thrombosis	1,345
Pulmonary embolism	1,406
Pulmonary embolism	1,375
Bruising	1,049
Contusion	774
Stroke	901
Cerebrovascular accident	414
Vascular	352
Haemorrhage/ coagulopathy	126
Clots	94



Adverse Reactions Reported for Covid Medicines - Clots/ Bruising/ Blood

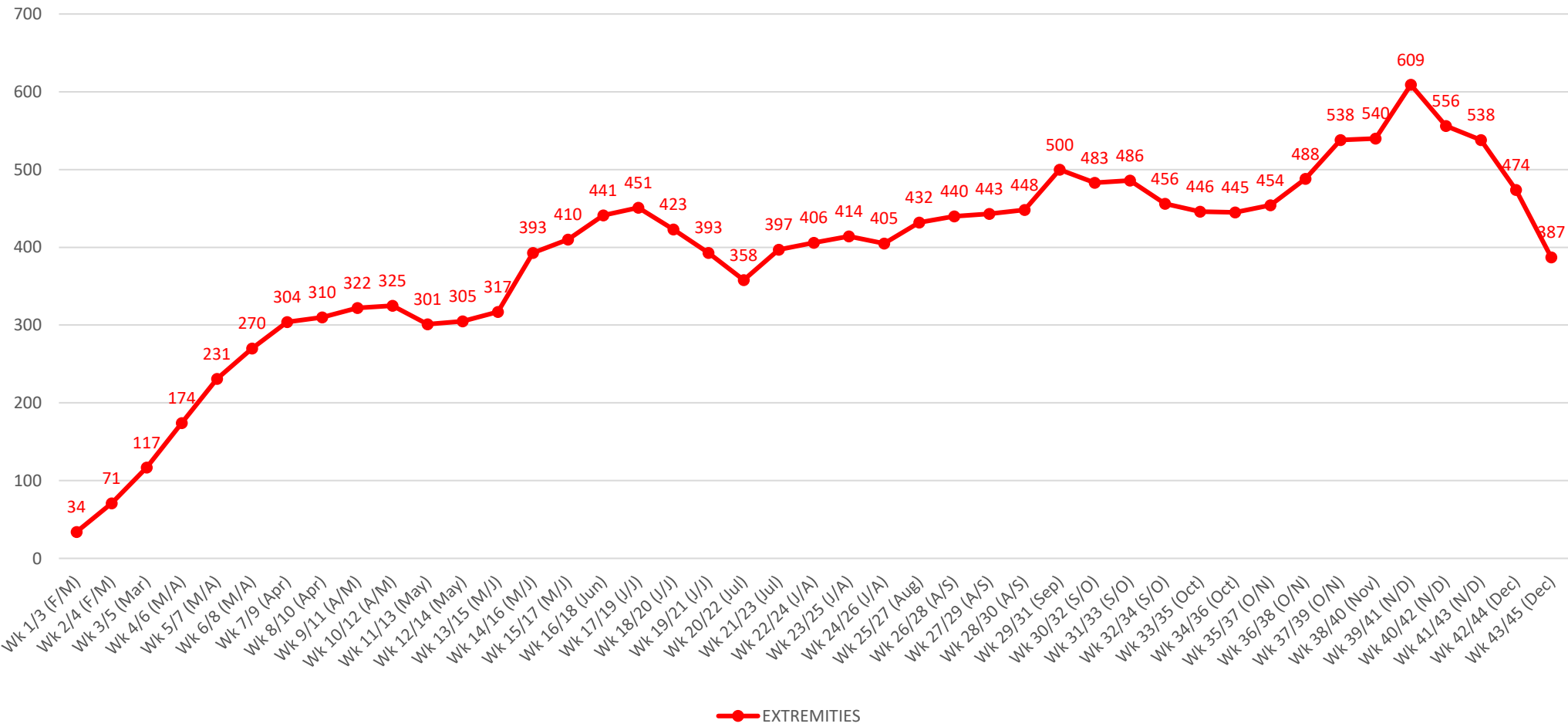




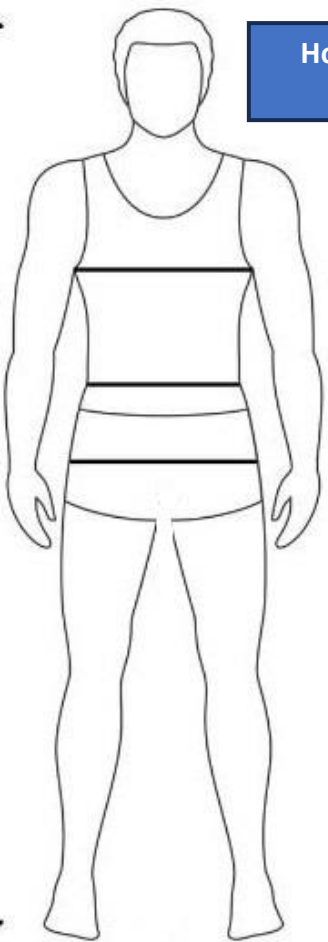
Extremities
5,686 (5.5%)

EXTREMITIES	5,686
Pain in extremity	3,893
Peripheral swelling	859

Adverse Reactions Reported for Covid Medicines - Extremities



*Steady increase,
peaks in Jun/Jul
and Nov/Dec*



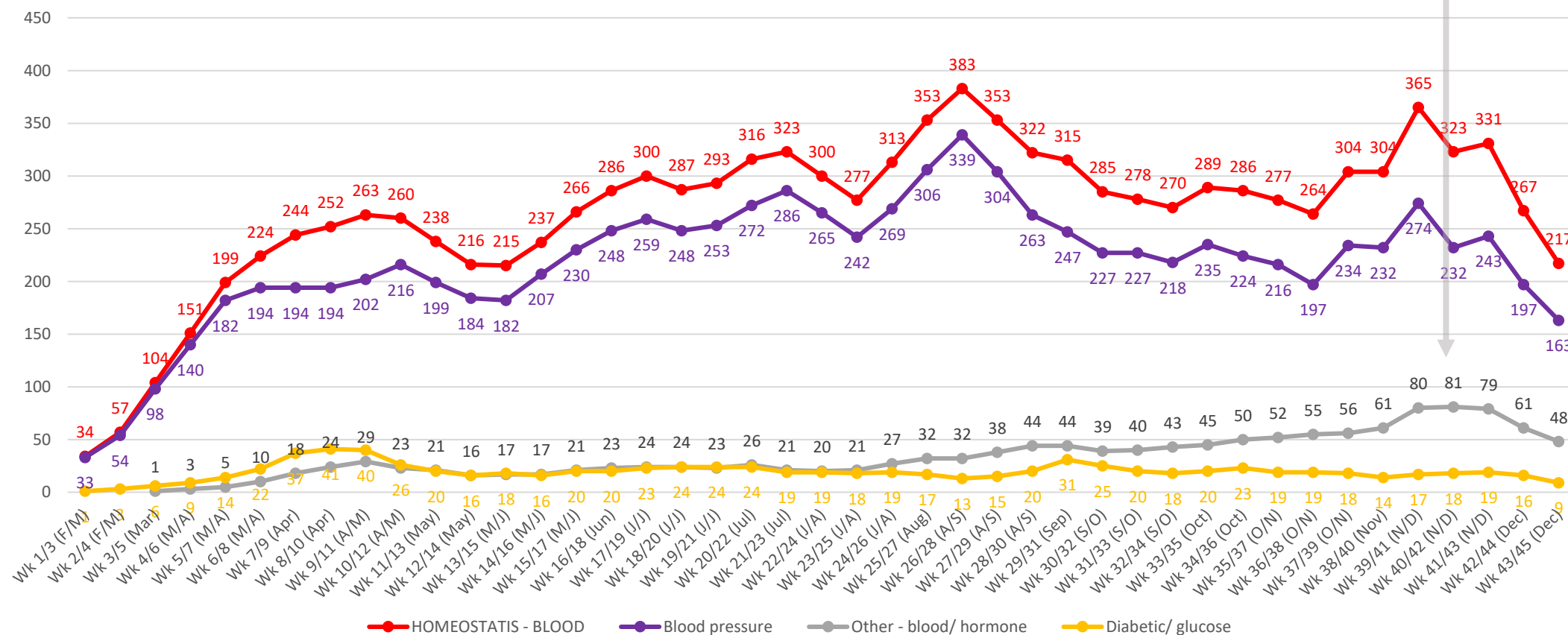
Homeostatis - Blood
3,866 (3.8%)

HOMEOSTATIS - BLOOD	3,866
Blood pressure	3,180
Hypertension	1,454
Blood pressure increased	776
Other - blood/ hormone	478
Blood creatine phosphokinase increased	45
Hyperthyroidism	44
Diabetic/ glucose	279
Blood glucose increased	92



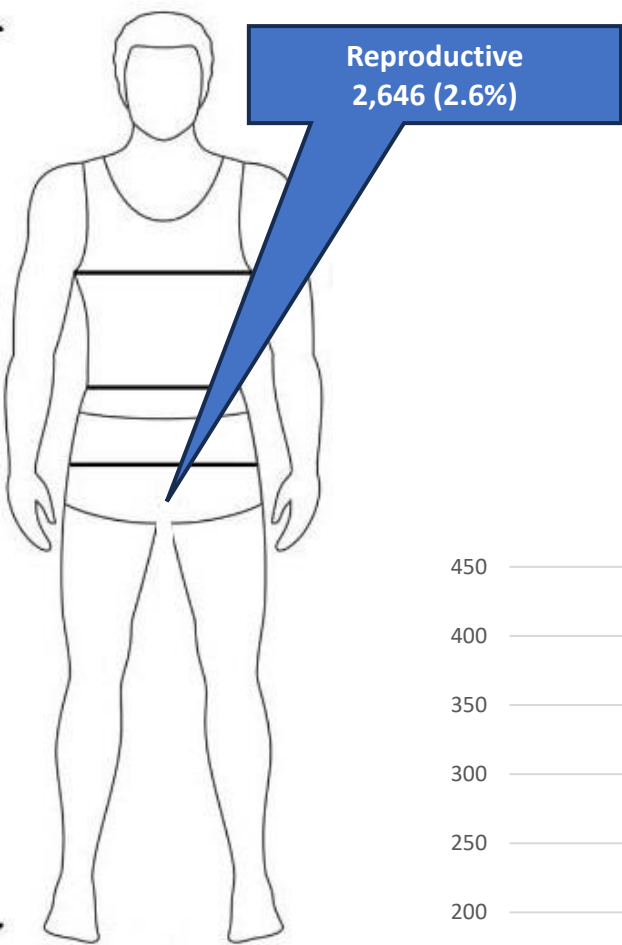
*"Other = blood/ hormone"
continues increasing*

Adverse Reactions Reported for Covid Medicines - Homeostatis - Blood



*Increased,
but declined Sep/Oct*





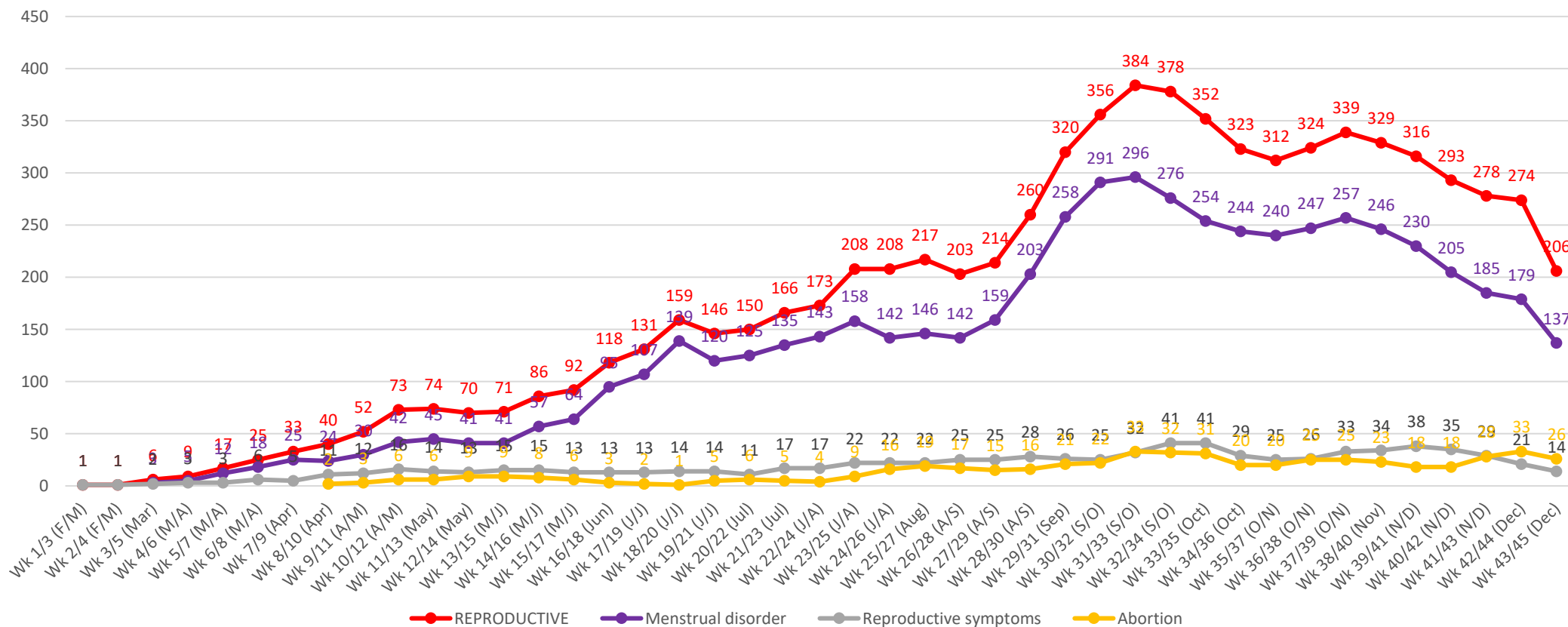
Reproductive
2,646 (2.6%)

REPRODUCTIVE	2,646
Menstrual disorder	1,959
Menstrual disorder	1,553
Reproductive symptoms	277
Groin pain	118
Abortion	184
Abortion spontaneous	157
Pregnancy/ birth defects	142
Reproductive disorders	116
Reproductive infections	71

***“Abortion” NOT
included in
“Reports of death”***



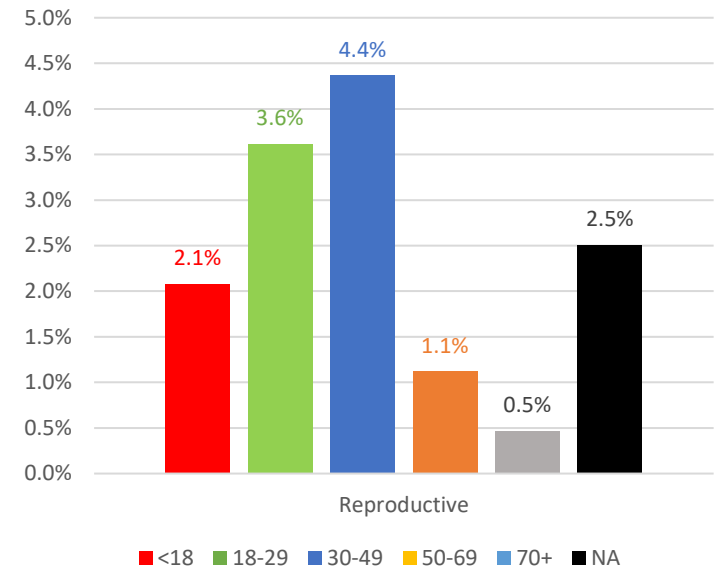
Adverse Reactions Reported for Covid Medicines - Reproductive



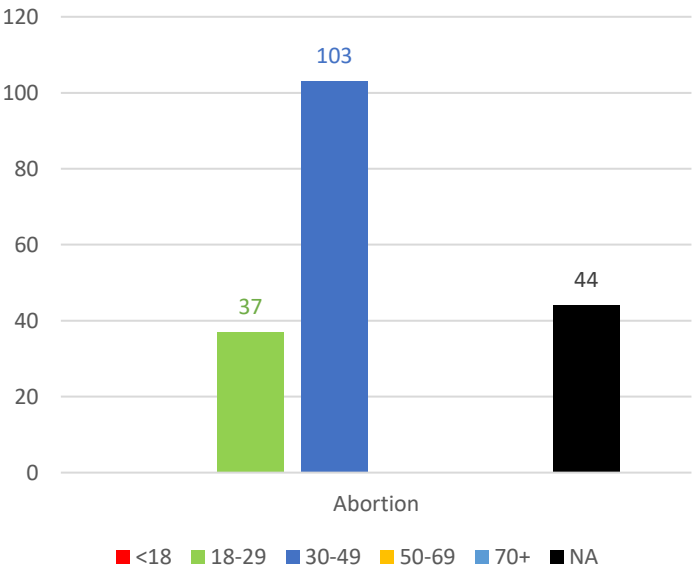
***Increased to
Sep/Oct, then
declined***

“Rare” reactions:

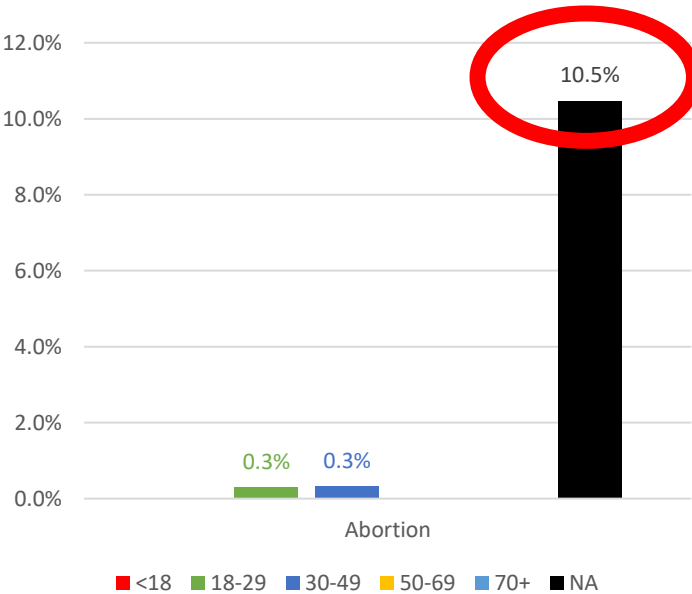
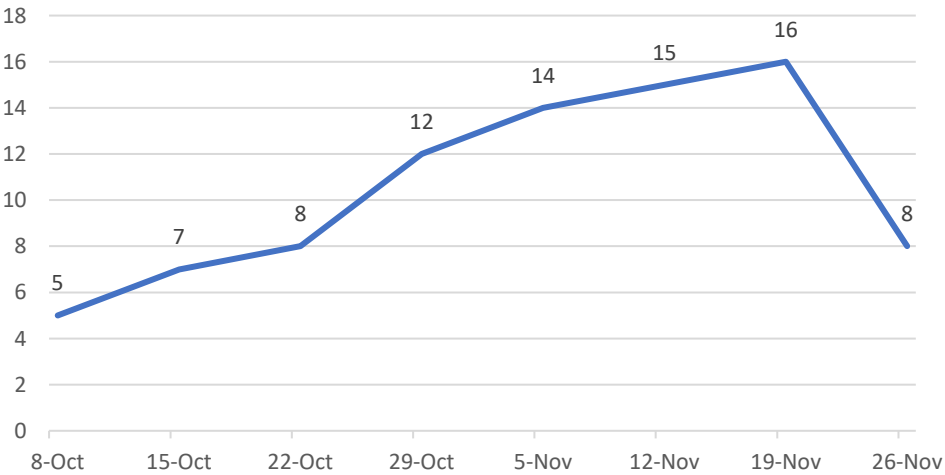
Rare¹ *adjective*
(of an event, situation, or condition) not occurring very often.



Abortion	184
Abortion spontaneous	157
Stillbirth	10
Foetal death	9
Abortion induced	3
Abortion threatened	2
Abortion missed	1
Abortion spontaneous incomplete	1
Product delivery mechanism issue	1

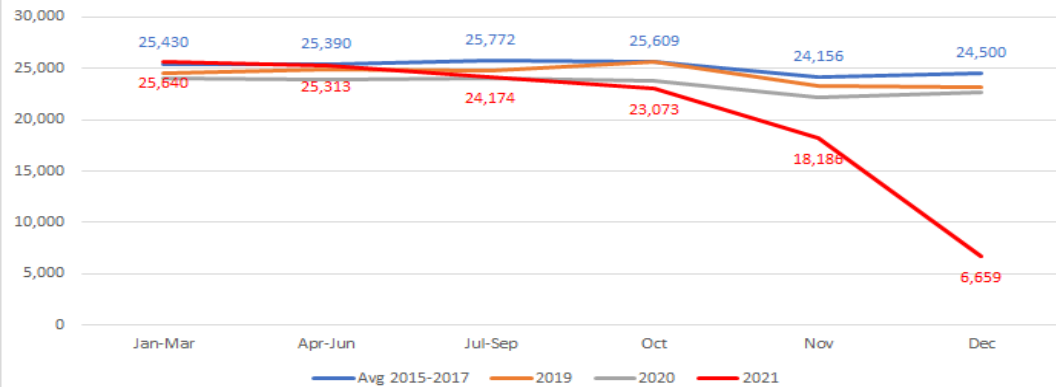


"Abortion spontaneous" reports released late

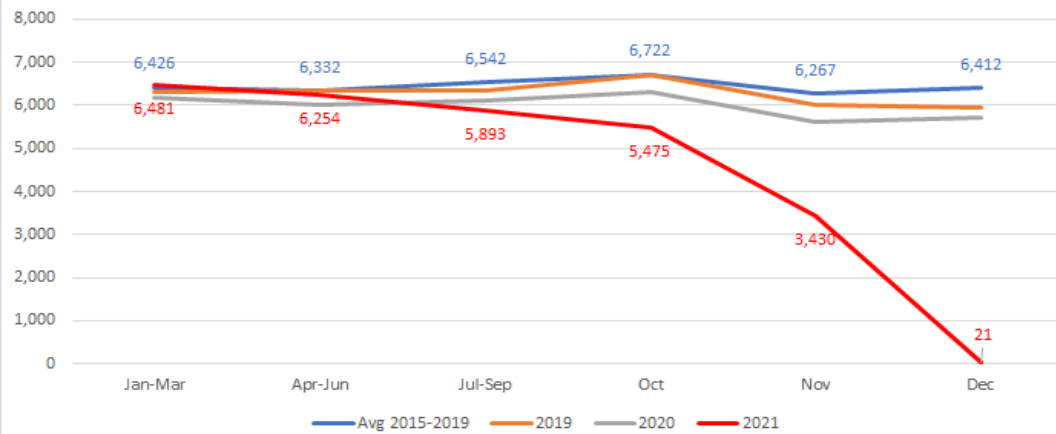


Birth rates:

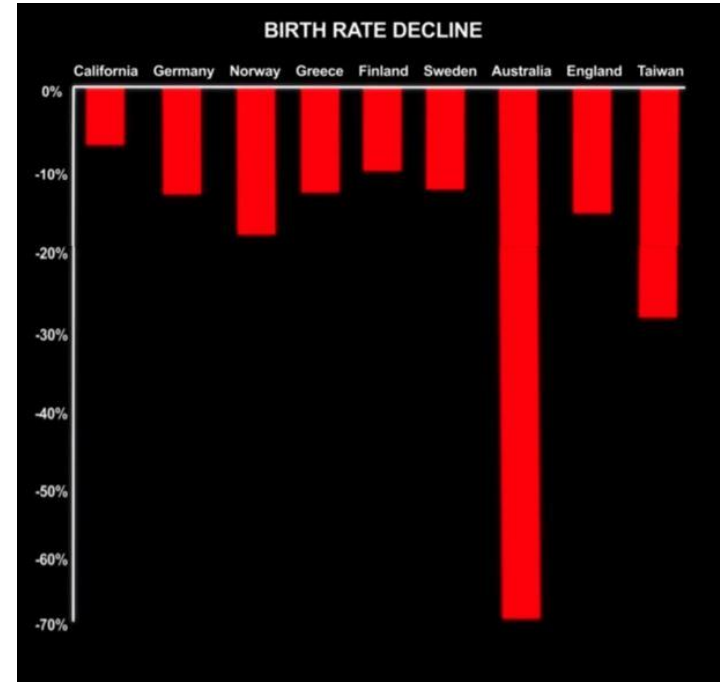
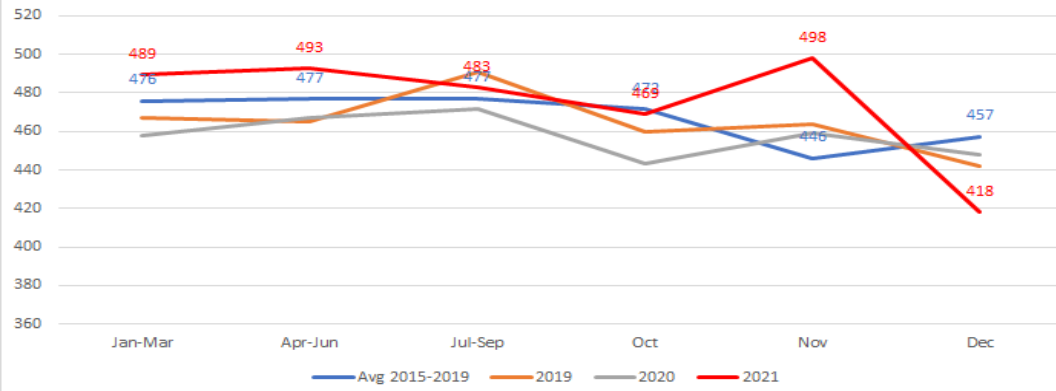
Australian Birth Rates



Victorian Birth Rates



Tasmania Birth Rates



Birth Rate by Month in Australia Visualised

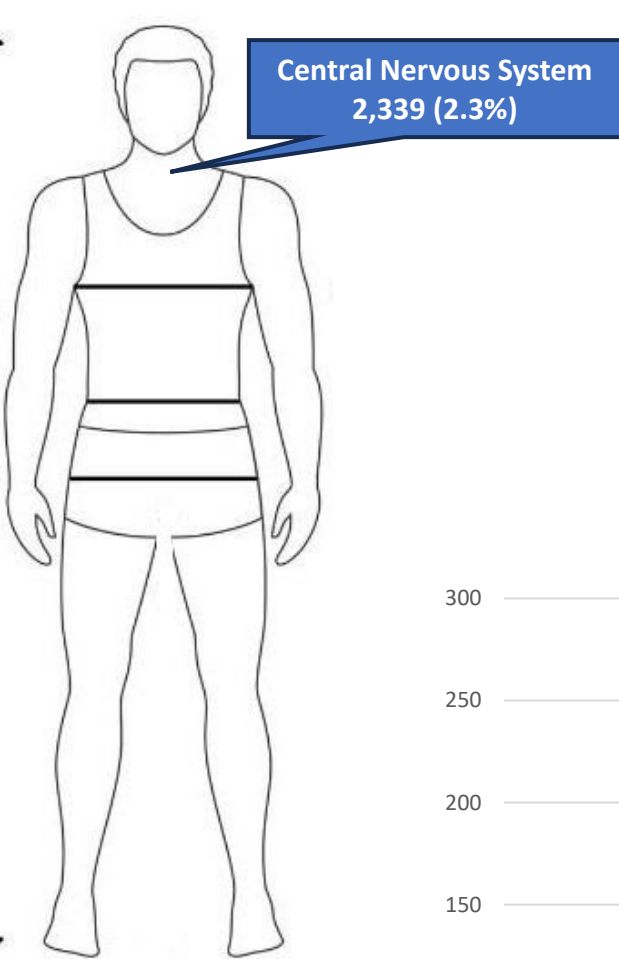
Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1975	20017	18660	20167	19092	20454	19156	20077	19034	19312	19434	18205	19104
1976	19293	18663	20260	19197	19274	18806	18903	18373	18751	18046	18111	18650
1977	18671	17919	20084	18722	18836	19287	19435	19139	19017	19070	17800	18077
1978	18751	18013	20221	18810	19317	18641	18454	19256	18811	18746	17742	18153
1979	18527	17960	20010	18841	19646	18249	19027	18800	18310	18612	17629	17588
1980	18923	18213	19559	18851	19786	19070	19120	18471	19010	19107	17255	19083
1981	19466	18537	20992	20315	20652	19721	20149	20028	20296	20004	18093	19382
1982	19481	18714	21555	19782	19970	19871	20229	20547	20327	20027	18714	19530
1983	19887	19359	22182	20460	20851	20115	20686	20649	20682	20315	18612	19185
1984	19688	19500	21667	19987	20715	19760	20229	20756	20123	20636	19304	19647
1985	20676	18998	21427	20393	21054	19527	20628	20818	20539	21124	19455	19379
1986	20025	18960	21106	20489	20651	19810	20942	20667	20897	21300	18863	20153
1987	20016	19151	21748	20539	20696	20111	21074	20424	21082	20385	19181	19758
1988	20210	19724	22208	20505	21051	20716	20705	21348	21843	21473	20431	21054
1989	20480	19416	21599	20243	21831	21330	21580	22121	22074	22156	20852	20882
1990	21255	20220	22918	21751	22360	21722	22312	22678	22415	23121	21036	20966
1991	21683	20045	22412	21889	22221	21309	21935	22008	21606	22073	19974	21071
1992	22020	21282	22757	21936	22401	21855	22861	22030	22721	22695	20538	21094
1993	21588	20223	22973	21727	22106	21876	22204	21918	22472	22207	20506	21663
1994	21908	20422	23642	21375	22097	21209	21997	22210	22586	22306	20866	21532
1995	21823	20463	23223	21154	22597	21690	22138	22405	22075	21953	20399	20149
1996	21151	20633	21926	20856	21851	20900	21822	21933	22088	22399	20920	21274
1997	21620	19632	21693	20929	21728	21050	22067	21456	21999	22492	19947	20662
1998	21012	19695	21884	21065	21165	20842	21980	21243	21837	21901	19900	20392
1999	21353	20020	22594	21203	21348	21283	21782	21724	22153	21258	19892	20652
2000	21589	20231	22241	20546	21928	20927	20814	21777	21713	22354	20513	19513
2001	20591	19614	22084	20729	21451	20588	21305	21968	21718	21742	20032	19726
2002	21516	19996	21799	20903	21493	20352	21619	21388	21704	22011	20125	20487
2003	20879	19450	21419	20567	21423	21231	21941	21633	22102	22568	19787	20776
2004	21651	20352	22379	21409	20971	19608	22422	21287	21906	21348	20494	20496
2005	21380	20464	23534	22594	22796	22264	22649	22974	23423	23132	21623	22178
2006	22537	20897	22996	22309	23200	22315	23940	24146	24390	24150	22806	22591
2007	24397	22638	25405	23411	24788	23750	24908	25235	24502	25186	23375	23053
2008	24726	23351	25027	24026	24403	23420	25570	24974	24955	25468	22959	25035
2009	24110	23407	25318	24800	24604	24344	25503	24403	25423	25897	23820	24667
2010	24851	23412	26670	24648	25393	25046	25282	24963	25063	24887	23273	23534
2011	24934	23658	26567	24803	25614	25093	24913	25237	25386	25068	24154	24298
2012	25745	24637	26397	25060	26394	25240	25940	26406	25463	26914	25392	24930
2013	26135	24111	26405	25117	26446	25007	25719	25495	25575	25931	24507	24867
2014	25344	24823	26430	25205	26505	25003	26325	25353	26088	26782	24353	25186
2015	25551	25892	26172	24994	25199	24942	26347	25589	26027	26009	24194	26114
2016	25396	25392	27365	25928	26293	26016	25785	26003	26248	25661	24387	24511
2017	25373	23480	26426	24461	25608	25070	24973	25795	25185	25156	23888	23774
2018	25529	23381	25768	24137	25387	24503	24915	25195	24385	25344	24123	23780
2019	24796	23293	25632	24666	26004	24041	25049	24666	24557	25616	23332	23231
2020	24611	22798	24794	23729	24424	23776	24490	23926	23760	23806	22238	22695
2021	24793	24695	27433	25342	25669	24928	24905	24060	23558	23073	18186	6659

22 Feb: 1A COVID 19 Vaccination commenced with priority to frontline healthcare workers, aged care and disability staff and residents. Birth Rates Source: ABS <https://bit.ly/3DUkxZM>

2017	25373	23480	26426	24461	25608	25070	24973	25795	25185	25156	23888	23774
2018	25529	23381	25768	24137	25387	24503	24915	25195	24385	25344	24123	23780
2019	24796	23293	25632	24666	26004	24041	25049	24666	24557	25616	23332	23231
2020	24611	22798	24794	23729	24424	23776	24490	23926	23760	23806	22238	22695
2021	24793	24695	27433	25342	25669	24928	24905	24060	23558	23073	18186	6659
		1	2	3	4	5	6	7	8	9		

22 Feb: 1A COVID 19 Vaccination commenced with priority to

@LCHF_Matt (Twitter)

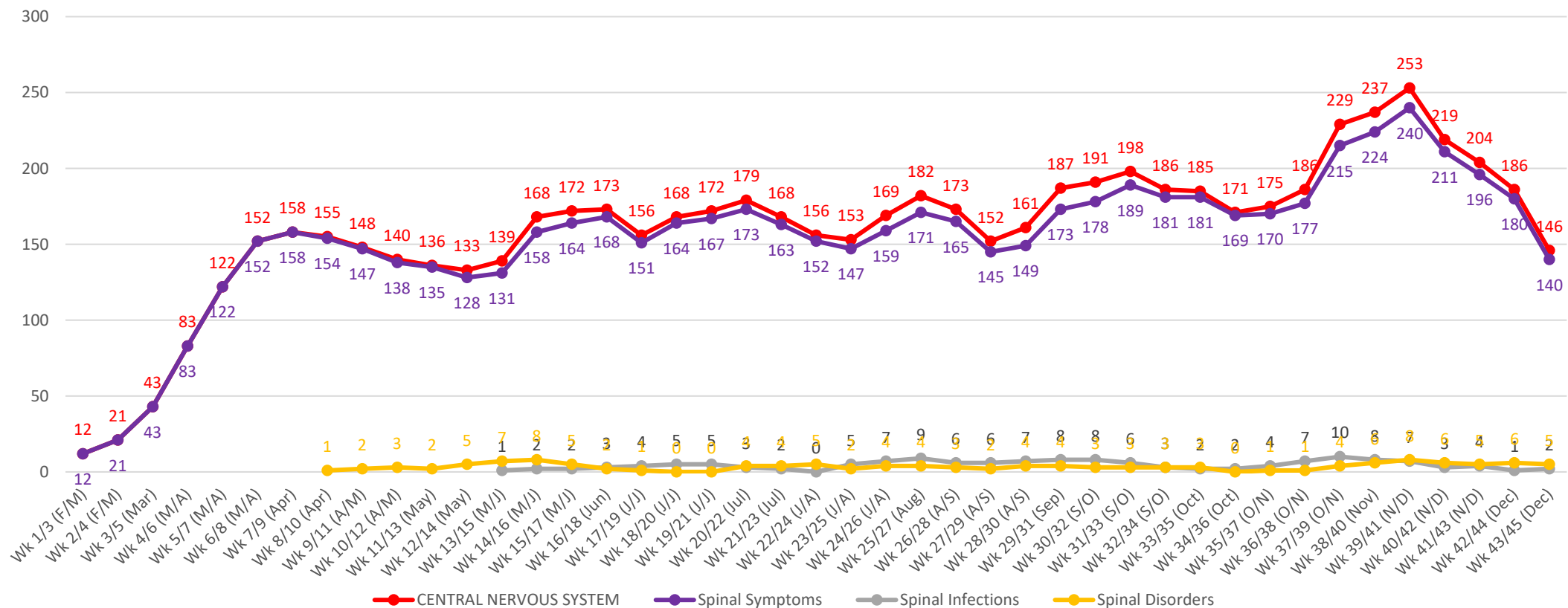


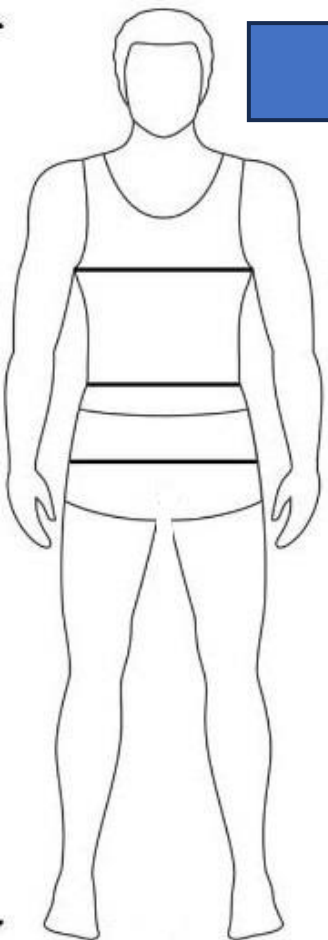
CENTRAL NERVOUS SYSTEM	2,339
Spinal Symptoms	2,253
Back pain	1,351
Neck pain	927
Spinal Infections	48
Myelitis transverse	24
Spinal Disorders	43
Intervertebral disc protrusion	11
Spinal Cord Procedures	6

Mainly Symptoms

"Spinal Symptoms" =
96% of "Central Nervous System"

Adverse Reactions Reported for Covid Medicines - Central Nervous System





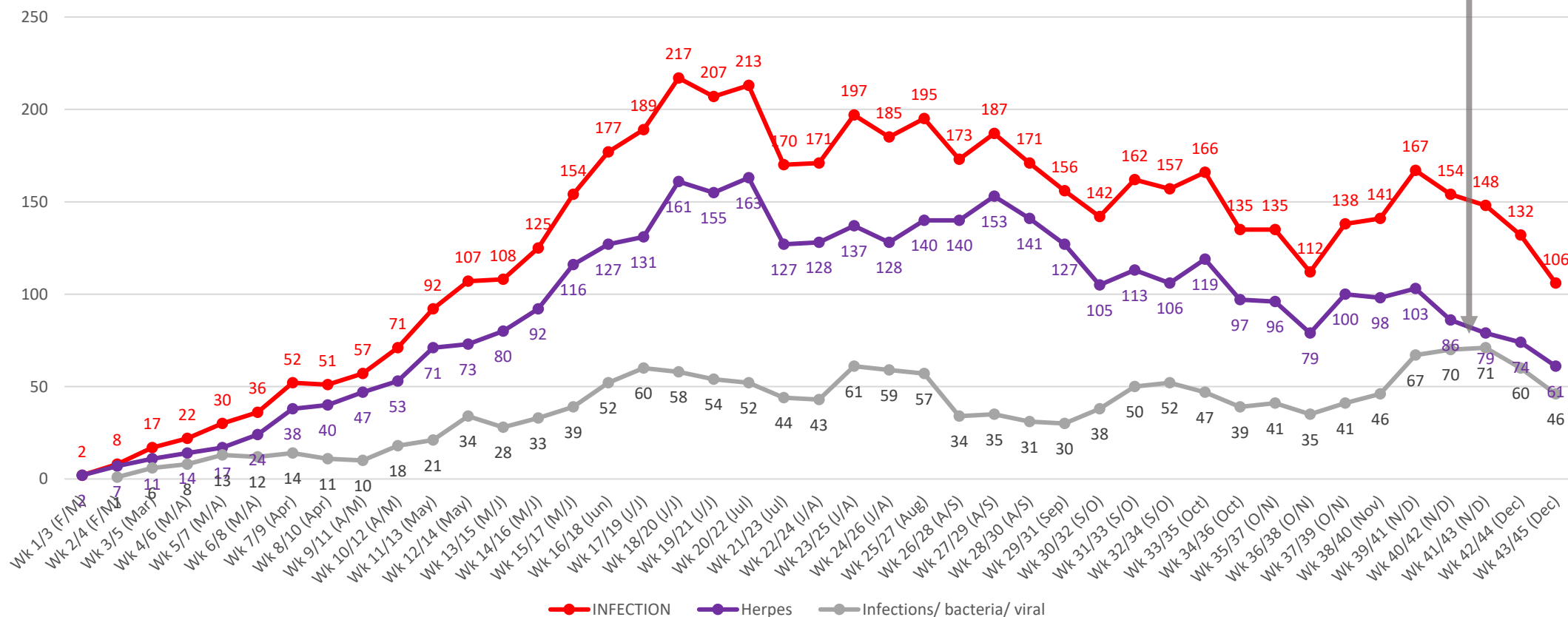
Infection
1,871 (1.8%)

INFECTION	1,871
Herpes	1,335
Herpes zoster (shingles)	1,084
Oral herpes	129
Infections/ bacteria/ viral	551
Inflammation	168
Viral infection	95
Infection	59



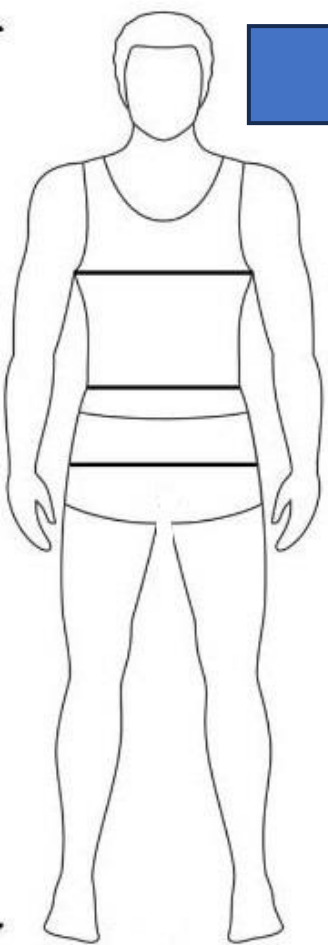
*"Infections/ bacteria/ viral"
continues increasing*

Adverse Reactions Reported for Covid Medicines - Infections



*Increase to Jun/Jul,
then decline*



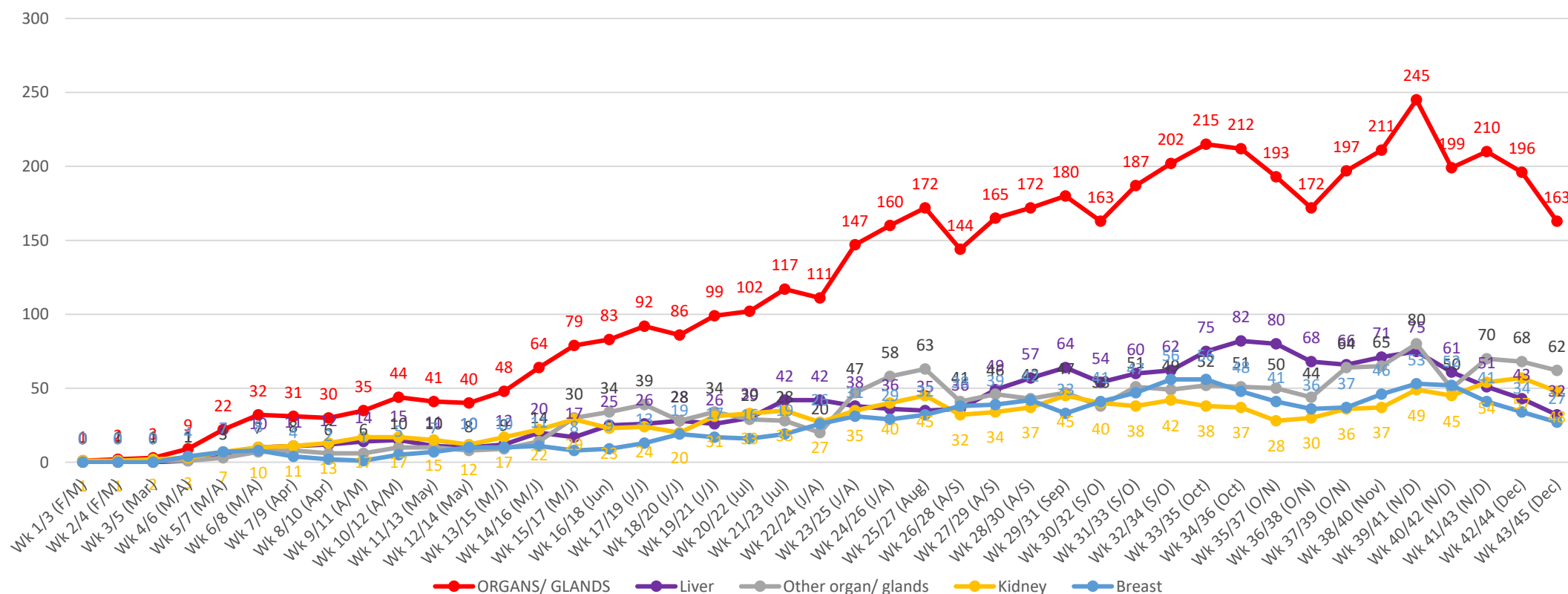


Organs/ Glands
1,728 (1.7%)

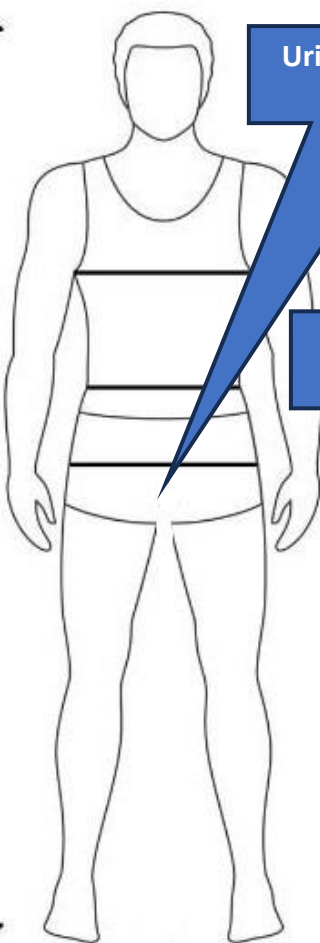
ORGANS/ GLANDS	1,728
Liver	525
C-reactive protein increased	257
Other organ/ glands	500
Appendicitis	145
Pancreatitis	72
Kidney	416
Renal pain	120
Breast	360
Breast pain	171
Breast swelling	62



Adverse Reactions Reported for Covid Medicines - Organs/ Glands



Steady increase



Urinary Tract Disorders
834 (0.8%)

Unresponsive
91 (0.1%)

URINARY TRACT	834
Bladder/ Urinary Tract Symptoms	527
Urinary Tract Infections	178
Urinary Tract Bleeding	166
Urinary Tract Disorders	13

UNRESPONSIVE	91
Unresponsive to stimuli	64
Coma scale abnormal	14



*“Unresponsive”
decline early*

Adverse Reactions Reported for Covid Medicines - Urinary Tract & Unresponsive

