Case Collection of Nagoya (Third report)

The Summary of Case Reporting of Medically Attended Long-term Adverse Events Following Coronavirus Disease 2019 (COVID-19) Vaccination

Nagoya City

Nagoya Medical Association,
General Incorporated Association

Aichi Nursing Association,
Public Interest Incorporated Association

Nagoya City

Nagoya is located at the approximate center of Japan. With apopulation of over 2.3 million, it serves as the urban hub of politics, economy, and culture for the Chubu Region.
History and culture including Atsuta Jingu, the three unifiers of Japan: Oda Nobunaga, Toyotomi Hideyoshi, and Tokugawa Ieyasu, and the Owari-Tokugawa family, are the basis for Nagoya's vitality and appeal.
Nagoya is now an attractive destination for many domesticand international tourists, who visit the city for its samurai history and culture and Nagoya Meshi. The hosting of the Asian Games and Asian Para Games and scheduled opening of the Linear Chuo Shinkansen line between Shinagawa and Nagoya offer the promise of continued interaction between people and further development of the local economy.

Nagoya Castle

Nagoya castle,know for the *kinshachi* (gold-plated tiger-headed carp statues) on its roof, is a symbol of Nagoya built in 1612 at the behest off Tokugawa leyasu(the founder and first shogun of the Tokugawa Shogunate).The *donjon*(main castle tower),rebuilt in 1959,has rich interior exhibits in addition to its beautiful exterior.Hommaru Palace,next to the main keep,was formerly used as a residence and govermment office and is open to the public since its completion of restoration in 2018.

Contents

<Glossary used in this summary>

- **Long-term adverse events**
  Symptoms that persist approximately 2 weeks or longer after receiving the COVID-19 vaccine
- **Cooperating medical facilities**
  Medical facilities that agreed to receive referred take on the treatment of the patients from the Nagoya Consultation Desk of Long-term Adverse Events Following COVID-19 Vaccination with suspected long-term adverse events following COVID-19 vaccination.
- **Vaccines against Omicron variant**
  Unless otherwise specified, it refers to the bivalent vaccines targeting the Omicron BA.1/BA.4-5 strain.

March 27, 2023	First report
September 25, 2023	Second report
March 25, 2024	Third report

The Nagoya City Investigation and Review Committee of Treatment Status of Medically Attended Long-term Adverse Events Following COVID-19 Vaccination

○ Purpose

This committee has been set up to conduct a survey on treatment status for medically attended long-term adverse events following coronavirus disease 2019 (COVID-19) vaccination and compile the results. The committee operates in a style in which the Nagoya COVID-19 Infectious Disease Control Office is in charge of general affairs and each committee member contributes to writing and advising.

○ Committee members

Committee member (honorific title omitted)	Affiliation/position
Motoaki Takenaka	Director, Nagoya Medical Association, General Incorporated Association
Husako Yuki	Executive Director, Aichi Nursing Association, Public Interest Incorporated Association
Fumio Matsubara	Former Deputy Director-General - Health Care Center, Health & Welfare Bureau, Nagoya City
Masayo Kojima	Deputy Director-General - Health Care Center, Health & Welfare, Nagoya City

・There is a committee with a similar name as us: the “Nagoya City Vaccine-related Health Damage Investigation Committee.” When health damage possibly related to vaccination occurs, this committee shall investigate and deliberate the case from a medical point of view. When the city submits a claim for health damage relief to the national government, review shall be performed mainly by this committee. As the two committes have different purposes, it is possible that a case of interest will be discussed by both parties in accordance with each objective.

1 Preface

We are pleased to announce the publication of the third report of the Summary of Case Reporting of Medically Attended Long-term Adverse Events Following Coronavirus Disease 2019 (COVID-19) Vaccination (Case Collection of Nagoya). We would like to take this opportunity to thank the Aichi Nursing Association for providing consultation services, cooperating medical facilities of the Nagoya Medical Association for their cooperation in the medical treatment and survey, and the Nagoya City Health and Welfare Bureau for compiling this report.

In October 2023, scientists who laid the foundation for the mRNA vaccine, the basic structure of the COVID-19 vaccine, were awarded the Nobel Prize. The progress of science and technology is very remarkable and is expected to be utilized in the ongoing fight between humanity and infectious diseases, as well as in the fight between emerging infectious diseases and science and technology. While vaccines have played a major role in this coronavirus pandemic, COVID-19 vaccines have a relatively high incidence of adverse events. In particular, the details of long-term adverse events seem to remain unknown. We believe that it is necessary to examine new technologies from various perspectives, both light and shadow.

Nagoya City was one of the first local governments that opened a consultation desk for people who suffered from symptoms thought to be long-term adverse events following COVID-19 vaccination. The city also has created a system that makes it easier for residents to receive medical consultations and treatment by listening to each individual's voice and guiding people to cooperating medical facilities.

We have been collecting cases from cooperating medical facilities and analyzing and publishing the overviews to share information. In this third report of Summary of Case Reporting in Nagoya, the survey period was extended, and data on the cases, such as clinical courses and treatment status, were added. We hope that this summary will be of help for those who are suffering from symptoms that are thought to be long-term adverse events, as well as for medical professionals providing treatment at medical facilities .

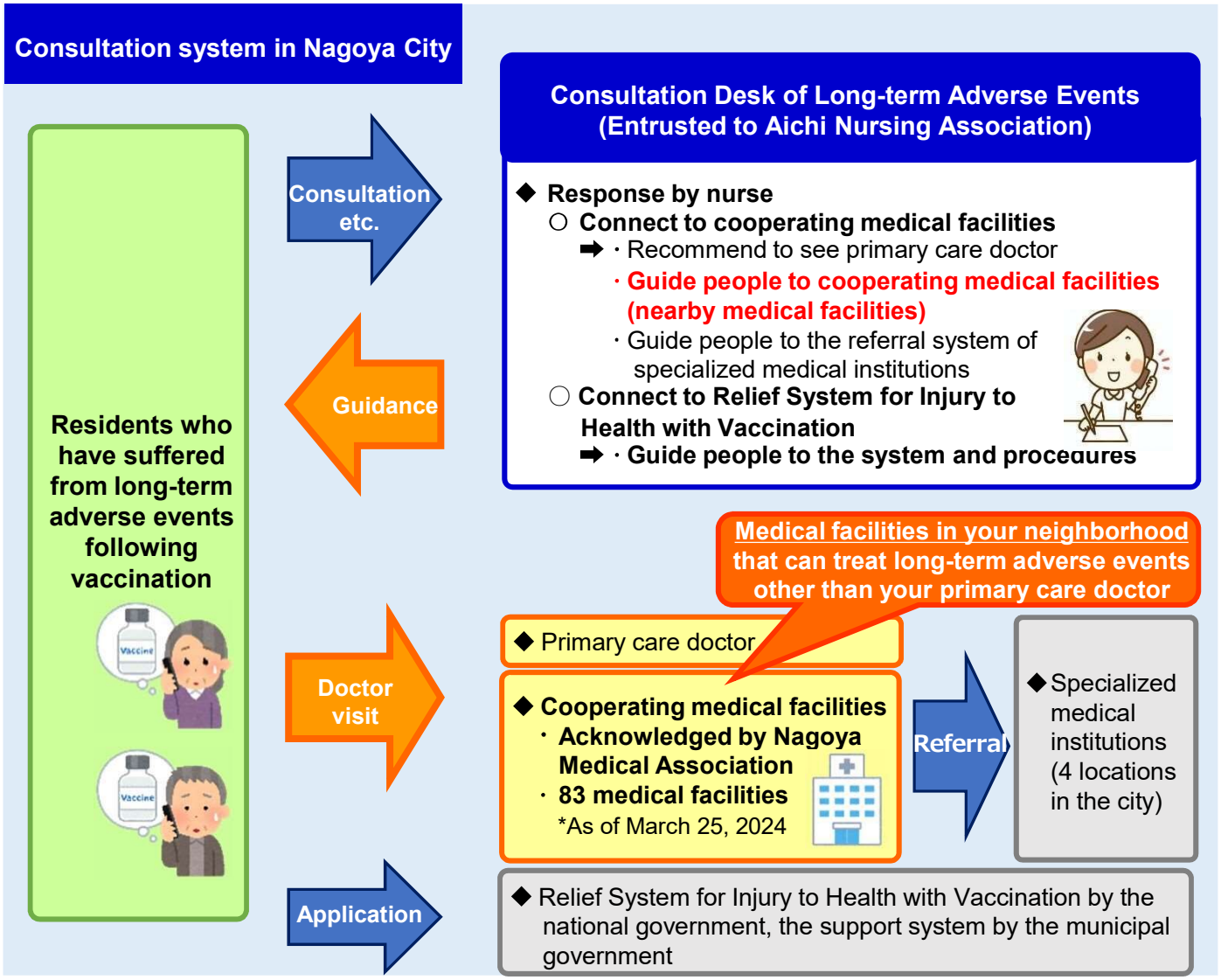
Motoaki Takenaka M.D.

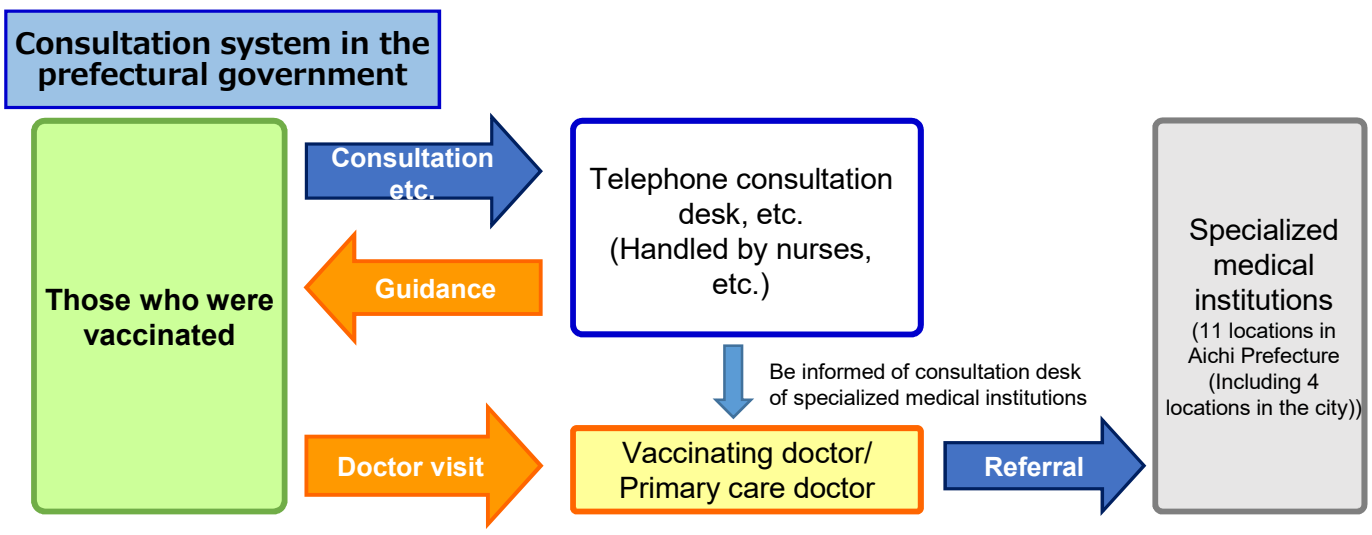
Director, Nagoya Medical Association,

General Incorporated Association

2 Overview of the consultation system for long-term adverse events in Nagoya City

A dedicated telephone consultation desk for residents who have suffered from symptoms that were thought to be long-term adverse events following COVID-19 vaccination opened on March 25, 2022 to guide people to cooperating medical facilities and a Relief System for Injury to Health with Vaccination. (See Document 1 for details of consultation results.)





3 Overview of the survey

(1) Background of the investigation

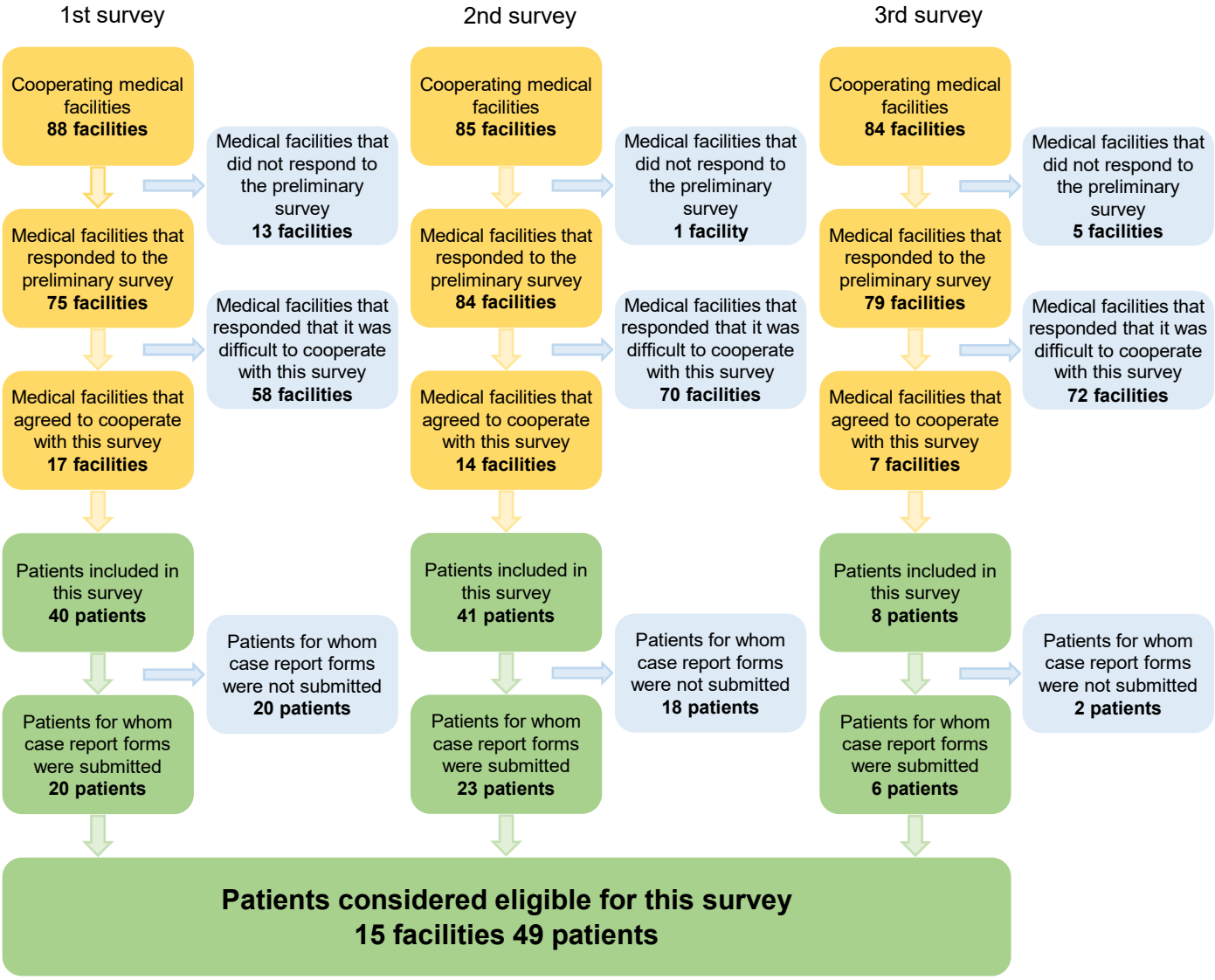
In the 1st survey, 20 patients who accessed the consultation desk from March 25, 2022, when it was opened, to June 30, 2022 were included and analyzed.

The survey included and analyzed another group of 23 patients who consulted the desk from July 1, 2022 to March 31, 2023 for the 2nd survey, and 6 patients from April 1 to September 30, 2023 for the 3rd survey.

Furthermore, follow-up surveys were performed on some of the patients reported in the first and second reports.

This is the thrid report of the summary analyzing 49 patients, including patients in all three surveys mentioned above.

(2) Flow of the survey



(3) Preliminary survey

In order to examine survey methods and eligible individuals, a preliminary questionnaire survey was performed among cooperating medical facilities regarding the number of medically attended patients with suspected long-term adverse events and the status quo.

Table 1 Consultation status of patients who visited cooperating medical facilities in the preliminary survey

Category	1st	2nd	3rd
Survey period	March 25, 2022 - June 30, 2022	July 1, 2022 - March 31, 2023	April 1, 2023 - September 30, 2023
Surveyed medical facilities	88	85	84
Number of responses (Response rate)	75 (85.2%)	84 (98.8%)	79 (94.0%)
Medical facilities where patients actually visited	47	30	12
Among those, medical facilities visited by patients who were confirmed to be "referral from the consultation desk".	29	11	7

Table 2 The number of patients and current status in the preliminary survey

		1st	2nd	3rd	Total
Survey period		March 25, 2022 - June 30, 2022	July 1, 2022 - March 31, 2023	April 1, 2023 - September 30, 2023	March 25, 2022 - September 30, 2023
Patients complaining of long-term adverse events (Response rate)		173 (100%)	131 (100%)	38 (100%)	342 (100%)
Current status of patients	**Treatment continues**	29 (16.8%)	5 (3.8%)	5 (13.2%)	39 (11.4%)
	Treatment has ended (Recovered)	30 (17.3%)	62 (47.3%)	13 (34.2%)	105 (30.7%)
	Referred patients to specialized medical facilities established by the prefecture	38 (22.0%)	20 (15.3%)	9 (23.7%)	67 (19.6%)
	Referred patients to other medical facilities	16 (9.2%)	22 (16.8%)	6 (15.8%)	44 (12.9%)
	No hospital visit despite patients being under treatment	29 (16.8%)	11 (8.4%)	1 (2.6%)	41 (12.0%)
	Others	8 (4.6%)	4 (3.1%)	4 (10.5%)	16 (4.7%)
	No answer	23 (13.3%)	7 (5.3%)	0 (0%)	30 (8.8%)

*The total may not add up to 100% due to rounding.

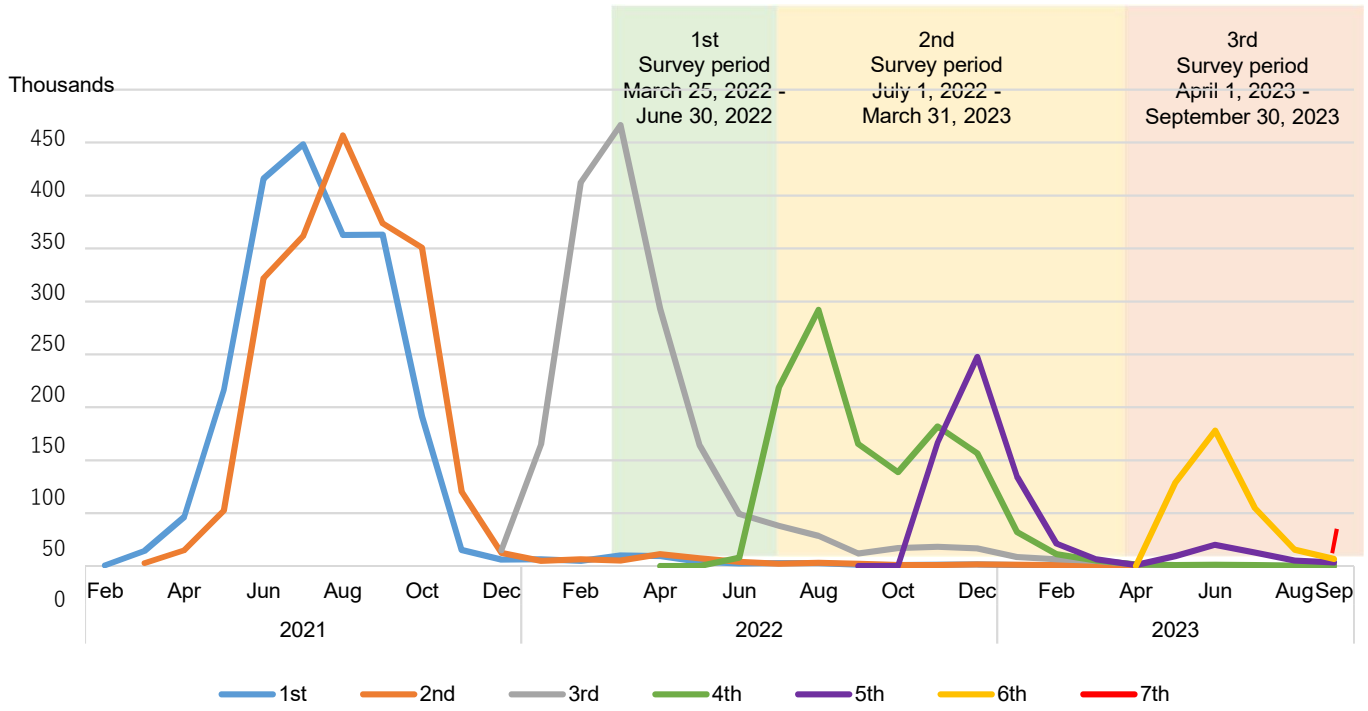
(4) This survey

Medical facilities that responded that they would cooperate with the survey in the preliminary survey were asked to submit case report forms*1 for individual patients.

Table 3 The number of patients in this survey

Category	1st	2nd	3rd	Total
Survey period*2	March 25, 2022 - June 30, 2022	July 1, 2022 - March 31, 2023	April 1, 2023 - September 30, 2023	March 25, 2022 - September 30, 2023
Surveyed medical facilities	17	14	7	27 *4
Medical facilities that responded (Response rate)	9 (52.9%)	7 (50.0%)	3 (42.9%)	15 *4
Patients included in this survey*3	40	41	8	89
Patients for whom case report forms were submitted (Response rate)	20 (50.0%)	23 (56.1%)	6 (75.0%)	49 (55.1%)

Monthly trends in the number of vaccine doses in the city



The city's COVID-19 vaccination program began with initial vaccinations (1st and 2nd doses) in February 2021, and since then, additional vaccinations, such as the 3rd, 4th, and 5th doses, have been carried out in sequence.
Meanwhile, the survey targets patients who visited cooperating medical facilities after March 25, 2022. Therefore, compared to the whole vaccinated population in the city, note that a deviation may exist in the number of vaccine doses and medical facilities visited in these target cases.

(5) Follow-up survey

Among the patients whose information was obtained and classified as “currently attending hospital” and “interrupted” in the 1st survey, “the 1st follow-up survey” was conducted on seven patients at the same time as the 2nd survey. Subsequently, for the eight patients whose information was obtained and classified as “currently attending hospital” and “interrupted” in the 1st and 2nd survey, “the 2nd follow-up survey” was conducted concurrently with the 3rd survey. In any of follow-up surveys, follow-up case report forms*1 were sent to the applicable medical facilities, and responses were obtained.

Table 4 Patients for whom follow-up to be performed

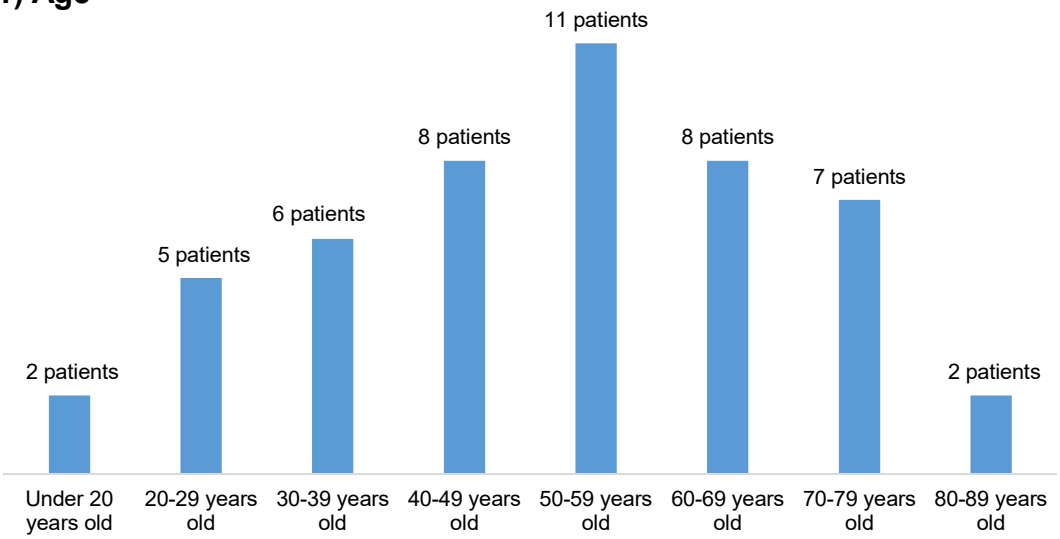
Category	1st follow-up survey	2nd follow-up survey
Surveyed medical facilities	5	6
Medical facilities that responded (Response rate)	5 (100%)	3 (50.0%)
Patients for whom follow-up was performed	7	8
Patients for whom case report forms were submitted (Response rate)	7 (100%)	3 (37.5%)

*1 The case report forms used in the 3rd survey and the 2nd follow-up survey were attached as Document 2.
*2 When a case report form was provided by a medical facility, patients outside of the target period were also included in the survey.
*3 Patients for whom medical facilities’ approval were obtained were included in the survey, and case report forms were asked to be submitted.
*4 Some medical facilities were overlapped in the 1st, 2nd, and 3rd surveys.

4 Demographics of patients

The survey included and analyzed a total 49 patients, including 20 patients in the 1st survey, 23 patients in the 2nd survey, and 6 patients in the 3rd survey. (Some figures were corrected after the publication of the 2nd report.)

(1) Age

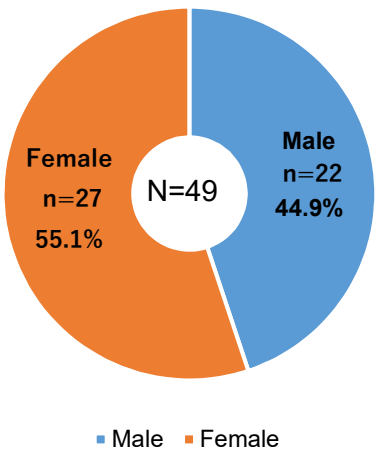


Youngest: 14 years old, Oldest: 82 years old

Trend: A wide range of age groups was reported. The sample distribution was roughly similar to that of the population, distribution of the total number of vaccine doses by age group.

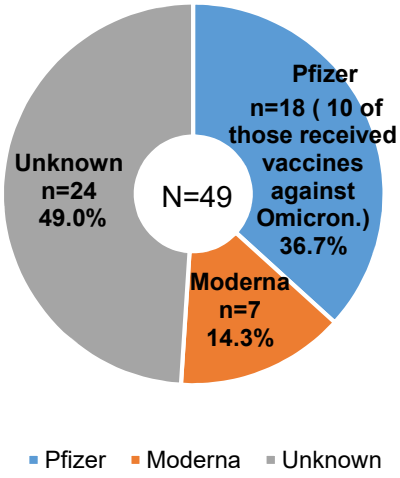
(P48 Document 3 (1) Total number of vaccine doses by age group)

(2) Male to female ratio



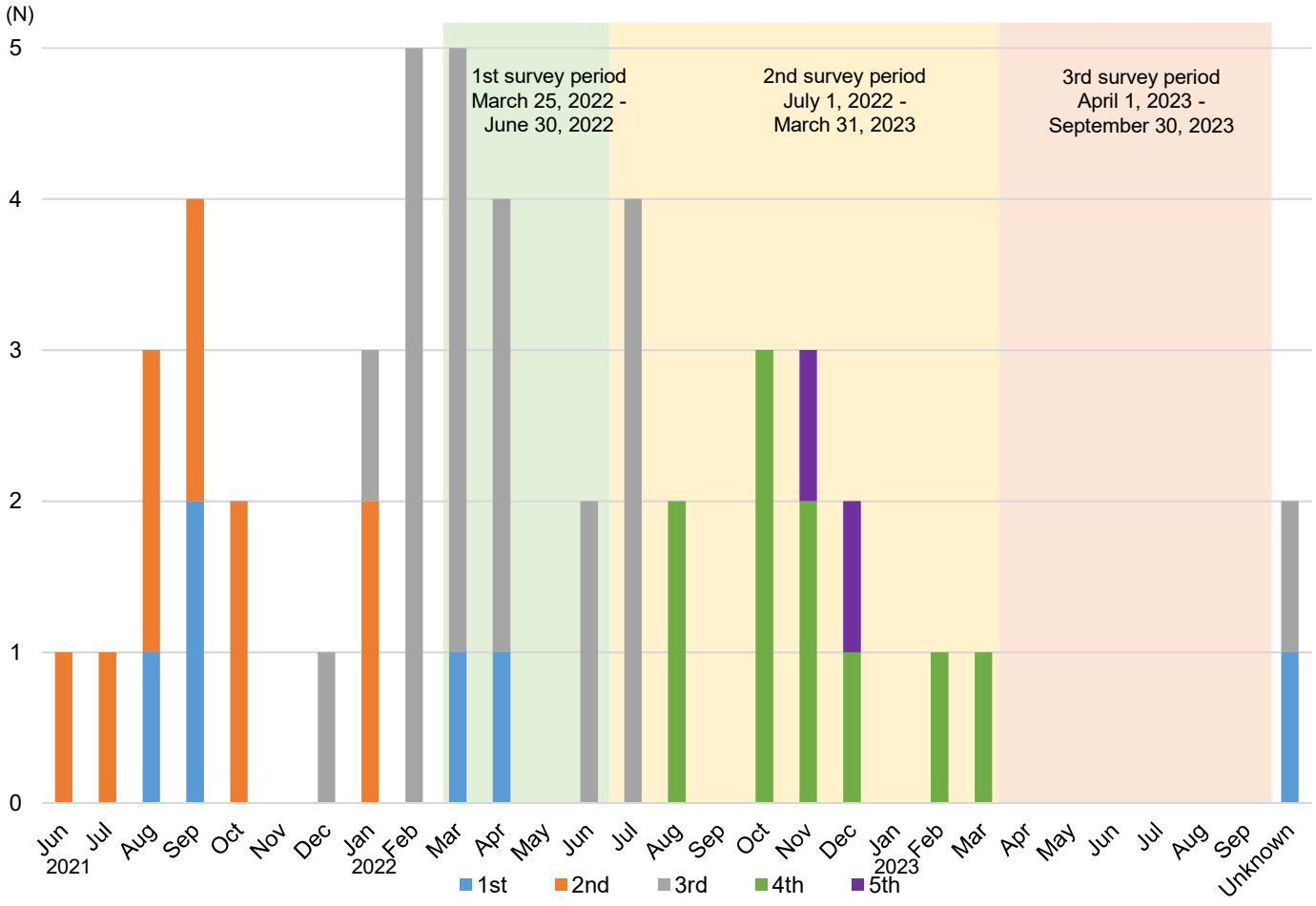
Trend: Slightly more females
(See P49 Document 3 (2) Male to female ratio)

(3) Types of vaccines used

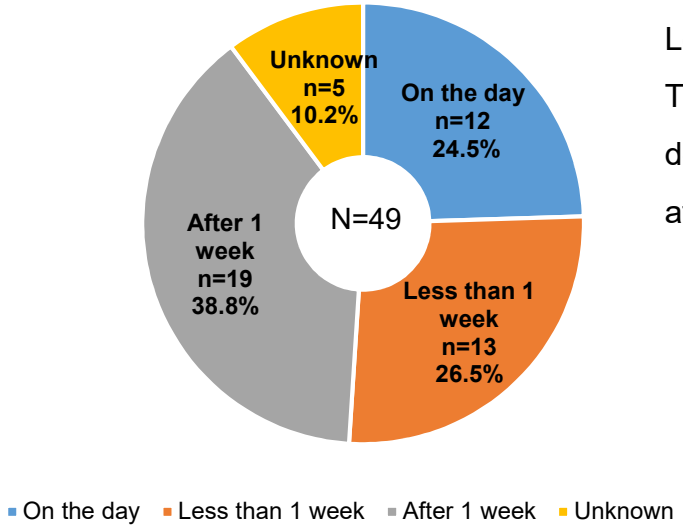


Trend: More patients with doses of Pfizer vaccine than those with doses of Moderna vaccine There were also many patients for whom the type of vaccine used is unknown.
(Refer to P50 Document 3 (3) Types of vaccines)

(4) The time of inoculation and the number of vaccine doses received



(5) Period from inoculation to the onset of symptoms

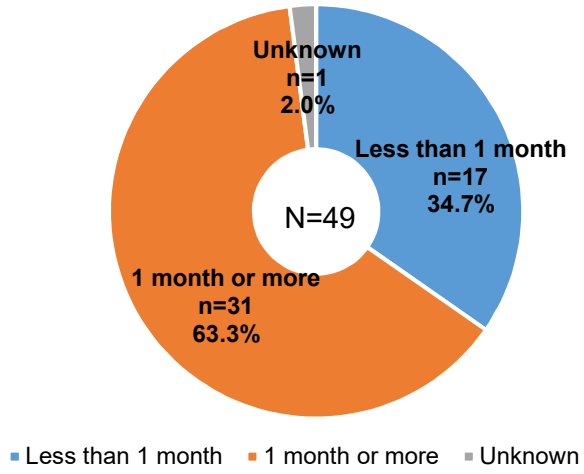


Shortest: Same day

Longest: About 6 months

Trend: Approximately half of the patients developed symptoms less than a week after vaccination.

(6) Period from vaccination to medical consultation

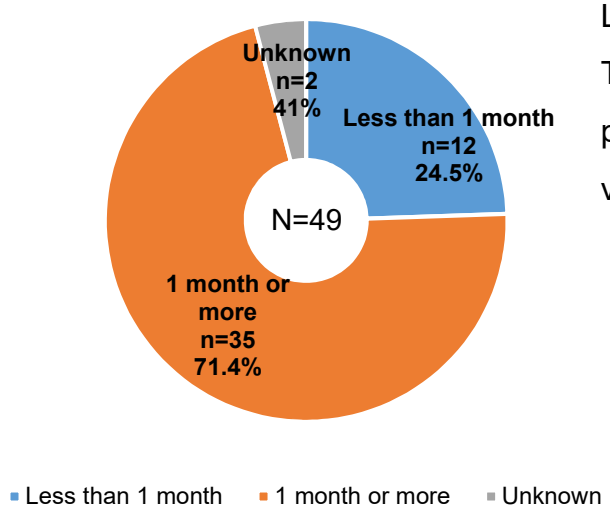


Shortest: 1 day

Longest: About 15 months

Trend: Approximately two-thirds of the patients took more than a month from onset of symptoms to medical consultation.

(7) Period from vaccination to the consultation

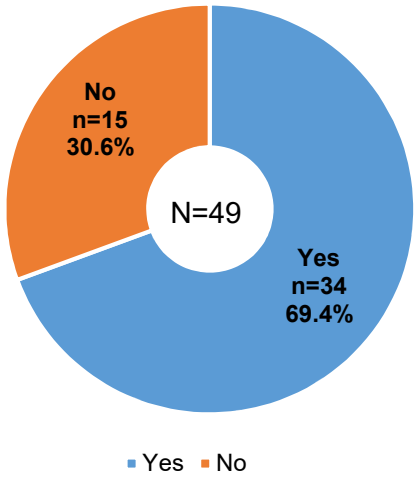


Shortest: 3 days

Longest: About 19 months

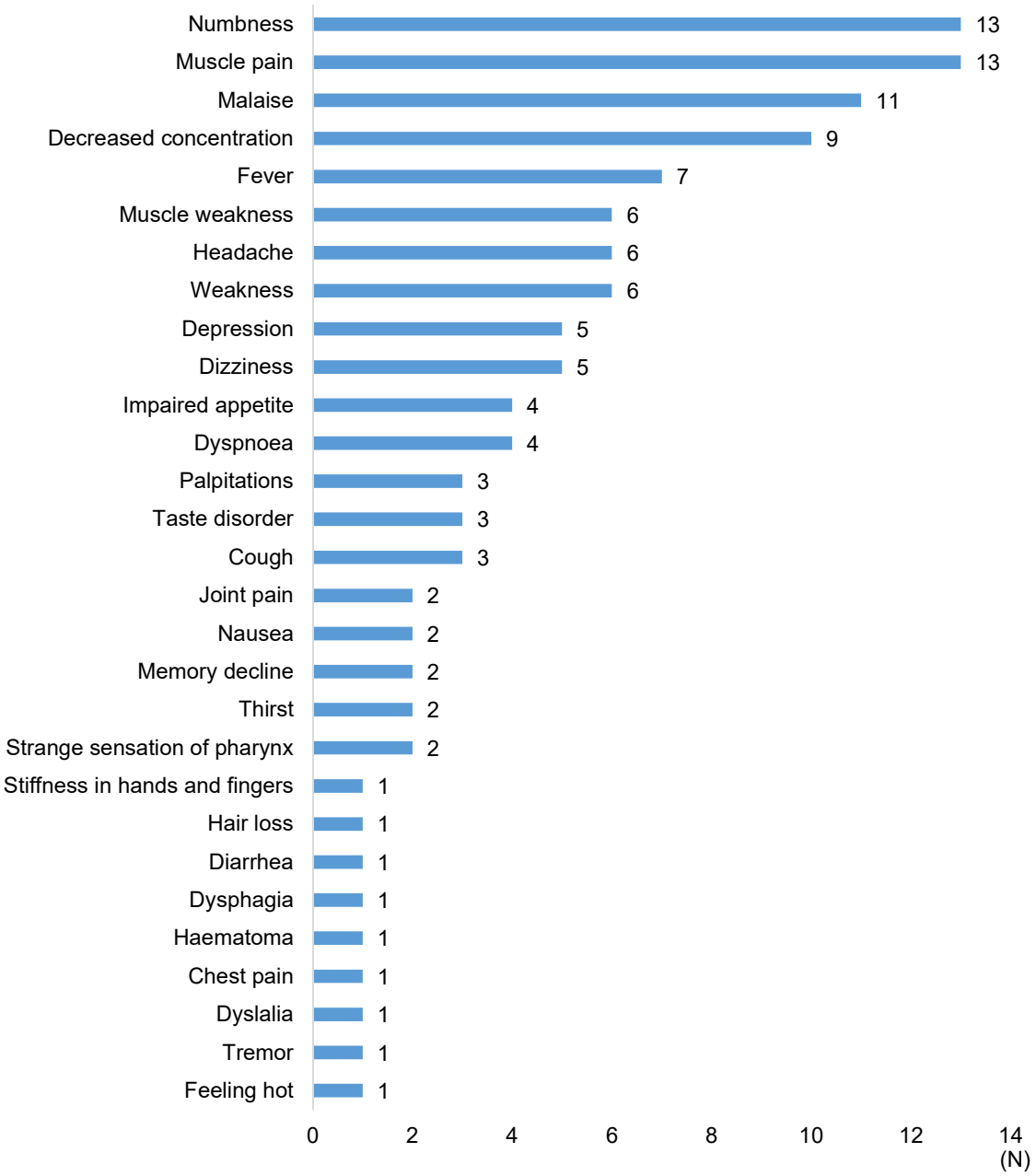
Trend: Approximately three-quarters of the patients took more than a month from vaccination to medical consultation.

(8) Underlying disease/medical history



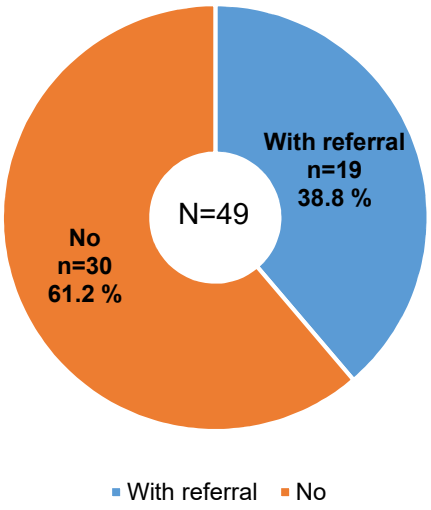
Trend: Approximately two-thirds of the patients had underlying diseases or a medical history; diabetes, mental illness, chronic heart disease, hypertension, and dyslipidemia (with some overlap) were seen more often.

(9) Major symptoms



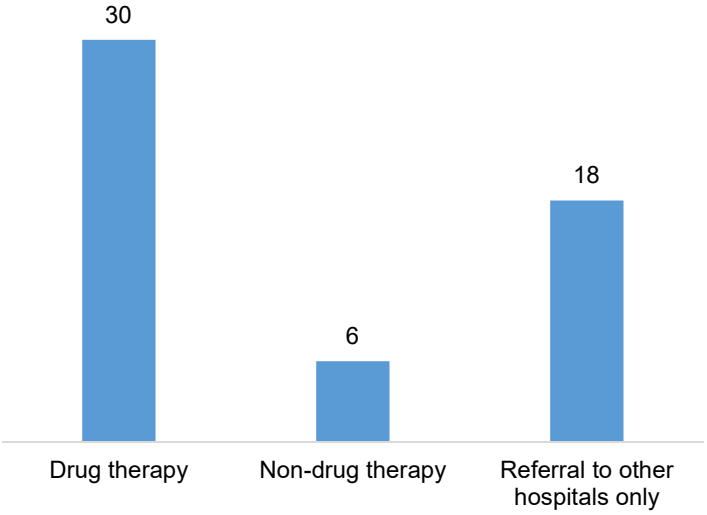
*Some overlap may exist due to patients with multiple complaints.

(10) With or without referral to specialized medical institutions



Trend: 40% of patients required referral to specialized medical institutions following medical consultation.

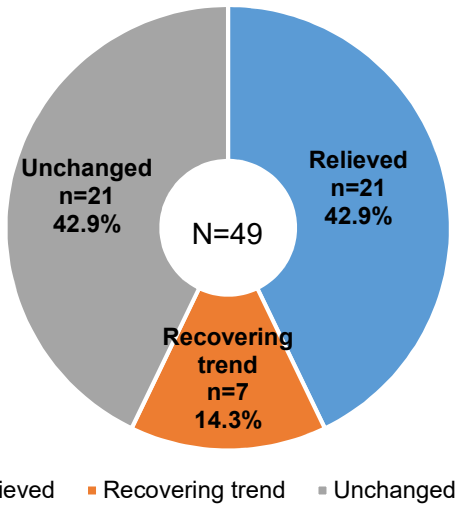
(11) Treatment overview



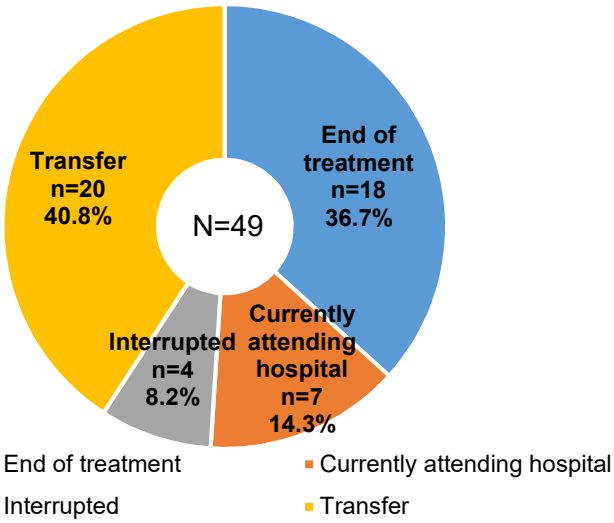
Trend: Many patients were treated by drug therapy.

* Some overlap may exist due to patients with multiple treatments.

(12) Clinical course (outcome)



(13) Current hospital attendance status (at the time of survey)



* Outcome is defined as follows in this summary.

Relieved	:	Conditions where symptoms have clearly improved
Recovering trend	:	Compared to the initial consultation, symptoms have improved; however, some complaints still remain.
Unchanged	:	Symptoms have not changed since the initial consultation.

*The total may not add up to 100% due to rounding.

5 Summary of case reports

Newly obtained data for patient numbers 1-20, 21-43, and 44-49 were included in the 1st survey, the 2nd survey, and the 3rd survey, respectively. Those with follow-up responses to the 1st follow-up survey and 2nd follow-up survey are marked with ★ and ★; contents are indicated in blue and red, respectively.

No.	Gender	Age groups	Vaccine	No. of vaccine doses	Underlying disease/ medical history	Major symptoms	Treatment	Outcome Hospital attendance status
1	Female	60	Original	2	Hypercholesterolemia	Numbness	Referred to a specialized medical institution (general internal medicine)	Recovering trend Transfer
2★	Male	50	Original	3	Chronic subdural hematoma	Malaise, dizziness, decreased concentration	Drug therapy (ninjin'yoeito, hochuekkito) ⇒ **At the time of follow-up, drug therapy (ninjin'yoeito, hochuekkito)**	Recovering trend Attending hospital
3★	Female	20	Original	3	-	Slight fever, malaise, depression	Drug therapy (daisaikoto, ethyl loflazepate) ⇒ **At the time of follow-up, drug therapy (ninjin'yoeito, hochuekkito)**	**Relieved End of treatment**
4	Male	50	Original	2	Hypertension, fat disorder, old myocardial infarction	Joint pain, pain in the left upper arm, difficulty raising the left upper limb	Drug therapy (acetaminophen), referred to a specialized medical institution (general internal medicine)	Unchanged Transfer
5	Female	60	Original	3	Diabetes, hypertension, heart disease, obesity	Taste disorder, left facial numbness, dysphagia	Drug therapy (ninjin'yoeito, polaprezinc), B-spot therapy, guidance on diet and exercise, etc.	Unchanged Interrupted
6	Female	50	Original	3	Uterine myoma	Taste disorder, strange sensation of pharynx, thirst	Drug therapy (ninjin'yoeito, polaprezinc, tranexamic acid), B-spot therapy	Relieved End of treatment
7	Female	80	Original	2	Chronic heart disease, hypertension	Dizziness	Drug therapy (betahistine, mecobalamin, adenosine triphosphate, ninjin'yoeito), non-drug therapy (exercise therapy)	Relieved End of treatment
8	Female	40	Original	3	Hypertension	Taste disorder	Drug therapy (polaprezinc, dexamethasone oral ointment)	Relieved End of treatment
9 ★★	Female	40	Original	3	Uterine myoma, acute hepatitis after EB virus infection	Numbness, fever, strange sensation of limbs, stiffness in hands and fingers ⇒ **At the time of follow-up, numbness**	Follow-up observation, non-drug therapy (rehabilitation) ⇒ **At the time of follow-up, drug therapy (mecobalamin)**	Recovering trend **Interrupted** **Interrupted**
10	Female	40	Original	2	Asthma, attending psychosomatic medical treatment	Headache, dizziness, numbness and pain in the right hand, pressure on the back of the head	Drug therapy (tofisopam, sertraline), handed over to attending physician (psychosomatic medicine)	Recovering trend Transfer
11 ★★	Male	20	Original	3	Mixed anxiety depressive disorder	Decreased concentration, depression, nervousness, anxiety, palpitations, early morning awakening ⇒ **At the time of follow-up, malaise**	Drug therapy (alprazolam, dosulepin, lemborexant, kamikihito, clotiazepam as needed) ⇒ **At the time of follow-up, drug therapy (alprazolam, lafutidine, dosulepin, kamikihito, dotinurad, lemborexant, ninjin'yoeito)** ⇒ **At the time of follow-up, drug therapy (oxazolam, dosulepin, lafutidine, ninjin'yoeito, vortioxetine hydrobromide)**	**Relieved** Attending hospital
12 ★★	Male	10	Original	1	Depressive state	Headache, decreased concentration, depression, abnormal feeling in pharyngolarynx ⇒**At the time of follow-up, depression, abnormal feeling in pharyngolarynx**	Drug therapy (oxazolam, escitalopram, pemafibrate, dotinurad) ⇒ **At the time of follow-up, drug therapy (esistalopram, ninjin'yoeito)**	**Relieved** **Interrupted**
13	Female	50	Original	1	-	Dyspnoea, chest pain, headache, fever, loss of appetite, weight loss	Follow-up observation, referral to specialized medical institutions (respiratory department, cardiovascular department), intravenous drip	Unchanged Transfer

No.	Gender	Age groups	Vaccine	No. of vaccine doses	Underlying disease/ medical history	Major symptoms	Treatment	Outcome Hospital attendance status
14	Male	30	Original	3	-	Dyspnoea, joint pain, muscle pain, malaise, weakness, numbness, fever, memory decline	Follow-up observation, no abnormalities found in a specialized medical institution, treatment and oral medication taken at another hospital (otolaryngology)	Unchanged Transfer
15★	Female	20	Original	3	-	Dyspnoea, muscle pain, headache, diarrhea, malaise, weakness, numbness, fever, depression, nausea, muscular weakness in limbs, impaired appetite **⇒ At the time of follow-up, muscle pain, nausea, impaired appetite, muscle weakness**	Follow-up observation, drug therapy (hochuekkito, mecobalamin) **⇒ At the time of follow-up, follow-up observation**	**Unchanged End of treatment**
16	Male	10	Original	2	-	Numbness in limbs	Follow-up observation, referral to specialized medical institutions (outpatient pain clinic) and acupuncture clinics	Unchanged Transfer
17★	Male	60	Original	3	Hyperuricemia, dyslipidemia, insomnia	Malaise	Drug therapy (saikokaryukotsuboreito), non-drug therapy (psychological counseling)	**Relieved End of treatment**
18	Male	70	Original	3	Diabetes, hypertension, right macular degeneration, cholelithiasis, post-cholecystectomy	Muscle pain, restricted range of motion in shoulder joint	Drug therapy (saikokaryukotsuboreito), referral to a specialized medical institution (orthopedic surgery)	Unchanged Transfer
19	Female	30	Original	2	Atopic dermatitis	Hair loss	Referral to a specialized medical institution (dermatology), laser treatment at another hospital	Unchanged Transfer
20	Female	40	Original	2	Suspected Hashimoto's disease	Muscle pain, malaise, nausea, loss of appetite, weight loss	Referral to specialized medical institutions (rheumatology, gastroenterology)	Unchanged Transfer
21	Female	30	Omicron	4	-	Palpitations, muscle pain, shortness of breath	Drug therapy (celecoxib, rebamipide, flurbiprofen tape)	Unchanged Interrupted
22	Male	40	Original	3	Ulcerative colitis	Muscle pain, muscle weakness, unable to lift shoulders	Drug therapy (loxoprofen, chlorphenesin, rebamipide, flurbiprofen tape), non-drug therapy (physical therapy)	Relieved End of treatment
23	Male	50	Omicron	4	Stomach ulcer	Muscle pain	Drug therapy (betamethasone suspension injection, dibucaine hydrochloride/sodium salicylate/calcium bromide injection)	Relieved End of treatment
24	Female	50	Original	3	Gastric cancer post-surgery, cervical cancer post-surgery, osteoporosis	Muscle pain	Drug therapy (celecoxib, rebamipide)	Relieved End of treatment
25	Male	60	Omicron	4	Chronic liver disease	Haematoma	Drug therapy (loxoprofen, rebamipide)	Relieved End of treatment
26	Female	60	Original	4	-	Muscle pain	Drug therapy (betamethasone suspension injection, dibucaine hydrochloride/sodium salicylate/calcium bromide injection)	Relieved End of treatment
27	Male	60	Original	2	Chronic heart disease	Muscle pain, muscle cramp	Drug therapy (betamethasone suspension injection, dibucaine hydrochloride/salicylate sodium/calcium bromide injection, chlorphenesin, celecoxib, rebamipide)	Relieved End of treatment
28	Female	70	Original	3	Chronic heart disease, diabetes	Muscle pain	Drug therapy (betamethasone suspension injection, dibucaine hydrochloride/sodium salicylate/calcium bromide injection)	Relieved End of treatment
29	Male	40	Omicron	4	Depression	Thirst	Drug therapy (ninjin'yoeito, polaprezinc), others (B-spot therapy)	Relieved End of treatment
30	Male	20	Original	3	-	Decreased concentration, malaise	Referred to a specialized medical institution	Unchanged Transfer
31	Female	70	Original	3	Chronic respiratory disease	Palpitations, decreased concentration, numbness	Referred to a specialized medical institution	Unchanged Transfer

No.	Gender	Age groups	Vaccine	No. of vaccine doses	Underlying disease/ medical history	Major symptoms	Treatment	Outcome Hospital attendance status
32	Female	70	Omicron	4	Endometriosis, diabetes, chronic heart disease (including hypertension)	Decreased concentration, headache, weakness	Referred to a specialized medical institution	Unchanged Transfer
33	Male	30	Original	3	Anxiety disorder	Numbness, malaise, slight fever, decreased concentration, memory decline	Referred to a specialized medical institution	Recovering trend Transfer
34	Female	50	Original	3	Hyperlipidemia	Weakness, muscle weakness, numbness	Referred to a specialized medical institution and diagnosed as involuntary movement of left leg, and detailed examination is underway.	Unchanged Transfer
35	Female	30	Original	1	-	Headache, jaw pain	Referred to a specialized medical institution (neurology), and detailed examination is underway.	Unchanged Transfer
36	Female	30	Original	3	Spasmodic dysphonia, atopic dermatitis	Cough, weakness	Referred to a specialized medical institution	Unchanged Transfer
37	Female	70	Original	4	-	Weakness, dyspnoea	Referred to a specialized medical institution	Relieved Transfer
38	Male	70	Original	2	-	Impaired appetite	Referred to other medical facilities	Unchanged Transfer
39	Female	20	Original	1	-	Cough, depression, malaise	Drug therapy (ethyl loflazepate, Kampo medicines)	Relieved End of treatment
40	Female	40	Original	1	-	Cough, dizziness, decreased concentration	Drug therapy (ninjin'yoeito, hochuekkito)	Relieved End of treatment
41	Male	50	Original	1	Chronic subdural hematoma	Decreased concentration, malaise	Drug therapy (Kampo medicines)	Unchanged Attending hospital
42	Male	80	Original	3	Chronic heart disease (including hypertension), diabetes, cerebral infarction, cerebral hemorrhage	Muscle weakness, lump on left hand	Transfer to a primary care doctor (orthopedic surgeon)	Unchanged Interrupted
43	Female	70	Original	3	-	Malaise, muscle weakness	Drug therapy (ninjin'yoeito)	Relieved End of treatment
44	Male	50	Omicron	4	Chronic heart disease (including hypertension)	Feeling hot, muscle pain	After referral to a specialized medical institution, he received drug therapy (celecoxib, rebamipide, betamethasone suspension injection, dibucaine hydrochloride/sodium salicylate/ calcium bromide injection).	Relieved Attending hospital
45	Male	60	Omicron	5	Epilepsy, cataracts, Hirayama disease (juvenile muscular atrophy of distal upper extremity)	Numbness, muscle pain	Drug therapy (celecoxib, rebamipide, betamethasone suspension injection, dibucaine hydrochloride/sodium salicylate/ calcium bromide injection).	Relieved End of treatment
46	Male	40	Original	2	Chronic heart disease (including hypertension), hives, schizophrenia	Numbness (head, abdomen, both thighs), fever	Referred to a specialized medical institution	Unchanged Transfer
47	Female	50	Omicron	5	Depression, epilepsy, anxiety neurosis	Dizziness	Non-drug therapy (counseling), encouraged to visit a specialized medical institution	Unchanged Attending hospital
48	Female	50	Omicron	4	Rheumatoid arthritis	Numbness, tremor, pain in ears and face	Drug therapy (duloxetine, arotinolol hydrochloride)	Recovering trend Attending hospital
49	Male	60	Omicron	4	-	Muscle weakness, dyslalia	Referred to a specialized medical institution	Recovering trend Transfer

6 Review of the case reports

(1) Overall trend

The most common symptoms were numbness and muscle pain (13 patients), followed by malaise, decreased concentration, fever, muscle weakness, headache, and weakness. A variety of other symptoms included depression and dizziness.
Those symptoms were mainly treated by drug therapy, with internal medical symptoms being primarily administered with the Japanese Kampo medicines (Kampo medicines) and motor symptoms often administered with anti-inflammatory analgesics.

(2) Trends and selected treatment by major symptoms

Numbness 13 patients (No. 1, 5, 9, 10, 14, 15, 16, 31, 33, 34, 45, 46, and 48)
- Many patients received Kampo medicines (hochuekkito, ninjin'yoeito), vitamin B12, and others.
- Some patients discontinued treatment spontaneously.
- Recovering trends were observed in 5 patients (No. 1, 9, 10, 33, and 48).
- Six patients (No. 14, 16, 31, 33, 34, and 46) were transferred to specialized medical institutions.

Muscle pain 13 patients (No. 14, 15, 18, 20, 21, 22, 23, 24, 26, 27, 28, 44, and 45)
- Six patients developed symptoms less than 1 week from the day of vaccination (No. 14, 22, 23, 24, 26, and 27).
- Two patients (No. 14 and 18) had joint pain along with muscle pain. Despite the use of analgesics and a Kampo medicine (saikokaryukotsuboreito), 1 of them (No. 18) did not show improvement. After transferring to a specialized medical institution, detailed examination was scheduled for suspected contracture of the joint of the left shoulder region.
- Among 9 patients (No. 21, 22, 23, 24, 26, 27, 28, 44, and 45) whose case report forms were submitted by the same orthopedic department, 6 patients (No. 23, 26, 27, 28, 44, and 45) who had inflammation at the injection site confirmed by echocardiography were relieved by the injection of steroids and a local anesthesia.
  Also, improvement was seen in 1 patient (No. 22) by the combination of anti-inflammatory analgesics and physical therapy and in another patient (No. 24) by anti-inflammatory analgesics alone.

Malaise 11 patients (No. 2, 3, 11, 14, 17, 20, 30, 33, 39, 41,and 43)
- Malaise was more common in relatively younger patients, and 3 patients (No. 3, 11, and 39) had accompanying depression.
- For patients complaining of malaise, Kampo medicines (ninjin'yoeito, hochuekkito, daisaikoto, kamikihito, saikokaryukotsuboreito, etc.) were often administered (No. 2, 3, 11, 17, 39, 41,and 43).
- Of the 4 patients relieved, 2 patients (No. 3 and 39) received tranquilizers and Kampo medicines (daisaikoto, etc.), and 2 patients (No. 17 and 43) received Kampo medicines alone (ninjin'yoeito, saikokaryukotsuboreito, etc.).
- One patient (No. 14), in which malaise during exertion and memory decline continued even after one month from the onset of symptoms, was transferred to a specialized medical institution.

Decreased concentration 9 patients (Patients 2, 11, 12, 30, 31, 32, 33, 40, and 41)

- Decreased concentration accompanied various symptoms, such as malaise, depression, palpitations, and numbness, in all patients.
- Two patients (Patients 11 and 12) had a history of mental illness. Although they were attending hospitals, their symptoms were relieved by antidepressants, anti-anxiety drugs, and Kampo medicines (kamikihito, ninjin'yoeito).
- Three patients had concurrent symptoms of malaise and dizziness and received Kampo medicines (ninjin'yoeito, hochuekkito, etc.) While 1 patient's symptom (Patient 40) was relieved, 2 patients (Patients 2 and 41) are currently continuing drug therapy.
- Four patients (Patients 30, 31, 32, and 33) were transferred to specialized medical institutions.

Headache 6 patients (Patients 10, 12, 13, 15, 32, and 35)

- Symptoms appeared around the day following vaccination in many patients.
- Three patients (Patient 13, 32, and 35) were transferred to specialized medical institutions.
- Two patients had a history of mental illness. One of them (Patient 10) had taken an autonomic nerve regulator and sleeping pills before vaccination, and the patient's symptoms improved after adjusting these drugs. Another patient (Patient 12) had symptoms of malaise, depression, and abnormal feeling in pharyngolarynx along with headache and was treated with antidepressants and anti-anxiety drugs. In the follow-up survey, although the headache remained, the general malaise and abnormal feeling in pharyngolarynx had improved 8 months later.

Muscle weakness 6 patients (Patients 15, 22, 34, 42, 43,and 49)

- Of the 2 patients relieved, relief was seen in 1 patient (Patient 22) by anti-inflammatory analgesics and physical therapy and in another patient (Patient 43) by a Kampo medicine (ninjin'yoeito).
- Since the symptoms of 1 patient (Patient 42) persisted more than 8 months, the patient was recommended to see a specialized medical institution.
- One patient (Patient 15) in her 20s had various symptoms, such as weakness in her limbs, gait disturbance, loss of consciousness, nausea, and dyspnoea, and was diagnosed by a specialist with postural orthostatic tachycardia syndrome. After receiving hochuekkito and vitamin B12 for 6 months, her numbness and weakness in the limbs were in a recovering trend; however, other symptoms remained unchanged.
- One patient (Patient 49) with accompanying dyslalia was diagnosed with cerebral infarction at a specialized medical institution; the patient was in a recovering trend after treatment.

Dizziness 5 patients (Patients 2, 7, 10, 40,and 47)

- Three patients received antivertigo drugs, vitamin B12, and Kampo medicines (ninjin'yoeito, hochuekkito). Of these, 2 patients (Patients 7 and 40) were relieved, and 1 patient (Patient 2) was in a recovering trend after administration of these drugs for more than 1 year.
- One patient with a history of mental illness (Patient 10) showed a recovering trend by an autonomic nerve regulator.

Impaired appetite 4 patients (Patients 13, 15, 20, and 38)
- Symptoms of back pain, nausea, and vomiting were also seen in 1 patient (Patient 20). A psychosomatic disorder was also suspected, and the patient was referred to a psychosomatic medicine clinic and a specialized medical institution.
- One elderly patient (Patient 38) had no abnormalities in endocrinological and upper gastrointestinal tract tests and was transferred to a comprehensive community care ward.

Dyspnoea 4 patients (Patients 13, 14, 15, and 37)
- Dyspnoea accompanied a wide range of symptoms, such as fever and numbness, in many patients.
- Three patients were followed up, and 2 of them (Patients 13 and 14) were referred to specialized medical institutions. One patient (Patient 15) received a Kampo medicine (hochuekkito) and vitamin B12, and a follow-up survey confirmed that the patient no longer had symptoms of dyspnoea.
- One patient (Patient 37) was hospitalized at a specialized medical institution for suspected Guillain-Barre syndrome and was discharged after symptoms were relieved.

(3) Follow-up survey

The 1st follow-up survey
- Symptoms were relieved in 4 (Patients 3, 11, 12, and 17) of the 7 patients, and 2 patients (Patients 2 and 9) continued to show a recovering trend from the time of the 1st survey. Of those relieved, 2 patients (Patients 3 and 17) completed treatment. Also, 2 patients (11 and 12), originally attending hospital for psychiatric symptoms, continue to receive drug therapy while their symptoms were relieved.
- One patient (Patient 15) continued to attend hospital because symptoms had not improved at the time of the 1st survey.
  Although only part of the symptoms were relieved at the time of the 2nd survey, treatment was completed.

The 2nd follow-up survey
- One patient (Patient 9) who interrupted treatment at the time of the 2nd survey remained interrupted.
- Of the 2 patients attending hospital at the time of the 2nd survey, 1 patient (Patient 11) currently receives drug therapy; however, the patient was in a recovering trend with reduced doses. One patient (Patient 12) interrupted treatment with no further hospital visits.

(4) Discussion

- Compared to the 1st and 2nd surveys, the number of consultations at the consultation desk and patients complaining of long-term adverse events in the preliminary survey in the 3rd survey have decreased significantly; consequently, the number of newly included patients also decreased.
- In this analysis (combining the 1st, 2nd, and 3rd surveys), the following trends were observed.
  - A wide range of symptoms following vaccination, including numbness, muscle pain, malaise, fever, headache, and psychiatric and neurological symptoms, were reported. General malaise was more common in the younger generation, and motor symptoms and otological symptoms were observed in the relatively older age groups as well. While approximately half of patients developed symptoms less than a week after vaccination, about two-thirds of patients took a month or longer from onset of symptoms to consultation. Also, approximately two-thirds of patients had underlying diseases or a medical history.
  - When we look at clinical courses, including follow-up survey results, symptoms of more than half of patients improved: 21 patients (42.9%) relieved and 7 patients (14.3%) in recovering trends. Although 21 patients remained unchanged, 15 of them were transferred and seemed to be treated at specialized medical institutions.
  - In these case reports, various treatments, primarily drug therapies, were tried in response to the various symptoms that occurred following COVID-19 vaccinations. Therefore, the results did not suggest the effectiveness of any specific treatment method.
- Through these surveys to date, however, we believe that general trends were confirmed in the symptoms thought to be long-term adverse events.
- Many of the symptoms observed were broadly consistent with those reported as adverse events in clinical trials during the development of the COVID-19 vaccine*[5].
- The symptoms observed were also similar to those described in “The fact-finding survey on long post-COVID vaccination syndrome (LPCVS)”*[6] and those reported as common long COVID or post-COVID conditions*[7,8]. According to “Management of Long COVID or Post-COVID Conditions, separate volume of Guide for Treatment of Coronavirus Disease 2019 (COVID-19) Infection (Version 2.0)”*[8], it is important to take a holistic approach since multiple factors are involved in the

development of long COVID or post-COVID conditions. This guide provides specific measures according to the symptoms. For patients complaining of neurological symptoms, for example, do not discontinue treatment just because there are no abnormalities in physical findings or test results, but rather put emphasis on symptomatic treatment and psychological support, such as advice on daily life and rehabilitation. The guide recommends to refer patients to specialists as necessary if symptoms have worsen. Such specific measures to deal with long COVID or post-COVID conditions are considered to be used as a treatment reference for symptoms following vaccination.

- Recently, it has become known that stress reactions induced by the act of vaccination itself (immunization stress-related reactions, ISRR), not limited to specific vaccines, can cause various symptoms. ISRR ranges from acute reactions, including the vasovagal reflex that occurs just before and after vaccination, to delayed neurological symptoms that occur several days later. This survey included similar symptoms in some patients. According to the definition of the WHO's manual*[9], “ISRR is thought to be caused by a complex interaction of psychological and social factors in addition to biological factors, and it is important to respond carefully depending on the symptoms”; this is also considered to be a useful treatment reference.
- This survey has some limitations. Of those who developed symptoms thought to be long-term adverse events following vaccination, only those who visited cooperating medical facilities were included in this survey. Of those surveyed, the response rate was limited to approximately 55%. Therefore, caution should be paid in the interpretation of the results.
- On the other hand, we consider this survey pioneering and rare, as there are still very few surveys on long-term adverse events following COVID-19 vaccination, and especially few on treatment methods for people who visited primary care settings.
- Also, the following were confirmed in the survey: the city's consultation desk responded to inquiries regarding long-term adverse events following COVID-19 vaccination and guided people who seem to require treatment to cooperating medical facilities; and those people actually visited medical facilities. We hope that the city’s consultation desk will continue to play an important role in helping people who are suffering from symptoms that are thought to be long-term adverse events following COVID-19 vaccination to receive appropriate treatment.

*5 Japanese Association of Vaccine Industries: Collection of Questions and Answers on Vaccination 2022. (Tables 5 to 8)
http://www.wakutin.or.jp/medical/pdf/qa_2022.pdf
*6 The fact-finding survey on long post-COVID vaccination syndrome (LPCVS) (Table 9)
https://www.mhlw.go.jp/content/10601000/001092282.pdf
*7 Long COVID or post-COVID conditions (Table 10)
Signs, symptoms, and conditions that continue after initial COVID-19 infection without any other specific causes, even though infectivity has disappeared. Signs, symptoms, and conditions may persist from the acute phase of the disease or newly develop/relapse during the clinical course of the disease.
*8 Ministry of Health, Labour and Welfare: "Management of Long COVID or Post-COVID Conditions, separate volume of Guide for Treatment of Coronavirus Disease 2019 (COVID-19) Infection Version 2.0" https://www.mhlw.go.jp/content/000952747.pdf
*9 WHO: A manual for program managers and health professionals to prevent, identify and respond to stress-related responses following immunization (ISRR).
https://apps.who.int/iris/bitstream/handle/10665/330277/9789241515948-jpn.pdf

Table 5 Adverse events in clinical trials of Pfizer vaccine

	5% or more	1% to less than 5%	Less than 1%	Frequency unknown
Local symptoms (injection site)	Pain (85.6%), swelling (10.3%), redness/erythema		Itching, feeling hot, internal haemorrhage, edema	
Psychiatric nervous system	Headache (59.4%)		Dizziness, lethargy, insomnia, facial paralysis	
Gastrointestinal	Diarrhea (14.8%)	Vomiting	Nausea, decreased appetite	
Respiratory			Oropharyngeal pain, nasal congestion	
Musculoskeletal	Muscle pain (38.8%) Joint pain (23.0%)		Pain in extremities, back pain	
Skin			Hyperhidrosis, rash, night sweats	
Vascular			Lymphadenitis	
Immune system				Hypersensitivity (rash, pruritus, erythema, hives, angioedema, facial swelling, etc.)
Others	Fatigue (66.0%), chills (36.0%), fever (16.8%)	Pain	Malaise, asthenia influenza-like symptoms	

"Vaccine Information Fact Sheet for Comirnaty Intramuscular Injection for 5 to 11 years old, Comirnaty Intramuscular Injection"
Pharmaceuticals and Medical Devices Agency
https://www.pmda.go.jp/PmdaSearch/iyakuDetail/GeneralList/631341D As of August 2023

Table 6 Adverse events in clinical trials of Moderna vaccine

	1% or more	Less than 1%	Frequency unknown
Local symptoms (Injection site)	Pain (92.6%), swelling/induration (16.5%), redness/erythema (12.2%), delayed reaction (pain, swelling, erythema, etc.), redness, swelling	Itching Hives	
Psychiatric nervous system	Headache (66.4%)		Acute peripheral facial nerve paralysis
Gastrointestinal	Nausea, vomiting (23.6%)		
Musculoskeletal	Muscle pain (60.4%), joint pain (44.6%)		
Skin		Rash	
Vascular	Lymphadenopathy (21.9%)		
Others	Fatigue (70.6%), chills (45.9%), fever (15.4%)	Facial swelling	

"Vaccine Information Fact Sheet for Spikevax Intramuscular Injection" Pharmaceuticals and Medical Devices Agency
https://www.pmda.go.jp/PmdaSearch/iyakuDetail/GeneralList/631341E As of August 2022

Table 7 Adverse events in clinical trials of AstraZeneca vaccine

	5% or more	1% to less than 5%	Less than 1%	Frequency unknown
Vascular			Lymphadenitis	Decreased platelets
Psychiatric nervous system	Headache (51.1%)		Dizziness, somnolence	
Gastrointestinal	Nausea (20.5%)	Vomiting	Lower limb, abdominal pain	
Skin			Hyperhidrosis, itching Rash, hives (less than 0.1%)	
Musculoskeletal	Muscle pain (43.5%), joint pain (26.6%)	Pain in extremities		
Local symptoms (Injection site)	Injection site tenderness (62.6%), injection site pain (54.7%), injection site warmth (17.9%), injection site bruising (17.9%), injection site itching (13.1%)	Injection site swelling, injection site redness, injection site induration		
Systemic symptoms	Fatigue (51.6%), malaise (43.8%), feeling of fever (33.5%), chills (31.0%), fever	Asthenia	Influenza-like symptoms	Angioedema

"Vaxzevria intramuscular injection package insert" revised in April 2022
(5th edition)

Table 8 Adverse events in clinical trials of Novavax vaccine

	10% or more	1% to less than 10%	Less than 1%
Local symptoms (injection site)	Tenderness (75.1%), pain (62.5%)	Redness/erythema, swelling, induration	Pruritis
Vascular			Lymphadenitis
Psychiatric nervous system	Headache (50.8%)		
Gastrointestinal	Nausea/vomiting (15.1%)		
Skin			Rash, erythema, pruritus, hives
Musculoskeletal	Muscle pain (51.4%), joint pain (23.6%)		
Others	Fatigue (53.0%), malaise (41.1%)	Fever, pain in extremities	Chills

"Nuvaxovid intramuscular injection package insert" revised in July 2022 (4th edition)

Table 9 Major symptoms that most interfere with daily life among the symptoms that led to consultation at the medical facility

Fever (37 degrees or higher)	48	Diarrhea	2	Lower extremity edema	1	Erythema	1	Movement disorder of left upper limb	1
Pain	26	Erythema, Moderna arm	2	Numbness in shoulders and back of head	1	Hoarseness	1	Hypoesthesia in left upper limb	1
Headache	24	Respiratory discomfort	2	Decreased activity	1	Extremities	1	Pain and difficulty in raising left upper limb	1
Malaise	23	Numbness	2	Hepatic impairment	1	Numbness of tongue	1	Weakness of left upper extremity	1
Joint pain	11	Hives	2	Hyperemia	1	Eczema	1	Decreased visual acuity in left eye	1
Palpitations	11	Edema	2	Facial flushing	1	Purpura	1	Numbness in left forearm ulna and 4th/5th fingers	1
Nausea/vomiting	10	Welts	2	Feeling of narrowing of airways	1	Cardiac arrest	1	Strange sensation/weakness in left hand	1
Chest pain	10	Gait disorder	2	Chest discomfort	1	Hives	1	Left side numbness	1
Consciousness disorder	7	Redness	2	Pleurisy	1	Genital bleeding	1	Frequent urination	1
Muscle pain	7	Anaphylaxis	1	Muscle weakness	1	Injection site redness and swelling	1	Insomnia	1
Hematuria	7	Feeling of dyspnoea	1	Swelling of mouth	1	Generalized rash	1	Tremulousness, tremor	1
Skin rash	7	Impaired consciousness, SpO2	1	Itching and redness in neck	1	Hair loss	1	Rash, itching	1
Rash	6	Strange sensation of pharynx, feeling of dyspnoea	1	Puffy feeling above neck	1	Weakness, numbness	1	Redness, itching	1
Shortness of breath	5	Strange sensation of pharynx, stuffy throat	1	Convulsions	1	Petechiae	1	Taste disorder	1
Abdominal pain	4	Itching sensation in pharynx	1	Convulsions	1	Pain, hives	1	Numbness in right wrist to fingertips	1
Swollen glands	4	Pharyngeal discomfort	1	Convulsions/consciousness disorder	1	Strange sensation of throat	1	Itching sensation in right eye	1
Strange sensation of pharynx	3	Decreased SpO2	1	Decreased blood pressure	1	Stuffy nose	1	Dizziness	1
Decreased concentration	3	Swallowing difficulty	1	Malaise, shortness of breath	1	Skin rash, erythema, Moderna arm	1	Numbness of lower back and upper extremities	1
Pharyngeal discomfort	2	Shivering chills	1	Oral mucosal edema	1	Pain in left axillary and clavicle	1	Bilateral hand numbness at distal side	1
Chills	2	Hyperventilation	1	Hypertension	1	Restricted range of motion in left joint	1	Bilateral hand numbness	1
Cough	2	Strange sensation of lower limbs	1	Swelling of lips	1	Numbness in left upper jaw	1	Inarticulateness	1

"The fact-finding survey on long post-COVID vaccination syndrome (LPCVS) (Third report)" January 26, 2024 Ministry of Health, Labour and Welfare
https://www.mhlw.go.jp/content/10601000/001198123.pdf

Table 10 Common long COVID or post-COVID conditions

·Fatigue ·Malaise ·Joint pain ·Muscle pain ·Cough ·Sputum ·Shortness of breath ·Chest pain ·Hair loss
·Memory impairment ·Decreased concentration ·Headache ·Depression ·Taste disorder ·Palpitations ·Diarrhea
·Abdominal pain ·Sleep disturbance ·Muscle weakness

"Management of Long COVID or Post-COVID Conditions, separate volume of Guide for Treatment of Coronavirus Disease 2019 (COVID-19) Infection (Version 2.0)" Ministry of Health, Labour and Welfare

7 Summing up

Vaccines are medicines that intentionally induce immunity to prevent the onset or reduce the severity of the specific diseases. Vaccinations may cause a number of unfavorable symptoms (adverse events), such as swelling and pain at the injection site, fever, and lymphadenopathy. The possibility to develop serious health problems (serious adverse events) is slight but cannot be ruled out. Therefore, any symptoms that occur following vaccination must be carefully handled.

The city opened the “Consultation Desk of Long-term Adverse Events” on March 25, 2022 with the cooperation of the Nagoya Medical Association and Aichi Nursing Association. It has guided people who seek medical consultation to cooperating medical facilities. This is the third report of the summary of the survey results on symptoms and treatment methods for patients who visited medical facilities that agreed to cooperate with this survey.

When the first report of this summary was published at the end of March 2022, the number of patients for whom we could investigate treatment status in detail was limited to 20 patients; a particular trend of characteristics of symptoms and treatment methods was not identified. Thanks to the great efforts of those involved, we were able to continue with the survey and increase the number of cases to 43 for the second report published at the end of September 2023 and 49 for this third report.

Most of the symptoms confirmed so far have been broadly consistent with those published as adverse events in clinical trials during the development of the major COVID-19 vaccines. Various treatments, including Kampo medicines, have been used depending on the symptoms. It was also confirmed that the majority of patients were relieved or in a recovering trend. Although the survey was based on responses from a limited number of medical facilities, we believe that we captured certain trends in symptoms and treatment for them.

The government requires doctors and medical facilities to report specific symptoms (anaphylaxis) and serious symptoms that possibly are related to vaccines following COVID-19 vaccination. It continues to collect and publish data, which specialists examine[*10].The government has also conducted a fact-finding survey of approximately 470 specialized medical institutions for long post-COVID vaccination

syndrome[*11], which confirmed similar results as ours. It is necessary to conduct further medical research as well as continuous collection of case reports to establish treatment strategies for the difficult-to-treat cases.

As a final note, we hope that this summary of case reporting will be of some help to those who are suffering from poor health following COVID-19 vaccination and medical professionals who provide treatment for them. We would like to express our sincere gratitude to the Nagoya Medical Association, the Aichi Nursing Association and all those at the medical facilities who took time out of their busy schedule to participate in the survey, as well as the committee members, Dr. Motoaki Takenaka, Ms. Husako Yuki, and Dr. Fumio Matsubara, for their efforts in preparing this summary.

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*10 Ministry of Health, Labour and Welfare: Reports of suspected adverse events following COVID-19 vaccination
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/vaccine_hukuhannou-utagai-houkoku.html

*11 Ministry of Health, Labour and Welfare: The fact-finding survey on long post-COVID vaccination syndrome (Second report)
https://www.mhlw.go.jp/content/10601000/001126457.pdf

[Document 1] Results of Consultation Desk of Long-term Adverse Events

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(1) Background

With widespread use of COVID-19 vaccines, Nagoya City has opened a consultation desk for residents who suffer from symptoms that are thought to be long-term adverse events following COVID-19 vaccination

The purpose is to guide people to a Relief System for Injury to Health with Vaccination and medical facilities that can be consulted on symptoms persisting for 2 weeks or more after inoculation and are thought to be adverse events following vaccination. The Aichi Nursing Association has employed highly experienced "Platinum Nurses" (nurses around the age of retirement) and begun providing consultation services from March 25, 2022 to date. In addition to the period covered in the second report, the third report has tallied up the number of consultations from April 1 to September 30, 2023.

(2) The number of consultations

The numbers of consultations in the 3rd survey from April 1 to September 30, 2023 and the total survey period from March 25, 2022 to September 30, 2023 were 322 (13.0%) and 2,471, respectively.

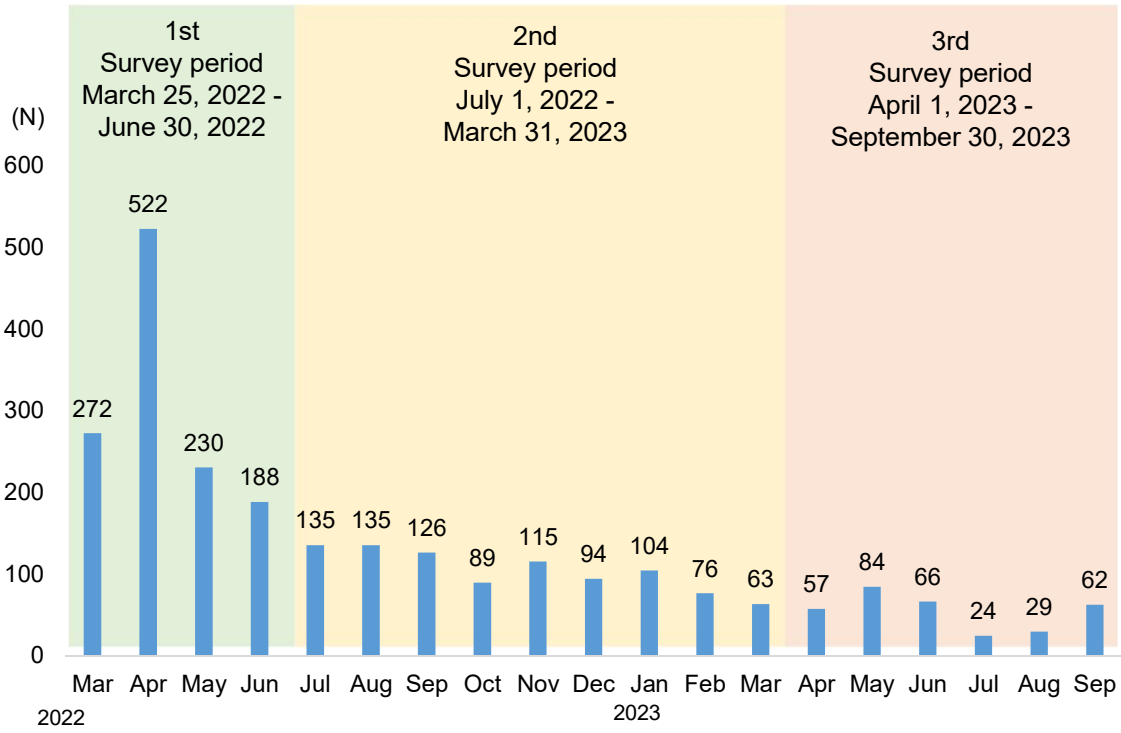


Figure 1 The number of consultations by month (N=2,471)

(3) Gender/Age groups

Broken down by gender, males, females, and unknow sex numbered 958 (38.8%), 1,488 (60.2%), and 25 (1.0%), respectively. (Figure 2)

Broken down by age group, 500 (20.2%) were in their 70s, followed by 459 (18.6%) in their 50s. (Figure 3)

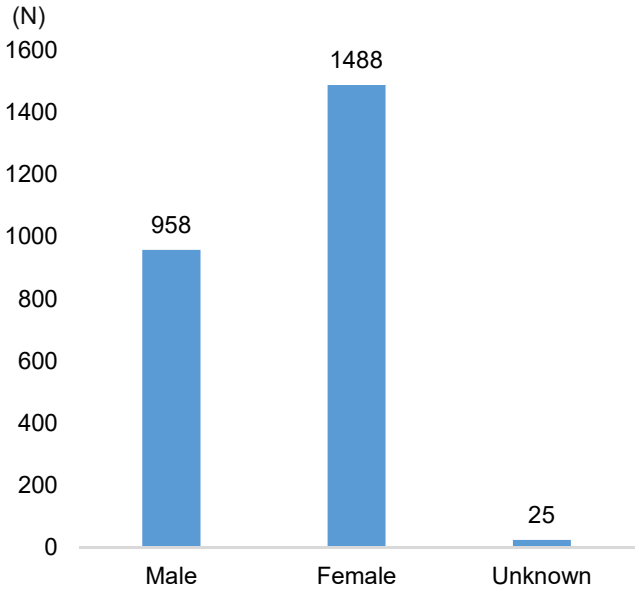


Figure 2 Breakdown by gender(N=2,471)

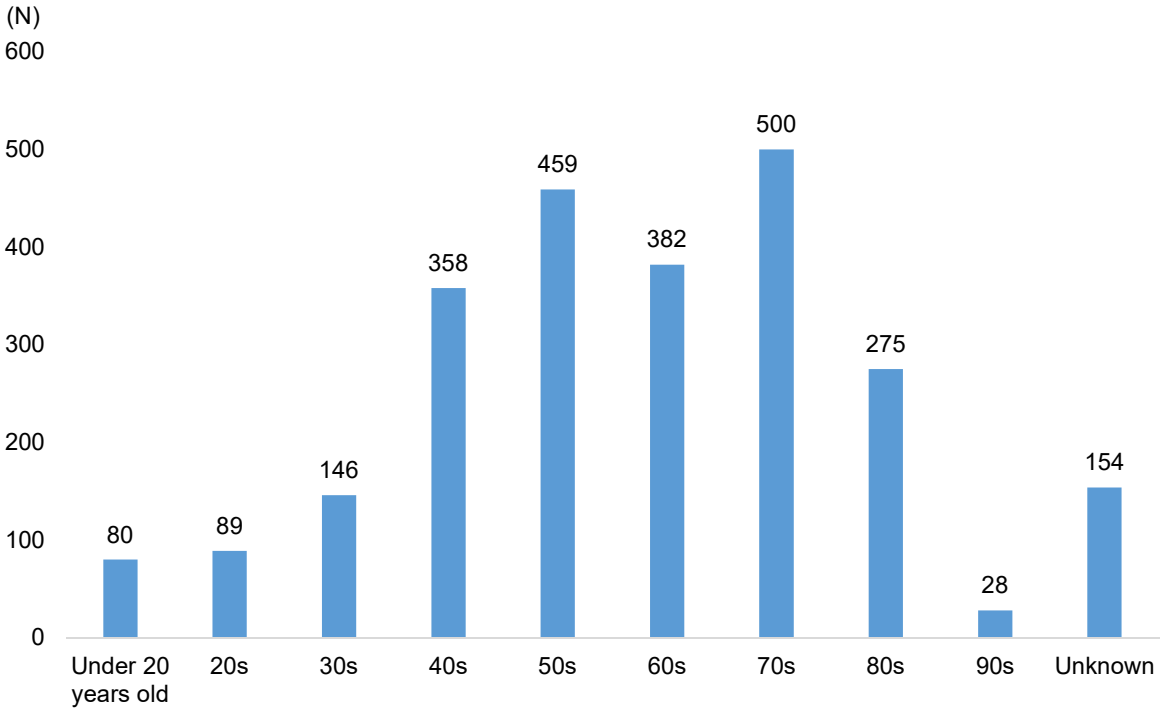


Figure 3 Breakdown by age group (N=2,471)

(4) Place of residence

Broken down by place of residence, Nagoya City, Aichi Prefecture excluding Nagoya City, and outside Aichi Prefecture numbered 1,755 (71.0%), 281 (11.4%), and 266 (10.8%), respectively.

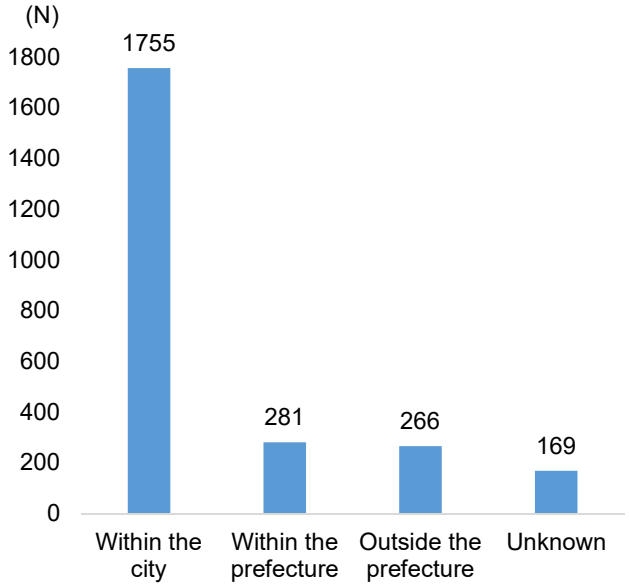


Figure 4 Breakdown by place of residence (N=2,471)

(5) Consultation content

Broken down by consultation content, consultation about visiting other medical facilities, confirmation and consultation about symptoms, and consultation about initial visits numbered 699 (28.3%), 560 (22.7%) and 377 (15.3%), respectively. These figures were followed by consultation about next inoculation, need for information about relief system, and complaining of symptoms (suffering).

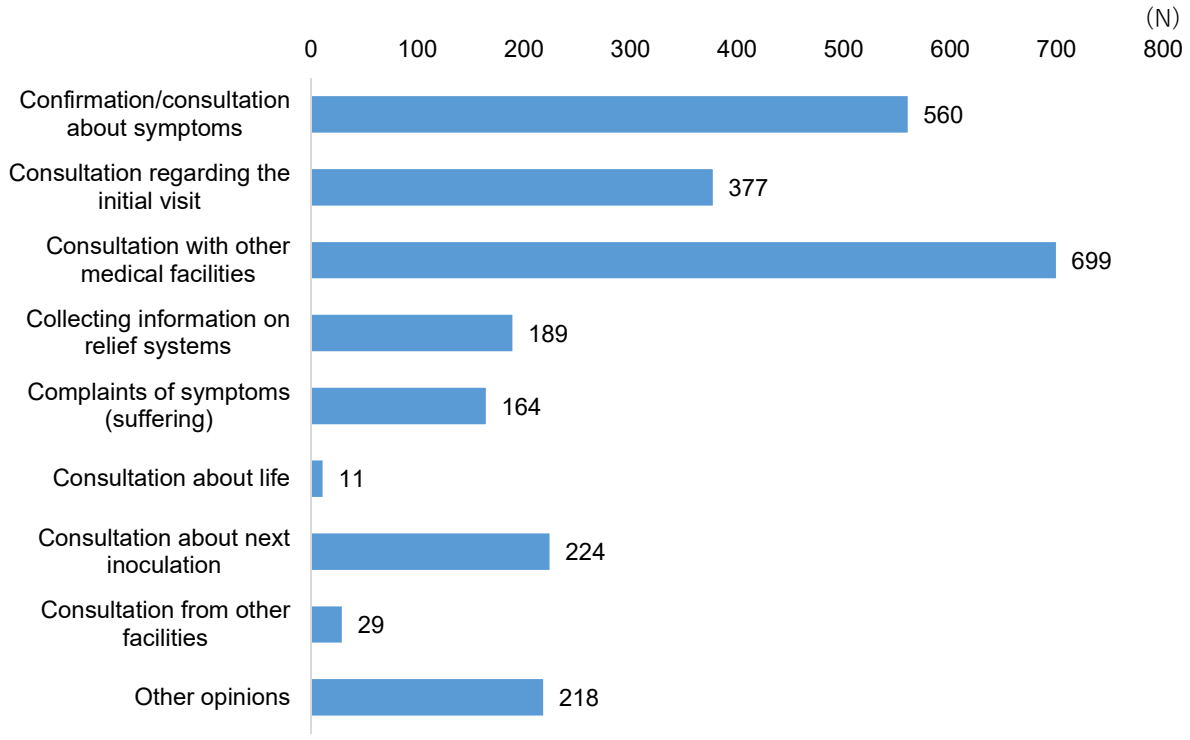


Figure 5 Breakdown by consultation content (N= 2,471)

(6) Time of consultation

The time of consultation was counted from the time when the person who consulted became aware that their symptoms might be adverse events following vaccination. Broken down by the time of consultation after inoculation, consultations from 6 months to less than 1 year, those from 1 month to less than 2 months, and those from 3 months to 6 months numbered 531 (21.5%), 312 (12.6%), and 303 (12.3%), respectively. Also, consultations more than 1 year numbered 227 (9.2%), suggesting cases with lingering adverse events.

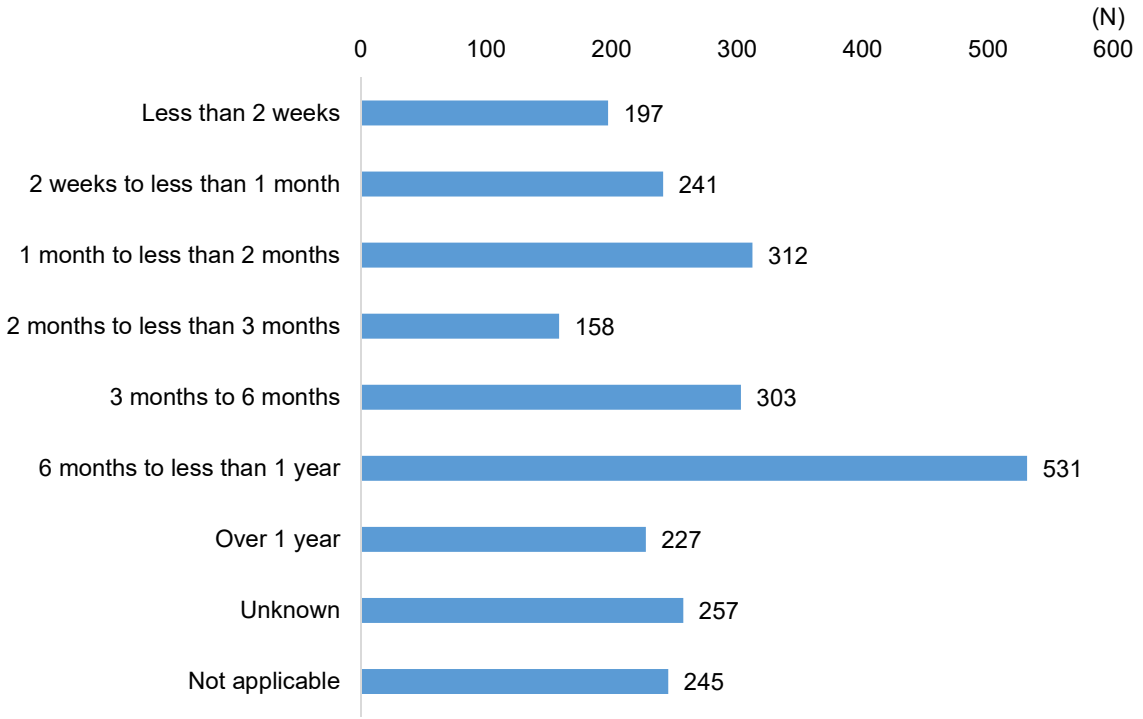


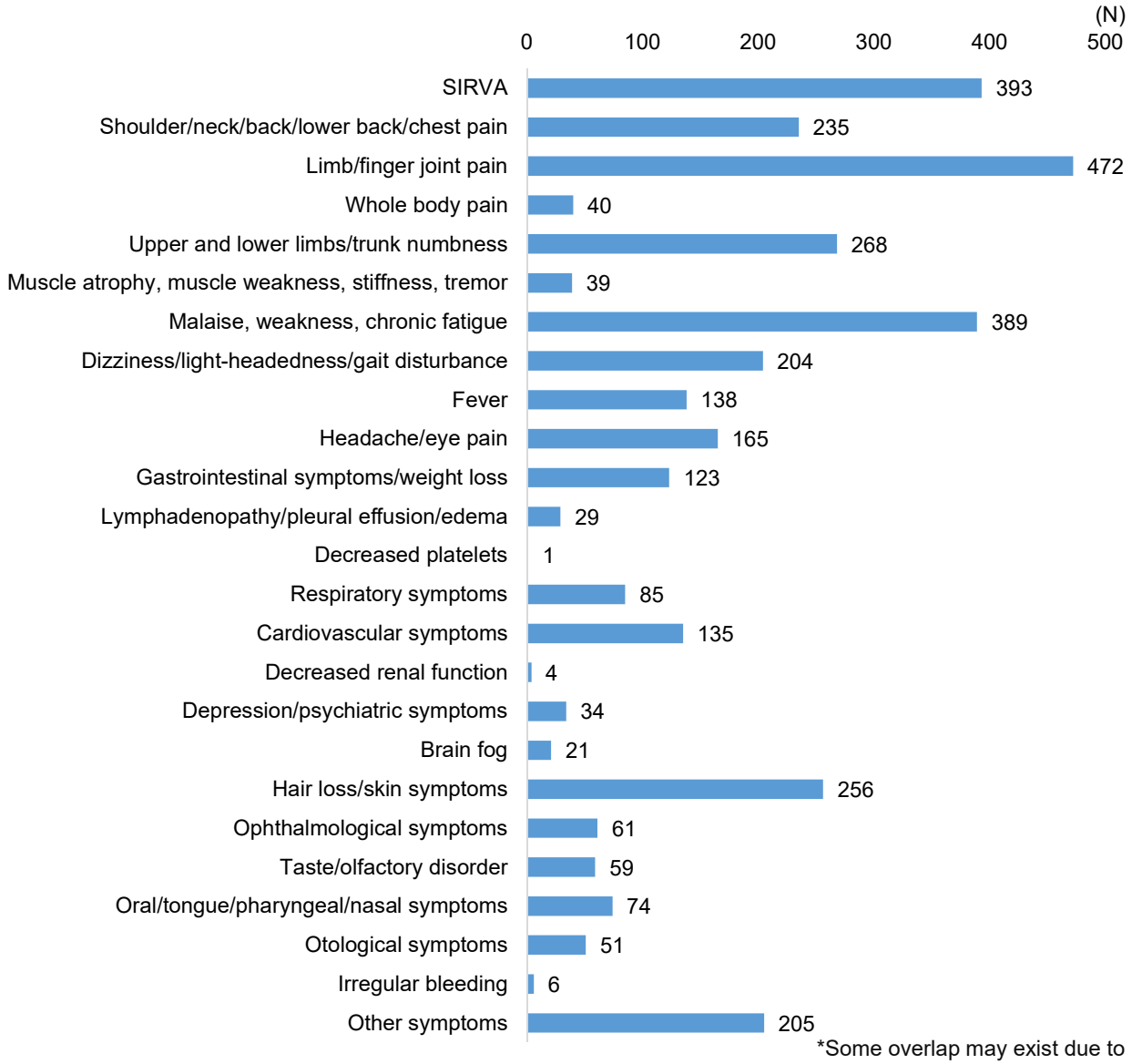
Figure 6: Time of consultation after vaccination (N= 2,471)

(7) Most bothersome symptoms

The most bothersome symptoms were 472 cases of limb/finger joint pain, 393 cases of SIRVA*, 389 cases of malaise/weakness/chronic fatigue, 268 cases of numbness in the upper and lower extremities/trunk, and 235 cases of shoulder/neck/back/lower back/chest pain, in that order.

Broken down by age group, the following symptoms were common for each age group: headache, eye pain, malaise, weakness, and chronic fatigue for those under 20 years of age; fatigue, weakness, and chronic fatigue for those in their 20s; fatigue, weakness, and chronic fatigue for those in their 30s; limb/finger joint pain for those in their 40s; and limb/finger joint pain and SIRVA for those in their 50s. (Figure 7)

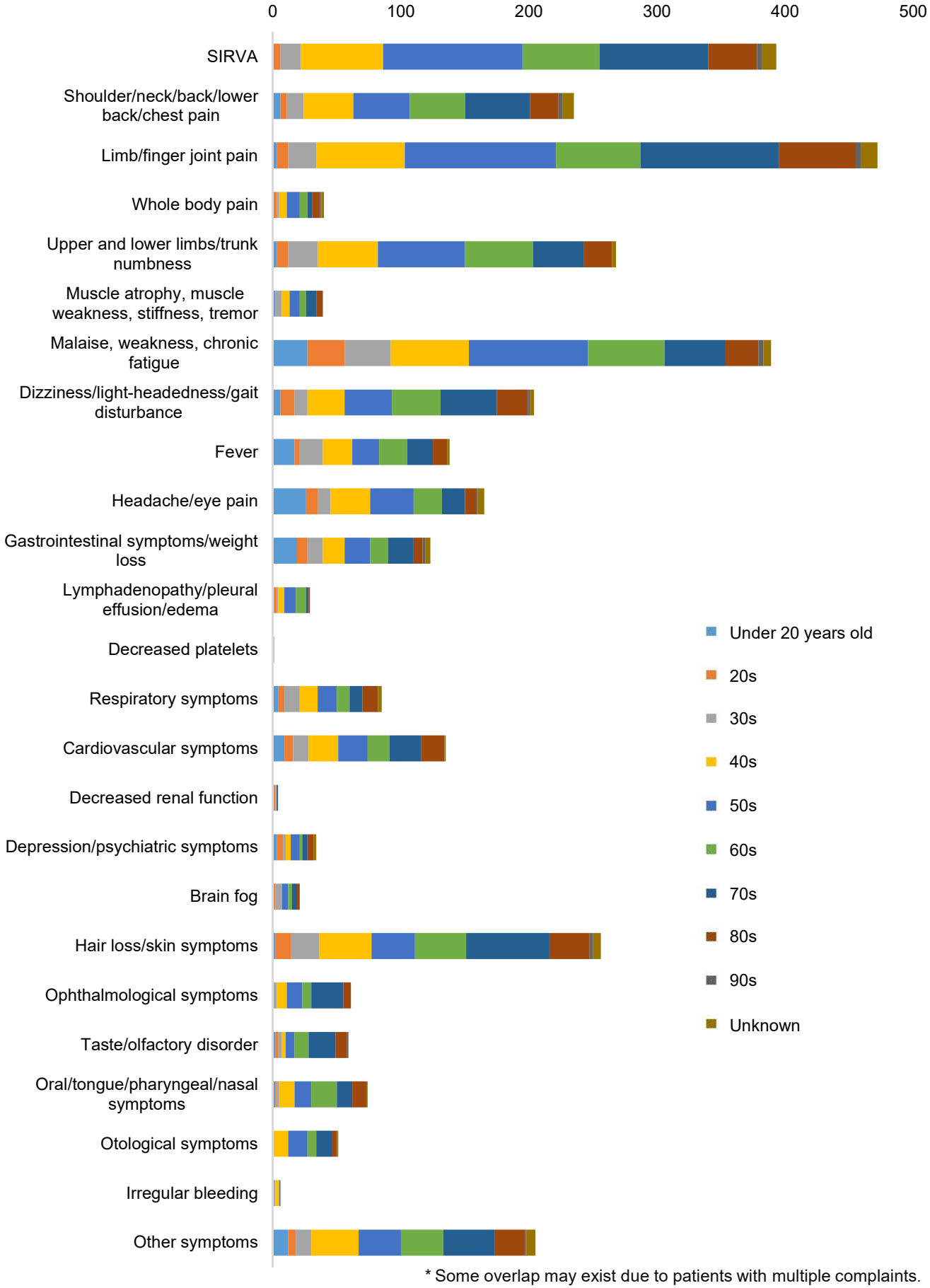
* Abbreviation for Shoulder Injury Related Vaccine Administration Translated as vaccination-related shoulder joint disorder, acute inflammation of the shoulder that occurs after vaccination (shoulder periarthritis, bursitis, rotator cuff inflammation, etc.), resulting in pain and restricted range of motion in the shoulder



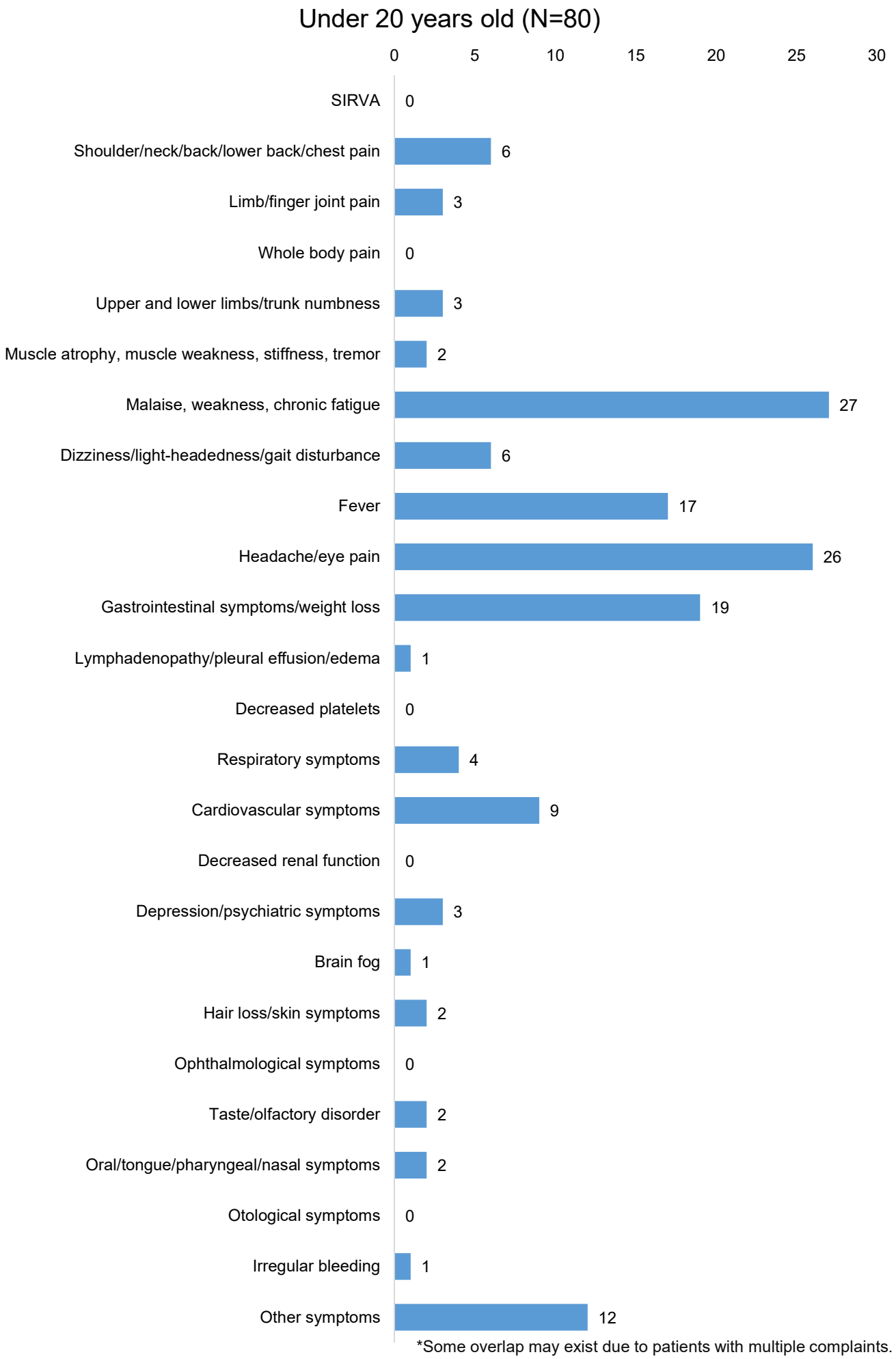
*Some overlap may exist due to patients with multiple complaints.

Figure 7 Most troublesome symptoms

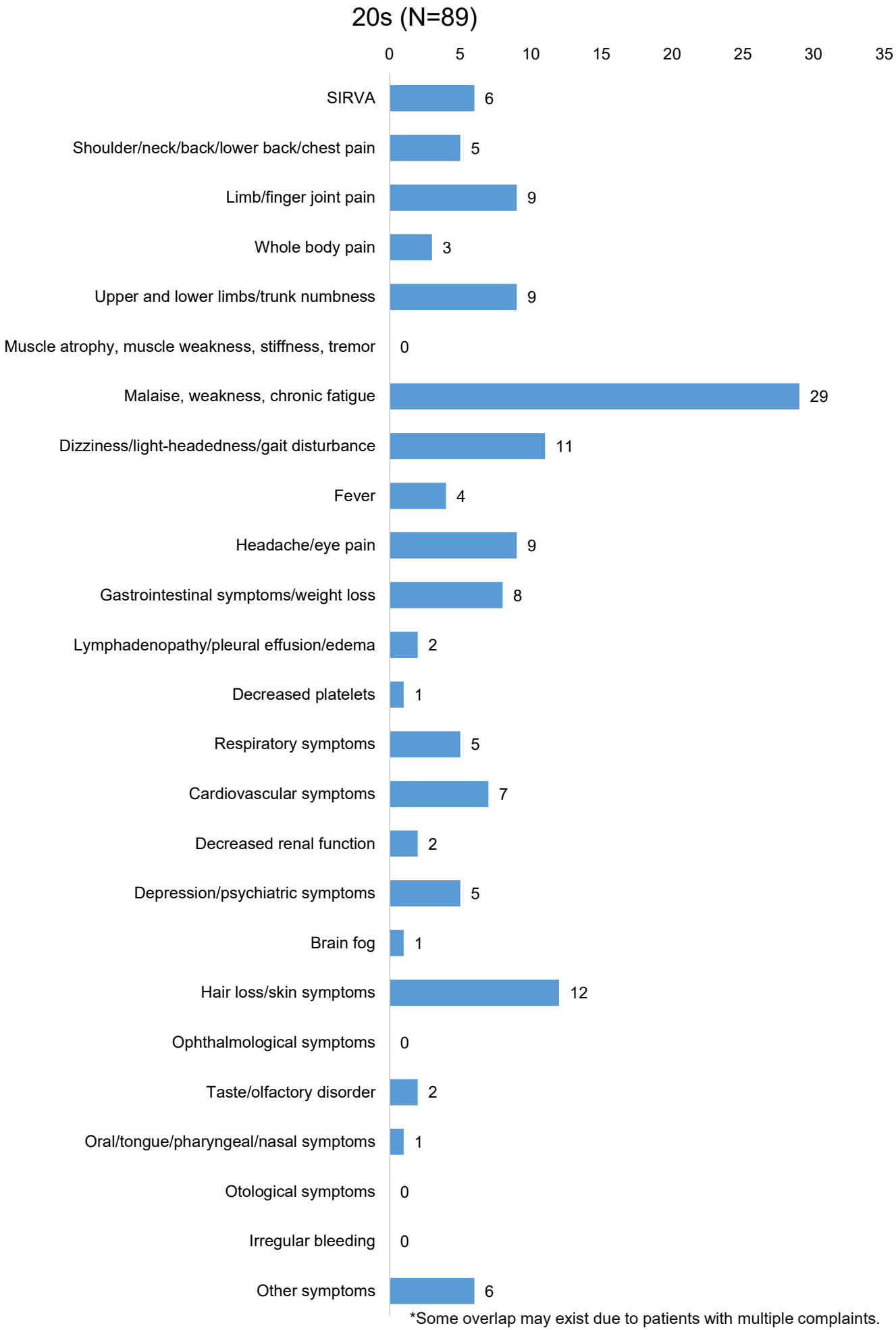
[Reference] Symptoms by age group (Results from March 25, 2022 to October 1, 2023)



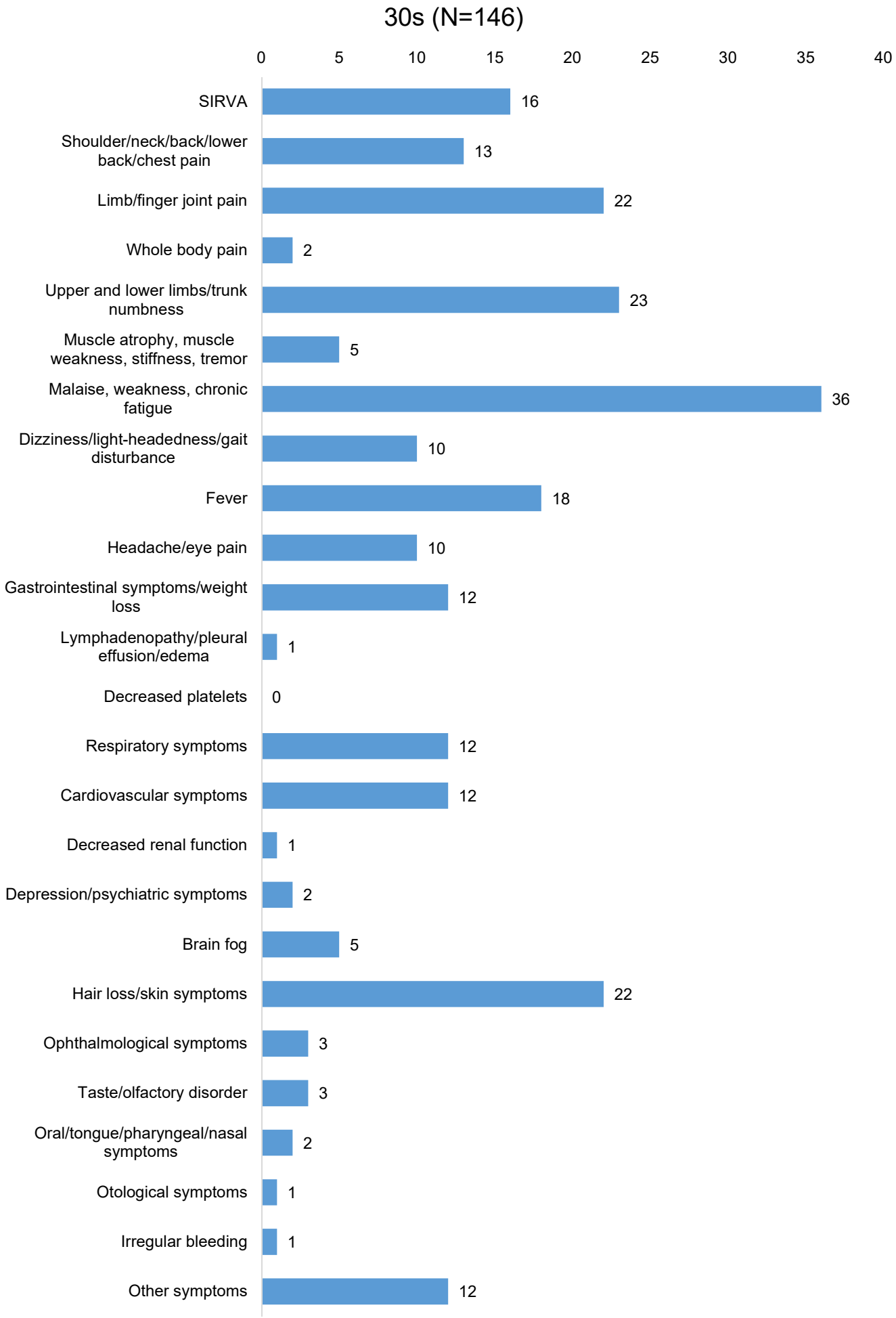
* Some overlap may exist due to patients with multiple complaints.



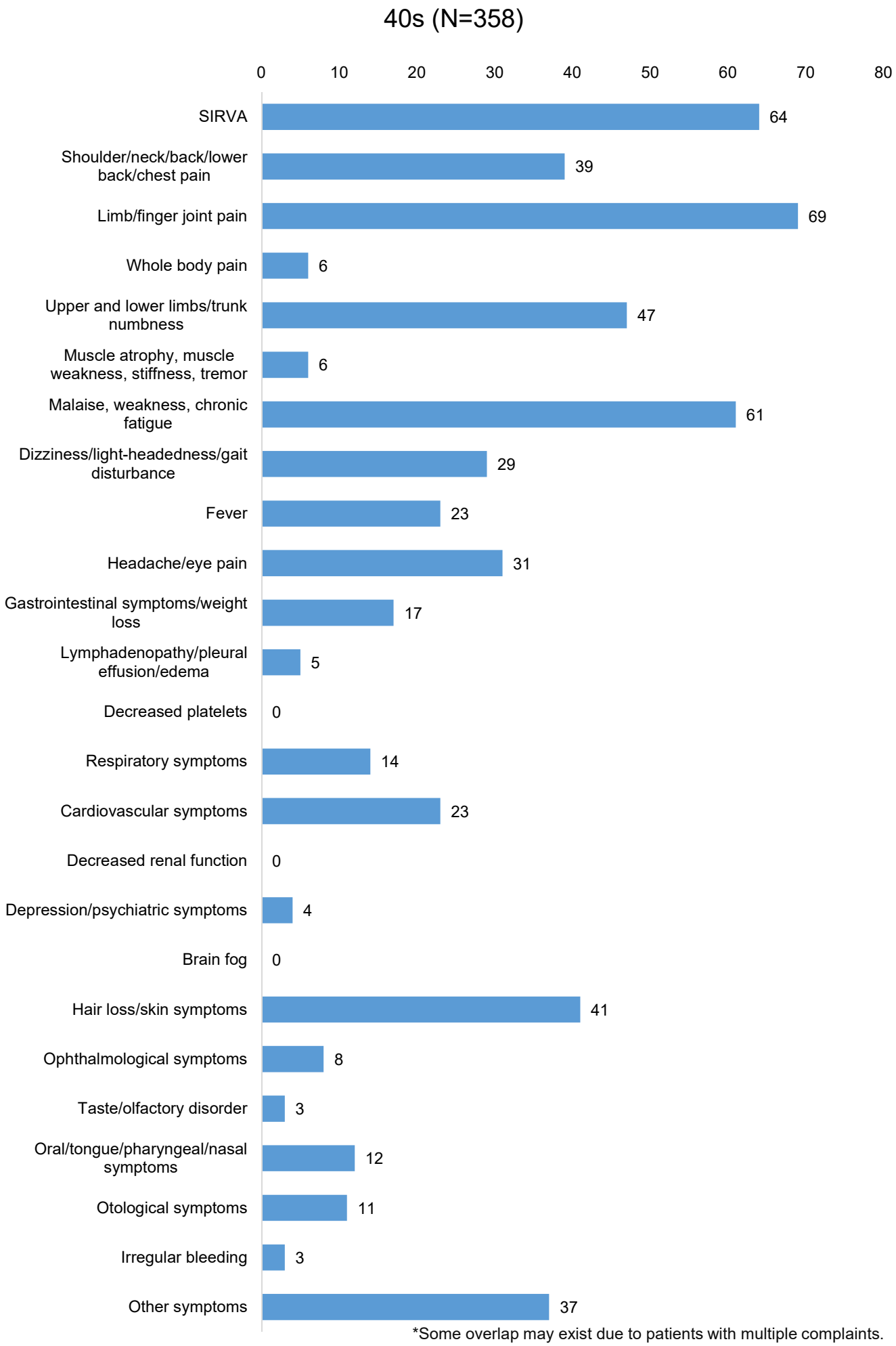
*Some overlap may exist due to patients with multiple complaints.



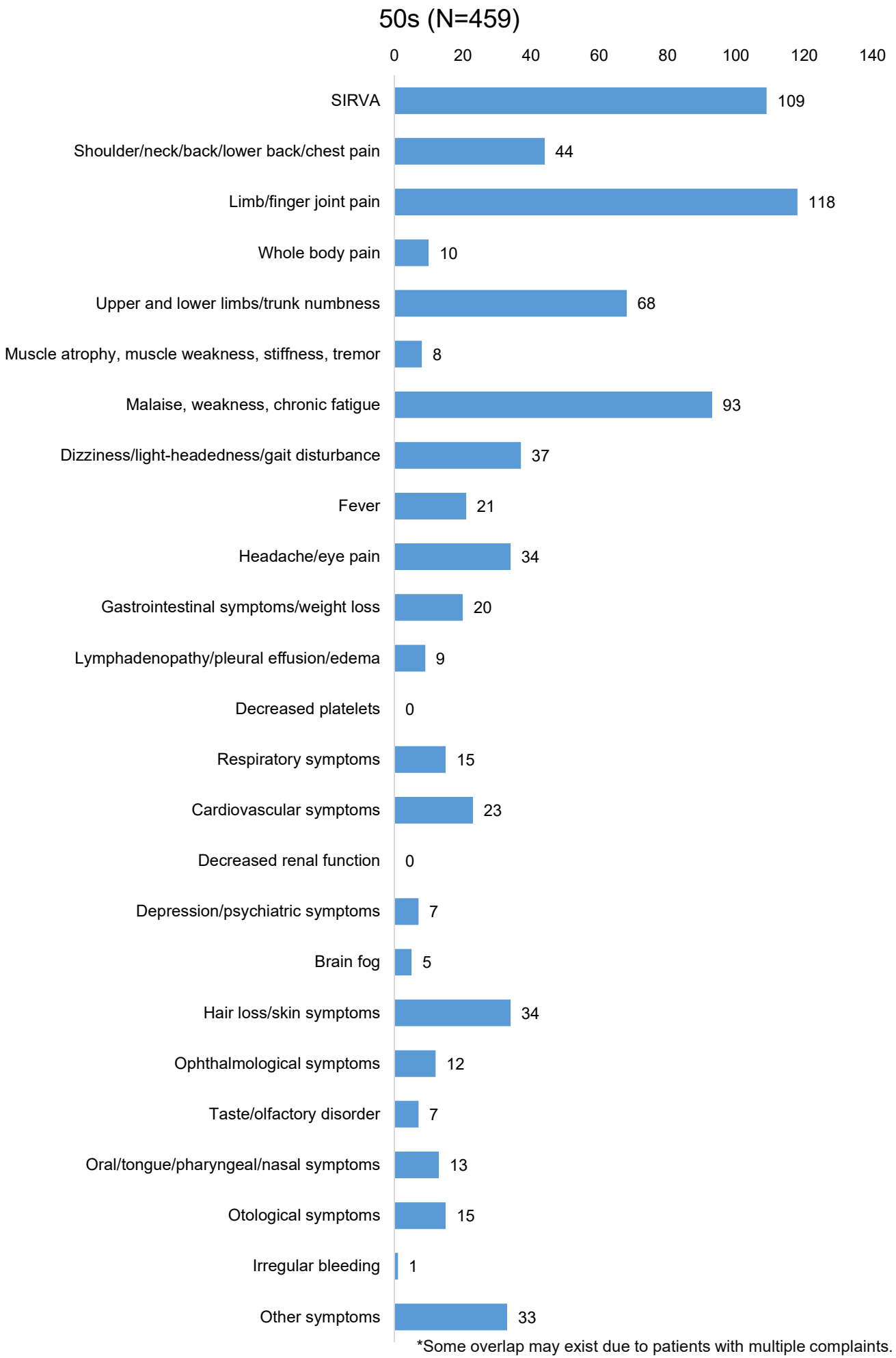
*Some overlap may exist due to patients with multiple complaints.



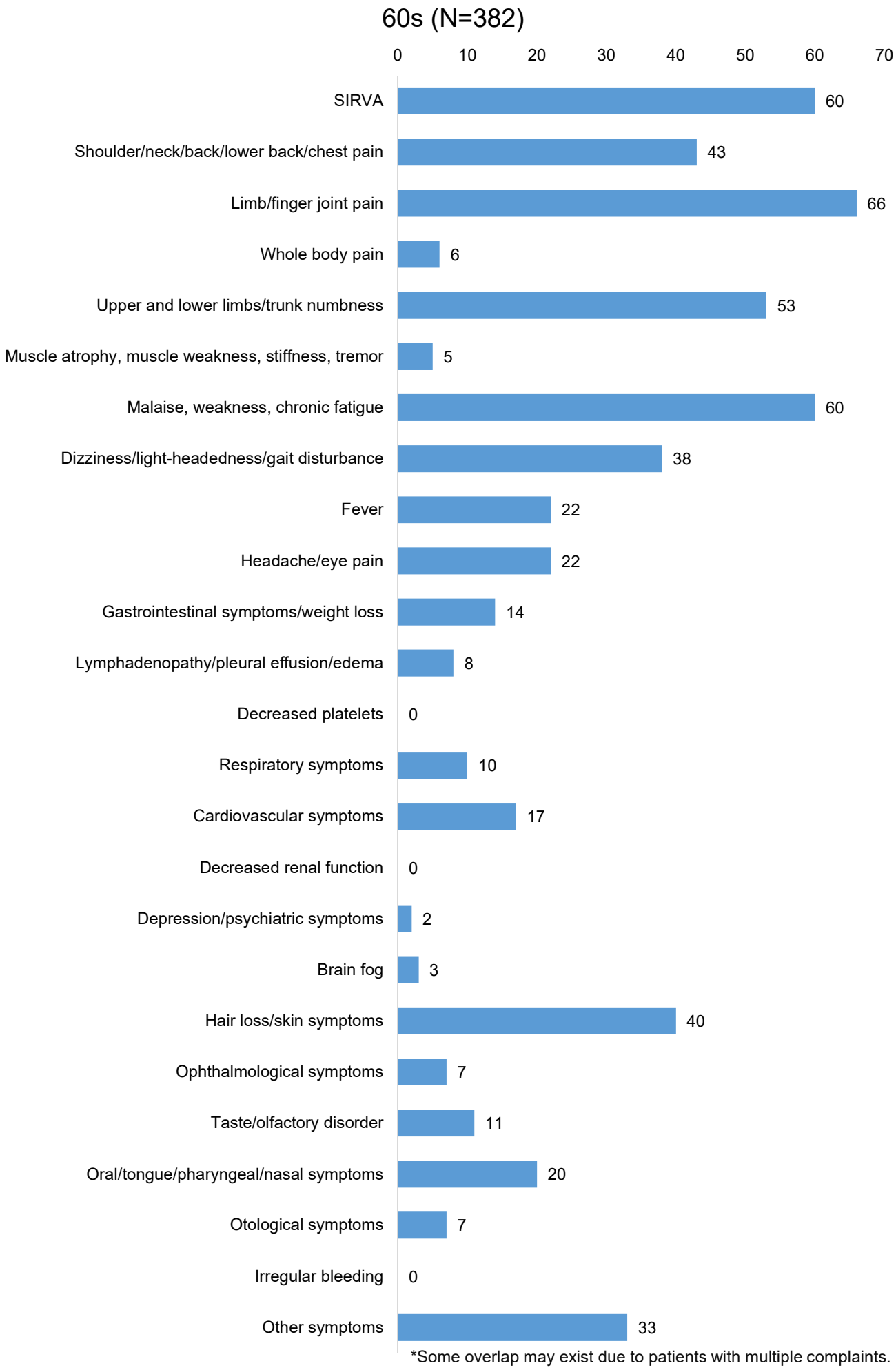
*Some overlap may exist due to patients with multiple complaints.



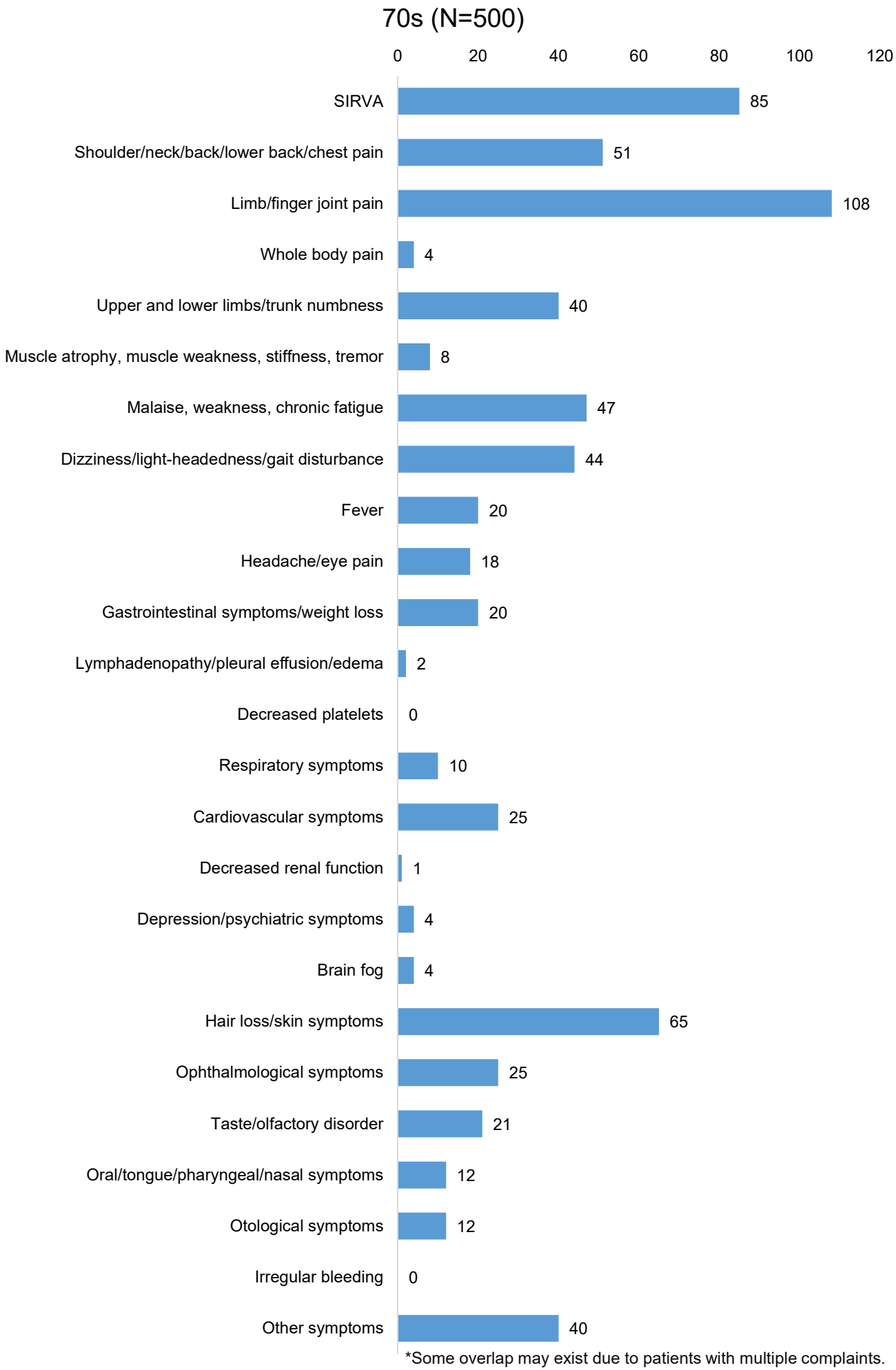
*Some overlap may exist due to patients with multiple complaints.



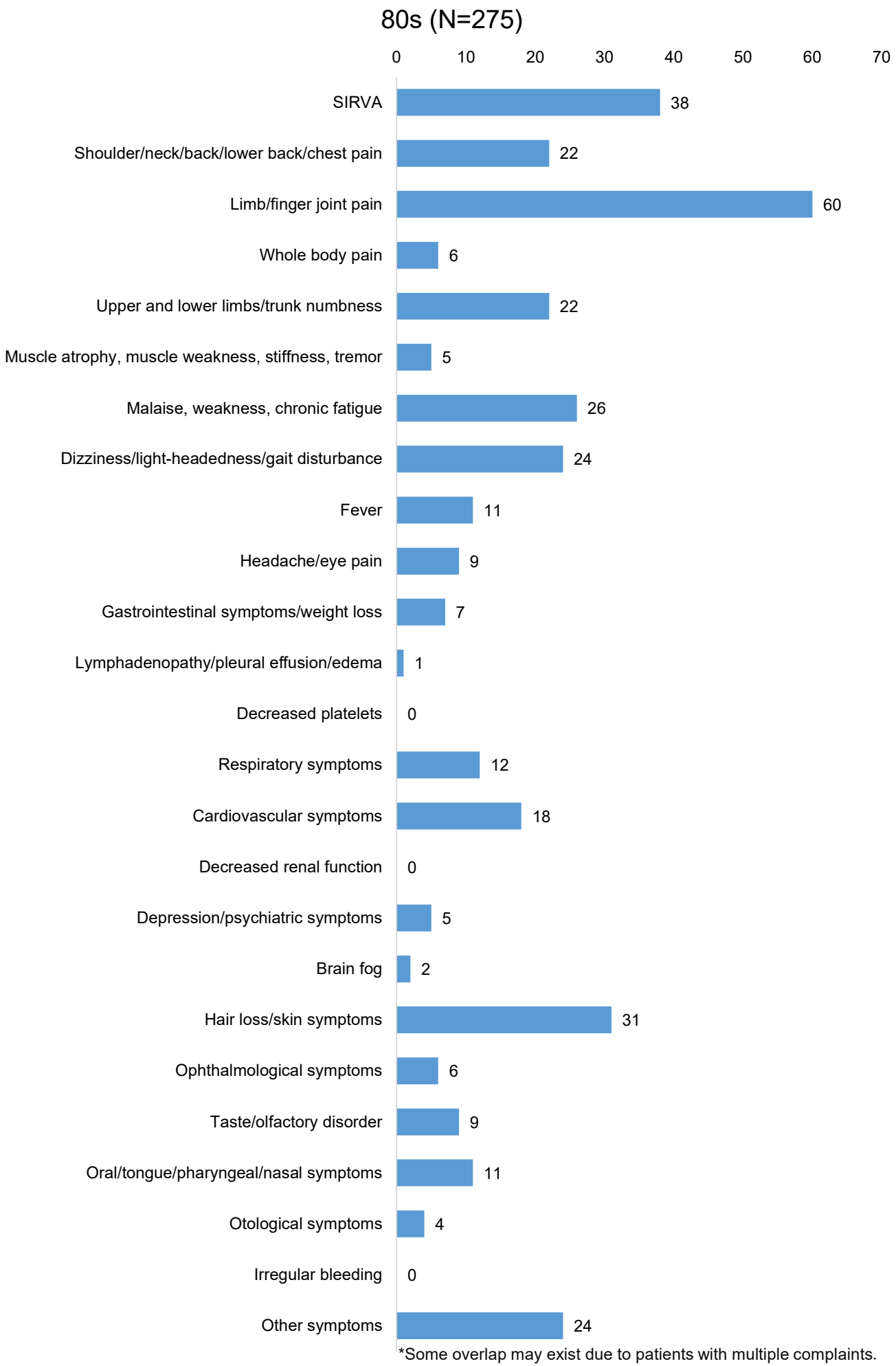
*Some overlap may exist due to patients with multiple complaints.



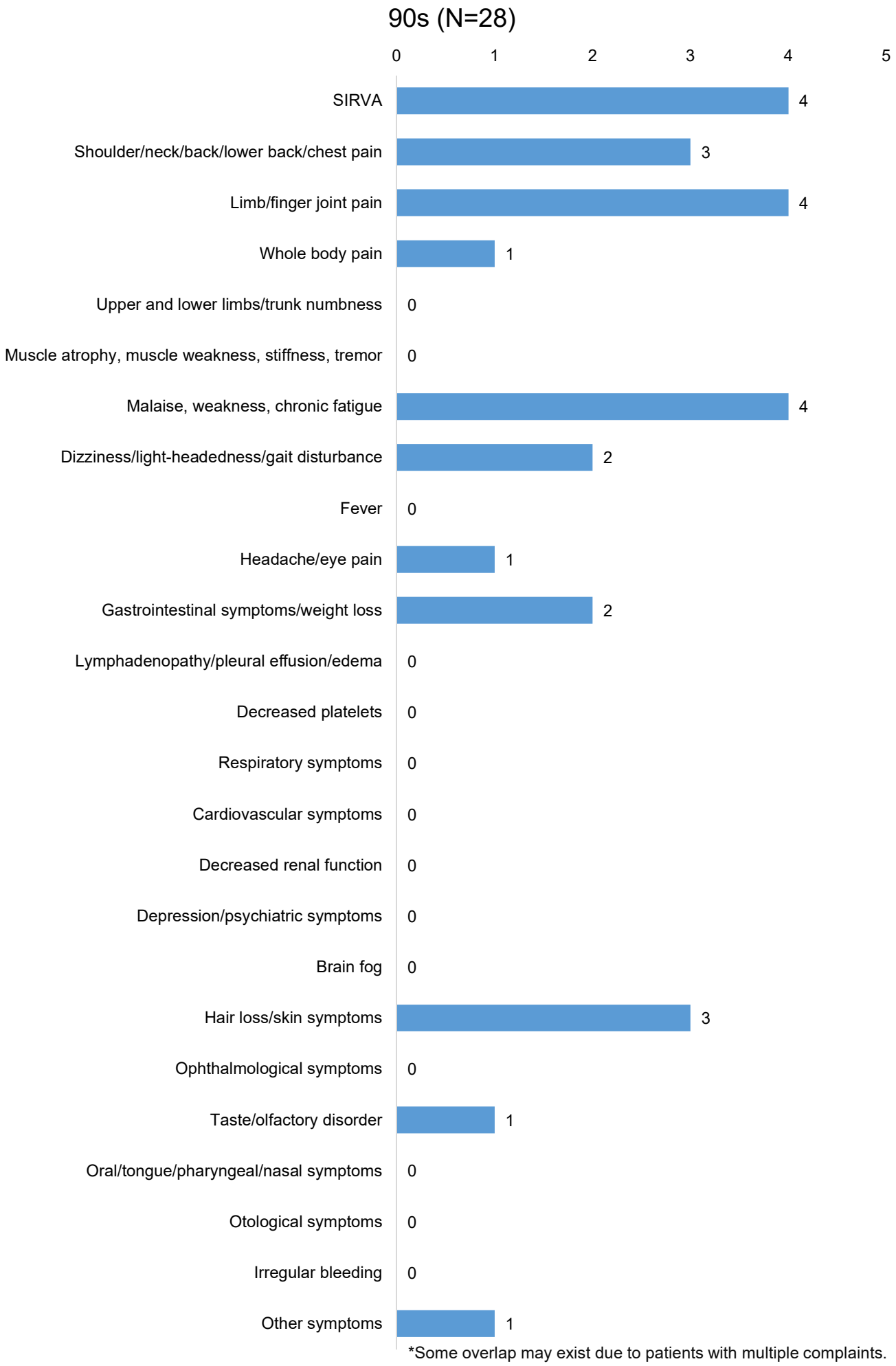
*Some overlap may exist due to patients with multiple complaints.



*Some overlap may exist due to patients with multiple complaints.



*Some overlap may exist due to patients with multiple complaints.



*Some overlap may exist due to patients with multiple complaints.

(8) Appearance of consultation desk

Case Report Form

Name of medical facility _____

(1)	Age	years old
	Gender	☐ Male ☐ Female ☐ Other
(2)	Date of onset	Month Day Year
	Initial visit	Month Day Year (Note) The first day of consultation with suspected adverse events
(3)	Major complaint (Symptoms following vaccination)	☐ Cough ☐ Dyspnoea ☐ Wheezing ☐ Chest pain ☐ Palpitations ☐ Joint pain ☐ Muscle pain ☐ Headache ☐ Nausea ☐ Malaise ☐ Dizziness ☐ Weakness ☐ Thirst ☐ Impaired appetite ☐ Diarrhea ☐ Abdominal pain ☐ Taste disorder ☐ Olfactory disorder ☐ Strange sensation of pharynx ☐ Dysphagia ☐ Numbness ☐ Stiffness in hands and fingers ☐ Muscle weakness ☐ Auditory disorder ☐ Memory decline ☐ Decreased concentration ☐ Sleep disturbance ☐ Depression ☐ Hair loss ☐ Skin rash ☐ Itching ☐ Others ( )
(4)	History of vaccination Date of vaccination	☐ 1st dose Date of vaccination ( ) Manufacturer (Pfizer, Moderna, unknown, other [ ]) Type (original [monovalent], BA.1/BA.4-5 [bivalent], XBB.1.5 [monovalent], unknown) ☐ 2nd dose Date of vaccination ( ) Manufacturer (Pfizer, Moderna, unknown, other [ ]) Type (original [monovalent], BA.1/BA.4-5 [bivalent], XBB.1.5 [monovalent], unknown) ☐ 3rd dose Date of vaccination ( ) Manufacturer (Pfizer, Moderna, unknown, other [ ]) Type (original [monovalent], BA.1/BA.4-5 [bivalent], XBB.1.5 [monovalent], unknown) ☐ 4th dose Date of vaccination ( ) Manufacturer (Pfizer, Moderna, unknown, other [ ]) Type (original [monovalent], BA.1/BA.4-5 [bivalent], XBB.1.5 [monovalent], unknown) ☐ 5th dose Date of vaccination ( ) Manufacturer (Pfizer, Moderna, unknown, other [ ]) Type (original [monovalent], BA.1/BA.4-5 [bivalent], XBB.1.5 [monovalent], unknown) ☐ 6th dose Date of vaccination ( ) Manufacturer (Pfizer, Moderna, unknown, other [ ]) Type (original [monovalent], BA.1/BA.4-5 [bivalent], XBB.1.5 [monovalent], unknown) ☐ 7th dose Date of vaccination ( ) Manufacturer (Pfizer, Moderna, unknown, other [ ]) Type (original [monovalent], BA.1/BA.4-5 [bivalent], XBB.1.5 [monovalent], unknown) ☐ Unknown

(5)	Medical history Underlying disease	
(6)	Regular medicine	☐ Yes (Drug name:) ☐ None ☐ Unknown
(7)	Family's disease history	☐ Yes ( ) ☐ None ☐ Unknown
(8)	Life history	☐ Yes ( ) ☐ None ☐ Unknown

(9)	Physical findings	
(10)	Tests that were performed	☐ Blood test ☐ Imaging ☐ Simple X-ray (site:) ☐ CT (site:) ☐ MRI (site:) ☐ Other imaging ( ) ☐ Physiological test ☐ Electrocardiogram ☐ Pulmonary function test ☐ Electroencephalogram ☐ Echo (site:) ☐ Other physiological tests ( ) ☐ Other tests
(11)	Treatment policy	☐ Drug therapy (drug name:) ☐ Administration of ivermectin (with / without) ☐ Non-drug therapy ( ) ☐ Referral to other hospitals only
(12)	Clinical courses etc.	**Please check one item that applies to the patient's current condition.** ☐ Relieved ☐ Recovering trend ☐ Unchanged ☐ Worsened Continued on next page

(12) Clinical courses etc.	**Please check one item that applies to the patient's current condition.** ☐ End of treatment ☐ Currently attending hospital ☐ Transfer ☐ Referred to specialized medical institutions (11 medical institutions in the prefecture) Name of medical facility ( ) ☐ Referred to other medical facilities (excluding specialized medical institutions) Name of medical facility ( ) ☐ Interrupted **Please describe the patient's progress in as much detail as possible.** (especially changes due to treatment, test results, etc.)
(13) Remarks	

Follow-up Survey Form

Name of medical facility _____

*This is a follow-up survey of patients provided in the 2nd report of summary of case reporting.

(1)	Age	years old
	Gender	☐ Male ☐ Female ☐ Other
(2)	Current major symptoms	☐ Cough ☐ Dyspnoea ☐ Wheezing ☐ Chest pain ☐ Palpitations ☐ Joint pain ☐ Muscle pain ☐ Headache ☐ Nausea ☐ Malaise ☐ Dizziness ☐ Weakness ☐ Thirst ☐ Impaired appetite ☐ Diarrhea ☐ Abdominal pain ☐ Taste disorder ☐ Olfactory disorder ☐ Strange sensation of pharynx ☐ Dysphagia ☐ Numbness ☐ Stiffness in hands and fingers ☐ Muscle weakness ☐ Auditory disorder ☐ Memory decline ☐ Decreased concentration ☐ Sleep disturbance ☐ Depression ☐ Hair loss ☐ Skin rash ☐ Itching ☐ Others ( )
(3)	Vaccination history since the last survey	☐ Not vaccinated since the last survey ☐ Unknown ☐ Vaccinated since the last survey ☐ No. of doses Date of vaccination ( ) Manufacturer (Pfizer, Moderna, unknown, other [ ]) Type (original [monovalent], BA.1/BA.4-5 [bivalent], XBB.1.5 [monovalent], unknown) ☐ No. of doses Date of vaccination ( ) Manufacturer (Pfizer, Moderna, unknown, other [ ]) Type (original [monovalent], BA.1/BA.4-5 [bivalent], XBB.1.5 [monovalent], unknown) *If you have any additional information, please enter it in the (6) Remarks section.
(4)	Treatment policy	☐ Drug therapy (drug name:) ☐ Administration of ivermectin (with/without) ☐ Non-drug therapy ( ) ☐ Referral to other hospitals only

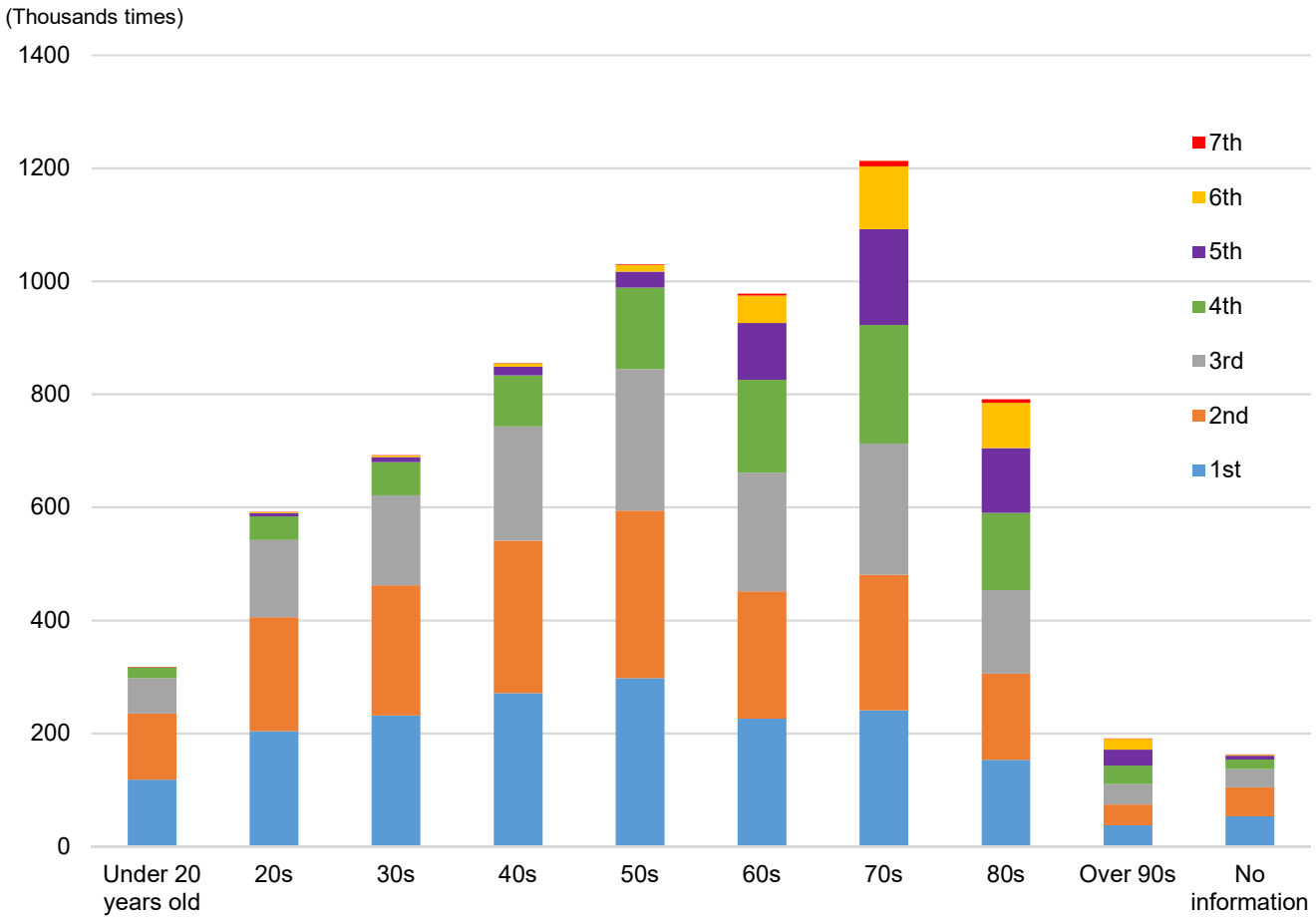
Enter by city

		Please check one item that applies to the patient's current condition. ☐ End of treatment ☐ Currently attending hospital ☐ Transfer ☐ Referred to specialized medical institutions (11 medical institutions in the prefecture) Name of medical facility ( ) ☐ Referred to other medical facilities (excluding specialized medical institutions) Name of medical facility ( ) ☐ Interrupted
(5)	Clinical courses etc.	**Please check one item that applies to the patient's current condition.** ☐ Relieved ☐ Recovering trend ☐ Unchanged ☐ Worsened **Please provide details about the patient's clinical courses after the last questionnaire submission.** (Please feel free to omit the parts completed in the last questionnaire).
(6)	Remarks	

[Document 3] **Vaccination status in Nagoya City**

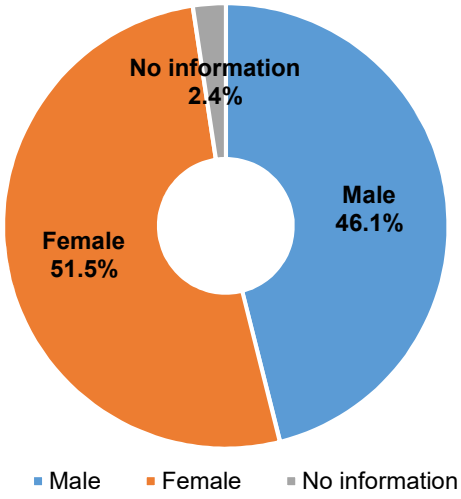
(1) Total number of vaccine doses by age group (as of September 30, 2023)

Total 6,819,841 times



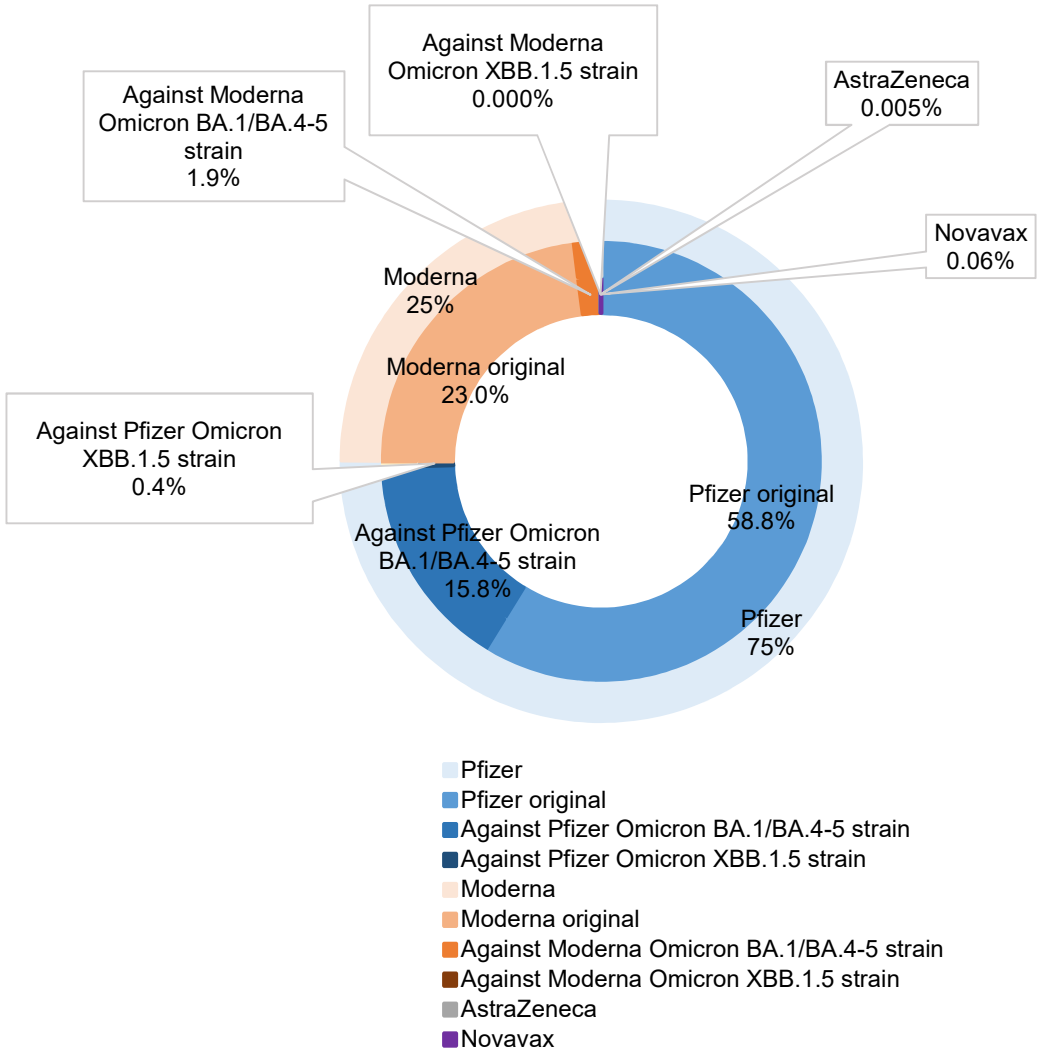
	1st	2nd	3rd	4th	5th	6th	7th	Total	Ratio
Under 20 years old	118,151	116,939	62,496	19,152	272	16	2	317,028	4.6%
20s	203,674	202,012	136,145	41,879	5,735	1,569	47	591,061	8.7%
30s	231,688	230,152	159,454	58,434	8,951	3,050	150	691,879	10.1%
40s	271,148	269,998	201,877	90,240	15,360	6,049	356	855,028	12.5%
50s	297,507	296,664	250,242	144,178	28,517	11,984	725	1,029,817	15.1%
60s	225,834	225,392	209,789	164,622	100,690	48,097	3,644	978,068	14.3%
70s	240,410	239,926	232,182	209,968	169,345	111,744	9,225	1,212,800	17.8%
80s	152,833	152,437	148,078	136,690	114,744	80,158	6,303	791,243	11.6%
Over 90s	37,084	36,934	35,890	33,222	27,886	19,247	844	191,107	2.8%
No information	53,074	51,300	32,029	17,143	7,090	1,154	20	161,810	2.4%
Total	1,831,403	1,821,754	1,468,182	915,528	478,590	283,068	21,316	6,819,841	100.0%

(2) Male to female ratio (as of September 30, 2023)



Male	3,142,979
Female	3,515,052
No information	161,810
Total	6,819,841

(3) Types of vaccines used (as of September 30, 2023)



Types of vaccines	Total no. of vaccine doses	Ratio
Pfizer original	4,009,963	58.8%
Against Pfizer Omicron BA.1/BA.4-5 strain	1,077,470	15.8%
Against Pfizer Omicron XBB.1.5 strain	28,470	0.4%
Moderna original	1,568,874	23.0%
Against Moderna Omicron BA.1/BA.4-5 strain	130,535	1.9%
Against Moderna Omicron XBB.1.5 strain	4	0.000%
AstraZeneca	355	0.005%
Novavax	4,170	0.06%
Total	6,819,841	100%