CLALLAM COUNTY BOARD OF HEALTH

AGENDA of October 21, 2025 @ 1:30 – 3:30 pm
Clallam County Courthouse
Board of Commissioners Meeting Room 160
223 E. 4th Street
Port Angeles, WA 98362

Board of Health meeting will also be available virtually at:

If you would like to participate in the meeting via Zoom audio only, call 253-215-8782 and join with Meeting ID: 935 7343 5754 and Passcode: 095863

If you would like to participate in the meeting via Zoom video conference, visit https://zoom.us/j/93573435754 join with Meeting ID: 935 7343 5754 and Passcode: 095863

This meeting can be viewed on a live stream at this link: https://clallamcountywa.gov/meetings

Public comment and questions can be directed to the Clerk of the Board at 360-417-2276 or nan.furford@clallamcountywa.gov

- Call to Order
- Roll Call
- Request for Modifications/Approval of Agenda
- Approval of Draft Meeting Minutes for September 16, 2025
- Action Items: None
- Public Comment for Agenda Items – *Please limit comments to three minutes*
- Health Officer: Infectious Disease Update
- Old Business and Information Items:
- Discussion Items:

  1. Board of Health – Term Expirations

- Board of Health Presentations:

  1. Olympic Region Clean Air Agency (ORCAA) – Jeff Johnston
  2. Opioid Settlement Funding For Harm Reduction Health Center - Staff

- Board of Health Public Hearings:
- Environmental Health Director
- HHS Director

- Future meeting agenda items:

    1. Vaccination Rates
    2. Air Quality and Noise Ordinance
    3. Climate Change
    4. Update on Behavioral Health Organization (BHO)
    5. Olympic Peninsula Healthy Communities Coalition

- Public Comment – *Please limit comments to three minutes*

- Adjournment

NEXT MEETING – December 16, 2025

INSTRUCTIONS FOR SPEAKING AT A BOARD OF HEALTH MEETING:

- Members of the public wishing to address the Board on general items may do so during the designated times on the agenda.
- Members of the public wishing to comment at the public hearing are asked to sign in on the sheet provided giving their name and place of residence.
- The Chair may limit the comment period to 3 minutes for each speaker subject to Board concurrence.
- Speakers, generally, will be heard in the order they signed up. All comments must be made from the speaker's rostrum and any individual making comments shall first state their name and address for the official record.
- General comments, applause, booing from members of the audience are inappropriate and may result in removal.

These guidelines are intended to promote an orderly system for conducting a public meeting/hearing so that each person has an opportunity to be heard and to ensure that exercising their right of free speech embarrasses no one.

Note: Written testimony presented by members of the public during the Board meeting is considered a public document and must be submitted to the Clerk of the Board. Copies of public documents from Board meetings are available by contacting the Public Records Department.

Members:
Chair, Mike French; Vice-Chair, Shahida Shahrir; Dr. Gerald Stephanz; Tia Skerbeck; Paul Cunningham; Jeff Gingell; Mark Ozias and Randy Johnson
Health and Human Services Staff:
Dr. Allison Berry, Health Official; Kevin LoPiccolo, Director; Jenny Oppelt, Deputy Director; Jennifer Garcelon, Environmental Health Director; Nan Furford, Clerk of the Board

DRAFT MEETING MINUTES SEPTEMBER 16, 2025

CLALLAM COUNTY BOARD OF HEALTH

AGENDA of September 16, 2025 @ 1:30 – 3:30 pm
Clallam County Courthouse
Board of Commissioners Meeting Room 160
223 E. 4th Street
Port Angeles, WA 98362
Meeting was held via Zoom (Video conference)

REGULAR MEETING OF THE CLALLAM COUNTY BOARD OF HEALTH

Call to Order: The meeting was called to order at 1:33 p.m.

Roll Call: Members present were Chair, Mike French; Commissioner Mark Ozias; Vice-Chair, Shahida Shahrir; Community Stakeholder, Dr. Gerald Stephanz; Jamestown S'Klallam Tribe, Paul Cunningham; Lower Elwha Klallam Tribe, Tia Skerbeck; Health Officer, Dr. Allison Berry; HHS Director, Kevin LoPiccolo; HHS Deputy Director, Jennifer Oppelt; Environmental Health Director, Jennifer Garcelon

Members absent: Commissioner Randy Johnson; City Council Member Representative, Jeff Gingell

Request for Modifications/Approval of Agenda
Motion by Commissioner Ozias, seconded by Gerald Stephanz, to approve the agenda. Motion carried unanimously.

ACTION TAKEN: The Board had unanimous consent to approve the agenda.

Approval of Draft Meeting Minutes for August 19, 2025
Motion by Commissioner Ozias, seconded by Shahida Shahrir, to approve the minutes. Motion carried unanimously.

Public Comment:
K Zelenka submitted an email (see attached handout).

Ed Bowen provided comments regarding the new COVID-19 vaccine and shared FDA information with the Board. He also discussed local air quality and smoke concerns.

Health Officer – Infectious Disease Update

Dr. Berry reported that COVID-19 emergency visits are increasing locally, reflecting an end of summer surge transitioning into the fall. Transmission has been higher among adults but is now increasing among school-aged children. Updated vaccines are available and show good protection against current strains. Discussion followed.

Old Business and Information Items:
None.

Discussion Items:
None.

Board of Health Presentations:

1. **Opioid Gap Report Request - Staff.**
   HHS Deputy Director Jennifer Oppelt and Moni Madjdi presented an overview of the proposed *Opioid Gap Report*.

   The Board of Health approved recommending allocation of $25,000 from the Opioid Settlement Funds to support development of the report. The recommendation will be forwarded to the Board of County Commissioners for final approval.

Board of Health Public Hearings:
None.

Environmental Health Director - Jennifer Garcelon
Jennifer Garcelon reported that it is *Septic Smart Week* and encouraged residents on septic systems to ensure inspections are current. Environmental Health staff will participate in *Riverfest* on Friday. Food Program invoices were mailed last month, with about half returned to date. *Crab Fest* will be the final major food event of the year. The Onsite team continues training, and information about current smoke and air quality is posted on the Clallam County Public Health Facebook page.

HHS Director – Kevin LoPiccolo
Director Kevin LoPiccolo reported that the department's budget meeting with the Board of County Commissioners is scheduled for October 9, 2025, and the department anticipates having a new Nurse Manager hired by that time. Discussion followed.

Public Comment
None.

Adjournment
The meeting was adjourned at 2:20 p.m.

Next Meeting – October 21, 2025

PASSED AND ADOPTED this _____ day of _____, 2025

CLALLAM COUNTY BOARD OF HEALTH

_____
Mike French, Chair

_____
Allison Berry, MD, MPH, Health Officer

ATTEST:

_____
Nan Furford, Clerk of the Board

EMAIL FROM
ED BOWEN

Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please call 800-835-4709 or 240-402-8010, extension 1. CBER Consumer Affairs Branch or send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use MNEXSPIKE safely and effectively. See full prescribing information for MNEXSPIKE.

MNEXSPIKE (COVID-19 Vaccine, mRNA) injectable suspension, for intramuscular use
2025-2026 Formula
Initial U.S. Approval: 2025

----------RECENT MAJOR CHANGES----------

Indications and Usage (1)	8/2025
Dosage and Administration, Dosing and Schedule (2.3)	8/2025
Warnings and Precautions, Myocarditis and Pericarditis (5.2)	6/2025

----------INDICATIONS AND USAGE----------

MNEXSPIKE is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

MNEXSPIKE is approved for use in individuals who are:

- 65 years of age and older, or
- 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19. (1)

----------DOSAGE AND ADMINISTRATION----------

- For intramuscular use.
- Administer MNEXSPIKE as a single 0.2 mL dose at least 3 months after the last dose of COVID-19 vaccine. (2.3)

----------DOSAGE FORMS AND STRENGTHS----------

MNEXSPIKE is an injectable suspension.
A single dose is 0.2 mL. (3)

----------CONTRAINDICATIONS----------

Do not administer MNEXSPIKE to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of MNEXSPIKE or to individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of SPIKEVAX (COVID-19 Vaccine, mRNA) or any Moderna COVID-19 vaccine authorized for emergency use. (4)

----------WARNINGS AND PRECAUTIONS----------

Analyses of postmarketing data from use of authorized or approved mRNA COVID-19 vaccines have demonstrated increased risks of myocarditis and pericarditis, with onset of symptoms typically in the first week following vaccination. The observed risk has been highest in males 12 years through 24 years of age. (5.2)

----------ADVERSE REACTIONS----------

Most commonly reported adverse reactions following administration of MNEXSPIKE (≥10%):

- *Participants 12 years through 17 years of age*: pain at the injection site (up to 68.8%), headache (up to 54.5%), fatigue (up to 47.3%), myalgia (up to 39.2%), axillary swelling or tenderness (up to 34.6%), chills (up to 31.6%), arthralgia (up to 23.9%), and nausea/vomiting (up to 16.1%). (6)
- *Participants 18 years through 64 years of age*: pain at the injection site (up to 74.8%), fatigue (up to 54.3%), headache (up to 47.8%), myalgia (up to 41.6%), arthralgia (up to 32.4%), chills (up to 24.3%), axillary swelling or tenderness (up to 21.7%), and nausea/vomiting (up to 13.8%). (6)
- *Participants 65 years of age and older*: pain at the injection site (up to 54.6%), fatigue (up to 43.0%), headache (up to 33.1%), myalgia (up to 30.5%), arthralgia (up to 25.7%), chills (up to 16.5%), nausea/vomiting (up to 11.4%), and axillary swelling or tenderness (up to 10.7%). (6)

To report SUSPECTED ADVERSE REACTIONS, contact ModernaTX, Inc. at 1-866-663-3762 or VAERS at 1-800-822-7967 or https://vaers.hhs.gov.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 8/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

MNEXSPIKE is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

MNEXSPIKE is approved for use in individuals who are:

- 65 years of age and older, or
- 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

2 DOSAGE AND ADMINISTRATION

For intramuscular use.

2.1 Preparation for Administration

- Verify that the label on the prefilled syringe states 2025-2026 Formula.
- If prefilled syringes of MNEXSPIKE are frozen, thaw before use following the instructions below.

Table 1: Thawing Conditions and Times

	Thaw in Refrigerator 2°C to 8°C (36°F to 46°F)	**Thaw at Room Temperature 15°C to 25°C (59°F to 77°F)**
Carton of 10 syringes	Thaw for 2 hours and 40 minutes	Thaw for 1 hour and 20 minutes
Carton of 2 syringes	Thaw for 1 hour and 40 minutes	Thaw for 40 minutes
Carton of 1 syringe	Thaw for 1 hour and 40 minutes	Thaw for 40 minutes
One syringe (removed from carton)	Thaw for 1 hour and 40 minutes	Thaw for 40 minutes

- After thawing, do not refreeze.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
- MNEXSPIKE is a white to off-white suspension. It may contain white or translucent product-related particulates. Do not administer if vaccine is discolored or contains other particulate matter.
- **Do not shake.**
- With tip cap upright, remove tip cap by twisting counterclockwise until tip cap releases.

Remove tip cap in a slow, steady motion. Avoid pulling tip cap while twisting.
- Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe.
- Discard after single use.

2.2 Administration

Administer MNEXSPIKE intramuscularly.

2.3 Dosing and Schedule

Administer MNEXSPIKE as a single 0.2 mL dose.

For individuals previously vaccinated with any COVID-19 vaccine, administer the dose of MNEXSPIKE at least 3 months after the last dose of COVID-19 vaccine.

3 DOSAGE FORMS AND STRENGTHS

MNEXSPIKE is an injectable suspension.

A single dose is 0.2 mL.

4 CONTRAINDICATIONS

Do not administer MNEXSPIKE to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of MNEXSPIKE *[see Description (11)]* or to individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of SPIKEVAX (COVID-19 Vaccine, mRNA) or any Moderna COVID-19 vaccine authorized for emergency use.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of MNEXSPIKE.

5.2 Myocarditis and Pericarditis

Analyses of postmarketing data from use of authorized or approved mRNA COVID-19 vaccines have demonstrated increased risks of myocarditis and pericarditis, with onset of symptoms typically in the first week following vaccination. The observed risk has been highest in males 12 years through 24 years of age.

Based on analyses of commercial health insurance claims data from inpatient and outpatient settings, the estimated unadjusted incidence of myocarditis and/or pericarditis during the period

1 through 7 days following administration of the 2023-2024 Formula of mRNA COVID-19 vaccines was approximately 8 cases per million doses in individuals 6 months through 64 years of age and approximately 27 cases per million doses in males 12 years through 24 years of age.

Although some individuals with myocarditis and/or pericarditis following administration of mRNA COVID-19 vaccines have required intensive care support, available data suggest that individuals typically have resolution of symptoms within a few days with conservative management.

Follow-up information on cardiovascular outcomes in hospitalized patients who had been diagnosed with COVID-19 vaccine-associated myocarditis is available from a longitudinal retrospective observational study. Most of these patients had received a two-dose primary series of an mRNA COVID-19 vaccine prior to their diagnosis. In this study, at a median follow-up of approximately 5 months post-vaccination, persistence of abnormal cardiac magnetic resonance imaging (CMR) findings that are a marker for myocardial injury was common. The clinical and prognostic significance of these CMR findings is not known[1] *[see Adverse Reactions (6.2)]*.

Information is not yet available about potential long-term sequelae of myocarditis or pericarditis following administration of mRNA COVID-19 vaccines.

The Centers for Disease Control and Prevention (CDC) has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

5.3 Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

5.4 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished immune response to MNEXSPIKE *[see Use in Specific Populations (8.6)]*.

5.5 Limitations of Vaccine Effectiveness

MNEXSPIKE may not protect all vaccine recipients.

6 ADVERSE REACTIONS

Most commonly (≥10%) reported adverse reactions following administration of MNEXSPIKE:

- Participants 12 years through 17 years of age: pain at the injection site (up to 68.8%), headache (up to 54.5%), fatigue (up to 47.3%), myalgia (up to 39.2%), axillary swelling

or tenderness (up to 34.6%), chills (up to 31.6%), arthralgia (up to 23.9%), and nausea/vomiting (up to 16.1%).

- Participants 18 years through 64 years of age: pain at the injection site (up to 74.8%), fatigue (up to 54.3%), headache (up to 47.8%), myalgia (up to 41.6%), arthralgia (up to 32.4%), chills (up to 24.3%), axillary swelling or tenderness (up to 21.7%), and nausea/vomiting (up to 13.8%).

- Participants 65 years of age and older: pain at the injection site (up to 54.6%), fatigue (up to 43.0%), headache (up to 33.1%), myalgia (up to 30.5%), arthralgia (up to 25.7%), chills (16.5%), nausea/vomiting (up to 11.4%), and axillary swelling or tenderness (up to 10.7%).

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Individuals 12 Years of Age and Older

Single Dose (Bivalent Original and Omicron BA.4/BA.5) in Vaccine-Experienced

The safety of MNEXSPIKE was evaluated in a randomized, observer-blind, active-controlled clinical trial conducted in the United States, United Kingdom, and Canada involving 11,417 participants 12 years of age and older who received a single dose of MNEXSPIKE (n=5,706) or comparator vaccine (Moderna COVID-19 Vaccine, Bivalent [Original and Omicron BA.4/BA.5] not U.S. licensed, authorized for emergency use; n=5,711) (Study 1, NCT05815498). MNEXSPIKE administered in the study contained 5 mcg mRNA encoding the membrane-bound, linked N-terminal domain (NTD) and receptor-binding domain (RBD) of the Spike (S) glycoprotein from SARS-CoV-2 Wuhan-Hu 1 strain (Original) and 5 mcg mRNA encoding the membrane-bound, linked NTD and RBD of the S glycoprotein from SARS-CoV-2 Omicron variant lineages BA.4 and BA.5. The comparator vaccine administered in the study contained 25 mcg mRNA encoding the S glycoprotein from SARS-CoV-2 Wuhan-Hu 1 strain (Original) and 25 mcg mRNA encoding the S glycoprotein from SARS-CoV-2 Omicron variant lineages BA.4 and BA.5. The median duration of follow-up for safety was 8.8 months.

In Study 1, the median age of the population was 56 years (range 12 through 96 years); 8.7% of participants were 12 years through 17 years, 62.6% were 18 years through 64 years, and 28.7% were 65 years and older. Overall, 45.7% of the participants were male, 54.3% were female, 13.2% were Hispanic or Latino, 82.2% were White, 11.2% were Black or African American, 3.6% were Asian, 0.4% were American Indian or Alaska Native, 0.1% were Native Hawaiian or Pacific Islander, 0.4% were other races, and 1.5% were Multiracial. Overall, 64.3% of study participants reported at least one CDC-defined high-risk condition for severe COVID-19. Demographic characteristics were similar between participants who received MNEXSPIKE and those who received the comparator vaccine.

All participants in the study, except one participant in the MNEXSPIKE group, had previously received at least one dose of a COVID-19 vaccine prior to the study with a median interval of 9.8 months since the last dose. Overall, 74.3% of participants (MNEXSPIKE=4,211; comparator vaccine=4,270) had evidence of prior SARS-CoV-2 infection at baseline (immunologic or virologic evidence of prior SARS-CoV-2 infection [defined as positive RT-PCR test and/or positive Elecsys immunoassay result at Day 1]).

Solicited Adverse Reactions

Local and systemic adverse reactions and use of antipyretic medication were solicited in an electronic diary for 7 days following injection (i.e., day of vaccination and the next 6 days) among participants who received MNEXSPIKE (n=5,702) and participants who received the comparator vaccine (n=5,706). Events that persisted for more than 7 days were followed until resolution.

The reported number and percentage of solicited local and systemic adverse reactions for 12 years through 17 years are presented in Table 2 and Table 3, 18 years through 64 years are presented in Table 4 and Table 5, and 65 years and older are presented in Table 6 and Table 7, respectively.

Table 2: Number and Percentage of Participants with Solicited Local Adverse Reactions Starting Within 7 Days* After Injection in Participants 12 Years Through 17 Years (Solicited Safety Set)

Local Adverse Reactions[a]	**MNEXSPIKE[b]** N=497 n (%)	**Comparator Vaccine[c]** N=495 n (%)
Pain[d]	342 (68.8)	390 (78.8)
Pain, Grade 3[d]	10 (2.0)	19 (3.8)
Axillary swelling or tenderness[d]	172 (34.6)	134 (27.1)
Axillary swelling or tenderness, Grade 3[d]	6 (1.2)	2 (0.4)
Swelling (hardness) ≥25 mm[e]	18 (3.6)	25 (5.1)
Swelling (hardness) >100 mm, Grade 3[e]	4 (0.8)	2 (0.4)
Erythema (redness) ≥25 mm[e]	6 (1.2)	13 (2.6)

* 7 days included day of vaccination and the subsequent 6 days. Events were collected in the electronic diary (e-diary).
N=Number of participants in the Solicited Safety Set.

n=Number of participants with listed solicited adverse reactions.
[a] Absence of rows for Grade 3 or Grade 4 adverse reactions indicates no events were reported.
[b] A vaccine encoding the membrane-bound, linked NTD and RBD of the S glycoprotein from SARS-CoV-2 Original and Omicron variant lineages BA.4/BA.5
[c] Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)
[d] Pain and axillary swelling or tenderness grading scale: no interference with activity (Grade 1); some interference with activity (Grade 2); prevents daily activity (Grade 3).
[e] Swelling and erythema grading scale: 25-50 mm / 2.5-5 cm (Grade 1); 51-100 mm / 5.1-10 cm (Grade 2); >100 mm / >10 cm (Grade 3).

Table 3: Number and Percentage of Participants with Solicited Systemic Adverse Reactions Starting Within 7 Days* After Injection in Participants 12 Years Through 17 Years (Solicited Safety Set)

Systemic Adverse Reactions[a]	**MNEXSPIKE[b]** N=497 n (%)	**Comparator Vaccine[c]** N=495 n (%)
Headache[d]	271 (54.5)	287 (58.0)
Headache, Grade 3[d]	35 (7.0)	20 (4.0)
Fatigue[d]	235 (47.3)	251 (50.7)
Fatigue, Grade 3[d]	34 (6.8)	22 (4.4)
Myalgia[d]	195 (39.2)	178 (36.0)
Myalgia, Grade 3[d]	28 (5.6)	17 (3.4)
Chills[e]	157 (31.6)	158 (31.9)
Chills, Grade 3[e]	6 (1.2)	1 (0.2)
Arthralgia[d]	119 (23.9)	117 (23.6)
Arthralgia, Grade 3[d]	10 (2.0)	6 (1.2)
Nausea/vomiting[f]	80 (16.1)	87 (17.6)
Nausea/vomiting, Grade 3[f]	0 (0)	2 (0.4)
Fever[g]	49 (9.9)	46 (9.3)
Fever, Grade 3[g]	4 (0.8)	2 (0.4)

Table 3: Number and Percentage of Participants with Solicited Systemic Adverse Reactions Starting Within 7 Days* After Injection in Participants 12 Years Through 17 Years (Solicited Safety Set)

Systemic Adverse Reactions[a]	MNEXSPIKE[b] N=497 n (%)	Comparator Vaccine[c] N=495 n (%)
Use of antipyretic or pain medication	186 (37.4)	211 (42.6)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).
N=Number of participants in the Solicited Safety Set.
n=Number of participants with listed solicited adverse reactions.
[a] No Grade 4 adverse reactions were reported.
[b] A vaccine encoding the membrane-bound, linked NTD and RBD of the S glycoprotein from SARS-CoV-2 Original and Omicron variant lineages BA.4/BA.5
[c] Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)
[d] Headache, fatigue, myalgia, arthralgia grading scale: no interference with activity (Grade 1); some interference with activity (Grade 2); prevents daily activity (Grade 3).
[e] Chills grading scale: no interference with activity (Grade 1); some interference with activity not requiring medical intervention (Grade 2); prevents daily activity and requires medical intervention (Grade 3).
[f] Nausea/vomiting grading scale: no interference with activity or 1-2 episodes/24 hours (Grade 1); some interference with activity or >2 episodes/24 hours (Grade 2); prevents daily activity, requires outpatient intravenous hydration (Grade 3).
[g] Fever grading scale: ≥38.0° – ≤38.4°C / ≥100.4° – ≤101.1°F (Grade 1); ≥38.5° – ≤38.9°C / ≥101.2°– ≤102.0°F (Grade 2); ≥39.0° – ≤40.0°C / ≥102.1° – ≤104.0°F (Grade 3).

Table 4: Number and Percentage of Participants with Solicited Local Adverse Reactions Starting Within 7 Days* After Injection in Participants 18 Years Through 64 Years (Solicited Safety Set)

Local Adverse Reactions[a]	MNEXSPIKE[b] N=3,573 n (%)	Comparator Vaccine[c] N=3,574 n (%)
Pain[d]	2,672 (74.8)	2,920 (81.7)
Pain, Grade 3[d]	38 (1.1)	49 (1.4)
Axillary swelling or tenderness[d]	777 (21.7)	749 (21.0)
Axillary swelling or tenderness, Grade 3[d]	11 (0.3)	15 (0.4)
Swelling (hardness) ≥25 mm[e]	140 (3.9)	246 (6.9)
Swelling (hardness) >100 mm, Grade 3[e]	11 (0.3)	19 (0.5)

Table 4: Number and Percentage of Participants with Solicited Local Adverse Reactions Starting Within 7 Days* After Injection in Participants 18 Years Through 64 Years (Solicited Safety Set)

Local Adverse Reactions[a]	MNEXSPIKE[b] N=3,573 n (%)	Comparator Vaccine[c] N=3,574 n (%)
Erythema (redness) ≥25 mm[e]	85 (2.4)	152 (4.3)
Erythema (redness) >100 mm, Grade 3[e]	9 (0.3)	17 (0.5)

* 7 days included day of vaccination and the subsequent 6 days. Events were collected in the electronic diary (e-diary).
N=Number of participants in the Solicited Safety Set.
n=Number of participants with listed solicited adverse reactions.
[a] No Grade 4 adverse reactions were reported.
[b] A vaccine encoding the membrane-bound, linked NTD and RBD of the S glycoprotein from SARS-CoV-2 Original and Omicron variant lineages BA.4/BA.5
[c] Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)
[d] Pain and axillary swelling or tenderness grading scale: no interference with activity (Grade 1); some interference with activity (Grade 2); prevents daily activity (Grade 3).
[e] Swelling and erythema grading scale: 25-50 mm / 2.5-5 cm (Grade 1); 51-100 mm / 5.1-10 cm (Grade 2); >100 mm / >10 cm (Grade 3).

Table 5: Number and Percentage of Participants with Solicited Systemic Adverse Reactions Starting Within 7 Days* After Injection in Participants 18 Years Through 64 Years (Solicited Safety Set)

Systemic Adverse Reactions[a]	MNEXSPIKE[b] N=3,573 n (%)	Comparator Vaccine[c] N=3,574 n (%)
Fatigue[d]	1,939 (54.3)	1,876 (52.5)
Fatigue, Grade 3[d]	170 (4.8)	156 (4.4)
Headache[d]	1,708 (47.8)	1,583 (44.3)
Headache, Grade 3[d]	90 (2.5)	76 (2.1)
Myalgia[d]	1,485 (41.6)	1,469 (41.1)
Myalgia, Grade 3[d]	144 (4.0)	105 (2.9)
Arthralgia[d]	1,159 (32.4)	1,094 (30.6)