Reportes al Sistema VAERS

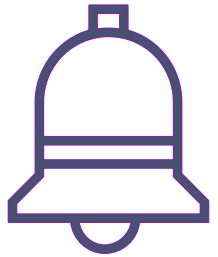
Programa de Vacunación

Departamento de Salud

Martes, 12 de enero de 2021

Objetivos
Vaccine Adverse Event Reporting System

VAERS no establece causalidad, pero identifica patrones inusuales que requieren investigacion adicional



- Detectar eventos adversos nuevos, inusuales o raros
- Monitorear el aumento de eventos adversos conocidos
- Identificar factores de riesgo para ciertos eventos adversos
- Determinar la seguridad de vacunas nuevas
- Determinar reportes en “cluster”
- Reconocer errores de administración persistentes

¿Quién puede reportar?

- Cualquier persona
- Proveedores de salud deben reportar ciertos eventos adversos

https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

¿Qué eventos adversos se deben reportar a VAERS luego de la vacunación contra COVID-19?

- Errores en la administración de la vacuna
- Lesión del hombro (SIRVA)

- Eventos adversos severos:
  *Muerte
  *Evento que amenaza la vida (ej. anafilaxia)
  *Hospitalización o prolongación de la hospitalización
  *Incapacidad persistente o significativa, disrupción de la habilidad de llevar a cabo funciones de la vida diaria
  *Defectos de nacimiento o congénitos

- Casos de síndrome inflamatorio multisistémico
- Casos de COVID-19 que resulten en hospitalización o muerte

Efectos secundarios comunes de las vacunas RNAm contra COVID-19

- Dolor, enrojecimiento, e inflamación del sitio de aplicación
- Fiebre, escalofríos
- Fatiga, mialgia, artralgia
- Cefalea
- Linfadenopatía axilar, cervical
- Nauseas, vómito, diarrea

Los animamos a reportar cualquier evento médico o problema de salud clínicamente importante que ocurra luego de la vacunación.

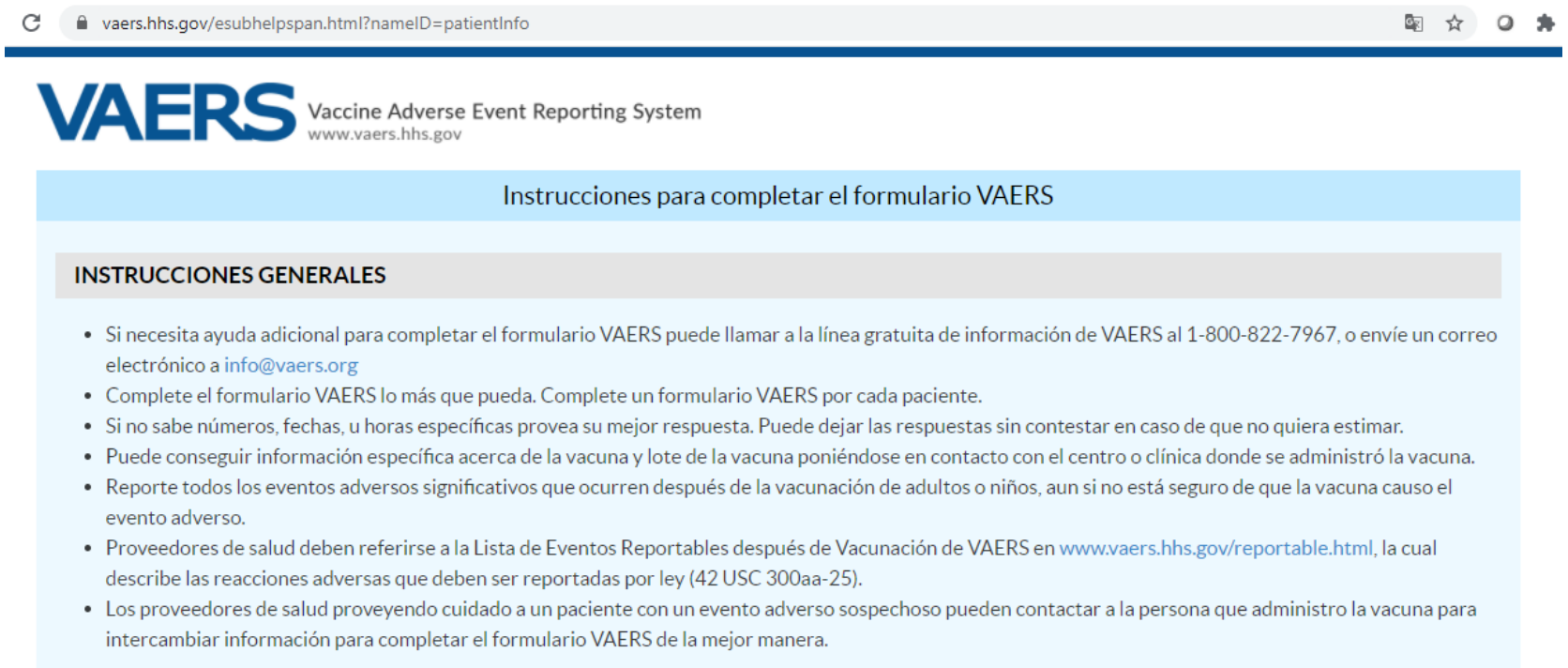
Reporte los eventos adversos aún si no esta seguro que fueron causados por la vacunación.

HIPAA permits reporting of vaccine adverse events and medical documentation to VAERS for public health purposes under 45 CFR § 164.512(b), as authorized by 42 USC 300aa-25.

¿Cómo reportar?

ONLINE

https://vaers.hhs.gov/esub/index.jsp



VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

About VAERS | Report an Adverse Event | VAERS Data | Resources | Submit Follow-Up Information

Completion Status

- [ ] **Patient Information**
- [ ] Reporter Information
- [ ] Facility Information
- [ ] Vaccine Information
- [ ] Additional Information

Report an Adverse Event - Patient Information

Instructions | en Español

Note: Fields marked with an * are essential and should be completed.

Item 1

Patient first name:

Patient last name:

Street address:

City:

State: Select State

County:

Zip code:

Phone:

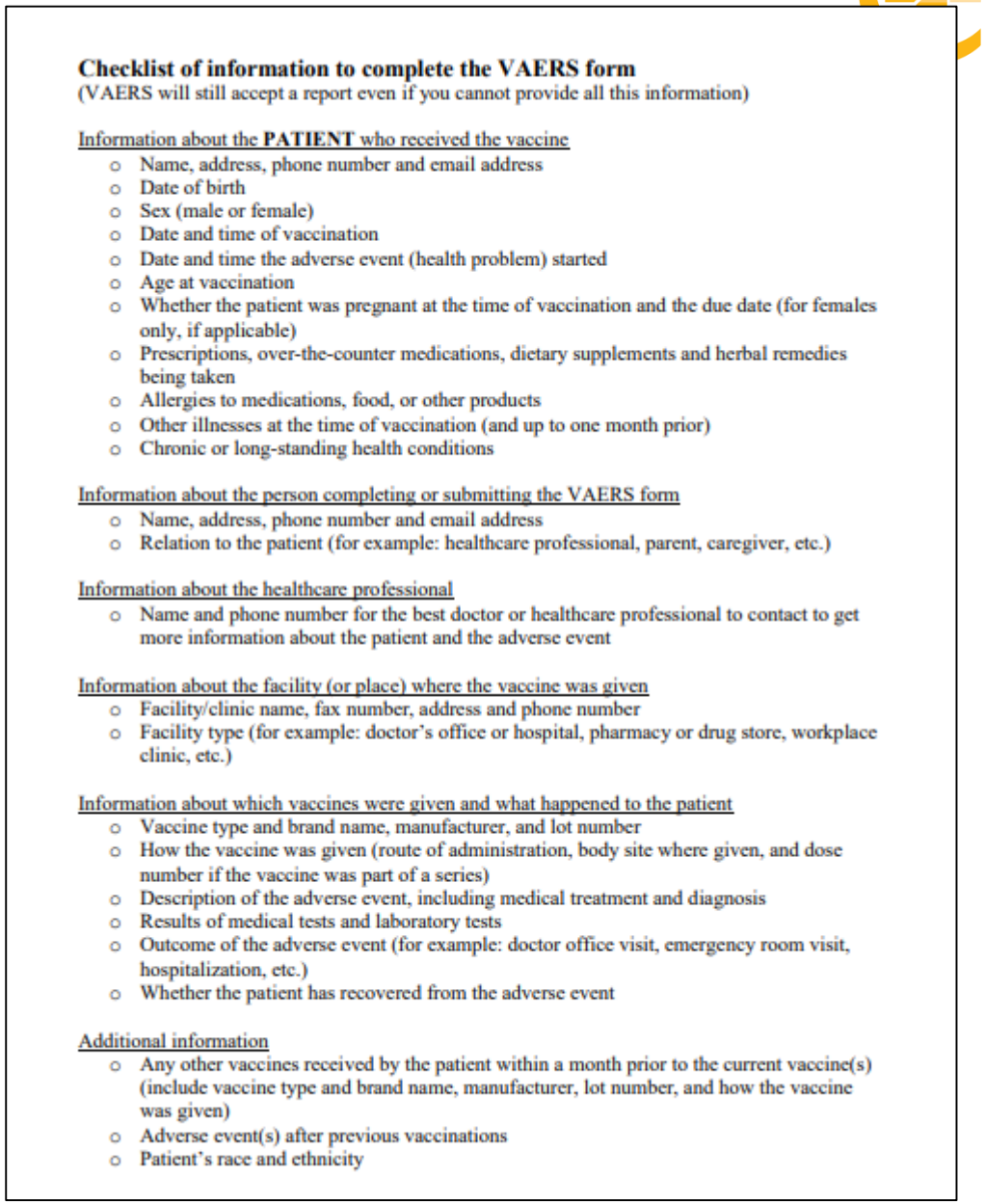
Email:

PROGRAMA de VACUNACIÓN

DEPARTAMENTO DE SALUD
GOBIERNO DE PUERTO RICO

Checklist

- Información del paciente (edad, sexo, DOB, dirección, embarazo, alergias)
- Información de la vacuna (fabricante, dosis, lote, ruta de administración)
- Hora y fecha del evento adverso
- Síntomas y desenlace clínico
- Resultados de laboratorio
- Información de contacto



Checklist of information to complete the VAERS form
(VAERS will still accept a report even if you cannot provide all this information)

Information about the **PATIENT** who received the vaccine
- Name, address, phone number and email address
- Date of birth
- Sex (male or female)
- Date and time of vaccination
- Date and time the adverse event (health problem) started
- Age at vaccination
- Whether the patient was pregnant at the time of vaccination and the due date (for females only, if applicable)
- Prescriptions, over-the-counter medications, dietary supplements and herbal remedies being taken
- Allergies to medications, food, or other products
- Other illnesses at the time of vaccination (and up to one month prior)
- Chronic or long-standing health conditions

Information about the person completing or submitting the VAERS form
- Name, address, phone number and email address
- Relation to the patient (for example: healthcare professional, parent, caregiver, etc.)

Information about the healthcare professional
- Name and phone number for the best doctor or healthcare professional to contact to get more information about the patient and the adverse event

Information about the facility (or place) where the vaccine was given
- Facility/clinic name, fax number, address and phone number
- Facility type (for example: doctor's office or hospital, pharmacy or drug store, workplace clinic, etc.)

Information about which vaccines were given and what happened to the patient
- Vaccine type and brand name, manufacturer, and lot number
- How the vaccine was given (route of administration, body site where given, and dose number if the vaccine was part of a series)
- Description of the adverse event, including medical treatment and diagnosis
- Results of medical tests and laboratory tests
- Outcome of the adverse event (for example: doctor office visit, emergency room visit, hospitalization, etc.)
- Whether the patient has recovered from the adverse event

Additional information
- Any other vaccines received by the patient within a month prior to the current vaccine(s) (include vaccine type and brand name, manufacturer, lot number, and how the vaccine was given)
- Adverse event(s) after previous vaccinations
- Patient's race and ethnicity

https://vaers.hhs.gov/docs/VAERS%202.0_Checklist.pdf

¿Cómo reportar?

FORMATO PDF https://vaers.hhs.gov/uploadFile/index.jsp

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Adverse events are possible reactions or problems that occur during or after vaccination.
Items 2, 3, 4, 5, 6, 17, 18 and 21 are ESSENTIAL and should be completed.
Patient identity is kept confidential. Instructions are provided on the last two pages.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use **Continuation Page** if needed)

1. Patient name: (first) (last)
Street address:
City: State: County:
ZIP code: Phone: ( ) Email:
2. Date of birth: (mm/dd/yyyy) 3. Sex: ☐ Male ☐ Female ☐ Unknown
4. Date and time of vaccination: (mm/dd/yyyy) Time: hh:mm ☐AM ☐PM
5. Date and time adverse event started: (mm/dd/yyyy) Time: hh:mm ☐AM ☐PM
6. Age at vaccination: ___ Years ___ Months 7. Today's date: (mm/dd/yyyy)
8. Pregnant at time of vaccination?: ☐ Yes ☐ No ☐ Unknown
(If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18)

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
10. Allergies to medications, food, or other products:
11. Other illnesses at the time of vaccination and up to one month prior:
12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name)
Relation to patient: ☐ Healthcare professional/staff ☐ Patient (yourself) ☐ Parent/guardian/caregiver ☐ Other:
Street address: ☐ Check if same as item 1
City: State: ZIP code:
Phone: ( ) Email:
14. Best doctor/healthcare professional to contact about the adverse event: Name: Phone: ( ) Ext:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
Fax: ( )
Street address: ☐ Check if same as item 13
City:
State: ZIP code:
Phone: ( )

16. Type of facility: (Check one)
☐ Doctor's office, urgent care, or hospital
☐ Pharmacy or store
☐ Workplace clinic
☐ Public health clinic
☐ Nursing home or senior living facility
☐ School or student health clinic
☐ Other:
☐ Unknown

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given) Use **Continuation Page** if needed

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)

21. Result or outcome of adverse event(s): (Check all that apply)

Importante

- Recibirá un número de confirmación para identificar su reporte
- VAERS lo contactará para obtener información de seguimiento, de ser necesario
- Por favor incluya información de contacto que asegure que el seguimiento del reporte puede hacerse rápidamente
- Usted puede enviar información adicional al fax 877-721-0366 o a través de la página web de VAERS https://vaers.hhs.gov/autoupload.html

PROGRAMA de VACUNACIÓN

DEPARTAMENTO DE SALUD
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https://vaers.hhs.gov/data.html

Options for Accessing VAERS Data

VAERS data is available in two ways:

Search data with an easy-to-use, menu-driven tool. Produce tables, maps, charts, and data extracts of vaccine adverse events.

☑ I have read and understand the disclaimer.

Search CDC Wonder

Download raw data for import into a database, spreadsheet, or text editing program.

☐ I have read and understand the disclaimer.

Download VAERS Data

Información de contacto

Soporte con los reportes y formularios
Dra. Zaira Kianes zaira.kianes@salud.pr.gov
Sr. Julián Cordero julian.cordero@salud.pr.gov

Soporte con aspectos clínicos de los reportes
Dra. Lourdes Pedraza lourdes.pedraza@salud.pr.gov
Dra. Liliana Sánchez-González naq5@cdc.gov

DO YOUR PART

for Vaccine Safety— Report to VAERS

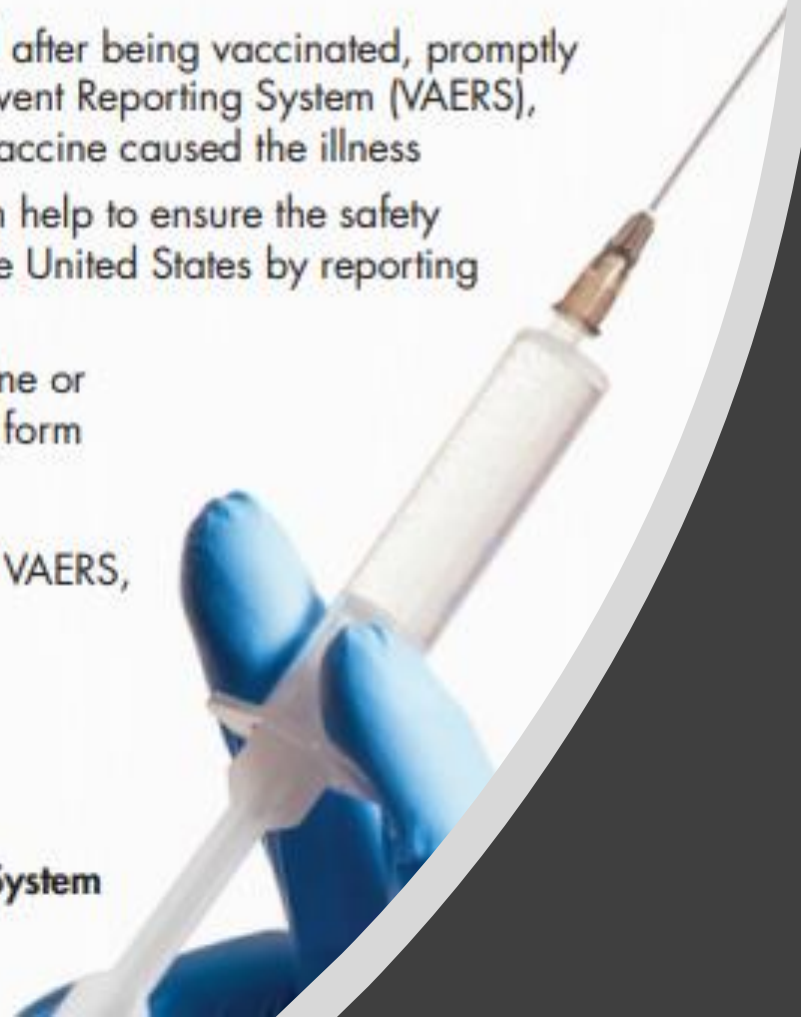
If one of your patients becomes ill after being vaccinated, promptly report it to the Vaccine Adverse Event Reporting System (VAERS), even if you are not sure that the vaccine caused the illness

As a healthcare provider, you can help to ensure the safety of vaccines given to patients in the United States by reporting adverse events to VAERS

- You may report to VAERS online or download and print a VAERS form at www.vaers.hhs.gov
- For additional information on VAERS, call (800) 822-7967

VAERS

Vaccine Adverse Event Reporting System



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¿Preguntas?