

From: Duffy, Jonathan M. (CDC/NCEZID/DHQP/ISO)
Sent: Wed, 14 Feb 2024 20:39:39 +0000
To: Su, John (CDC/NCEZID/DHQP/ISO); McNeil, Michael (CDC/NCEZID/DHQP/ISO)
Subject: ACCV slides for clearance
Attachments: CDCupdate_ACCV_2024-03.pptx

The ACCV meeting will be on March 7. I need to send the slides to the VICP staff in advance by early next week. My draft slides are attached. I will be entering these into eClearance and wanted to let you know that they should be routed to you soon in the system.



Centers for Disease Control and Prevention (CDC) Immunization Safety Office (ISO) Update

**Advisory Commission on Childhood Vaccines (ACCV) meeting March 7,
2024**

Jonathan Duffy, MD, MPH
Immunization Safety Office
Centers for Disease Control and Prevention



- V-safe is a vaccine safety monitoring system that lets you share with CDC how you or your dependent feel after getting a participating vaccine. After you register, V-safe will send you personalized and confidential health check-ins via text messages or emails to ask how you feel after vaccination. Which vaccines are being monitored in V-safe? 2023- 2024 Updated COVID-19 Vaccines Respiratory Syncytial Virus (RSV) Vaccines For older adults (aged 60 and older) For pregnant people

Recent CDC vaccine safety publications

Post-marketing Safety Surveillance of Hexavalent Vaccine in the Vaccine Adverse Event Reporting System

- Assessed the safety of hexavalent vaccine:DTaP-IPV-Hib-HepB (trade name Vaxelis, MSP Vaccine Company)Vaccine Adverse Event Reporting SystemJune 26, 2019, through June 16, 2023 Five hundred-one reports of adverse events (AEs) were identified21 (4.2%) were serious. Most frequently reported AEs were fever (10.2%) and injection site erythema (5.4%). During the period of this study, a total of 2 million doses of DTaP-IPV-Hib-HepB were distributed in the US.AEs reported were consistent with findings from prelicensure studies.

Epidemiology of Upper Limb Complex Regional Pain Syndrome in a Retrospective Cohort of Persons Aged 9-30 Years, 2002-2017

- Complex regional pain syndrome (CRPS) incidence rates over a time period spanning human papillomavirus (HPV) vaccine licensure and published case reports of CRPS following HPV vaccination
Vaccine Safety Datalink
Patients aged 9–30 years between January 2002 and December 2017
113 cases were verified through abstraction and adjudication. Most verified cases (73%) were associated with a clear precipitating event (eg, non–vaccine-related injury, surgical procedure). The authors identified only 1 case in which a practitioner attributed CRPS onset to HPV vaccination
Analysis of CRPS incidence over time showed no statistically significant increases in rates following the 2006 licensure and recommendation of HPV vaccine or following the first publicized case report suggesting a link between HPV vaccination and CRPS in 2013

Tdap vaccination during pregnancy and risk of chorioamnionitis and related infant outcomes

- An increased risk of chorioamnionitis in people receiving tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine during pregnancy has been reported
Vaccine Safety Datalink Retrospective observational cohort study of pregnant people ages 15–49 years with singleton pregnancies ending in live birth during October 2016–September 2018
Included 118,211 pregnant people; 103,258 (87%) received Tdap vaccine during pregnancy; 8098 (7%) were diagnosed with chorioamnionitis
Tdap vaccine exposure during pregnancy was not associated with chorioamnionitis, preterm birth, or adverse infant outcomes

Safety of measles, mumps, and rubella vaccine in adolescents and adults in the Vaccine Safety Datalink

- Measles, mumps, and rubella vaccine (MMR) may be given to adolescents and adults
Vaccine Safety Datalink Included adolescents (aged 9–17 years) and adults (aged ≥ 18 years) who received ≥ 1 dose of MMR from January 1, 2010–December 31, 2018
276,000 doses of MMR given to adolescents and adults were studied
Clinically serious outcomes were rare
Common non-serious outcomes included arthropathy, injection site reaction, and rash

CDC COVID-19 vaccine safety publications

- Background rates of adverse events of special interest for COVID-19 vaccines: A multinational Global Vaccine Data Network (GVDN) analysis. Postmenopausal bleeding after COVID-19 vaccination. Simultaneous administration of mRNA COVID-19 bivalent booster and influenza vaccines. Safety signal identification for COVID-19 bivalent booster vaccination using tree-based scan statistics in the Vaccine Safety Datalink. Safety Monitoring of Novavax COVID-19 Vaccine Among Persons Aged ≥ 12 Years – United States, July 13, 2022 – March 13, 2023.

CDC COVID-19 vaccine safety publications, continued

- Safety of simultaneous vaccination with COVID-19 vaccines in the Vaccine Safety Datalink. Medically Attended Acute Adverse Events in Pregnant People After Coronavirus Disease 2019 (COVID-19) Booster Vaccination. Reporting rates for VAERS death reports following COVID-19 vaccination, December 14, 2020–November 17, 2021. Safety of COVID-19 mRNA Vaccination Among Young Children in the Vaccine Safety Datalink. CDC COVID-19 Vaccine Pregnancy Registry: Design, data collection, response rates, and cohort description.

Advisory Committee on Immunization Practices (ACIP) meeting highlights

COVID-19 Vaccines

- Since September 2022, bivalent mRNA COVID-19 vaccines have been recommended in the United States, but the variants these vaccines were designed to protect against are no longer circulating widely. In September and October 2023, the Food and Drug Administration approved and authorized updated 2023–2024 Formula monovalent XBB.1.5 component–containing COVID-19 vaccines, formulated to target current variants more closely, specifically Omicron variant XBB.1.5, for persons aged ≥ 6 months. On September 12, 2023, the Advisory Committee on Immunization Practices recommended vaccination with updated COVID-19 vaccines for all persons aged ≥ 6 months.

Meningococcal Vaccines

- ACIP approved the following recommendations by majority vote at its October 25-26, 2023 meeting and they have been adopted by the CDC Director. Pfizer's MenABCWY vaccine may be used when both MenACWY and MenB are indicated at the same visit. **1) Healthy individuals aged 16–23 years (routine schedule) when shared clinical decision-making favors administration of MenB vaccination, 2) individuals aged 10 years and older at increased risk of meningococcal disease (e.g., due to persistent complement deficiencies, complement inhibitor use, or functional or anatomic asplenia) due for both vaccines.

Mpox Vaccines

- ACIP approved the following recommendations by majority vote at its October 25-26, 2023 meeting and they have been adopted by the CDC Director. ACIP recommends vaccination* with the 2-dose JYNNEOS vaccine series for persons aged 18 years and older at risk for mpox¶*This is an interim recommendation that ACIP will revisit in 2-3 years§Dose 2 administered 28 days after dose 1¶Persons at risk:Gay, bisexual, and other men who have sex with men, transgender or nonbinary people who in the past 6 months have had one of the following:A new diagnosis of ≥1 sexually transmitted diseaseMore than one sex partnerSex at a commercial sex venueSex in association with a large public event in a geographic area where mpox transmission is occurringSexual partners of persons with the risks described in abovePersons who anticipate experiencing any of the above

Source: <https://www.cdc.gov/vaccines/acip/recommendations.html>

Respiratory Syncytial Virus (RSV) Vaccines – Maternal

- In August 2023, the Food and Drug Administration approved Pfizer RSV vaccine for pregnant persons at 32–36 weeks' gestation to prevent RSV-associated lower respiratory tract infection (LRTI) in infants aged <6 months. On September 22, 2023, CDC's Advisory Committee on Immunization Practices recommended RSV vaccine for pregnant persons at 32–36 weeks' gestation using seasonal administration (meaning September–January in most of the United States) to prevent RSV-associated LRTI in infants aged <6 months.

Influenza Vaccines

- Influenza Vaccines in Pregnancy presentations: Safety of Quadrivalent Recombinant Influenza Vaccine in Pregnant Women and their Infants
Pregnancy Outcomes with cclIV4 (Flucelvax): Post Marketing Study
Effectiveness of Maternal Influenza Vaccination during Pregnancy
Against Influenza-associated Hospitalizations & ED Visits in Infants <6 Months of Age

Influenza Vaccines

- Co-administration of Vaccines in Adults presentations: Safety of Simultaneous versus Sequential Administration of mRNA COVID-19 and Quadrivalent Inactivated Influenza (IIV4) Vaccines Safety of Simultaneous Vaccination with Zoster Vaccine Recombinant (RZV) and Quadrivalent Adjuvanted Inactivated Influenza Vaccine (aIIV4) Update on COVID-19 and Influenza Vaccine Safety

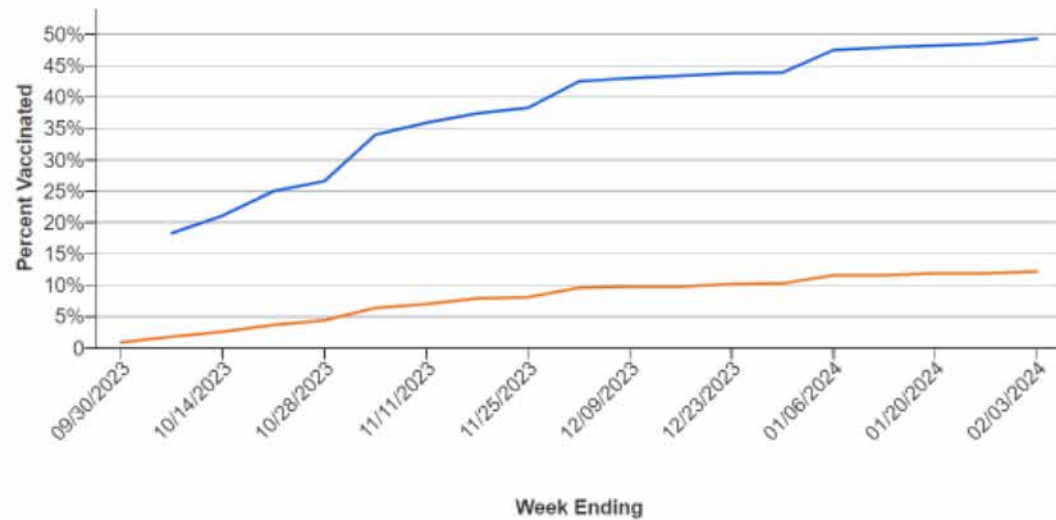
Vaccination coverage

Respiratory Illness Vaccination Trends 2023-2024, based on weekly updated National Immunization Survey (NIS) findings, data as of 02/08/2024

Children aged 6 months – 17 years

Weekly Cumulative Percent Vaccinated in the United States

Cumulative percent of children 6 months-17 years vaccinated with COVID-19 or influenza vaccine.

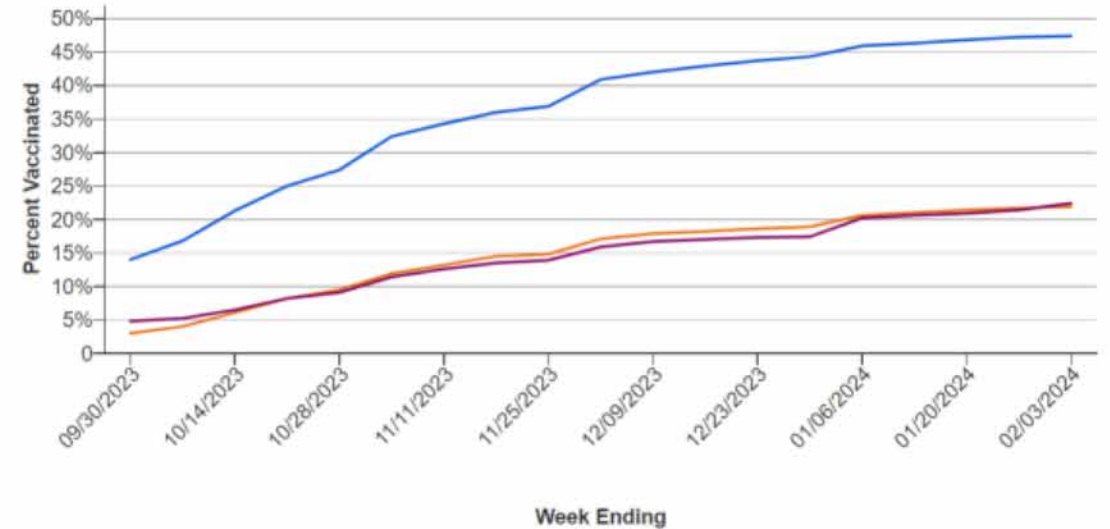


● COVID-19 ● Influenza

Adults aged 18+ years

Weekly Cumulative Percent Vaccinated in the United States

Cumulative percent of adults vaccinated with COVID-19 (18+ years), influenza (18+ years), or RSV (60+ years) vaccine.



● COVID-19 (18+ years) ● Influenza (18+ years) ● RSV (60+ years)

Source: <https://www.cdc.gov/respiratory-viruses/data-research/dashboard/vaccination-trends-children.html>

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



Sent: Wed, 21 Feb 2024 02:21:30 +0000
To: Nordlund, Kristen (CDC/NCEZID/OD)
Subject: FW: GVDN paper

Hi Kristen,

Please see below. Any update on the talking points?

What baffles me is that the GVDN findings are based on ICD-10 coding – the reported excess cases haven't been chart confirmed (such as what we did for Matt's JAMA myocarditis paper). And except for ADEM (which the authors warned to interpret cautiously), all the findings had been previously reported. In other words, not much new here.

But the media releases

From: Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>
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Hi everyone!

I was told that the article will be highlighted tomorrow on BBC's [Science in Action](#).

-Julianne

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A few additional:

- [Large study funded by CDC identifies rare COVID-19 vaccine risks \(ScrippsNews\)](#)
- [COVID vaccines linked to neurological, blood, and heart-related issues \(Earth\)](#)
- [COVID vaccines linked to slight increases in heart, brain, blood disorders: study \(NYPost\)](#)

Martha Sharan
Press Officer

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Thanks Curt!

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This gives you an idea:

[Largest multicountry COVID study links vaccines to potential adverse effects – Straight Arrow News \(san.com\)](https://www.straightarrownews.com/largest-multicountry-covid-study-links-vaccines-to-potential-adverse-effects)

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Ditto, thanks for sharing.

Offhand, do we have an idea of the slant and readership of these outlets (left/right, naturopathic, etc.)? I haven't heard of a number of these outlets.

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Thanks for sending this, Martha!

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Hi Everyone:

Additional coverage below:

[Largest multicountry COVID study links vaccines to potential adverse effects | The Hill](#)

[Covid vaccine study finds link to health symptoms \(gbnews.com\)](#)

[Largest-ever COVID vaccine study links shot to small increase in heart and brain conditions | Fox News](#)

[Largest Covid vaccine study ever finds shots are linked to small increased risk of neurological, blood and heart disorders - but they are still extremely rare | Daily Mail Online](#)

[Covid Vaccine Side Effects: Largest-Ever COVID Vaccine Study Links COVID Shots To Minor Increase in Heart And Brain Issues | Health News, Times Now \(timesnownews.com\)](#)

[Largest multicountry COVID study links vaccines to potential adverse effects \(yahoo.com\)](#) – from The Hill

[Largest Covid-19 vaccine study yet finds links to health conditions | South China Morning Post \(scmp.com\)](#)

[Largest Covid Vaccine Study Yet Finds Links to Health Conditions - Bloomberg](#)

[Largest COVID vaccine study yet evaluates adverse events of special interest \(medicalxpress.com\)](#)

[How dangerous are COVID vaccines? Global study | Fortune Well](#)

[COVID-19 vaccine linked to possible health issues: study \(newsnationnow.com\)](#)

[COVID Vaccines Linked To Slight Increase In Heart And Brain Issues: Large-Scale Study \(medicaldaily.com\)](#)

[Study of 99 million COVID-vaccinated people finds links to brain, heart problems - Washington Times](#)

[People vaccinated for Covid have increased risk of neurological diseases – study — RT World News](#)

[Pfizer, Moderna and AstraZeneca COVID vaccines hurt hearts and minds, says biggest multi-nation study – Firstpost](#)

[Adverse events linked to Covid vaccines revealed in latest study \(biznews.com\)](#)

[Groundbreaking Global Study on 99 Million Vaccinated People Reveals Increases in Neurological, Blood, and Heart Conditions Associated with COVID-19 Vaccines | The Gateway Pundit | by Jim Hoft](#)

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Hi Tanya – will check, but if there is any additional it was published without involving DHQP. We did not get any media inquiries directly

Thanks,
Martha

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Hi Martha and Curt,

Sharing these articles on the GVDN story. Have you seen additional coverage?

Thanks!

Forbes

[Covid Vaccines Linked To Small Increase In Heart And Brain Disorders, Study Finds—But Risk From Infection Is Far Higher \(msn.com\)](#)

MSN

[Largest-ever COVID vaccine study links shot to small increase in heart and brain conditions \(msn.com\)](#)

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Sent: Wed, 21 Feb 2024 02:23:47 +0000
To: Nordlund, Kristen (CDC/NCEZID/OD)
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Hi Kristen,

Please see below. Any update on the talking points?

From a scientific standpoint, there really isn't much new in the GVDN paper – except for the ADEM signal (which the authors warned to interpret cautiously, given the wide confidence intervals). But as their media releases demonstrate, it's not what you say, but how you say it.

And they said it in a way that drew a lot of attention... 🙄

- John

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Additional coverage below:

[Largest multicountry COVID study links vaccines to potential adverse effects | The Hill](#)

[Covid vaccine study finds link to health symptoms \(gbnews.com\)](#)

[Largest-ever COVID vaccine study links shot to small increase in heart and brain conditions | Fox News](#)

[Largest Covid vaccine study ever finds shots are linked to small increased risk of neurological, blood and heart disorders - but they are still extremely rare | Daily Mail Online](#)

[Covid Vaccine Side Effects: Largest-Ever COVID Vaccine Study Links COVID Shots To Minor Increase in Heart And Brain Issues | Health News, Times Now \(timesnownews.com\)](#)

[Largest multicountry COVID study links vaccines to potential adverse effects \(yahoo.com\) – from The Hill](#)

[Largest Covid-19 vaccine study yet finds links to health conditions | South China Morning Post \(scmp.com\)](#)

[Largest Covid Vaccine Study Yet Finds Links to Health Conditions - Bloomberg](#)

[Largest COVID vaccine study yet evaluates adverse events of special interest \(medicalxpress.com\)](#)

[How dangerous are COVID vaccines? Global study | Fortune Well](#)

[COVID-19 vaccine linked to possible health issues: study \(newsnationnow.com\)](#)

[COVID Vaccines Linked To Slight Increase In Heart And Brain Issues: Large-Scale Study \(medicaldaily.com\)](#)

[Study of 99 million COVID-vaccinated people finds links to brain, heart problems - Washington Times](#)

[People vaccinated for Covid have increased risk of neurological diseases – study — RT World News](#)

[Pfizer, Moderna and AstraZeneca COVID vaccines hurt hearts and minds, says biggest multi-nation study – Firstpost](#)

[Adverse events linked to Covid vaccines revealed in latest study \(biznews.com\)](#)

[Groundbreaking Global Study on 99 Million Vaccinated People Reveals Increases in Neurological, Blood, and Heart Conditions Associated with COVID-19 Vaccines | The Gateway Pundit | by Jim Hoft](#)

*Martha Sharan
Press Officer
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787*

From: Sharan, Martha (CDC/NCEZID/DHQP/OD)
Sent: Tuesday, February 20, 2024 8:57 AM
To: Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>

Cc: Gill, Curtis (CDC/NCEZID/DHQP/OD) (CTR) <gsi3@cdc.gov>

Subject: RE: GVDN paper

Hi Tanya – will check, but if there is any additional it was published without involving DHQP. We did not get any media inquiries directly

Thanks,
Martha

*Martha Sharan
Press Officer
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787*

From: Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>

Sent: Tuesday, February 20, 2024 8:52 AM

To: Sharan, Martha (CDC/NCEZID/DHQP/OD) <liu4@cdc.gov>; Gill, Curtis (CDC/NCEZID/DHQP/OD) (CTR) <gsi3@cdc.gov>

Subject: GVDN paper

Hi Martha and Curt,

Sharing these articles on the GVDN story. Have you seen additional coverage?

Thanks!

Forbes

[Covid Vaccines Linked To Small Increase In Heart And Brain Disorders, Study Finds—But Risk From Infection Is Far Higher \(msn.com\)](#)

MSN

[Largest-ever COVID vaccine study links shot to small increase in heart and brain conditions \(msn.com\)](#)

Sent: Mon, 12 Feb 2024 20:21:08 +0000
To: Bell, Michael MD (CDC/NCEZID/DHQP/OD); Su, John (CDC/NCEZID/DHQP/ISO)
Cc: Helfand, Rita (CDC/NCEZID/OD)
Subject: RE: GVDN O/E

Hi Mike and John-

Just spoke to Rita about this paper. Wanted to update the both of you.

From: Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>
Sent: Monday, February 12, 2024 2:56 PM
To: Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>; Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>
Cc: Helfand, Rita (CDC/NCEZID/OD) <rz7@cdc.gov>
Subject: RE: GVDN O/E

Perfect – thank you both!!

From: Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>
Sent: Monday, February 12, 2024 2:32 PM
To: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>
Cc: Helfand, Rita (CDC/NCEZID/OD) <rz7@cdc.gov>
Subject: RE: GVDN O/E

Hi Mike- We are working on the Talking Points for the GVDN O/E paper. Tanya H should have them to me soon for review and then will share with John for final approval.

We are also going to work on TPs for the Australian paper, just in case the paper is posted online.

I am hoping to provide the TPs for the GVDN O/E paper to Jeremy this evening.

Thanks,
Julianne

From: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>
Sent: Monday, February 12, 2024 2:24 PM
To: Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>; Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>
Cc: Helfand, Rita (CDC/NCEZID/OD) <rz7@cdc.gov>
Subject: RE: GVDN O/E

Hi Mike,

(b)(5)

- John

From: Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>
Sent: Monday, February 12, 2024 1:42 PM
To: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>; Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>
Cc: Helfand, Rita (CDC/NCEZID/OD) <rz7@cdc.gov>
Subject: RE: GVDN O/E

Thanks John!

Confirming that the talking points and, for the hearing, the numbers that Dan requested last week have been sent up?

~Mike

From: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>
Sent: Monday, February 12, 2024 1:12 PM
To: Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>; Craig, Michael R. (CDC/NCEZID/DHQP/OD) <bez7@cdc.gov>; Srinivasan, Arjun (CDC/NCEZID/DHQP/OD) <beu8@cdc.gov>; Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>; Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD) <ybz5@cdc.gov>; Goodman, Jeremy A. (CDC/NCEZID/DHQP/OD) <vhj2@cdc.gov>; Nordlund, Kristen (CDC/NCEZID/OD) <hok4@cdc.gov>; Kroop, Seth (CDC/NCEZID/DHQP/OD) <wpw7@cdc.gov>
Cc: Fleming-Dutra, Katherine E. (CDC/NCIRD/CORVD) <ftu2@cdc.gov>; Jackson, Brendan R. (CDC/NCIRD/OD) <iyn0@cdc.gov>; Panagiotakopoulos, Lakshmi (CDC/NCIRD/CORVD) <xfq3@cdc.gov>; Wallace, Megan (CDC/NCIRD/CORVD) <phu3@cdc.gov>; Wharton, Melinda (CDC/NCIRD/OD) <mew2@cdc.gov>; Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>; Helfand, Rita (CDC/NCEZID/OD) <rz7@cdc.gov>
Subject: GVDN O/E

Hi all,

Just an update: the OE paper for COVID-19 vaccination by GVDN is available online (although I am having difficulties downloading a copy). Please see below link.

- John

[COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network \(GVDN\) cohort study of 99 million vaccinated individuals - ScienceDirect](#)

From: Hamburger, Tanya (CDC/NCEZID/DHQP/OD)
Sent: Tue, 13 Feb 2024 14:12:59 +0000
To: Gee, Julianne (CDC/NCEZID/DHQP/ISO)
Subject: RE: GVDN O/E

Oh my

From: Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>
Sent: Tuesday, February 13, 2024 8:37 AM
To: Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>
Subject: FW: GVDN O/E

From: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>
Sent: Tuesday, February 13, 2024 8:37 AM
To: Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>
Subject: RE: GVDN O/E

Okay, thanks. Just trying to learn how to keep abreast of pending papers. (Although in this case, we had a heads up they'd be published together.)

- John

From: Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>
Sent: Tuesday, February 13, 2024 8:33 AM
To: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>
Subject: RE: GVDN O/E

I went to Vaccine's website.

[Vaccine | Journal | ScienceDirect.com by Elsevier](#)

From: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>
Sent: Tuesday, February 13, 2024 8:29 AM
To: Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>
Subject: RE: GVDN O/E

Thanks for the heads up, Julianne. How did you learn these papers were online? Did you watch for them, or receive notice in some fashion?

- John

From: Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>
Sent: Tuesday, February 13, 2024 8:18 AM
To: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>; Bell, Michael MD (CDC/NCEZID/DHQP/OD)

<zzb8@cdc.gov>; Craig, Michael R. (CDC/NCEZID/DHQP/OD) <bez7@cdc.gov>; Srinivasan, Arjun (CDC/NCEZID/DHQP/OD) <beu8@cdc.gov>; Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>; Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD) <ybz5@cdc.gov>; Goodman, Jeremy A. (CDC/NCEZID/DHQP/OD) <vhj2@cdc.gov>; Nordlund, Kristen (CDC/NCEZID/OD) <hok4@cdc.gov>; Kroop, Seth (CDC/NCEZID/DHQP/OD) <wpw7@cdc.gov>
Cc: Fleming-Dutra, Katherine E. (CDC/NCIRD/CORVD) <ftu2@cdc.gov>; Jackson, Brendan R. (CDC/NCIRD/OD) <iyn0@cdc.gov>; Panagiotakopoulos, Lakshmi (CDC/NCIRD/CORVD) <xfq3@cdc.gov>; Wallace, Megan (CDC/NCIRD/CORVD) <phu3@cdc.gov>; Wharton, Melinda (CDC/NCIRD/OD) <mew2@cdc.gov>; Helfand, Rita (CDC/NCEZID/OD) <rz7@cdc.gov>
Subject: RE: GVDN O/E

Good morning,

Vaccine posted the Australian self-controlled case series paper this morning that evaluated ADEM and TM following COVID-19 vaccine. The site that conducted this analysis is a GVDN site.

[Acute disseminated encephalomyelitis and transverse myelitis following COVID-19 vaccination – A self-controlled case series analysis \(sciencedirectassets.com\)](https://www.sciencedirectassets.com)

I will be with working the vaccine safety comms team to develop talking points.

Thanks,
Julianne

From: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>
Sent: Monday, February 12, 2024 1:12 PM
To: Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>; Craig, Michael R. (CDC/NCEZID/DHQP/OD) <bez7@cdc.gov>; Srinivasan, Arjun (CDC/NCEZID/DHQP/OD) <beu8@cdc.gov>; Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>; Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD) <ybz5@cdc.gov>; Goodman, Jeremy A. (CDC/NCEZID/DHQP/OD) <vhj2@cdc.gov>; Nordlund, Kristen (CDC/NCEZID/OD) <hok4@cdc.gov>; Kroop, Seth (CDC/NCEZID/DHQP/OD) <wpw7@cdc.gov>
Cc: Fleming-Dutra, Katherine E. (CDC/NCIRD/CORVD) <ftu2@cdc.gov>; Jackson, Brendan R. (CDC/NCIRD/OD) <iyn0@cdc.gov>; Panagiotakopoulos, Lakshmi (CDC/NCIRD/CORVD) <xfq3@cdc.gov>; Wallace, Megan (CDC/NCIRD/CORVD) <phu3@cdc.gov>; Wharton, Melinda (CDC/NCIRD/OD) <mew2@cdc.gov>; Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>; Helfand, Rita (CDC/NCEZID/OD) <rz7@cdc.gov>
Subject: GVDN O/E

Hi all,

Just an update: the OE paper for COVID-19 vaccination by GVDN is available online (although I am having difficulties downloading a copy). Please see below link.

- John

[COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network \(GVDN\) cohort study of 99 million vaccinated individuals - ScienceDirect](#)

From: Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD)
Sent: Mon, 12 Feb 2024 19:24:04 +0000
To: Goodman, Jeremy A. (CDC/NCEZID/DHQP/OD); Gee, Julianne (CDC/NCEZID/DHQP/ISO); Hamburger, Tanya (CDC/NCEZID/DHQP/OD); Carter, Danielle (CDC/NCEZID/DHQP/OD); Wahlquist, Tabatha (CDC/NCEZID/DHQP/OD) (CTR); Su, John (CDC/NCEZID/DHQP/ISO)
Cc: Sharan, Martha (CDC/NCEZID/DHQP/OD)
Subject: RE: GVDN O/E

Adding Martha for awareness

From: Goodman, Jeremy A. (CDC/NCEZID/DHQP/OD) <vhj2@cdc.gov>
Sent: Monday, February 12, 2024 1:58 PM
To: Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>; Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>; Carter, Danielle (CDC/NCEZID/DHQP/OD) <lwu9@cdc.gov>; Wahlquist, Tabatha (CDC/NCEZID/DHQP/OD) (CTR) <umy9@cdc.gov>; Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>
Cc: Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD) <ybz5@cdc.gov>
Subject: RE: GVDN O/E

I believe that's in the report in the acknowledgements on page 10 but it didn't have a source beyond "CDC"

Jeremy Goodman, MBA (*he/him/his*)
Public Health Analyst, Policy Team
Division of Healthcare Quality Promotion, Office of the Director
Centers for Disease Control and Prevention
404-639-3325

From: Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>
Sent: Monday, February 12, 2024 1:49 PM
To: Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>; Goodman, Jeremy A. (CDC/NCEZID/DHQP/OD) <vhj2@cdc.gov>; Carter, Danielle (CDC/NCEZID/DHQP/OD) <lwu9@cdc.gov>; Wahlquist, Tabatha (CDC/NCEZID/DHQP/OD) (CTR) <umy9@cdc.gov>; Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>
Cc: Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD) <ybz5@cdc.gov>
Subject: RE: GVDN O/E

ISO funded GVDN through a grant.
Do you need the amount?

From: Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>
Sent: Monday, February 12, 2024 1:48 PM
To: Goodman, Jeremy A. (CDC/NCEZID/DHQP/OD) <vhj2@cdc.gov>; Carter, Danielle (CDC/NCEZID/DHQP/OD) <lwu9@cdc.gov>; Wahlquist, Tabatha (CDC/NCEZID/DHQP/OD) (CTR) <umy9@cdc.gov>; Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>; Su, John

(CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>

Cc: Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD) <ybz5@cdc.gov>

Subject: RE: GVDN O/E

+ Julianne and John for awareness

From: Goodman, Jeremy A. (CDC/NCEZID/DHQP/OD) <vhj2@cdc.gov>

Sent: Monday, February 12, 2024 1:46 PM

To: Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>; Carter, Danielle (CDC/NCEZID/DHQP/OD) <lwu9@cdc.gov>; Wahlquist, Tabatha (CDC/NCEZID/DHQP/OD) (CTR) <umy9@cdc.gov>

Cc: Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD) <ybz5@cdc.gov>

Subject: RE: GVDN O/E

Thanks Tanya! Basically we need a response to those suggesting that there's a conflict of interest here since CDC funded this work. Preferably would want to know which group(s) at CDC funded it/source of funding and language on CDC interactions with GVDN on this, if any (e.g., reviewed final report, etc.)

Jeremy Goodman, MBA *(he/him/his)*
Public Health Analyst, Policy Team
Division of Healthcare Quality Promotion, Office of the Director
Centers for Disease Control and Prevention
404-639-3325

From: Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>

Sent: Monday, February 12, 2024 1:41 PM

To: Goodman, Jeremy A. (CDC/NCEZID/DHQP/OD) <vhj2@cdc.gov>; Carter, Danielle (CDC/NCEZID/DHQP/OD) <lwu9@cdc.gov>; Wahlquist, Tabatha (CDC/NCEZID/DHQP/OD) (CTR) <umy9@cdc.gov>

Cc: Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD) <ybz5@cdc.gov>

Subject: RE: GVDN O/E

Hi Jeremy,

Connecting you with Danielle and Tabatha who are working to get the talking points drafted and ready for John/Julianne between 2-3 today.

Thanks! Tanya

From: Goodman, Jeremy A. (CDC/NCEZID/DHQP/OD) <vhj2@cdc.gov>

Sent: Monday, February 12, 2024 1:36 PM

To: Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>; Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD) <ybz5@cdc.gov>

Cc: Kroop, Seth (CDC/NCEZID/DHQP/OD) <wpw7@cdc.gov>; Helfand, Rita (CDC/NCEZID/OD) <rz7@cdc.gov>

Subject: RE: GVDN O/E

Tanya, is there a link to a working doc for the TPs on this report? There's a difficult Q&A we want to make sure is covered RE: funding that we want to make sure Dan has for the hearing.

Jeremy Goodman, MBA *(he/him/his)*
Public Health Analyst, Policy Team
Division of Healthcare Quality Promotion, Office of the Director
Centers for Disease Control and Prevention
404-639-3325

From: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>

Sent: Monday, February 12, 2024 1:12 PM

To: Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>; Craig, Michael R. (CDC/NCEZID/DHQP/OD) <bez7@cdc.gov>; Srinivasan, Arjun (CDC/NCEZID/DHQP/OD) <beu8@cdc.gov>; Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>; Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD) <ybz5@cdc.gov>; Goodman, Jeremy A. (CDC/NCEZID/DHQP/OD) <vhj2@cdc.gov>; Nordlund, Kristen (CDC/NCEZID/OD) <hok4@cdc.gov>; Kroop, Seth (CDC/NCEZID/DHQP/OD) <wpw7@cdc.gov>

Cc: Fleming-Dutra, Katherine E. (CDC/NCIRD/CORVD) <ftu2@cdc.gov>; Jackson, Brendan R. (CDC/NCIRD/OD) <iyn0@cdc.gov>; Panagiotakopoulos, Lakshmi (CDC/NCIRD/CORVD) <xfq3@cdc.gov>; Wallace, Megan (CDC/NCIRD/CORVD) <phu3@cdc.gov>; Wharton, Melinda (CDC/NCIRD/OD) <mew2@cdc.gov>; Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>; Helfand, Rita (CDC/NCEZID/OD) <rz7@cdc.gov>

Subject: GVDN O/E

Hi all,

Just an update: the OE paper for COVID-19 vaccination by GVDN is available online (although I am having difficulties downloading a copy). Please see below link.

- John

[COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network \(GVDN\) cohort study of 99 million vaccinated individuals - ScienceDirect](#)

Sent: Tue, 20 Feb 2024 16:06:06 +0000
To: Sharan, Martha (CDC/NCEZID/DHQP/OD); Gee, Julianne (CDC/NCEZID/DHQP/ISO); Hamburger, Tanya (CDC/NCEZID/DHQP/OD)
Cc: Gill, Curtis (CDC/NCEZID/DHQP/OD) (CTR); Carter, Danielle (CDC/NCEZID/DHQP/OD); Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD)
Subject: RE: GVDN paper

Ditto, thanks for sharing.

Offhand, do we have an idea of the slant and readership of these outlets (left/right, naturopathic, etc.)? I haven't heard of a number of these outlets – and others I consider questionable in terms of accurate reporting (e.g., many consider RT World News a pro-Russian propaganda mouthpiece).

- John

From: Sharan, Martha (CDC/NCEZID/DHQP/OD) <liu4@cdc.gov>
Sent: Tuesday, February 20, 2024 10:41 AM
To: Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>; Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>; Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>
Cc: Gill, Curtis (CDC/NCEZID/DHQP/OD) (CTR) <qsi3@cdc.gov>; Carter, Danielle (CDC/NCEZID/DHQP/OD) <lwu9@cdc.gov>; Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD) <ybz5@cdc.gov>
Subject: RE: GVDN paper

+ Katy and Danielle

Martha Sharan
Press Officer
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>
Sent: Tuesday, February 20, 2024 10:38 AM
To: Sharan, Martha (CDC/NCEZID/DHQP/OD) <liu4@cdc.gov>; Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>; Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>
Cc: Gill, Curtis (CDC/NCEZID/DHQP/OD) (CTR) <qsi3@cdc.gov>
Subject: RE: GVDN paper

Thanks for sending this, Martha!

From: Sharan, Martha (CDC/NCEZID/DHQP/OD) <liu4@cdc.gov>
Sent: Tuesday, February 20, 2024 10:37 AM
To: Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>; Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>; Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>

Cc: Gill, Curtis (CDC/NCEZID/DHQP/OD) (CTR) <gsi3@cdc.gov>

Subject: RE: GVDN paper

Hi Everyone:

Additional coverage below:

[Largest multicountry COVID study links vaccines to potential adverse effects | The Hill](#)

[Covid vaccine study finds link to health symptoms \(gbnews.com\)](#)

[Largest-ever COVID vaccine study links shot to small increase in heart and brain conditions | Fox News](#)

[Largest Covid vaccine study ever finds shots are linked to small increased risk of neurological, blood and heart disorders - but they are still extremely rare | Daily Mail Online](#)

[Covid Vaccine Side Effects: Largest-Ever COVID Vaccine Study Links COVID Shots To Minor Increase in Heart And Brain Issues | Health News, Times Now \(timesnownews.com\)](#)

[Largest multicountry COVID study links vaccines to potential adverse effects \(yahoo.com\)](#) – from The Hill

[Largest Covid-19 vaccine study yet finds links to health conditions | South China Morning Post \(scmp.com\)](#)

[Largest Covid Vaccine Study Yet Finds Links to Health Conditions - Bloomberg](#)

[Largest COVID vaccine study yet evaluates adverse events of special interest \(medicalxpress.com\)](#)

[How dangerous are COVID vaccines? Global study | Fortune Well](#)

[COVID-19 vaccine linked to possible health issues: study \(newsnationnow.com\)](#)

[COVID Vaccines Linked To Slight Increase In Heart And Brain Issues: Large-Scale Study \(medicaily.com\)](#)

[Study of 99 million COVID-vaccinated people finds links to brain, heart problems - Washington Times](#)

[People vaccinated for Covid have increased risk of neurological diseases – study — RT World News](#)

[Pfizer, Moderna and AstraZeneca COVID vaccines hurt hearts and minds, says biggest multi-nation study – Firstpost](#)

[Adverse events linked to Covid vaccines revealed in latest study \(biznews.com\)](#)

[Groundbreaking Global Study on 99 Million Vaccinated People Reveals Increases in Neurological, Blood, and Heart Conditions Associated with COVID-19 Vaccines | The Gateway Pundit | by Jim Hoft](#)

Martha Sharan
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Cc: Gill, Curtis (CDC/NCEZID/DHQP/OD) (CTR) <qsi3@cdc.gov>
Subject: RE: GVDN paper

Hi Tanya – will check, but if there is any additional it was published without involving DHQP. We did not get any media inquiries directly

Thanks,
Martha

Martha Sharan
Press Officer
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Off.: 404-639-2683
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From: Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>
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Subject: GVDN paper

Hi Martha and Curt,

Sharing these articles on the GVDN story. Have you seen additional coverage?

Thanks!

Forbes

[Covid Vaccines Linked To Small Increase In Heart And Brain Disorders, Study Finds—But Risk From Infection Is Far Higher \(msn.com\)](#)

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[Largest-ever COVID vaccine study links shot to small increase in heart and brain conditions \(msn.com\)](#)

From: Gill, Curtis (CDC/NCEZID/DHQP/OD) (CTR)
Sent: Tue, 20 Feb 2024 17:27:03 +0000
To: Su, John (CDC/NCEZID/DHQP/ISO); Sharan, Martha (CDC/NCEZID/DHQP/OD); Gee, Julianne (CDC/NCEZID/DHQP/ISO); Hamburger, Tanya (CDC/NCEZID/DHQP/OD)
Cc: Carter, Danielle (CDC/NCEZID/DHQP/OD); Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD)
Subject: RE: GVDN paper

Sure thing.

From: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>
Sent: Tuesday, February 20, 2024 12:25 PM
To: Gill, Curtis (CDC/NCEZID/DHQP/OD) (CTR) <qsi3@cdc.gov>; Sharan, Martha (CDC/NCEZID/DHQP/OD) <liu4@cdc.gov>; Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>; Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>
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Subject: RE: GVDN paper

Interesting. Thanks, Curtis!

- John

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Subject: RE: GVDN paper

+ Katy and Danielle

Martha Sharan
Press Officer
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

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Subject: RE: GVDN paper

Thanks for sending this, Martha!

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Hi Everyone:

Additional coverage below:

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[Largest Covid vaccine study ever finds shots are linked to small increased risk of neurological, blood and heart disorders - but they are still extremely rare | Daily Mail Online](#)

[Covid Vaccine Side Effects: Largest-Ever COVID Vaccine Study Links COVID Shots To Minor Increase in Heart And Brain Issues | Health News, Times Now \(timesnownews.com\)](#)

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[Largest Covid-19 vaccine study yet finds links to health conditions | South China Morning Post \(scmp.com\)](#)

[Largest Covid Vaccine Study Yet Finds Links to Health Conditions - Bloomberg](#)

[Largest COVID vaccine study yet evaluates adverse events of special interest \(medicalxpress.com\)](#)

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[COVID-19 vaccine linked to possible health issues: study \(newsnationnow.com\)](#)

[COVID Vaccines Linked To Slight Increase In Heart And Brain Issues: Large-Scale Study \(medicaldaily.com\)](#)

[Study of 99 million COVID-vaccinated people finds links to brain, heart problems - Washington Times](#)

[People vaccinated for Covid have increased risk of neurological diseases – study — RT World News](#)

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*Martha Sharan
Press Officer
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787*

From: Sharan, Martha (CDC/NCEZID/DHQP/OD)

Sent: Tuesday, February 20, 2024 8:57 AM

To: Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>
Cc: Gill, Curtis (CDC/NCEZID/DHQP/OD) (CTR) <qsi3@cdc.gov>
Subject: RE: GVDN paper

Hi Tanya – will check, but if there is any additional it was published without involving DHQP. We did not get any media inquiries directly

Thanks,
Martha

Martha Sharan
Press Officer
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
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From: Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>
Sent: Tuesday, February 20, 2024 8:52 AM
To: Sharan, Martha (CDC/NCEZID/DHQP/OD) <liu4@cdc.gov>; Gill, Curtis (CDC/NCEZID/DHQP/OD) (CTR) <qsi3@cdc.gov>
Subject: GVDN paper

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Forbes

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From: Gee, Julianne (CDC/NCEZID/DHQP/ISO)
Sent: Thu, 22 Feb 2024 17:35:29 +0000
To: Su, John (CDC/NCEZID/DHQP/ISO); Sharan, Martha (CDC/NCEZID/DHQP/OD)
Cc: Hamburger, Tanya (CDC/NCEZID/DHQP/OD); Carter, Danielle (CDC/NCEZID/DHQP/OD); Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD)
Subject: Re: GVDN paper

This was most likely intentional. We knew about this being on BBC Science in Action earlier this week.

From: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>
Sent: Thursday, February 22, 2024 12:31 PM
To: Sharan, Martha (CDC/NCEZID/DHQP/OD) <liu4@cdc.gov>; Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>
Cc: Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>; Carter, Danielle (CDC/NCEZID/DHQP/OD) <lwu9@cdc.gov>; Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD) <ybz5@cdc.gov>
Subject: RE: GVDN paper

The GVDN paper is getting media attention because of its media release: the title of the podcast includes language taken straight from the release. 🙄

I'll add their cohort was 99 million vaccinated persons; the U.S. has 230 million who've completed primary series vaccination. We've also got almost 253 million doses of Moderna vaccine administered. Arguably, ours is bigger. 🙄 (Although technically those data are not a study.)

At least we have talking points now.

- John

From: Sharan, Martha (CDC/NCEZID/DHQP/OD) <liu4@cdc.gov>
Sent: Thursday, February 22, 2024 12:22 PM
To: Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>
Cc: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>; Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>; Carter, Danielle (CDC/NCEZID/DHQP/OD) <lwu9@cdc.gov>; Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD) <ybz5@cdc.gov>
Subject: FW: GVDN paper

Hi everyone – Curt has been keeping an eye on this.

It's showing up as the lead topic on the next podcast, but it still hasn't posted - maybe in about 15 min.

[BBC World Service - Science In Action, Largest ever covid safety study](#)

Thanks,

Martha

Martha Sharan
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CDC/Division of Healthcare Quality Promotion
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From: Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>
Sent: Tuesday, February 20, 2024 8:45 PM
To: Sharan, Martha (CDC/NCEZID/DHQP/OD) <liu4@cdc.gov>; Gill, Curtis (CDC/NCEZID/DHQP/OD) (CTR) <qsi3@cdc.gov>; Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>; Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>
Cc: Carter, Danielle (CDC/NCEZID/DHQP/OD) <lwu9@cdc.gov>; Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD) <ybz5@cdc.gov>
Subject: RE: GVDN paper

Hi everyone!

I was told that the article will be highlighted tomorrow on BBC's [Science in Action](#).

-Julianne

From: Sharan, Martha (CDC/NCEZID/DHQP/OD) <liu4@cdc.gov>
Sent: Tuesday, February 20, 2024 2:20 PM
To: Gill, Curtis (CDC/NCEZID/DHQP/OD) (CTR) <qsi3@cdc.gov>; Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>; Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>; Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>
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A few additional:

- [Large study funded by CDC identifies rare COVID-19 vaccine risks \(ScrippsNews\)](#)
- [COVID vaccines linked to neurological, blood, and heart-related issues \(Earth\)](#)
- [COVID vaccines linked to slight increases in heart, brain, blood disorders: study \(NYPost\)](#)

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Thanks Curt!

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MSN

[Largest-ever COVID vaccine study links shot to small increase in heart and brain conditions \(msn.com\)](#)

From: Hall, Aron (CDC/NCIRD/CORVD)
Sent: Tue, 20 Feb 2024 17:39:24 +0000
To: Daskalakis, Demetre (CDC/NCIRD/OD); Su, John (CDC/NCEZID/DHQP/ISO); Barry, Brooke (CDC/NCIRD/OD); Wentworth, David E. (CDC/NCIRD/CORVD); Bell, Michael MD (CDC/NCEZID/DHQP/OD); Hardister, Elizabeth (CDC/NCIRD/OD); Greco Kone, Rebecca (CDC/NCIRD/OD)
Cc: Limbago, Brandi (CDC/NCIRD/OD); Jernigan, Daniel B. (CDC/NCEZID/OD)
Subject: RE: IOD REQUEST
Attachments: RE: IOD REQUEST

Not to pre-empt our ISO colleagues (and welcome further input/clarification directly), but Megan Wallace graciously provided the attached response/docs from our ISO colleagues.

Aron

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Tuesday, February 20, 2024 12:31 PM
To: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>; Barry, Brooke (CDC/NCIRD/OD) <bmb8@cdc.gov>; Wentworth, David E. (CDC/NCIRD/CORVD) <gl19@cdc.gov>; Hall, Aron (CDC/NCIRD/CORVD) <esg3@cdc.gov>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>; Hardister, Elizabeth (CDC/NCIRD/OD) <prz8@cdc.gov>; Greco Kone, Rebecca (CDC/NCIRD/OD) <ftm1@cdc.gov>
Cc: Limbago, Brandi (CDC/NCIRD/OD) <bbl7@cdc.gov>; Jernigan, Daniel B. (CDC/NCEZID/OD) <dbj0@cdc.gov>
Subject: RE: IOD REQUEST

Thanks. Please provide more details as soon as possible.

1. Would ne good to know who/how funded
2. TPs sooner than later would be helpful- sorry for the push.

Thanks!
Demetre

Demetre C. Daskalakis, M.D., M.P.H. (he/his)
Director
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, GA 30329-4027
Email: ddaskalakis@cdc.gov or yzq5@cdc.gov
Special Assistant: Elizabeth Hardister prz8@cdc.gov
Executive Assistant: Darrell Grier ung9@cdc.gov

From: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>
Sent: Tuesday, February 20, 2024 12:13 PM

To: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>; Barry, Brooke (CDC/NCIRD/OD) <bmb8@cdc.gov>; Wentworth, David E. (CDC/NCIRD/CORVD) <gll9@cdc.gov>; Hall, Aron (CDC/NCIRD/CORVD) <esg3@cdc.gov>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>; Hardister, Elizabeth (CDC/NCIRD/OD) <prz8@cdc.gov>; Greco Kone, Rebecca (CDC/NCIRD/OD) <ftm1@cdc.gov>
Cc: Limbago, Brandi (CDC/NCIRD/OD) <bbl7@cdc.gov>; Jernigan, Daniel B. (CDC/NCEZID/OD) <dbj0@cdc.gov>
Subject: RE: IOD REQUEST

Hi Demetre,

GVDN was funded by a grant from CDC, funds for which came from COVID-19 funds. We can get back to you with more details as desired.

(b)(5)

- John

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Tuesday, February 20, 2024 11:30 AM
To: Barry, Brooke (CDC/NCIRD/OD) <bmb8@cdc.gov>; Wentworth, David E. (CDC/NCIRD/CORVD) <gll9@cdc.gov>; Hall, Aron (CDC/NCIRD/CORVD) <esg3@cdc.gov>; Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>; Hardister, Elizabeth (CDC/NCIRD/OD) <prz8@cdc.gov>; Greco Kone, Rebecca (CDC/NCIRD/OD) <ftm1@cdc.gov>
Cc: Limbago, Brandi (CDC/NCIRD/OD) <bbl7@cdc.gov>; Jernigan, Daniel B. (CDC/NCEZID/OD) <dbj0@cdc.gov>
Subject: Re: IOD REQUEST

+ Rebecca

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From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Tuesday, February 20, 2024 11:27:51 AM
To: Barry, Brooke (CDC/NCIRD/OD) <bmb8@cdc.gov>; Wentworth, David E. (CDC/NCIRD/CORVD) <gll9@cdc.gov>; Hall, Aron (CDC/NCIRD/CORVD) <esg3@cdc.gov>; Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>; Hardister, Elizabeth (CDC/NCIRD/OD) <prz8@cdc.gov>
Cc: Limbago, Brandi (CDC/NCIRD/OD) <bbl7@cdc.gov>; Jernigan, Daniel B. (CDC/NCEZID/OD)

<dbj0@cdc.gov>

Subject: IOD REQUEST

Hi there!

Getting a request from iOD about this study. Do we know where in CDC funds this network or study. We have also been asked for a few TPs on this study. I have included ISO colleagues in case they have more insight.

<https://www.msn.com/en-us/health/other/ar-BB1iuvvi>

Questions:

1. what is CDC involvement?
2. What are the top line messages (TPs) that we can share.

[@Hardister, Elizabeth \(CDC/NCIRD/OD\)](#) can you help chase this down?

Thanks

Demetre

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From: Wallace, Megan (CDC/NCIRD/CORVD)
Sent: Tue, 20 Feb 2024 17:25:37 +0000
To: Fleming-Dutra, Katherine E. (CDC/NCIRD/CORVD); Hall, Aron (CDC/NCIRD/CORVD); McMorrow, Meredith (CDC/NCIRD/CORVD); Patel, Pragna (CDC/NCIRD/CORVD)
Cc: Wentworth, David E. (CDC/NCIRD/CORVD)
Subject: RE: IOD REQUEST
Attachments: Media release FINAL - GVDN observed vs expected 19Feb2024.pdf, Supporting communications FINAL- GVDN observed vs expected 19Feb2024.docx

Hi all,

Attached are the talking points provided from ISO. I don't think the myocarditis/pericarditis information is anything we didn't already know. (b)(5)

(b)(5)

(b)(5) It's also important to note the absolute risk captured here is exceedingly low (five more observed than expected events based on 1,035,871 person-years and 10.5 million doses administered). In the discussion of this paper they also point to [this paper](#) which concluded that chances of having a neurological event following acute SARS-CoV-2 infection were up to 617-fold higher than following COVID vaccination.

(b)(5)

All the best,
Megan

From: Fleming-Dutra, Katherine E. (CDC/NCIRD/CORVD) <ftu2@cdc.gov>
Sent: Tuesday, February 20, 2024 11:33 AM
To: Hall, Aron (CDC/NCIRD/CORVD) <esg3@cdc.gov>; McMorrow, Meredith (CDC/NCIRD/CORVD) <bwe3@cdc.gov>; Patel, Pragna (CDC/NCIRD/CORVD) <plp3@cdc.gov>; Wallace, Megan (CDC/NCIRD/CORVD) <phu3@cdc.gov>
Cc: Wentworth, David E. (CDC/NCIRD/CORVD) <gll9@cdc.gov>
Subject: RE: IOD REQUEST

+ Megan who is aware of this paper already for her input (although she is out tomorrow), but I think this is mostly in ISO's lane

From: Hall, Aron (CDC/NCIRD/CORVD) <esg3@cdc.gov>
Sent: Tuesday, February 20, 2024 11:31 AM
To: Fleming-Dutra, Katherine E. (CDC/NCIRD/CORVD) <ftu2@cdc.gov>; McMorrow, Meredith (CDC/NCIRD/CORVD) <bwe3@cdc.gov>; Patel, Pragna (CDC/NCIRD/CORVD) <plp3@cdc.gov>
Cc: Wentworth, David E. (CDC/NCIRD/CORVD) <gll9@cdc.gov>
Subject: FW: IOD REQUEST
Importance: High

Katherine, Meredith, and Pragna,

Do you have any insights on the study ([COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network \(GVDN\) cohort study of 99 million vaccinated individuals - ScienceDirect](#)) referenced in the news story below? If not, could we please identify an appropriate SME to review and provide CORVD input? Seem mostly in ISO lane, but I'm sure our SMEs would have valuable perspective.

Thanks,
Aron

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Tuesday, February 20, 2024 11:28 AM
To: Barry, Brooke (CDC/NCIRD/OD) <bmb8@cdc.gov>; Wentworth, David E. (CDC/NCIRD/CORVD) <gll9@cdc.gov>; Hall, Aron (CDC/NCIRD/CORVD) <esg3@cdc.gov>; Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>; Hardister, Elizabeth (CDC/NCIRD/OD) <prz8@cdc.gov>
Cc: Limbago, Brandi (CDC/NCIRD/OD) <bbl7@cdc.gov>; Jernigan, Daniel B. (CDC/NCEZID/OD) <dbj0@cdc.gov>
Subject: IOD REQUEST
Importance: High

Hi there!

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<https://www.msn.com/en-us/health/other/ar-BB1iuvvi>

Questions:

1. what is CDC involvement?
2. What are the top line messages (TPs) that we can share.

[@Hardister, Elizabeth \(CDC/NCIRD/OD\)](#) can you help chase this down?

Thanks
Demetre

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Media Release

19 February 2024

99 million people included in largest global vaccine safety study

Global Vaccine Data Network utilises vast data sets to detect potential vaccine safety signals

The Global Vaccine Data Network (GVDN) assessed 13 neurological, blood, and heart related medical conditions to see if there was a greater risk of them occurring after receiving a COVID-19 vaccine. This was one of eight studies in the [Global COVID Vaccine Safety \(GCoVS\) Project](#).

Recently published in the journal [Vaccine](#), this observed versus expected rates study included 99 million people (over 23 million person-years of follow-up) from 10 collaborator sites across eight countries. The study identified the pre-established safety signals for myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the thin sac covering the heart) after **mRNA vaccines**, and Guillain-Barré syndrome (muscle weakness and changed sensation (feeling)), and cerebral venous sinus thrombosis (type of blood clot in the brain) after **viral vector vaccines**.

Possible safety signals for **transverse myelitis** (inflammation of part of the spinal cord) after viral vector vaccines and **acute disseminated encephalomyelitis** (inflammation and swelling in the brain and spinal cord) after viral vector and mRNA vaccines were identified. So far, these findings were further investigated by the GVDN site in Victoria, Australia. Their study and results are described in the [accompanying paper](#).

Results are available for public review on GVDN's [interactive data dashboards](#).

Observed versus expected analyses are used to detect potential vaccine safety signals. These studies look at all people who received a vaccine and examine if there is a greater risk for developing a medical condition in various time periods after getting a vaccine compared with a period before the vaccine became available.

Lead author Kristýna Faksová of the Department of Epidemiology Research, Statens Serum Institut, Copenhagen, Denmark, remarked that use of a common protocol and aggregation of the data through the GVDN makes studies like this possible. "The size of the population in this study increased the possibility of identifying rare potential vaccine safety signals," she explains. "Single sites or regions are unlikely to have a large enough population to detect very rare signals."

GVDN Co-Director Dr. Steven Black states, "GVDN supports a coordinated global effort to assess vaccine safety and effectiveness so that vaccine questions can be addressed in a more rapid, efficient, and cost-effective manner. We have a number of studies underway to build upon our understanding of vaccines and how we understand vaccine safety using big data."

GVDN Co-Director Dr. Helen Petousis-Harris states, "By making the data dashboards publicly available, we are able to support greater transparency, and stronger communications to the health sector and public."

The GCoVS Project was made possible with support by the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (HHS) to allow the comparison of the safety of vaccines across diverse global populations.

[About the Global Vaccine Data Network \(GVDN\)](#)



Established in 2019 and with data sourced from millions of individuals across six continents, the GVDN collaborates with renowned research institutions, policy makers, and vaccine related organisations to establish a harmonised and evidence-based approach to vaccine safety and effectiveness. The GVDN is supported by the Global Coordinating Centre based at Auckland UniServices Ltd, a not-for-profit, stand-alone company that provides support to researchers and is wholly owned by the University of Auckland. Aiming to gain a comprehensive understanding of vaccine safety and effectiveness profiles, the GVDN strives to create a safer immunisation landscape that empowers decision making for the global community. For further information, visit globalvaccinatedatane트워크.org.

Disclaimer:

This news release summarises the key findings of the GVDN observed versus expected study. To view the full publication in Vaccine, visit doi.org/10.1016/j.vaccine.2024.01.100. This project is supported by the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totalling US\$10,108,491 with 100% percentage funded by CDC/HHS. The contents are those of the author and do not necessarily represent the official views of, nor an endorsement by, CDC/HHS, or the U.S. Government. For more information, please visit cdc.gov.

ENDS

Media inquiries: gvdn@auckland.ac.nz and communications@uniservices.co.nz

Supporting communications

Observed vs. expected study paper and data dashboard publication

19 February 2024

GVDN LinkedIn post 1

Global Vaccine Data Network announces the launch of informative data dashboards using health data from around the world to identify potential vaccine risks and safety signals. In collaboration with key partners, Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (HHS), the dashboards are a result of a coordinated global effort.

Now available to the medical and scientific community, the media, and the public, the data dashboards provide unparalleled information to many vaccine-related questions, opening a new door to transparency and vaccine safety.

([link to dashboards](#))

GVDN LinkedIn post 2

Global Vaccine Data Network has announced the publication of COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network (GVDN) cohort study of 99 million vaccinated individuals in Vaccine and the accompanying release of interactive data dashboards – the culmination of nearly three years of work by many collaborators. We are proud of this groundbreaking work and the immense impact it will have, providing clear and strong communication to the health sector and public about how we understand vaccine safety.

(link to [Vaccine](#))

Communication announcement / Extranet post

Global Vaccine Data Network (GVDN) has announced the publication of *COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network (GVDN) cohort study of 99 million vaccinated individuals* in [Vaccine](#) and the accompanying release of interactive data dashboards – the culmination of nearly three years of work by many collaborators. We are proud of this groundbreaking work and the immense impact it will have, providing clear and strong communication to the health sector and public about how we understand vaccine safety.

This study assessed 13 neurological, blood, and heart related medical conditions to see if there was a greater risk of them happening after receiving a COVID-19 vaccine. This was one of eight studies in the Global COVID Vaccine Safety Project. The study identified the pre-established safety signals for myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the thin sac covering the heart) after mRNA vaccines, and Guillain-Barré syndrome (muscle weakness and changed sensation (feeling), and cerebral venous sinus thrombosis (type of blood clot in the brain) after viral vector vaccines.

Possible safety signals for transverse myelitis (inflammation of part of the spinal cord) after viral vector vaccines and acute disseminated encephalomyelitis (inflammation and swelling in the brain and spinal cord) after viral vector and mRNA vaccines were identified. These findings require further investigation.



Data are available for public review on GVDN's [interactive data dashboards](#).

We want to recognise lead author Kristýna Faksová of the Department of Epidemiology Research, Statens Serum Institut, Copenhagen, Denmark, and everyone internally and externally who contributed to The Global COVID Vaccine Safety (GCoVS) Project, bringing this work to life.

With this accomplishment, our work moves forward to critical next steps ensuring that vaccine safety and effectiveness research continues at the international level to better understand the very rare and adverse risks that exist, and which can only be studied through surveillance of very large populations.

Thank you all for your tremendous contributions.

Steven Black, GVDN Co-Director

Helen Petousis-Harris, GVDN Co-Director

Jim Buttery, GVDN Co-Director

Toolkit for GVDN Partners

Talking points/Key messages

- This is the largest global vaccine safety study of its kind.
- It was published in the journal [Vaccine](#) in February 2024.
- The study included 99 million people from 10 sites across eight countries and commenced in 2021.
- GVDN is committed to transparency and has provided interactive dashboards so that expedient and comprehensive information is available to the health sector, media, and the public.
- This type of study compares the risk for an adverse event in various periods after exposure to a vaccine and is an excellent approach for detecting potential rare safety signals for further study.
- The study confirmed pre-established safety signals for myocarditis, pericarditis following mRNA vaccines and, Guillain-Barré syndrome, and cerebral venous sinus thrombosis following viral vector vaccines.
- Possible safety signals for transverse myelitis after viral vector vaccines and acute disseminated encephalomyelitis after viral vector and mRNA vaccines were identified and informed further investigations.
- The size of the population being studied increased the possibility of identifying rare potential vaccine safety signals that single sites or regions are unlikely to have a large enough population to find.
- This was one of eight studies in the Global COVID Vaccine Safety Project.
- The Global COVID Vaccine Safety (GCoVS) Project, established in 2021 under the multinational Global Vaccine Data Network™ (GVDN®), facilitates comprehensive assessment of vaccine safety.
- The GVDN works with over 30 partners and collaborators across six continents in the areas of vaccine research, regulation, and government policy.
- Some of the GVDN's major international partners and collaborators include the US CDC, Brighton Collaboration, VAC4EU, and the African Local Initiative for Vaccinology Expertise (ALIVE).
- Results are available for public review on GVDN's [interactive data dashboards](#).
- The lead author of the manuscript is Kristýna Faksová of the Department of Epidemiology Research, Statens Serum Institut, Copenhagen, Denmark.



LinkedIn sample post

An impressive coordinated global effort, our partners at Global Vaccine Data Network announced the launch of a new data dashboard that serves as a critical resource for understanding vaccine risks and safety signals. The largest-ever vaccine safety study, these efforts reach beyond what single sites or regions would be able to amass. GVDN's efforts culled data from 99 million people from 10 sites across eight countries providing clear and strong communication to the health sector and public about how we understand vaccine safety.

[PARTNER ORGANISATION] is delighted to be a collaborator and we recognise and thank the GVDN for leading the way, as well as members of our organisation who contributed to The Global COVID Vaccine Safety (GCoVS) Project.

The dashboards are a groundbreaking tool as GVDN works with partners to grow capacity for active vaccine safety surveillance.

Read the full press release and access the dashboards here.

Facebook posts

Option 1

The largest-ever vaccine safety study was just published by our partners at Global Vaccine Data Network, giving the health sector and public access to informative, interactive data dashboards. GVDN is committed to transparency and ensuring expedient and comprehensive information is available to all. Visit the dashboards to find the results of their study including 99 million people from 10 sites across eight countries.

Link: Read the full press release and access the dashboards here.

Option 2

An important component to public's understanding of vaccine safety is access to information and clear data on the very rare risks. Now, the public has access to the largest-ever vaccine safety study with Global Vaccine Data Network's data dashboard.

Link: Read the full press release and access the dashboards here.

Option 3

With our partners at Global Vaccine Data Network, [PARTNER ORGANISATION] is excited to announce the launch of new interactive data dashboards that gives the health sector and the public access to vast vaccine safety data. The result of a global collaboration, the data informed a study including 99 million people from 10 sites across eight countries, the largest-ever of its kind.

Link: Read the full press release and access the dashboards here.

X (previously Twitter) posts

Option 1



NEW: Global Vaccine Data Network launched data dashboards. Utilising data from 99 million people, 10 sites, and 8 countries, anyone can access data on potential rare vaccine risks, opening doors clearer understanding of vaccine safety. Link: <https://www.globalvaccinedatanetwork.org/Data-Dashboards>

Option 2

An incredible accomplishment, Global Vaccine Data Network launched interactive public data dashboards to share vast information on vaccine safety and transparency. The result of a global effort, we are proud to be a collaborator. Learn more here: <https://www.globalvaccinedatanetwork.org/Data-Dashboards>

Option 3

ANNOUNCEMENT: Access unprecedented new data dashboards from our partners at Global Vaccine Data Network. Includes rare vaccine risk and safety data culled from 99 million people, 10 sites, and across 8 countries. <https://www.globalvaccinedatanetwork.org/Data-Dashboards>

Questions & answers

1) Why does having a larger population from many countries increase the strength of the study's results?

The size of the population being studied increased the possibility of identifying rare potential vaccine safety signals that single sites or regions are unlikely to have a large enough population to find.

To detect very rare events that may be associated with vaccines we need very large populations because:

- To identify a two-fold risk of a vaccine-associated event that occurs in once in 100,000 people, we need to compare 2.35 million people who have received the vaccine with 2.35 million people who have not.
- There is wide variability in the types and manufacturers of vaccines used in different countries.
- We need to explore the risk in subgroups such as older people and children.

2) If there are known risks in vaccines, why is the public encouraged to continue to get vaccinated?

The risks identified through these vast studies are incredibly rare and GVDN's work allows for vaccine questions to be addressed in a more rapid, efficient, and cost-effective manner to provide clearer communication to the public.

3) How does GVDN's work address vaccine hesitancy?

While vaccine hesitancy and anti-vaccine communication have become global and resources to address these issues have been developed, the ability to respond to such concerns has remained largely fractured without coordination between countries.

With increasing use of large-linked health databases in many countries of the world and multi-country collaborations, it is now possible to standardise approaches and rapidly evaluate rare vaccine safety concerns through initiatives such as the Global Vaccine Data Network™.

4) Are patients aware that their medical data is being utilised in a global study?

Using a common protocol, this observational cohort study compared observed with expected rates of 13 selected AESI across neurological, haematological, and cardiac outcomes. Expected rates were obtained by participating sites using pre-COVID-19 vaccination healthcare data stratified by age and sex. Vaccinated



individuals are not identifiable in any way and information was procured from electronic healthcare data. The GVDN takes appropriate security measures to protect all data.

5) Why did GVDN conduct this study?

Since declaration of the COVID-19 pandemic by the World Health Organization (WHO) on March 11, 2020, more than 13.5 billion doses of COVID-19 vaccines have been administered worldwide. As of November 2023, at least 70.5% of the world's population had received at least one dose of a COVID-19 vaccine. This unparalleled scenario underscores the pressing need for comprehensive vaccine safety monitoring as very rare adverse events associated with COVID-19 vaccines may only come to light after administration to millions of individuals.

6) What are the eight countries that participated in the study?

Patient types included hospital inpatients (Australia – New South Wales, France, New Zealand, Scotland), and combinations of inpatient and outpatient emergency department patients (Argentina, Australia – Victoria, Canada, Denmark, Finland).

7) What were the study periods and follow up periods?

The study periods varied across countries, commencing on the date of the site-specific COVID-19 vaccination program rollout, and concluding at the end of data availability. In general, the COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network (GVDN) cohort study of 99 million vaccinated individuals spanned from December 2020 until August 2023. The shortest study period observed occurred in Australia – New South Wales, 11 months from February 2021 to December 2021. Argentina had the longest study period, from December 2020 to August 2023, encompassing a total of 32 months.

8) For how long after vaccination doses was patient data observed?

The risk intervals used after each dose were 0–7 days, 8–21 days, 22–42 days, and 0–42 days. For each vaccination dose, day 0 was denoted the day of vaccine receipt.

9) What vaccines were researched for the purposes of this study?

The study included 14 vaccines in use across the participating sites:

- Comirnaty or Riltazinameran or Pfizer/BioNTech COVID-19 Vaccine Bivalent [Pfizer/BioNTech]
- Comirnaty or Tozinameran Paediatric [Pfizer/BioNTech or Fosun-BioNTech]
- Convidecia or Convidence [CanSino]
- CoronaVac or Sinovac [Sinovac Biotech]
- Covaxin [Bharat Biotech]
- Covilo or SARS-CoV-2 Vaccine (Vero Cell) [Sinopharm (Beijing)]
- Covovax or Nuvaxoid [Novavax or Serum Institute of India]
- Elasomeran or Spikevax or TAK-919 Half Dose [Moderna or Takeda]
- Inactivated (Vero cell) [Sinopharm (Wuhan)]
- Janssen [Janssen/Johnson & Johnson]
- MVC-COV1901 [Medigen]
- Spikevax bivalent Original/Omicron [Moderna]
- Sputnik Light or Gam-COVID-Vac [Gamaleya Research Institute]
- Sputnik V [Gamaleya Research Institute]



For the paper and the resulting data dashboards, we focused on three vaccines that recorded the highest number of doses administered, Pfizer/BioNTech BNT162b2, Moderna mRNA-1273, and Oxford/Astra Zeneca/Serum Institute of India ChAdOx1 vaccines.

10) What ages were the participants considered in the study?

All ages eligible to receive vaccine were included. Expected rates were obtained by participating sites using pre-COVID-19 vaccination healthcare data stratified by age and sex only. Other specific demographic factors were not part of the study.

11) What were the greatest potential risks identified and noted for further study?

The study identified the pre-established safety signals for myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the thin sac covering the heart) after mRNA vaccines, and Guillain-Barré syndrome (muscle weakness and changed sensation (feeling), and cerebral venous sinus thrombosis (type of blood clot in the brain) after viral vector vaccines.

Possible safety signals for transverse myelitis (inflammation of part of the spinal cord) after viral vector vaccines and acute disseminated encephalomyelitis (inflammation and swelling in the brain and spinal cord) after viral vector and mRNA vaccines were identified. So far, these findings have been further investigated by the GVDN site in Victoria, Australia. Their study and results are described in the [accompanying paper](#).

12) Are there limitations to be considered within this study?

We consider our approach suitable for application in large datasets representing average populations. Differences in healthcare infrastructure and surveillance across countries may be a limiting factor. Also, age- and sex-specific historic background rates that are not adjusted for factors like prior disease may not provide a suitable comparison, for example, in the early stages of a vaccination campaigns where people with co-morbidities were vaccinated prior to other population groups.

This type of approach is designed to detect possible safety signals for follow up and is therefore sensitive. Other studies are required to verify signals.

13) Where does GVDN get its funding?

The GVDN works closely with vaccine safety experts around the world, global health agencies, and other global non-profit health alliances. The GVDN received seeding money from the Gates Foundation in 2019 for a meeting, relies on research grants for specific vaccine safety monitoring projects, and is hosted by UniServices, a not-for-profit company that is wholly owned by Waipapa Taumata Rau | University of Auckland.

The GCoVS project specifically is supported by the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totalling US\$10,108,491 with 100% per cent funded by CDC/HHS.

The Ontario site contributing to this study was supported by Public Health Ontario and by ICES, which is funded by an annual grant from the Ontario Ministry of Health. JCK is supported by a Clinician-Scientist Award from the University of Toronto Department of Family and Community Medicine.

14) What is a viral vector vaccine?



Viral vector vaccines use a modified version of a different virus as a vector to deliver protection.

15) Does GVDN work on other projects besides Global COVID Vaccine Safety (GCoVS) Project?

Yes. [Click here](#) to view other GVDN projects.

16) Are there additional studies taking place?

Yes. We have a number of studies underway to build upon our understanding of vaccines and how we understand vaccine safety using big data. [Click here](#) to view other GVDN projects.

17) Who is the intended audience for the GVDN's data dashboards?

The intended audience for the GVDN website, dashboard(s), protocol(s), and blog(s) are:

Individuals, groups, and institutions interested in vaccines, vaccine safety and effectiveness and communicating about vaccines, including:

- Global health agencies, global non-profit alliances, and national health bodies
- Health professional groups and colleges
- Health professionals
- Academics and researchers
- Community leaders who want to guide and support local confidence in vaccines and vaccine safety
- A broad public audience interested in how vaccine safety is being monitored
- Countries looking at the infrastructure needed to monitor vaccine effectiveness and safety

18) Where can media requests and questions be directed?

Media inquiries: gvdn@auckland.ac.nz and communications@uniservices.co.nz.

From: Goodman, Jeremy A. (CDC/NCEZID/DHQP/OD)
Sent: Tue, 20 Feb 2024 17:18:05 +0000
To: Kroop, Seth (CDC/NCEZID/DHQP/OD); Bell, Michael MD (CDC/NCEZID/DHQP/OD); Su, John (CDC/NCEZID/DHQP/ISO); Gee, Julianne (CDC/NCEZID/DHQP/ISO); Broder, Karen (CDC/NCEZID/DHQP/ISO); Hamburger, Tanya (CDC/NCEZID/DHQP/OD); Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD); Helfand, Rita (CDC/NCEZID/OD); Nordlund, Kristen (CDC/NCEZID/OD)
Cc: Jernigan, Daniel B. (CDC/NCEZID/OD)
Subject: RE: IOD REQUEST
Attachments: BLUF GVDN .docx

Attached is the BLUF DHQP prepped for the hearing. Regarding the funding, Julianne and John can confirm but my understanding was this was COVID-19 supplemental funding.

Jeremy Goodman, MBA (*he/him/his*)
Public Health Analyst, Policy Team
Division of Healthcare Quality Promotion, Office of the Director
Centers for Disease Control and Prevention
404-639-3325

From: Kroop, Seth (CDC/NCEZID/DHQP/OD) <wpw7@cdc.gov>
Sent: Tuesday, February 20, 2024 12:15 PM
To: Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>; Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>; Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>; Broder, Karen (CDC/NCEZID/DHQP/ISO) <krb2@cdc.gov>; Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>; Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD) <ybz5@cdc.gov>; Helfand, Rita (CDC/NCEZID/OD) <rz7@cdc.gov>; Nordlund, Kristen (CDC/NCEZID/OD) <hok4@cdc.gov>; Goodman, Jeremy A. (CDC/NCEZID/DHQP/OD) <vhj2@cdc.gov>
Cc: Jernigan, Daniel B. (CDC/NCEZID/OD) <dbj0@cdc.gov>
Subject: RE: IOD REQUEST

Adding [@Goodman, Jeremy A. \(CDC/NCEZID/DHQP/OD\)](#) because I think he may have worked with ISO on some talking points and background info re this study for the hearing last week.

From: Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>
Sent: Tuesday, February 20, 2024 12:10 PM
To: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>; Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>; Broder, Karen (CDC/NCEZID/DHQP/ISO) <krb2@cdc.gov>; Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>; Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD) <ybz5@cdc.gov>; Helfand, Rita (CDC/NCEZID/OD) <rz7@cdc.gov>; Nordlund, Kristen (CDC/NCEZID/OD) <hok4@cdc.gov>; Kroop, Seth (CDC/NCEZID/DHQP/OD) <wpw7@cdc.gov>
Cc: Jernigan, Daniel B. (CDC/NCEZID/OD) <dbj0@cdc.gov>
Subject: Fwd: IOD REQUEST

Expanding within our shop for awareness/contribution.

-m

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Tuesday, February 20, 2024 11:30 AM
To: Barry, Brooke (CDC/NCIRD/OD) <bmb8@cdc.gov>; Wentworth, David E. (CDC/NCIRD/CORVD) <gll9@cdc.gov>; Hall, Aron (CDC/NCIRD/CORVD) <esg3@cdc.gov>; Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>; Hardister, Elizabeth (CDC/NCIRD/OD) <prz8@cdc.gov>; Greco Kone, Rebecca (CDC/NCIRD/OD) <ftm1@cdc.gov>
Cc: Limbago, Brandi (CDC/NCIRD/OD) <bbl7@cdc.gov>; Jernigan, Daniel B. (CDC/NCEZID/OD) <dbj0@cdc.gov>
Subject: Re: IOD REQUEST

+ Rebecca

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From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Tuesday, February 20, 2024 11:27:51 AM
To: Barry, Brooke (CDC/NCIRD/OD) <bmb8@cdc.gov>; Wentworth, David E. (CDC/NCIRD/CORVD) <gll9@cdc.gov>; Hall, Aron (CDC/NCIRD/CORVD) <esg3@cdc.gov>; Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>; Hardister, Elizabeth (CDC/NCIRD/OD) <prz8@cdc.gov>
Cc: Limbago, Brandi (CDC/NCIRD/OD) <bbl7@cdc.gov>; Jernigan, Daniel B. (CDC/NCEZID/OD) <dbj0@cdc.gov>
Subject: IOD REQUEST

Hi there!

Getting a request from iOD about this study. Do we know where in CDC funds this network or study. We have also been asked for a few TPs on this study. I have included ISO colleagues in case they have more insight.

<https://www.msn.com/en-us/health/other/ar-BB1iuvvi>

Questions:

1. what is CDC involvement?
2. What are the top line messages (TPs) that we can share.

[@Hardister, Elizabeth \(CDC/NCIRD/OD\)](#) can you help chase this down?

Thanks
Demetre

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- The journal *Vaccine* has posted an in-press article which uses data from The Global Vaccine Data Network (GVDN). This multinational study includes data on over 99 million individuals who received various COVID-19 vaccines.
- This global cohort study conducted Observed vs. Expected analyses of selected Adverse Events of Special Interest after COVID-19 vaccination, using data from eight countries participating in the Global COVID Vaccine Safety (GCoVS) Project of the Global Vaccine Data Network (GVDN).
- The GCoVS Project, initiated in 2021, is a Centers for Disease Control and Prevention (CDC)-funded global collaboration of investigators and data sources from multiple nations for the purpose of COVID-19 vaccine safety monitoring.
- This study corroborated many of the outcomes previously identified by other vaccine safety systems, including those of CDC and FDA, as associated or possibly associated with COVID-19 vaccination. These outcomes include myocarditis/pericarditis following mRNA vaccines, and CVST (likely reflecting TTS) and GBS following Janssen vaccine.
- A potential safety signal for acute disseminated encephalomyelitis (ADEM) after receipt of the Moderna RNA vaccine was noted. However, only a few cases were identified (7 cases out of 36 million Moderna RNA vaccine recipients), and ADEM is a rare condition. The authors noted that additional study of this potential signal was required.
- While this study had a large population to detect very rare adverse events, it used electronically coded data to identify potential cases, and did not confirm those cases using medical records. These data came from different systems that may use different coding practices. Whether these results were driven by one site is therefore unknown.
- To follow up on these results, a large Australian site conducted a self-controlled case series analysis to examine the associations of ADEM and transverse myelitis (TM) with COVID-19 vaccination. This study did not find an association with ADEM and Moderna's vaccine. It did find that ADEM and TM were associated with Astra Zeneca's vaccine. The in-press paper describing these study results is posted on *Vaccine's* website.
- Almost 253 million doses of Moderna mRNA COVID-19 vaccine have been administered in the United States. However, CDC vaccine safety surveillance systems (including the Vaccine Safety Datalink (VSD) and the Vaccine Adverse Event Reporting System (VAERS)) have identified no safety signal for ADEM and this vaccine.

From: Su, John (CDC/NCEZID/DHQP/ISO)
Sent: Wed, 21 Feb 2024 22:33:30 +0000
To: Daskalakis, Demetre (CDC/NCIRD/OD); Barry, Brooke (CDC/NCIRD/OD); Wentworth, David E. (CDC/NCIRD/CORVD); Hall, Aron (CDC/NCIRD/CORVD); Bell, Michael MD (CDC/NCEZID/DHQP/OD); Hardister, Elizabeth (CDC/NCIRD/OD); Greco Kone, Rebecca (CDC/NCIRD/OD)
Cc: Limbago, Brandi (CDC/NCIRD/OD); Jernigan, Daniel B. (CDC/NCEZID/OD)
Subject: RE: IOD REQUEST
Attachments: CLEARED_GVDN COVID-19 Study TPs_022124.docx, CLEARED_AustraliaStudy_COVID-19 Vaccine TPS_022124.docx

Good afternoon, all,

Please see enclosed cleared talking points for the GVDN and accompanying Australian studies that were published in *Vaccine*, the latter of which has attracted media attention. Please let me know if you have any questions. Thanks for your patience!

- John

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Tuesday, February 20, 2024 11:30 AM
To: Barry, Brooke (CDC/NCIRD/OD) <bmb8@cdc.gov>; Wentworth, David E. (CDC/NCIRD/CORVD) <gl19@cdc.gov>; Hall, Aron (CDC/NCIRD/CORVD) <esg3@cdc.gov>; Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>; Hardister, Elizabeth (CDC/NCIRD/OD) <prz8@cdc.gov>; Greco Kone, Rebecca (CDC/NCIRD/OD) <ftm1@cdc.gov>
Cc: Limbago, Brandi (CDC/NCIRD/OD) <bbl7@cdc.gov>; Jernigan, Daniel B. (CDC/NCEZID/OD) <dbj0@cdc.gov>
Subject: Re: IOD REQUEST

+ Rebecca

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From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Tuesday, February 20, 2024 11:27:51 AM
To: Barry, Brooke (CDC/NCIRD/OD) <bmb8@cdc.gov>; Wentworth, David E. (CDC/NCIRD/CORVD) <gl19@cdc.gov>; Hall, Aron (CDC/NCIRD/CORVD) <esg3@cdc.gov>; Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>; Hardister, Elizabeth (CDC/NCIRD/OD) <prz8@cdc.gov>
Cc: Limbago, Brandi (CDC/NCIRD/OD) <bbl7@cdc.gov>; Jernigan, Daniel B. (CDC/NCEZID/OD) <dbj0@cdc.gov>
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[@Hardister, Elizabeth \(CDC/NCIRD/OD\)](#) can you help chase this down?

Thanks
Demetre

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CLEARED REACTIVE TALKING POINTS

Product being announced:

In press publication

Announcement Title: [COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network \(GVDN\) cohort study of 99 million vaccinated individuals - ScienceDirect](#)

If this is a publication, where is this article being published?

[Vaccine](#)

Proposed Announcement Date/Launch:

Available online February 12, 2024

Spokesperson(s):

TBD

(b)(5)

(b)(5)

Obtained by ICANdecide.org via FOIA

(b)(5)

Obtained by ICANdecide.org via FOIA

(b)(5)

Obtained by ICANdecide.org via FOIA

CLEARED REACTIVE TALKING POINTS

Product Being Announced (Publication, Initiative, HAN, Science/Technical Brief, Other [please specify]):
Publication

Announcement Title (Initiative/Publication Name and Topic): Acute disseminated encephalomyelitis and transverse myelitis following COVID-19 vaccination – A self-controlled case series analysis

If this is a publication, where is this article being published? *Vaccine*
[Acute disseminated encephalomyelitis and transverse myelitis following COVID-19 vaccination – A self-controlled case series analysis - ScienceDirect](#)

Proposed Announcement Date/Launch: Feb. 12, 2024

Spokesperson(s): TBD

(b)(5)

(b)(5)

Obtained by ICANdecide.org via FOIA

(b)(5)

Obtained by ICANdecide.org via FOIA

From: Anderson, Steven
Sent: Tue, 13 Feb 2024 17:36:26 +0000
To: Su, John (CDC/NCEZID/DHQP/ISO); Forshee, Richard (FDA/CBER)
Subject: RE: [EXTERNAL] FW: GVDN O/E

Thank you for sharing this John!

Steve

Steve Anderson, Ph.D., M.P.P.
Director
Office of Biostatistics and Pharmacovigilance
Center for Biologics Evaluation and Research
U. S. Food & Drug Administration
10903 New Hampshire Ave.
Bldg 71, Room 5234
Silver Spring, MD 20993

Phone: 240-402-8577

email: steven.anderson@fda.hhs.gov

From: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>
Sent: Tuesday, February 13, 2024 12:04 PM
To: Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>
Subject: [EXTERNAL] FW: GVDN O/E

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi folks,

FYSA: please see below email. The GVDN O/E analysis and Australian self-controlled study are now online at *Vaccine*. Our comms folks are working on talking points; please feel free to have your comms folks reach out to them (or vice versa) to coordinate. Thanks!

(Apologies, meant to send out sooner...)

- John

From: Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>
Sent: Tuesday, February 13, 2024 8:18 AM
To: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>; Craig, Michael R. (CDC/NCEZID/DHQP/OD) <bez7@cdc.gov>; Srinivasan, Arjun (CDC/NCEZID/DHQP/OD) <beu8@cdc.gov>; Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>; Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD) <ybz5@cdc.gov>; Goodman, Jeremy

A. (CDC/NCEZID/DHQP/OD) <vhj2@cdc.gov>; Nordlund, Kristen (CDC/NCEZID/OD) <hok4@cdc.gov>; Kroop, Seth (CDC/NCEZID/DHQP/OD) <wpw7@cdc.gov>
Cc: Fleming-Dutra, Katherine E. (CDC/NCIRD/CORVD) <ftu2@cdc.gov>; Jackson, Brendan R. (CDC/NCIRD/OD) <iyn0@cdc.gov>; Panagiotakopoulos, Lakshmi (CDC/NCIRD/CORVD) <xfq3@cdc.gov>; Wallace, Megan (CDC/NCIRD/CORVD) <phu3@cdc.gov>; Wharton, Melinda (CDC/NCIRD/OD) <mew2@cdc.gov>; Helfand, Rita (CDC/NCEZID/OD) <rz7@cdc.gov>
Subject: RE: GVDN O/E

Good morning,

Vaccine posted the Australian self-controlled case series paper this morning that evaluated ADEM and TM following COVID-19 vaccine. The site that conducted this analysis is a GVDN site.

[Acute disseminated encephalomyelitis and transverse myelitis following COVID-19 vaccination – A self-controlled case series analysis \(sciencedirectassets.com\)](https://www.sciencedirect.com/science/article/pii/S1526957623000000)

I will be with working the vaccine safety comms team to develop talking points.

Thanks,
Julianne

From: Su, John (CDC/NCEZID/DHQP/ISO) <ezu2@cdc.gov>
Sent: Monday, February 12, 2024 1:12 PM
To: Bell, Michael MD (CDC/NCEZID/DHQP/OD) <zzb8@cdc.gov>; Craig, Michael R. (CDC/NCEZID/DHQP/OD) <bez7@cdc.gov>; Srinivasan, Arjun (CDC/NCEZID/DHQP/OD) <beu8@cdc.gov>; Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>; Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD) <ybz5@cdc.gov>; Goodman, Jeremy A. (CDC/NCEZID/DHQP/OD) <vhj2@cdc.gov>; Nordlund, Kristen (CDC/NCEZID/OD) <hok4@cdc.gov>; Kroop, Seth (CDC/NCEZID/DHQP/OD) <wpw7@cdc.gov>
Cc: Fleming-Dutra, Katherine E. (CDC/NCIRD/CORVD) <ftu2@cdc.gov>; Jackson, Brendan R. (CDC/NCIRD/OD) <iyn0@cdc.gov>; Panagiotakopoulos, Lakshmi (CDC/NCIRD/CORVD) <xfq3@cdc.gov>; Wallace, Megan (CDC/NCIRD/CORVD) <phu3@cdc.gov>; Wharton, Melinda (CDC/NCIRD/OD) <mew2@cdc.gov>; Gee, Julianne (CDC/NCEZID/DHQP/ISO) <dzg2@cdc.gov>; Helfand, Rita (CDC/NCEZID/OD) <rz7@cdc.gov>
Subject: GVDN O/E

Hi all,

Just an update: the OE paper for COVID-19 vaccination by GVDN is available online (although I am having difficulties downloading a copy). Please see below link.

- John

[COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network \(GVDN\) cohort study of 99 million vaccinated individuals - ScienceDirect](#)

Sent: Tue, 20 Feb 2024 17:30:36 +0000
To: Bell, Michael MD (CDC/NCEZID/DHQP/OD); Craig, Michael R. (CDC/NCEZID/DHQP/OD); Srinivasan, Arjun (CDC/NCEZID/DHQP/OD); Hamburger, Tanya (CDC/NCEZID/DHQP/OD); Capers, Catherine (Katy) (CDC/NCEZID/DHQP/OD); Goodman, Jeremy A. (CDC/NCEZID/DHQP/OD); Kroop, Seth (CDC/DDID/NCEZID/DHQP); Nordlund, Kristen (CDC/NCEZID/OD); Gee, Julianne (CDC/NCEZID/DHQP/ISO); Broder, Karen (CDC/OID/NCEZID); Sharan, Martha (CDC/NCEZID/DHQP/OD)
Cc: Wallace, Megan (CDC/NCIRD/CORVD); Panagiotakopoulos, Lakshmi (CDC/NCIRD/CORVD); Wharton, Melinda (CDC/NCIRD/OD); Helfand, Rita (CDC/NCEZID/OD)
Subject: update -- media attention
Attachments: RE: GVDN paper

Good afternoon, all,

Please see enclosed.

From: Sharan, Martha (CDC/NCEZID/DHQP/OD)
Sent: Tue, 20 Feb 2024 15:37:07 +0000
To: Hamburger, Tanya (CDC/NCEZID/DHQP/OD); Gee, Julianne (CDC/NCEZID/DHQP/ISO); Su, John (CDC/NCEZID/DHQP/ISO)
Cc: Gill, Curtis (CDC/NCEZID/DHQP/OD) (CTR)
Subject: RE: GVDN paper

Hi Everyone:

Additional coverage below:

[Largest multicountry COVID study links vaccines to potential adverse effects | The Hill](#)

[Covid vaccine study finds link to health symptoms \(gbnews.com\)](#)

[Largest-ever COVID vaccine study links shot to small increase in heart and brain conditions | Fox News](#)

[Largest Covid vaccine study ever finds shots are linked to small increased risk of neurological, blood and heart disorders - but they are still extremely rare | Daily Mail Online](#)

[Covid Vaccine Side Effects: Largest-Ever COVID Vaccine Study Links COVID Shots To Minor Increase in Heart And Brain Issues | Health News, Times Now \(timesnownews.com\)](#)

[Largest multicountry COVID study links vaccines to potential adverse effects \(yahoo.com\) – from The Hill](#)

[Largest Covid-19 vaccine study yet finds links to health conditions | South China Morning Post \(scmp.com\)](#)

[Largest Covid Vaccine Study Yet Finds Links to Health Conditions - Bloomberg](#)

[Largest COVID vaccine study yet evaluates adverse events of special interest \(medicalxpress.com\)](#)

[How dangerous are COVID vaccines? Global study | Fortune Well](#)

[COVID-19 vaccine linked to possible health issues: study \(newsnationnow.com\)](#)

[COVID Vaccines Linked To Slight Increase In Heart And Brain Issues: Large-Scale Study \(medicaldaily.com\)](#)

[Study of 99 million COVID-vaccinated people finds links to brain, heart problems - Washington Times](#)

[People vaccinated for Covid have increased risk of neurological diseases – study — RT World News](#)

[Pfizer, Moderna and AstraZeneca COVID vaccines hurt hearts and minds, says biggest multi-nation study – Firstpost](#)

[Adverse events linked to Covid vaccines revealed in latest study \(biznews.com\)](#)

[Groundbreaking Global Study on 99 Million Vaccinated People Reveals Increases in Neurological, Blood, and Heart Conditions Associated with COVID-19 Vaccines | The Gateway Pundit | by Jim Hoft](#)

Martha Sharan
Press Officer
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Sharan, Martha (CDC/NCEZID/DHQP/OD)
Sent: Tuesday, February 20, 2024 8:57 AM
To: Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>
Cc: Gill, Curtis (CDC/NCEZID/DHQP/OD) (CTR) <qsi3@cdc.gov>
Subject: RE: GVDN paper

Hi Tanya – will check, but if there is any additional it was published without involving DHQP. We did not get any media inquiries directly

Thanks,
Martha

Martha Sharan
Press Officer
CDC/Division of Healthcare Quality Promotion
Off.: 404-639-2683
Cell: 404-998-1787

From: Hamburger, Tanya (CDC/NCEZID/DHQP/OD) <dln7@cdc.gov>
Sent: Tuesday, February 20, 2024 8:52 AM
To: Sharan, Martha (CDC/NCEZID/DHQP/OD) <liu4@cdc.gov>; Gill, Curtis (CDC/NCEZID/DHQP/OD) (CTR) <qsi3@cdc.gov>
Subject: GVDN paper

Hi Martha and Curt,

Sharing these articles on the GVDN story. Have you seen additional coverage?

Thanks!

Forbes

[Covid Vaccines Linked To Small Increase In Heart And Brain Disorders, Study Finds—But Risk From Infection Is Far Higher \(msn.com\)](#)

MSN

[Largest-ever COVID vaccine study links shot to small increase in heart and brain conditions \(msn.com\)](#)

From: Carter, Danielle (CDC/NCEZID/DHQP/OD)
Sent: Tue, 13 Feb 2024 14:03:45 +0000
To: Houlihan, Catherine (CDC/NCIRD/OD) (CTR); Crist, Matthew (CDC/NCEZID/DHQP/ISO); Olson, Christine (CDC/NCEZID/DHQP/ISO); Broder, Karen (CDC/NCEZID/DHQP/ISO); McNeil, Michael (CDC/NCEZID/DHQP/ISO); Shay, David (CDC/NCEZID/DHQP/ISO); Duffy, Jonathan M. (CDC/NCEZID/DHQP/ISO); Hause, Anne M. (CDC/NCEZID/DHQP/ISO); Weintraub, Eric (CDC/NCEZID/DHQP/ISO); Shimabukuro, Tom (CDC/NCIRD/ID); Marquez, Paige L. (CDC/NCEZID/DHQP/ISO); Su, John (CDC/NCEZID/DHQP/ISO); Gee, Julianne (CDC/NCEZID/DHQP/ISO); Moro, Pedro (CDC/NCEZID/DHQP/ISO); Hamburger, Tanya (CDC/NCEZID/DHQP/OD); Goodman, Jeremy A. (CDC/NCEZID/DHQP/OD); Sharan, Martha (CDC/NCEZID/DHQP/OD); Gill, Curtis (CDC/NCEZID/DHQP/OD) (CTR); Sharma, Andrea J. (CDC/NCEZID/DHQP/ISO)

[COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network \(GVDN\) cohort study of 99 million vaccinated individuals - ScienceDirect](#)