From: GDD-OUTBREAK (CDC)
Sent: Fri, 8 Sep 2023 17:16:11 -0400
To: Undisclosed recipients:
Subject: Global Disease Detection Operations Center Daily Report and Weekly Map - 09/08/2023
Attachments: Congo_Typhoid_EpiCurve_20230908.JPG, Congo_Typhoid_Map_20230908.JPG, GDDOC_2023_09_08.pdf

****** Global Disease Detection Operations Center (GDDOC) Daily Report for 09/08/2023 ******

******** FOR INTERNAL CDC USE ONLY ********

At A Glance:

Of International Importance[1]

- (Update) Acute Gastrointestinal Syndrome in Congo - **Additional cases reported but trending downwards**
- (New) Cholera in Burundi - **Outbreak declared**
- (Update) Diphtheria in Guinea - **Outbreak continues**
- (Update) Legionellosis in Poland - **Second travel-associated case reported in Norway**

General Attachments:

- GDDOC_2023_09_08.pdf

Agent/Disease:	**Acute Gastrointestinal Syndrome**
Country/Territory:	**Congo**
Location:	**Epicenter in Dolisie**
Geoscope[4]:	**Medium**
Public Health Impact[5]:	**Medium**

Source:	**Republic of Congo Ministry of Health; NCEZID/DFWED; WHO - AFRO; GHC/DGHP; WHO**
GDDOC First Notified On:	**07/25/2023**
GDDOC Last Reported On:	**08/25/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**
Attachments:	• Congo_Typhoid_EpiCurve_20230908.JPG • Congo_Typhoid_Map_20230908.JPG

Description:

The GDD Operations Center (GDDOC) is monitoring an outbreak of potential multiple etiologies in the Republic of Congo.

In July 2023 an increase in persons with fever, abdominal pain, headache, vertigo, anorexia, asthenia, diarrhea, and vomiting was observed in the city of Dolisie, Niari Department. An investigation began, and stool samples were collected from patients in several health facilities. According to the WHO Regional Office for Africa, culture and microscopy of these samples yielded isolates of several bacteria: *Campylobacter jejuni*, *Shigella flexneri*, *Salmonella* spp., and *Escherichia coli* O157. Partners are seeking additional details on the laboratory results and methods used. On 17 July 2023, the Congolese Ministry of Health and Population (MOHP) declared concurrent outbreaks of cholera, shigellosis, and typhoid fever.

As of 24 August, MOHP has reported a total of 2,389 suspected cases and 52 deaths since 28 June (case fatality proportion = 2.2%). This represents an increase of 119 suspected cases and two deaths since our last report with data as of 15 August. Of these 2,389 suspected cases, 1,200 are suspected to be typhoid fever, 1,120 are suspected to be shigellosis, and 69 are suspected to be cholera. Among the suspected cases, 88 have had surgery to address intestinal perforation possibly due to typhoid fever.

The epicenter of the outbreak is Dolisie city with 2,087 suspected cases and 33 deaths. Dolisie has also registered over 600 hospital admissions among suspected cases with many public and private health facilities overflowing. Other affected departments include Kouilou, Point-Noire, Bouenza, Pool, and Brazzaville. Please see the attached epidemic curve and map, courtesy of the MOHP, depicting suspected cases of typhoid, cholera, and shigellosis.

MOHP and partners are carrying out various response activities, including case investigations to identify the source of infection. Some stool samples were sent to international laboratories, though results were reportedly inconclusive. According to the National Public Health Laboratory, *Vibrio cholerae* O1 Inaba was identified in eight samples. Toxigenicity testing is advised to confirm cholera etiology according to WHO and the Global Task Force on Cholera

Control standards. Risk communication and community engagement is being undertaken in the affected areas.

GDDOC will continue to monitor this outbreak and provide updates as warranted.

Agent/Disease:	**Cholera**
Country/Territory:	**Burundi**
Location:	**Bujumbura, Gatumba, and Rugombo**
Geoscope[4]:	**Medium**
Public Health Impact[5]:	**Medium**
Source:	**Burundi Ministry of Public Health and the Fight against AIDS (MSPLS); NCEZID/DFWED; GHC/GID**
GDDOC First Notified On:	**09/06/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**

Description:

The GDD Operations Center (GDDOC) is monitoring a cholera outbreak in Burundi, declared by the Ministry of Public Health and Fight against HIV/AIDS of Burundi on 6 September 2023.

As of 6 September, at least 15 suspected cases have been reported in the municipalities of Bujumbura, Gatumba, and Rugombo located in the western region of the country. As of 5 September, 22 cholera patients were receiving treatment at the (b)(6) in the (b)(6) municipality. Additionally, three patients were admitted in Gatumba and five in Rugombo, all in cholera treatment centers (CTC).

Burundi reports outbreaks of cholera regularly every year. However, the current situation is concerning since the outbreak is affecting Bujumbura, the capital of Burundi and located on Lake Tanganyika. The Democratic Republic of the Congo (DRC) and Zambia, which also share

borders with Lake Tanganyika, have reported cholera cases in recent weeks. There is an urgent need to address the water, sanitation, and hygiene (WASH) gaps in the affected health districts, including providing sufficient potable water to the population and access to clean latrines. In addition, the risk communication and community engagement activities need to be reinforced with the implication of community leaders and community health workers.

The GDDOC last reported on cholera in Burundi earlier this year in February 2023 with nearly 130 cases with one death (0.7%). In 2019, GDDOC reported as of 12 November 2019, a total of 1,074 cases with seven deaths (CFP = 0.7%) attributable to cholera had been reported from 10 of Malawi's 29 districts.

The GDDOC will provide updates as information becomes available.

Agent/Disease:	**Diphtheria**
Country/Territory:	**Guinea**
Location:	**Districts of Siguiri, Kankan, Mandiana, and Kouroussa**
Geoscope[4]:	**Low**
Public Health Impact[5]:	**Medium**
Source:	**CDC - Guinea; GHC/DGHP; NCIRD/DBD/MVPDB**
GDDOC First Notified On:	**07/20/2023**
GDDOC Last Reported On:	**08/31/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**

Description:

The GDD Operations Center (GDDOC) has been following reports of a diphtheria outbreak in Guinea.

According to the National Health Security Agency (ANSS), as of epidemiological week 35, a total of 154 diphtheria cases (13 confirmed) including 48 deaths (13 confirmed) have been reported since first case was reported in Siguiri on 4 July 2023. This is an increase of 41 suspected cases and 13 deaths since EW 33. Four districts are affected including Siguiri, Mandiana, Kourassa, and Kankan; the majority of suspected cases and deaths (129 cases, 36 deaths) were reported in Siguiri district.

Response activities remain ongoing, including case investigations and contact tracing, strengthening of lab diagnostics, data harmonization between districts and regions, and risk

communication and community engagement. Médecins Sans Frontières (MSF), in collaboration with ANSS has been supporting clinical management since early August; efforts remain ongoing to acquire a sufficient supply of diphtheria antitoxin (DAT).

Planning is ongoing for vaccination of at-risk and contact groups. According to WHO/UNICEF Estimates of National Immunization Coverage data, the 2022 DTP-containing vaccine coverage rate was 62% for the 1st dose and 47% for the 3rd dose, both below the 80-85% coverage required to maintain community protection.

CDC-Guinea has been in communications with CDC-HQ SMEs to provide informal consultation to ANSS regarding various aspects of response efforts, including lab testing and clinical management with DAT.

Diphtheria is a clinical syndrome caused by an exotoxin produced by the toxin-producing strains of the bacterium *C. diphtheriae*. Most commonly, toxigenic infection results in respiratory or cutaneous disease. Diphtheria and its complications, including death, are caused by effects of the toxin and may include airway blockage, myocarditis, polyneuropathy, and kidney failure. Transmission is most often person-to-person through respiratory droplets though may also occur from exposure to infected skin lesions. Diphtheria occurs worldwide, particularly in countries with suboptimal vaccination coverage.

Agent/Disease:	**Legionellosis**
Country/Territory:	**Poland**
Location:	**Podkarpackie Province, Lublin Province**
Geoscope[4]:	**Medium**
Public Health Impact[5]:	**Medium**
Source:	**Poland Ministry of Health; Poland Chief Sanitary Inspectorate; European CDC; WHO**
GDDOC First Notified On:	**08/24/2023**
GDDOC Last Reported On:	**09/01/2023**
Public Health Event:	**Of International Importance**

Event Type: **Human**

Description:

The GDD Operations Center (GDDOC) is monitoring an outbreak of Legionnaires' disease in Rzeszów, Podkarpackie Province, Poland.

As of 8 September, authorities in Rzeszów have reported 166 cases with 22 deaths (case-fatality proportion (CFP) = 13.3%). This represents an increase of eight cases and four deaths since our last report, with data through 1 September. Adults between 60 and 90 years are the most affected age group, and the median age of all cases is 73. The age of the deceased (11 males, 11 females) ranged from 53-98 years, and all had comorbidities.

Symptom onset of the index case occurred on 30 July. The outbreak was initially reported by the State District Sanitary Inspector in Rzeszów on 18 August, when there were 15 confirmed cases. Of the 166 cases, 11 have been confirmed by PCR testing of respiratory samples. The remainder have been confirmed through urine antigen tests.

As of 7 September, the majority of the cases reside in the following locations within Podkarpackie Province: (b)(6)

(b)(6)

One case has been reported in (b)(6) in neighboring Lublin Province.

On 7 September, Norway reported details concerning a case of Legionnaires' disease in a Polish citizen who is a (b)(6) who stayed in an accommodation in the affected province. The individual visited (b)(6) during the incubation period from (b)(6) Epidemiological and microbiological investigations of the case are ongoing in (b)(6) to identify any association to Rzeszów. This is the second travel-associated case reported following a stay in the affected province. The first was reported in (b)(6), in an individual

(b)(6)

over that time. The patient developed symptoms on 19 August and was hospitalized in (b)(6) on (b)(6)

On 25 August, the Polish Ministry of Health and State Sanitary Inspectorate (MoH) announced that it is conducting an epidemiological investigation, including interviews with patients and their relatives, to determine the source of the outbreak. Additionally, in response to the outbreak, meetings of the crisis staff of the Mayor of Rzeszów are being held daily. The response team is mapping all positive cases, water sampling sites, and cooling towers. Public fountains, water sprays, public water sources in Rzeszów have all been shut down temporarily. The Rzeszów Municipal Water and Sewage Company carried out the routine disinfection of the water supply of the City of Rzeszów on 27 August. Healthcare units and long-term care facilities have been instructed to carry out additional inspections of their water systems. The municipal water system is considered the most likely source, and samples have been collected.

Six water samples taken on 28 August 2023 from cooling systems/condensers of four industrial enterprises did not show the presence of *Legionella*. As of 4 September, while still awaiting the results from further investigations, the confirmation of *Legionella* presence exceeding national norms was received for city tap water (from some residential locations of positive cases), one healthcare facility, one public utility building, and a district heating substation. Despite these ongoing efforts, however, the source of the infection has not yet been determined.

According to media, Poland's security officers are also monitoring findings from the investigation. Rzeszów is the capital of Podkarpackie province, in southeastern Poland, near the border with Ukraine, (b)(5)

(b)(5)

Legionnaires' disease is a serious type of pneumonia caused by *Legionella* bacteria. *Legionella* bacteria are found naturally in freshwater environments, like lakes and streams. The bacteria can become a health concern when they grow and spread in man-made building water systems like centralized air-cooling systems, showerheads, or complex plumbing systems. *Legionella* spreads when it gets into droplets that are small enough for humans to inhale. Less commonly, people can get sick by aspiration of drinking water containing *Legionella*. Legionnaires' disease takes its name after *Legionella* was discovered during an outbreak investigation following an outbreak among those who went to a Philadelphia Convention of the American Legion in 1976.

GDDOC is in touch with subject-matter experts and will provide more information on this outbreak as it becomes available.

Mission Statement
Global Disease Detection Operations Center

The mission of the CDC Global Disease Detection Operations Center is to provide a single source of reliable, comprehensive, and high quality information on international disease outbreaks and other health threats, by 1) systematically collecting and analyzing international health event data for early detection, classifying the health risk associated with these events, disseminating event information, and facilitating appropriate and rapid interventions, and 2) by leveraging CDC program expertise and formal and informal networks, including other CDC partners.

Key

[1]**Public Health Event Of International Importance** is a verified disease outbreak or a health threat that meets one of the following criteria:

1. Is one of the following: SARS, polio (wild - type), smallpox or a new subtype of influenza

2. Presents a serious threat to the public health

3. Is unusual or an unexpected event

4. Poses a significant risk for international spread that potentially requires international intervention

5. Potentially causes restrictions of trade or travel

[2]**Public Health Event Under Investigation** is a disease outbreak or a health threat that potentially meets one of the above criteria, but, at the moment, is not yet verified.

[3]**Public Health Event For Information** is a description of a verified health event that does not meet one of the above criteria but is of interest to the public health community.

Risk Scales

[4]**Geographic Scope** refers to the observed geographic distribution and rapidity of spread for an outbreak and is categorized as follows:

High	Events affecting several multi-national regions or continuing spread beyond national borders
Medium	Events affecting a multi-national region or continuing spread within a national border
Low	Events limited to sub-national areas

[5]**Public Health Impact** refers to actual or potential severity of illness, ease of transmission, public fear, or economic affects and is categorized as follows:

High	Agent that is or potentially: highly pathogenic, highly transmittable, new or emerging, or has significant potential to disrupt travel/trade
Medium	Agent that has moderate potential to cause morbidity/mortality
Low	Agent that has low potential to cause morbidity/mortality

Daily Reports Archives: CDC staff receiving the Global Disease Detection Operations Center (GDDOC) Daily Report may directly access the report archives here: Report Archives. Please note that the hyperlinks in this report that lead to PDF files and the GDDOC Daily Report Archives are accessible only within the CDC Network.

This report is produced by the Global Disease Detection Operations Center (GDDOC)
Global Health Center
U.S. Centers for Disease Control and Prevention (CDC)
1600 Clifton Road NE, Mailstop H21
Atlanta, GA 30333

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Lawrence Hinkle, MSPH, Analyst
Brandon Hugueley, MPH, Analyst
Valerie Mize, MPH, Analyst
Valentina Osorio, MPH, Analyst
Sana Uchikoba, MD, Analyst
Violaine Muhemedi, MPH, Emergency Coordinator
Candace Page, MPH, Emergency Coordinator

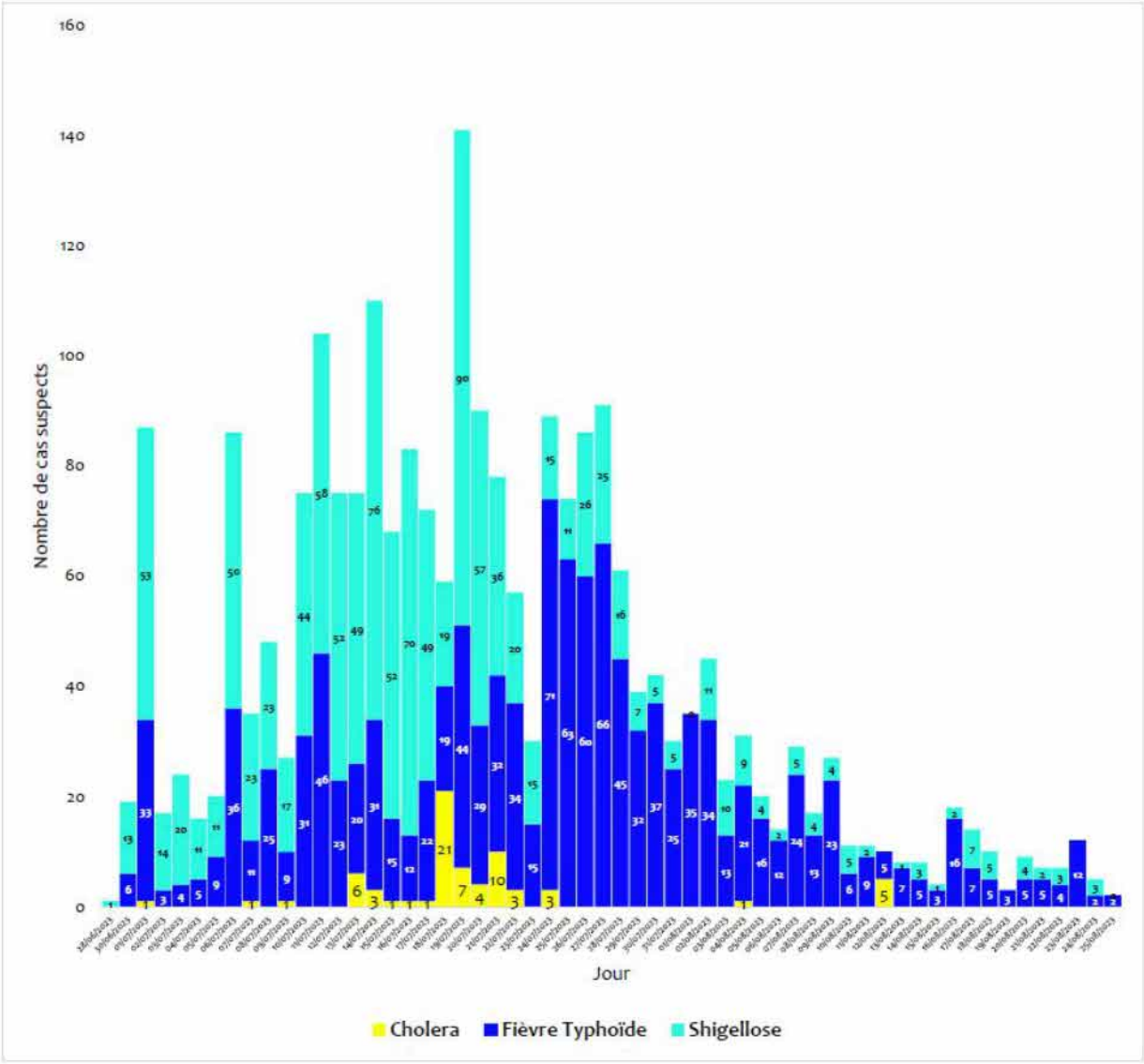
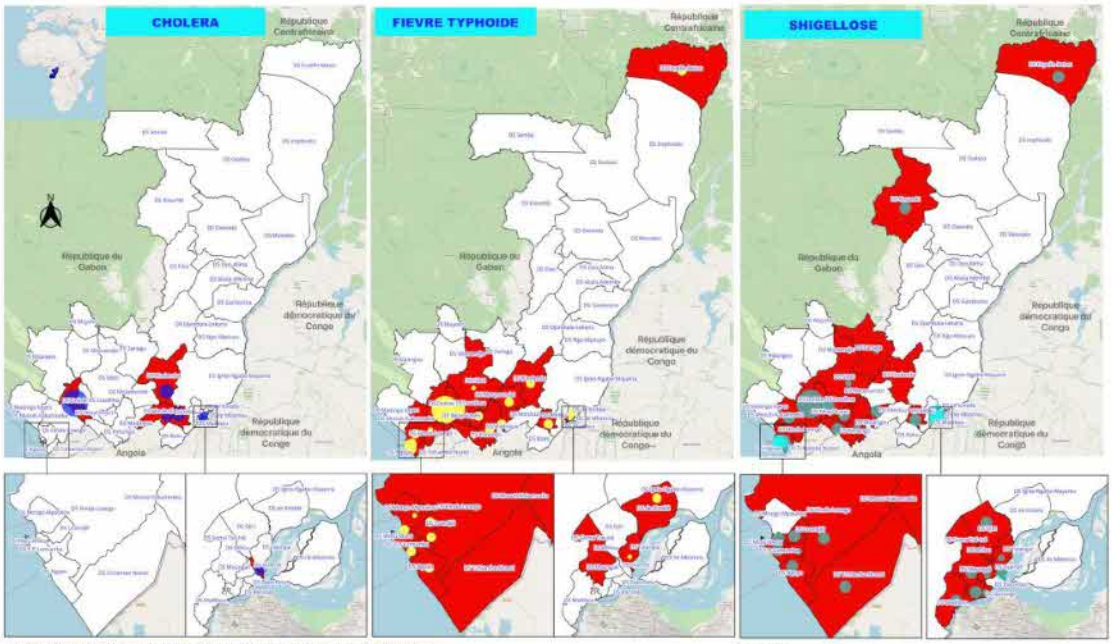


Figure 1. Répartition des cas suspects de shigellose, de fièvre typhoïde et de choléra à la date du 25 août 2023.

CARTOGRAPHIE DES CAS SUSPECTS DE CHOLERA, SHIGELLOSE ET DE FIEVRE TYPHOIDE PAR DISTRICT SANITAIRE AU CONGO, A LA DATE DU 24 AOUT 2023.



Cartographie des cas suspects de Cholera,de Fièvre Typhoide et de Shigellose par département.
La Ville de Dolisie est l'épicentre des épidémies de Cholera, de Fièvre Typhoide et de Shigellose déclarés le 28 juin 2023.

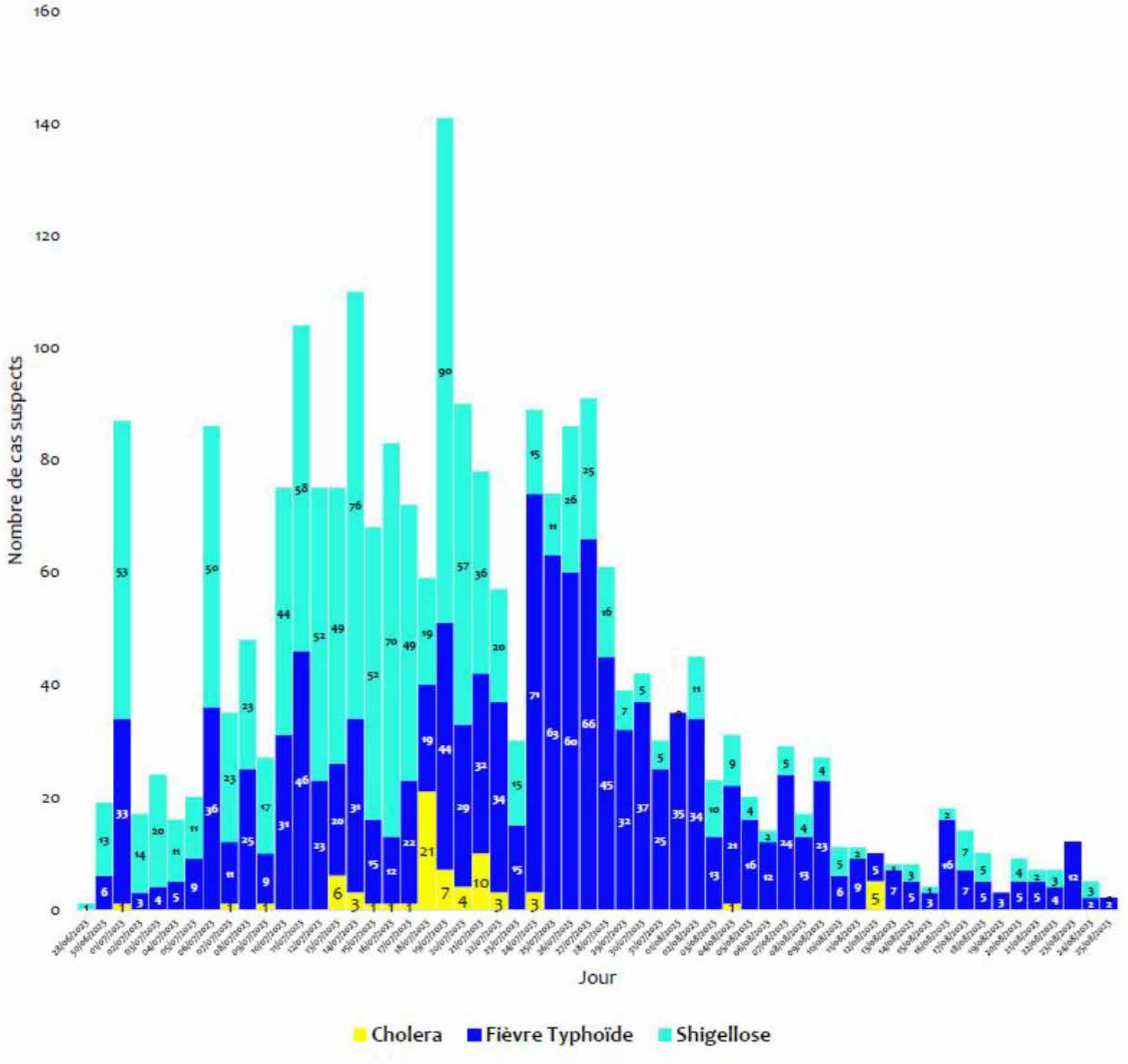
World Health Organization

0 300 600 km

LEGENDE

Cholera2	Fievre Typhoide	Shigellose
1 - 1	1 - 1	0 - 1
1 - 20	1 - 100	1 - 50
20 - 30	100 - 250	50 - 100
30 - 50	250 - 500	100 - 500
50 - 65	500 - 1000	500 - 1000
	1000 - 1500	

DISTRICT_SANITAIRES2
District Sanitaire sain
District sanitaire en épidémie



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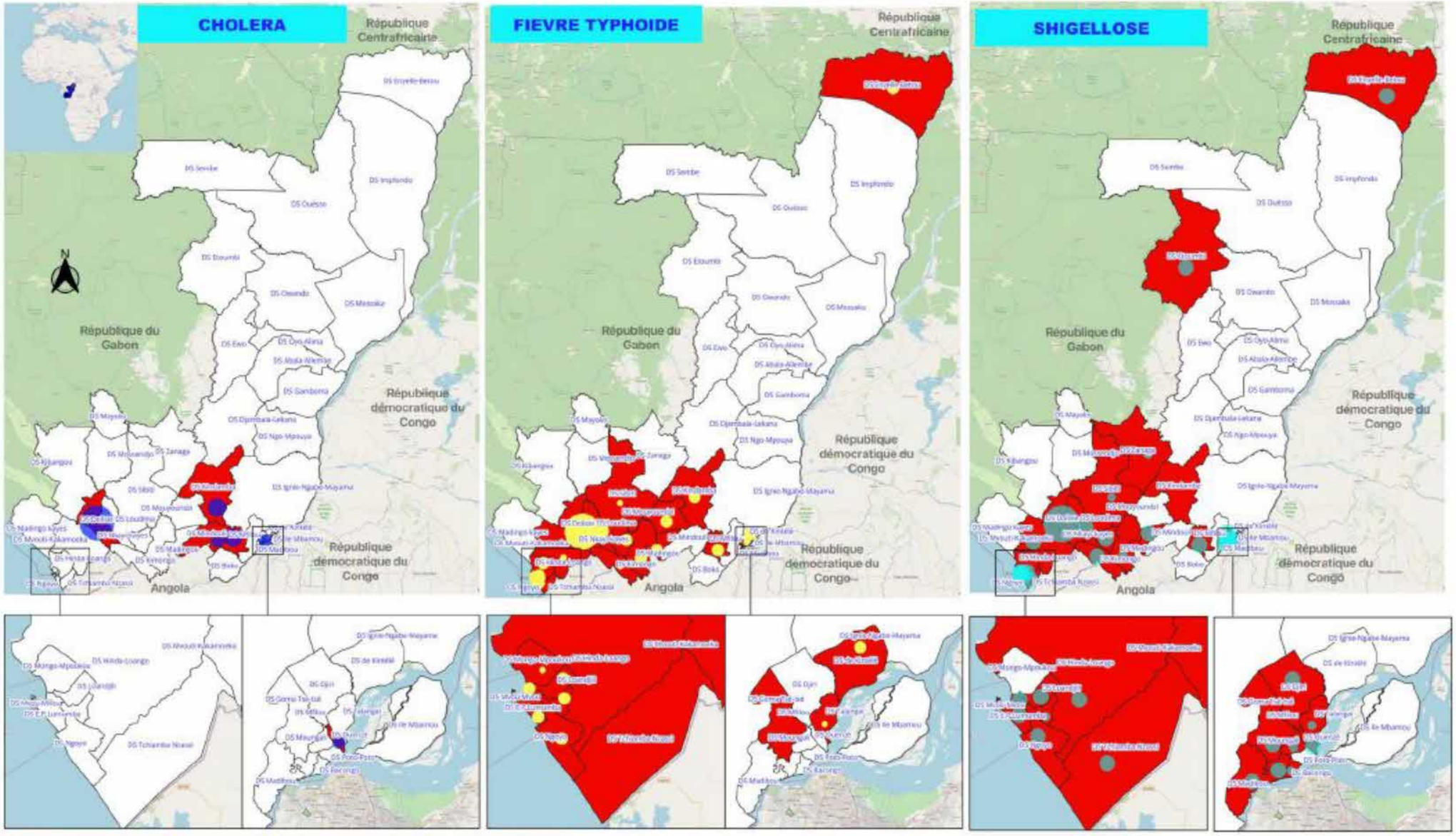


Cartographie des cas suspects de Cholera,de Fièvre Typhoïde et de Shigellose par département.
La Ville de Dolisie est l'épicentre des épidémies de Cholera, de Fièvre Typhoïde et de Shigellose déclarés le 28 juin 2023.

World Health Organization

0 300 600 km

LEGENDE

Cholera2
- 1 - 1
- 1 - 20
- 20 - 30
- 30 - 50
- 50 - 65

Fievre Typhoide
- 1 - 1
- 1 - 100
- 100 - 250
- 250 - 500
- 500 - 1000
- 1000 - 1500

Shigellose
- 0 - 1
- 1 - 50
- 50 - 100
- 100 - 500
- 500 - 1000

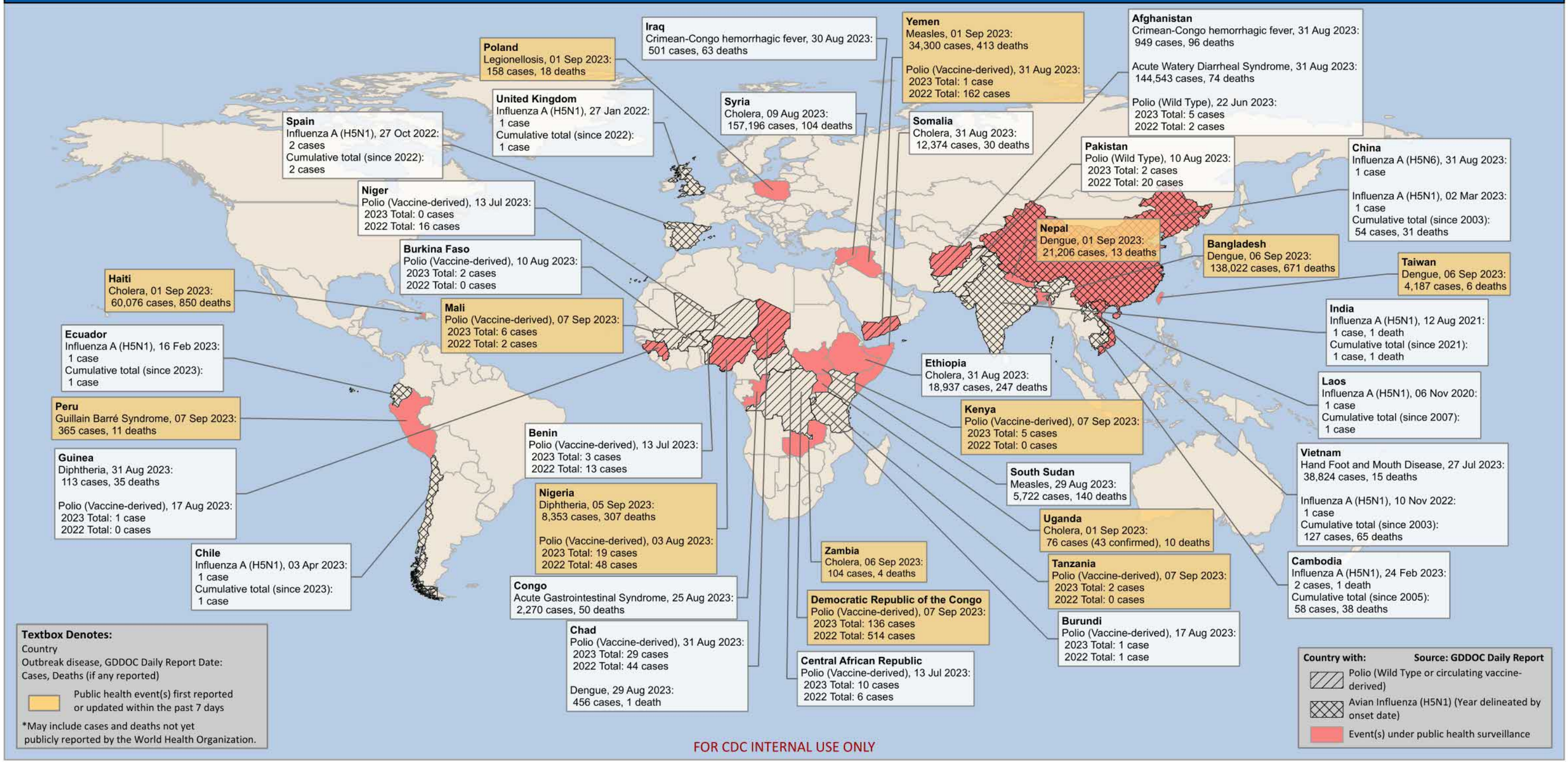
DISTRICT_SANITAIRE52
- District Sanitaire sain
- District sanitaire en épidémie

Global Disease Detection Operations Center (GDDOC)

Public Health Events of International Importance Under Surveillance

08 September 2023

The map shows verified public health events under active surveillance by GDDOC; data as of 07 September 2023



FOR CDC INTERNAL USE ONLY

From: Shah, Nirav (CDC/IOD)
Sent: Tue, 12 Sep 2023 11:58:51 +0000
To: Cohen, Mandy K. (CDC/IOD)
Cc: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP); Griffis, Kevin (CDC/IOD/OC); Wolff, Kate L. (CDC/IOD/OCS)
Subject: RE: ACIP blog post

Thank you, Director. (b)(5)

From: Cohen, Mandy K. (CDC/IOD) (b)(6)
Sent: Monday, September 11, 2023 11:12 PM
To: Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Cc: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <yzq5@cdc.gov>; Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>; Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Subject: Re: ACIP blog post

Thanks - (b)(5) Sorry I didn't see all the detail you had on myocarditis in here….my fault. Doing too many things at once. Apologies!

(b)(5)

Nothing else from me.

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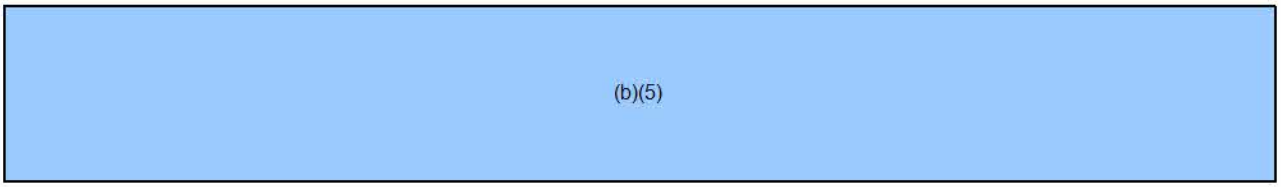
From: Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Sent: Monday, September 11, 2023 8:04:40 PM
To: Cohen, Mandy K. (CDC/IOD) (b)(6)
Cc: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <yzq5@cdc.gov>; Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>; Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Subject: ACIP blog post

Director,

Here is a link to the current draft of the ACIP blog post: ACIP blog.docx

(b)(5)



Happy to discuss more tomorrow,
Nirav

Nirav D. Shah
Principal Deputy Director, U.S. CDC

From: Cohen, Mandy K. (CDC/IOD)
Sent: Tue, 12 Sep 2023 01:16:32 +0000
To: Shah, Nirav (CDC/IOD)
Cc: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP); Griffis, Kevin (CDC/IOD/OC); Wolff, Kate L. (CDC/IOD/OCS)
Subject: Re: ACIP blog post

(b)(5)

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Sent: Monday, September 11, 2023 8:04:40 PM
To: Cohen, Mandy K. (CDC/IOD) (b)(6)
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Nirav D. Shah
Principal Deputy Director, U.S. CDC

From: Cohen, Mandy K. (CDC/IOD)
Sent: Tue, 12 Sep 2023 01:11:53 +0000
To: Shah, Nirav (CDC/IOD)
Cc: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP); Griffis, Kevin (CDC/IOD/OC); Wolff, Kate L. (CDC/IOD/OCS)
Subject: Re: ACIP blog post

The blog doesn't address myocarditis at all.

(b)(5)

Thanks

Get Outlook for iOS
From: Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Sent: Monday, September 11, 2023 8:04:40 PM
To: Cohen, Mandy K. (CDC/IOD) (b)(6)
Cc: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <yzq5@cdc.gov>; Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>; Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
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(b)(5)

Happy to discuss more tomorrow,
Nirav

Nirav D. Shah
Principal Deputy Director, U.S. CDC

From: Griffis, Kevin (CDC/IOD/OC)
Sent: Mon, 11 Sep 2023 21:33:16 +0000
To: Cohen, Mandy K. (CDC/IOD)
Cc: Shah, Nirav (CDC/IOD)
Subject: RE: draft language

(b)(5)

From: Cohen, Mandy K. (CDC/IOD) (b)(6)
Sent: Monday, September 11, 2023 4:35 PM
To: Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>
Cc: Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: Re: draft language

Just confirm I got that right with the team….but am pulling it from the slides.

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From: Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>
Sent: Monday, September 11, 2023 4:07:09 PM
To: Cohen, Mandy K. (CDC/IOD) (b)(6)
Cc: Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: RE: draft language

That works. It keeps it consistent with the blog.

From: Cohen, Mandy K. (CDC/IOD) (b)(6)
Sent: Monday, September 11, 2023 3:10 PM
To: Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>
Cc: Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: RE: draft language

(b)(5)

From: Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>
Sent: Monday, September 11, 2023 2:55 PM
To: Cohen, Mandy K. (CDC/IOD) (b)(6)

Cc: Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: draft language

Hi Mandy,
Let us know if these work for the op-ed.

-kevin

(b)(5)

Kevin C. Griffis
Director, Office of Communications
Centers for Disease Control and Prevention
tvw8@cdc.gov | 404.639.4480 (o) | 202.701.4520 (c)

From: Shah, Nirav (CDC/IOD)
Sent: Thu, 7 Sep 2023 13:02:17 +0000
To: Cohen, Mandy K. (CDC/IOD)
Subject: RE: Status

Thank you – glad to hear that all is on track.

Similarly, things are proceeding smoothly on our end.

From: Cohen, Mandy K. (CDC/IOD) (b)(6)
Sent: Thursday, September 7, 2023 8:19 AM
To: Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>
Subject: Fwd: Status

Get Outlook for iOS

From: Califf, Robert <(b)(6)@fda.hhs.gov>
Sent: Thursday, September 7, 2023 8:14:29 AM
To: Cohen, Mandy K. (CDC/IOD) (b)(6)
Subject: Status

Talked with Peter this am. Things are on track. FDA reviews should be coming to your team over next 24-48 hours so they can digest and prepare presentations. We're making sure we have an update on myocarditis— (b)(5)

I have concerns but ready to work on the rollout as helpful.

rmc

From: Cohen, Mandy K. (CDC/IOD)
Sent: Fri, 8 Sep 2023 19:38:07 +0000
To: Wolff, Kate L. (CDC/IOD/OCS); Shah, Nirav (CDC/IOD); Fristedt, Andi Lipstein (CDC/IOD); Griffis, Kevin (CDC/IOD/OC); Berger, Sherri (CDC/IOD); Houry, Debra E. (CDC/IOD)
Subject: ACIP rollout/message doc - comments/edits
Attachments: Rollout_Plan_COVID19_ACIP_Fall_23_24 mkc.docx

Here are some comments/edits to the doc. Not sure if my comments can be seen on the original link, so sharing here attached.

(b)(5)

From: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Sent: Friday, September 8, 2023 1:19 PM
To: Cohen, Mandy K. (CDC/IOD) (b)(6) Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>; Fristedt, Andi Lipstein (CDC/IOD) <lsa5@cdc.gov>; Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>; Berger, Sherri (CDC/IOD) <sob8@cdc.gov>; Houry, Debra E. (CDC/IOD) <vjz7@cdc.gov>
Subject: RE: FDA press release

And draft decision memo attached here – ACIP slides will come at EOD today.

From: Wolff, Kate L. (CDC/IOD/OCS)
Sent: Friday, September 8, 2023 12:54 PM
To: Cohen, Mandy K. (CDC/IOD) (b)(6) Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>; Fristedt, Andi Lipstein (CDC/IOD) <lsa5@cdc.gov>; Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>; Berger, Sherri (CDC/IOD) <sob8@cdc.gov>; Houry, Debra E. (CDC/IOD) <vjz7@cdc.gov>
Subject: RE: FDA press release

Attached is our draft press release that is in clearance.

I am also including the full/**in progress** roll out document that is capturing a lot of draft messaging that is **still in development**, but wanted you to see at the end there is a list of web sites that will be updated as part of the roll out.

ACIP materials coming next.

-kate

From: Cohen, Mandy K. (CDC/IOD) (b)(6)
Sent: Friday, September 8, 2023 12:18 PM
To: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>; Fristedt, Andi Lipstein (CDC/IOD) <lsa5@cdc.gov>; Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>; Berger, Sherri (CDC/IOD) <sob8@cdc.gov>
Subject: Re: FDA press release

(b)(5)

Get Outlook for iOS

From: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Sent: Friday, September 8, 2023 11:49:10 AM
To: Cohen, Mandy K. (CDC/IOD) <jbc7@cdc.gov>; Shah, Nirav (CDC/IOD) <yyy8@cdc.gov>; Fristedt, Andi Lipstein (CDC/IOD) <lsa5@cdc.gov>; Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>; Berger, Sherri (CDC/IOD) <sob8@cdc.gov>
Subject: FW: FDA press release

(b)(5)

Does this give us enough of a launching point or do we need to revisit our language or do we want to get folks on the phone?

Thanks!
Kate

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Friday, September 8, 2023 11:38 AM
To: Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>; Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>; Berger, Sherri (CDC/IOD) <sob8@cdc.gov>
Cc: Felberbaum, Michael (FDA/OC) <Michael.Felberbaum@fda.hhs.gov>; Griffis, Kevin (CDC/IOD/OC)

<tvw8@cdc.gov>
Subject: FDA press release

Steve/Kate/Sherri – just making sure you've seen our PR and the language that we're using to describe the vaccines. I think this is consistent if not identical with "annual vaccine"

Julie

Julia C. Tierney, JD (she/her)
Chief of Staff

U.S. Food and Drug Administration
(301) 796-8602 (office) (forwarded)
(b)(6) (cell)
Julia.Tierney@fda.hhs.gov
Executive Assistant: Jane.Goldschmidt@fda.hhs.gov

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(b)(5)

(b)(5)

From: Cohen, Mandy K. (CDC/IOD)
Sent: Tue, 12 Sep 2023 02:26:48 +0000
To: Griffis, Kevin (CDC/IOD/OC)
Subject: Fwd: Cohen Op-ed - EDITS FROM NYT
Attachments: NYT Op-ed_Dr. Mandy Cohen consolidated edits pf.docx

A few minor things from Paul.

Get Outlook for iOS
From: Friedrichs, Paul A. EOP/OPPR <(b)(6)
Sent: Monday, September 11, 2023 8:27 PM
To: Cohen, Mandy K. (CDC/IOD) (b)(6)
Subject: RE: Cohen Op-ed - EDITS FROM NYT

Mandy
I think this actually reads better because it almost sounds like you're telling a story to all of us. Nicely done. A few minor edits.

Finally got (b)(5)
(b)(5)

Thanks for the great collaboration
Paul

From: Cohen, Mandy K. (CDC/IOD) (b)(6)
Sent: Monday, September 11, 2023 6:09 PM
To: Friedrichs, Paul A. EOP/OPPR <(b)(6)>; Shahpar, Cyrus G. EOP/NSC <(b)(6)
Subject: Fwd: Cohen Op-ed - EDITS FROM NYT

Latest op-ex with edits after nytimes reviewed. They asked me to add a first paragraph about me….

(b)(5)

Let me know asap if you see any inaccuracies….

Mandy

Get Outlook for iOS

From: Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>
Sent: Monday, September 11, 2023 5:57:08 PM
To: Cohen, Mandy K. (CDC/IOD) (b)(6) Tracy Zimmerman

<tracy@neimandcollaborative.com>
Cc: Wolff, Kate L. (CDC/IOD/OCS) <uqq9@cdc.gov>
Subject: RE: Cohen Op-ed - EDITS FROM NYT

Attached is the version of the NYT op-ed with consolidated edits, including the new opening and (b)(5). Most of the NYT edits were related to style.

From: Cohen, Mandy K. (CDC/IOD) (b)(6)
Sent: Monday, September 11, 2023 1:43 PM
To: Tracy Zimmerman <tracy@neimandcollaborative.com>; Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>
Subject: RE: Cohen Op-ed - EDITS FROM NYT

(b)(5)

From: Tracy Zimmerman <tracy@neimandcollaborative.com>
Sent: Monday, September 11, 2023 1:42 PM
To: Cohen, Mandy K. (CDC/IOD) (b)(6) Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>
Subject: Re: Cohen Op-ed - EDITS FROM NYT

I like it.

tracy zimmerman | vp policy & communications

neimand collaborative social impact marketing

1100 vermont avenue, nw, suite 200, washington dc 20005

main 202-637-9732 ext 115 | cell 919-518-3099

>www.neimandcollaborative.com<

From: Cohen, Mandy K. (CDC/IOD) <(b)(6)
Sent: Monday, September 11, 2023 1:41 PM
To: Tracy Zimmerman <tracy@neimandcollaborative.com>; Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>
Subject: RE: Cohen Op-ed - EDITS FROM NYT

Ok – so how about….

(b)(5)

(b)(5)

From: Tracy Zimmerman <tracy@neimandcollaborative.com>
Sent: Monday, September 11, 2023 1:37 PM
To: Cohen, Mandy K. (CDC/IOD) (b)(6) Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>
Subject: Re: Cohen Op-ed - EDITS FROM NYT

(b)(5)

tracy zimmerman | vp policy & communications

neimand collaborative social impact marketing

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main 202-637-9732 ext 115 | cell 919-518-3099

>www.neimandcollaborative.com<

From: Cohen, Mandy K. (CDC/IOD) (b)(6)
Sent: Monday, September 11, 2023 1:24 PM
To: Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>; Tracy Zimmerman <tracy@neimandcollaborative.com>
Subject: RE: Cohen Op-ed - EDITS FROM NYT

(b)(5)

From: Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>
Sent: Monday, September 11, 2023 1:22 PM
To: Cohen, Mandy K. (CDC/IOD) (b)(6) Tracy Zimmerman <tracy@neimandcollaborative.com>
Subject: RE: Cohen Op-ed - EDITS FROM NYT

(b)(5)

(b)(5)

From: Cohen, Mandy K. (CDC/IOD) (b)(6)
Sent: Monday, September 11, 2023 1:16 PM
To: Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>; Tracy Zimmerman <tracy@neimandcollaborative.com>
Subject: RE: Cohen Op-ed - EDITS FROM NYT

Also I think we need to add to this line.

(b)(5)

From: Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>
Sent: Monday, September 11, 2023 12:59 PM
To: Cohen, Mandy K. (CDC/IOD) (b)(6) Tracy Zimmerman <tracy@neimandcollaborative.com>
Subject: FW: Cohen Op-ed - EDITS FROM NYT

Please see below. They are encouraging the writing of a new first paragraph. Let me know what you think.

From: McDonald, Jason (CDC/IOD/OC) <gnf0@cdc.gov>
Sent: Monday, September 11, 2023 12:53 PM
To: Griffis, Kevin (CDC/IOD/OC) <tvw8@cdc.gov>
Subject: FW: Cohen Op-ed

From: Alexandra Sifferlin
Sent: Monday, September 11, 2023 11:10 AM
To: McDonald, Jason (CDC/IOD/OC) <gnf0@cdc.gov>
Subject: Re: Cohen Op-ed

Hi Jason,

Thank you very much for getting this back to us early today. I've attached my edit. I think readers are going to gain a lot from this clear explanation about the boosters.

Most of my edits are very small. My one bigger suggestion is if we can try a new beginning that introduces Dr. Cohen to readers/Americans a bit more. I think it would be helpful to either have a bit more first-person writing about her experience with Covid and/or how she views this current moment. We have a very large readership and it may be some readers' first engagement with her in the first-person. Just a bit more narrative (like the ending) will help make the piece feel very approachable off

the bat. I think the current first paragraph is a great second paragraph. I've put in some specific suggestions.

Let me know if you have any questions.

Thank you!
Alexanda

(b)(5)

(b)(5)

(b)(5)

From: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP)
Sent: Wed, 30 Aug 2023 15:30:23 +0000
To: Shah, Nirav (CDC/IOD); Cohen, Mandy K. (CDC/IOD)
Subject: FW: Pfizer and BioNTech Receive Positive CHMP Opinion for Omicron XBB.1.5-adapted COVID-19 Vaccine in the European Union

FYSA

Pfizer and BioNTech Receive Positive CHMP Opinion for Omicron XBB.1.5-adapted COVID-19 Vaccine in the European Union

- *The updated COVID-19 vaccine is tailored to the Omicron XBB.1.5 sublineage of SARS-CoV-2 and is recommended for individuals 6 months of age and older*
- *Recommendation based on pre-clinical data showing that the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine generates an improved response against multiple XBB-related sublineages, including XBB.1.5, XBB.1.16, XBB.2.3, and EG.5.1 (Eris), which continue to dominate globally*[1]
- *Doses will be ready to ship to applicable EU member states immediately upon authorization by the European Commission*

August 30, 2023 10:00 AM Eastern Daylight Time

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended marketing authorization for the companies' Omicron XBB.1.5-adapted monovalent COVID-19 vaccine (COMIRNATY® Omicron XBB.1.5) administered as a single dose for individuals 5 years of age and older, regardless of prior COVID-19 vaccination history. The Committee has also recommended the updated vaccine for children 6 months through 4 years of age as part or all of the primary three-dose vaccination series, depending on how many prior doses they received, or as single dose for those with a history of completion of a COVID-19 primary vaccination course or prior SARS-CoV-2 infection.

The European Commission (EC) will review the CHMP's recommendation and is expected to make a final decision soon. Following a decision from the EC, the updated vaccine will be ready to ship to applicable EU member states immediately. Pfizer and BioNTech have been manufacturing the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine at risk to ensure supply readiness ahead of the upcoming fall and winter season when the demand for COVID-19 vaccination is expected to increase.[2]

"This season's vaccine is ready to ship as soon as the final regulatory decision is made, so that people across Europe can better help protect themselves against COVID-19 illness as the risk rises," said Albert Bourla, Chairman and Chief Executive Officer at Pfizer. "It's been nearly a year since many citizens in the European Union were vaccinated against COVID-19 and the updated formulation provides the opportunity for them to receive a vaccine more closely matched to current sublineages."

"As COVID-19 is expected to adopt a seasonal pattern, similar to other respiratory viruses, we remain committed to providing COVID-19 vaccines that are better matched to relevant circulating variants or

sublineages to people worldwide, to support vaccinations in the upcoming fall and winter season," said Prof. Ugur Sahin, M.D., CEO and Co-founder of BioNTech. "Omicron XBB-related sublineages are antigenically distant from prior Omicron strains and continue to account for the vast majority of COVID-19 cases globally. The updated COVID-19 vaccine aims to further improve protection against severe illness and hospitalization."

The CHMP's recommendation is based on the full body of previous clinical, non-clinical, and real-world evidence supporting the safety and efficacy of the COVID-19 vaccines by Pfizer and BioNTech. Further, the application included pre-clinical data showing that the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine generates a substantially improved response against multiple XBB sublineages, including XBB.1.5, XBB.1.16, and XBB.2.3, compared to the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine. Additional pre-clinical data demonstrate that serum antibodies induced by the updated COVID-19 vaccine, when compared to the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine, also effectively neutralize the globally dominant and recently WHO-designated variant of interest EG.5.1 (Eris).[3]

Pfizer and BioNTech have also filed an application with the U.S. Food and Drug Administration (FDA) requesting approval of their Omicron XBB.1.5-adapted monovalent COVID-19 vaccine for individuals 6 months of age and older. A decision is expected in the coming days. The companies have submitted data for the updated COVID-19 vaccine to other regulatory authorities around the world.

The COVID-19 vaccines (COMIRNATY®) by Pfizer and BioNTech are based on BioNTech's proprietary mRNA technology and were developed by both companies. BioNTech is the Marketing Authorization Holder for COMIRNATY and its adapted vaccines (COMIRNATY Original/Omicron BA.1; COMIRNATY Original/Omicron BA.4/BA.5) in the United States, the European Union, the United Kingdom, Canada and other countries, and the holder of emergency use authorizations or equivalents in the United States (jointly with Pfizer) and other countries.

INDICATION & AUTHORIZED USE

AUTHORIZED USE

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is FDA authorized under Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 6 months of age and older.

EMERGENCY USE AUTHORIZATION

Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals aged 6 months of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

IMPORTANT SAFETY INFORMATION

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects the immune system
- are pregnant, plan to become pregnant, or are breastfeeding

- have received another COVID-19 vaccine
- have ever fainted in association with an injection

- The vaccine may not protect everyone

- A person should **NOT** get Pfizer-BioNTech COVID-19 Vaccine, Bivalent if they have had a severe allergic reaction after a previous dose of Pfizer-BioNTech COVID-19 Vaccine*, Pfizer-BioNTech COVID-19 Vaccine, Bivalent, or COMIRNATY® (COVID-19 Vaccine, mRNA) or to any ingredients in these vaccines.

- There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination. If you experience a severe allergic reaction, call 9-1-1 or go to the nearest hospital

Seek medical attention right away if you have any of the following symptoms:

- difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, dizziness, and weakness

- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received Pfizer-BioNTech COVID-19 Vaccine, Bivalent, Pfizer-BioNTech COVID-19 Vaccine, or COMIRNATY (COVID-19 Vaccine, mRNA). The observed risk is higher among adolescent males and adult males under 40 years of age than among females and older males, and the observed risk is highest in males 12 through 17 years of age. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. **Seek medical attention right away if the vaccine recipient has any of the following symptoms:**

- Chest pain

- Shortness of breath or difficulty breathing
- Feelings of having a fast-beating, fluttering, or pounding heart

Additional symptoms, particularly in children, may include:

- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

- Fainting can happen after getting injectable vaccines, including Pfizer-BioNTech COVID-19 Vaccine, Bivalent. For this reason, your vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination

- People with weakened immune systems may have a reduced immune response to Pfizer-BioNTech COVID-19 Vaccine, Bivalent

Side effects that have been reported with Pfizer-BioNTech COVID-19 Vaccine, Bivalent, Pfizer-BioNTech COVID-19 Vaccine, or COMIRNATY (COVID-19 Vaccine, mRNA) include:

- Severe allergic reactions
- Non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Injection site pain/tenderness
- Tiredness
- Headache
- Muscle pain
- Chills
- Joint pain
- Fever
- Injection site swelling
- Injection site redness
- Nausea
- Feeling unwell
- Swollen lymph nodes (lymphadenopathy)
- Decreased appetite
- Diarrhea
- Vomiting
- Arm pain
- Fainting in association with injection of the vaccine
- Dizziness
- Irritability

These may not be all the possible side effects of these vaccines. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away.

- Individuals should always ask their healthcare providers for medical advice about adverse events. Report vaccine side effects to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to www.vaers.hhs.gov/reportevent.html. In addition, individuals can report side effects to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985

Please click for Pfizer-BioNTech COVID-19 Vaccine, Bivalent Vaccination Provider and Recipient and Caregiver EUA Fact Sheets

*The Original Pfizer-BioNTech COVID-19 Vaccine is no longer authorized for use in the United States.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical

companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on and follow us on Twitter at X (twitter.com) and Pfizer Inc. (@pfizer_news) / X (twitter.com), Pfizer | LinkedIn, youtube.com/pfizer and like us on Facebook at Pfizer - Home | Facebook.

Pfizer Disclosure Notice

The information contained in this release is as of August 30, 2023. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's efforts to combat COVID-19, the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine, the BNT162 mRNA vaccine program, and Pfizer and –BioNTech's COVID-19 vaccines, defined collectively herein as COMIRNATY (including regulatory applications pending with the European Commission and the U.S. Food and Drug Administration (FDA) for an Omicron XBB.1.5-adapted monovalent COVID-19 vaccine, data submitted for an Omicron XBB.1.5-adapted monovalent COVID-19 vaccine to other regulatory authorities, qualitative assessments of available data, potential benefits, expectations regarding demand for COVID-19 vaccination, expectations for clinical trials, potential regulatory submissions, the anticipated timing of data readouts, regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply) involving substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with pre-clinical and clinical data (including Phase 1/2/3 or Phase 4 or pre-clinical data for COMIRNATY, or any vaccine candidate in the BNT162 program, including the data discussed in this release) in any of our studies in pediatrics, adolescents, or adults or real world evidence, including the possibility of unfavorable new pre-clinical, clinical or safety data and further analyses of existing pre-clinical, clinical or safety data or further information regarding the quality of pre-clinical, clinical or safety data, including the risk that additional data against newer Omicron sublineages could differ from previously reported data; the ability to produce comparable clinical or other results for COMIRNATY, any vaccine candidate or any other vaccines that may result from the BNT162 program or any other COVID-19 program, including the rate of vaccine effectiveness and safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial and additional studies, in real world data studies or in larger, more diverse populations following commercialization; the ability of COMIRNATY, any vaccine candidate or any future vaccine to prevent COVID-19 caused by emerging virus variants; the risk that use of the vaccine will lead to new information about efficacy, safety, or other developments, including the risk of additional adverse reactions, some of which may be serious; the risk that pre-clinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when additional data from the BNT162 mRNA vaccine program or other COVID-19 programs will be published in scientific journal publications and, if so, when and with what modifications and interpretations; whether regulatory authorities will be satisfied with the design of and results from existing or future pre-clinical and clinical studies; whether and when submissions to request emergency use or conditional marketing authorizations for COMIRNATY or any future vaccines in additional populations, for a potential booster dose for COMIRNATY, any vaccine candidate or any potential future vaccines (including potential future annual boosters or re-vaccinations), and/or other biologics license and/or emergency use authorization applications or amendments to any such applications may be filed

in particular jurisdictions for COMIRNATY, any vaccine candidates or any other potential vaccines that may arise from the BNT162 program, and if obtained, whether or when such emergency use authorizations or licenses, or existing emergency use authorizations, will expire or terminate; whether and when any applications that may be pending or filed for COMIRNATY (including any requested amendments to the emergency use or conditional marketing authorizations and including the applications pending with the FDA and the European Commission for the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine), any vaccine candidates or other vaccines that may result from the BNT162 program or any other COVID-19 program may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine's benefits outweigh its known risks and determination of the vaccine's efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of a vaccine, including the authorization or approval of products or therapies developed by other companies; disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers, including our relationship with BioNTech; the risk that demand for any products may be reduced, no longer exist or not meet expectations, which may lead to excess inventory on-hand and/or in the channel or reduced revenues; challenges related to and uncertainties regarding the timing of a transition to the commercial market for any of our products; uncertainties related to the public's adherence to vaccines and boosters; risks related to our ability to achieve our revenue forecasts for COMIRNATY or any potential future COVID-19 vaccines; the risk that other companies may produce superior or competitive products; risks related to the availability of raw materials to manufacture or test a vaccine; challenges related to our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the risk that we may not be able to successfully develop other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant-based or next generation vaccines or potential combination respiratory vaccines; the risk that we may not be able to maintain manufacturing capacity or access to logistics or supply channels commensurate with global demand for our vaccines, which would negatively impact our ability to supply our vaccines within the projected time periods; whether and when additional supply or purchase agreements will be reached or existing agreements will be completed or renegotiated; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; pricing and access challenges; challenges related to public confidence in, or awareness of COMIRNATY; uncertainties around future changes to applicable healthcare policies and guidelines issued by the U.S. federal government in connection with the declared termination of the federal government's COVID-19 public health emergency as of May 11, 2023; trade restrictions; potential third party royalties or other claims; the uncertainties inherent in business and financial planning, including, without limitation, risks related to Pfizer's business and prospects, adverse developments in Pfizer's markets, or adverse developments in the U.S. or global capital markets, credit markets, regulatory environment or economies generally; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

About BioNTech

Biopharmaceutical New Technologies (BioNTech) is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor CAR) T cells, several protein-based therapeutics, including bispecific immune checkpoint modulators, targeted cancer antibodies and antibody-drug conjugate (ADC) therapies, as well as small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including DualityBio, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, OncoC4, Regeneron, Sanofi, and Pfizer.
For more information, please visit www.BioNTech.com.

BioNTech Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not be limited to, statements concerning: BioNTech's efforts to combat COVID-19; the collaboration between BioNTech and Pfizer; the rate and degree of market acceptance of BioNTech's COVID-19 vaccine, including the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine; qualitative assessments of available data and expectations of potential benefits; regulatory submissions and regulatory approvals or authorizations and expectations regarding manufacturing, distribution and supply; expectations regarding anticipated changes in COVID-19 vaccine demand, including changes to the ordering environment; and expected regulatory recommendations to adapt vaccines to address new variants or sublineages. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data, including the data discussed in this release, and including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; BioNTech's pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after BioNTech's initial sales to national governments; the future commercial demand and medical need for initial or booster doses of a COVID-19 vaccine; the availability of raw materials to manufacture a vaccine; our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery; competition from other COVID-19 vaccines or related to BioNTech's other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; the timing of and

BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; the ability of BioNTech's COVID-19 vaccines to prevent COVID-19 caused by emerging virus variants; BioNTech's and its counterparties' ability to manage and source necessary energy resources; BioNTech's ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of BioNTech's third-party collaborators to continue research and development activities relating to BioNTech's development candidates and investigational medicines; the impact of the COVID-19 pandemic on BioNTech's development programs, supply chain, collaborators and financial performance; unforeseen safety issues and potential claims that are alleged to arise from the use of BioNTech's COVID-19 vaccine and other products and product candidates developed or manufactured by BioNTech; BioNTech's and its collaborators' ability to commercialize and market BioNTech's COVID-19 vaccine and, if approved, its product candidates; BioNTech's ability to manage its development and expansion; regulatory developments in the United States and other countries; BioNTech's ability to effectively scale BioNTech's production capabilities and manufacture BioNTech's products, including BioNTech's target COVID-19 vaccine production levels, and BioNTech's product candidates; risks relating to the global financial system and markets; and other factors not known to BioNTech at this time.
You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Report on Form 6-K for the period ended June 30, 2023 and in subsequent filings made by BioNTech with the U.S. Securities and Exchange Commission ("SEC"), which are available on the SEC's website at www.sec.gov. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on BioNTech's current expectations and speak only as of the date hereof.

[1] World Health Organization. COVID-19 Weekly Epidemiological Update. Available at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports

[2] Wiemken TL, Khan F, Nguyen JL, Jodar L, McLaughlin JM. Is COVID-19 seasonal? A time series modeling approach. *medRxiv*. 2022:2022.06.17.22276570.

[3] World Health Organization. EG.5 Initial Risk Evaluation. Available at: https://www.who.int/docs/default-source/coronaviruse/09082023eg.5_ire_final.pdf?sfvrsn=2aa2daee_1

Category: Vaccines

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From: Califf, Robert
Sent: Sun, 10 Sep 2023 16:02:27 +0000
To: Marks, Peter (FDA/CBER); Cohen, Mandy K. (CDC/IOD)
Cc: Tierney, Julia (FDA/OC)
Subject: FW: [EXTERNAL] some thoughts on SARS-CoV2 and other vaccines for respiratory infections in children

An example from the (not totally distant) field.

rmc

From: "Danny Benjamin, M.D., Ph.D." <danny.benjamin@duke.edu>
Date: Sunday, September 10, 2023 at 11:39 AM
To: Robert Califf <(b)(6)@fda.hhs.gov>
Subject: [EXTERNAL] some thoughts on SARS-CoV2 and other vaccines for respiratory infections in children

Dr. Califf,
I have been asked by pediatricians from rural North Carolina how to discuss COVID-19 boosters in their communities. Rural pediatricians face unique challenges related to COVID-19 receptiveness due to the combination of lower mortality in children and vaccine misinformation.

Post-pandemic, I find it helpful to approach COVID just as I would any other respiratory viral infection. So I have started the conversation by asking 'do you recommend flu vaccine'? To which the answer is always 'yes'. I then ask 'would you give RSV vaccine if you could'? To which the answer is also, 'yes'.

Vaccination, similar to any decision in medicine, is a benefit-risk decision. So I compare data related to vaccine safety & efficacy for 3 common respiratory infections in children: influenza, RSV, and COVID. The data are impressive, and especially strong. We have been vaccinating (and boosting) for flu for decades. The comparison to flu and RSV is helpful to put the decisions around COVID in context.

Table 1

Outcome/Age		Flu[1,2]/100,000	Flu/100,000		RSV[1]/100,000	RSV/100,000		COVID[3]/100,000	COVID/100,000
		Partial Coverage	Vaccinated		Unvaccinated	Vaccinated		Unvaccinated	Vaccinated
Mortality									
12-17 yr old									
5-11 yr old									

1-4 yr old								
<1 year								
Hospitalization								
12-17 yr old		17			39		66	<5
5-11 yr old		29			48		32	<5
1-4 yr old		59			357		88	--
<1 year		181			2381		89	--
Myocarditis								
12-17 yr old								
5-11 yr old								
1-4 yr old								
<1 year								
[1]Influenza and RSV averaged over 7 seasons prior to pandemic; vaccine								
[2]Influenza vaccination rate was <100% pre-pandemic;								
[3]COVID-19 see clinical trial data and MMWR publication December 2021								

I am then routinely asked about the booster, and how much data we have for COVID boosters, and “is that enough”. Again, flu is especially helpful here. I then remind my peers of the concepts related to assessing influenza boosters, and compare that to COVID such as might be outlined in

Table 2

Data Source	Influenza		COVID-19
Children who received vaccine in primary trials			
Children who received vaccine 2018-2023			
People who received vaccine in booster evaluation			
Animal data for booster evaluation			

danny

Danny Benjamin, M.D., Ph.D.
Kiser-Arena Distinguished Professor of Pediatrics, Duke University

From: GDD-OUTBREAK (CDC)
Sent: Thu, 10 Aug 2023 17:54:58 -0400
To: Undisclosed recipients:
Subject: Global Disease Detection Operations Center Daily Report - 08/10/2023
Attachments: Epi Curve Diphtheria Nigeria 2023 EW30 31July2023_NCDC.jpg, Epicurve Suspected Cholera EW30 2022 - EW30 2023.jpg, Haiti_cholera_10AUG2023.jpg, Epicurve AWD 1 Jan- 5 Aug 2023.jpg

****** Global Disease Detection Operations Center (GDDOC) Daily Report for 08/10/2023 ******

******** FOR INTERNAL CDC USE ONLY ********

At A Glance:

Of International Importance[1]

- (Update) Diphtheria in Nigeria - **Response activities continue**
- (Update) Crimean-Congo Hemorrhagic Fever in North Macedonia - **Second confirmed case of CCHF**
- (Update) Cholera in Somalia - **Outbreak continues**
- (Update) Cholera in Haiti - **Cases in children 1-4 years surpass 12,000**
- (Update) Acute Watery Diarrheal Syndrome in Afghanistan - **Outbreak continues**
- (b)(4)

Agent/Disease: **Diphtheria**

Country/Territory: **Nigeria**

Location: **Widespread**

Geoscope[4]: **Medium**

Public Health Impact[5]:	**Medium**
Source:	**Nigeria Center for Disease Control (NCDC); NCHHSTP/DSTDP; WHO/UNICEF Joint Reporting Form on Immunization (JRF); CDC - Nigeria; GHC/GID**
GDDOC First Notified On:	**01/17/2023**
GDDOC Last Reported On:	**07/25/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**
Attachments:	• Epi Curve Diphtheria Nigeria 2023 EW30 31July2023_NCDC.jpg

Description:

The Global Disease Detection Operations Center (GDDOC) has been monitoring reports of diphtheria in Nigeria.

According to NCDC, an additional 815 suspected diphtheria cases have been reported over the past two weeks for a cumulative total of 4,160 suspected cases reported from epidemiological week (EW) 19, 2022 to EW 30, 2023 (data as of 31 July). Please see epidemic curve from EW 19, 2022 - EW 30, 2023, courtesy of NCDC. The 4,160 suspected cases were reported from 27 states across 139 local government areas (LGAs) in the country; the majority (3,234, 77.7%) of the suspected cases were reported from Kano state, followed by Yobe (477), Katsina (132), Kaduna (101), Bauchi (54), FCT (41) and Lagos (30).

Of the 4,160 suspected cases reported, 1,534 (36.9%) were either lab confirmed (87); epidemiologically linked (158); or clinically compatible (1,289). These 1,534 cases were distributed across 56 LGAs in eleven states. Among the 1,534 cases, the majority (1,018, 57%) occurred in children aged 1 – 14 years; 137 deaths, reflecting an increase of 39 over the past two weeks, were recorded (case fatality proportion [CFP] = 8.9%); 1,257 (81.9%) were not fully vaccinated with a diphtheria toxoid-containing vaccine.

The most recent WHO UNICEF Estimates of National Immunization Coverage (WUENIC) data for Nigeria in 2022 indicates 70% coverage for 1st dose diphtheria toxoid-containing vaccine and 62% coverage for 3rd dose, both below the goal of 95% coverage with three doses for the

primary series recommended by WHO. Two rounds of outbreak response vaccination campaigns have been conducted in five high-risk LGAs in Kano. Another round is scheduled for 21 August in 33 LGAs of four states: Bauchi, Katsina, Yobe and Kaduna. The target age group is 0-14 years.

Members of the National Rapid Response Team have been deployed to affected states to conduct field investigations. A National Diphtheria & Pertussis Technical Working Group is coordinating the response. The establishment of a diphtheria incident management system (IMS) is being supported in the affected states. MoH in collaboration with partners and WHO are working to increase available doses of diphtheria antitoxin (DAT) for use in case management to be administered along with antibiotics.

Diphtheria is an acute, bacterial disease caused by toxin-producing strains of *Corynebacterium diphtheriae*. Diphtheria and its complications, including death, are caused by effects of the toxin and may include airway blockage, myocarditis, polyneuropathy, and kidney failure. Transmission is most often person-to-person through respiratory droplets. Transmission may also occur from exposure to infected skin lesions. Diphtheria occurs worldwide, particularly in countries with suboptimal vaccination coverage. A CDC Travel Notice (Alert - Level 2, Practice Enhanced Precautions) was issued regarding Diphtheria in Nigeria on 24 February 2023 and updated 23 July 2023.

Agent/Disease:	**Crimean-Congo Hemorrhagic Fever**
Country/Territory:	**North Macedonia**
Location:	**Municipality of Stip**
Geoscope[4]:	**Low**
Public Health Impact[5]:	**High**
Source:	**Institute of Public Health of the Republic of Northern Macedonia**
GDDOC First Notified On:	**08/02/2023**
GDDOC Last Reported On:	**08/03/2023**
Public Health Event:	**Of International Importance**

Event Type: **Human**

Description:

The Global Disease Detection Operations Center (GDDOC) has been monitoring reports of Crimean-Congo hemorrhagic fever (CCHF) virus in North Macedonia.

The first confirmed case of CCHF was detected from the Municipality of Stip on 21 July in a [redacted] who became ill with symptoms compatible with CCHF and was hospitalized and died on [redacted] Subsequently, a second confirmed case was detected in [redacted] who was a close contact with the first case.

Initial symptoms started on 3 August 2023 with fever and muscle pain. On 4 August, the patient was hospitalized at the [redacted] where symptomatic therapy was prescribed, and diagnostic tests were performed.

Investigations so far have not revealed the route of transmission. As of 2 August, there have been 17 identified contacts; seven employees of the clinic and 10 family members who participated in a religious gathering. Of these, all family members and one employee are assessed as medium risk and the rest as low risk. Samples from the secondary case were positive for CCHF-specific IgM and IgG antibodies by ELISA and viral RNA by RT-PCR.

In 1971, the first described outbreak of this disease in the Republic of Northern Macedonia was in a family of 13, in the village of Chiflik, Tetovo, with two fatalities. After this outbreak, a case was confirmed in 2010.

CCHF is caused by infection with a tick-borne virus (*Nairovirus*) in the family *Bunyaviridae*. The disease was first characterized in the Crimea in 1944 and given the name Crimean hemorrhagic fever. It was then later recognized in 1969 as the cause of illness in the Congo, thus resulting in the current name of the disease. Crimean-Congo hemorrhagic fever is found in Eastern Europe, particularly in the former Soviet Union, throughout the Mediterranean, in northwestern China, central Asia, southern Europe, Africa, the Middle East, and the Indian subcontinent.

Agent/Disease: **Cholera**

Country/Territory:	**Somalia**
Location:	**Widespread**
Geoscope[4]:	**Medium**
Public Health Impact[5]:	**Medium**
Source:	**UN Office for the Coordination of Humanitarian Affairs (OCHA); WHO - EMRO; WHO - Somalia; WHO; Somalia Ministry of Health; GHC/DGHP**
GDDOC First Notified On:	**02/21/2017**
GDDOC Last Reported On:	**07/28/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**
Attachments:	• Epicurve Suspected Cholera EW30 2022 - EW30 2023.jpg

Description:

The GDD Operations Center (GDDOC) is continuing to monitor an outbreak of cholera in Somalia, ongoing since 2022.

From epidemic week (EW) 1 to EW 30, 2023, a total of 11,704 cases of acute watery diarrhea suspected to be attributable to cholera with 30 deaths (case-fatality proportion (CFP) = 0.26%) have been reported from 28 drought-affected districts in Somalia. This is an increase of 544 cases and no deaths since our last report with data as of EW 28. Of the total cases, 6,295 (53.8%) are in children aged below five years and 6,023 (51.5%) have been reported in females. Of the total deaths, 20 (66.7%) have been in children aged under five years. Please see the attached epidemic curve, courtesy of WHO Country Office in Somalia, depicting suspected cases of cholera reported by EW from EW 30, 2022 to EW 30, 2023.

Of 1,554 stool samples collected since EW 1, 2023, 167 (10.75%) have tested positive for *Vibrio cholerae* 01 serotype Ogawa. Laboratory confirmation is being conducted by culture at the National Public Health Laboratory, in Mogadishu.

The Ministry of Health (MoH), WHO, and other health partners have scaled up implementation of cholera response interventions in drought-affected districts with a focus on Jubaland state, which is the current epicenter of the ongoing outbreak. Somalia has had uninterrupted cholera transmission in drought-affected districts since 2022, and in Banadir region since the drought period of 2017. The current outbreak is a result of an increasing number of people who have no access to safe water and proper sanitation because of drought.

The GDDOC last reported on cholera in Somalia from February 2017 to January 2019; as of 7 January 2019, the MoH had reported 6,731 cases of cholera with 46 deaths (CFP = 0.68%) since the beginning of that outbreak.

The GDDOC will provide updates as information becomes available.

Agent/Disease:	**Cholera**
Country/Territory:	**Haiti**
Location:	**Widespread**
Geoscope[4]:	**High**
Public Health Impact[5]:	**Medium**
Source:	**CDC - Haiti; WHO - PAHO; Haiti Ministère de la Santé Publique et de la Population; NCEZID/DFWED; GHC/DGHP**
GDDOC First Notified On:	**10/02/2022**
GDDOC Last Reported On:	**07/24/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**
Attachments:	• Haiti_cholera_10AUG2023.jpg

Description:

The GDD Operations Center (GDDOC) is monitoring an outbreak of cholera in Haiti.

As of 4 August 2023, the Haiti Ministère de la Santé Publique et de la Population (MSPP) reported 58,230 suspected cases (3,696 confirmed) of cholera with 823 deaths in Haiti since 29 September 2022. This is an increase of 2,763 suspected cases, 113 confirmed cases, and 16 deaths since our last report with data as of 18 July. Of the total deaths, 575 have been in institutions and 248 were community deaths. Please see the attached epidemic curve, courtesy of MSPP, depicting cases of cholera from September 2022 to August 2023.

As of 4 August 2023, a total of 54,102 patients have been hospitalized with suspected cholera and the median age of hospitalized patients remains 17 years. Of the total suspected cases, 53.4% have been reported in males, and the most affected age groups are children aged from 1 to 4 years (12,166 cases), children aged from 5 to 9 years (8,661), and adults aged from 20 to 29 years (7,763).

On 13 June, the Global Alert and Response Network (GOARN) issued a Request for Assistance to support MSPP in strengthening surveillance and response with a particular focus on early warning and response nationwide. Consideration for potential candidates to deploy is underway by GOARN.

Public health staff in Haiti remain on high alert because of ongoing insecurity, which continues to impede response efforts.

The GDDOC will provide updates as information becomes available.

Agent/Disease:	**Acute Watery Diarrheal Syndrome**
Country/Territory:	**Afghanistan**
Location:	**Widespread**
Geoscope[4]:	**Medium**
Public Health Impact[5]:	**Medium**
Source:	**WHO - EMRO; WHO - Afghanistan**
GDDOC First Notified On:	**07/08/2022**
GDDOC Last Reported On:	**08/03/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**
Attachments:	• Epicurve AWD 1 Jan- 5 Aug 2023.jpg

Description:

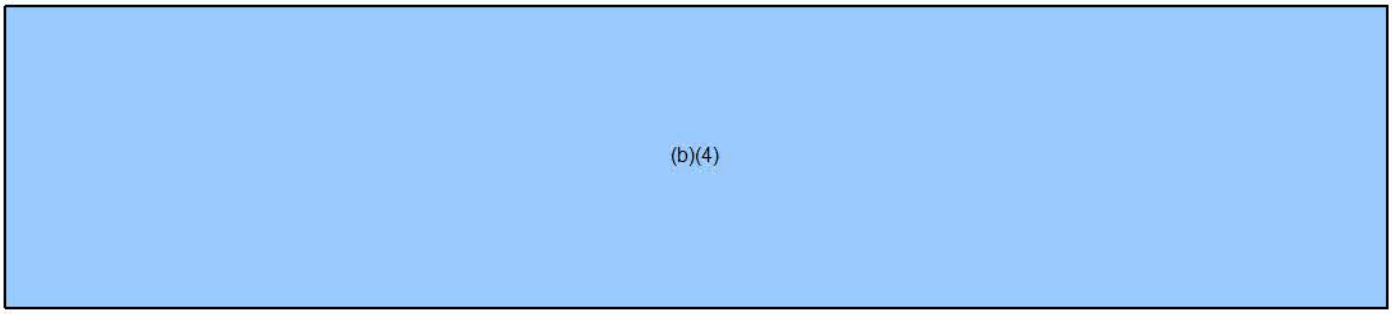
The GDD Operations Center (GDDOC) is monitoring an outbreak of acute watery diarrhea (AWD) in Afghanistan.

Between epidemic week (EW) 1 and EW 31 2023, a total of 120,574 suspected cases of AWD with 59 deaths (case-fatality proportion (CFP) = 0.05%) have been reported by the WHO Country Office (CO) for Afghanistan. Data reported this week include reports from 597 of 613 sentinel surveillance sites. This is an increase of 7,716 cases and six deaths since our last report with data as of EW 30. During EW 31, 7,474 new cases with five new deaths were reported from 231 districts. The general trend of cases has been rising since EW 10 which is linked to the summer season. Of the total cases, 68,784 (57.0%) are in children aged below five years and 59,796 (49.6%) cases have been reported in females. Please see the attached map, depicting AWD attack rate per 10,000 population by province and epidemic curve, depicting cases of AWD by reporting week from EW 1 to EW 31, 2023 both courtesy of the WHO CO.

In response to the outbreak, a national task force was established within the Ministry of Public Health (MoPH) to lead the response at the national and subnational levels. Active case finding is ongoing in outbreak-affected areas, and with the assistance of international partners, investigation kits, rapid diagnostic kits, and treatment supplies are being deployed to affected areas. Additionally, health care workers have been trained AWD case management with more planned for the coming weeks. During EW 31, 32 surveillance support team (SST) members from Central West region were trained on outbreak investigations and reporting as well as laboratory sample collection and transportation which brings the total number of SST members trained since the beginning of 2023 to 195. Currently, SSTs are actively participating in outbreak investigation and response activities in 34 provinces. During EW 31, AWD information, education, and communication brochures and posters were distributed in the provinces of Badakhshan, Balkh, and Kabul.

The GDDOC last actively monitored AWD, then attributable to cholera, in Afghanistan in 2008; as of 20 October 2008, there were 5,403 cases with 24 deaths (CFP = 0.44%) reported from 17 provinces in Afghanistan since the beginning of September 2008.

The GDDOC will provide updates as information becomes available.



(b)(4)

Mission Statement
Global Disease Detection Operations Center

The mission of the CDC Global Disease Detection Operations Center is to provide a single source of reliable, comprehensive, and high quality information on international disease outbreaks and other health threats, by 1) systematically collecting and analyzing international health event data for early detection, classifying the health risk associated with these events,

disseminating event information, and facilitating appropriate and rapid interventions, and 2) by leveraging CDC program expertise and formal and informal networks, including other CDC partners.

Key

[1]**Public Health Event Of International Importance** is a verified disease outbreak or a health threat that meets one of the following criteria:

1. Is one of the following: SARS, polio (wild - type), smallpox or a new subtype of influenza

2. Presents a serious threat to the public health

3. Is unusual or an unexpected event

4. Poses a significant risk for international spread that potentially requires international intervention

5. Potentially causes restrictions of trade or travel

[2]**Public Health Event Under Investigation** is a disease outbreak or a health threat that potentially meets one of the above criteria, but, at the moment, is not yet verified.

[3]**Public Health Event For Information** is a description of a verified health event that does not meet one of the above criteria but is of interest to the public health community.

Risk Scales

[4]**Geographic Scope** refers to the observed geographic distribution and rapidity of spread for an outbreak and is categorized as follows:

High	Events affecting several multi-national regions or continuing spread beyond national borders

Medium	Events affecting a multi-national region or continuing spread within a national border
Low	Events limited to sub-national areas

[5]**Public Health Impact** refers to actual or potential severity of illness, ease of transmission, public fear, or economic affects and is categorized as follows:

High	Agent that is or potentially: highly pathogenic, highly transmittable, new or emerging, or has significant potential to disrupt travel/trade
Medium	Agent that has moderate potential to cause morbidity/mortality
Low	Agent that has low potential to cause morbidity/mortality

(b)(5)

(b)(5)

Daily Reports Archives: CDC staff receiving the Global Disease Detection Operations Center (GDDOC) Daily Report may directly access the report archives here: Report Archives. Please note that the hyperlinks in this report that lead to PDF files and the GDDOC Daily Report Archives are accessible only within the CDC Network.

This report is produced by the Global Disease Detection Operations Center (GDDOC)
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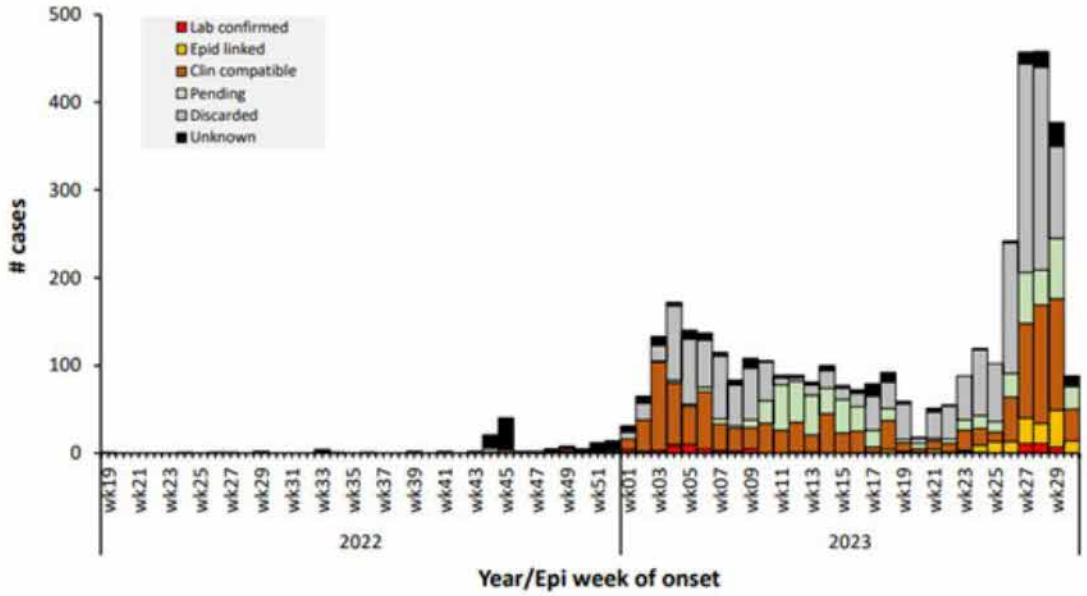
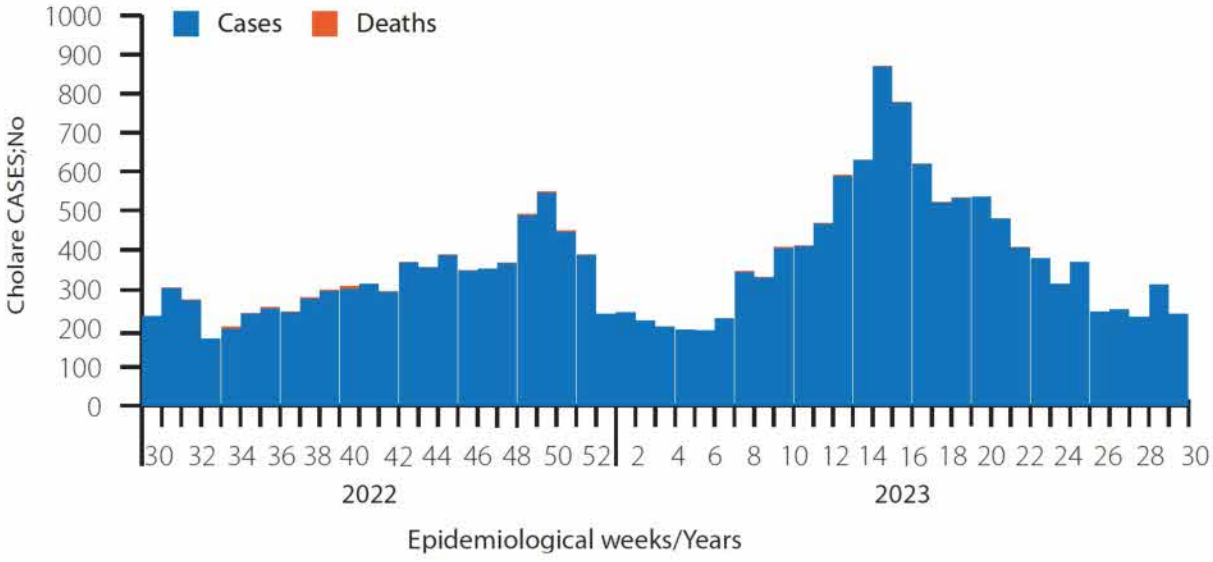
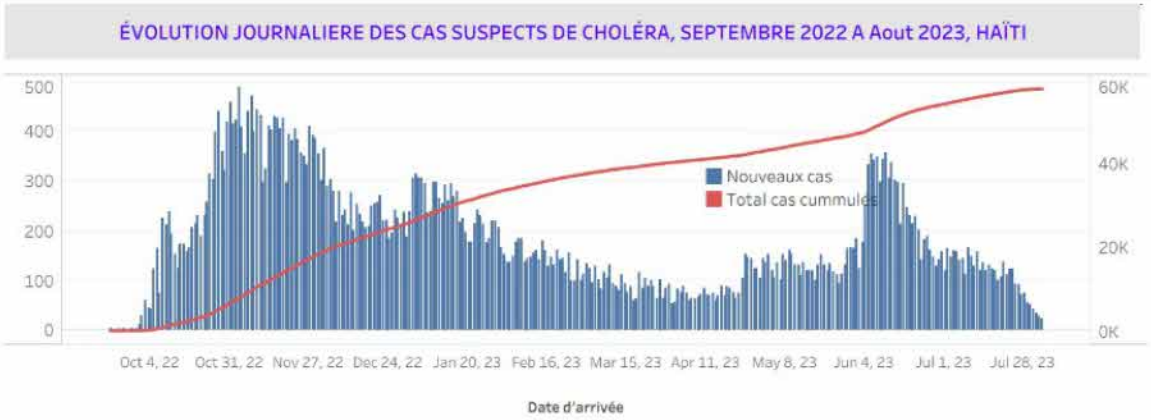


Figure 1: Epi-curve of diphtheria cases by year/epi-week and classification in Nigeria, May 2022 – July 2023

Figure 1: Epidemiological curve for cholera cases and deaths in Somalia 2022-2023





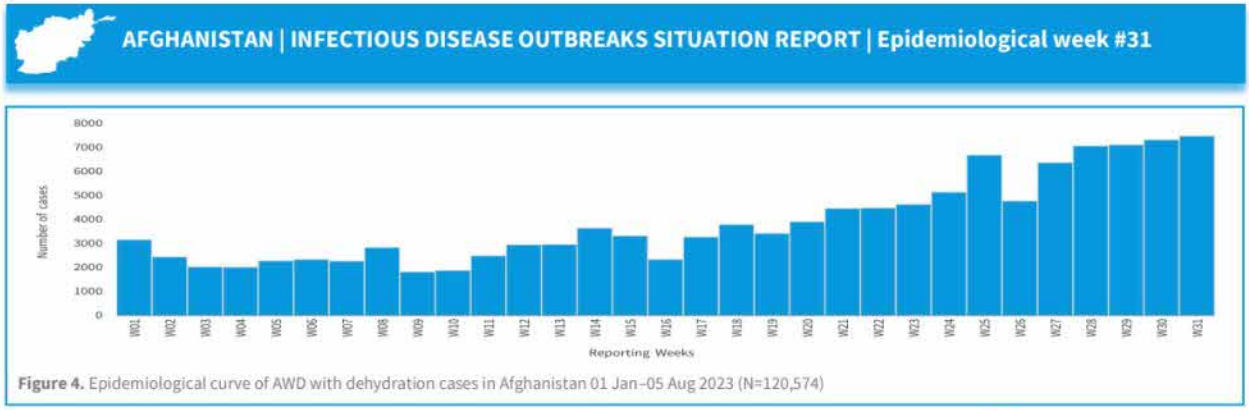


Figure 4. Epidemiological curve of AWD with dehydration cases in Afghanistan 01 Jan–05 Aug 2023 (N=120,574)

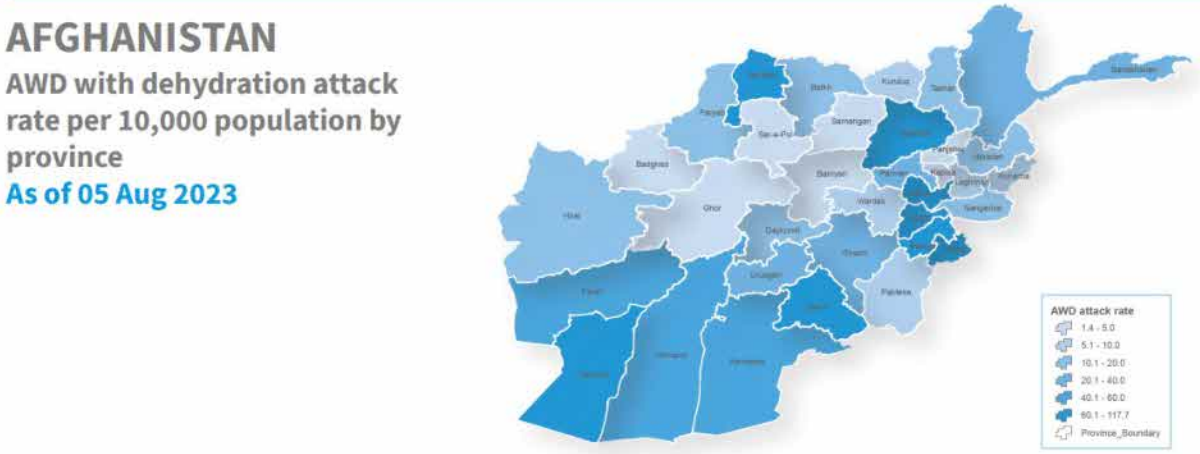
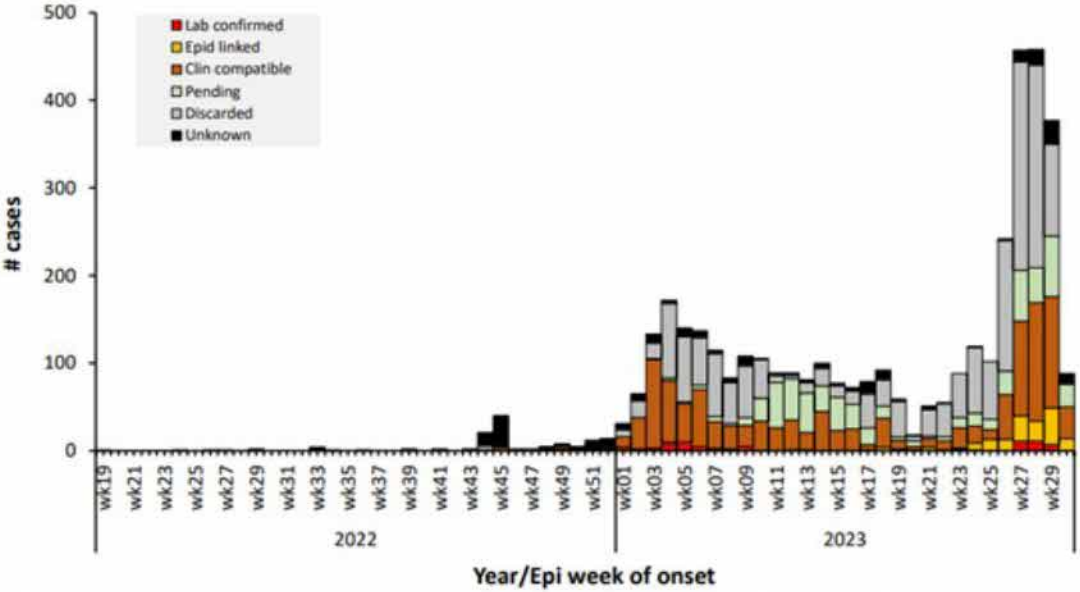


Figure 5. AWD with dehydration attack rate per 10,000 population by province in Afghanistan, 01 Jan–05 Aug 2023



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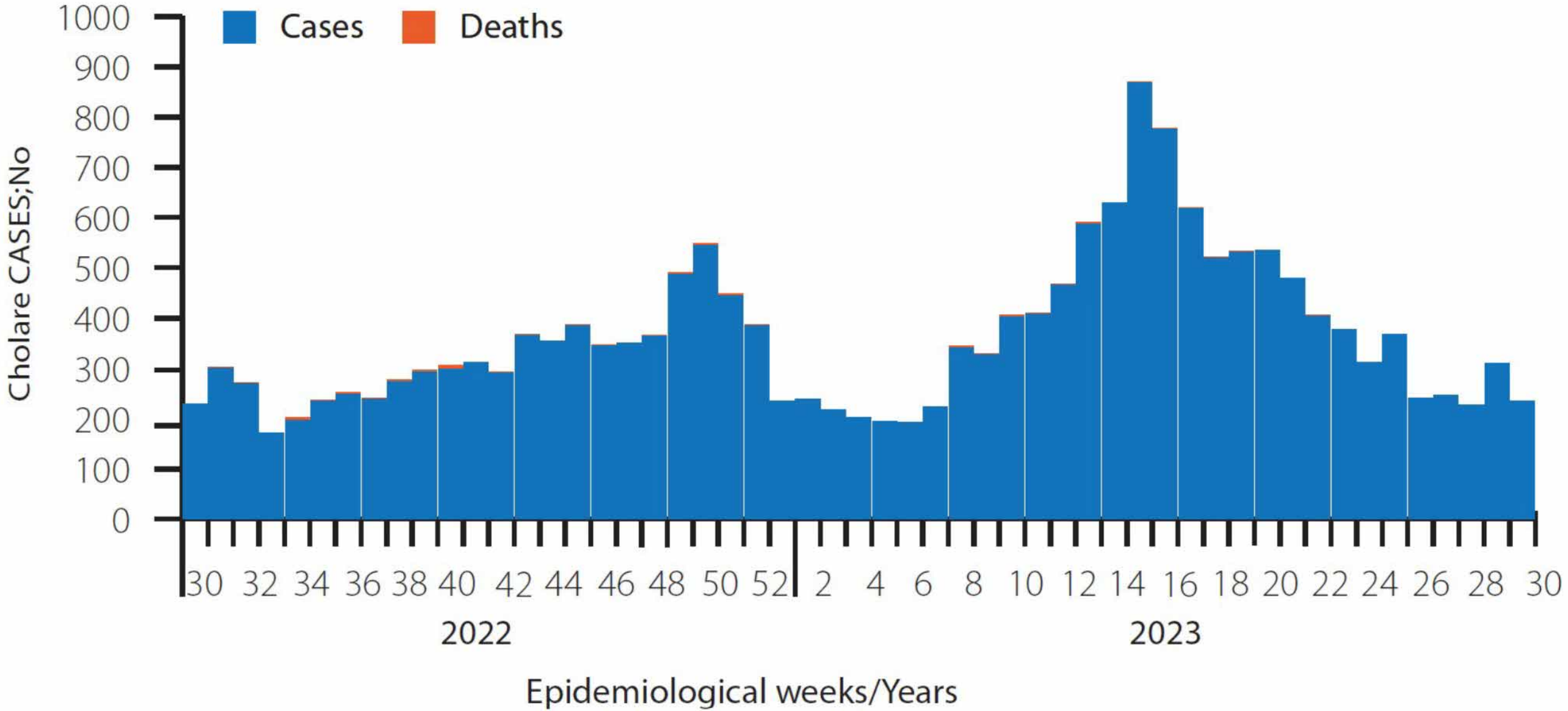

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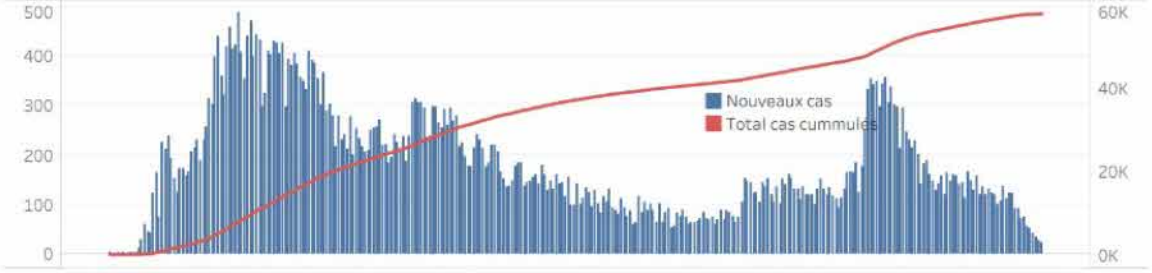


Figure 4. Epidemiological curve of AWD with dehydration cases in Afghanistan 01 Jan–05 Aug 2023 (N=120,574)

AFGHANISTAN

AWD with dehydration attack rate per 10,000 population by province

As of 05 Aug 2023

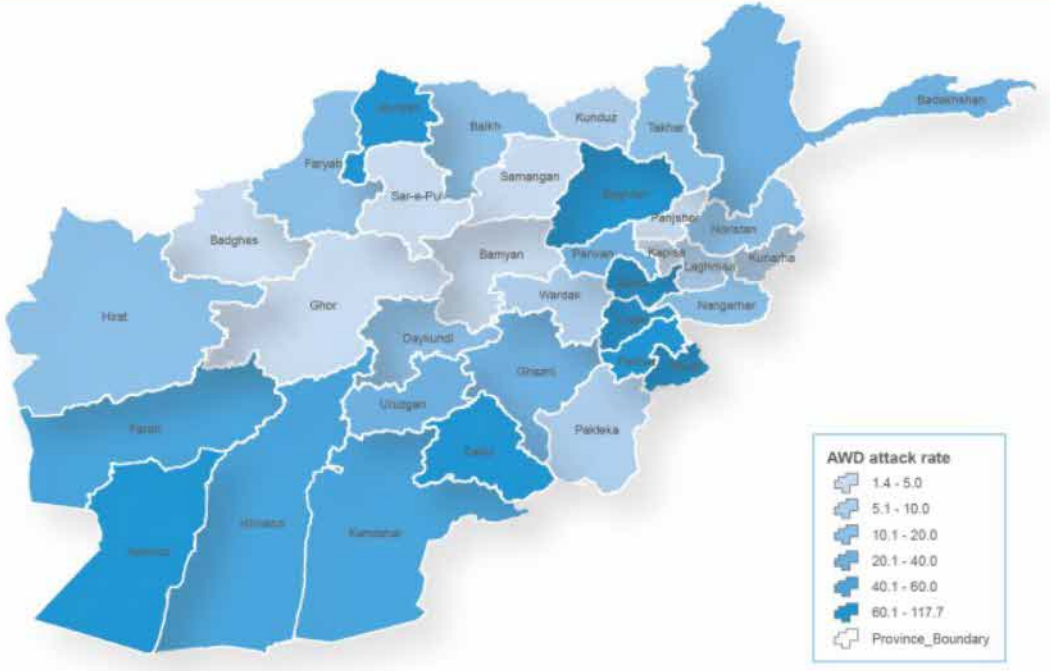


Figure 5. AWD with dehydration attack rate per 10,000 population by province in Afghanistan, 01 Jan–05 Aug 2023

From: GDD-OUTBREAK (CDC)
Sent: Thu, 17 Aug 2023 17:47:31 -0400
To: Undisclosed recipients:
Subject: Global Disease Detection Operations Center Daily Report - 08/17/2023
Attachments: Epicurve AWD 1 Jan- 12 Aug 2023.jpg, Epi Curve Diphtheria Nigeria 2023 EW31 Aug2023_NCDC.JPG

****** Global Disease Detection Operations Center (GDDOC) Daily Report for 08/17/2023 ******

******** FOR INTERNAL CDC USE ONLY ********

At A Glance:

Of International Importance[1]

- (Update) Acute Watery Diarrheal Syndrome in Afghanistan - **Outbreak continues**
- (Update) Diphtheria in Nigeria - **Outbreak continues**
- (New) Polio (Vaccine-derived) in Guinea - **One new case**

(b)(4)

For Information[3]

- (New) COVID-19 in Denmark, Israel - **BA.2.86 designated as new variant under monitoring**

Agent/Disease:	**Acute Watery Diarrheal Syndrome**
Country/Territory:	**Afghanistan**
Location:	**Widespread**
Geoscope[4]:	**Medium**
Public Health Impact[5]:	**Medium**
Source:	**WHO - EMRO; WHO - Afghanistan**
GDDOC First Notified On:	**07/08/2022**
GDDOC Last Reported On:	**08/10/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**

Attachments:

- Epicurve AWD 1 Jan- 12 Aug 2023.jpg

Description:

The GDD Operations Center (GDDOC) is monitoring an outbreak of acute watery diarrhea (AWD) in Afghanistan.

Between epidemic week (EW) 1 and EW 32 2023, a total of 128,880 suspected cases of AWD with 63 deaths (case-fatality proportion (CFP) = 0.05%) have been reported by the WHO Country Office (CO) for Afghanistan. Data reported this week include reports from 598 of 613 sentinel surveillance sites. This is an increase of 8,306 cases and four deaths since our last report with data as of EW 31. During EW 32, 8,255 new cases with four new deaths were reported from 241 districts. During EW 32, the new deaths were reported from the provinces of Kabul (2), Ghazni (1), and Urozgan (1). The general trend of cases has been rising since EW 10 which is linked to the summer season. Of the total cases, 73,578 (57.1%) are in children aged below five years and 63,899 (49.6%) cases have been reported in females. Please see the attached map, depicting AWD attack rate per 10,000 population by province and epidemic curve, depicting cases of AWD by reporting week from EW 1 to EW 32, 2023 both courtesy of the WHO CO.

In response to the outbreak, a national task force was established within the Ministry of Public Health (MoPH) to lead the response at the national and subnational levels. A total of 226 focal points have been trained on e-surveillance in seven regions including Central East, Central West, Northeast, East, West, South, and North. A total number of 195 surveillance support team (SST) members have been trained since the beginning of 2023. Currently, SSTs are actively participating in outbreak investigation and response activities in 34 provinces. Additionally, a total of 762 health care workers have been trained on AWD case management in five regions including Central, Central Highland, West, North, and East with 350 more workers expected to be trained in the coming weeks. Thirty-four provinces have been supplied with a total of 3,750 Cary-Blair transport media and 330 rapid diagnostic tests to confirm AWD cases. Seven laboratories in the country have recently received diagnostic supplies and technical capacity for confirming AWD including the Central Public Health Laboratory, Infectious Disease Hospital in Kabul, and regional reference laboratories in Kandahar, Paktya, Nangarhar, Balkh, and Herat.

The GDDOC last actively monitored AWD, then attributable to cholera, in Afghanistan in 2008; as of 20 October 2008, there were 5,403 cases with 24 deaths (CFP = 0.44%) reported from 17 provinces in Afghanistan since the beginning of September 2008.

The GDDOC will provide updates as information becomes available.

Agent/Disease:	**Diphtheria**
Country/Territory:	**Nigeria**
Location:	**Widespread**
Geoscope[4]:	**Medium**
Public Health Impact[5]:	**Medium**
Source:	**Nigeria Center for Disease Control (NCDC); NCHHSTP/DSTDP; WHO/UNICEF Joint Reporting Form on Immunization (JRF); CDC - Nigeria; GHC/GID**
GDDOC First Notified On:	**01/17/2023**
GDDOC Last Reported On:	**08/10/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**
Attachments:	• Epi Curve Diphtheria Nigeria 2023 EW31 Aug2023_NCDC.JPG

Description:

The Global Disease Detection Operations Center (GDDOC) has been monitoring reports of diphtheria in Nigeria.

According to the Nigeria Center for Disease Control (NCDC), 105 confirmed diphtheria cases (including 2 deaths) were reported from Kano (97), Katsina (6) and Yobe (2) states, out of 178 suspected cases during epidemiological week (EW) 31, compared to 223 cases reported in the previous week. Cumulative total is 5,328 suspected cases and 2,462 confirmed cases including 188 deaths (case fatality proportion [CFP] = 7.6%) reported from epidemiological week (EW) 19, 2022 to EW 31, 2023 (data as of 14 August). Please see attached epidemic curve, depicting

cases of diphtheria from EW 19, 2022 to EW 31, 2023, courtesy of NCDC. The 5,328 suspected cases were reported from 27 states across 139 local government areas (LGAs) in the country; majority of the suspected cases were reported from Kano state.

Among the 2,462 confirmed cases, the majority (68.4%) occurred in children aged 1 – 14 years; only 20.7% were fully vaccinated with a diphtheria toxoid-containing vaccine.

The most recent WHO UNICEF Estimates of National Immunization Coverage (WUENIC) data for Nigeria in 2022 indicates 70% coverage for 1st dose diphtheria toxoid-containing vaccine and 62% coverage for 3rd dose, both below the goal of 95% coverage with three doses for the primary series recommended by WHO. Two rounds of outbreak response vaccination campaigns have been conducted in five high-risk LGAs in Kano. Another round is scheduled for 21 August in 33 LGAs of four states: Bauchi, Katsina, Yobe and Kaduna. The target age group is 0-14 years.

NCDC has activated the national Diphtheria Emergency Operations Center (EOC) to coordinate the response and deployed National Rapid Response Teams to affected States to conduct field investigations. Efforts to harmonize surveillance and laboratory data from across states and laboratories are ongoing. The Ministry of Health (MoH) in collaboration with partners and WHO are working to increase available doses of diphtheria antitoxin (DAT) for use in case management to be administered along with antibiotics. CDC is discussing with the Diphtheria EOC incident manager on potential area of support. Current challenges include incomplete reporting and sub-optimal surveillance data quality from some of the states, delays in uploading and updating lab results from states on their line lists, and non-compliance with the use of standardized line lists.

Diphtheria is an acute, bacterial disease caused by toxin-producing strains of *Corynebacterium diphtheriae*. Diphtheria and its complications, including death, are caused by effects of the toxin and may include airway blockage, myocarditis, polyneuropathy, and kidney failure. Transmission is most often person-to-person through respiratory droplets. Transmission may also occur from exposure to infected skin lesions. Diphtheria occurs worldwide, particularly in countries with suboptimal vaccination coverage. A CDC Travel Notice (Alert - Level 2, Practice Enhanced Precautions) was issued regarding Diphtheria in Nigeria on 24 February 2023 and updated 23 July 2023.

Agent/Disease:	**Polio (Vaccine-derived)**
Country/Territory:	**Guinea**
Location:	**Kankan**
Geoscope[4]:	**High**

(b)(4)

(b)(4)

(b)(4)

Agent/Disease:	**COVID-19**
Country/Territory:	**Denmark, Israel**
Location:	**Unspecified**
Source:	**Denmark Ministry of Health; Israel Ministry of Health; WHO; NCIRD/CORVD**
GDDOC First Notified On:	**08/14/2023**
Public Health Event:	**For Information**
Event Type:	**Human**

Description:

The GDD Operations Center (GDDOC) is closely monitoring reports of a highly divergent variant of SARS-CoV-2, recently assigned the PANGO lineage of BA.2.86.

On 13 August 2023, a genetic sequence of SARS-CoV-2 was uploaded to GISAID from Israel. The sequence has 37 amino acid differences in the spike protein compared to XBB.1.5. On 14 August, two similar sequences were uploaded from Denmark. All three sequences were collected from patients in late July, and no epidemiological linkage between them has been identified. On 17 August, an additional sequence was identified in the United States from a sample collected on 3 August. On 17 August, this variant received the designated PANGO lineage of BA.2.86, and WHO designated it among variants under monitoring (VUMs) based on the large number of mutations identified.

Neither of the two cases from Denmark were immunocompromised and they have no epidemiological link between them. Case investigations are underway to better characterize the exposure history, onward transmission, and clinical outcomes of these patients. To date, this new variant has not been associated with an increase in cases, hospitalizations or deaths, but CDC is closely monitoring the situation domestically and internationally. Such highly divergent lineages are not uncommon, but they tend to be from immunocompromised individuals with a chronic infection. The occurrence of multiple cases across different regions of the world is concerning.

Genetic sequencing efforts of SARS-CoV-2 have dropped precipitously in recent months, making it difficult to track new variants in many if not most areas of the world.

GDDOC will continue to monitor this event and provide updates as necessary.

Mission Statement
Global Disease Detection Operations Center

The mission of the CDC Global Disease Detection Operations Center is to provide a single source of reliable, comprehensive, and high quality information on international disease outbreaks and other health threats, by 1) systematically collecting and analyzing international health event data for early detection, classifying the health risk associated with these events, disseminating event information, and facilitating appropriate and rapid interventions, and 2) by leveraging CDC program expertise and formal and informal networks, including other CDC partners.

Key

[1]**Public Health Event Of International Importance** is a verified disease outbreak or a health threat that meets one of the following criteria:

1. Is one of the following: SARS, polio (wild - type), smallpox or a new subtype of influenza

2. Presents a serious threat to the public health

3. Is unusual or an unexpected event

4. Poses a significant risk for international spread that potentially requires international intervention

5. Potentially causes restrictions of trade or travel

[2]**Public Health Event Under Investigation** is a disease outbreak or a health threat that potentially meets one of the above criteria, but, at the moment, is not yet verified.

[3]**Public Health Event For Information** is a description of a verified health event that does not meet one of the above criteria but is of interest to the public health community.

Risk Scales

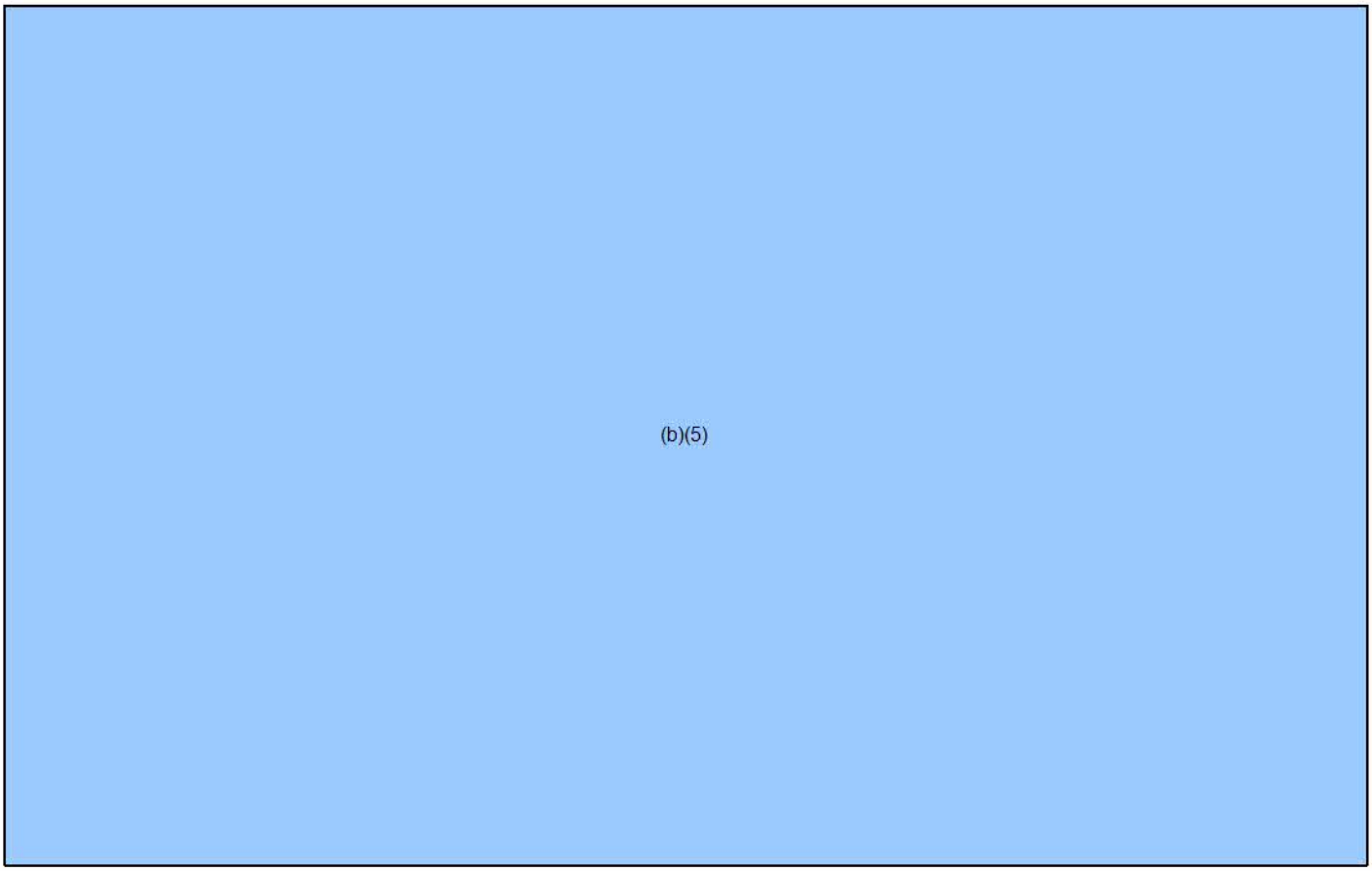
[4]**Geographic Scope** refers to the observed geographic distribution and rapidity of spread for an outbreak and is categorized as follows:

High	Events affecting several multi-national regions or continuing spread beyond national borders
Medium	Events affecting a multi-national region or continuing spread within a national border
Low	Events limited to sub-national areas

[5]**Public Health Impact** refers to actual or potential severity of illness, ease of transmission, public fear, or economic affects and is categorized as follows:

High	Agent that is or potentially: highly pathogenic, highly transmittable, new or emerging, or has significant potential to disrupt travel/trade
Medium	Agent that has moderate potential to cause morbidity/mortality
Low	Agent that has low potential to cause morbidity/mortality

(b)(5)



Daily Reports Archives: CDC staff receiving the Global Disease Detection Operations Center (GDDOC) Daily Report may directly access the report archives here: Report Archives. Please note that the hyperlinks in this report that lead to PDF files and the GDDOC Daily Report Archives are accessible only within the CDC Network.

This report is produced by the Global Disease Detection Operations Center (GDDOC)
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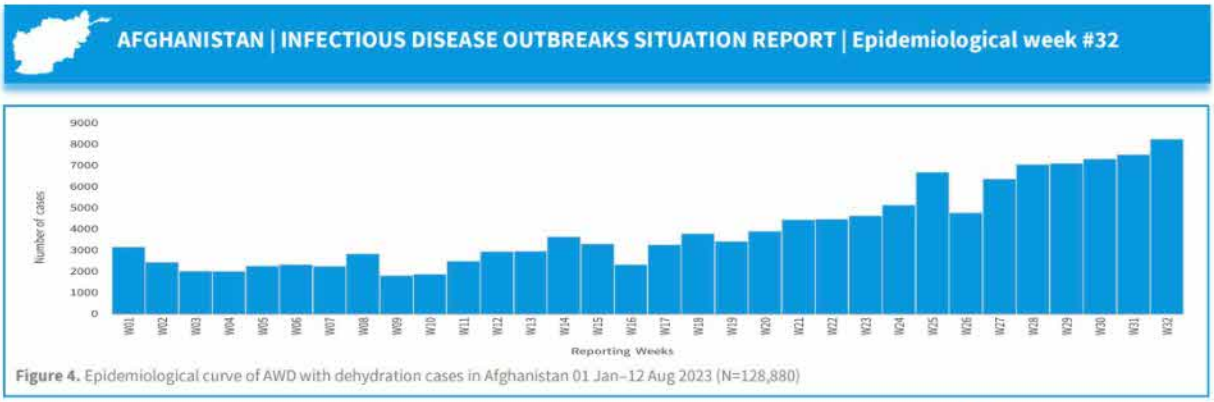


Figure 4. Epidemiological curve of AWD with dehydration cases in Afghanistan 01 Jan–12 Aug 2023 (N=128,880)

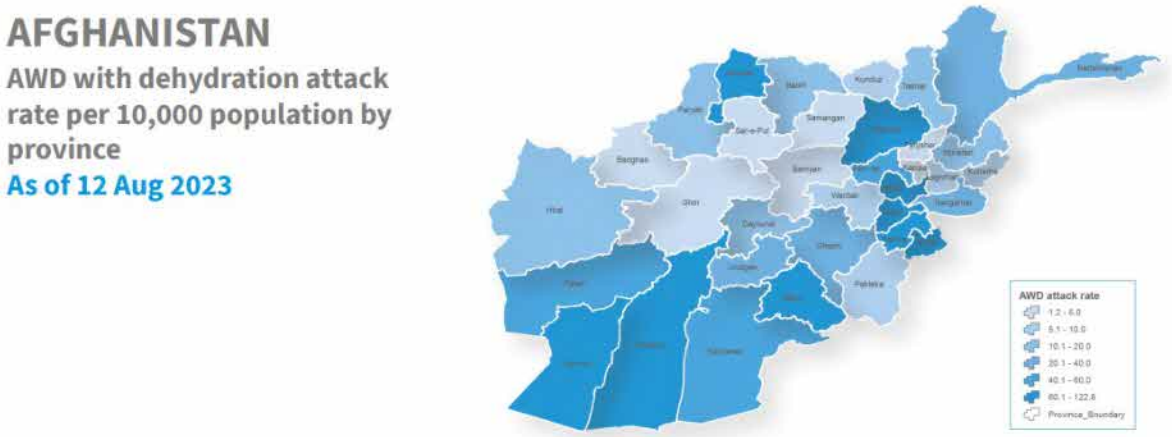


Figure 5. AWD with dehydration attack rate per 10,000 population by province in Afghanistan, 01 Jan–12 Aug 2023

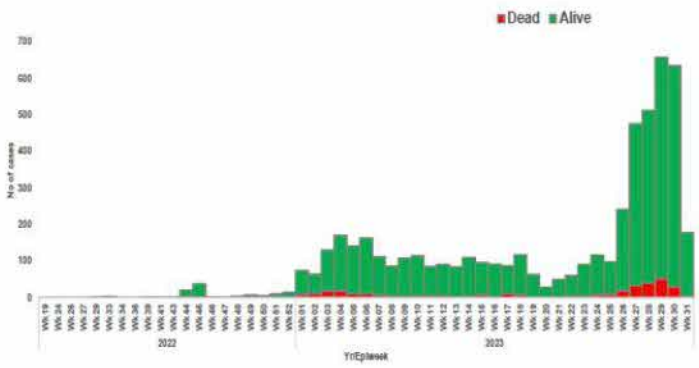


Figure 5: Epicurve of suspected Diphtheria cases in Nigeria, Wk 19, 2022 to wk 31, 2023

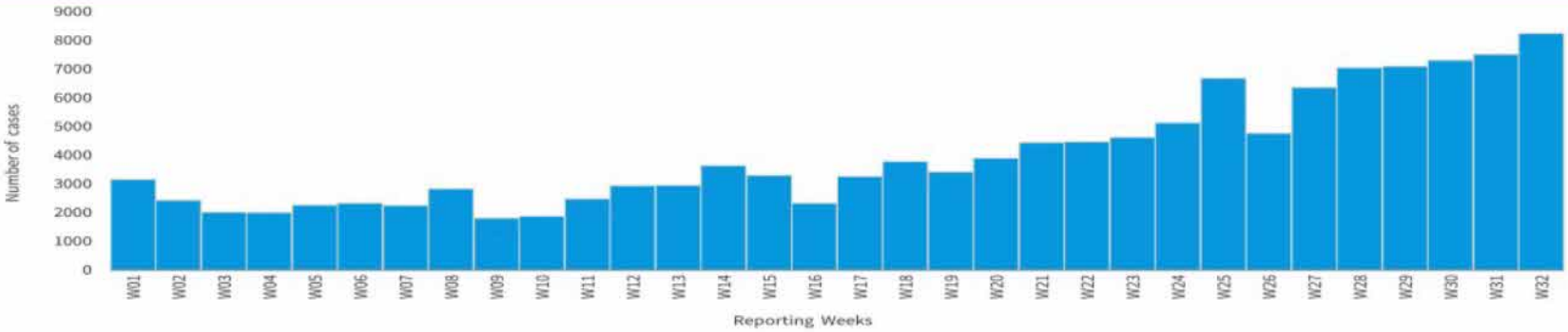


Figure 4. Epidemiological curve of AWD with dehydration cases in Afghanistan 01 Jan–12 Aug 2023 (N=128,880)

AFGHANISTAN

AWD with dehydration attack rate per 10,000 population by province

As of 12 Aug 2023

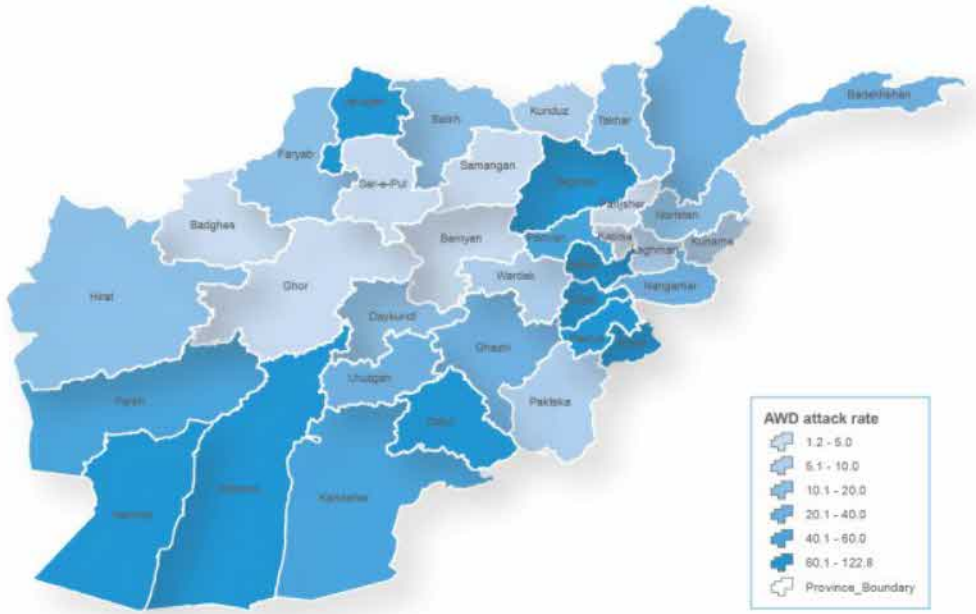


Figure 5. AWD with dehydration attack rate per 10,000 population by province in Afghanistan, 01 Jan–12 Aug 2023

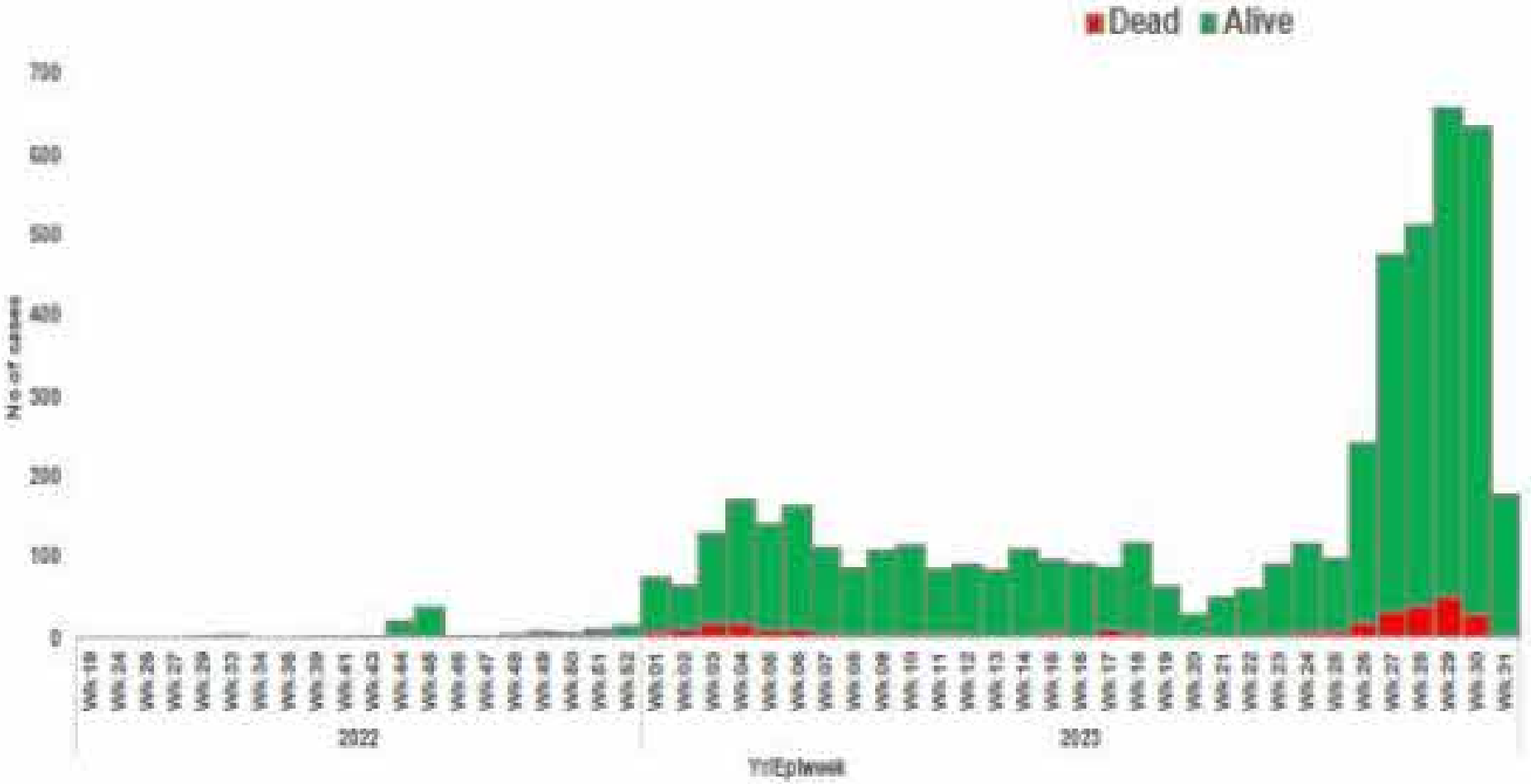


Figure 5: Epicurve of suspected Diphtheria cases in Nigeria, Wk 19, 2022 to wk 31, 2023

From: GDD-OUTBREAK (CDC)
Sent: Thu, 31 Aug 2023 19:32:03 -0400
To: Undisclosed recipients:
Subject: Global Disease Detection Operations Center Daily Report - 08/31/2023
Attachments: Map DiphtheriaGuinea_EW33 20230822_ANSS.jpg, Epi Curve Diphtheria Nigeria 2023 EW33_WHO-NCDC.jpg, DrugSens Diphtheria Nigeria 2023 EW33_WHO-NCDC.jpg, Dengue EpiCurve 2017-2023 EW33 Peru_MINSA.jpg, CCHF Afghanistan 2017_2023.PNG, Epicurve CCHF Afghanistan Jan 1_26 Aug 2023.PNG, Map CCHF Afghanistan Jan 1_26 Aug 2023.PNG, Epicurve Somalia Cholera EW30 2022 - EW33 2023.jpg, Epicurve AWD 1 Jan- 26 Aug 2023.jpg

****** Global Disease Detection Operations Center (GDDOC) Daily Report for 08/31/2023 ******

******** FOR INTERNAL CDC USE ONLY ********

At A Glance:

Of International Importance[1]

- (New) Crimean-Congo Hemorrhagic Fever in Afghanistan - **Cases surpass previous combined 3-year total**
- (New) Diphtheria in Guinea - **Response activities ongoing**
- (Update) Diphtheria in Nigeria - **Second wave continues**
- (Update) Acute Watery Diarrheal Syndrome in Afghanistan - **Outbreak continues**
- (Update) Cholera in Ethiopia - **Drought continues, limiting response**
- (Update) Cholera in Somalia - **Outbreak continues**
- (Update) Dengue in Peru - **Declining trend continues**
- (Update) Influenza A (H5N6) in China - **Additional epidemiologic information available**

(b)(4)

For Information[2]

- (Update) COVID-19 in Canada, Denmark, France, Israel, Portugal, South Africa, Sweden, Thailand, United Kingdom - **Additional countries reporting BA.2.86**
- (New) Influenza [Animal (Highly Pathogenic)] in Argentina - **Reports of H5N1 in sea lions**
- (New) Influenza [Animal (Highly Pathogenic)] in Russia - **Report of H5N1 in a seal**

Agent/Disease:	**Crimean-Congo Hemorrhagic Fever**
Country/Territory:	**Afghanistan**
Location:	**Widespread**
Geoscope[4]:	**Medium**
Public Health Impact[5]:	**High**
Source:	**GHC; WHO - Afghanistan**
GDDOC First Notified On:	**08/27/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**
Attachments:	• CCHF Afghanistan 2017_2023.PNG • Epicurve CCHF Afghanistan Jan 1_26 Aug 2023.PNG • Map CCHF Afghanistan Jan 1_26 Aug 2023.PNG

Description:

The Global Disease Detection Operations Center has been monitoring reports of Crimean-Congo hemorrhagic fever (CCHF) in Afghanistan.

From 1 January to 26 August 2023, a total of 949 cases have been suspected for CCHF with 96 associated deaths (case-fatality proportion = 10.1%). The cumulative number of suspected cases this year so far surpasses the combined total reported in the last three years following the COVID-19 pandemic (2020-2022) of 660 cases. During epidemiological week (EW) 34, 37 new suspected cases were reported. The highest weekly number of suspected cases this year were reported in EW 26 when 119 cases were recorded. In attachment, please see an epidemiologic curve provided by the WHO Afghanistan country office showing the weekly number of suspected cases and deaths by EW as of EW 34. Also, please see the comparison of weekly cases reported through EW 23, 2023 compared to the average of weekly total cases from the past six years (2017-2022) provided by the WHO Afghanistan country office. During this year, a total of 844 samples have been collected throughout the country and 290 (34.4%) were positive for CCHF.

The suspected cases have been reported from 25 provinces with more than half coming from the provinces of Kabul (339, 37.2%), Balkh (149, 16.2%), Herat (74, 8.1%), and Kandahar (69, 7.6%) as of EW 33. Provinces reporting the highest number of deaths were Kabul (46, 47.9%)

and Balkh (14, 14.6%) as of EW 34. Please see the attached map of CCHF cases by province reported this year provided by the WHO Afghanistan country office.

CCHF is endemic in Afghanistan, however, the present outbreak situation has deteriorated, exceeding yearly averages from the past six years of surveillance in 2023. Factors considered for the increase in the number of cases include environmental and ecological changes impacting vector proliferation, population migration especially between Pakistan and Iran, and enhanced surveillance and laboratory capacities over the years. Healthcare workers have also been affected including two documented outbreaks in the northern and southern regions of the country.

In response to the outbreak, the Ministry of Public Health has been coordinating committee meetings with partners to discuss how to limit the spread of the outbreak including interventions in hotspot areas. Meetings have also been held across relevant sectors (public health, agriculture, technology) to coordinate preparedness and response measures for CCHF. Other actions include response activities by surveillance support teams, distribution of CCHF-specific laboratory kits, trainings for laboratory staff, revision of case management guidelines, trainings for clinicians, procurement of treatment and medical supplies including personal protection equipment, carrying out public health awareness campaigns, trainings for social mobilizers, and community engagement.

The GDDOC will provide updates as information becomes available.

Agent/Disease:	**Diphtheria**
Country/Territory:	**Guinea**
Location:	**Districts of Siguiri, Kankan, Mandiana, and Kouroussa**
Geoscope[4]:	**Low**
Public Health Impact[5]:	**Medium**
Source:	**CDC - Guinea; GHC/DGHP; NCIRD/DBD/MVPDB**
GDDOC First Notified On:	**07/20/2023**
Public Health Event:	**Of International Importance**

Event Type: **Human**

Attachments:
- Map DiphtheriaGuinea_EW33 20230822_ANSS.jpg

Description:

The GDD Operations Center (GDDOC) has been following reports of a diphtheria outbreak in Guinea.

According to the National Health Security Agency (ANSS), as of 22 August, a total of 113 diphtheria cases (7 confirmed) including 35 deaths (4 confirmed) have been reported since first case was reported in Siguiri on 4 July 2023. The majority of cases were reported in Siguiri district (97 cases, 19 deaths), followed by Kankan (8, 8), Mandiana (6, 6), and Kouroussa (2, 2). Please see attached map of affected districts, courtesy of ANSS.

Response activities include coordination meetings, case investigations and contact tracing/follow-up, and risk communication and community engagement efforts. Challenges include data harmonization between districts and regions as well as delays and constraints in laboratory diagnostic sampling, testing, and communication of results. Médecins Sans Frontières (MSF), in collaboration with ANSS has been supporting clinical management since early August; efforts remain ongoing to acquire a sufficient supply of diphtheria antitoxin (DAT).

Planning is ongoing for vaccination of at-risk and contact groups. According to WHO/UNICEF Estimates of National Immunization Coverage data, the 2022 DTP-containing vaccine coverage rate was 62% for the 1st dose and 47% for the 3rd dose, both below the 80-85% coverage required to maintain community protection.

CDC-Guinea has been in communications with CDC-HQ SMEs to provide informal consultation to ANSS regarding various aspects of response efforts, including lab testing and clinical management with DAT.

Diphtheria is a clinical syndrome caused by an exotoxin produced by the toxin-producing strains of the bacterium *C. diphtheriae*. Most commonly, toxigenic infection results in respiratory or cutaneous disease. Diphtheria and its complications, including death, are caused by effects of the toxin and may include airway blockage, myocarditis, polyneuropathy, and kidney failure. Transmission is most often person-to-person through respiratory droplets though may also occur from exposure to infected skin lesions. Diphtheria occurs worldwide, particularly in countries with suboptimal vaccination coverage.

Agent/Disease:	**Diphtheria**
Country/Territory:	**Nigeria**
Location:	**Widespread**
Geoscope[4]:	**Medium**
Public Health Impact[5]:	**Medium**
Source:	**Nigeria Center for Disease Control (NCDC); NCHHSTP/DSTDP; WHO/UNICEF Joint Reporting Form on Immunization (JRF); CDC - Nigeria; GHC/GID; WHO; NCIRD/DBD/MVPDB**
GDDOC First Notified On:	**01/17/2023**
GDDOC Last Reported On:	**08/17/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**
Attachments:	• Epi Curve Diphtheria Nigeria 2023 EW33_WHO-NCDC.jpg • DrugSens Diphtheria Nigeria 2023 EW33_WHO-NCDC.jpg

Description:

The Global Disease Detection Operations Center (GDDOC) is continuing to monitor the diphtheria outbreak in Nigeria. The second wave of a diphtheria outbreak in 2023 continues in Nigeria with high numbers of cases reported and additional local government areas (LGAs) newly affected.

According to WHO, an additional 1,963 suspected diphtheria cases have been reported over the past three weeks for a cumulative total of 7,291 suspected cases reported from epidemiological week (EW) 19, 2022 to EW 33, 2023 (data as of 19 August). A total of 27 LGAs reported at least one clinically compatible case in the last three EWs compared to 15 LGAs that had an active case in the preceding three weeks. The current outbreak that was first detected in Kano and Lagos states has since developed into the first nationwide diphtheria outbreak on record, affecting 27 out of the 36 states and the FCT. The majority (98%) of suspected cases were reported from Kano (5,514), Yobe (763), Katsina (316), Kaduna (101), Bauchi (54), Federal Capital Territory (FCT) (41) and Lagos (30). Of the 7,291 suspected cases reported, 3,869 (53.1%) were either lab confirmed (160), epidemiologically linked (15), or clinically compatible (3,694); 267 deaths were reported for a case-fatality proportion of 7%. From previous EW 31 data, the majority of cases occurred in children aged 1 – 14 years and only ~20% had been fully vaccinated with a diphtheria toxoid-containing vaccine. Please see the attached epidemic curve from EW 19, 2022 - EW 33, 2023, courtesy of WHO with data sourced from Nigeria Center for Disease Control (NCDC).

Corynebacterium diphtheriae and *Corynebacterium ulcerans* isolates have been identified through molecular testing as the species driving this outbreak, with the highest being *C. diphtheriae*. Antibiotic susceptibility tests for 62 isolates have been carried out and the findings revealed that all isolates were resistant to penicillin, and most were resistant to trimethoprim-sulfamethoxazole and ciprofloxacin, while being susceptible to erythromycin. Thus, erythromycin has become the drug of choice in management of this outbreak.

NCDC continues to lead and coordinate response activities through the National Diphtheria Emergency Operations Center (EOC), including risk communication and community engagement, case investigations and contact tracing by National Rapid Response Teams, laboratory testing, and clinical management. Thus far, 5,750 vials of diphtheria anti-toxin (DAT) have been purchased of which 4,950 have been delivered and deployed to the states since December 2022. The NCDC estimates that 12,000 additional DAT vials may be needed to respond to the outbreak. DAT supply is reported by WHO to be currently constrained as there is a limited number of manufacturers and large outbreaks are being reported in different regions of the world. The lack of DAT accessibility hampers effective outbreak response. Emergency procurement of additional DAT, intravenous erythromycin and other medicines for case management has been initiated. CDC is discussing potential areas of support with the Diphtheria EOC incident manager. A CDC Travel Notice (Alert - Level 2, Practice Enhanced Precautions) was issued regarding Diphtheria in Nigeria on 24 February 2023 and updated 23 July 2023.

The most recent WHO UNICEF Estimates of National Immunization Coverage (WUENIC) data for Nigeria in 2022 indicates 70% coverage for 1st dose diphtheria toxoid-containing vaccine

and 62% coverage for 3rd dose, both below the 80-85% coverage required to maintain community protection. Outbreak response vaccination campaigns have been conducted in Kano state prioritizing the highest burden LGAs, using tetanus-diphtheria (Td) vaccines and targeting children aged 4-14 years. A total of 438,092 children were reached. The National Primary Health Care Development Agency (NPHCDA) is planning to conduct outbreak response vaccination activities in high burden states across the country in two phases. Phase 1 will be in 25 high burden LGAs in Bauchi, Kaduna, Katsina and Yobe states. Phase 2 will be conducted in three rounds in six high burden states (Bauchi, FCT, Kaduna, Kano, Katina and Yobe). The reinforcement of routine immunization activities throughout the country is still in progress. Due to insecurity, especially in Northeast Nigeria, vaccination coverage remains suboptimal.

Agent/Disease:	**Acute Watery Diarrheal Syndrome**
Country/Territory:	**Afghanistan**
Location:	**Widespread**
Geoscope[4]:	**Medium**
Public Health Impact[5]:	**Medium**
Source:	**WHO - EMRO; WHO - Afghanistan**
GDDOC First Notified On:	**07/08/2022**
GDDOC Last Reported On:	**08/17/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**
Attachments:	• Epicurve AWD 1 Jan- 26 Aug 2023.jpg

Description:

The GDD Operations Center (GDDOC) is monitoring an outbreak of acute watery diarrhea (AWD) in Afghanistan.

Between epidemic week (EW) 1 and EW 34 2023, a total of 144,543 suspected cases of AWD with 74 deaths (case-fatality proportion (CFP) = 0.05%) have been reported by the WHO Country Office (CO) for Afghanistan. Data reported this week include reports from 580 of 613 sentinel surveillance sites. This is an increase of 15,663 cases and 11 deaths since our last report with data as of EW 32. During EW 34, 7,510 new cases with eight new deaths were reported from 223 districts. During EW 34, the new deaths were reported from the provinces of (b)(6) Of the total cases, 82,883 (57.3%) are in children aged below five years and 71,809 (49.7%) cases have been reported in females. Please see the attached map, depicting AWD attack rate per 10,000 population by province and

epidemic curve, depicting cases of AWD by reporting week from EW 1 to EW 34, 2023 both courtesy of the WHO CO.

In response to the outbreak, a national task force was established within the Ministry of Public Health (MoPH) to lead the response at the national and subnational levels. A total of 254 focal points have been trained on e-surveillance in eight regions including Central East, Central West, Northeast, East, West, South, North, and Southeast. A total number of 195 surveillance support team (SST) members have been trained since the beginning of 2023. Currently, SSTs are actively participating in outbreak investigation and response activities in 34 provinces. Additionally, a total of 820 health care workers have been trained on AWD case management in six regions including Central, Central Highland, West, North, Northeast, and East. Thirty-four provinces have been supplied with a total of 4,350 Cary-Blair transport media and 330 rapid diagnostic tests to confirm AWD cases. Seven laboratories in the country have recently received diagnostic supplies and technical capacity for confirming AWD including the Central Public Health Laboratory, Infectious Disease Hospital in Kabul, and regional reference laboratories in Kandahar, Paktya, Nangarhar, Balkh, and Herat.

The GDDOC last actively monitored AWD, then attributable to cholera, in Afghanistan in 2008; as of 20 October 2008, there were 5,403 cases with 24 deaths (CFP = 0.44%) reported from 17 provinces in Afghanistan since the beginning of September 2008.

The GDDOC will provide updates as information becomes available.

Agent/Disease:	**Cholera**
Country/Territory:	**Ethiopia**
Location:	**Regions of Somali, Oromia, SNNP, Sidama, Amhara**
Geoscope[4]:	**Medium**
Public Health Impact[5]:	**Medium**
Source:	**NCEZID/DFWED; UN Office for the Coordination of Humanitarian Affairs (OCHA); WHO - AFRO; GHC/DGHP**
GDDOC First Notified On:	**09/26/2022**
GDDOC Last Reported On:	**08/04/2023**

Public Health Event:	**Of International Importance**
Event Type:	**Human**

Description:

The GDD Operations Center (GDDOC) is monitoring an outbreak of cholera in Ethiopia.

As of 25 August 2023, 18,937 suspected cases of cholera with 247 deaths (case-fatality proportion = 1.30%) have been reported from the regions of Oromia, Somali, Southern Nations, Nationalities, and Peoples' (SNNP), Sidama, and Amhara since 27 August 2022. This is an increase of 2,613 cases and 35 deaths since our last report, with data as of 31 July.

Drought has limited access to water for a robust WASH response, which is critical amidst the reported low access to safe water, low latrine coverage, and open defection practices. Emergency water treatment kits have been installed in prioritized woredas in Oromia and Somali to minimize the health risks of using contaminated water. Additional efforts are ongoing to engage with development partners for improving water supply systems, particularly in cholera hotspot woredas where the population relies on untreated river or pond water, and woredas with high rates of open defecation.

The CDC Ethiopia country office is working closely with the Ethiopian Public Health Institute and is supporting the government in the response to this outbreak.

The GDDOC will provide updates as information becomes available.

Agent/Disease:	**Cholera**
Country/Territory:	**Somalia**
Location:	**Widespread**
Geoscope[4]:	**Medium**

Public Health Impact[5]:	**Medium**
Source:	**UN Office for the Coordination of Humanitarian Affairs (OCHA); WHO - EMRO; WHO - Somalia; WHO; Somalia Ministry of Health; GHC/DGHP**
GDDOC First Notified On:	**02/21/2017**
GDDOC Last Reported On:	**08/10/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**
Attachments:	• Epicurve Somalia Cholera EW30 2022 - EW33 2023.jpg

Description:

The GDD Operations Center (GDDOC) is continuing to monitor an outbreak of cholera in Somalia, ongoing since 2022.

From epidemic week (EW) 1 to EW 33, 2023, a total of 12,374 cases of acute watery diarrhea suspected to be attributable to cholera with 30 deaths (case-fatality proportion (CFP) = 0.24%) have been reported from 28 drought-affected districts in Somalia. This is an increase of 670 cases and no deaths since our last report with data as of EW 30. Of the total cases, 6,640 (53.7%) are in children aged below five years and 6,382 (51.6%) have been reported in females. Of the total deaths, 20 (66.7%) have been in children aged under five years. Please see the attached epidemic curve, courtesy of WHO Country Office in Somalia, depicting suspected cases of cholera reported by EW from EW 30, 2022 to EW 33, 2023.

Of 1,676 stool samples collected since EW 1, 2023, 174 (10.9%) have tested positive for *Vibrio cholerae* 01 serotype Ogawa. Laboratory confirmation is being conducted by culture at the National Public Health Laboratory, in Mogadishu.

The Ministry of Health (MoH), WHO, and other health partners have scaled up implementation of cholera response interventions in drought-affected districts with a focus on Jubaland state, which is the current epicenter of the ongoing outbreak. Somalia has had uninterrupted cholera transmission in drought-affected districts since 2022, and in Banadir region since the drought

period of 2017. The current outbreak is a result of an increasing number of people who have no access to safe water and proper sanitation because of drought.

The GDDOC last reported on cholera in Somalia from February 2017 to January 2019; as of 7 January 2019, the MoH had reported 6,731 cases of cholera with 46 deaths (CFP = 0.68%) since the beginning of that outbreak.

The GDDOC will provide updates as information becomes available.

Agent/Disease:	**Dengue**
Country/Territory:	**Peru**
Location:	**Widespread**
Geoscope[4]:	**High**
Public Health Impact[5]:	**Medium**
Source:	**Peru Ministry of Health; NCEZID/DVBD/DB; WHO - PAHO; CDC South America (SAM) Regional Office; UN Office for the Coordination of Humanitarian Affairs (OCHA); Florida Department of Health, United States**

GDDOC First Notified On:	**03/28/2023**
GDDOC Last Reported On:	**08/07/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**
Attachments:	• Dengue EpiCurve 2017-2023 EW33 Peru_MINSA.jpg

Description:

The GDD Operations Center (GDDOC) is continuing to monitor dengue activity in Peru.

Overall, the national trend of weekly cases continues to decline since peaking at epidemiological week (EW) 20. As the southern hemisphere enters the colder and drier months, cases are declining in parts of the region in the Americas, as is seen in Peru.

According to the Ministry of Health (MINSA), there have been a total of 239,237 confirmed and probable cases and 410 deaths reported in Peru from EW 1 to 33, 2023. This is an increase of 16,617 probable and confirmed cases and 30 deaths since EW 30. The highest number of cases in 2023 were reported in the following departments: Piura (72,181), Lambayeque (32,404), Lima (31,951), and La Libertad (23,751). Please see epidemic curves, showing probable and confirmed dengue cases from 2017- 2023 up to EW 33, as of 30 August, courtesy of MINSA. Among the total cases, 11.3% reported warning signs during clinical illness and 0.4% were reported to be severe cases. The highest number of cases were in persons aged 30-59 years (91,408, 38%), followed by persons 18-29 years (52,723, 22%), children 0-11 years (40,342, 17%), adolescents 12-17 years (30,287, 13%), and persons 60 years and older (24,477, 10%).

Response activities continue in surveillance and epidemiological investigations; clinical management; vector control; and risk communication and community engagement.

Peru is endemic for dengue. According to MINSA, intense and prolonged rains associated with the weather phenomenon called El Niño Costero along with Peru's first cyclone (Cyclone Yaku) in many decades, contributed to the worst dengue outbreak in Peru in more than a decade. El Niño Costero is expected to continue through the summer of 2024.

Dengue is a vector-borne infectious disease caused by four dengue viruses (DENV1-4), which are predominantly transmitted by *Aedes aegypti* and *Aedes albopictus* mosquitos. Dengue is endemic throughout the tropics and subtropics, including areas in Asia, Africa, and the Americas.

Agent/Disease:	**Influenza A (H5N6)**
Country/Territory:	**China**
Location:	**Sichuan province**
Geoscope[4]:	**Low**
Public Health Impact[5]:	**Medium**
Source:	**Hong Kong Center for Health Protection; NCIRD/ID; WHO**
GDDOC First Notified On:	**08/18/2023**
GDDOC Last Reported On:	**08/23/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**

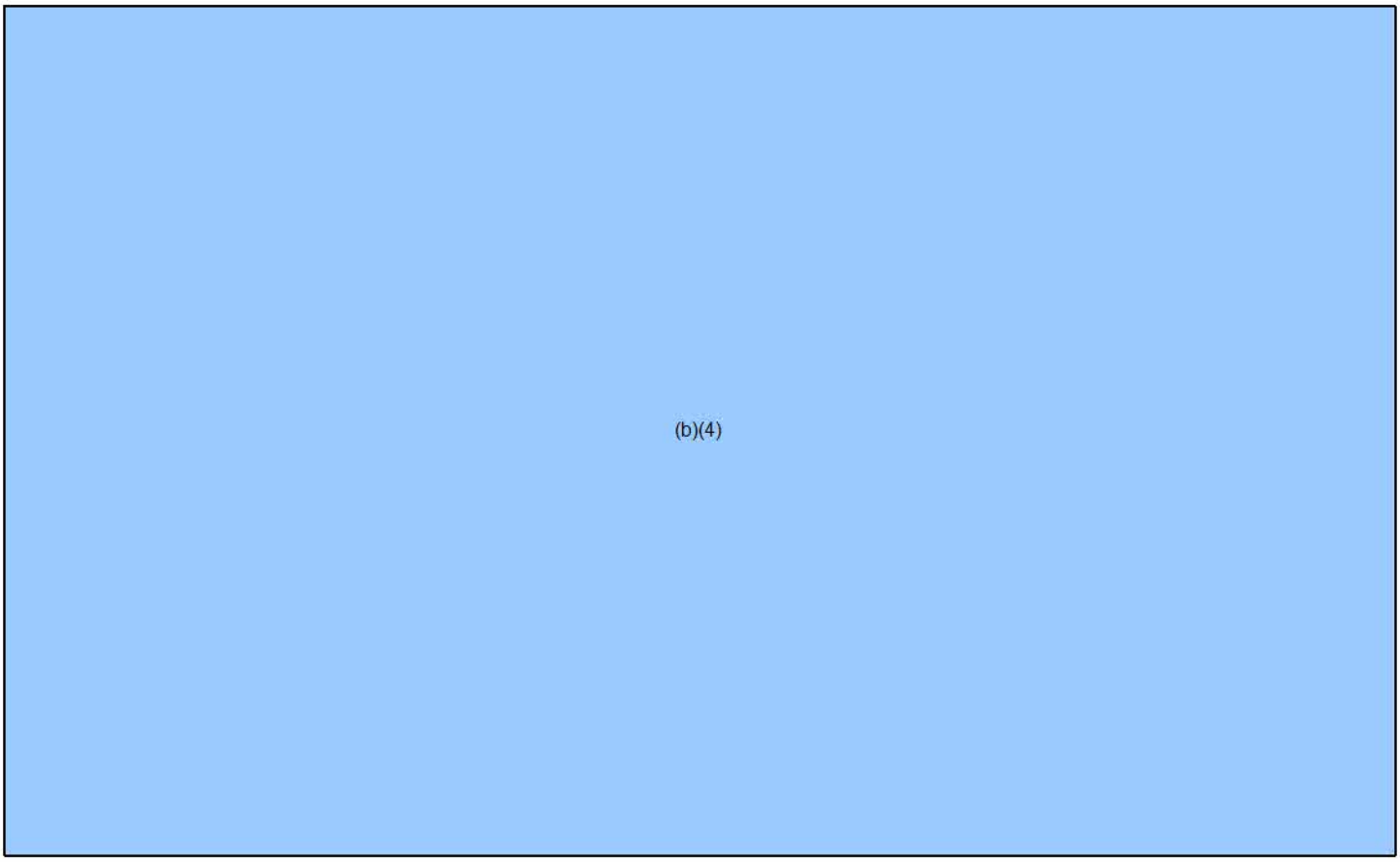
Description:

This is an update to the human infection with avian influenza A (H5N6) virus in Sichuan province, China.

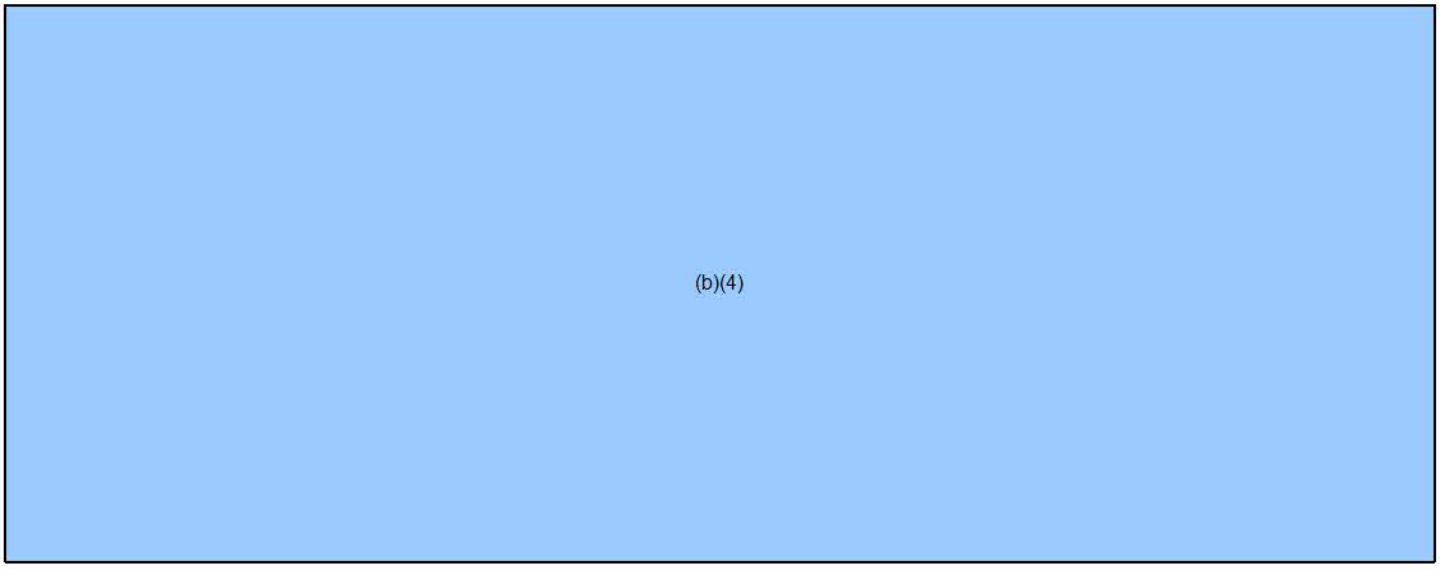
This infection was in a (b)(6) who lives in the (b)(6) (b)(6) had exposure to (b)(6) prior to illness onset on 16 July 2023, was hospitalized on (b)(6) with severe pneumonia, and remains hospitalized in severe condition. Samples were collected from close contacts and the environment; samples from the environment tested positive for avian influenza A (H5N6) virus. No close contacts had developed symptoms at the time of reporting.

Since 2014, a total of 86 laboratory-confirmed cases of human infection with avian influenza A (H5N6) virus with 33 deaths (case-fatality proportion = 38.4%) have been reported from China to WHO. The breakdown of cases reported from China per year, according to date of onset of illness, includes 2014 (2 cases), 2015 (6), 2016 (9), 2017 (2), 2018 (4), 2019 (1), 2020 (5), 2021 (36), 2022 (18), 2023 (3).

The GDDOC will provide additional information as it becomes available.



(b)(4)



Agent/Disease:	**COVID-19**
Country/Territory:	**Canada, Denmark, France, Israel, Portugal, South Africa, Sweden, Thailand, United Kingdom**
Location:	**Multiple Locations**
Source:	**WHO; NCIRD/CORVD; Ministries of Health**
GDDOC First Notified On:	**08/14/2023**
GDDOC Last Reported On:	**08/24/2023**
Public Health Event:	**For Information**
Event Type:	**Human**

Description:

The GDD Operations Center (GDDOC) is closely monitoring reports of a highly divergent variant of SARS-CoV-2, recently assigned the PANGO lineage of BA.2.86.

As of 31 August 2023, 29 human cases of variant BA.2.86 have been identified in nine countries: Denmark (10 cases), Sweden (5), the United States (4), South Africa (3), the United Kingdom (2), Portugal (2), Israel (1), Canada (1), and France (1). Wastewater testing for SARS-CoV-2 and subsequent genetic sequencing has also yielded samples positive for the variant in Thailand,

Denmark, the United Kingdom, Norway, and in the United States, and there have been preliminary reports of positive wastewater samples from Switzerland.

On 30 August 2023, CDC published a Risk Assessment Summary summarizing what is known about BA.2.86. The United Kingdom Health Security Agency also published a risk assessment on 18 August. On 17 August, WHO designated it among variants under monitoring (VUMs) based on the large number of mutations identified.

Case investigations are underway to better characterize the exposure history, onward transmission, and clinical outcomes of these patients. To date, this new variant has not been associated with an increase in cases, hospitalizations or deaths, but CDC is closely monitoring the situation domestically and internationally. Such highly divergent lineages are not uncommon, but they tend to be from immunocompromised individuals with a chronic infection. The occurrence of multiple cases across different regions of the world is concerning. Genetic sequencing efforts of SARS-CoV-2 have dropped precipitously in recent months, making it difficult to track new variants in many if not most areas of the world.

GDDOC will continue to monitor this event and provide updates as necessary.

Agent/Disease:	**Influenza [Animal (Highly Pathogenic)]**
Country/Territory:	**Argentina**
Location:	**Puerto Loyola, Rio Grande, Necochea, La Loberia**
Source:	**World Organization for Animal Health (WOAH)**
GDDOC First Notified On:	**08/28/2023**
Public Health Event:	**For Information**
Event Type:	**Non-Human**

Description:

The GDD Operations Center (GDDOC) has learned of highly pathogenic avian influenza (HPAI) A (H5N1) virus identified in sea lions in Argentina.

According to WOAH, specimens taken from South American sea lions *Otaria flavescens* found dead in Puerto Loyola, Rio Grande, Necochea, and La Loberia, Argentina tested positive for HPAI H5N1 virus by real-time reverse transcription PCR at the Dirección General de Laboratorios y Control Técnico, Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA). Epizoologic investigations are ongoing.

Sea lions are unusual host species for avian influenza; carnivores can become infected with avian influenza viruses by consuming carcasses of birds infected with avian influenza virus.

The GDDOC will provide additional information as it becomes available.

Agent/Disease:	**Influenza [Animal (Highly Pathogenic)]**
Country/Territory:	**Russia**
Location:	**Mordvinov Bay**
Source:	**World Organization for Animal Health (WOAH)**
GDDOC First Notified On:	**08/28/2023**
Public Health Event:	**For Information**
Event Type:	**Non-Human**

Description:

The GDD Operations Center (GDDOC) has learned of highly pathogenic avian influenza (HPAI) A (H5N1) virus identified in a northern fur seal in Russia.

According to WOAH, specimens taken from a northern fur seal *Callorhinus ursinus* found dead near Mordvinov Bay, Russia tested positive for HPAI H5N1 virus by real-time reverse transcription PCR at the Federal Centre for Animal Health (FGI ARRIAH). Epizoologic investigations are ongoing.

Seals are unusual host species for avian influenza; carnivores can become infected with avian influenza viruses by consuming carcasses of birds infected with avian influenza virus.

The GDDOC will provide additional information as it becomes available.

Mission Statement
Global Disease Detection Operations Center

The mission of the CDC Global Disease Detection Operations Center is to provide a single source of reliable, comprehensive, and high quality information on international disease outbreaks and other health threats, by 1) systematically collecting and analyzing international health event data for early detection, classifying the health risk associated with these events, disseminating event information, and facilitating appropriate and rapid interventions, and 2) by leveraging CDC program expertise and formal and informal networks, including other CDC partners.

Key

[1]**Public Health Event Of International Importance** is a verified disease outbreak or a health threat that meets one of the following criteria:

1. Is one of the following: SARS, polio (wild - type), smallpox or a new subtype of influenza

2. Presents a serious threat to the public health

3. Is unusual or an unexpected event

4. Poses a significant risk for international spread that potentially requires international intervention

5. Potentially causes restrictions of trade or travel

[2]**Public Health Event Under Investigation** is a disease outbreak or a health threat that potentially meets one of the above criteria, but, at the moment, is not yet verified.

[3]**Public Health Event For Information** is a description of a verified health event that does not meet one of the above criteria but is of interest to the public health community.

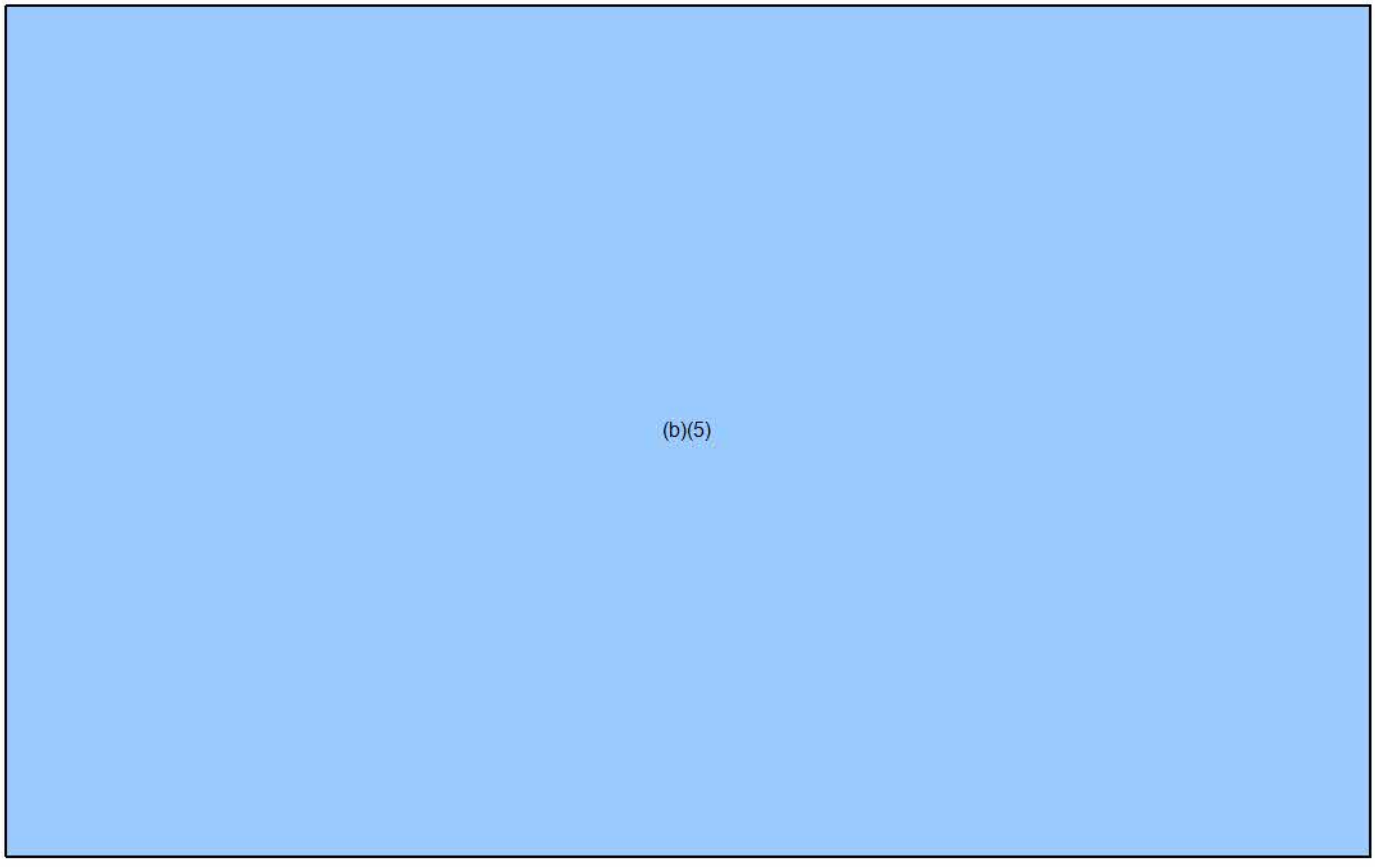
Risk Scales

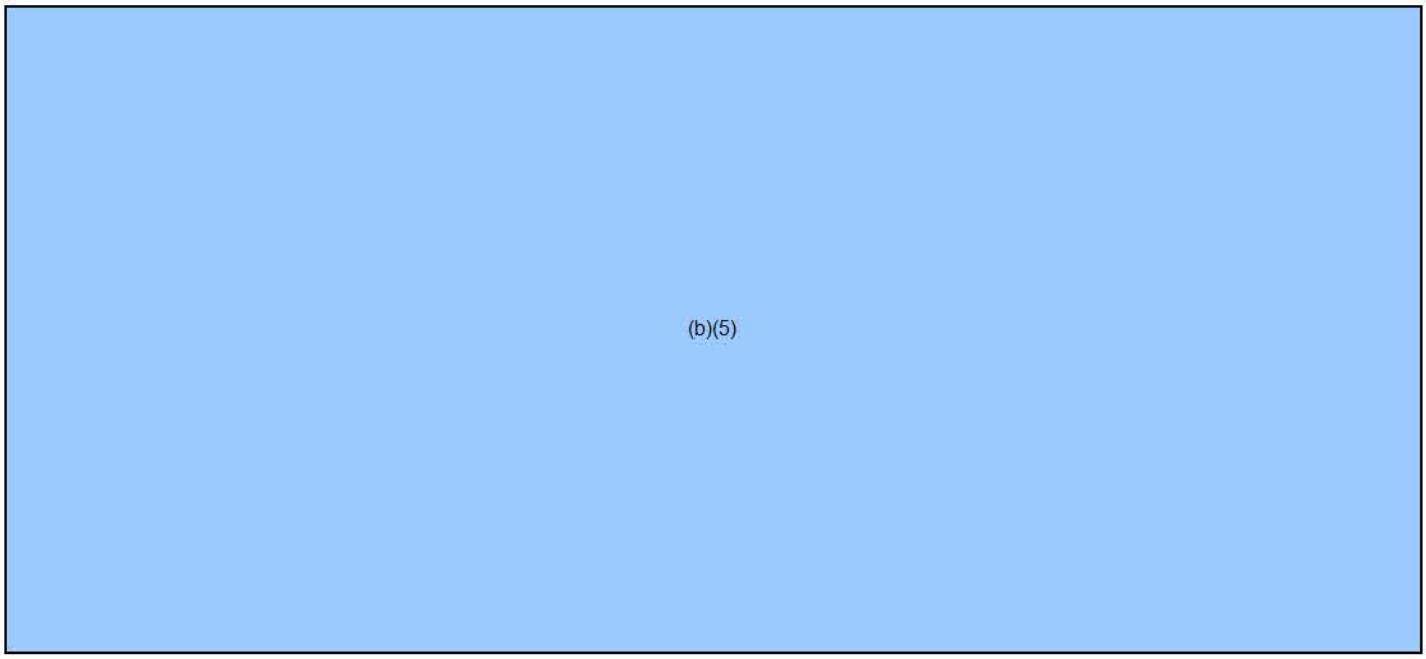
[4]**Geographic Scope** refers to the observed geographic distribution and rapidity of spread for an outbreak and is categorized as follows:

High	Events affecting several multi-national regions or continuing spread beyond national borders
Medium	Events affecting a multi-national region or continuing spread within a national border
Low	Events limited to sub-national areas

[5]**Public Health Impact** refers to actual or potential severity of illness, ease of transmission, public fear, or economic affects and is categorized as follows:

High	Agent that is or potentially: highly pathogenic, highly transmittable, new or emerging, or has significant potential to disrupt travel/trade
Medium	Agent that has moderate potential to cause morbidity/mortality
Low	Agent that has low potential to cause morbidity/mortality





This report is produced by the Global Disease Detection Operations Center (GDDOC)
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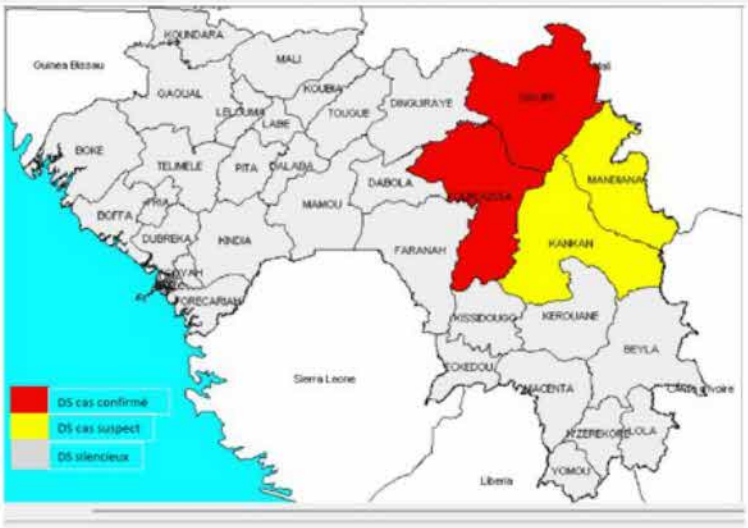
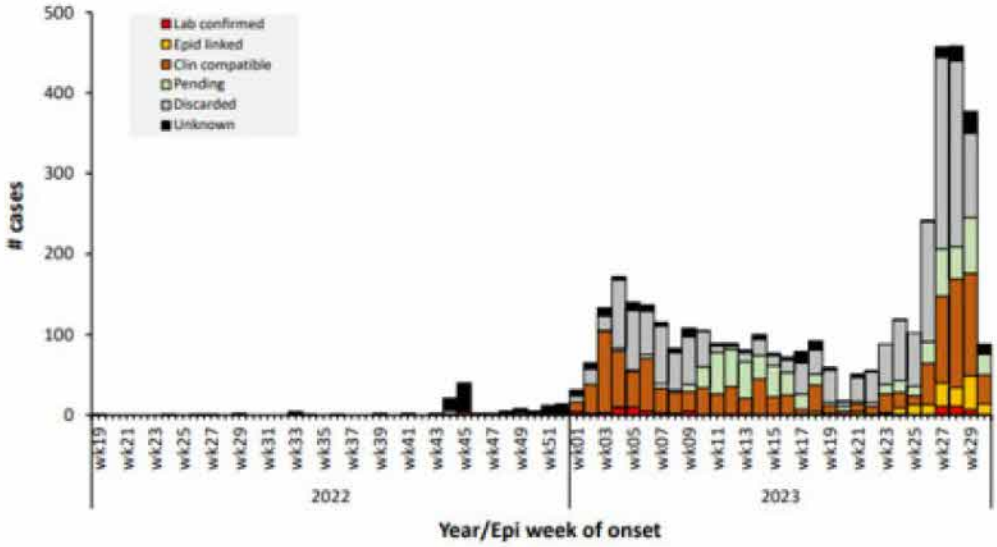
C3. DIPHTERIE

Carte 3 : Distribution spatiale cas confirmés et suspects de diphtérie, Guinée, S33, 2023



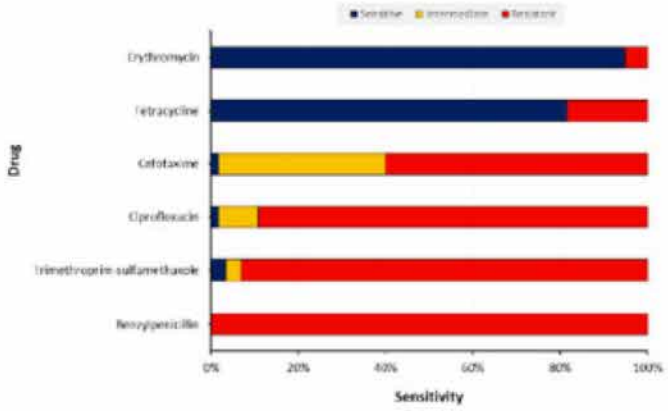
Données actualisées par la région

Figure 1: Diphtheria cases by year/epi-week in Nigeria, epi-week 19 2022 – epi-week 31 2023

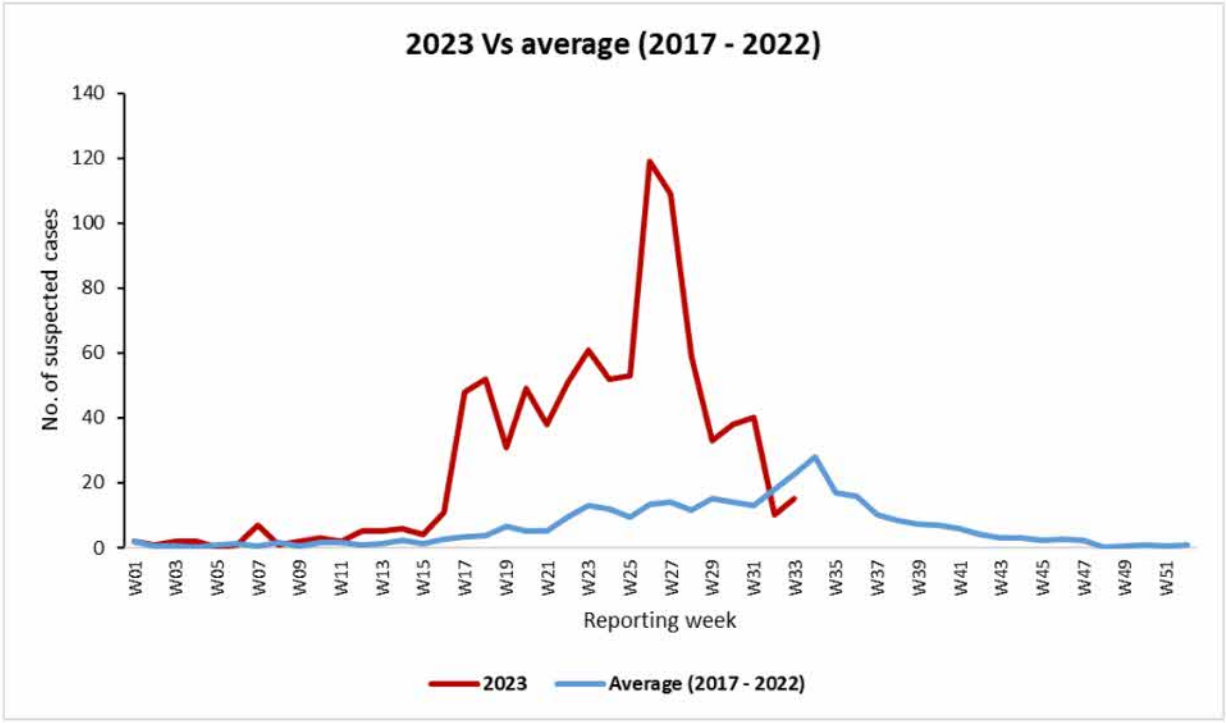


Source: NCDC

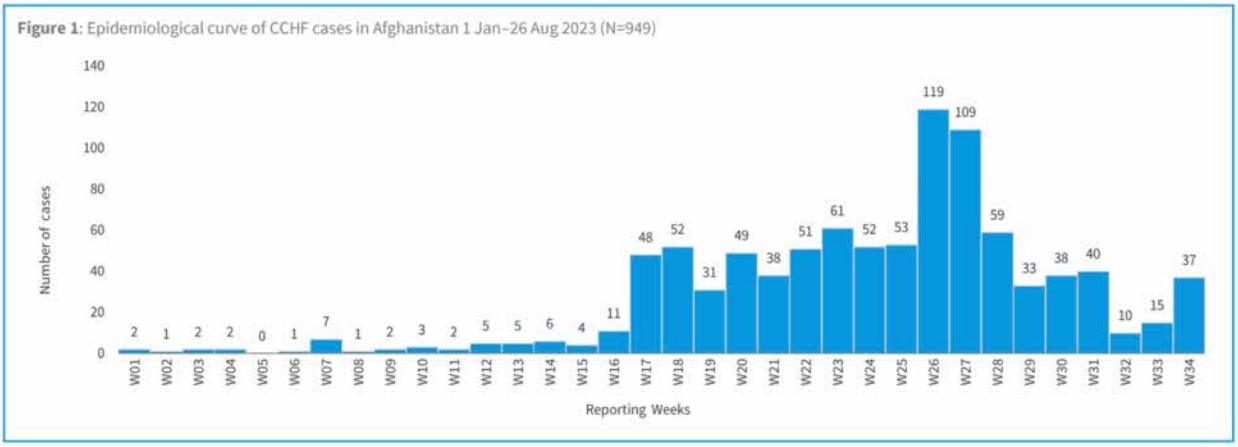
Figure 2: Drug sensitivity results of toxigenic *Corynebacterium diphtheriae* isolated in Nigeria, May 2022 – July 2023.



Source: NCDC



Comparison of weekly distribution of suspected CCHF cases, 2023 Vs average of last 6 years (2017 – 2022), Afghanistan



AFGHANISTAN

Geographical Distribution of Crimean-Congo Hemorrhagic Fever (CCHF) cases by Province

As of 26 Aug 2023

Figure 2. Geographical Distribution of Crimean-Congo Hemorrhagic Fever (CCHF) cases by Province in Afghanistan, 01 Jan–26 Aug 2023

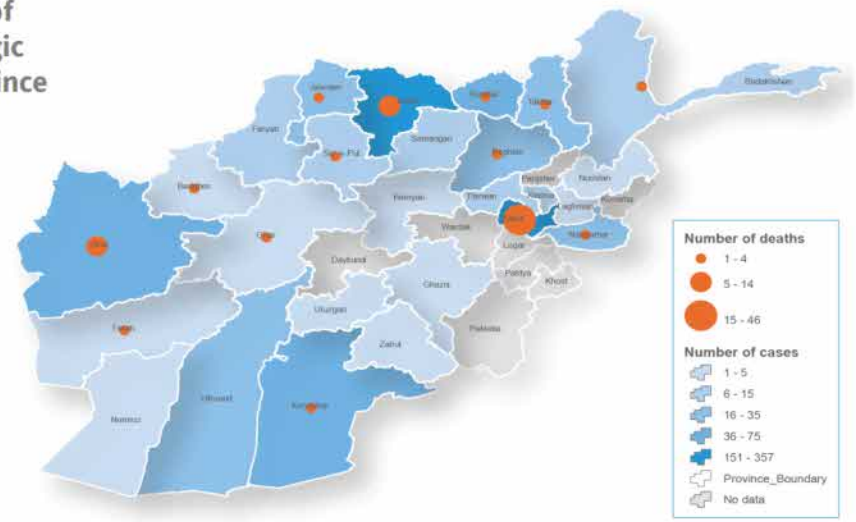


Figure 1: Epidemiological curve for cholera cases and deaths in Somalia 2022-2023

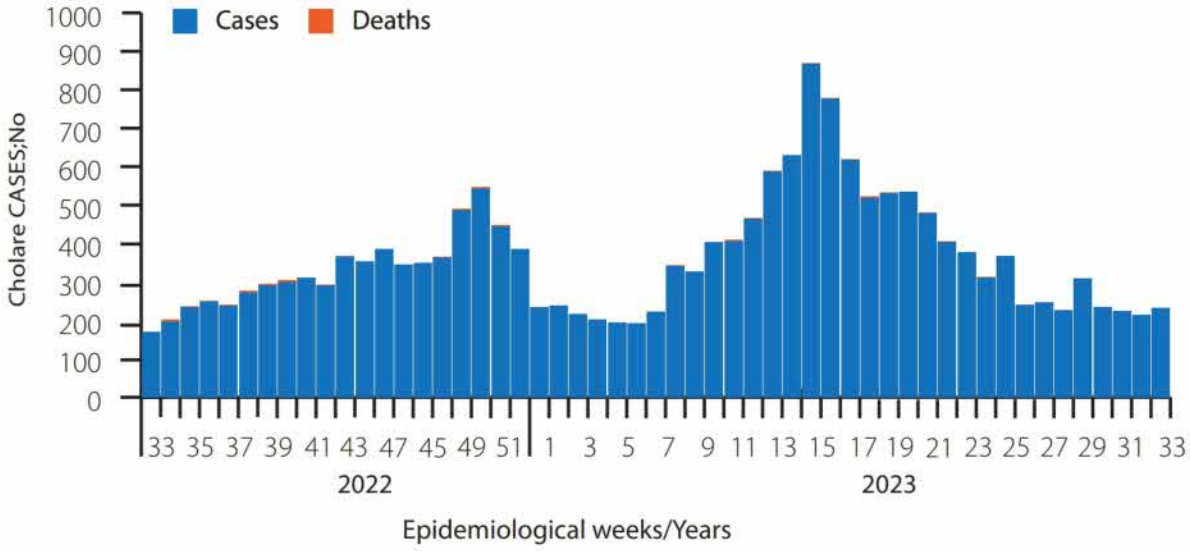
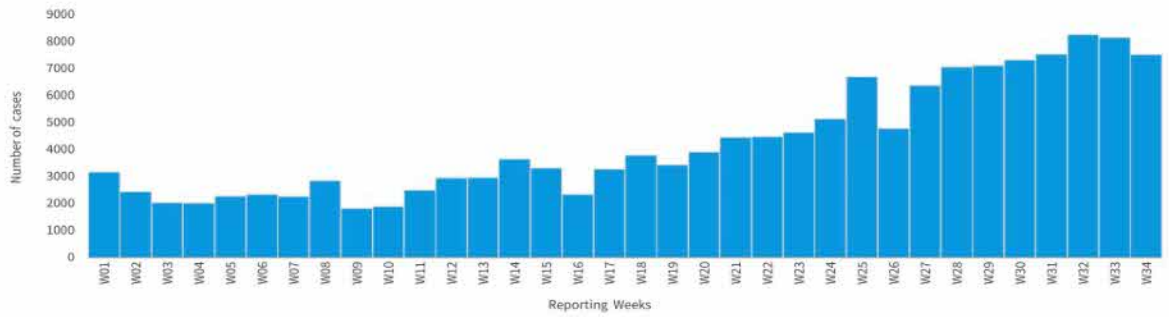


Figure 3. Epidemiological curve of AWD with dehydration cases in Afghanistan 01 Jan–26 Aug 2023 (N=144,543)



AFGHANISTAN

AWD with dehydration attack rate per 10,000 population by province

As of 26 Aug 2023

Figure 4. AWD with dehydration attack rate per 10,000 population by province in Afghanistan, 01 Jan–26 Aug 2023

C3. DIPHTERIE

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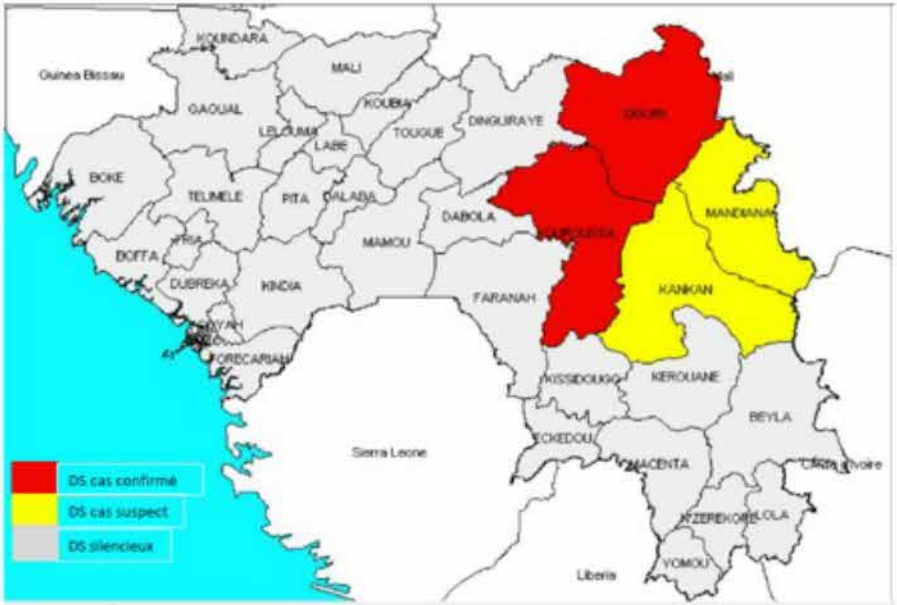

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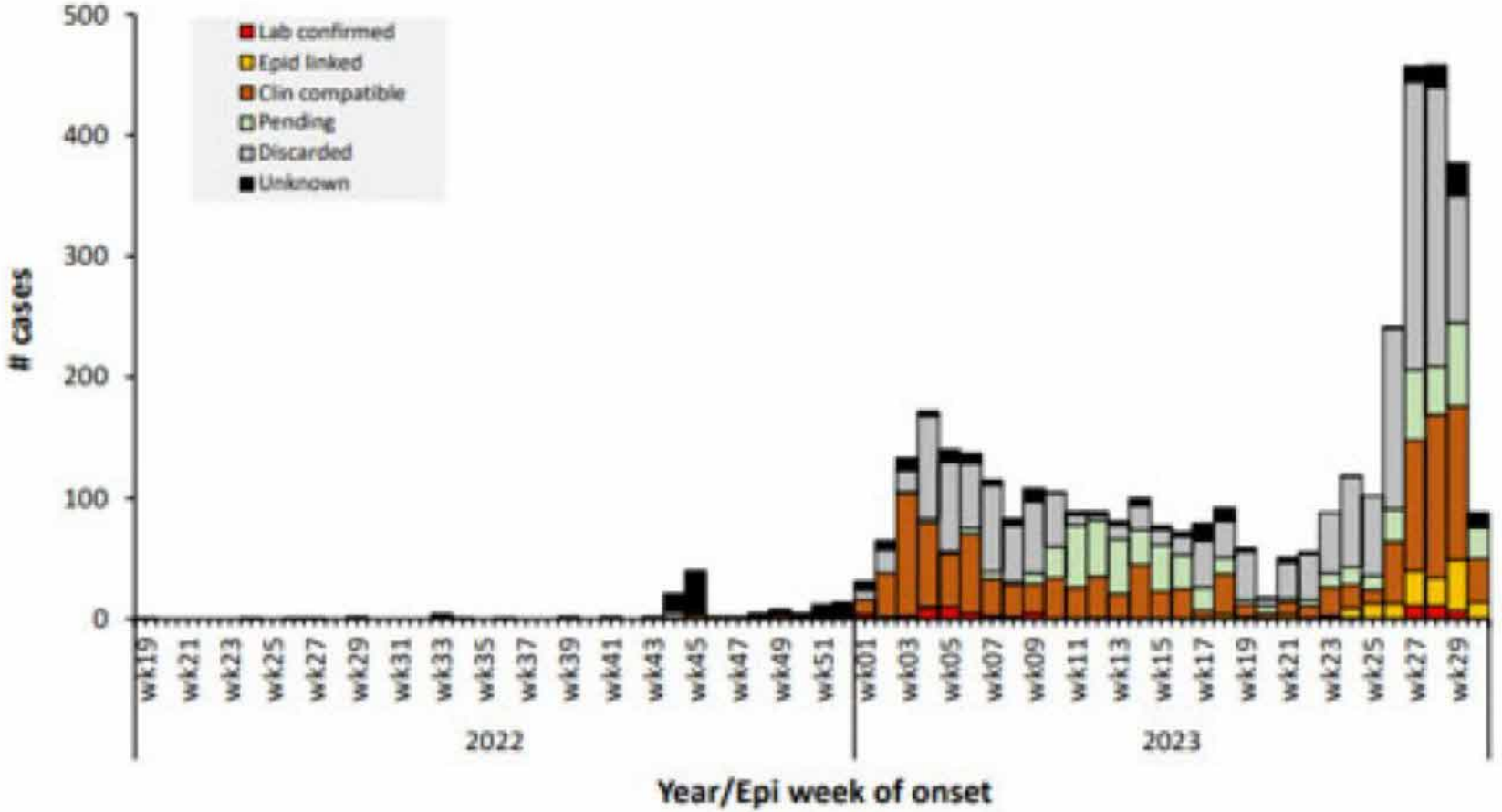

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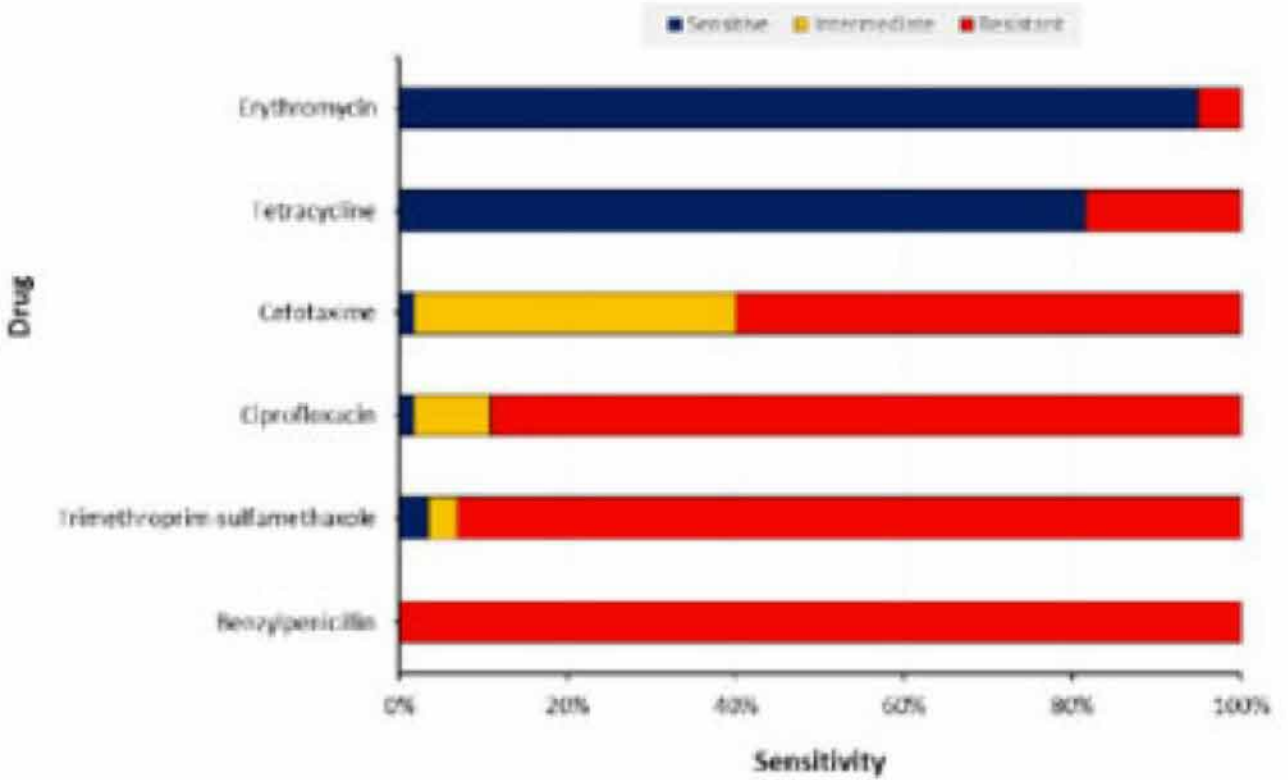
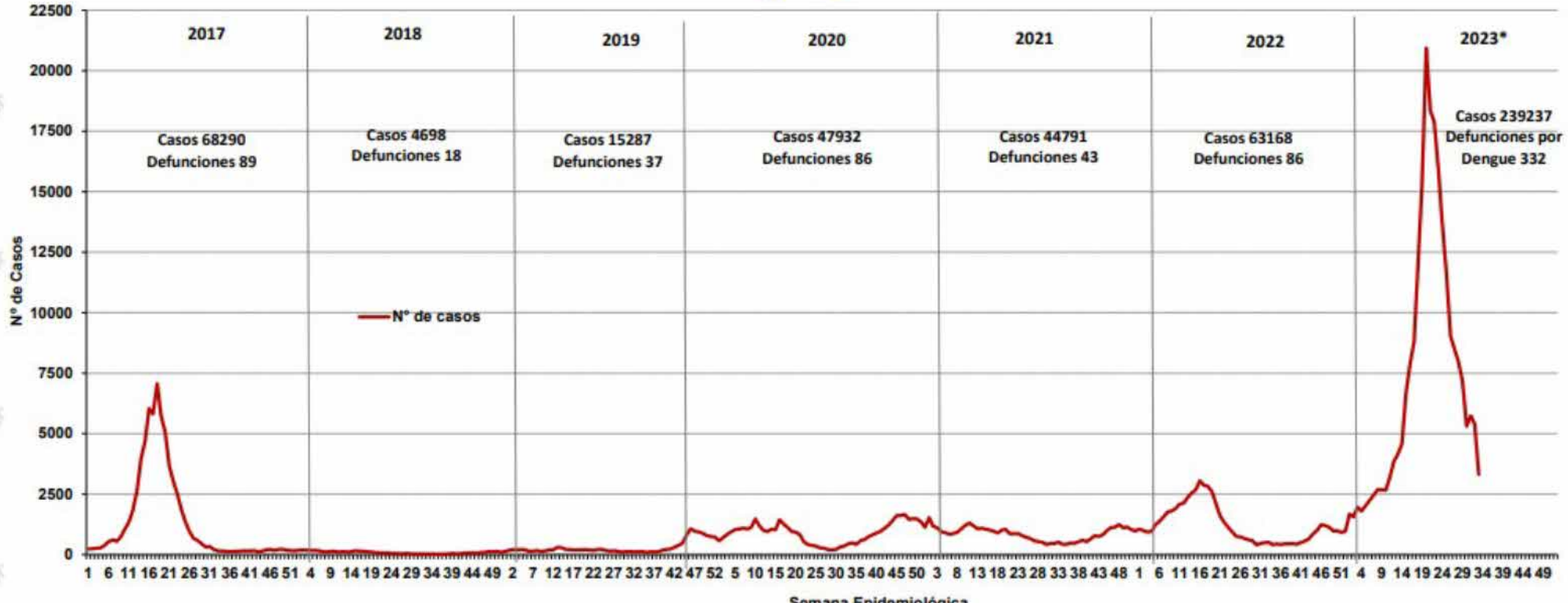
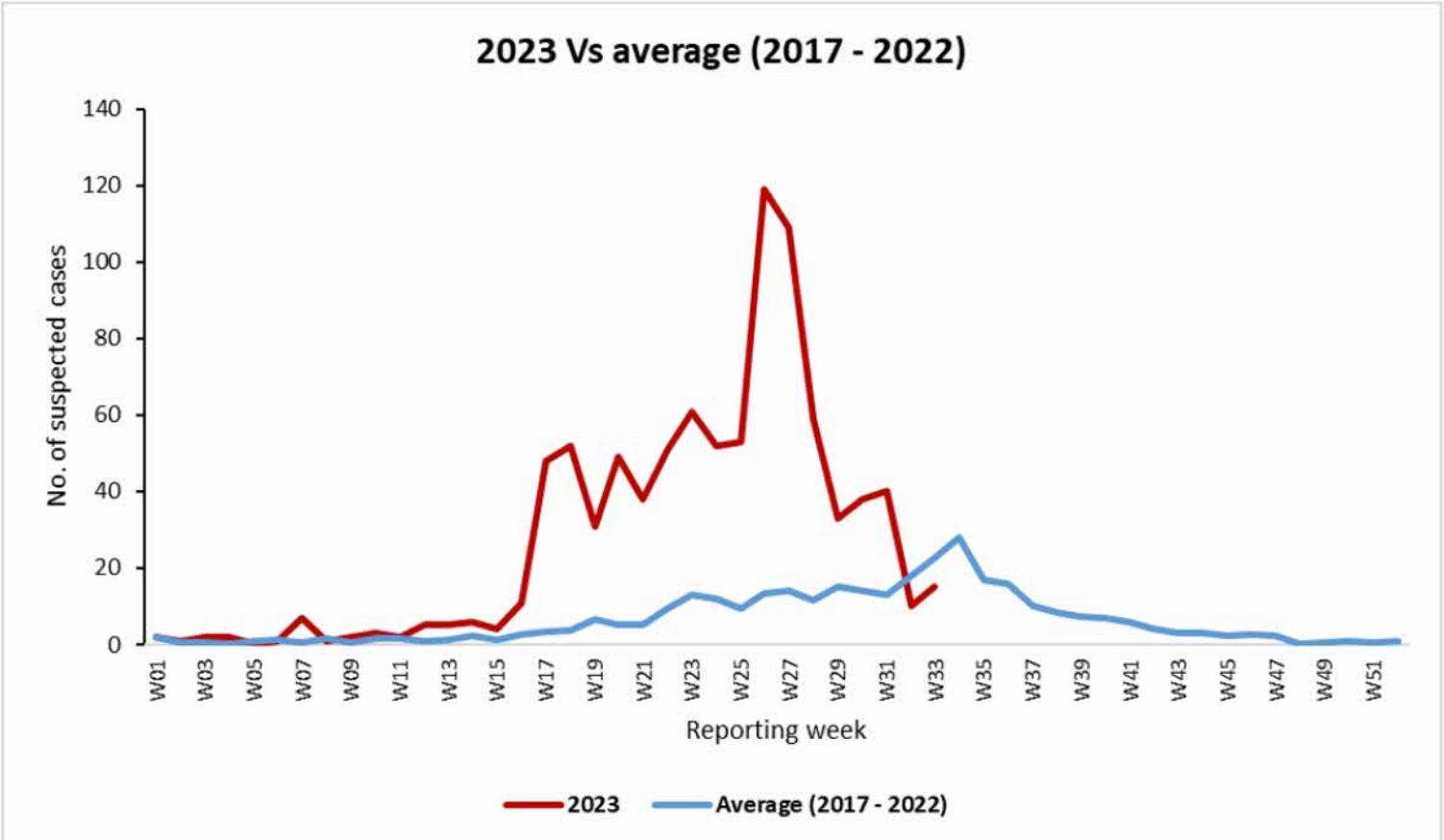


Source: NCDC

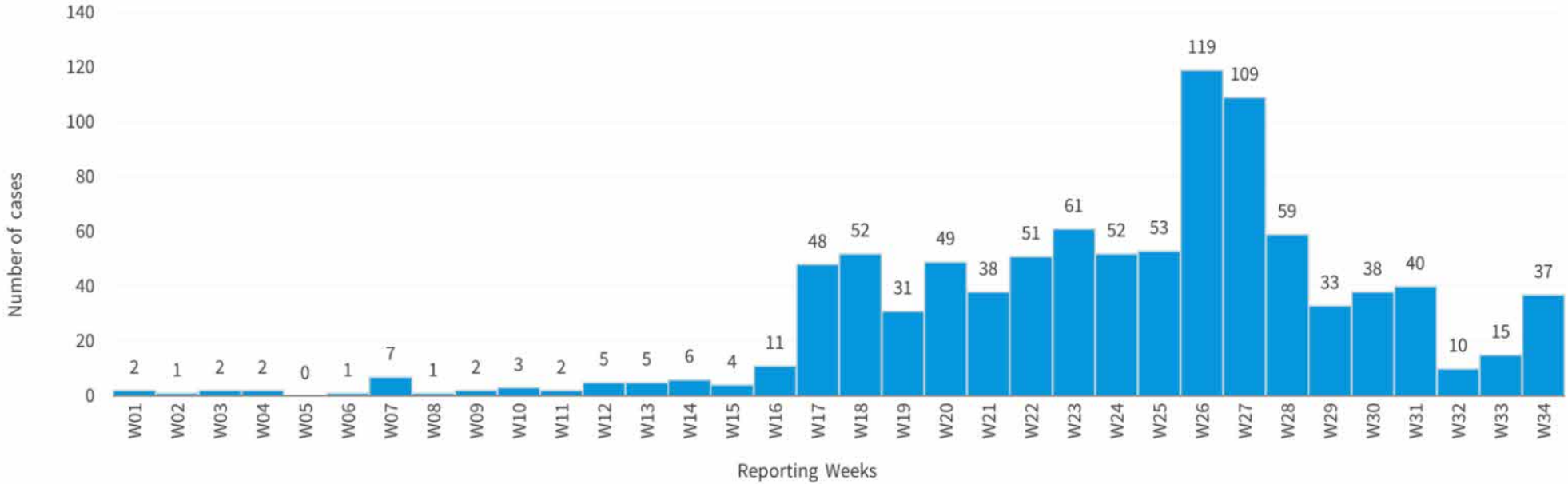
Número de casos de dengue, Perú 2017 – 2023*





Comparison of weekly distribution of suspected CCHF cases, 2023 Vs average of last 6 years (2017 – 2022), Afghanistan

Figure 1: Epidemiological curve of CCHF cases in Afghanistan 1 Jan–26 Aug 2023 (N=949)



AFGHANISTAN

Geographical Distribution of Crimean-Congo Hemorrhagic Fever (CCHF) cases by Province

As of 26 Aug 2023

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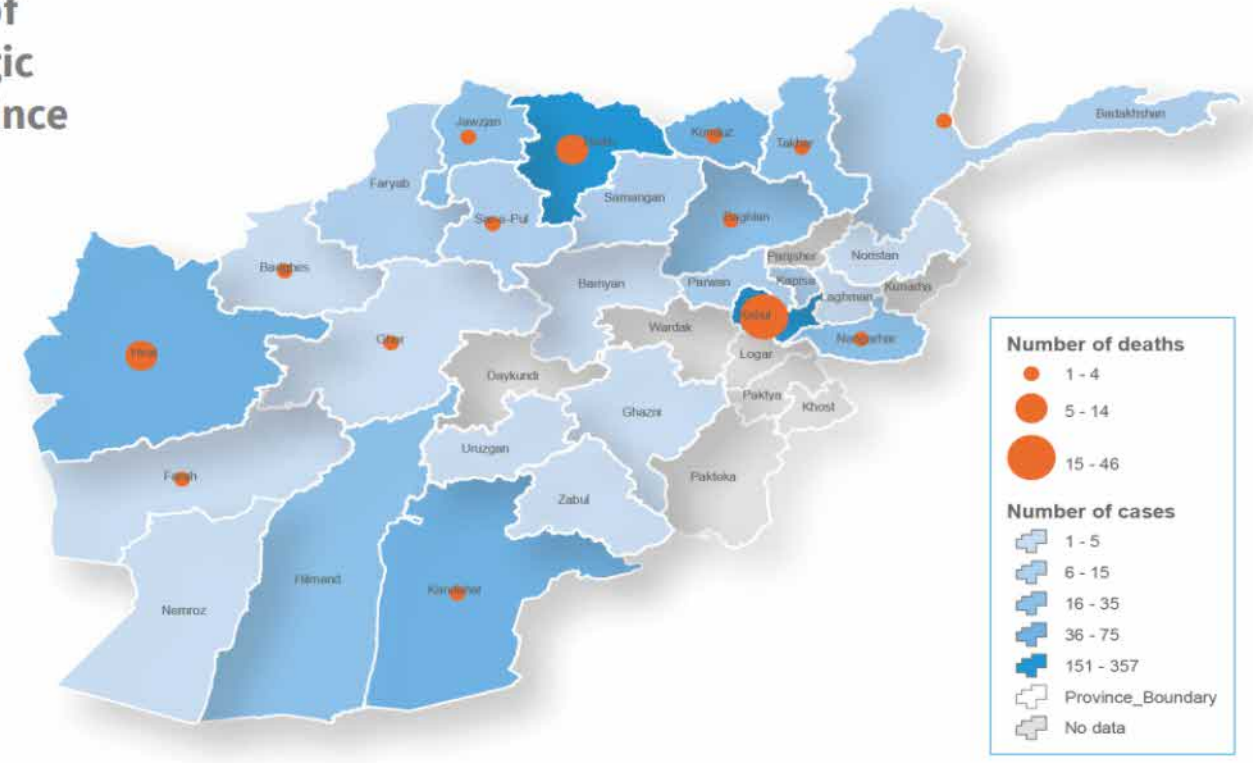

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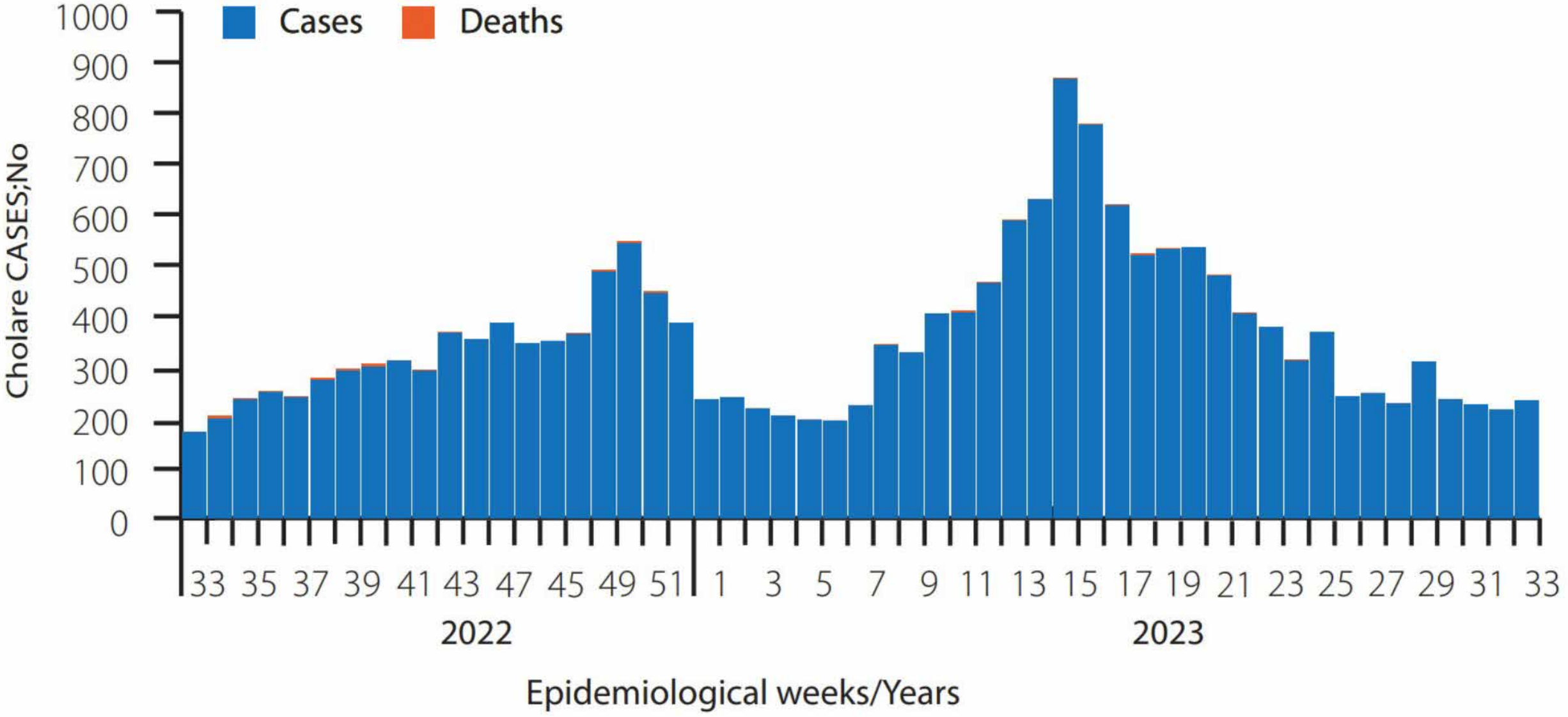

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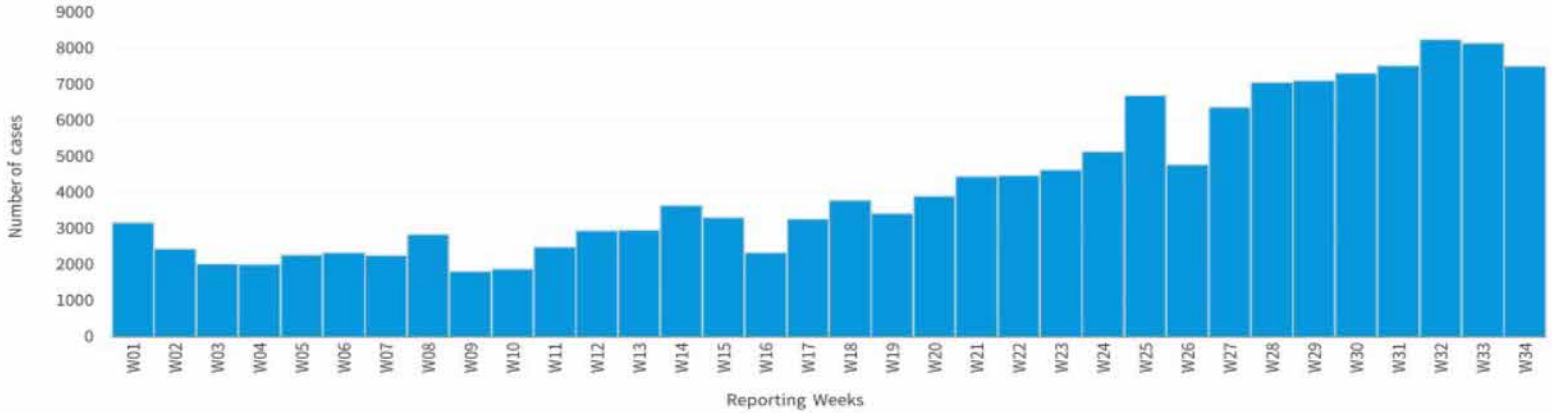

AFGHANISTAN

AWD with dehydration attack rate per 10,000 population by province

As of 26 Aug 2023

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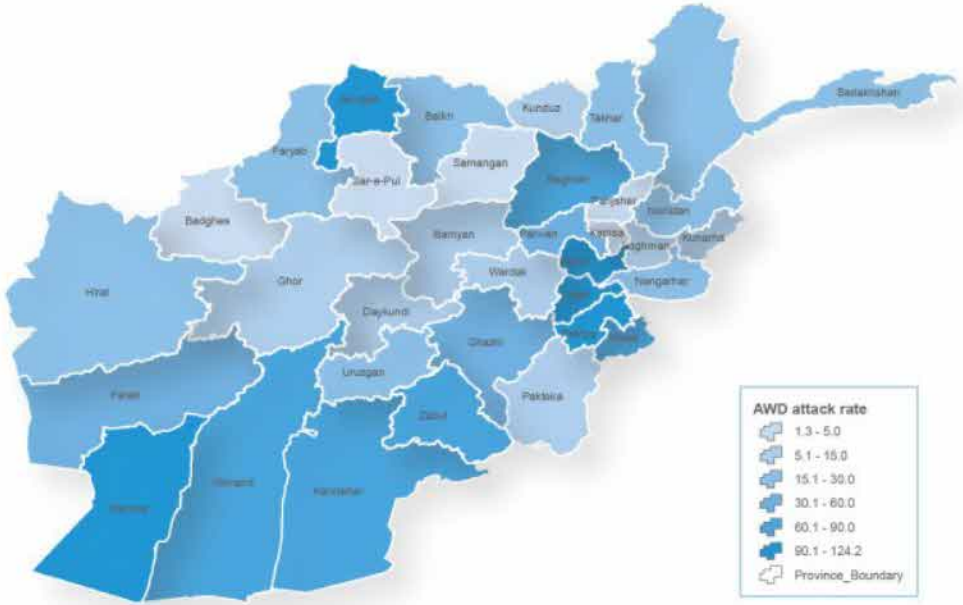

From: GDD-OUTBREAK (CDC)
Sent: Tue, 5 Sep 2023 17:12:08 -0400
To: Undisclosed recipients:
Subject: Global Disease Detection Operations Center Daily Report - 09/05/2023
Attachments: Epicurve Measles Ethiopia Aug 2021-Aug 2023.jpg, Map Ethiopia Measles 4 Sep 2023.jpg, Epi Curve Diphtheria Nigeria 2023 EW34_NCDC.jpg

****** Global Disease Detection Operations Center (GDDOC) Daily Report for 09/05/2023 ******

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At A Glance:

Of International Importance[1]

- (Update) Diphtheria in Nigeria - **Outbreak continues**
- (Update) Measles (Rubeola) in Ethiopia - **Active measles outbreaks in 23 woredas**

Agent/Disease:	**Diphtheria**
Country/Territory:	**Nigeria**
Location:	**Widespread**
Geoscope[4]:	**Medium**
Public Health Impact[5]:	**Medium**

Source:	**Nigeria Center for Disease Control (NCDC); NCHHSTP/DSTDP; WHO/UNICEF Joint Reporting Form on Immunization (JRF); CDC - Nigeria; GHC/GID; WHO; NCIRD/DBD/MVPDB**
GDDOC First Notified On:	**01/17/2023**
GDDOC Last Reported On:	**08/31/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**
Attachments:	• Epi Curve Diphtheria Nigeria 2023 EW34_NCDC.jpg

Description:

The Global Disease Detection Operations Center (GDDOC) is continuing to monitor the diphtheria outbreak in Nigeria.

According to NCDC, an additional 1,062 suspected diphtheria cases have been reported over the past week for a cumulative total of 8,353 suspected cases reported from epidemiological week (EW) 19, 2022 to EW 34, 2023. Please see epidemic curve from EW 19, 2022 - EW 34, 2023, courtesy of NCDC. The 8,353 suspected cases were reported from 26 states and the Federal Capital Territory (FCT); the majority of the suspected cases were reported from Kano state.

Of the 8,353 suspected cases reported, 4,717 (56%) including 307 deaths were either lab confirmed, epidemiologically linked, or clinically compatible in 16 states and the FCT. Among the 4,717 cases, the majority (3,466, 73%) occurred in children aged 1 – 14 years; 22.7% were fully vaccinated with a diphtheria toxoid-containing vaccine.

The most recent WHO UNICEF Estimates of National Immunization Coverage (WUENIC) data for Nigeria in 2022 indicates 70% coverage for 1st dose diphtheria toxoid-containing vaccine and 62% coverage for 3rd dose, both below the 80-85% coverage required to maintain community protection. Outbreak response vaccination campaigns have been conducted in Kano

state prioritizing the highest burden LGAs, using tetanus-diphtheria (Td) vaccines and targeting children aged 4-14 years. Additional outbreak response vaccination activities in high burden states across the country are being planned.

NCDC continues to lead and coordinate response activities through the National Diphtheria Emergency Operations Center (EOC), including risk communication and community engagement, case investigations and contact tracing by National Rapid Response Teams, laboratory testing, and clinical management. Emergency procurement of additional diphtheria anti-toxin (DAT), intravenous erythromycin and other medicines is ongoing. CDC is discussing potential areas of support with the Diphtheria EOC incident manager. A CDC Travel Notice (Alert - Level 2, Practice Enhanced Precautions) was issued regarding Diphtheria in Nigeria on 24 February 2023 and updated 23 July 2023.

Diphtheria is a clinical syndrome caused by an exotoxin produced by the toxin-producing strains of the bacterium *C. diphtheriae*. Most commonly, toxigenic infection results in respiratory or cutaneous disease. Diphtheria and its complications, including death, are caused by effects of the toxin and may include airway blockage, myocarditis, polyneuropathy, and kidney failure. Transmission is most often person-to-person through respiratory droplets though may also occur from exposure to infected skin lesions. Diphtheria occurs worldwide, particularly in countries with suboptimal vaccination coverage.

Agent/Disease:	**Measles (Rubeola)**
Country/Territory:	**Ethiopia**
Location:	**Multiple regions**
Geoscope[4]:	**Medium**
Public Health Impact[5]:	**Medium**
Source:	**CGH/GID; CDC - Ethiopia; Ethiopia Ministry of Health**
GDDOC First Notified On:	**01/15/2022**
GDDOC Last Reported On:	**08/22/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**
Attachments:	• Epicurve Measles Ethiopia Aug 2021-Aug 2023.jpg • Map Ethiopia Measles 4 Sep 2023.jpg

Description:

The GDD Operations Center (GDDOC) is continuing to monitor measles activity in Ethiopia.

According to the Ethiopian Ministry of Health (MoH), a total of 25,088 measles cases with 244 deaths (case fatality proportion = 0.97%) have been reported from 12 August 2021 to 4 September 2023. This is an increase of 1,256 cases and 7 deaths since the last report with data as of 21 August 2023. Active measles outbreaks continue in 23 woredas in the regions of Afar, Amhara, Gambella, Oromia, Sidama, Somali, South West Ethiopia Peoples' Region, and Tigray. Please see the attached epidemic curve depicting cases of measles by date of rash onset from 12 August 2021 to 29 August 2023, and map showing outbreak affected woredas as of 4 September 2023, courtesy of the MoH.

Recent response activities include intensifying routine immunization activities, enhancing surveillance through active case searches including by health extension workers, ongoing case management including vitamin A supplementation and nutritional screening of patients, risk communication and community mobilization activities through locally tailored approaches, ongoing training for frontline responders, and regular coordination meetings with stakeholders. Furthermore, measles outbreak response training has been provided to 61 surveillance officers and frontline healthcare workers from the Tigray Region.

Challenges to the response include both vaccine and operational cost shortages for a reactive vaccine campaign for which an application for Measles and Rubella Program funding has been in process since April, delayed detection, reporting, and outbreak investigations for newly detected outbreaks, security problems preventing optimal response activities, and the ongoing drought with malnutrition which aggravates the outbreak.

This measles outbreak occurs against a complex humanitarian context caused by concurrent epidemics, drought, floods, malnutrition, armed conflict, and other crises that disrupt childhood vaccinations. A nationwide preventive measles supplemental immunization activities (SIA) campaign was conducted from 22-31 December 2022 except in all of Tigray and portions of Oromia (12 woredas) and Benishangul Gumuz (7 woredas) due to insecurity. More than 14.5 million children under five were vaccinated during the nationwide preventive SIA campaign, achieving 94.2% administrative coverage. The Tigray component of the national preventive SIA was held from 27 March to 7 April 2023 in 76 out of 93 woredas in which 830,000 children aged 6-59 months received the measles vaccine. A post campaign coverage survey is still being planned. According to WHO UNICEF Estimates of National Immunization Coverage, measles-containing-vaccine first and second doses (MCV1 and MCV2) coverage in 2022 were estimated at 56% and 48%, respectively, far below the goal of 95% coverage with two doses as recommended by WHO. The sub-optimal immunization coverage over multiple years leaves a large number of people at risk.

Additionally, gaps in implementation of active surveillance likely result in under-reporting of cases and deaths and potentially larger outbreaks.

The GDDOC will provide additional information as it becomes available.

Mission Statement
Global Disease Detection Operations Center

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Key

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2. Presents a serious threat to the public health

3. Is unusual or an unexpected event

4. Poses a significant risk for international spread that potentially requires international intervention

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[2]**Public Health Event Under Investigation** is a disease outbreak or a health threat that potentially meets one of the above criteria, but, at the moment, is not yet verified.

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Risk Scales

[4]**Geographic Scope** refers to the observed geographic distribution and rapidity of spread for an outbreak and is categorized as follows:

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Low	Events limited to sub-national areas

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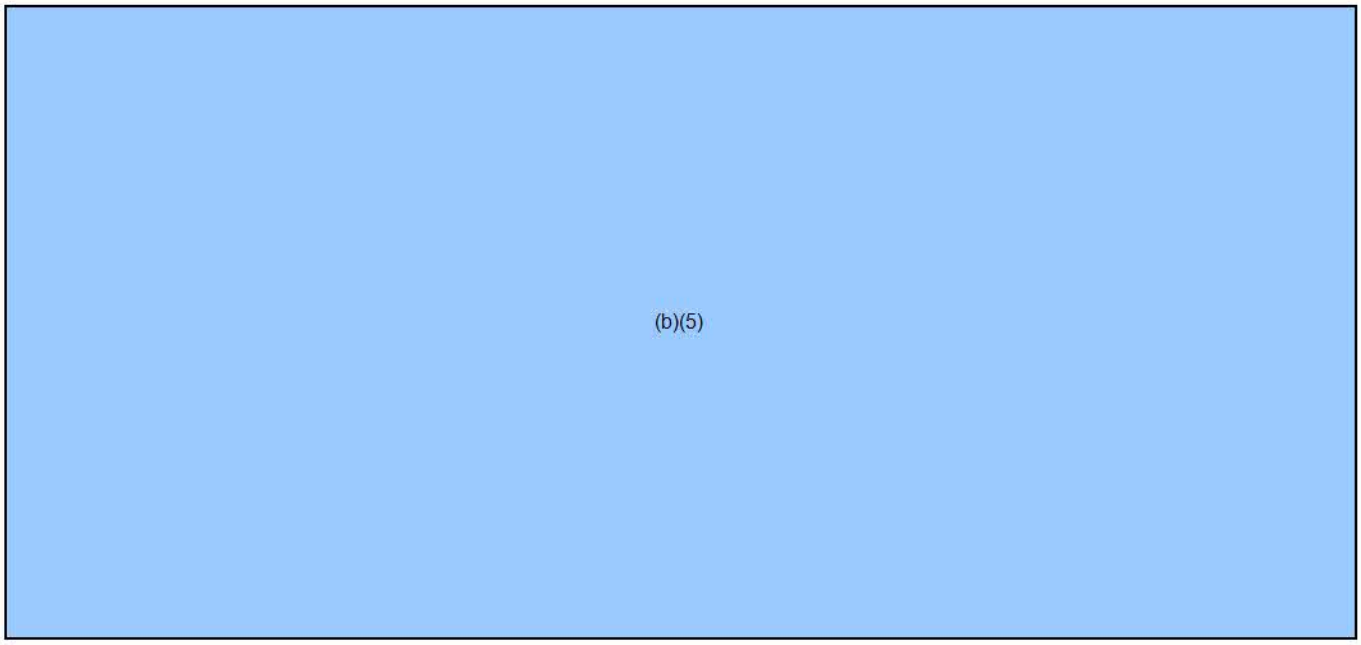
Low	Agent that has low potential to cause morbidity/mortality

(b)(5)



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This report is produced by the Global Disease Detection Operations Center (GDDOC)
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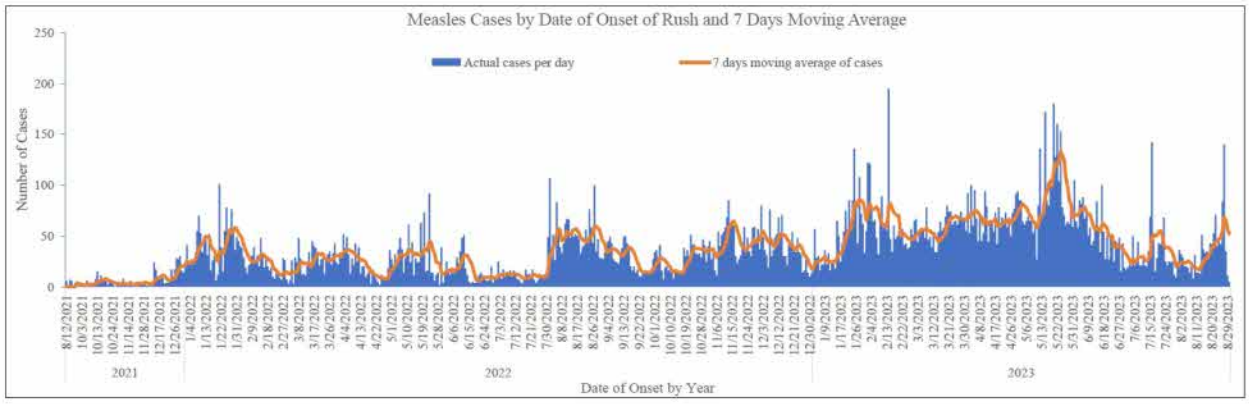
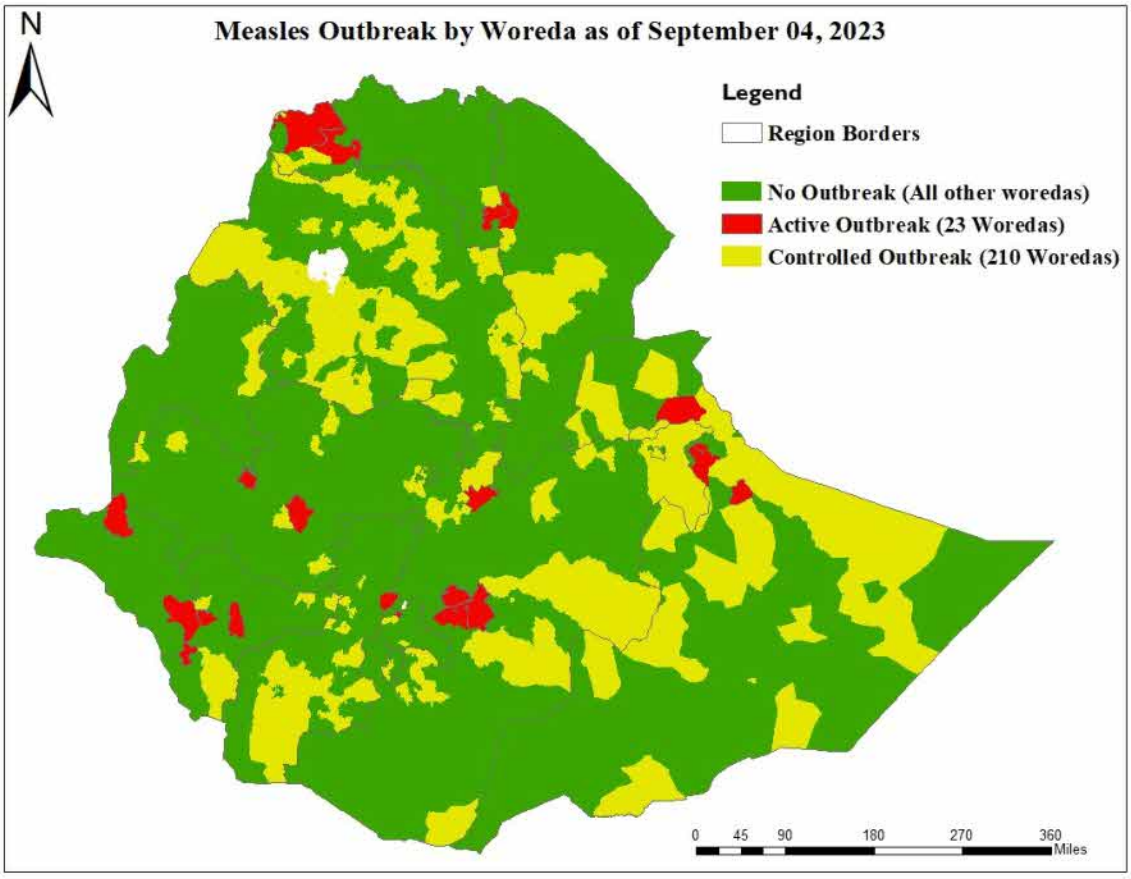




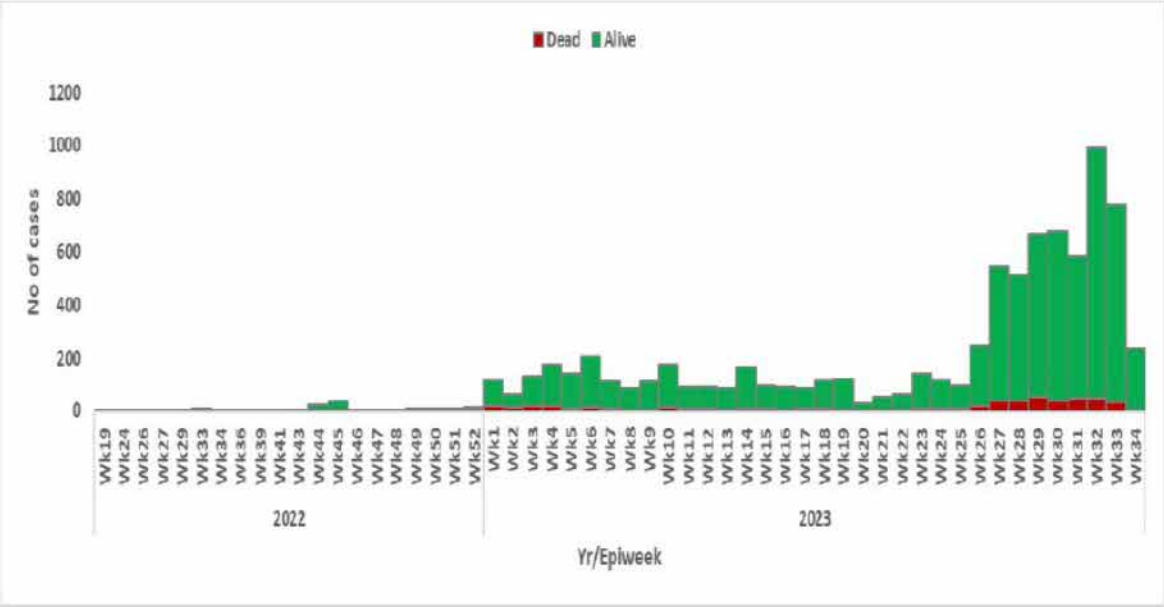
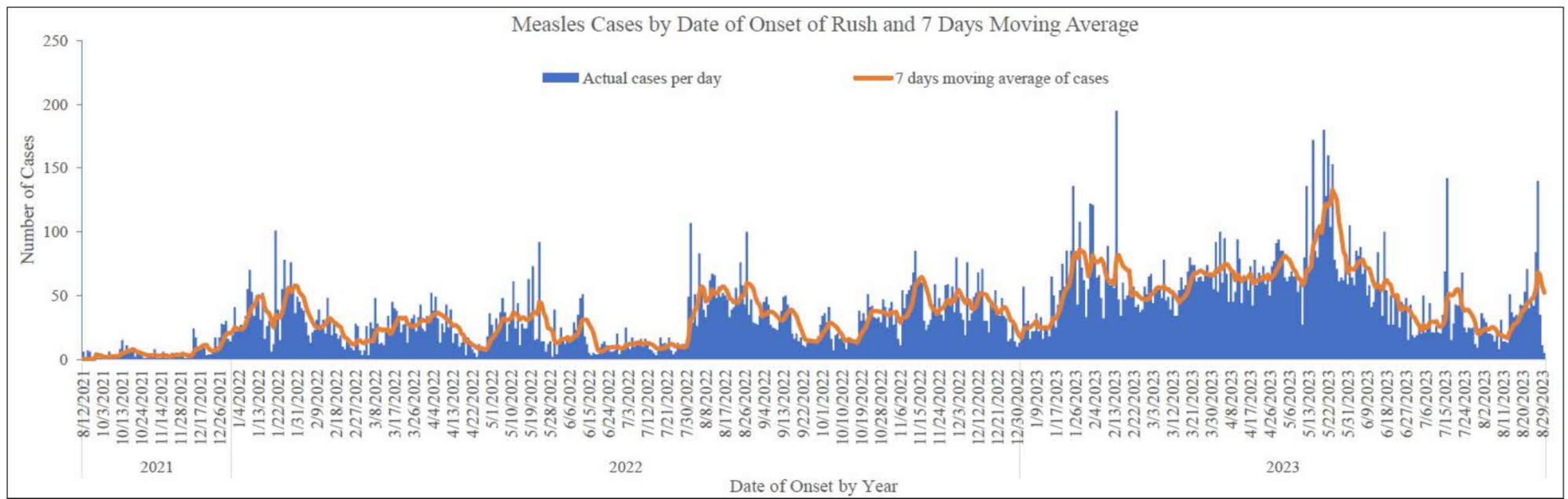


Figure 5: Epicurve of suspected Diphtheria cases in Nigeria, Wk 19, 2022 to wk 34, 2023


Measles Cases by Date of Onset of Rush and 7 Days Moving Average
Actual cases per day
7 days moving average of cases
Number of Cases
250
200
150
100
50
0
8/12/2021
10/3/2021
10/13/2021
10/24/2021
11/14/2021
11/28/2021
12/17/2021
12/26/2021
1/4/2022
1/13/2022
1/22/2022
1/31/2022
2/9/2022
2/18/2022
2/27/2022
3/8/2022
3/17/2022
3/26/2022
4/4/2022
4/13/2022
4/22/2022
5/1/2022
5/10/2022
5/19/2022
5/28/2022
6/6/2022
6/15/2022
6/24/2022
7/3/2022
7/12/2022
7/21/2022
7/30/2022
8/8/2022
8/17/2022
8/26/2022
9/4/2022
9/13/2022
9/22/2022
10/1/2022
10/10/2022
10/19/2022
10/28/2022
11/6/2022
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12/12/2022
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1/26/2023
2/4/2023
2/13/2023
2/22/2023
3/3/2023
3/12/2023
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4/8/2023
4/17/2023
4/26/2023
5/6/2023
5/13/2023
5/22/2023
5/31/2023
6/9/2023
6/18/2023
6/27/2023
7/6/2023
7/15/2023
7/24/2023
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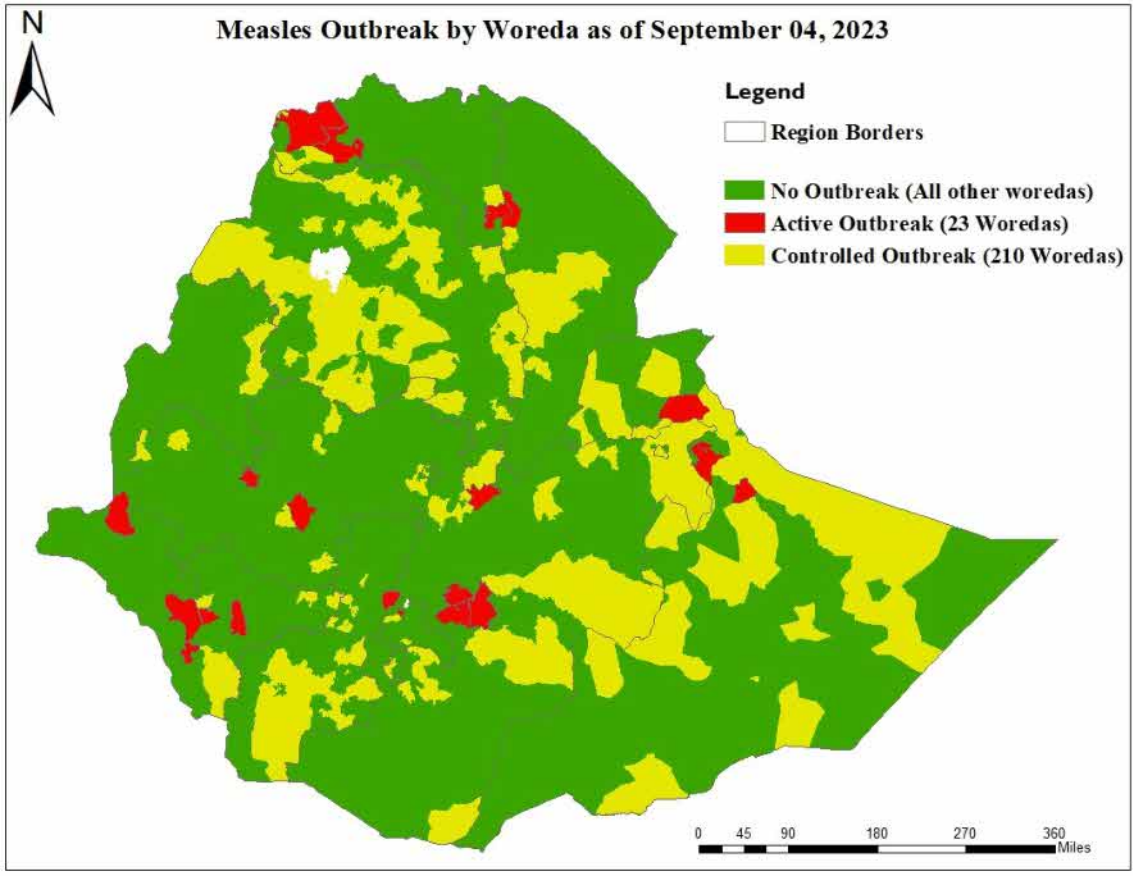
2021
2022
2023
Date of Onset by Year


N
Measles Outbreak by Woreda as of September 04, 2023
Legend
Region Borders
No Outbreak (All other woredas)
Active Outbreak (23 Woredas)
Controlled Outbreak (210 Woredas)
0 45 90 180 270 360
Miles

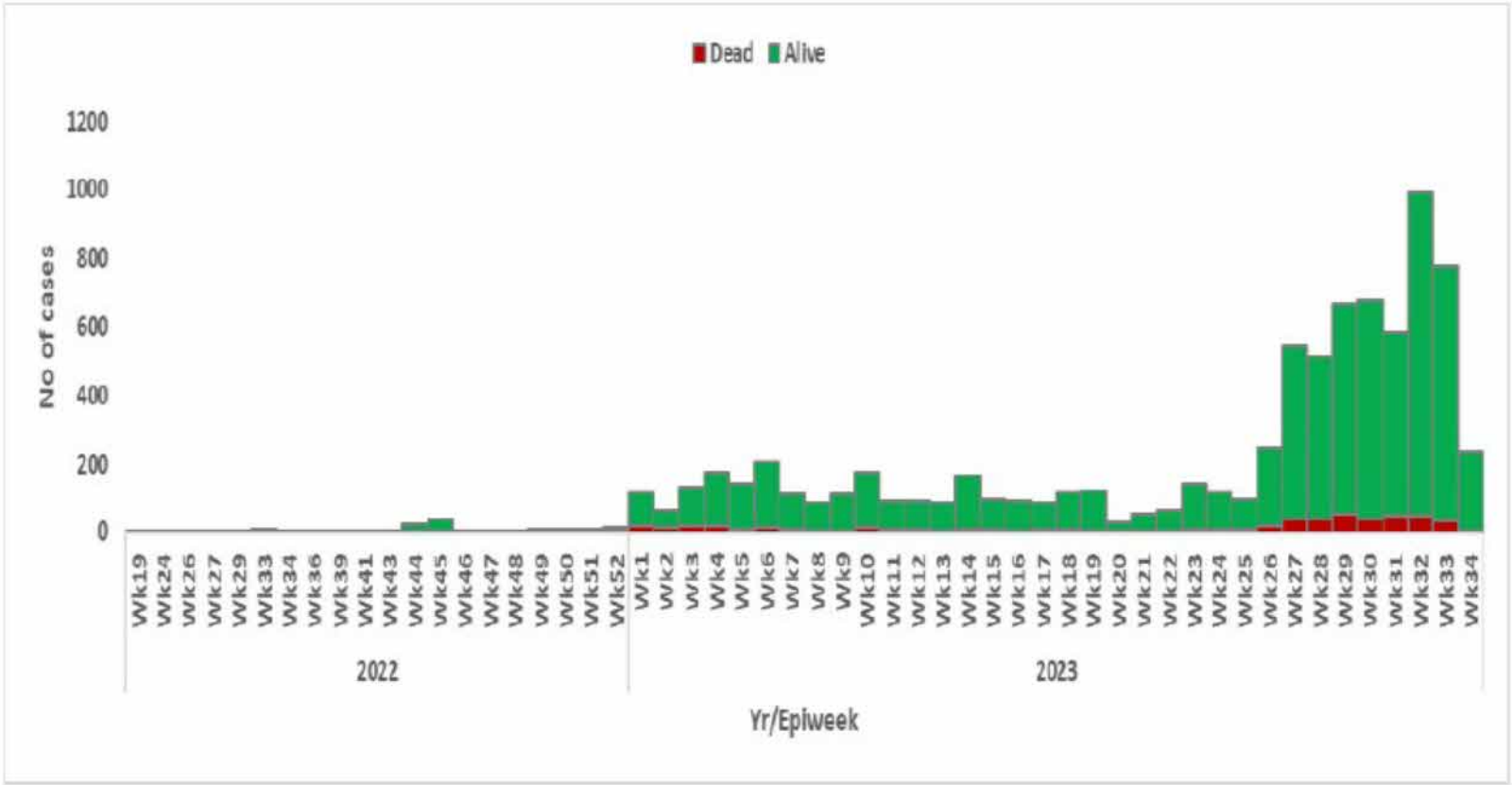


Figure 5: Epicurve of suspected Diphtheria cases in Nigeria, Wk 19, 2022 to wk 34, 2023

From:	GDD-OUTBREAK (CDC)
Sent:	Tue, 12 Sep 2023 17:21:20 -0400
To:	Undisclosed recipients:
Subject:	Global Disease Detection Operations Center Daily Report - 09/12/2023
Attachments:	dengue_bangladesh_epi_curve_MOHFW_2023_September_12.JPG

****** Global Disease Detection Operations Center (GDDOC) Daily Report for 09/12/2023 ******

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At A Glance:

Of International Importance[1]

- (New) Diphtheria in Vietnam - **Response activities underway**
- (Update) Diphtheria in Nigeria - **Response activities continue**
- (Update) Dengue in Bangladesh - **Outbreak continues**

Agent/Disease:	**Diphtheria**
Country/Territory:	**Vietnam**
Location:	**Provinces of Hà Giang, Dien Bien, and Thai Nguyen**
Geoscope[4]:	**Low**
Public Health Impact[5]:	**Medium**
Source:	**CDC - Vietnam; Vietnam Ministry of Health; WHO/UNICEF Joint Reporting Form on Immunization (JRF); Dien Bien Province (Vietnam) Ministry of Health**
GDDOC First Notified On:	**09/07/2023**

Public Health Event: **Of International Importance**

Event Type: **Human**

Description:

GDD Operations Center (GDDOC) is monitoring reports of diphtheria in Vietnam.

As of 12 September, twelve cases and two deaths have been reported in three provinces: Hà Giang, Dien Bien, and Thai Nguyen, all in Northern Vietnam. The outbreak mainly affects the (b)(6) Lab testing of close contacts of the cases is also ongoing.

In Hà Giang Province (Northeast Region), the first suspected cases were reported on 21 August in (b)(6) Yen Minh District is now also affected, as well as Dong Van and Hà Giang City. As of 10 September, 65 suspected cases have been identified through active surveillance efforts. Lab testing conducted at National Institute of Hygiene and Epidemiology (NIHE) has yielded positive results for seven of the 61 samples tested thus far. Health officials indicate that the recent fatal case marks the first diphtheria case reported in Hà Giang since 2004.

In Dien Bien Province (Northwest Region), the first suspected case was reported in (b)(6) (b)(6) lab testing confirmed *Corynebacterium* on 26 August. As of 9 September, a total of three cases have been confirmed. Earlier in 2023, a small diphtheria outbreak with two cases (1 fatal) had occurred in (b)(6) in the April-May timeframe, followed by outbreak response vaccination efforts in the affected commune and surrounding high-risk areas.

In (b)(6) (Northeast Region), out of 11 suspected cases, two (b)(6) who were residents of (b)(6) were confirmed to have diphtheria; (b)(6)

The Ministry of Health has established response teams to investigate cases, conduct surveillance, coordinate patient management and direct prevention efforts, including risk communication and community engagement in the affected provinces. Vaccination efforts with Tetanus-Diphtheria (Td) vaccine are being planned for persons 5 to 20 years of age in high-risk communes. Although 2022 national WHO/UNICEF Estimates of National Immunization Coverage for DTP-containing vaccine for 1st and 3rd doses are 92% and 91% respectively, the 2022 coverage for children less than 2 years of age is 73%. In districts with diphtheria cases, the coverage is low and estimated to be approximately 67-78%.

CDC-Vietnam has been working with CDC-HQ diphtheria SMEs to share material from WHO's diphtheria outbreak toolkit with MOH. CDC-Vietnam is also providing technical and financial support for NIHE to mobilize FETP staff for outbreak investigations.

Agent/Disease:	**Diphtheria**
Country/Territory:	**Nigeria**
Location:	**Widespread**
Geoscope[4]:	**Medium**
Public Health Impact[5]:	**Medium**
Source:	**Nigeria Center for Disease Control (NCDC); NCHHSTP/DSTDP; WHO/UNICEF Joint Reporting Form on Immunization (JRF); CDC - Nigeria; GHC/GID; WHO; NCIRD/DBD/MVPDB**
GDDOC First Notified On:	**01/17/2023**
GDDOC Last Reported On:	**09/05/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**

Description:

The Global Disease Detection Operations Center (GDDOC) is continuing to monitor the diphtheria outbreak in Nigeria.

According to NCDC, an additional 1,045 suspected diphtheria cases have been reported over the past week for a cumulative total of 9,398 suspected cases reported from epidemiological week (EW) 19, 2022 to EW 35, 2023 in 31 states. The majority of the suspected cases were reported from Kano state.

Of the 9,398 suspected cases reported, 5,570 (59%) including 327 deaths were either lab confirmed, epidemiologically linked, or clinically compatible in 16 states and the FCT, for an increase of 853 since EW 34. Among the 5,570 cases, the majority (greater than 73%) occurred in children aged 1 – 14 years; this age range also accounts for highest fatalities. According to EW 34 data, 22.7% were fully vaccinated with a diphtheria toxoid-containing vaccine.

The most recent WHO UNICEF Estimates of National Immunization Coverage (WUENIC) data for Nigeria in 2022 indicates 70% coverage for 1st dose diphtheria toxoid-containing vaccine and 62% coverage for 3rd dose, both below the 80-85% coverage required to maintain community protection. Routine immunization intensification has been implemented in local government areas (LGAs) with high zero dose burden and in those affected by outbreaks. Outbreak response vaccination campaigns have been conducted in the highest burden LGAs, using tetanus-diphtheria (Td) vaccines and targeting children aged 4-14 years. Additional outbreak response vaccination activities in high burden states across the country are being planned for the fall of 2023.

NCDC continues to lead and coordinate response activities through the National Diphtheria Emergency Operations Center (EOC), including risk communication and community engagement, case investigations and contact tracing by National Rapid Response Teams, laboratory testing, and clinical management. Emergency procurement of additional diphtheria anti-toxin (DAT), intravenous erythromycin and other medicines is ongoing. CDC is currently supporting health worker trainings, EOC operations and the immunization response. Additional support requested by the Diphtheria EOC incident manager, along with UNICEF, is for CDC to support reagents for testing. A CDC Travel Notice (Alert - Level 2, Practice Enhanced Precautions) was issued regarding Diphtheria in Nigeria on 24 February 2023 and updated 23 July 2023.

Diphtheria is a clinical syndrome caused by an exotoxin produced by the toxin-producing strains of the bacterium *C. diphtheriae*. Most commonly, toxigenic infection results in respiratory or cutaneous disease. Diphtheria and its complications, including death, are caused by effects of the toxin and may include airway blockage, myocarditis, polyneuropathy, and kidney failure. Transmission is most often person-to-person through respiratory droplets though may also occur from exposure to infected skin lesions. Diphtheria occurs worldwide, particularly in countries with suboptimal vaccination coverage.

Agent/Disease:	**Dengue**
Country/Territory:	**Bangladesh**
Location:	**Widespread**
Geoscope[4]:	**Medium**
Public Health Impact[5]:	**Medium**

Source:	**Bangladesh Ministry of Health and Family Welfare; WHO; NCEZID/DVBD/DB; CDC - Bangladesh; WHO - Bangladesh**
GDDOC First Notified On:	**07/25/2023**
GDDOC Last Reported On:	**09/06/2023**
Public Health Event:	**Of International Importance**
Event Type:	**Human**

Attachments:

- dengue_bangladesh_epi_curve_MOHFW_2023_September_12.JPG

Description:

The GDD Operations Center (GDDOC) is monitoring reports of increased dengue activity in Bangladesh.

From 1 January to 12 September, a total of 154,228 cases of dengue with 752 deaths (case fatality proportion [CFP] = 0.49%) were reported by the Ministry of Health and Family Welfare (MoHFW), an increase of 16,206 cases and 81 deaths since GDDOC's previous report with data as of 28 August. All cases and deaths reported are among hospitalized patients, with laboratory confirmation of dengue. This year's outbreak is the largest on record, with both the number of cases and the number of deaths having surpassed those reported in all previous years. Please see attached epidemic curve, showing cases and deaths reported by month in 2023, courtesy of MoHFW.

All eight divisions in the country are reporting cases. The most affected division is Dhaka, accounting for 59.0% of cases and 75.5% of deaths. Dhaka City, the largest city in Bangladesh, located in Dhaka Division, has reported 44.7% of the total number of cases and 70.6% of deaths. The most affected age group is 21 – 25-year-olds (15.3% of cases) followed by 26 – 30-year-olds (13.2%) and 16 – 20-year-olds (13.0%); males account for 61.7 % of cases while females account for 57.8% of deaths.

In response, the MoHFW is conducting refresher training for medical personnel on dengue clinical case management, conducting death reviews, collecting hospital surveillance data nationally and issuing a daily sitrep; distributing rapid test kits, IV saline solution, and other supportive medicines to health facilities; conducting serotype testing, and coordinating risk communication and community engagement. Partners have developed and are disseminating standard messaging to the public. The city corporations under the Ministry of Local Government,

Rural Development, and Cooperatives are implementing mosquito control measures and conducting mass awareness campaigns.

The GDDOC facilitated the deployment of two epidemiologists and one laboratorian from CDC Dengue Branch to provide on-site technical assistance for response activities in collaboration with MoHFW. Furthermore, CDC has been supporting epidemiologists in all city corporations and in Rohingya refugee camps who are directly involved in dengue control efforts. CDC is also participating in national coordination and health cluster meetings and providing technical assistance.

On 28 August, WHO published a Dengue Situation Report detailing the current outbreak in Bangladesh.

Dengue is endemic in Bangladesh with recurrent outbreaks. However, the current dengue outbreak is unusual in its scale and seasonality. The high incidence of dengue cases this year is taking place in the context of the late arrival, and expected prolonged duration, of the monsoon season. Additionally, the pre-monsoon *Aedes* survey showed that the density of mosquitoes, and the number of potential hotspots is at the highest level in the past five years.

Dengue is a mosquito-borne viral infection caused by four dengue virus serotypes (DENV-1 – 4). DENV-2 was the predominant circulating serotype in Bangladesh until 2018, when it was replaced by DENV-3. During this outbreak, DENV-2 has been identified as the primary circulating serotype. A second infection with a different serotype increases the risk of severe dengue.

The GDDOC will provide updates as information becomes available.

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U.S. Centers for Disease Control and Prevention (CDC)
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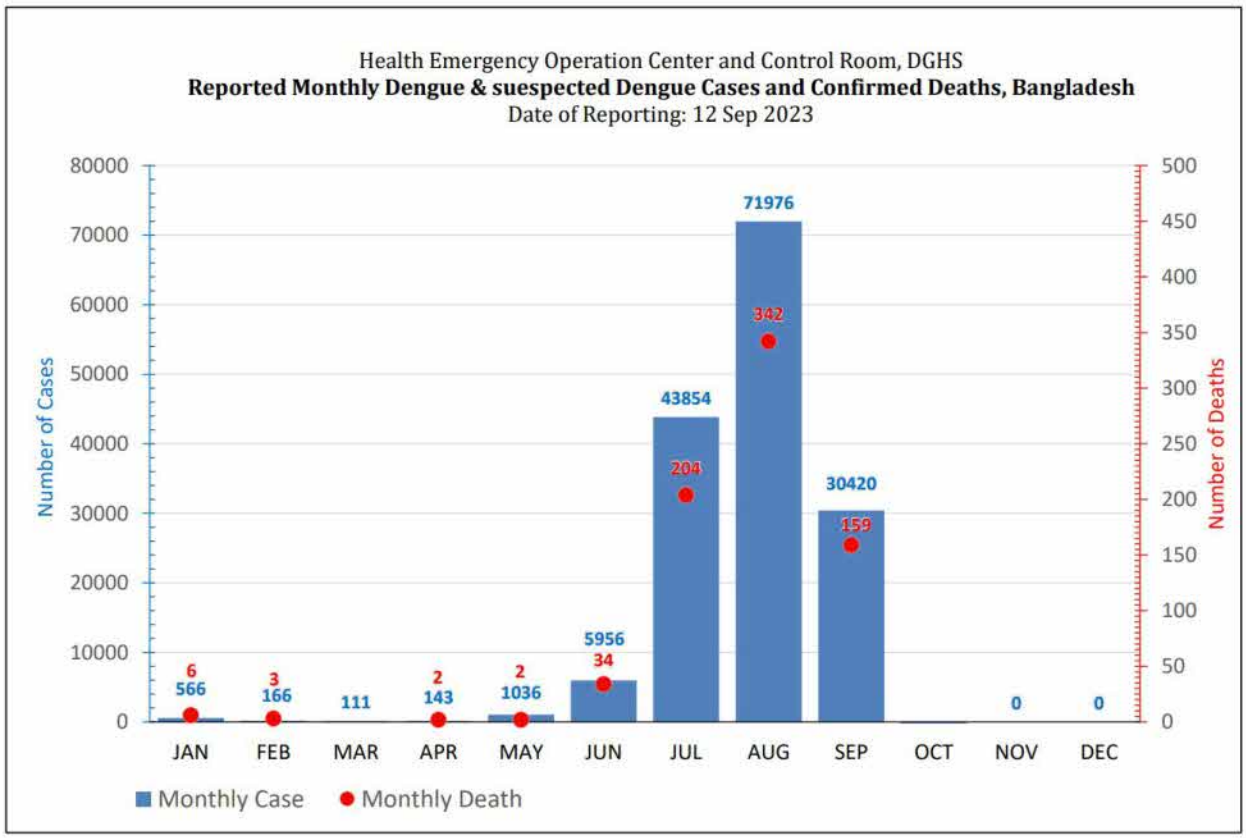
Health Emergency Operation Center and Control Room, DGHS
Reported Monthly Dengue & suespected Dengue Cases and Confirmed Deaths, Bangladesh
Date of Reporting: 12 Sep 2023
Number of Cases
Number of Deaths
80000
70000
60000
50000
40000
30000
20000
10000
0
500
450
400
350
300
250
200
150
100
50
0
6
566
3
166
111
2
143
2
1036
5956
34
43854
204
71976
342
30420
159
0
0
JAN
FEB
MAR
APR
MAY
JUN
JUL
AUG
SEP
OCT
NOV
DEC
Monthly Case
Monthly Death

Health Emergency Operation Center and Control Room, DGHS

Reported Monthly Dengue & suespected Dengue Cases and Confirmed Deaths, Bangladesh

Date of Reporting: 12 Sep 2023