

## I. Executive summary

### EU Threats

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#### Influenza - Multistate (Europe) - Monitoring 2016-2017 season

Opening date: 13 October 2016

Latest update: 3 February 2017

Influenza transmission in Europe shows a seasonal pattern, with peak activity during winter months. ECDC monitors influenza activity in Europe during the winter season and publishes its weekly report on the [Flu News Europe website](#).

→ Update of the week

During week 4/2017, influenza activity remained elevated across the region with 28 of 43 countries reporting increased activity.

An updated risk assessment on seasonal influenza in EU/EEA countries was published by [ECDC](#) on 27 January 2017.

### Non EU Threats

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#### Yellow fever - Brazil - 2016-2017

Opening date: 16 January 2017

Latest update: 3 February 2017

Yellow fever is a viral infection that is present in some tropical areas of Africa and South America. The virus is transmitted by mosquitoes, which also act as an important reservoir. Since 6 January 2017, Brazil has been experiencing an outbreak of yellow fever.

→ Update of the week

Since the beginning of the outbreak, five states have reported autochthonous transmission of yellow fever: Minas Gerais, Espírito Santo and São Paulo have reported confirmed locally-acquired cases, while Bahia and Tocantins have reported suspected locally-acquired cases.

As of 2 February 2017, 826 cases (including 155 confirmed) have been reported in Brazil. This represents an increase of 315 cases (including 67 confirmed) since the last CDTR. The most-affected state remains Minas Gerais, with 740 cases (including 138 confirmed) reported.

The World Health Organization (WHO) issued "[Temporary yellow fever vaccination recommendations for international travellers related to current situation in Brazil](#)" on 31 January 2017.

## Influenza A(H7N9) - China - Monitoring human cases

Opening date: 31 March 2013

Latest update: 3 February 2017

In March 2013, a novel avian influenza A(H7N9) virus was detected in patients in China. Since then, and up to 2 February 2017, 918 cases have been reported to WHO, including at least 359 deaths. No autochthonous cases have been reported outside China. Most cases are isolated, and sporadic zoonotic transmission from poultry to humans is the most likely explanation for the outbreak.

→Update of the week

Due to the large increase in human infection with avian influenza A(H7N9) virus in China, September 2016 – January 2017 ECDC updated the [rapid risk assessment](#) on 27 January 2017.

According to the health authorities in Hong Kong, between 22 and 28 January 2017, there have been 10 new human cases of avian influenza A(H7N9) reported in China; Henan (2 cases), Hubei (2 cases), Hunan (2 cases), Liaoning (2 cases), Guizhou (1 case) and Shandong (1 case). Since March 2013 (as of February 1, 2017), there have been 1 043 human cases of avian influenza A(H7N9) reported globally. These cases have not yet been acknowledged by WHO and do not appear in the summary.

## Chikungunya - Dengue - Zika - Multistate (world) - Monitoring global outbreaks

Opening date: 27 January 2017

Latest update: 3 February 2017

Chikungunya, dengue and zika virus infections are vector-borne diseases that affect from 50 to 100 million people each year. In the past decade, all three diseases have been reported across an increasingly wide area of the world. Chikungunya is present in Asia, Africa and, since 2013/2014, in the Caribbean, the Americas and the Pacific. Dengue is present in Asia, the Pacific, the Caribbean, the Americas and Africa. Zika is also present in Asia, the Pacific, the Caribbean, the Americas and Africa. No autochthonous chikungunya, dengue and Zika cases, related to vector-borne transmission were detected in EU/EEA Member States in 2016.

From 1 February to 18 November 2016, Zika virus infection and the related clusters of microcephaly cases and other neurological disorders constituted a public health emergency of international concern (PHEIC). Since 2015, and as of 27 January 2017, 72 countries and territories have reported evidence of mosquito-borne transmission of the virus.

→Update of the week

### Monthly summary

This month, the significant events for dengue, chikungunya and zika are:

- In 2016, Brazil reported a major increase of chikungunya cases compared with 2015.
- In December 2016, Pakistan reported the first chikungunya confirmed cases since a decade.
- [Angola](#) reported the first autochthonous Zika cases on 7 January 2017.

## Cholera - Multistate (World) - Monitoring global outbreaks

Opening date: 20 April 2006

Latest update: 3 February 2017

Cholera outbreaks are repeatedly being reported from several countries in Africa, Asia and the Americas.

→Update of the week

During January 2017, reports on cholera outbreaks were identified regarding Haiti, Yemen, Central and Western African countries.

## II. Detailed reports

### Influenza - Multistate (Europe) - Monitoring 2016-2017 season

Opening date: 13 October 2016

Latest update: 3 February 2017

#### Epidemiological summary

##### Week 4/2017 (23-29 January 2017)

Influenza activity remained elevated across the region with 28 of 43 countries reporting increased activity. Most countries reported stable or decreasing respiratory disease activity compared with the previous week. Excess all-cause mortality among the elderly has been observed in the past 4 to 5 weeks in many of the 18 countries that provide data on excess all-cause mortality and, most likely, this is mainly due to the circulation of influenza A(H3N2) virus. The proportion of influenza virus detections among sentinel surveillance specimens was 51%, similar to that in the previous week.

The great majority of influenza viruses detected were type A (95%) and, of those subtyped, 97% were A(H3N2). Most of the hospitalised laboratory-confirmed cases reported have occurred in people aged 65 years or older.

##### Season overview

Influenza activity started early this season compared with previous seasons.

Week 46/2016 is the earliest week that the overall influenza-positivity rate in sentinel specimens reached 10% since the emergence of A(H1N1)pdm09 viruses in the 2009 season; during the last six seasons this occurred between weeks 48 and 51. Since week 40/2016, influenza A viruses have predominated, accounting for 96% of all sentinel detections; the great majority (99%) of subtyped influenza A viruses from sentinel sites has been A(H3N2).

In an influenza season in which A(H3N2) viruses predominate, elderly populations might be expected to be most severely affected. Indeed, confirmed cases of influenza A infection reported from hospitals have predominantly been in adults aged over 65 years.

So far, circulating A(H3N2) viruses are antigenically similar to the vaccine strain. While about two-thirds of the A(H3N2) viruses genetically characterised belong to a new genetic subclade (3C.2a1), those that have been antigenically characterised are similar to the vaccine strain (clade 3C.2a).

Early monitoring of vaccine effectiveness in Finland and Sweden suggests levels of effectiveness similar to estimates from annual multi-country studies between the 2011–2012 and 2014–2015 seasons with 26% (95% CI 22% to 30%) and 24% (95% CI 11% to 34%) vaccine effectiveness, respectively, in persons aged 65 years and older. Given typically suboptimal vaccination coverage, the partial effectiveness of influenza vaccines, rapid use of neuraminidase inhibitors (NAIs) for laboratory-confirmed or probable cases of influenza infection should be considered for vaccinated and non-vaccinated patients at risk of developing complications. Reduced susceptibility to Zanamivir has been observed among one tested virus so far this season.

A risk assessment on seasonal influenza in EU/EEA countries was published by ECDC on 24 December 2016 and was updated on 25 January 2017. The above description is in line with the findings of these assessments.

#### ECDC assessment

This season, influenza viruses, mainly A(H3N2), began circulating early in the EU/EEA. It is too early to predict the intensity in primary care and the severity in secondary care, but if A(H3N2) continues to predominate, there is a risk that people over 65 years of age will be the most severely affected, possibly increasing pressure on healthcare systems.

An updated risk assessment on seasonal influenza in EU/EEA countries was published by [ECDC](#) on 27 January 2017.

#### Actions

ECDC monitors influenza activity in Europe during the winter season and publishes its weekly report on the [Flu News Europe website](#). Risk assessments for the season are available from the European Centre for Disease Prevention and Control ([ECDC](#)) and the [WHO Regional Office for Europe](#) websites.

### Yellow fever - Brazil - 2016-2017

Opening date: 16 January 2017

Latest update: 3 February 2017

#### Epidemiological summary

On 6 January 2017, Brazil reported an outbreak of yellow fever. The index case had onset of symptoms on 18 December 2016. The first laboratory confirmation was notified on 19 January 2017.

As of 2 February 2017, Brazil has reported 826 cases (671 suspected and 155 confirmed), including 139 deaths (82 suspected and 57 confirmed), in five states. The case fatality rate is 16.8% among all cases and 36.8% among confirmed cases.

States reporting suspected and confirmed cases:

- *Minas Gerais* has reported 740 cases (602 suspected and 138 confirmed), including 128 deaths (77 suspected and 51 confirmed).
- *Espírito Santo* has reported 65 cases (52 suspected and 13 confirmed), including eight deaths (five suspected and three confirmed).
- *São Paulo* has reported seven cases (three suspected and four confirmed), including three confirmed deaths.

States reporting suspected cases:

- *Bahia* has reported eight suspected cases, none fatal.
- *Tocantins* has reported four suspected cases, none fatal.

Investigations are ongoing to determine the probable infection site of two further suspected cases.

The Ministry of Health of Brazil has launched mass vaccination campaigns targeting the affected areas.

**Sources:** [Brazil MoH](#) ; [Minas Gerais MoH](#)

## ECDC assessment

The risk of yellow fever transmission in the EU/EEA is currently very low as it depends on the virus being introduced by viraemic travellers to an area with an established, competent and active mosquito vector population.

In Brazil, authorities have reported only sylvatic cases in 2016 and 2017. However, this outbreak should be carefully monitored as the establishment of an urban yellow fever cycle would have the potential to quickly affect a large number of people. Therefore, EU/EEA Member States should consider a range of options for response.

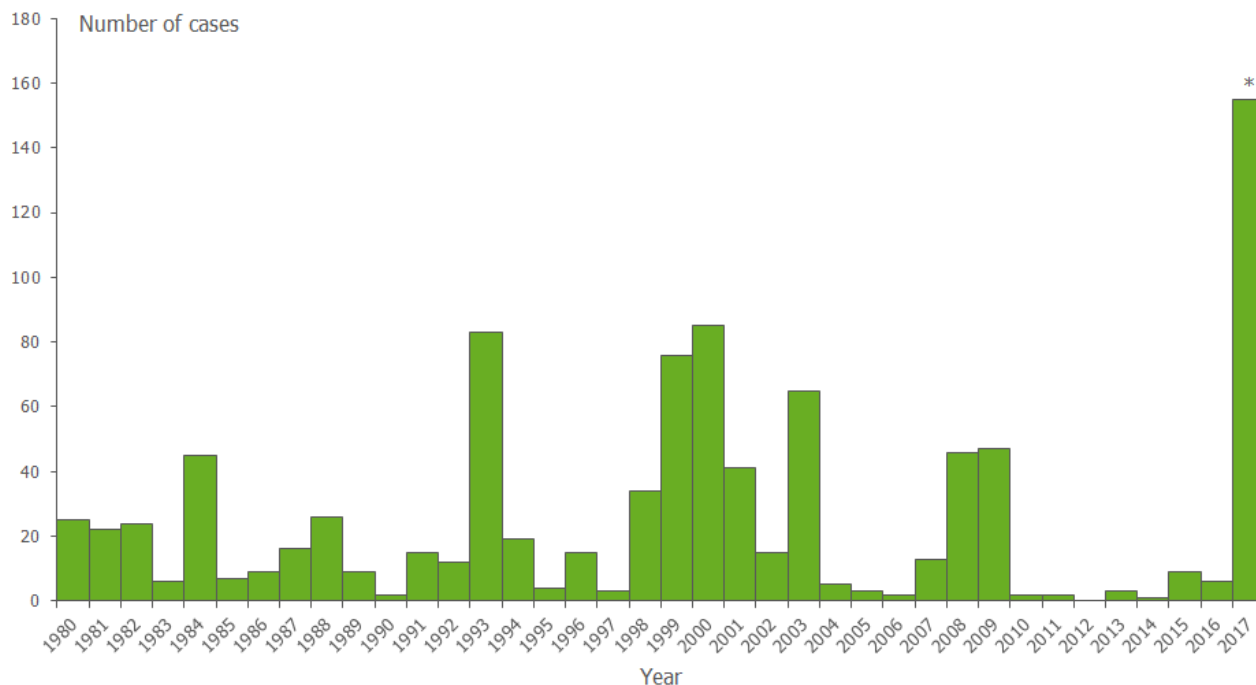
EU/EEA citizens who travel to, or live in, areas where there is evidence of yellow fever virus transmission, particularly in the states of Brazil reporting confirmed local transmission, should consider the risk of yellow fever, check their vaccination status and get medical advice about getting vaccinated against yellow fever.

## Actions

ECDC monitors closely this event in collaboration with WHO. ECDC has published a [rapid risk assessment](#) on 26 January 2017. ECDC has also published an [epidemiological update](#) and a [map for travel advice](#).

### Distribution of confirmed human cases of yellow fever by year, Brazil, 1980 – 2 February 2017

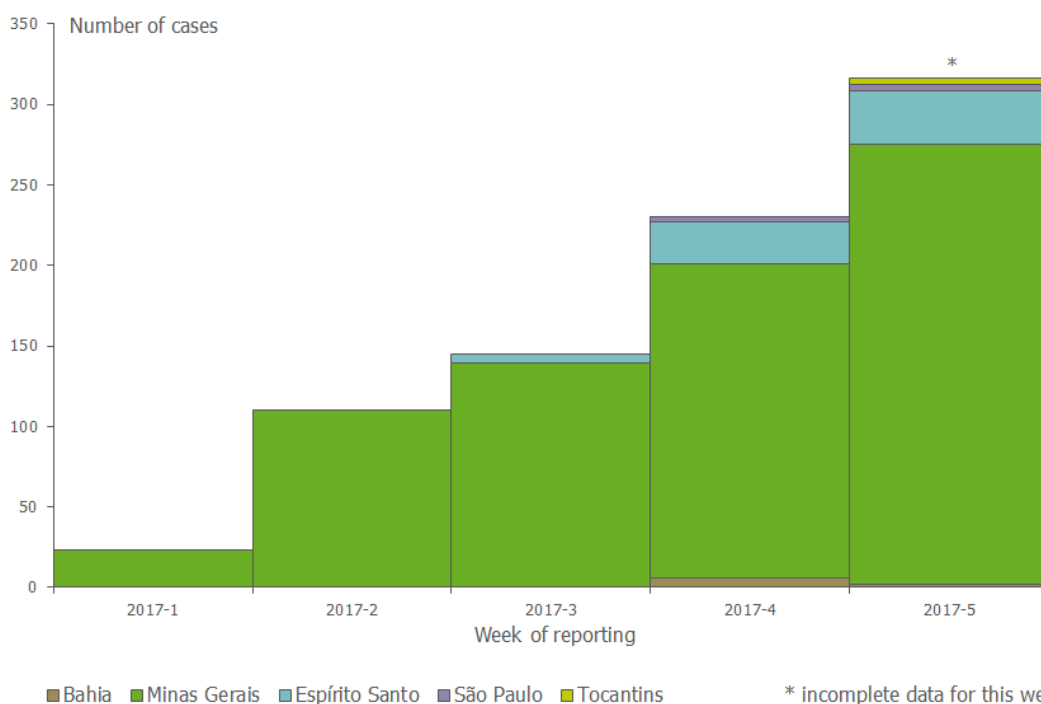
ECDC



\* Data available up to 2 February 2017

### Distribution of suspected and confirmed human cases of yellow fever by week, Brazil, 2017

ECDC



\* incomplete data for this week

### Distribution of human cases of yellow fever by state, Brazil, 2017

ECDC

	All cases	Suspected cases	Confirmed cases
Minas Gerais	740	602	138
Espírito Santo	65	52	13
São Paulo	7	3	4
Bahia	8	8	0
Tocantins	4	4	0
Under investigation	2	2	0
<b>Total</b>	<b>826</b>	<b>671</b>	<b>155</b>



Hunan (46), Jiangxi (25), Shandong (12), Xinjiang Uygur (10), Beijing (9), Guizhou (6), Hebei (4), Henan (6), Guangxi (3), Hubei (5), Jilin (2), Tianjin (2), Liaoning (3), Hong Kong (20) and two case in Macau and four cases in Taiwan.

Three imported cases have also been reported: one in Malaysia and two in Canada.

**Web sources:** [Chinese CDC](#) | [WHO](#) | [WHO FAQ page](#) | [ECDC](#) | [Hong Kong CHP](#)

## ECDC assessment

This is the fifth Northern Hemisphere winter season with human cases due to A(H7N9) infections. During this wave the number of human cases is already higher than during the whole last wave in 2015/16 with a significantly higher number than in the last two waves within the same period of time. A steep increase of human cases has been reported since the beginning of December 2016 from China, the epidemiology however, does not seem to have changed during this season.

The majority of recently reported human cases are associated with exposure to infected live poultry or contaminated environments, including markets where live poultry are sold. The age of the infected humans is comparable with previous waves. Influenza A(H7N9) viruses continue to be detected in poultry and their environments in the areas where human cases are occurring, however more human cases are detected in rural areas. The upsurge of human cases is most likely due to a higher environmental contamination particularly related to live bird markets.

At present, the most immediate threat to EU citizens is to those living or visiting influenza A(H7N9)-affected areas in China. It is advisable to avoid live bird markets or backyard farms as well as contact with live poultry or their droppings. Food should be only consumed properly cooked. The environmental contamination and thus higher risk of exposure to A(H7N9) highlights the possibility of travel-related cases also being detected in Europe, especially also related to the upcoming Chinese New Year 28th of January. The recent upsurge of human cases due to a higher risk of exposure indicates the possibility of sporadic imported cases to Europe. However, the risk of the disease spreading within Europe via humans is still considered low, as the virus does not appear to transmit easily from human-to-human and the investigations do not support sustained human-to-human transmission.

## Actions

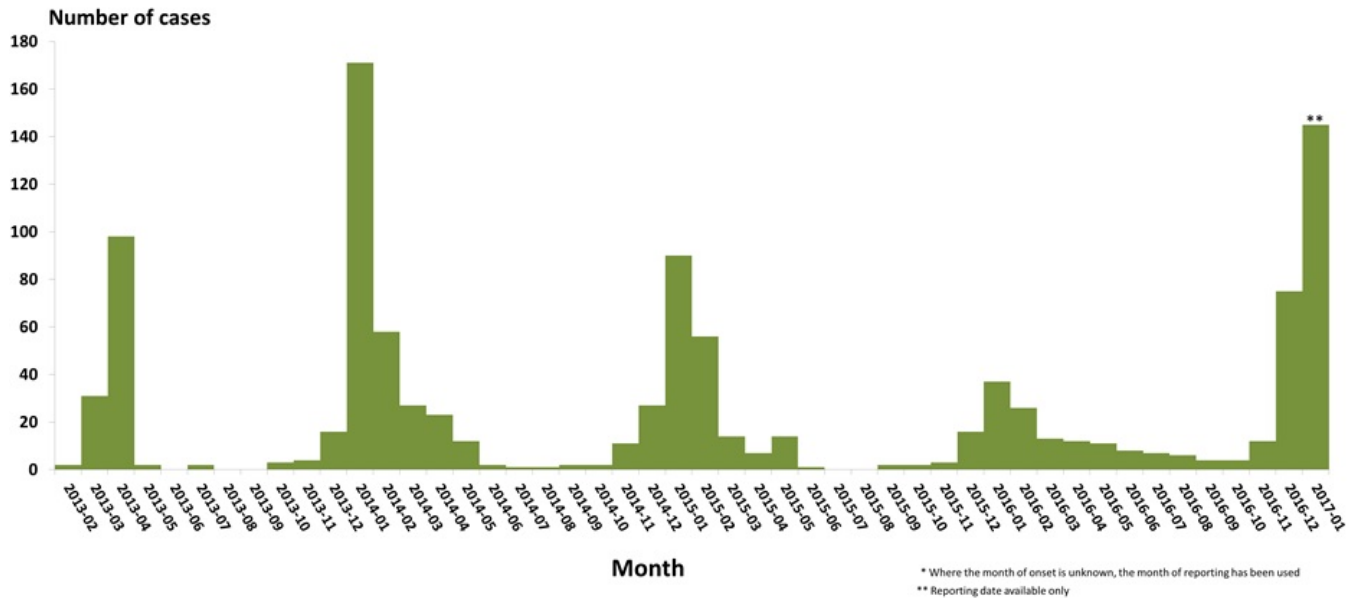
ECDC published a guidance document entitled [Supporting diagnostic preparedness for detection of avian influenza A\(H7N9\) viruses in Europe](#) for laboratories on 24 April 2013.

ECDC published an updated [Rapid Risk Assessment](#) on 27 January 2017.



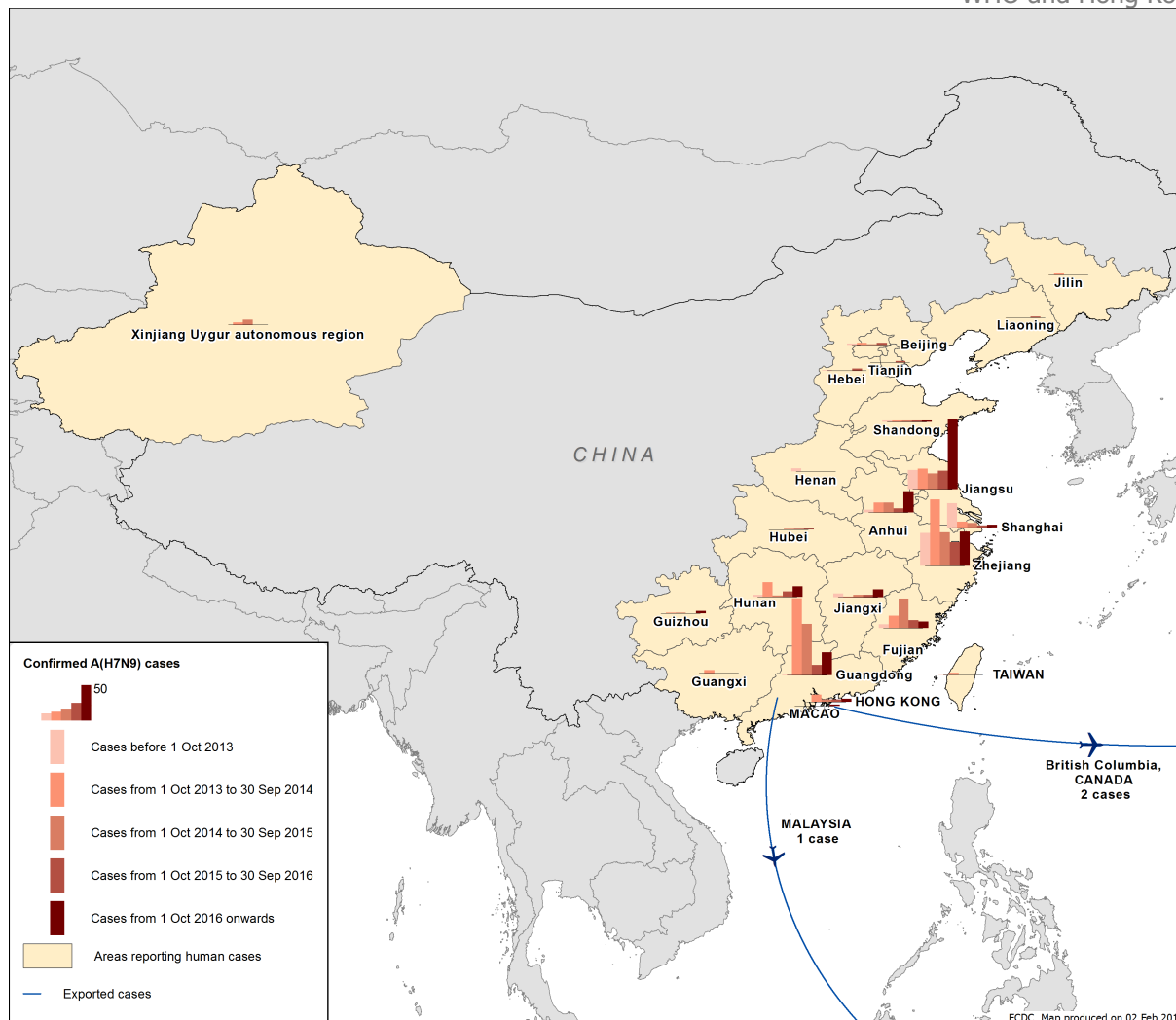
Distribution of confirmed cases of A(H7N9) by month February 2013 to January 2017

WHO and Hong Kong CHP



## Distribution of confirmed cases of A(H7N9) by five periods(weeks 07/2013 to 5/2017)

WHO and Hong Kong CHP



## Chikungunya - Dengue - Zika - Multistate (world) - Monitoring global outbreaks

Opening date: 27 January 2017

Latest update: 3 February 2017

### Epidemiological summary

#### Europe

No autochthonous cases of chikungunya and dengue virus infection were reported in EU Member States in 2016 and 2017.

No mosquito-borne Zika virus transmission has been reported in EU. As of 18 January 2017, seven countries (France, Germany, Italy, Netherlands, Portugal, Spain, the UK) reported [person-to-person](#) Zika virus transmission.

Since June 2015 (week 26), 21 countries (Austria, Belgium, Czech Republic, Denmark, Finland, France, Greece, Hungary, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom) reported 2 086 travel-associated Zika virus infections through [The European Surveillance System](#) (TESSy). Over the same time period, nine EU/EEA Member States reported 107 Zika cases among pregnant women.

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## Americas and the Caribbean

### *Chikungunya*

In 2016, the Pan American Health Organization ([PAHO](#)) reported 498 027 suspected and confirmed cases, including 172 deaths, in the Americas and Caribbean region.

The most affected countries were Brazil, Bolivia, Colombia and Honduras. In 2016, Brazil reported the highest number of chikungunya cases in the Americas (408 657 vs 23 630 in 2015).

Since the beginning of 2017 and as of 27 January 2017, the Pan American Health Organization (PAHO) has reported 458 suspected and confirmed cases in the Americas and Caribbean region.

### *Dengue*

In 2016 the Pan American Health Organization ([PAHO](#)) reported almost 2.3 million confirmed and probable cases, including 1 032 deaths, in the Americas and Caribbean region. The most affected countries were Brazil, Paraguay, Mexico and Colombia. In 2016, Brazil reported the highest number of dengue cases in the Americas (1 569 753 which is a stable figure compared with 2015).

Since the beginning of 2017 and as of 1 February 2017, the Pan American Health Organization (PAHO) has reported 5 959 suspected and confirmed cases in the Americas and Caribbean region.

### *Zika*

In the US, [Florida](#) continues to report sporadic cases (the latest reported on 27 January 2017) while Mexico shows a decreasing trend. In Central America, Belize and Panama are reporting a growing trend while the other countries in the sub-region as well as in Caribbean do not show a variation in the reported cases. In the southern part of the continent, Bolivia, Peru and Paraguay are reporting an increasing trend. Brazil has reported 5 273 cases from week 2016-47 to week 2017-02.

## Asia

### *Chikungunya*

Chikungunya fever cases are reported from India (no update since last monthly overview) and Pakistan. Since the end of 2016 and as of 14 January 2017, [Pakistan](#) reported 510 suspected Chikungunya fever cases from Saudabad and Lyari areas.

### *Dengue*

In 2016, the most affected countries in Asia are India, Malaysia, Vietnam, Sri Lanka and Thailand. Despite the high cumulative number of cases, India, Malaysia and Singapore are showing a decreasing trend.

As of 31 December 2016, 2076 cases of dengue were reported in [China](#) in 2016, which is lower than in the same period in 2015. [Laos](#) is reporting a nationwide outbreak with 235 cases in 2017.

Since the beginning of 2017 and as of 26 January 2017, [Malaysia](#) reported 6 951 dengue cases, which is comparable with the figure in 2016 for the same period.

During 2016, 3 340 cases of the viral fever were reported in Rawalpindi, [Pakistan](#), including seven deaths, mainly from Islamabad and rural areas surrounding the capital (2755 cases). In 2015, 5 000 cases and 10 deaths were reported.

Since the beginning of 2017 and as of 27 January 2017 in [Singapore](#) the cumulative number of dengue cases is 296. This is relatively low compared to 2016 where 2 443 cases were reported in the first four weeks of January.

### *Zika*

[Singapore](#) reported its first locally-acquired case of Zika virus infection on 27 August 2016, since then and until the end of 2016, around 500 locally acquired cases were recorded in Singapore. In the first four weeks of 2017, one additional case was reported. According to media reports quoting the local authorities, [Thailand](#) reported over 600 confirmed Zika cases in 2016.

Since April 2016, [Vietnam](#) reported around 200 cases of Zika virus infection, including additional cases reported in January 2017. In [Malaysia](#) and the [Philippines](#), new locally-acquired cases have been reported in December 2016 bringing the number of Zika cases to 10 and 53 respectively.

## Pacific region and Australia

### *Chikungunya*

No outbreaks detected.

### *Dengue*

Between 1 and 13 January 2017, [Australia](#) reported 35 notifications of dengue fever, compared with 86 during the same period of 2016. [Queensland Health](#) reported two outbreaks in December 2016 and January 2017 of locally-acquired dengue: Boigu Island reported two confirmed cases of DENV-1 and Cairns and Hinterland reported one confirmed case of DENV-3.

[French Polynesia](#) reported 21 confirmed dengue cases between 19 December 2016 and 1 January 2017. Four (18%) of them were confirmed as DENV-1 infection.

Since the beginning of 2017 and as of 30 January 2017, [New Caledonia](#) reported 309 cases.

As of 5 November 2016, there were 176,411 suspected cases of dengue reported in [Philippines](#) in 2016, including 422 deaths. The figures are comparable with last year for the same period.

Since 15 August and as of 15 January 2017, 8 538 suspected cases of dengue have been detected on the [Solomon Islands](#), 924 out of 2 222 tested cases (41.6%) were considered positive. Dengue virus serotype 2 (DENV-2) was detected in 35 out of 51 samples (69%).

### **Zika**

[American Samoa](#) reported 1 004 suspected cases including 58 laboratory confirmed from 1 January 2016 to 1 December 2016.

### **Africa**

**Chikungunya:** no major outbreak detected this month.

### **Dengue**

As of 17 January 2017, Burkina Faso reported 2536 suspected and probable cases, including 20 deaths. The outbreak is largely under control with small numbers or zero new suspect cases reported daily.

Since December 2016, an outbreak of dengue is ongoing in [Cape Verde](#).

### **Zika**

[Angola:](#) On 2 February 2017, media quoting the local authorities in Angola, reported the third case of locally acquired Zika virus infection in the country. The case is a woman who gave birth to a baby with microcephaly.

## ECDC assessment

### **Chikungunya**

Outbreaks are still ongoing in the Americas and the Pacific region but at a lower level than during the same period last year, except for Brazil that reported significantly more cases in 2016 compared to 2015.

### **Dengue**

Dengue is widely spread in tropical and subtropical regions. Introduction and autochthonous transmission of dengue fever in Europe is possible where competent vectors are present.

### **Zika**

The spread of the Zika virus in the Americas and Asia is likely to continue as the vectors (*Aedes aegypti* and *Aedes albopictus* mosquitoes) are widely distributed there. As neither treatment nor vaccines are available, prevention is based on personal protection measures. Pregnant women should consider postponing non-essential travel to Zika-affected areas.

Europe is vulnerable to the autochthonous transmission of arboviruses. The risk of onward transmission in Europe is linked to importation of the virus by viraemic patients in areas with competent vectors (*Aedes albopictus* in mainland Europe, primarily around the Mediterranean, and *Aedes aegypti* on Madeira). Autochthonous transmission from an imported viraemic case is possible during the summer season in the EU. Continued vigilance is needed to detect imported cases in tourists returning to the EU from affected regions.

## Actions

ECDC monitors this threats on a monthly basis. ECDC is preparing an update of the Zika risk assessment published on 28 October 2016.

## Cholera - Multistate (World) - Monitoring global outbreaks

Opening date: 20 April 2006

Latest update: 3 February 2017

### Epidemiological summary

In [Haiti](#) the weekly number of new cases has been decreasing since mid-November 2016.

### Central and West Africa 2016 summary

According to a summary report, published on 27 January 2017, 30 977 cases including 849 deaths, (case-fatality rate 2.7%) were reported in 2016 in Central and West Africa.

The majority of the cases (92%) were from the Congo River basin (DR Congo, Central African Republic and Congo Brazzaville). The southern part of the Guinea gulf basin faced two active outbreaks in Benin and Nigeria.

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An outbreak, which started in week 42, 2016, in Ghana, resulted in 602 cases (mainly in Cape Coast. Sporadic cases were reported in Togo (Lomé).

Other countries in the sub-region such as Liberia, Cote d'Ivoire, and Cameroon reported suspected cases which were confirmed negative in the laboratory. None to date has resulted in the isolation of *Vibrio cholerae O1*. Mauritania, Burkina Faso, Guinea, Guinea Bissau, Mali and Senegal remained cholera-free in 2016.

According to media reports in 2016, 720 cases were recorded **Ghana**, with Cape Coast recording as high as 695 cases. The outbreak of the disease in the Cape Coast Metropolis in October 2016 has protracted into January 2017 with a record of 12 cases with no deaths, however, no new reported cases have been recorded for the past two weeks.

In **Burundi**, the outbreak, which started in July 2016 was declared over in December, however since then new cases have been reported. According to media reports, since 21 December 2016 until 10 January 2017, an outbreak is affecting more than 130 people.

In **Angola**, since mid-December 2016 and as of 23 January 2017, 150 cases including 10 deaths have been reported in Zaire, Cabinda and Benguela. Angola has faced cholera epidemics since 2006 as a result of poverty, inadequate water and sanitation systems, and limited access to health services.

In **Somalia**, between 1 January and 22 January 2017, 2 236 suspected cholera cases, including 32 deaths (case-fatality rate of 1.4%) have been reported according to WHO. Of the 2 236 cases *Vibrio Cholerae O1* has been laboratory confirmed in 10 stool samples collected from Bay, Banadir and Lower Shabelle regions.

In 2016, a 15 619 suspected cases of cholera, including 531 associated deaths (case-fatality rate 3.39%), were reported. The current weekly trend of suspected cholera cases continues to increase and further spreading to other locations throughout the country is not unexpected.

In **South Sudan**, cholera outbreaks have been confirmed in 9 (32%) of 28 states countrywide. The affected states include Imatong, Eastern Lakes, Jubek, Terekeka, Jonglei, Western Bieh, Northern Liech, Southern Liech; and Eastern Nile. In Southern Liech, one case from Ganyiel was confirmed in week 52 of 2016. Suspect cholera cases were reported in Mayendit and Ayod but are not confirmed. Cumulatively 150 (35.7 %) of the samples tested positive for *Vibrio Cholerae inaba* in the National Public Health Laboratory as of 15 January 2017.

According to media reports in **Sudan**, twelve people have died and 500 are infected with watery diarrhoea in the states of Khartoum, Red Sea and Gedaref during the past week.

In **Tanzania**, since the first case was recorded in early December 2016 and as of 31 December, 91 cases including three deaths have been reported in Karema Division.

In **Kenya**, Kisumu county health department has issued a warning as the water levels are low during this time of the year and people are consuming the same stagnant water.

In **Yemen**, between 10 and 18 January 2017, 1 866 new suspected cases of cholera have been reported; no additional deaths. The weekly trend of reported cholera cases remains unchanged, although a decrease in the reported cases have been observed in a number of the affected governorates. Poor accesses to healthcare services along with limited active case-findings due to insecurity are severely compromising the effectiveness of the ongoing response operations. As of 18 January, 17 334 suspected cases of cholera, including 99 associated deaths were reported across the country, with a case-fatality rate of 0.6%. Of these, 189 cases were laboratory-confirmed for *Vibrio cholerae O1*.

**Source:** [Cholera platform](#) | [Haitian MoH](#) | [media](#)

## ECDC assessment

European travellers should seek information on how to prevent cholera contamination prior to visiting affected areas.

## Actions

ECDC continues to monitor cholera outbreaks globally through its epidemic intelligence activities to identify significant changes in epidemiology and will report on a monthly basis.

The Communicable Disease Threat Report may include unconfirmed information which may later prove to be unsubstantiated.