



RAPID RISK ASSESSMENT

Ebola virus disease outbreak in Equateur Province, Democratic Republic of the Congo

First update, 25 May 2018

Main conclusions and options for response

This is the ninth Ebola virus disease (EVD) outbreak in the Democratic Republic of the Congo (DRC) since the discovery of the virus in 1976.

From 4 April until 20 May 2018, 49 cases and 26 deaths have been recorded: of which 22 are confirmed, 21 are probable and six are suspected cases. Cases have been reported from the Bikoro health zone (n=29; 10 confirmed and 19 probable), the Iboko health zone (n=16; eight confirmed, two probable and six suspected) and the Wangata health zone (n=4; all confirmed) [1]. The current outbreak is taking place in health zones neighbouring the Congo River, which is an important pathway of trade and travel. In addition, four confirmed EVD cases have been reported in the health zone of Wangata within the port city of Mbandaka which has a population of 1.2 million people. These factors have raised concerns about an increased probability of the spread of the disease at the national level. The identification of EVD cases in the urban area of Mbandaka city and around Tumba Lake both connected to the Congo River increases the risk of regional spread to other provinces of DRC and neighbouring countries (namely Republic of the Congo and the Central African Republic). ECDC is closely monitoring this outbreak in liaison with the Ministry of Health in DRC, WHO and other partners, and will re-evaluate the risk for EU/EEA citizens if necessary according to epidemiological findings.

Under the coordination of the Ministry of Health in the DRC, the timely EVD outbreak response is being implemented with the support of UN agencies and international partners. The strategic activities being implemented for the prevention and control of this outbreak include: coordination of the response activities, enhanced epidemiological surveillance for early detection of cases and contact tracing, increase of laboratory capacity, appropriate case management, reinforcement of infection prevention and control (IPC) measures, ensuring safe and dignified burials, social mobilisation and community engagement.

For the European Union/European Economic Area (EU/EEA) citizens living in, or travelling through areas of DRC not known to have EVD cases, the risk of exposure is very low, provided they adhere to the recommended precautions. The overall risk of introduction and further spread of Ebola virus within the EU/EEA is currently considered to be very low.

Options for response and risk reduction

Travel to affected areas

Visitors and residents in EVD-affected areas face a low risk of becoming infected in the community if the following precautions are strictly followed:

- avoiding contact with symptomatic patients and their bodily fluids;
- avoiding contact with corpses and/or bodily fluids from deceased patients;
- avoiding contact with wild animals (including primates, forest antelopes, rodents and bats), both alive and dead;
- avoiding consumption of 'bush meat';
- washing hands regularly using soap or antiseptics.

In addition, the following generic precautions are advisable:

- wash and peel fruit and vegetables before consumption;
- practice 'safe sex'.

The use of the candidate vaccine rVSV-ZEBOV is limited to the ring vaccination administration strategy for the emergency response and control of the EVD outbreak according to the Strategic Advisory Group of Experts on Immunization (SAGE). Specifically, the current strategy could include, but is not be limited to, 'contacts and contacts of contacts of EVD cases; local and international healthcare and front-line workers in the affected areas and healthcare and front-line workers in areas at risk of expansion of the outbreak'. Currently the vaccine is not available or recommended for travellers in the DRC or in the affected areas. For more detailed information, see the disease background and WHO's '[Frequently asked questions on Ebola virus disease vaccine](#)' updated on 18 May 2018 [2].

Screening of travellers

The Emergency Committee under the International Regulations (2005) was convened by the Director General of WHO on 18 May and concluded that 'the conditions for a Public Health Emergency of International Concern (PHEIC) have not currently been met' [3]. Based on the advice of the Emergency Committee, WHO does not recommend the application of any travel and trade restrictions to DRC. The Committee also noted that 'Exit screening, including at airports and ports on the Congo river, is considered to be of great importance; however entry screening, particularly in distant airports, is not considered to be of any public health or cost-benefit value.'

Exit screening measures are increasingly implemented in DRC both at Kinshasa airport and Mbandaka airport. More information about the value of entry screening during the unprecedented EVD outbreak in Guinea, Sierra Leone and Liberia, is available in the Rapid Risk Assessment, eighth update, 18 November 2014 [4]. Exit screening at the border is part of a continuum of measures to contain the epidemic at the source, in conjunction with educating travellers on risk and self-reporting in case of symptoms. Containment measures also include increased vigilance for detection and management of suspect cases on board of conveyances and at points of exit.

To reduce the likelihood of Ebola virus introduction into the EU/EEA, the following options for response can be considered depending on specific situations:

- A traveller presenting with symptoms (e.g. fever $>38^{\circ}\text{C}$) at an airport where exit screening exists for EVD symptoms for travellers from affected areas should not be allowed to board a flight. It is important to note that only an infected symptomatic person is able to spread the virus to others.
- A passenger who develops symptoms while on board a commercial flight should be isolated and his/her condition ascertained upon reaching the destination. Should the passenger be confirmed as having EVD, contact tracing of passengers should be initiated according to the recommendations for contact tracing in aircraft, set out in the RAGIDA guidelines [5].
- Travellers who stayed in a recently affected area should be made aware that if they are asymptomatic during their journey but develop symptoms compatible with EVD after arrival in an EU/EEA Member State, they should self-isolate and contact health services at the first signs of illness that are compatible with EVD, mentioning their potential exposure. Secondary transmission to caregivers in the family and at healthcare facilities cannot be ruled out, especially if the affected person would present with symptoms likely to result in the exposure of contacts to bodily fluids, and if no appropriate infection prevention and control measures were implemented.
- There is also the potential for introduction into the EU through the return of an infected healthcare worker involved in responding to any EVD outbreak. However, this risk is very low and should not result in subsequent exposure of contacts, given the symptom monitoring protocol implemented for healthcare workers upon return from missions.
- More information is available for individual exposure assessment in the rapid risk assessment, [Outbreak of Ebola virus disease in West Africa, Eighth update](#), 18 November 2014, and a summary of the recent developments on post-exposure prophylaxis and risk stratification can be found in a comprehensive review by Fisher et al. (2017) [4,6].

Source and date of request

ECDC internal decision, 17 May 2018.

Public health issue

This updated rapid risk assessment addresses the public health related risks associated with the current EVD outbreak in DRC, in particular the potential of extension to neighbouring countries and regions in DRC and its implications for EU/EEA Member States. Notably, this RRA reviews the possible risk for EU/EEA citizens living or travelling in DRC, and the subsequent risk associated with the potential for EVD introduction and spread within the EU/EEA. This update was triggered by the new developments in the EVD outbreak such as laboratory-confirmed EVD cases in the urban Wangata health zone in the port city of Mbandaka, Equateur Province, DRC.

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Experts from the World Health Organization contributed to this risk assessment. Although experts from WHO reviewed the risk assessment, the views expressed in this document do not necessarily represent the views of WHO.

Disease background information

Disease background

Infections with Ebola viruses originating from Africa cause a severe disease in humans called Ebola virus disease. There are five species of the genus *Ebolavirus* (Filoviridae family): *Zaire ebolavirus*, *Sudan ebolavirus*, *Reston ebolavirus*, *Tai Forest ebolavirus*, and *Bundibugyo ebolavirus* [7-9]. Ebola viruses are biosafety level-4 pathogens (BSL-4; risk group 4) and require special containment measures and barrier protection, particularly for healthcare workers.

The incubation period is usually four to ten days but can be as short as two days and as long as 21 days. The symptoms usually consist of a sudden onset of fever, malaise, headache, muscle pain and sore throat. This phase can be followed by symptoms and clinical manifestations from several organ systems (gastrointestinal, neurological, vascular, cutaneous and respiratory). Severe exhaustion, haemorrhagic manifestations and multi-organs failure are reported in the severe form of EVD. The case-fatality ratio for *Zaire ebolavirus* infections is estimated to be between 44% and 90% [10].

Ebola viruses are highly transmissible through direct contact with infected blood, secretions, tissues, organs and other bodily fluids from dead or living infected animals or persons [11]. Transmission via objects contaminated with infected bodily fluids (fomites) is possible [12]. The principal mode of transmission in human outbreaks is person-to-person through direct contact with a symptomatic or dead case. Airborne transmission has not been documented. The risk of transmission is considered low in the early phase of human disease. Burial ceremonies and the handling of dead bodies can play an important role in disease transmission as can healthcare of EVD cases without appropriate infection prevention and control measures for EVD.

More information about EVD is available in the ECDC [Factsheet about Ebola and Marburg fevers](#) and WHO fact sheets on [Ebola virus disease](#).

Diagnostics and diagnostic capacity in EU/EEA

EVD is diagnosed by detection of Ebola virusRNA in whole blood, plasma, or serum during the acute phase of illness using RT-PCR [13]. Viral RNA can usually be detected up to a few days upon disappearance of symptomatology. Virus RNA may also be detected in other body fluids, such as semen, saliva and urine [14]. Throat swabs are suitable for virus detection in deceased patients. Virus RNA has been detected in seminal fluid and in the breast milk of survivors months to years after acute illness, posing a risk for sexual or mother-to-child transmission, respectively. Identification of acute infection based on serology is uncommon.

According to the latest 2016 EULabCap survey, only one EU/EEA Member State does not have national capacity or a formal agreement with other laboratories to diagnose Ebola virus [15]. The majority of the countries (n=22) are able to perform molecular detection at BSL3 level or have formal agreements with a BSL3 laboratory in another EU/EEA member state. Seven countries were able to perform further characterisation at BSL4 level [15].

In addition, a survey on the status of Ebola virus diagnostics, bio risk management and quality assurance within the European region was recently jointly published by laboratory networks EMERGE and EVD-LabNet [16]. A complete overview of Ebola virus diagnostic capacity in the EU/EEA can be found in the [EVD-LabNet directory](#).

Treatment

Early supportive treatment can improve the chances of recovery [17]. Potential new Ebola therapies and vaccines were reviewed during two WHO meetings on 4–5 and 29–30 September 2014 and further assessed by scientific review [18,19]. Several of these potential drugs have in the past month been used in experimental treatment of individual EVD cases.

During the first WHO consultation meeting on potential Ebola therapies and vaccines in September 2014, there was a consensus that 'the use of whole-blood therapies and convalescent blood serums needs to be considered as a matter of priority' [20]. WHO has developed an ethical framework known as Monitored Emergency Use of Unregistered Interventions (MEURI) which established criteria to be met for access to investigational therapeutics for individual patients outside of clinical trials [21]).

Among the candidate treatments under consideration, three experimental treatments were identified:

- ZMapp, a combination of three humanised monoclonal antibodies which block or neutralise the *Zaire ebolavirus*;
- TKM-Ebola, a combination of modified small interfering RNAs targeting the *Zaire ebolavirus* L polymerase;
- Favipiravir, a viral RNA polymerase inhibitor with capacity to inhibit many RNA viruses and already authorised in Japan for novel influenza virus infections.

These candidate treatments have shown promise in non-human primate models. None of these drugs are licensed for treatment of EVD and their availability is currently limited.

The European Medicines Agency (EMA) has started to review available information on a larger panel of Ebola treatments currently under development in order to support fast-track authorisation in the EU/EEA and decision-making by health authorities [22].

Vaccine development

The first WHO consultation meeting identified two vaccines in the advanced stages of development:

- a recombinant vesicular stomatitis virus (VSV) vaccine expressing a Zaire surface glycoprotein (rVSV-ZEBOV), which induces a *Zaire ebolavirus* specific immune response;
- a non-replicative chimpanzee adenovirus type 3 vaccine (cAd3-ZEBOV) also containing the gene for the *Zaire ebolavirus* surface glycoprotein.

Phase 1 and 2 trials for rVSV-ZEBOV have been initiated in the USA, in Africa and Europe on 16 000 volunteers, and have been judged safe for use in humans based on available results [2]. In addition, this vaccine was tested in Guinea among 7 500 adults in 2015 and the trial demonstrated that the vaccine was safe and protective against Ebola infection.

According to the Strategic Advisory Group of Experts on Immunization (SAGE), in case of an outbreak due to EVD Zaire, the candidate vaccine rVSV-ZEBOV can promptly be deployed under the Expanded Access framework, with informed consent and in compliance with Good Clinical Practice [2]. In this context only, the 'ring' vaccination administration strategy would be adapted to the context and the amount of vaccine supply available, and could include, but not be limited to: 'contacts and contacts of contacts of EVD cases; local and international healthcare and front-line workers in the affected areas and healthcare and front-line workers in areas at risk of expansion of the outbreak' [2]. The vaccine is currently not available or recommended for travellers in the DRC or in the affected areas (WHO [Frequently asked questions on Ebola virus disease vaccine](#)).

Surveillance in EU/EEA Member States

Viral haemorrhagic fevers including EVD are notifiable diseases in the EU/EEA and need to be reported in a timely manner. An Ebola case definition for reporting in the EU was released by ECDC in 2014 ([EVD case definition](#) for EU surveillance).

Event background information

According to the current information available, the current outbreak was identified following the investigations of a cluster of 17 community deaths in the health area of Ikoko Impenge located in Bikoro health zone (HZ), Equateur Province, in the western part of DRC. The province shares borders with the Republic of the Congo and is crossed by the Congo River which links this region to the capital cities of the Republic of the Congo, the Central African Republic and DRC [23].

The event was notified by the provincial health authorities of Equateur on 3 May 2018 [24]. Following the rapid deployment of field investigations on 5 May 2018, the EVD outbreak was declared by the Ministry of Health of DRC on 8 May 2018, following the identification by Institut National de Recherche Biologique (INRB), Kinshasa, DRC of two cases positive for Ebola virus Zaire (RT-PCR) among five suspected cases [25].

This is the ninth epidemic of EVD in DRC since the first description of Ebola virus Zaire in the northern part of DRC [26-28]. The last outbreak in the Equateur province was in 2014 and affected 66 people (case-fatality ratio: 74%). The most recent outbreak in DRC occurred in May 2017 in Bas Uele province in the northeast part of DRC with 21 suspected and five confirmed cases [29].

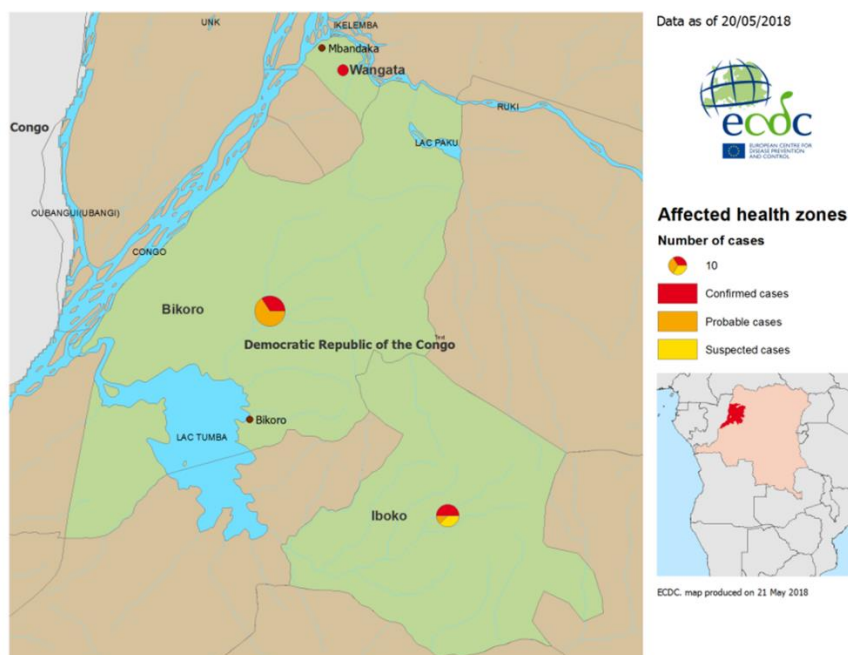
From 4 April until 20 May 2018, the authorities in DRC reported that 49 cases of EVD have been recorded, categorised as: 22 confirmed, 21 probable and six suspected cases. Of the 49 cases, 26 were fatal (case-fatality ratio: 53%); and five of these cases were health workers [1]. So far, the cases have been reported from Bikoro health zone (n=29; 10 confirmed and 19 probable), Iboko health zone (n=16; eight confirmed, two probable and six suspected) and Wangata health zone (n=4; all confirmed). The health zone of Bikoro is rural with an estimated population of 163 000 inhabitants and 19 health centres [30]. The health zone of Wangata is located in the port city of Mbandaka with a population 1.2 million inhabitants [30]. Overall, 45 cases were reported from remote and hard-to-reach areas and four in an urban setting. Of note, the village of Ikoko-Impenge in the Ikoko Impenge health area is located 45 km from the Bikoro city on the shore of Lake Tumba, not covered by the telephone network and not accessible by road. Two cases identified in the Waganta health zone in Mbandaka city (one suspected and one confirmed) report having attended funerals in Bikoro HZ. As of 20 May 2018, more than 628 contacts are being identified [1].

Under the coordination of the Ministry of Health in DRC, the EVD outbreak response is being implemented with the support of UN agencies and international partners. The European Union Civil Protection Mechanism has been activated, following a request for assistance received from the WHO [1]. The main strategic activities for the prevention and control of this EVD outbreak include: coordination of the response, enhanced epidemiological surveillance for early case detection and contact tracing, increased laboratory capacity, appropriate case management, reinforcement of infection prevention and control (IPC) measures, ensuring safe and dignified burials, social mobilisation and community engagement. WHO also supports Ebola vaccination of high risk populations in DRC. Health workers operating in affected areas are being vaccinated and community outreach has started to prepare for the 'ring' vaccination [31].

A mobile laboratory was deployed to the Bikoro reference hospital on 12 May 2018 (operational by 16 May 2018) and a second mobile laboratory has been deployed in Mbandaka port city [30]. Médecins Sans Frontières is setting up two Ebola Treatment Centres (ETCs) in Mbandaka and Bikoro, with 20 beds each [32]. In addition, more than 7 500 doses of the rVSV-ZEBOV Ebola vaccine have been deployed to support further deployment of 'ring' vaccination strategy integrated into the EVD outbreak responses activities [31,33].

According to the Emergency Committee under the International Health Regulation (2005) (IHR) held on 18 May, this event does not meet the criteria of a public health event of international concern [3].

Figure 1. Geographical distribution of confirmed, probable and suspected cases of Ebola virus disease, Equateur Province, Democratic Republic of Congo, as of 20 May 2018



Of note, a comprehensive summary of the contextual information about affected locations and Equateur province is available in the [ACAPS Briefing note](#) dated 14 May 2018, and through the [accessibility map of the affected EVD areas](#) provided by Medecins Sans Frontieres [34,35].

ECDC threat assessment for the EU

The occurrence of an EVD outbreak in the Equateur Province of DRC located within the Congo Basin tropical forests of Central Africa is not unexpected since it is recognised as an area of circulation of Ebola virus [27,36]. According to the information available, the outbreak was detected after the report of a significant cluster of community deaths within the Bikoro health zone. The record of recent cases demonstrates the existence of active chains of EVD transmission. Improvement in the understanding of the outbreak based on current investigations would support a better assessment of possible EVD outbreak trajectories. Current investigation and contact tracing activities were able to detect EVD cases early on in the neighbouring health zone of Iboko and in the urban health zone of Wangata in the port city of Mbandaka located on the Congo River. These events highlight the spread to more populated areas [37].

A timely and comprehensive public health response to this outbreak is ongoing with the support of UN agencies and partners under the coordination of national health authorities experienced in managing EVD outbreaks. The envisaged implementation of an rVSV-ZEBOV 'ring' vaccination strategy is an additional and significant response tool in the portfolio of options for response, which was not used in the control of previous EVD outbreaks in DRC. Therefore, the early public health response should be better able to mitigate the public health risk associated with this outbreak.

This outbreak is occurring in the complex humanitarian context of DRC with recurrent infectious diseases outbreaks, difficult access to the affected health zones in rural settings during the rainy season and limited functionalities of rural health infrastructures – such as limited water, sanitation and hygiene (WASH) resources, low infection prevention and control standards, shortages of medical supplies. These are challenges intended to be addressed by the comprehensive strategic EVD outbreak response plan.

Uncertainties remain about the initial event which resulted in this EVD outbreak emergence (index case unknown) and its development and current extent. Those uncertainties are anticipated to be clarified through the ongoing enhanced epidemiological and laboratory investigations. The identification of EVD outbreak cases in the urban area of Mbandaka city or around Tumba Lake both connected to the Congo River, which constitutes a major regional exchange waterway, increases the probability of spread to other provinces of DRC and neighbouring countries (namely Republic of the Congo and the Central African Republic).

According to WHO's third external situation report dated 18 May 2018 and based on the latest WHO risk assessment [30], the public health risk associated with this event is estimated to be very high at the national level, high at regional level and low at the international level.

Risk to EU/EEA citizens living or traveling in DRC

The probability of exposure of EU/EEA citizens living in or travelling through areas of DRC not known to have outbreak cases is very low in general as transmission of the Ebola virus occurs in the context of direct contact with sick or dead persons or animals infected with Ebola. Due to the current limited number of cases and affected areas, the risk of infection through daily interaction in the community in Equateur province remains low if visitors and long-term residents adhere to the recommended precautions (see [Green Box](#)).

Risk of introduction and further spread within the EU/EEA

The most likely mode of introduction into the EU/EEA would be through an infected traveller coming from the affected area. The likelihood of EVD-infected individuals arriving in the EU is expected to be minimal due to the limited outbreak size (less than 50 EVD cases), and the fact that its epicentre is currently reported to be primarily in remote and rural areas of Equateur Province, according to available information. Therefore, the overall risk of introduction and further spread of Ebola virus within the EU/EEA is currently considered to be very low. For comparison, during the substantially larger EVD outbreak in West Africa in 2014, which included a total of about 28 600 cases and 11 300 deaths, only one local transmission occurred in the EU/EEA (Spain) in a healthcare worker attending to an evacuated Ebola patient [38]. However, if there is a substantial increase in the number of cases or in the geographical spread of the EVD outbreak the probability of introduction in Europe may increase.

To date, WHO advises against the application of any travel or trade restrictions on the Democratic Republic of the Congo based on the currently available information and in accordance with the IHR 2005 [30]. Travel restrictions and active screening of passengers on arrival from affected area in DRC at sea ports, airports or ground crossings in non-affected countries are also not currently recommended by WHO. Exit screening measures are increasingly implemented in DRC both at Kinshasa airport and Mbandaka airport. More information about the value of entry screening during the unprecedented EVD outbreak in Guinea, Sierra Leone and Liberia, is available in the Rapid Risk Assessment Eighth update, 18 November 2014 [4]. Exit screening at borders is part of a continuum of measures to contain the epidemic at the source, in conjunction with educating travellers on risk and self-reporting in case of symptoms. Containment measures also include increased vigilance for detection and management of suspect cases on board of conveyances and at point of exit.

Specific risks related to transmission through substances of human origin

According to the EU Blood Directive [39], current geographic deferrals for malaria also exclude residents and travellers from EVD-affected countries from donating blood. An ECDC technical report assessing the risk of EVD transmission through substances of human origin was published in October 2014. The document offers guidance on the safety of donations where potential donors are travellers returning from Ebola-affected countries, people exposed to Ebola virus and patients who have recovered from EVD [40]. Based on the experience of the previous outbreak in West Africa, individuals who have ever been infected with EBOV are permanently excluded from donating of blood cells and tissues in the UK[41]. In its latest guidance [42], the US Food and Drug Administration (FDA) also recommends an indefinite deferral of a blood donor with a history of EVD infection or disease (excluding donors of convalescent plasma for treatment of EVD) and eight week deferral of a donor after:

- returning from a country with widespread transmission of EVD or with cases in urban areas with uncertain control measures;
- the last close contact with a person confirmed to have Ebola virus infection or disease or a person under investigation in whom the diagnosis is pending;
- the last sexual contact with a person known to have recovered from EVD regardless of the time since the person's recovery;
- notification by authorities that he or she may have been exposed to a person with EVD.

Disclaimer

ECDC issues this risk assessment document based on an internal decision and in accordance with Article 10 of Decision No 1082/13/EC and Article 7(1) of Regulation (EC) No 853/2004 establishing a European centre for disease prevention and control (ECDC). In the framework of ECDC's mandate, the specific purpose of an ECDC risk assessment is to present different options on a certain matter with their respective advantages and disadvantages. The responsibility on the choice of which option to pursue and which actions to take, including the adoption of mandatory rules or guidelines, lies exclusively with the EU/EEA Member States. In its activities, ECDC strives to ensure its independence, high scientific quality, transparency and efficiency.

This report was written with the coordination and assistance of an Internal Response Team at the European Centre for Disease Prevention and Control. All data published in this risk assessment are correct to the best of our knowledge at the time of publication. Maps and figures published do not represent a statement on the part of ECDC or its partners on the legal or border status of the countries and territories shown.

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