Joint UKBTS Professional Advisory Committee (1)

Position Statement

Geographical Disease Risk Index – addition and removal of specific country risk

May 2020

Approved by: Standing Advisory Committee on Transfusion Transmitted Infections

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Guidance for addition/removal of an infectious disease risk entry (GDRI)

Background

Information relating to current and emerging infectious threats is assessed by the UK Blood Services Horizon Scanning process, the information originating from a variety of sources including the Rapid Alert System for Blood and the UK Early Warning and Response System. In addition, ECDC produce rapid risk/outbreak assessments to support countries in the EU in their response to public health threats which include potential options for response; specific transfusion safety measures for non-mandatory infectious diseases (with the exception of WNV) are not defined at EU/EEA level. Temporary deferral, based on the answers to specific questions about recent travel history in an area endemic or epidemic for relevant microbiological agents, is the most frequent method used by UK Blood Services to minimise the risk of transmission of infection via transfusion. Alternative measures include nucleic acid screening of donated blood, pathogen inactivation of platelet and plasma products, and if feasible blood collection can be suspended in an affected area and blood components supplied from unaffected areas. These risks may vary over time and new diseases and outbreaks may occur. The Geographical Disease Risk Index (GDRI), a listing of all countries/states and their known relevant infectious disease endemicity, is used to assist in the deferral of donors; this list is compiled specifically for risks to the blood and tissue supply in the United Kingdom and may vary from risks or recommendations provided for the protection of travellers.

The mechanism for the review and update of the entries in the GDRI against a country is an issue that has arisen on occasions, but which has not been fully dealt with. For example, a complaint was received from a donor who had recently returned from Japan (early 2017) and had been deferred for 4/52 because Japan still has a Dengue risk listed against it in the GDRI. This risk was originally added following the large Dengue outbreak in Tokyo in 2014, which was quickly dealt with and effectively contained by the Japanese authorities. Japan does not currently have Dengue risk on the UK Government travel advisory website, on Travax or on the USA CDC travel section; the last reported case was in 2014. At the 7th September 2017 SACTTI meeting it was agreed that the Dengue risk against Japan could be removed; it was also agreed that a formalised process to allow a risk entry to be added or removed would be prepared.

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Addition of an infectious risk entry to the GDRI

Once UK Blood Services have received information pertaining to a new infectious risk/outbreak (through horizon scanning process, Early Warning and Response System [EWRS] or alternative rapid alert systems) a decision is required whether the risk is sufficient to require an entry being added to the GDRI; a number of factors can be analysed to assist in the decision-making process.

- Is a competent vector present e.g. the competent mosquito vector for chikungunya is present in many countries within the EU (particularly around the Mediterranean coast) and is the population susceptible? The presence of the vector and the introduction of the virus are necessary conditions for local transmission.
- Is there a good surveillance system in place? Early detection of imported cases is vital for preventing onward transmission. Are there competent diagnostic laboratories capable of confirming cases? Can the UK Blood Services be confident that the case numbers being reported are accurate? If either of these is not in place UK Blood Services should err on the side of caution as a small number of cases may reflect only a small proportion of actual numbers.
- Does the country have a national response plan in place? After an autochthonous case and/or an outbreak is detected epidemiological and entomological investigations to assess the potential of onward transmission and guide vector control measures aimed at lowering mosquito population density should be triggered.
- What is the size of the outbreak? A risk entry need not necessarily be applied to, for example, a small cluster of cases in a specific locality, particularly if the factors described above are in place (e.g. the 2017 outbreak of chikungunya in the Var region of South France was not considered to indicate a significant risk and no GDRI entry was considered; the outbreak was successfully restricted to 15 confirmed plus two probable cases in two clusters located in close proximity to each other with no onward transmission due to effective surveillance and public health responses).
- Has/have the local Blood Service(s) or their national regulator implemented measures in response to an outbreak (e.g. use of PI for platelets, cessation of blood collection, NAT testing); Blood services and their regulators therefore consider the blood supply unsafe.
- Are UK blood donors likely to travel to the outbreak area? A risk entry need not necessarily be applied if the area is remote/non-urban/infrequently visited by UK travellers (e.g. a] in 2017 Italy experienced four clusters of autochthonous chikungunya outbreaks in four clusters in the cities of Anzio, Latina and Rome in the Lazio region, and the city of Guardavalle Marina in the Calabria region. Whereas significant UK donors visiting Italy may visit Rome, the Guardavalle Marina region is primarily visited by Italian tourists. A GDRI risk entry was applied to the Lazio region for the duration for the outbreak whereas no entry was applied for the Guardavalle Marina region. Additional factors assisted this decision; number of cases and timing of outbreak in year i.e. colder weather therefore reduced/absent mosquito activity, b] in 2017 six cases of locally acquired malaria were

reported in a rural agriculture area of Greece; five of the cases were *P.vivax*, and one was *P.falciparum*. Whereas *P.vivax* cases had been reported previously in migrant workers in this region the *P.falciparum* case was of more concern. However, public health follow up determined that the *P.falciparum* case was very likely to have been nosocomially acquired. No GDRI risk entry was applied to the region, nor had any been applied as a result of previous malaria outbreaks in the same area of Greece.)

Removal of an infectious risk entry to the GDRI

Many of the considerations for the addition of an infectious risk entry to the GDRI can be applied to assist in the decision making process for removal of an infectious risk entry.

For sporadic autochthonous outbreaks such as the 2017 chikungunya outbreaks in Italy and France, UK Blood Services can remove the GDRI risk entry if the following conditions exist:

- At least two incubations periods after the last reported case have passed.

  Note: For countries with a high capacity for diagnostic testing, consistent timely reporting of diagnostic results, a comprehensive surveillance system and/or a temperate climate or island setting, the WHO have defined the interruption of vector-borne Zika transmission as the absence of ZIKV infection 3 months after the last confirmed case[1].

- If an outbreak has officially been declared as ended by WHO, ECDC etc. Accurate and reliable data on outbreaks are available from any of the following - WHO, ECDC, CDC, Travax, PHE. UK Blood services will also defer potential donors for a defined time period after a country has had the risk removed (e.g. 28 days for chikungunya, 6 months for Ebola).
- Good surveillance and national health response measures are in place. Temporary localised arthropod control measures during epidemics, in high density urbanised areas, can play an important but transient role in reducing the impact on humans and animals of emerging arboviruses.
- Measures instigated by the local Blood Service in response to an outbreak are stopped (e.g. use of PI for platelets, cessation of blood collection, NAT testing); Blood Services and their regulators therefore consider the blood supply safe.
- If the vector is absent. In many European countries most species of mosquito are unable to over-winter hence then end of the mosquito season corresponds to the end of the outbreak in that region.

[1] http://apps.who.int/iris/bitstream/10665/254619/1/WHO-ZIKV-SUR-17.1-eng.pdf?ua=1

- In such areas where transmission has been interrupted but the potential for future transmission remains and the WHO, ECDC etc are silent on whether an outbreak has ended, an appropriate approach for UK Blood Services to remove a GDRI risk entry from such an area/country would be lack of new locally acquired cases for one year after the last locally acquired case was identified, and no cases identified in travellers.

For more complex risk entries/removals the ABO Risk-Based Decision-Making Framework for Blood Safety can be used to assist in the decision making process.

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