17 Transfusion-Transmitted Infection (TTI) n=1 event, 2 recipients

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Definition of a TTI:

A report was classified as a transfusion-transmitted infection if, following investigation:

- **The recipient had evidence of infection following transfusion with blood components and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection**

and, either:

- **At least one component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection**

or:

- **At least one component received by the infected recipient was shown to contain the agent of infection**

Note that for the purposes of the European Union (EU) legislation, serious adverse reactions (SAR) are defined as any reactions in patients that are 'life-threatening, disabling or incapacitating, or which result in or prolong hospitalisation or morbidity.' These must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) (a legal requirement). This includes all confirmed transfusion-transmitted infections.

Summary

United Kingdom (UK) Blood Service investigations in 2014 have confirmed that there were:

- No proven bacterial transfusion-transmissions reported in 2014
- Two near miss bacterial incidents
- One transfusion-transmitted hepatitis E virus (HEV) incident following a transfusion in 2014 affecting 2 recipients

The risk of bacterial transmission is not completely abolished by bacterial screening of platelets. Therefore the UK Blood Services and hospitals are reminded that visual inspection of packs before issue and use is a crucial safety step in minimising potential bacterial transfusion transmissions. The Blood Service should be informed immediately of significant adverse reactions including those suspected of being the result of bacterial contamination of a component.

The risk of a screened component transmitting hepatitis B virus (HBV), hepatitis C virus (HCV) or human immunodeficiency virus (HIV) in the UK is very low. Nevertheless, to maintain haemovigilance, investigations are performed if a recipient is suspected to have been infected via transfusion.

Blood donations in the UK are not currently screened for HEV. The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) has set up a working group to consider the risk of hepatitis E transmission via blood and what action, if any, should be taken.

Table 17.2 shows the number of confirmed TTI incidents, by year of transfusion with total infected recipients and outcomes (death, major morbidity, minor morbidity) in the UK between October 1996 and December 2014 (Scotland included from October 1998).

Introduction

This chapter describes the possible transfusion-transmitted infection incidents investigated by the UK Blood Services and reported to the National Health Service Blood and Transplant (NHSBT)/Public Health England (PHE) Epidemiology Unit in 2014.

Summary of reports made to the NHSBT/PHE Epidemiology Unit in 2014

During 2014, the UK Blood Services were asked to investigate 117 suspected TTI incidents, a similar number to recent years, consisting of 93 possible bacterial cases and 24 suspected viral incidents (Figure 17.1).

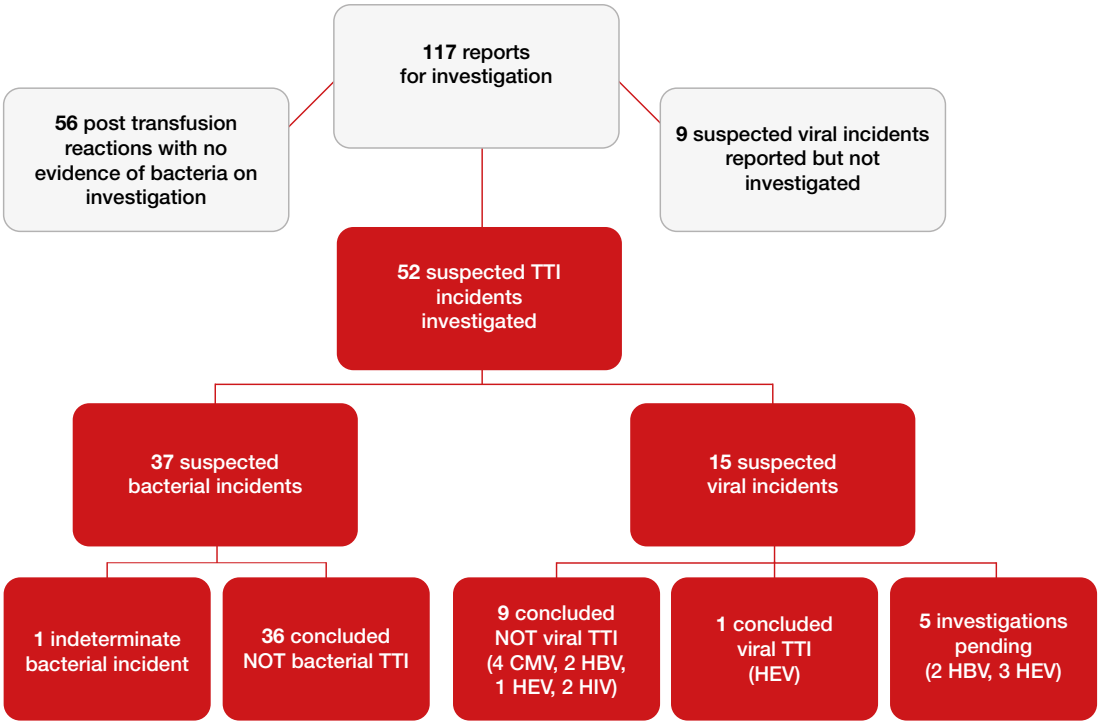

Figure 17.1: Outcome of reports of suspected TTIs made to the NHSBT/PHE Epidemiology Unit in 2014*

**HCV investigations where the transfusion was prior to screening are not included in above figure*

CMV=cytomegalovirus

Bacterial reports 2014

A total of 56/93 packs returned to the Blood Service with a request for bacterial culture following a patient reaction had no bacteria detected in the pack, and no positive patient blood culture reported by the hospital. These possible transfusion reactions may have been reported to SHOT as ATRs if moderate to severe reaction occurred. In 36 possible bacterial cases, the recipient's transfusion reaction was probably not caused by bacteria from a transfusion of a blood component from the UK Blood Services. One case remained indeterminate as packs were not available for culture but the patient was known to have underlying septicaemia prior to transfusion.

Bacterial TTIs 2014

There were no proven bacterial incidents in 2014 but two near miss incidents are described below.

Bacterial contamination of platelets not identified by screening

Two similar near miss incidents (reported May and December 2014) were investigated by the UK Blood Services. There were no obvious errors in sampling or screening processes in either case although culture bottles were not available for inspection.

- Two units of apheresis platelets were issued from one donation. On day four, the hospital reported a clump in the index pack, resulting in the recall of the associated pack. Although *Staphylococcus aureus* was isolated from the index pack, pack two looked normal and on culture there was no evidence of bacterial contamination. Bacterial screening was negative for both packs at day seven. The donor had given three previous donations. *S. aureus* was cultured from swabs taken from the donor. All isolates were indistinguishable from the strain isolated from the pack. The donor has since been permanently withdrawn
- In the second case three apheresis units were manufactured from one donation. The hospital observed clumps in the index unit on day five, at which point the unit was returned and the two other associated packs recalled. Bacterial screening was negative at day seven for all three packs. On return of the index pack *S. aureus* was isolated from the index pack. The two associated packs had already been transfused at the time of recall but no adverse reaction was reported in either case. At the time of writing bacterial typing is ongoing

Bacterial TTIs 1996-2014

The last documented confirmed bacterial TTI was in 2009, but this predated universal bacterial screening of platelets throughout the UK Blood Services and the lack of cases may not, therefore, be totally explained by the introduction of screening. Conversely screening of platelet components cannot guarantee freedom from bacterial contamination. Packs are released for issue as 'negative-to-date' which may be before bacteria have multiplied sufficiently to trigger an initial screening reaction. On the other hand, an initial screen reactive result may be a false positive result, or related to bacteria which are of low pathogenicity and unlikely to cause any noticeable reaction in the recipient.

Overall, a total of 36/43 bacterial transfusion-transmissions to individual recipients (33 incidents) have been caused by the transfusion of platelets, and 7/43 by red cells (Table 17.2) since reporting began.

Viral TTI reports 2014

In 2014 nine suspected viral incidents reported to the Blood Service were not investigated for the following reasons: positive HBV antibody results were due to passive antibody transfer during intravenous immunoglobulin therapy (2); HCV infection was not confirmed; infection was not proven to be absent prior to transfusion.

Viral investigations 2014

Fifteen reports of suspected viral TTIs made in 2014 were investigated. One suspected HEV incident was confirmed as a TTI according to the above definition, Case 1.

Case 1: Report of HEV transmission

A male recipient in his 70s with multiple chronic medical problems, known alcoholic liver disease and lower gastrointestinal bleeding secondary to diverticulitis received red cells, platelets and fresh frozen plasma (FFP) in September 2014 totalling 17 donor exposures. He was discharged from hospital but subsequently readmitted with hepatic encephalopathy. Investigation included testing for viral hepatitis markers, with results consistent with acute hepatitis E infection.

HEV is most commonly transmitted through food but can be transmitted through blood components if a donor donates during the viraemic phase of infection. The local Health Protection Team reported the case to the Blood Service for investigation. Testing of the 17 donation archive samples identified two with HEV markers: one indicative of previous exposure while one, from which the FFP had been transfused to the recipient, was HEV ribonucleic acid (RNA) positive without detectable antibodies. The viraemic

donor, who had been completely asymptomatic, provided a further blood sample to confirm clearance of the virus and seroconversion. The associated red cells from the viraemic donor were transfused in October 2014 and the recipient had shown no symptoms of HEV infection. A blood sample in February 2015 had test results consistent with a resolving HEV infection: anti-HEV IgM and IgG positive, and HEV RNA low level positive. The recipient had received chemotherapy and radiotherapy one year previously, no doubt accounting for the delayed clearance of the HEV infection, which was nevertheless expected to resolve over the following months.

Viral TTIs 1996-2014

The year of transfusion may be many years prior to the year in which the case is investigated and reported to SHOT because of the chronic nature, and therefore late recognition, of some viral infections. Since 1996, 26 confirmed incidents of transfusion-transmitted viral infections have been documented, involving a total of 32 recipients. HBV is the most commonly reported proven viral TTI in the UK. This is partly because the 'window period' where an infectious donation from a recently infected donor cannot be detected by the screening tests is longer than for HCV or HIV, despite nucleic acid testing (NAT).

Risks of HBV, HCV or HIV being transmitted by transfusion

The risks of a component potentially infectious for HBV, HCV or HIV being released for use in the UK are very low (Table 17.1) (PHE 2014).

	HBV	HCV	HIV
Number per million donations	0.46	0.026	0.17
95% confidence interval	0.14-0.87	0.01-0.07	0.10-0.82
At 2.3 million donations per year testing will not identify a potentially infectious window period donation every:	year	16-17 years	2-3 years

**The window period is the time at the start of an infection before the tests can detect it*

Table 17.1: The estimated risk of a potentially infectious HBV, HCV or HIV window period* donation entering the UK blood supply: 2011-2013

Far fewer TTIs are observed in practice than estimated in Table 17.1, partly because the estimates have wide uncertainty and the model is based on the risk in all packs released. The model does not incorporate pack non-use, recipient susceptibility to infection, or underascertainment/underreporting, for example due to recipients dying from an underlying medical condition before a chronic asymptomatic viral condition is identified, or, in the case of HBV, an asymptomatic acute infection.

HEV commentary

The UK Blood Services' Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI) is alerted to any new infectious threats to the UK blood supply through a wide range of reporting mechanisms, and will commission risk assessments where necessary to inform decisions on whether action should be taken to protect the safety of the blood supply (JPAC 2013). There has been a recent increase in the number of cases of HEV reported to the UK Blood Services for investigation as suspected TTI incidents, probably due to increased awareness (Beale et al. 2011). An HEV study conducted jointly by NHSBT and PHE to address the growing concern about HEV and blood safety identified 18 transmissions from 79 HEV viraemic donors with no major consequences for the recipients observed to date; only one recipient developed apparent but clinically mild post-transfusion hepatitis (Hewitt et al. 2014). The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) has set up an HEV working group due to report in 2015 to consider the risk of hepatitis E transmission via blood and what action, if any, should be taken.

CMV commentary

Four investigations for CMV infection, three in premature babies and one in an elderly recipient, were carried out in 2014. This was a higher number than usual, possibly due to increased awareness and/or tendency to report cases since the changes in recommendations for the use of CMV-screened blood components. There has been no reported proven CMV TTI in the UK and one indeterminate case out of a

total of 10 investigations for suspected CMV TTI since surveillance began in 1996 up to December 2014. CMV is a herpes virus that gives rise to a life-long infection which is mostly asymptomatic. Significant disease may occur in certain groups, such as fetuses, neonates and immunocompromised individuals. In the UK up to 50-60% of adults are CMV seropositive, with an estimated seroconversion rate of 1% per annum. A CMV seropositive individual can have asymptomatic or symptomatic reactivation of latent virus throughout life, with opportunities for transmission. This is a cell-associated virus and it is normally found in lymphocytes, but during periods of high virus replication, excess virus can be readily detectable in plasma. A proportion of donations are screened by the UK Blood Services for CMV antibody to provide a 'CMV ***sero***negative' inventory of cellular components, which are provided to hospitals on request.

SaBTO has recommended that CMV seronegative red cell and platelet components should be provided for intrauterine transfusions, neonates and pregnant women while leucodepletion was considered adequate risk reduction for all other patients requiring transfusion, including other groups of immunocompromised patients (SABTO 2012).

Parasitic TTIs

There were no reported parasitic infections for investigation in 2014. There have been two proven malaria TTIs reported to SHOT, the last in 2003 (Table 17.2). Malaria antibody testing was not applicable at the time according to information supplied at donation, and the donor selection guidelines were updated after these incidents to minimise the risk of further malaria TTIs (Kitchen et al. 2005). The current selection guidelines on deferral and additional testing for malaria can be accessed at the UK transfusion guidelines web pages at http://www.transfusionguidelines.org.uk/red-book

Variant Creutzfeld-Jakob Disease (vCJD) 2014

There were no vCJD investigations in 2014.

vCJD 1996-2014

Three vCJD incidents (Table 17.2) took place prior to the introduction of leucodepletion and other measures taken by the UK Blood Services to reduce the risk of vCJD transmission by blood, plasma and tissue products. All these measures have been reviewed and endorsed by SaBTO (SABTOa 2013).

vCJD control measures

Risk assessment and research into vCJD continues. New data suggest 1 in 2000 people in the UK may be carriers of vCJD (Gill et al. 2013). Despite international research efforts there is currently no suitable blood test available for screening blood donations for vCJD. SaBTO is continuing to review the measures in place to prevent transmission through blood transfusion (SABTOb 2013, DH 2013). This includes considering the best uses of donations from people in the UK believed to be at lower risk of vCJD i.e. those born since January 1996 and not thought to be exposed via the food chain. These young adults became old enough to donate in the UK from January 2013. A House of Commons Select Committee inquiry to determine if the control measures in place are sufficient to minimise transfusion-transmitted infection in light of the potential for large numbers of carriers published its report in July 2014 (Science and Technology Committee 2014). This is available on the parliament website together with the government response.

Year of transfusion*	Number of incidents (recipients) by infection											Implicated component			
	Bacteria	HAV	HBV	HCV	HEV	HIV	HTLV I	Parvovirus (B19)	Malaria	vCJD/ prion	Total	RBC	Pooled platelet	Apheresis platelet	FFP
Pre 1996	0	0	1 (1)	0	0	0	2 (2)	0	0	0	**3 (3)**	3	0	0	0
1996	0	1(1)	1 (1)	1 (1)	0	1 (3)	0	0	0	1 (1)	**5 (7)**	5	1	0	1
1997	3 (3)	0	1 (1)	1 (1)	0	0	0	0	1 (1)	2 (2)	**8 (8)**	6	1	1	0
1998	4 (4)	0	1 (1)	0	0	0	0	0	0	0	**5 (5)**	2	1	2	0
1999	4 (4)	0	2 (3)	0	0	0	0	0	0	‡ (1)	**6 (8)**	5	3	0	0
2000	7 (7)	1 (1)	1 (1)	0	0	0	0	0	0	0	**9 (9)**	1	5	3	0
2001	5 (5)	0	0	0	0	0	0	0	0	0	**5 (5)**	0	4	1	0
2002	1 (1)	0	1 (1)	0	0	1 (1)†	0	0	0	0	**3 (3)**	2	1	0	0
2003	3 (3)	0	1 (1)	0	0	0	0	0	1 (1)	0	**5 (5)**	1	1	3	0
2004	††	0	0	0	1 (1)	0	0	0	0	0	**1 (1)**	1	0	0	0
2005	2 (2)	1 (1)	1 (1)	0	0	0	0	0	0	0	**4 (4)**	1	3	0	0
2006	2 (2)	0	0	0	0	0	0	0	0	0	**2 (2)**	0	1	1	0
2007	3 (3)	0	0	0	0	0	0	0	0	0	**3 (3)**	2	1	0	0
2008	4 (6)	0	0	0	0	0	0	0	0	0	**4 (6)**	0	2	4	0
2009	2 (3)	0	0	0	0	0	0	0	0	0	**2 (3)**	1	0	2	0
2010	0	0	0	0	0	0	0	0	0	0	**0**	0	0	0	0
2011	0	0	1 (2)	0	1 (2)	0	0	0	0	0	**2 (4)**	2	0	0	2
2012	0	0	1 (1)	0	1 (1)	0	0	1(1)	0	0	**3 (3)**	2	0	0	1
2013	0	0	0	0	0	0	0	0	0	0	**0**	0	0	0	0
2014	0	0	0	0	1 (2)	0	0	0	0	0	**1 (2)**	1	0	0	1
Number of incidents	**40**	**3**	**12**	**2**	**4**	**2**	**2**	**1**	**2**	**3**	**71**				
Number of infected recipients	43	3	14	2	6	4	2	1	2	4	**81**	**35**	**24**	**17**	**5**
Death due to, or contributed to, by TTI	11	0	0	0	0	0	0	0	1	3	**15**				
Major morbidity	28	2	14	2	3	4	2	1	1	1§	**58**				
Minor morbidity	4	1	0	0	3	0	0	0	0	0	**8**				
Implicated component															
RBC	7	1	11	2	3	2	2	1	2	4	**35**				
Pooled platelet	20	2	1	0	0	1	0	0	0	0	**24**				
Apheresis platelet	16	0	1	0	0	0	0	0	0	0	**17**				
FFP	0	0	1	0	3	1	0	0	0	0	**5**				

Table 17.2: Number of confirmed TTI incidents*, by year of transfusion with total infected recipients and outcomes (death, major morbidity, minor morbidity) in the UK between October 1996 and December 2014 (Scotland included from October 1998)**

Numbers in brackets refer to recipients

**No screening was in place for vCJD, human T cell lymphotropic virus (HTLV), hepatitis A virus (HAV), HEV or parvovirus B19 at the time of the documented transmissions. In both malaria transmissions, malaria antibody testing was not applicable at the time according to information supplied at donation*

*** Year of transfusion may be prior to year of report to SHOT due to delay in recognition of chronic infection*

† The two HIV incidents were associated with window period donations (anti-HIV negative/HIV RNA positive) before HIV NAT screening was in place. A third window period donation in 2002 was transfused to an elderly patient, who died soon after surgery. The recipient's HIV status was therefore not determined and not included

†† In 2004 there was an incident involving contamination of a pooled platelet pack with Staphylococcus epidermidis, which did not meet the TTI definition because transmission to the recipient was not confirmed, but it would seem likely. This case was classified as 'not transfusion-transmitted'

‡ Same blood donor as one of the 1997 transmissions so counted as the same incident; note: counted as two separate incidents in previous reports

§ A further prion case died but transfusion was not implicated as the cause of death. The outcome was assigned to major morbidity instead because although there was post-mortem evidence of abnormal prion proteins in the spleen the patient had died of a condition unrelated to vCJD and had shown no symptoms of vCJD prior to death

For further information or alternative breakdown of data please contact the National Coordinator for Transfusion Transmitted Infections via the NHSBT/PHE Epidemiology Unit at epidemiology@nhsbt.nhs.uk

Learning points and recommendations from previous years are still relevant and have been combined into the advice below:

A recipient has had a reaction during a transfusion – could it be due to bacteria in the pack?

Yes bacterial contamination is a factor to be considered, although no bacterial TTIs have been reported since 2009.

- Screening of platelets will not prevent units with bacteria present entering the supply. Platelets are released as negative-to-date. Bacterial transmissions may occur via red cells, which are not screened for bacteria

Before transfusion: be vigilant. Clumps in the (platelet) pack? Send it back!

- Visual inspection of packs before issue and use remains a crucial safety step in minimising risk of bacterial transfusion transmitted infection
- Visual inspection of packs can alert staff to signs of bacterial growth (Figure 17.2). Two near miss incidents involving *S. aureus* in platelet packs were reported in 2014
- Swift reporting of a suspected contaminated pack allows recall to occur before any associated* packs are used

Figure 17.2: Example of a platelet pack contaminated with Staphylococcus aureus

**Note: There may be associated packs produced from the same donation which have been issued perhaps to different hospitals who will be unaware of the potential problem. Clumps may not appear in the associated pack. Both apheresis and pooled platelets may have associated packs. An apheresis donation is made by a single donor and may be split into several platelet packs. A pooled platelet pack is currently made from the whole blood donations from four donors whose donations are also used to make red cell packs*

After transfusion: report promptly to Blood Service, retain and return pack

- Report a suspected bacterial transfusion transmitted infection (TTI) promptly to the Blood Service to allow recall of any associated packs for testing
- Retain suspected bacterially contaminated packs, even if near empty, for return to the Blood Service as the residue can be washed out and cultured
- If you are sampling packs locally for bacterial testing, use ports rather than breaching the pack to minimise environmental contamination of the pack

Advice on clinical management and investigation of serious adverse reactions can be obtained from the hospital consultant responsible for blood transfusion and the British Committee for Standards in Haematology (BCSH) guideline on investigation and management of acute transfusion reactions (BCSH Tinegate et al. 2012).

A recipient of a blood transfusion(s) has been found to have a viral infection – could it be the blood?

Yes, although very rare and other sources should be explored

- The risk of transfusion-transmitted HBV, HCV or HIV is very low in the UK
- Clinicians investigating suspected viral TTIs should explore all possible risk exposures in parallel with the Blood Service investigations, in order to determine the patient's most likely source of infection. HEV is commonly transmitted by food for example. Investigation includes checking records and

testing samples taken prior to the implicated transfusion(s) to check that the recipient was not infected prior to transfusion

A transfusion investigation will not commence until the infection status of the recipient has been clarified

- Investigation of possible HCV transmission in individuals who are HCV polymerase chain reaction (PCR) negative, HCV antibody reactive, will not commence unless HCV antibody reactivity has been confirmed using two different assays, because of the possibility of non-specific antibody reactivity. If not locally available, the Blood Service can perform the required testing
- Cytomegalovirus (CMV) seroconversion should be demonstrated by testing samples from before and after transfusion in parallel by the same laboratory
- Immunoglobulin therapy can lead to passive transfer of antibodies which may be confused with infection (Parker et al. 2014). Careful review of the markers and timing can rule out infection before a report is made to the UK Blood Services
- The local microbiologist/virologist should be consulted for advice.

Archive samples kept by hospitals and the Blood Service help verify infection status, timing and source

- Hospitals and Blood Services investigating a possible viral TTI are reminded of the importance of locating any archived recipient samples (transfusion-related or not) for testing. It is important that laboratories facilitate access to those samples (with due consent of appropriate parties including the patient)
- The large number of donors to investigate in some cases, and the retrospective nature of some investigations, emphasises the importance of UK Blood Services maintaining an easily accessible system for archive samples

How do I report a suspected TTI for investigation by the Blood Service?

- Guidance on reporting an incident, and the required supporting information, for suspected transfusion transmitted infections (TTIs) for hospitals served by NHSBT can be found on the Requests for Investigation of Adverse Events & Reactions page at: http://hospital.blood.co.uk/diagnostic-services/reporting-adverse-events/
- For other UK Blood Services please contact the local Blood Centre

Do I need to report potential TTIs to MHRA and SHOT?

Yes, report as soon as practical to both systems and remember to update the outcome

- Clinical staff requesting an investigation into a possible transfusion-transmitted infection (TTI) by the UK Blood Services are reminded to report as soon as practical to Serious Adverse Blood Reactions and Events (SABRE) and SHOT
- Reporters should update their report once the outcome of the UK Blood Services investigation is known
- Even if bacterial TTI is excluded in a case of transfusion reaction, the case should still be reported to SHOT and the MHRA as an ATR if necessary
- Cases of suspected transmission of infection should be reported even if not currently screened for by the Blood Service

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