

# Pigs or blood – which is to blame?

# Hepatitis E Virus in England & Wales a SaBTO slant

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# Hepatitis E virus



- 4 genotypes affecting humans (G1-G4)
  - G3 found in UK, foodborne pork products
- High thermal stability
- Difficult to culture slow growing
- "Large scale, low impact zoonosis"
- Immunocompetent >99% infections asymptomatic; self limiting
- Immunocompromised Persistent infections recognised; can lead to fibrosis and cirrhosis







## How did we get to where we are?



**SaBTO:** Professional advisory committee through Department of Health to Ministers (ToR). Working groups use a safety framework for any initiative:

- a. Safety driven
- b. Component supply initiative
- c. Clinical driven initiative

mitigation of HEV risk

2012/13 Donor transmission study <sup>1</sup> 1:2848 donors RNA + 42% transmission SaBTO establish HEV working party 2013 – July 2015 accepted recommendations for HEV-testing of donors.\*

final guidance for the use of HEV-negative blood components was approved by SaBTO on 13th January 2016

<sup>\*</sup> Letter sent to HSCT/SOT physicians from SaBTO chair

<sup>&</sup>lt;sup>1</sup> Hewitt et al Lancet 2014



## How did we get to where we are?



Issue of HEV RNA screened donations introduced in March 2016 in England \*

SaBTO safety framework set an early review of HEV screening - HEV working party set up
June 2016 +

Final recommendations to be presented to SaBTO 1st November 2016

\* NHS Blood and Transplant extended this recommendation to neonates <1 year of age

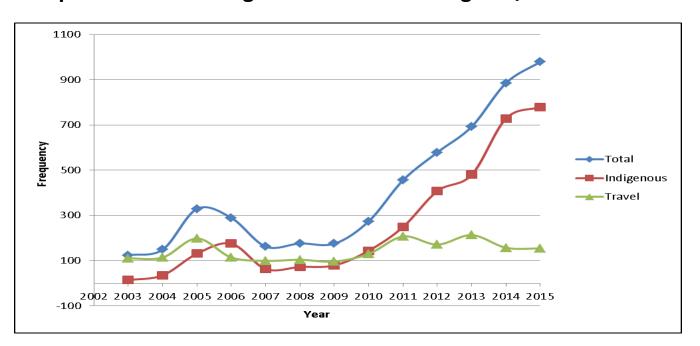
‡ Review: Direct costs faced by NBS, Impact on mitigating hazard, patient, component supply, linkages to other initiatives, external considerations, operational considerations, value for money.

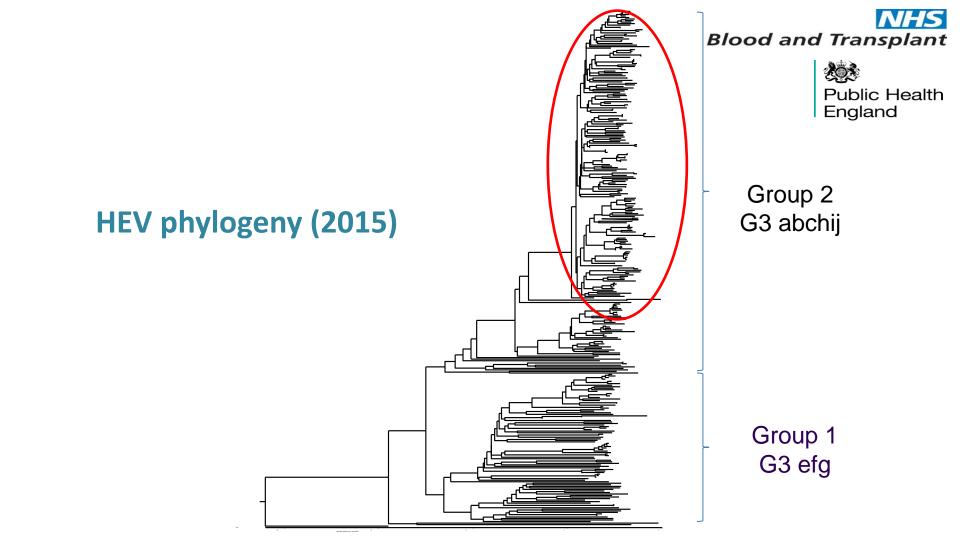


## Why does this matter?



#### Imported versus indigenous infection in England/Wales







#### HEV RNA screening of blood donations (England)



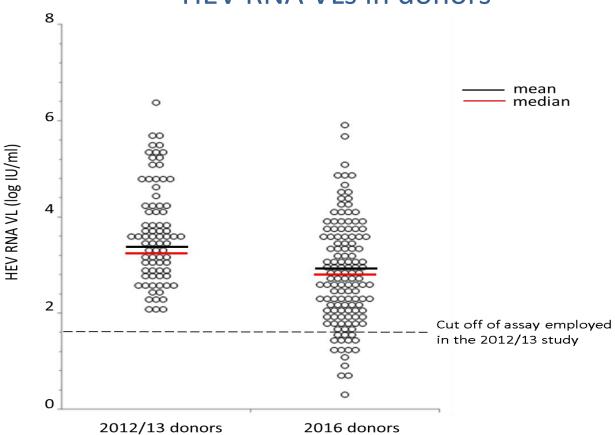
| Month | No. samples tested for HEV | Positive samples |
|-------|----------------------------|------------------|
| Feb   | 603                        | 1                |
| Mar   | 26853                      | 24               |
| Apr   | 40279                      | 25               |
| May   | 43443                      | 34               |
| Jun   | 48072                      | 27               |
| Jul   | 47589                      | 29               |
| Total | 206839                     | 140              |

- All confirmed reactive in reference laboratory
- 80% HEV Ab negative
- Current HEV RNA prevalence rate of 1:1477
- Increase in attack rate from 2012/2013 data HEV RNA prevalence was 1:2850

### Blood and Transplant



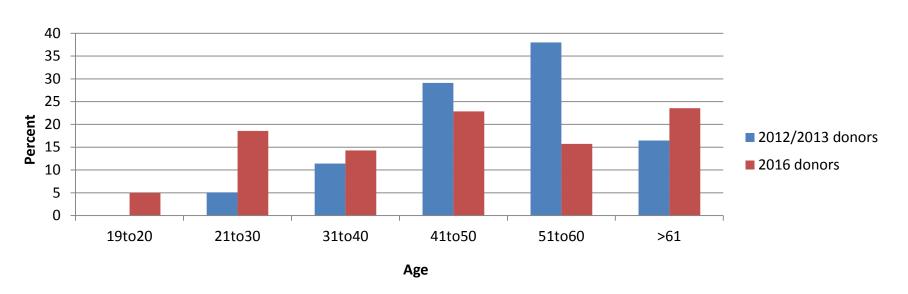






#### **Donor demography**



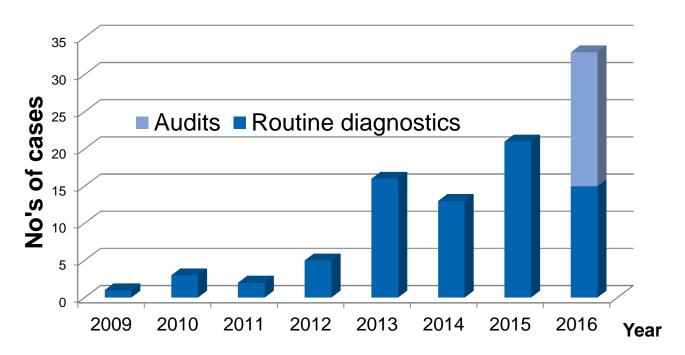


• 70% of 2016 HEV-infected donors are male, 63% of donor panel are male



#### Chronic HEV England & Wales 2009-2016 (n=94)





Recently established an enhanced surveillance of chronic HEV infections



#### Many unanswered questions



- Chronic Infections
  - Best strategies for identifying patients with persistent HEV infections?
  - Which immunosuppressed cohorts are at-risk of persistent/chronic HEV?
  - What are the rates for progression to cirrhosis?
  - What are the best monitoring and treatment strategies?
- Is the current donor screening policy fit for purpose SaBTO HEV Working Group?



#### SaBTO current framework: HEV working party



- Undertake an assessment of the cost-effectiveness of different strategies to reduce the risk of acquisition via blood components and consequent harm to vulnerable patient groups. Advise SaBTO on whether current strategy continues or with additional measures.
- Review feedback from stakeholders on current operational practices and consider whether further advice would be helpful.
- Review SaBTO's clinical recommendations on the use of HEV-screened components in light of feedback received.
- Review evidence for HEV transmission via transplanted organs, stem cells and tissues. Advise SaBTO on whether to recommend implementation of measures to reduce risk of infection from these substances.

## SaBTO HEV working party

Public Health England

1

 Patient groups; defining who is at risk of harm from HEV infection

2

• Cost effectiveness considerations

3

Operational implications

Due to report to main SaBTO meeting 1<sup>st</sup> November 2016, with prior stakeholder meeting



## Summary



- England remains in a period of heightened activity for HEV; dominant emergent group 2 (3c) viruses
- Selective screening of blood donations in place
  - HEV RNA prevalence rate of 1:1477; lower HEV RNA levels; shift in donor demography
- Persistent infections occur in immunocompromised but extent of problem and at-risk groups undefined
- Root cause lies with animal husbandry outside UK



#### **Acknowledgements**

#### Public Health England

Samreen Ijaz, Richard Tedder, Bengü Said, Dilys Morgan,
 Clarissa Oeser, Becky Haywood, Felicia Stanford

#### NHS Blood and Transplant

Su Brailsford, Patricia Hewitt, Claire Reynolds, Alan Kitchen





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