

The need for importing plasma – an NHSBT perspective



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LOWER-VCJD RISK PLASMA: REQUIREMENT NISS Blood and Transplant

Lower-vCJD risk plasma established as a requirement for all cryo/FFP recipients born on or after 1st January 1996 (the "Club96" cohort)

Deemed not to have been exposed to the vCJD-causing prion in the UK food chain

LOWER-vCJD RISK PLASMA: STRUCTURE Blood and Transplant

NHS

- **vCJD REQUIREMENT**
- **SAFETY**
- **DEMAND** challenges
- **SUPPLY challenges**
- **FUTURE**

DISCLOSURES

LOWER-VCJD RISK PLASMA: REQUIREMENT NISS Blood and Transplant

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LOWER-vCJD RISK PLASMA: SAFETY



Estimated vCJD prevalence for a number of source countries with respect to the UK

| Country | | Estimated log reduction in prevalence relative to UK | | | | | | | | | | | | |
|--------------|----------------|--|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------|-----------------|-----------------|-----------------|--|
| | P ¹ | P ^{2a} | P ^{2b} | P ^{2a} | P ^{2b} | P ^{2a} | P ^{2b} | P ^{2a} | P ^{2b} | P^{2a} | P ^{2b} | P ^{2a} | P ^{2b} | |
| | no UAF | | | with UAFi | | with UAFii | | no UAF | | with UAFi | | with UAFii | | |
| | no BAF | | | | | | | with BAF | | | | | | |
| Australia | - | 'Infinite' | - | - | - | - | - | 4.1 | - | - | - | - | - | |
| Austria | - | 3.8 | 3.9 | 2.8 | 3.0 | 4.1 | 4.2 | 2.9 | 2.9 | 2.6 | 2.7 | 2.9 | 2.9 | |
| Belgium | - | 2.6 | 2.4 | 1.8 | 1.6 | 2.8 | 2.6 | 2.6 | 2.4 | 1.8 | 1.6 | 2.8 | 2.6 | |
| Canada* | - | 4.6 | 4.5 | - | - | - | - | 4.2 | 4.2 | - | - | - | - | |
| Denmark | - | 3.3 | 3.1 | 2.8 | 2.5 | 3.6 | 3.4 | 2.0 | 2.0 | 1.9 | 1.9 | 2.0 | 2.0 | |
| Finland | - | 4.1 | 4.2 | 4.4 | 4.5 | 4.4 | 4.5 | 3.5 | 3.5 | 3.6 | 3.6 | 3.6 | 3.6 | |
| France* | 0.9 | 2.6 | 2.3 | 2.0 | 1.7 | 2.3 | 2.0 | 1.2 | 1.2 | 1.1 | 1.1 | 1.2 | 1.1 | |
| Germany | - | 2.7 | 4.3 | 2.4 | 4.0 | 3.0 | 4.6 | 2.0 | 2.1 | 1.9 | 2.1 | 2.1 | 2.1 | |
| Ireland | 0.8 | 1.9 | 0.9 | 1.5 | 0.6 | 1.8 | 0.9 | 0.7 | 0.6 | 0.7 | 0.4 | 0.7 | 0.5 | |
| Italy* | 2.2 | 2.9 | 3.1 | 1.9 | 2.1 | 3.2 | 3.4 | 2.1 | 2.2 | 1.7 | 1.9 | 2.2 | 2.2 | |
| Netherlands* | 1.3 | 2.9 | 2.8 | 2.2 | 2.1 | 3.2 | 3.1 | 1.6 | 1.6 | 1.5 | 1.5 | 1.6 | 1.6 | |
| New Zealand | - | 'Infinite' | - | - | - | - | - | 4.3 | - | - | - | - | - | |
| Norway | - | 'Infinite' | - | 'Infinite' | - | 'Infinite' | 'Infinite' | 3.2 | - | 3.2 | - | 3.2 | - | |
| Poland | - | 3.7 | 3.5 | 3.2 | 3.0 | 4.0 | 3.8 | 3.6 | 3.4 | 3.2 | 2.9 | 3.8 | 3.6 | |
| Portugal | 1.2 | 1.4 | 1.5 | 0.4 | 0.5 | 0.9 | 1.0 | 1.4 | 1.5 | 0.4 | 0.5 | 0.9 | 1.0 | |
| Spain* | 1.6 | 2.3 | 2.3 | 1.4 | 1.4 | 2.3 | 2.4 | 2.1 | 2.1 | 1.3 | 1.4 | 2.1 | 2.2 | |
| Sweden | - | 5.2 | - | 5.5 | - | 5.5 | - | 3.2 | - | 3.2 | - | 3.2 | - | |
| Switzerland | - | 1.9 | 1.7 | - | - | - | - | 1.9 | 1.7 | - | - | - | - | |
| UK* | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | |
| U.S | - | 5.2 | 6.0 | - | - | - | - | 4.9 | 5.1 | - | - | - | - | |

Source: SaBTO – "Importation of plasma as a vCJD risk reduction measure: reconsideration of "acceptable" source countries" Parker, Bennett, Daraktchiev, March/April 2013



IMPORTATION

- Only Australia, Canada, Finland, NZ, Norway, Sweden, Poland, Austria and the US meet the required 2.5 log risk reduction threshold
- Of these, only Austria and Poland have the capacity to meet current UK and their own national domestic requirements and offer surmountable logistic challenges

LOWER-vCJD RISK PLASMA: SAFETY



PATHOGEN INACTIVATION

- Importation manages the vCJD risk element
- PI manages the risks from different viral prevalence in non-UK populations relative to UK population
- NHSBT uses the "MB" PI system

LOWER-VCJD RISK PLASMA: CHALLENGES Blood and Transplant

DEMAND-SIDE CHALLENGES

- Ever-increasing recipient cohort defined by DOB, not by age
- Changing recipient demographics
- Changing recipient "habits"

LOWER-VCJD RISK PLASMA: CHALLENGES Blood and Transplant

SUPPLY-SIDE CHALLENGES

- Small pool of suitable supply "markets"
 - "Seller's market"
 - Cost
- Ability to speedily react to demand changes
- FFP or cryoprecipitate?



SUPPLY-SIDE CHALLENGES





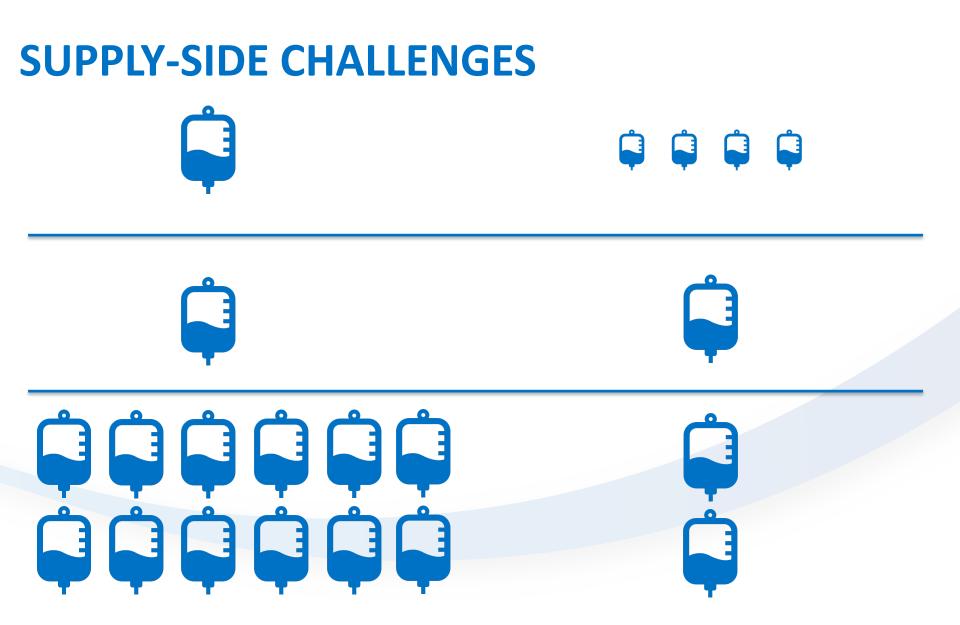












LOWER-VCJD RISK PLASMA: THE FUTURE?

- UK supply? ("to PI or not to PI")
 - Speed of implementation?
 - Speed of hospital return?
 - Competitive UK plasma market?
 - Continuing import requirement?
 - Long-term sustainability?
 - Prioritisation of cryo?
 - Hospital risk-based decisions?
- The "B" word



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