Leading the 2016/17 review of (blood) donor selection

13th September 2017

Dr Chas Newstead Chair Working group

Hofstadter's Law: It always takes longer than you expect, even when you take into account Hofstadter's Law. -Douglas Hofstadter, professor of cognitive science (b. 15 Feb 1945)

Introduce Self

- Consultant Renal Physician (Leeds) since 1993, retired 2016
- Major clinical interest transplantation medicine
- Managerial contributions:
  - Guideline development for British Transplantation Society
  - Managerial Lead Leeds Renal Service
  - Project Chair electronic requesting / reporting (Leeds)
  - Chair paired exchange working group for renal transplantation for UK Transplant (as was)
  - Chair Renal Dialysis clinical reference group
  - Contributor to national renal transplant organisation and matching "rules"

- SaBTO Member from Autumn 2014

- No conflicts of interest

Blood donor selection criteria

- Designed to ensure safety of donor
- Are similar (but different) for tissues / cells / gametes

- Minimise risk of transmission of blood borne infections (BBIs) to recipients of products
  - As part of risk management donors are asked to report a number of behaviours that may increase the risk of BBIs

Blood donor selection criteria last underwent (major) review in 2011

- Change from life-time to twelve months deferral after sex between men
- No change to life-time deferral for commercial sex workers (no real data)
- Estimated with 2.5 million blood donations in UK per year “that ...will NOT identify approximately two HBV every year, one HCV every 33 years, one HIV every two years” (page 37 of 2011 report, paraphrased)

Blood donor selection criteria last underwent (major) review in 2011

- Used window periods of (page 36 of 2011 report):

Virus	Assay	Estimated Average Window Period (days)
HBV	HBsAg	66.8
	HBV DNA	38.3
HCV	Anti-HCV	59
	HCV RNA	4
HIV	Anti-HIV	15
	Antigen/antibody	11
	HIV RNA	9

- Predicted risk of TTI as (page 38 of 2011 report):

Table 6: Estimates of frequency of HBV, HCV, HIV and HTLV I infectious donations issued per million donations tested, UK: 2007-2009.

Risk due to	HBV[1]	HCV[2]	HIV[3]	HTLV I[4]
Window period Donation				
Per million	1.39	0.01	0.19	0.04

What has changed since 2011?

- Experience of the 2011 change from life-time to twelve months deferral after sex between men
- Information from a large on-line survey of blood donor “adherence” to deferral rules
- Increased experience of interpretation of most modern tests

- Societal changes for example civil partnerships
- Penrose report

- Our (2017) remit much wider than MSM & CSW

Donor Selection Working Group 2016 -2017

- Experts from SaBTO (6), UK Blood Services (4)and NHS (4)
- Stakeholder representation from patient groups (3), health charities and LGBT consortium (4)
- Experts on ethics and behaviour/motivation (2)
- Started with an open meeting with stakeholders and interested parties

Remit of the Donor Selection Working Group

The working group will: “review the evidence base for donor selection, deferral and exclusion in the UK in relation to social behaviours that may increase the risk of acquiring specific blood-borne infections (HIV, HBV, HCV, syphilis).”

Remit of the Donor Selection Working Group

“In addition the group will review the risk that these infections could be acquired following procedures that involve piercing of the skin as well as flexible endoscopy, a procedure specifically covered by blood safety legislation. “

Key evidence and work streams

- Updated information on infections of interest including window periods
- Epidemiology papers were prepared on the donor selection criteria

- Workstreams on: see next two slides

Due by when	June 2016	July 2016	Oct 2016	Nov 2016	Jan 2017	March 2017	April 2017	Post Ministerial decisions	Lead
Results of compliance questionnaire as relevant to BBIs / TTIs	X								Su Brailsford
Rate of TTIs (with current deferral rules)	X								Su Brailsford
Rate of diagnosis of (the big 4) BBIs in current new and returning blood donors	X								Su Brailsford
Risk factors for BBIs in current new and returning blood donors	X								Su Brailsford
Risk factors for BBIs in general population	X								Su Brailsford
Results of PH-E work on trying to assess whether men in civil partnerships are at risk of BBIs	X								Su Brailsford
What is the BBI risk post tattoos	X								Su Brailsford
What is the BBI risk post acupuncture	X								Su Brailsford
What is the BBI risk post ivdu	X								Su Brailsford
What is the BBI risk post distant past injections	X								Su Brailsford
What is the BBI risk post piercings	X								Su Brailsford
What is the BBI risk post cosmetic injections	X								Su Brailsford
What is the BBI risk post flexible endoscopy	X								Su Brailsford
What is the BBI risk post sex with commercial sex workers	X								Su Brailsford
What is the BBI risk post sex with individuals domiclied outside of UK	X								Su Brailsford
What is the change in residual risk of TTI if change deferral rules and donors are compliant with them	X								Su Brailsford
What is the current performance of tests for diagnosing BBIs, and the window period for those tests		X							Alan Kitchen / Stephen Thomas
Post donation processing influence on infection control		X							Stephen Thomas
International comparisons / practices / experience		X							Moira Carter
Influences on altruism in general population and compliance with medical "rules"		X							Eamonn Ferguson

Due by when	June 2016	July 2016	Oct 2016	Nov 2016	Jan 2017	March 2017	April 2017	Post Ministerial decisions	Lead
Ethical considerations		X							Anne Slowther
Can we individualise risk assessment			X						Richard Gilson / Stephen Field / (Stuart Blackmore)
Safeguards against emergent infections			X						Alan Kitchen
Background and process			X						Chas Newstead / secretariate
Influences on donor motivation			X						Eamonn Ferguson
Decision on recommendations to change (or not) donor selection rules				X					All
What's special / different about tissues / cells / gametes				X					Akila Chandrasekar / Allison Murdoch
Effect on blood (tissues / cells) supply of recommended changes					X				Gail Miflin / Stephen Field / Moira Carter / Stephen Thomas
Operational impact of changes					X				Stephen Thomas / Moira Carter
Is what we propose legal					X				DoH legal team
Collating all that has gone before into report						X			Chas Newstead / all
Submission to SaBTO							X		Chas Newstead / SaBTO members
Communication of outcomes								X	

SoHO have a risk of transmitting infection

- For blood (cells / tissues) key determinates of risk are the window period of infectious agents and donors compliance with deferral “rules”

- We accepted the same level of tolerable risk as was done in effect in 2011 at less than one in one million donations
- Modelled the effects of potential changes to recipients’ safety using a “most risky scenario”

Safety framework

Six stages:

1: Preparation

2: Problem formulation

3: Participation strategy

4: Conducting risk assessments

5: Evaluation

6: Decisions

Patient Risk

Frequency *Determine tolerability for the given frequency/severity combinations.*	**Severity**			
	Low Transient morbidity with minimal impact on wellbeing; no need for hospitalisation (or prolonged stay); minimal or no investigation required; minimal (symptomatic) or no treatment required.	**Moderate** Significant morbidity with some impact on wellbeing; need for hospitalisation (or prolonged stay); and/or some specific investigation and treatment required. No significant risk of death or long-term disability.	**High** Significant morbidity as defined previously, with some significant risk (less than 50%) of death or long-term disability.	**Catastrophic** Significant morbidity as defined previously, with a high risk (50% or more) of death or long-term disability.
Very Low Less than 1:5,000,000 (<0.2)	Tolerable	Tolerable	Tolerable	Tolerable
Low 1:1,000,000 to 1:5,000,000 (1.0 - 0.2)	Tolerable	Tolerable	Tolerable	Intolerable
Moderate 1:250,000 to 1:1,000,000 (4.0 – 1.0)	Tolerable	Tolerable	Intolerable	Intolerable
High 1:1 to 1:250,000 >4.0	Tolerable	Intolerable	Intolerable	Intolerable

Key steps, as I saw them

- Assemble working group
- Early (and continuous) stakeholder involvement
- Decide Terms of Reference
- Gant chart, lead authors, deadlines
- Gave myself an early (easy!) task as an exemplar
- Near weekly teleconferences
- Adopted association of blood operators framework for risk acceptance
- I generated (cut and pasted) first draft of report