Donor Selection

Safety or Discrimination?

Let's talk about sex and gender!!

BBTS SIG 2017

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Why Now , Why BBTS

- SaBTO review on Donor Selection 2017

- Increased pressure for ongoing change
  - Scottish Parliamentary debate in 2016
  - UK All Parties Parliamentary Group Inquiry into Blood Donation
  - Freedom to Donate

- Cultural change

- Donor and Staff Feedback

- Discrimination damages mental health

- Can we do this better in the front line of Donor Selection?

Changing Culture In Scotland

- Civil Partnerships introduced in Scotland 2005
- 5465 civil partnerships –end 2015
- Same sex marriage in Dec 14
- 2038 marriages by end of 2015
- Same sex couple adoption rights protected by 2010 Equalities Act

History & Background

During 1980s deferral introduced as evidence of cohorts at higher risk emerged

- •Men who had sex with men
- •Sexually active in High endemic Countries
- •Intravenous drug users
- •Blood Product recipients
- •Commercial Sex Workers
- •Sexual partners of those above

As knowledge increased on HIV and improvements in Testing some deferrals reduced to 12 months

These deferral largely stayed the same in UK until SaBTO review in 2010

- •Reduced MSM deferral to 12 months
- •Rejected reduction of Commercial sex workers deferral
- •Mandated the UK services to undertake compliance study

•Australia led the change introducing a 12 month deferral in 2001 other counties are following

•SaBTO review initiated in 2016

Perceptions and Misconceptions

Discrimination?

- Moral Obligation to recipients and to those who wish to donate that needs to be balanced

- Moral justification for discriminating against a potential donor is based on the moral obligation to protect others and the donor from harm

- Empirical evidence that certain activities are associated with higher risk together with window period when infection undetectable may justify deferral based on risk rather than certainty

- Relies on assessment on whether the risk is sufficient to justify treating donors differently

- IBTS conference concluded that it was not discriminatory to defer where risks were evident **but** that it was discriminatory to defer for longer than necessary

- It is essential to maintain trust in order to ensure that those affected comply

- More likely if those affected have a voice and if changes are transparent

Donor Feedback

I get regularly tested but was told I was a risk!

Not at Risk but you rejected me!

My husband and I came together and were told not to darken your door again!!

Embarrassed and humiliated by the experience

I wanted to do something good and left feeling awful!

I am monogamous and my partner is faithful"!

Current Risks and Health Inequalities

- Data quoted in Scottish Parliamentary Debate 2016
  - 8% of MSM in Scotland HIV positive
  - <0.1% of non IVDU Heterosexuals HIV positive
  - 80 x difference in health inequalities

- 2017 PrEP approved in Scotland to reduce incidence of HIV

- UK blood services surveillance of infections and risk indicates that
  - 31% of HIV detected identify Sex between Men as the risk factor with 44.5% of recent infections
  - 32% are in relation to heterosexual sex with a high risk partner with 12% recent infections
  - Recent infection indicates increased risk of donation during the window period and therefore risk to the patient

- If there was no health inequality we wouldn't be having this discussion

The UK donor survey 64,439 respondents

- 4045 people had undergone recent piercing/tattooing/acupuncture

- Compliance with the lifestyle deferrals was > 99%.

- 395 non-compliant donors to UK-wide lifestyle deferrals
- Of which:
  - 87 men had had sex with another man in the past year
  - 29 people had been paid for sex (ever)
  - 187 people had had sex with a high risk partner in the past year
  - 35 people had been injected with non-prescribed drugs in the past

  - Data presented to SaBTO 14 April 2015 ITEM 8 Paper

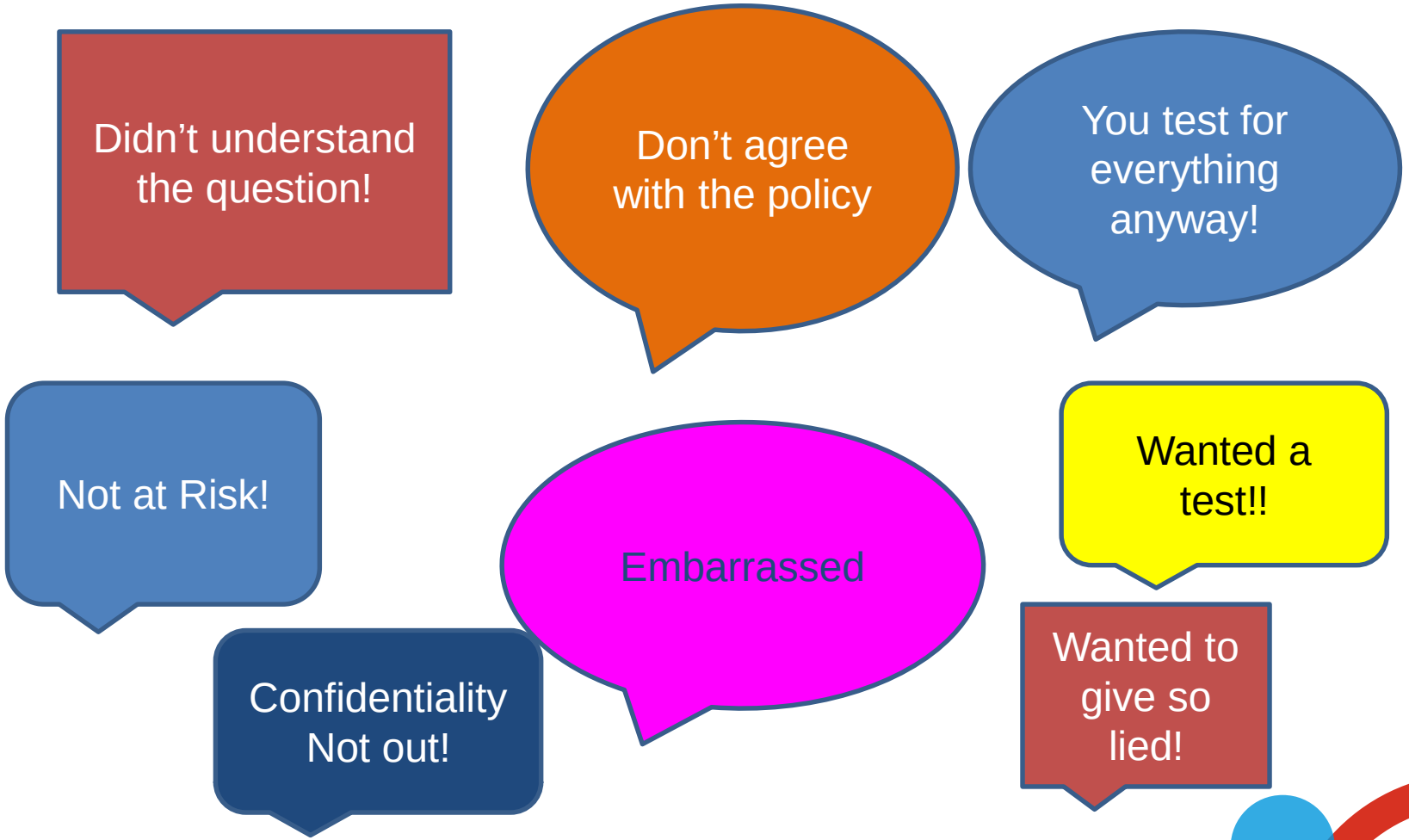
Compliance

What do we know about compliance ? (UK blood Donor Survey)				
	MSM All	MSM New	MSM Repeat	All Male
MSM Responded	251	119	132	20065
MSM Sex <12 Months	74	29	45	74
Compliance	70.52%	75.63%	65.91%	99.63%

- 70% with new partner
- 10% with history of STI
- 40% aged 17-24

- UK Donor Survey following 2011 SaBTO review
- Biggest compliance survey undertaken
- Overall compliance >99.9% all responders
- Compliance in MSM cohort lower
- No associated increase in risk as observed additional cases of HIV/HBV/HCV lower than modelled to support the change from permanent to 12months

Reasons for Non Compliance



What's happened since Nov 2011

2005-2011					
Donors Deferred R05X	Deferred more than once	Returned after 2011	More than one Visit	Number Donating ≥ 3	Number Donating >10
676	14	38	19	14	1
	2.1%	5.6%	2.8%	2.1%	0.1%
Post 2011-2016					
Donors Deferred R75N	Deferred more than once	Returned after Deferral	More than one Visit	Number Donating ≥3	Number Donating >10
183	1	20	10	6	0
	0.5%	10.9%	5.5%	3.3%	0.0%

- 65% reduction in average deferrals for sex between men

deferral_code	Deferral Reason
R05X	Man had oral/anal sex with another man ever
R11N	Sex with a man who has sex with man
R15N	Sex with person from high endemic area
R75N	Man had oral/anal sex with man<12 months

2017 SaBTO

- SaBTO commissioned a further review on Donor Selection in 2016
- Multidisciplinary group with wide range of stakeholders
- Wider remit to consider
  - Sexual risk of infection(MSM, HEC, CSW)
  - Non sexual risks(Piercing and Tattoo, Acupuncture, Endoscopy and IVDU)

- Assessed Feasibility of individual Risk assessment

- Considered operational feasibility

- Reviewed International Experience

- Considered how technology could help

- Reviewed the residual risks and testing performance

- Wide ranging recommendations for change

2017 SaBTO Review- Blood Donation

Sexual Risks -Three Month Deferral after

- Sex between men.
- Someone who has received money or drugs for sex.
- Someone who has been sexually active in a high endemic area for HIV/AIDS.
- The Sexual partners of those listed above
- Sex with a high-risk partner injected or been injected with non medically prescribed drugs

Non Sexual risks

- **No deferral after:**
- Endoscopy, body piercing, acupuncture or tattooing carried out in UK
- **Three month deferral after:**
- Endoscopy, body piercing, acupuncture, tattooing performed out of UK or non-commercial premises in the UK.
- **One Year deferral after:**
- Injection of not medically prescribed drugs.

- The non sexual changes require changes in the BSQR so cannot be implemented at this time
- Also require expansion of the definition of qualified practitioner
- HBV NAT considered to replace the need for Hep B Core test reduced deferral for Endoscopy, Body Piercing and Tattooing to 4 months

2017 SaBTO Review-

for haematopoietic stem cells and tissue donation

- **No deferral after:**
- Endoscopy, body piercing, acupuncture or tattooing carried out in UK
- Donors with long term partners born in areas where HIV is endemic and partner is tested negative

- **Three month deferral after:**
- Endoscopy, body piercing, acupuncture, tattooing performed out of UK or non-commercial premises in the UK.
- Sex between men.
- Sex with a person who has received money or drugs for sex.
- Someone who has received money or drugs for sex.
  Deferral period may be reduced by individual risk assessment if risk of acquiring an infectious disease outweighed by risk of delaying transplantation
- Sex with a partner resident and sexually active in a high risk area for HIV/AIDS.
- Sex with a partner who was previously resident and sexually active in a high risk area and who has not been screened by the blood service.
- Sex with a high-risk partner (ie with HIV, HBV, HCV, syphilis, HTLV, person who has received money or drugs fro sex or has injected or been injected with non medically prescribed drugs.

- **One Year deferral after:**
- Habitual use of intravenous drugs of addition (can be reduced if supported by NAT testing and dependant on clinical circumstances).

2017 SaBTO Review- Gametes

- Sperm: testing at donation and then five months later with sperm released (after this quarantine) if negative

- Eggs: testing one month before donation and on day of donation.

The Rationale for Change

Estimated Infectious Window Periods for HBV,HCV,HIV and Syphilis				
Window Period (Days)	HBV	HCV	HIV	Syphilis
NAT pooled 24	30	4	9	n/a
Serology Only	66.8 (Ag)	59 (Ab)	11 (Ag/Ab) 15(Ab)	28
Residual Risk (1 per x Million donations)	1.3	40.4	5.7	1.96
No per Million entering blood supply	0.79	0.025	0.18	0.511

- Expert advice to use window period as a guide for length of deferral period
- Minimum of x2 indicated
- Best advice to use x3
- Longest window period should dictate the deferral period (ie. HBV)

“Worst case” modelling results for three month deferral since last at risk behaviour

	MSM	HRP-MSM	HRP-HEC	HRP-BBV	HRP-CSW	PWID	HRP-PWID
TTI/million donations	0.35	0.24	0.27	0.27	0.27	0.15	0.09
Average years between TTI	2.5	2.5	2.5	2.5	2.5	10.4	10.4

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International Experience

NHS National Services Scotland

Individual Risk assessment –
The Holy Grail of Donor Selection

- What does individual risk assessment mean?
- SaBTO experts struggled with this
- Treating donors Equally could make it less individual
- How do we fill the gaps in evidence ?
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- How could we identify cohorts at lower risk?
- Can we safely assess couples together?
- How can we make progress?
- Is there a middle road?

Framing the Hypothesis

There is a cohort of sexually active MSM who are a low risk of infection and that blood services could reliably identify them and enable blood donation.

What evidence would we need to prove or disprove this theory?

The available evidence based is scant and does not represent the who MSM cohort.

It is no longer acceptable to say we do not have the evidence to make change and then not to look for it

We need to consider who should collate the evidence

There are cost and resource implications for Blood Services and Public Health bodies

A brief summary of the 2014 data analysis comparing three cohorts of MSM from the Scottish bar study provided by Lisa McDaid is given below That indicates that the overall HIV % positive is 4.6% compared to the 3.6% and 3.1% in the No Sexual Contact and Lower risk cohorts respectively, while in the high risk cohort (representing 52% of the sample) the rate of positive tests was 5.7%.

	Number	% of Sample	% HIV positive Saliva Samples	% Undiagnosed
No Sexual contact last 12 months	83	6%	3.60%	33%
Sexual contact last 12 months **not** high risk	553	41%	3.10%	23.50%
Sexual contact last 12 months **high risk**	703	52%	5.70%	37.50%
Total Group	1340		4.60%	34.40%

The Future

•SaBTO accepted recommendations in June 17 –report published in July
•Recommended to the UK departments of Health
•Scottish Government accepted recommendations in full and asked us to make progress towards individual risk based selection and consider paired assessment of affected donors
•Changes in Sexual Risks to be implemented Nov 17(NHSBT and SNBTS) and Jan 17 (WBS) ?? NIBTS
•SNBTS first meeting of working party
•DOH England endorsed those permissible under current BSQR
•APPG made a number of recommendations and sought a commitment to make progress towards individual risk based assessment
•Can we use technology differently to promote greater awareness of sexual risk
•Need much greater understanding of transgender issues and how to address them
•Need to consider how we support front line staff
•It a journey that needs to continue

Evidence Supporting Changes in Body Piercing and Endoscopy

Experience in 2014 from HB core Antibody tests (in England

- 30,255 tested
- No positives where indication to test was:
  - Piercing, n = 24,233
  - Endoscopy, n = 4930
- 29 positive of which:
  - 27 permanent condition
  - 1 unknown risk
  - 1 past history of jaundice

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