December 2020

Can donor selection policy move from a population-based donor selection policy to one based on a more individualised risk assessment? Conclusions from the For the Assessment of Individualised Risk (FAIR) group

1. Executive summary and recommendations

For the Assessment of Individualised Risk (FAIR) steering group have taken an evidence-based approach to review whether the UK blood services could move to a more individualised blood donor selection policy. This work has focussed on behaviours associated with acquiring blood borne infections (BBIs) and using both epidemiology and behavioural science we have made recommendations as to donor eligibility. The work has focussed on men who have sex with men (MSM) and what changes could be introduced now as a move towards a more individualised donor selection policy.

The epidemiological review looks at the literature relating to higher risk sexual behaviours and markers of risk; observed data in current donors and risk factors, and survey data on behaviours and acceptability of questions in current donors. The behavioural work including focus groups and surveys of a range of stakeholders including donors, potential donors, staff, MSM and patients and assessment of reproducibility, acceptability and robustness of potential questions. The work also explored the concept of risk and how communication with current and new donors could ensure that donors understand the importance of donor selection in maintaining blood safety and protecting blood recipients from infection.

The current donor health check asks a number of general questions about donor health and specific questions about infection in the donor's partner. Questions relating to infection risk are asked of donors and risks in their partners including injecting drug use, paying for sex and for men, whether they have had sex with another man in the last 3 months. The donor selection guidelines for men who have sex with men were changed in 2017 resulting in a change from a 12 month to 3 month deferral from last sex with a man, (Northern Ireland made this change in 2020). There is no evidence that this change to donor selection policy has impacted on the safety of the blood supply in the UK.

Current blood safety measures include both donor selection and donation testing, over recent years the sensitivity of donation screening has improved with the introduction of smaller NAT pool sizes. Overall rates of infection in donors have decreased with the exception of syphilis where the rise in infections has mirrored that in the general population. There are a small number of reports of syphilis being transmitted by transfusion but these have been from whole blood or fresh plasma. There have been no reports of transmission in the UK.

Since the time of the last SaBTO review in 2017 a number of countries have reduced their time based deferral for MSM, including Canada, USA (3 months), and The Netherlands (4 months).

Considerations and recommendations for a more individualised risk-based donor selection policy are as follows:

1. A review of the current epidemiological literature and observed data in donors and the wider population has identified the following behaviours as having increased risk of acquiring BBIs through sex: a bacterial sexually transmitted infection (STI) in the last 12 months, chemsex,

sex under the influence of drugs except cannabis and Viagra, multiple or new sexual partners. Analysis of psychometric data using principle components analysis showed that certain behaviours shared common covariance specifically: new sexual partner, multiple partners chemsex and recent STI diagnosis. People who reported one of these behaviours also had a higher probability of reporting one of the other behaviours too. However, it is acknowledged that these questions are open to impression management bias which will need to be managed. Questions related to behaviours with higher epidemiological risk have high reliability. These epidemiological higher risk questions map 100% onto the proposed gateway question. Those who score higher on the epidemiological higher risk factors perceive their risk of a future STI to be higher and therefore may be more likely to self-defer and not donate.

2. The group agreed that a more individualised risk-based approach should be taken to blood donor selection policy. The group explored how such an individualised risk approach could be applied to allow more men who have sex with men (MSM) to become donors. Specifically, this would result in a move from a population-based 3 month deferral for all MSM to a donor selection policy based on deferral of potential donors with higher risk behaviours associated with acquiring infections. It was acknowledged that this is the first step towards a donor selection policy entirely based on an individual assessment of risk.
3. Any current approach to a more individualised risk assessment must take into account the evidence but also what is practical given the current paper- based donor health check (DHC) system. Wales currently has an electronic system which is only used on session. Although all countries are exploring electronic donor health check systems, which may eventually allow completion ahead of session, this is not currently available.
4. This initial step towards a more individualised risk-based policy includes the introduction of gender neutral questions. Participants in the focus groups, and other stakeholders, were very keen that any changes to the donor health check should be communicated to current and new donors and that information was clear about the reason for this approach. There was also a recommendation to rename the DHC to emphasise that this is not only about donor health but also recipient safety.
5. The group recommends that two new questions should be asked of all donors reporting sex: 1) treatment for gonorrhoea or syphilis in the last 12 months and 2) history of chemsex in the last 3 months.
6. It was acknowledged that the current deferral for PrEP will remain in place. If the outcome of the review of national PrEP guidelines including impact on PrEP on HIV testing suggests that

the current deferral could be removed a further recommendation to SaBTO will be made. It is recommended that JPAC should refer current PrEP selection criteria in September 2021.

The current question asking about a partner's HIV status and donor eligibility should be reviewed considering current HIV treatment options and undetectable status.

7. Current questions relating to donor health, travel and partner risk should remain.
8. It is proposed that all potential donors who have ever had sex will be asked if they had a new sexual partner or more than one sexual partner in the last 3 months. If 'yes', donors will be asked if they had anal sex with their partner(s) regardless of whether they consistently used condoms. From this, donors who have had one sexual partner who was not new in the last 3 months are eligible to donate irrespective of gender, gender of partner or type of sex. This policy would mean that MSM in long-term partnerships would be eligible to donate. Donors who have had a new partner or more than one sexual partner in last 3 months are eligible if they had oral or vaginal sex, but not if have had anal sex with or without a condom.

   Other options were considered including asking all donors about condom use regardless of sexual behaviour if donors reported >1 or a new partner in the last 3 months, however this would result in significant donor loss including donors who are currently eligible.
9. The group also considered whether those donors who would be deferred under the proposed multiple/new partner/anal sex question could be retained if consistent condom use was reported. The psychometric work concluded that questions about condom use did not result in reliable responses compared to other behaviours. In addition there were concerns that more detailed questioning would be more difficult in a session environment due to limited privacy However, an electronic donor health check could potentially facilitate more detailed questions like these and it is recommended that future work should be undertaken to see how computer assisted donor health check could be implemented.
10. It is recommended that the new donor selection process should be piloted, this may be as a table-top exercise, prior to full implementation to ensure training materials and monitoring processes are appropriate.
11. An impact assessment should consider how the proposed questions would affect gay and bisexual men, women from minority ethnic groups and trans persons.
12. A number of recommendations have been made in terms of language used including use of risk versus safety, and ways of recruiting donors. In addition, the psychometric work supports the use of prompts prior to donation to remind donors to think about recent behaviours.
13. The process for managing deferrals should be reviewed to ensure that staff understand the reasons for deferral and can explain this to donors. In addition, it is recommended that the

UK blood services review their communications to ensure that deferred donors are not thanked for their donation.

14. The group acknowledged that any implementation would need to take into account the current pressures due to the response to the COVID-19 pandemic.
15. A plan for implementation and evaluation should be devised. Recommendations for routine monitoring of infections, compliance with donor selection criteria and donor loss are made in this report. Syphilis screening should be maintained as a useful measure to of donor behaviour.
16. There is a concern that the questions themselves may deter new donors, especially questions about anal sex and the importance of communications with current and potential donors is acknowledged.
17. Patients have recommended that more should be done to make donors aware of the impact of donation on their lives, they are concerned that any change may result in a reduction in donors but trust the blood services to maintain the safety of the blood supply.
18. A number of developments for donor selection questions have been identified. As such a process for future proofing the recommendations should be developed such that any adjustments can be made effectively. The group was very clear that if accepted these recommendations are the first step towards a truly individualised donor selection policy and as such the donor selection guidelines should remain under regular yearly review by JPAC and SaBTO.