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The impact of the new tick-box questionnaire, and the personal donor interview, on donor deferrals in the East of Scotland

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SUMMARY. The impact of a new tick-box questionnaire (TBQ) and personal donor interview (PDI) on donor and recipient safety was assessed over an 18-month and a 13-month period, respectively, by prospectively studying individual donors prior to and after the introduction of the new methodology. A 'hit' was defined as an instance where the TBQ or PDI prompted a donor to divulge information which they would not otherwise have divulged, with the new information having an impact on donor eligibility. There was a 'hit' rate of 0·19% for TBQ and 0·65% for PDI. Of these donors, 33% in the TBQ category and 14% of PDIs were reinstated, 24% and 32%, respectively, were deferred because of a malaria/chagas risk, and 16% of the 'hits' related to donor safety issues. When assessing recipient safety, particularly risk of a window period viral transmission, PDI is very significantly superior at identifying such donors (14 times better). Such information establishes the important safety aspects of these interventions and requires that further work be done to see whether PDIs, in particular, may be better targeted to specific groups of donors.

Key words: blood safety, donor selection.

The safety of blood components with regards to microbiological transmission is of paramount importance to the Transfusion Services. Testing for mandatory markers has increased significantly in sensitivity (Allain, 1998) and single-component viral inactivation methods are being developed, although these are currently restricted to fresh frozen plasma (FFP) (Prowse, 1999). However, these methodologies cannot guarantee 100% safety and will obviously not pick up viruses or prions which are not or cannot be tested for. Residual risk is currently very low (Barbara, 1998; Koerner *et al.*, 1998; Regan *et al.*, 2000) but the importance of appropriate donor selection cannot be underestimated.

Donor selection methods are aimed not only to exclude donors who, through their lifestyle, place themselves at higher risk of transmitting infections or disease but are also aimed at preventing donors from donating who may be harmed by the donation process. Numerous donor screening methods have been used for both new and regular donors and their effectiveness has been evaluated (Silvergleid *et al.*, 1989; Mayo *et al.*, 1991; Galea, 1997). The Scottish National Blood Transfusion Service (SNBTS) has been at the forefront of implementing appropriate donor selection criteria. This study was done prospectively to evaluate significant changes in donor screening methodology introduced in one Scottish region (Dundee and East Scotland).

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MATERIALS AND METHODS

1 The tick-box questionnaire (TBQ) which is printed on the back of the Donor Session Record was introduced for all donors in July 1997. In it, 'yes/no' answers are requested to questions designed to assess individuals' eligibility to donate blood.

Prior to July, only *first-time* donors were asked to complete such a questionnaire: *returning* donors were simply asked to read the 'Blood Safety Leaflet', which highlighted behaviour which may engender a risk of being infected with HIV or hepatitis.

As from the end of July 1997, all the responses to the questionnaire (TBQ) were reviewed by a 'health screener' (donor attendant), who also asked a set of verbal questions relating to recent medical/travelling history and comprehension of the questions asked. If there were any positive replies in the questionnaire or to

the minimum verbal questions, the health screener referred the donor to a nurse or a doctor. Apart from the new format questionnaire, this constituted no alteration to our standard donor screening procedure. Any interaction between a nurse/doctor and a donor, arising from this screening procedure, did not constitute a Personal Donor Interview, as defined below.

2 During the late 1990s, SNBTS also decided to phase in the introduction of the Personal Donor Interview (PDI) on a region by region basis. The PDI, for first-time and two-year lapsed donors, was introduced in the East of Scotland region in January 1998. This interview, undertaken by a nurse or doctor, allows careful review of the responses to the TBQ, followed by direct oral questions regarding possible risk behaviour.

Thus, for every donor attendance from 27/7/97 onwards, the TBQ was completed. From 1/1/98, first time and two year lapsed donors, after completing the TBQ, were also subjected to a PDI.

Very soon after the introduction of these new screening methods, it became clear that both methods were prompting donors to divulge information which had a bearing on their eligibility to donate. We therefore decided to audit such events prospectively.

DEFINITIONS

A 'TBQ hit' was defined as follows: in response to the new questionnaire, a donor divulges information which would have been pertinent at the time of a previous attendance(s), and which results in a change in donor eligibility, or a change to how his donation can be used. It follows that a 'TBQ hit' can only arise in the case of returning donors, since first-time donors have never been exposed to any previous donor screening method.

An example would be a donor who has donated five times in the last two years is prompted to say that he is currently taking beta-blockers which he started three years ago.

A 'PDI hit' was defined as follows: in response to the interview, a first-time or two-year lapsed donor is prompted to divulge information which he failed to divulge when completing the TBQ. An example would be a new donor who completes the questionnaire with no adverse responses; however, when interviewed, he states that he is currently on treatment with beta-blockers.

All possible TBQ or PDI 'hits' were passed to and reviewed by the same Medical Officer to ensure consistency of approach. In doubtful cases, the Medical Officer sought further information from sessional staff or donors' general practitioners.

Since each individual served as his/her own control, every event was considered significant.

The study was conducted during the period 1 August 1997 – 31 January 1999 (18 months of the TBQ, 13 months of the PDI).

RESULTS

A total of 21 607 donors were exposed to the TBQ, resulting in 42 'hits' (a rate of 0·19%). and 5703 donors had a PDI, resulting in 37 'hits' (a rate of 0·65%). These events are categorized in Fig. 1.

Risks not related to viral transmission

Twenty-two donors (24% of TBQ and 32% of PDI hits) were deferred because of possible malaria or Chagas disease.

Thirteen donors (17% of TBQ and 16% of PDI hits) were deferred when it became apparent that there may be an unacceptable risk of them being harmed by donating.

Nine donors (14% of TBQ and 8% of PDI hits) were deferred because their blood would have constituted a possible noninfective risk for recipients (e.g. transfer of malignant cells, passive transfer of autoimmune antibody) or because there was a change in how their donations could be used (e.g. self-prescribed aspirin which precludes the use of platelets from the donation).

Nineteen donors (33% of TBQ and 14% of PDI hits) were eventually reinstated once information was obtained from general practitioners, more than half of whom had originally been deferred because of a history of jaundice/hepatitis or possible malignancy.

Risk of window-period viral or prion transmission

Sixteen donors (five previous donors picked up by TBQ and 11 new donors via PDI) were deferred because they were prompted by the new screening methods to admit that they may pose a threat of viral or prion transmission. Seven of these donors constituted a risk because of possible viral exposure via *sexual* contact, all of whom only divulged these details once they reached the PDI stage.

Figure 2 gives some indication of how much more powerful the PDI is compared to the TBQ as a donor selection method in terms of: overall 'hit' rate (37/5703 : 42/21 607); donor deferral (temporary and permanent) for perceived risk of window period viral/prion transmission (11/5703 : 5/21 607); *permanent* donor deferral for perceived risk of window

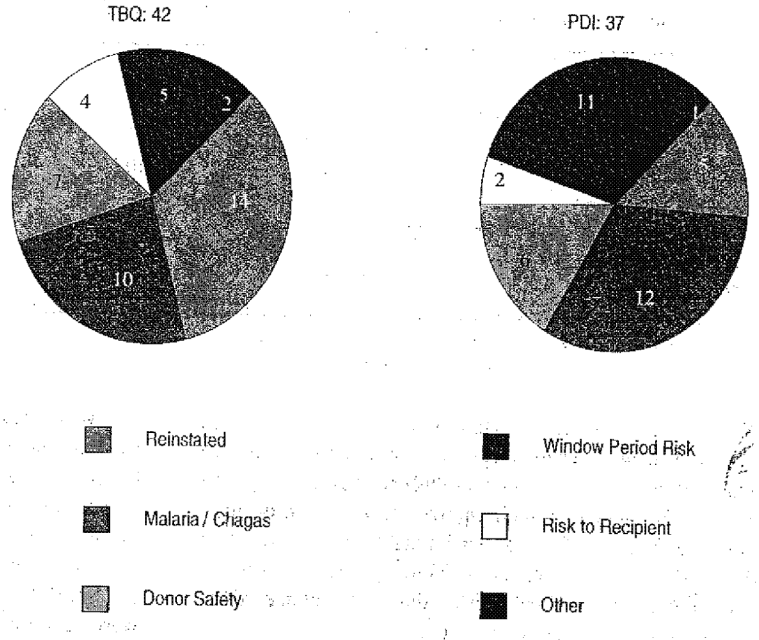

Fig. 1. TBQ and PDI 'hits' by category.

period viral/prion transmission (5/5703 : 3/21 607); donor deferral for only *viral* transmission (11/5703 : 3/21 607). In the latter instance, PDI is almost 14 times more powerful than the TBQ in elucidating the risk.

Incidence of hepatitis C positive donors during the study period

Table 1 compares the rate of hepatitis C positive donations, before, and during, the study period, for the East of Scotland, and for the whole of Scotland. For the whole of Scotland, the rate of hepatitis C positive donations remains more or less constant, whereas for the East of Scotland region, the rate of hepatitis C positive donations amongst new donors appears to have risen significantly during the study period. Three of these four donors had a PDI, and two of them subsequently admitted that they knew at the time of donation that they should not have given blood.

DISCUSSION

It is important to note that a simple change in format from verbal to written replies (TBQ) accounted for

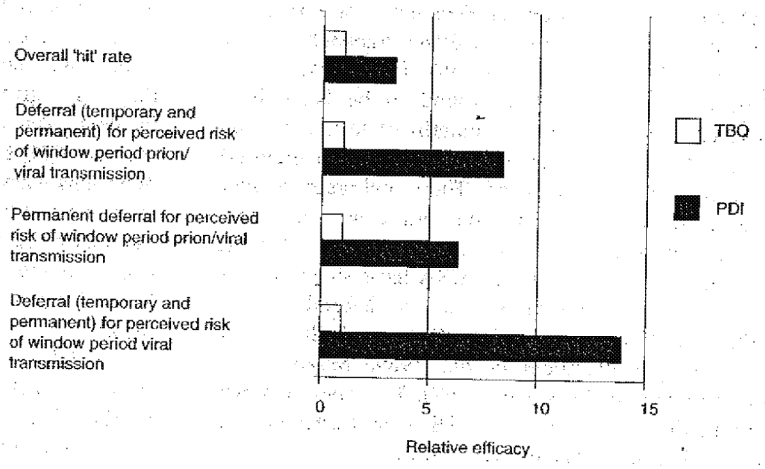

Fig. 2. Efficacy of the PDI compared with the TBQ.

Table 1. Hepatitis C positive donations before and during the study period

	Pre Study Period	HCV positive (%)	Study Period	HCV positive (%)
a. Donations: East of Scotland				
All donations	44 235	4 (0·009)	38 227	4 (0·010)
New donations	4569	0 (0)	3938	3 (0·076)
b. Donations: Whole of Scotland				
All donations	471 133	96 (0·020)	381 566	70 (0·018)
New donations	47 091	50 (0·106)	43 812	42 (0·096)

53% (42/79) of 'hits'. This is significant and it is essential to audit these responses on a regular basis to establish what changes in the TBQ format are required and the frequency of such changes to maintain optimal donor responses. This is particularly important, since the TBQ is shown to all (including regular) donors and there is a real risk that an element of complacency will set in.

We have shown that PDIs are also very effective. Of the donors in this study who were prompted to divulge additional important information, 47% (37/79) did so in response to the PDI. In particular, all of those donors who admitted to high-risk sexual contact did so in response to the personal interview, having failed to mention this on the TBQ. In fact, PDI was most powerful in this context. We recognize that donors may be inhibited from giving frank answers on a printed questionnaire (e.g. lack of privacy, attendance with friends or work colleagues). However, within the East of Scotland there is a system whereby a 'health screener' reviews the responses to the questionnaire in private with each donor. We are therefore reasonably confident that we are measuring the true effectiveness of the PDI.

Our findings confirm the evidence that already exists that direct oral questioning does have an impact in reducing the threat of transfusion-transmitted viral infection. Crawford *et al.* (1994) found that, of the Scottish donors who were found to be hepatitis C positive during the first six months of testing for this agent, 39% were aware that they were in a high-risk category when they donated. These authors concluded that a searching predonation interview may have resulted in the deferral of at least some of these individuals. Studies from the USA have shown a two- to five-fold increase in the rate of deferral for risk behaviour following the introduction of direct oral questioning (Silvergleid *et al.*, 1989; Mayo *et al.*, 1991; Gimble & Friedman, 1992). We have moreover defined the situation where a PDI is most effective, i.e. in revealing high-risk sexual contact.

It is true that PDIs are directed towards first-time and two-year lapsed donors and hence a different population to that exposed only to the TBQ. However, the PDI is so much more powerful in identifying risk that differences in donor epidemiology between the two groups of donors are unlikely to account for the differences noted in capturing risk. Moreover, the PDI group of donors were exposed to a TBQ and did not divulge the information at that stage.

The introduction of new methods of donor screening has other benefits too. It is worth noting that 19 of the 79 donors who were deferred following the introduction of the TBQ and PDI were subsequently reinstated after further information was obtained by the Medical Officer. This may reflect an over-cautious approach on the part of our nursing staff. However, although labour-intensive, the diagnosis/reasons for which they were originally deferred have been confirmed and these donors are now reinstated with an increased level of safety. The fact that 15 of these donors have since returned to donate suggests that donors on the whole have not been discouraged by the processes to which they were exposed. The TBQ teased out seven donors who were donating at possible personal risk to themselves and we have thereby possibly prevented donor adverse effects. However, one wonders whether some donor criteria need modification – collectively they had given 270 donations previously without incident. Ten donors were deferred after completing the new TBQ because of malarial or Chagas' risk. This represents what must be a small gain in recipient safety, at the cost of having to reconcile the deferrals with the fact that we had already placed at issue 118 units of red cells from these donors. The introduction of malaria and *T. cruzi* antibody testing will aid significantly in this regard.

We did not formally measure the duration of each interview, but 4 min is a reasonable estimate of the average time spent on each PDI. On this basis, the total time spent interviewing only new and lapsed donors over

a 13-month period represents 13 person weeks for our region alone (30 000 whole blood donations per annum). Add to this the cost and time taken to train staff, possible donor disaffection and disruption to smooth donor flow, especially at university sessions with a high rate of first-time donors, then the resources required to support personal interviews are quite considerable. However, we believe that the benefits derived are well worth the effort.

Although our study suggests that the PDI may be very effective in detecting high-risk behaviour amongst the donor population, it was rather disappointing to find that at least two donors, who had been exposed to the TBQ and PDI, persisted in donating, despite the fact that they knew when volunteering that they participated in risk behaviour. This is not a new phenomenon and other studies have shown similar data (Lefrere *et al.*, 1992). This represents the residual risk that cannot be minimized except by ensuring the best conditions for eliciting donors' honesty in answering sensitive questions. This area merits further investigation.

The definitive evidence to support the role of improved donor selection methods would be obtained if it could be demonstrated that a donor had been deferred during a window period. Such a study would have numerous logistical problems in terms of the large numbers that need to be enrolled and the taking of a blood sample from a deferred donor at the time of deferral and then perhaps three months later. Although it is unlikely that such a study would ever be done, routine nucleic acid testing may provide the answers without such a study taking place. However, even without such definitive evidence, this study shows that the introduction of the tick-box questionnaire and personal interviews for new and lapsed donors are extremely effective. We believe the implications for refining them and extending them to other groups of donors should be investigated. Further epidemiological studies on donor mandatory markers are being carried out to see whether better targeting of specific groups of donors (e.g. young males) for such interviewing is possible and, indeed, beneficial.

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