NATIONAL BLOOD SERVICE

Exclusion of previously transfused blood donors- MSBT Submission

Contents

1. Summary

This paper summarises the way in which the NBS would undertake to defer previously transfused blood donors, if required to do so, in the light of a recent possible transmission of vCJD through a blood transfusion. It identifies the NBS' preferred implementation plan and risks associated with the plan and in varying from the plan. The MSBT is posed a number of questions that need to be answered before the NBS can proceed any further.

The paper is written from the premise that the MSBT will wish to defer transfused donors. This is based on the recommendations of the ad-hoc meeting of experts held at the DoH on 15th December 2003.

This paper is written on behalf to the NBS, however the MSBT will be aware of the impact of its decisions on other UK blood services.

2. Points for MSBT consideration

The MSBT is asked to consider and make recommendations on the following points. Discussion can be found about each area in the paper.

	Decision Required
1	Is the critical date of transfusion after which a donor is excluded to be 1st January 1980 or some other date? If it is to be another date what is that date and why?
2	Does the exclusion cover transfusions received in the UK only? If not, where does it cover?
3	Does the MSBT endorse the donor categories? If so does the MSBT endorse the approach to reviewing certain categories within 6 months from the implementation date?
4	Does the MSBT endorse the blood component categories defining a transfusion? If not what does the MSBT recommend?
5	Does the MSBT support the recommendations surrounding the announcement and implementation dates? If not what does the MSBT recommend and why?
6	Does the MSBT support the proposed recovery plan? • Specifically, does it support the donor recovery plans and costs, including the use of NHS Direct? • Does it support the view that more focus must be placed on appropriate use and that this requires a funding stream and a performance management mechanism? • Does the MSBT support the contingency plan for managing chronic stock shortages? If any of these are not supported what does the MSBT recommend and why?
7	The MSBT to note the recommendation that there should not be a look-back exercise for those donors who identify themselves as previously having been transfused?
8	Should a chronic and lengthy shortage of blood result from this policy, despite the best combined efforts of all parties to avoid it, would the MSBT contemplate reversing its decision to defer previously transfused donors? If so, how would it do this and under what circumstances? If not, what alternative strategies would you consider to mitigate the shortages?

3. Background

Since 1997, the UK Blood Transfusion Services have taken a number of steps to reduce the possible risk of vCJD transmission by blood or blood products. These include importing plasma from the USA, leucodepletion and promotion of the appropriate clinical use of blood and tissues.

The UK BTS position statement on Creutzfeld-Jakob Disease has recently been updated with the announcement of the first possible transmission of vCJD by blood

transfusion in December 2003. The donor was well at the time of donation in 1996 but died in 2000 from vCJD. The recipient died in the autumn of 2003 with a diagnosis of vCJD.

This has prompted an evaluation of further measures the NBS needs to take to reduce the possible risk of transmission by blood transfusion. There is clearly a need to balance this risk with that of having inadequate blood stocks to meet appropriate clinical demand.

In December 2003 an ad-hoc meeting with representatives from the DoH, NBS, SEAC and MSBT identified several strategies to reduce the unknown risk of transmission of vCJD by blood transfusion. One of these was to defer previously transfused donors from donating blood. Following this meeting the Secretary of State for Health made an announcement in the House on 17th December which asked MSBT to consider further measures that would enhance the safety of the UK blood supply.

This document outlines the way in which the NBS would exclude donors who have been transfused since 1st January 1980 and the risks associated with deferring previously transfused donors.

The underlying premise on which the NBS has been planning since the ad-hoc meeting on 14th December is that the meeting decided that the NBS should defer previously transfused donors and that we are tasked to achieve this at the lowest risk possible to the blood supply, accepting that not all factors are within our control.

4. Nature of proposed exclusion and rationale

The criteria in the table below are those against which exclusion decisions will be made. They will be reviewed within six months of the implementation date. As well as reviewing the specific criteria around excluding previously transfused donors this review must consider other potential risk reduction measures in order that resources can be effectively targeted most appropriately.

Date after which transfusion would result in exclusion.	1st January 1980 (It is generally accepted that there would have been no dietary exposure to BSE in the UK before 1980)
Transfused Donors	• Know that they received a transfusion of one of the specified components since the specified date. These will be excluded.
Uncertain donors	• Donors answer "don't know" or "maybe". • Will not be excluded but a note will be made in Pulse (the donor record). Donors will be asked to let us know if they subsequently realise that they had a transfusion.

Donors excluded from donating from implementation date of new criteria.	• Whole blood donors • New apheresis donors • Apheresis donors returning to whole blood panels • New applicants to the British Bone Marrow Registry
Donors able to continue donating pending further analysis and decision.	In order to maintain adequate blood stocks, at present the exclusion does not apply to • Existing apheresis (platelet, plasma and granulocyte) donors • Existing & new tissue donors • Existing & new cord blood • Existing Stem cell and bone marrow donors • Autologous donors/recipients who are certain they received autologous blood.
Where transfusion happened	Transfusion in the UK.
Blood component recipients	A donor is deemed to have received blood i.e. had a blood transfusion if in the qualifying period they have received any of the following • Whole blood (widely used in the 1980s) • Red Cells • Plasma (FFP) - does not include pooled FFP e.g. Octaplas - made from non-UK plasma • Platelets • Cryoprecipitate • Cryo-depleted plasma
Plasma product recipients	Recipients of any fractionated plasma **are not affected by this policy**. This includes albumin and immunoglobulin – e.g. anti-D in Rh D negative women, anti-tetanus, and anti-hepatitis A immunoglobulin.

Rationale

Donor exclusion is a risk reduction measure. Previous measures relating to vCJD (leucodepletion, plasma importation) have also been about risk reduction. In deciding to implement risk reduction measures, a judgement is being made which seeks to balance the risk of vCJD transmission; the risk of having an inadequate supply of blood for those needing transfusion and the risk of the Blood Services suffering operational failure through attempting too many change initiatives at one time.

MSBT have previously considered more extensive donor exclusion measures which are not being recommended for implementation at this stage. This is because the risk to the adequacy of the blood supply and therefore patient lives is considered to be too high. MSBT has also considered other measures which are not being recommended for implementation at this stage. This is because the management and implementation of the measures that are being recommended would be seriously compromised, leading to a much greater risk of operational failure. Once the current measures have been fully implemented and the impact understood, further measures will be considered.

The proposed exclusion strategy is only a risk reduction strategy. It will not remove the risk of transmission through transfusion, for example where the donor is infected through the food chain. The only way to completely remove the risk of transmission through having a blood transfusion is to not have the transfusion.

The advantages of the proposed approach are set out below:

- It is clear in terms of the proposed transfusion exclusion date and there is a logic supporting that date.
- It focuses on whether the donor knows they have had a transfusion and excludes them only if they know they have. We submit that excluding donors who are uncertain whether they have been transfused at this stage risks major supply shortages with low added benefit because:-
    1. Uncertain donors will be likely to overstate the possibility of their being transfused, because they will be aware that the question is being asked for safety reasons
    2. The chance of a blood recipient being in the donor age range AND having a medical condition which permits future donation AND being unaware of the transfusion is low. Particularly since the HIV outbreak of the 1980's, there has been strong pressure not to transfuse young patients for non-life threatening conditions. Data from the North of England shows that only 28% of transfusion recipients are alive and still of donation age 5 years after transfusion, and at least 50% of these will be ineligible on medical grounds (Wallis et al, Personal Communication).

  The impact of implementing the exclusion including "don't knows" on stocks is highlighted below in section 7.2 and in appendix 1.
- It will not require donors to seek information from their hospital records if they are unsure – which would be a significant burden on the NHS, for a potentially small return.
- Evidence from look-backs suggests that medical records are poor when it comes to recording blood transfusion history so any wider exclusion criteria would be difficult to implement.
- It focuses on whole blood donors in the first instance, thus reducing concerns about platelet availability for the chronically and seriously ill such as cancer patients.
- It adopts an 80:20 approach, concentrating on the biggest risk reduction area first. Decisions around stem cells, bone marrow, cord blood and tissues, where the considerations and implications of exclusion **may** be very different, will be made later.

5. Implementation Date

Implementation is proposed for 5th April 2004. This coincides with the date that new Donor Health Check Questionnaire (DHCQ) will be implemented and these questionnaires will contain the new question on blood transfusion. This date has already been widely advertised to blood donors. Donors have been told that from 5th April old questionnaires will not be accepted at donor sessions.

Implementing prior to this date will leave the NBS operating at risk and significantly increase the risk to security of the blood supply. The risks associated with the earlier implementation date are detailed in the table below.

Risk	Explanation
Stock levels at exclusion date	It is apparent that the critical period, which will affect our ability to ensure supply continuity, will be April to June 2004. It is during this period that stock typically falls, and under an uncorrected exclusion scenario that fall will be very steep. This will be exacerbated if implementation is in February as there will have been less opportunity to build stock in the January and February period when stock is usually increasing. In the February implementation scenario there will be no immediate stock fall (assuming the 3.3% estimate is correct) for almost 2 months after implementation. In this situation we should not be lulled into a false sense that we have avoided a negative impact. Stock will still run out in September 2004 with no compensating activity.
System resilience	The Pulse IT links between our contact centres and the NBS is at full capacity as a result of the successful roll-out of blood donor appointments on sessions. Large increases in call volumes at any one time stretch the system which is already working at full capacity. This cuts the link, leaving us unable to answer donor queries, capture donor data or support underlying collection. The implementation plan relies on the contact centres to deal with the majority of exclusions to free up collection staff to collect blood. The enhanced link will not be available before mid-February and will need to be extensively tested
Staff training	All donor facing staff will need to be trained in the new procedures to capture donor details. This covers c 3000 staff. Earlier implementation means that training will be completed more quickly and errors are more likely to occur. This is a particular issue in 3 areas • Capturing and recording information correctly. Failure will result in us continuing to invite donors who have been transfused to sessions with both cost and customer service implications • Dealing with uncertain donors who we currently wish to keep in the system. Deferring these donors will significantly increase the numbers excluded and so reduce the security of supply. However, this is a reversal of usual policies where if unsure we defer. • Increasing the risk of error could cause session loses to rise further.

Availability of donor information	Lead times for leaflet production are such that we would be unable to insert any explanatory material into donor invitation letters for implementation prior to 5th April. Consequently many donors would have little or no knowledge of the new exclusion criteria when arriving at sessions, regardless of the media campaign supporting the announcement. This would • increase the number of donors excluded at session, • increase donation time at session for those donors who don't know about the change – with a knock –on effect on other donors • reduce satisfaction levels of both excluded and remaining donors. We know that donor satisfaction with session experience is a key determinant of whether donors return and we will not be able to cope with the consequences of losing even more donors through a poor session experience on top of those already being excluded.
Variation to session processes	To achieve an implementation before 5th April would require exclusions to be done by clinically trained Health Care Professionals (HCP) only. This would mean that all previously transfused donors would have to be seen by an HCP, who would be diverted from their normal functions including interviewing much needed new & returning donors.
Readiness of Hospital Trusts Blood Shortage contingency plans	The NBTC working group on contingency planning for blood shortages has highlighted the significant amount of work that has to be undertaken by ALL hospitals who receive blood in order to be able to effectively manage shortages when they occur. It is their view that Trusts will not be ready if the new criteria are implemented in February.

6. Answering the concerns of donors and patients

It is proposed that the NBS Contact Centre and Donor Session HCPs are able to answer straightforward questions. However, any individual, be they a donor or a patient who contacts us worried about whether they may have contracted vCJD is redirected to NHS Direct. Costs associated with this are not known. It is very difficult to estimate the volume of calls but NHS Direct may be able to take this up in their baseline activity.

7. Impact on sufficiency of blood supply

This analysis draws on and further analyses the results of the December 2000 transfusion history surveys conducted by the NBS and previously presented to the MSBT.

7.1 Proposed exclusion approach - exclude only those answering "yes" when asked if they have received blood

Collection

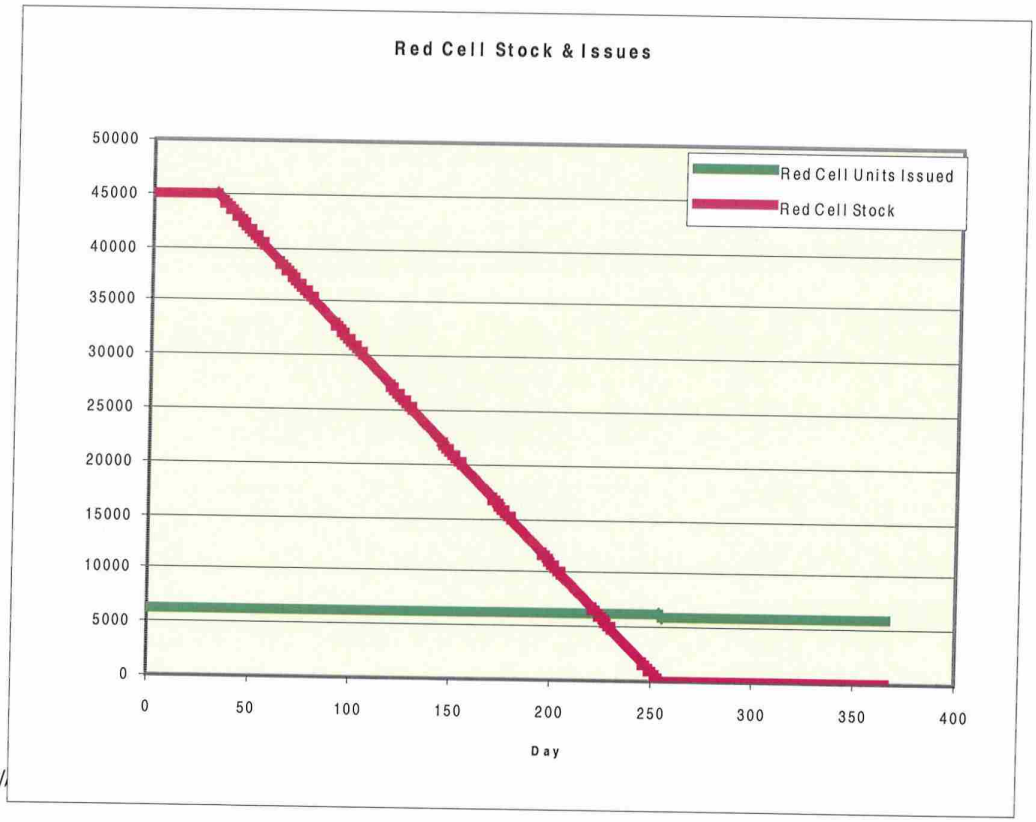
The analysis finds that **3.2%** donors and **3.3%** donations would be lost based on the survey questions asked in 2000. In December 2003 the NBS active donor base stood at 1.688m donors and collection for the year is forecast to be 2.52m units. Thus the losses would equate to approximately 53k donors and 75k units of whole blood. This is the equivalent of about 9 days worth of collection at normal capacity, which can be compared with a stockholding of about 7 days currently.

Impact on NBS blood stocks

The loss of approximately 3.2% of donors is well within the typical shrinkage of the donor base experienced in successive years since 2000. However there is a significant difference between these two scenarios. It is likely that a significant proportion of donor base shrinkage has resulted from the active cleansing, and general settling of the donor database. Therefore many of the donors included in the net reduction of numbers have not donated for many years and represent no real loss of collection potential. This is evidenced by the fact that as donor numbers have fallen average donation frequency (per active donor) has risen – a mathematical inevitability if you collect a similar amount of blood from a smaller donor group.

The donors lost as a result of previous transfusion will be a much broader cross-section of the donor pool, and as previously show, are in fact a slightly above-average group in terms of donation frequency. Therefore the loss of 3.2% of donors for this reason is likely to have a greater impact on collections than the mathematical loss of donors due to general donor base shrinkage.

Hence the remainder of this analysis assumes a straight 3.3% reduction in collection rates from the first day of exclusion. The analysis in this section assumes that there will be no compensatory promotion to offset losses. These factors are analysed in the next section.



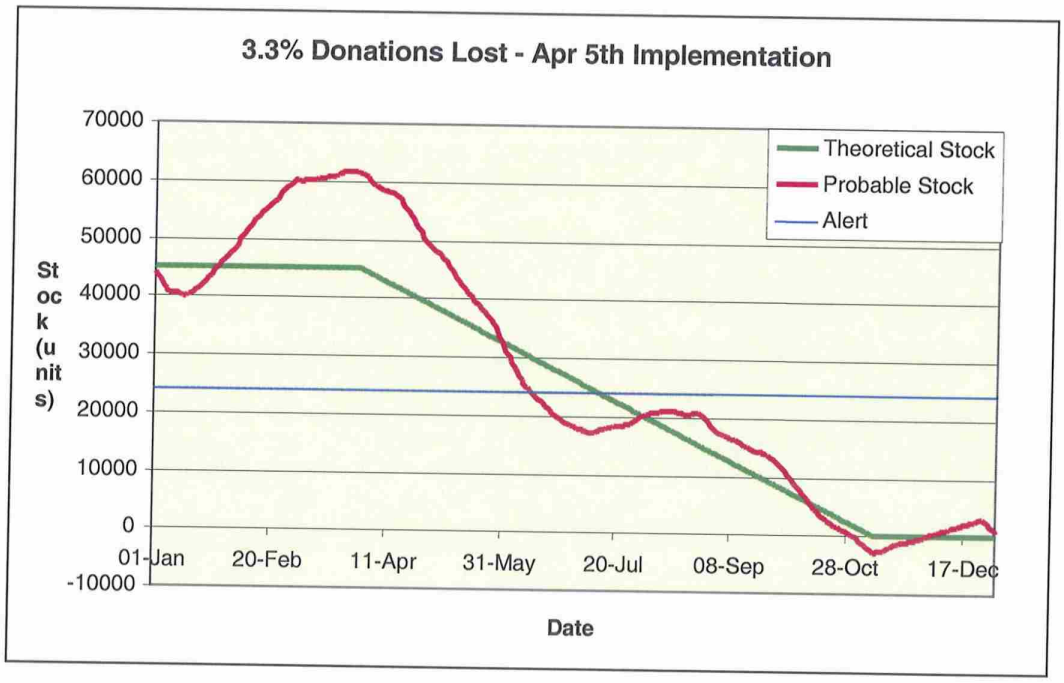
G/

The chart above shows a theoretical model of how stock and issues would be impacted by a 3.3% reduction in collections starting (on the chart) on day number 32. This shows that, assuming a previous steady state (in which collections and issues are exactly matched to hold a steady stock of 45,000 units) exclusion would cause an immediate and moderate under-collection resulting in a steady decline in stock levels.

In this theoretical scenario stock levels would fall below the alert level (3.5 days stock) 102 days after exclusion commences. Stock would continue to fall until, 254 days after exclusion, there would be no NBS stock whatever – at which point issues would be limited to 96.7% of overall demand. In practice, of course, the logistics of transferring blood between sites and processing lead times would mean that restrictions to supply would occur much sooner – some time between the 100th and 255th day after exclusion commences.

In practice the effect on stock will be superimposed on the typical stock cycle which can be highly variable. In this context the timing of the exclusion will be critical – if it starts when the stock cycle is rising this will delay (but not mitigate) the impact of exclusion. If it occurs at a time when the cycle is falling this will accelerate the impact and bring forward the start of supply problems (assuming no compensatory promotion).

The following chart shows what the effect of exclusion might be on stock[1] if it is implemented on 5th April 2004.



The model reflects a positive stock trend in January and early February which suggests stock would continue to build until late February. If implementation takes place in early April this will coincide with a time when the stock cycle is at a natural peak – the loss of donors accelerates the natural stock fall. However since the peak achieved is higher than it would be if exclusion were earlier – In February -(because

[1] The 'probable' stock line in the chart is estimated by superimposing the theoretical stock line on an average stock cycle based on stock information from January 2000 to December 2003

stock build has continued throughout February and March) the stock line bottoms out at a higher level – though still below the alert level.

Without compensatory promotion, there is a slight reversal in stock decline during the summer, however the stock level continues downward in the autumn and ultimately stock reaches zero in October.

The critical dates are summarised in the table below:

	Apr 5th
Start of Stock Decline	01/04/2004
Date Stock Falls Below 50k units	28/04/2004
Date Stock Hits Stock Alert (3.5 days)	13/07/2004
Date Stock Hit Zero	31/10/2004

Compensating for Donors Lost

Increasing Frequency

To replace the 3.3% of donations lost would require an increase in donation frequency from remaining donors of **3.4%**[2]

During financial year 2003/04 (to date) average monthly donation frequency has varied between 1.28 and 1.46 (annualised figures) – or nearly 12%. These values were achieved in successive months (October and November 2003), showing that short-term variations of the magnitude required could be achieved. Whether this rate of increase can be sustained is less clear.

Recruitment

The average value of a new recruit in the first 12 months after recruitment is currently 0.92 donations – down from 1.17 in 1999. The loss of 3.3% of donations is approximately 75,000 units (collected). This would imply that recruitment would need to be boosted by around **82,000** during the first 12 months following implementation of exclusion above the level of recruitment needed to replace other attrition and lapsing. This would need to be phased over the year as much of the value of a new recruit is gained shortly after recruitment, when the first donation is made (because return rates are poor many never make a second donation).

There would also be a need for ongoing elevated recruitment into the second and subsequent year following exclusion because of the high drop out rate of new donors following recruitment. This will need to be modelled out in detail.

Conclusions on impact on blood availability

Based on an assumption of 3.3% loss of donations (3.2% of donors) the impact of deferring previously transfused donors under the conditions considered is considerable but not of the order that would have occurred with 8% or 15% exclusion with a more far-reaching exclusion policy.

It is apparent that the critical period which will affect our ability to ensure supply continuity will be April to June 2004. It is during this period that stock typically falls,

[2] 3.3 / 96.7

and under an uncorrected exclusion scenario that fall will be very steep and take us below the alert level of 3.5 days. Our ability to maintain supplies will be very largely determined by whether we are able to boost collection rates sufficiently during the April to June period.

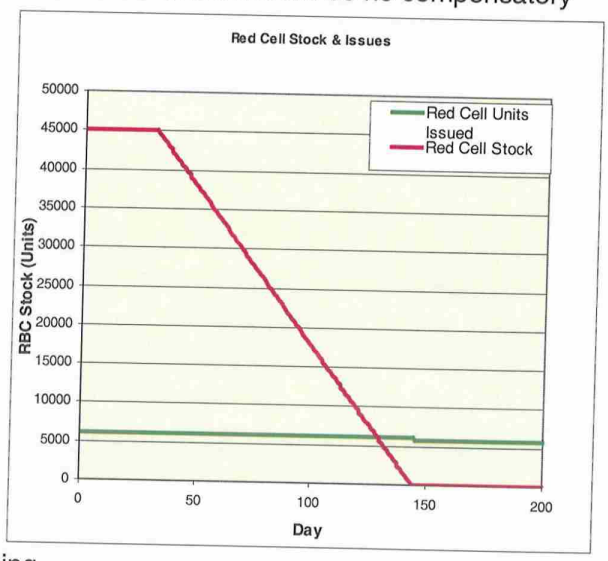
In terms of compensating for the donors and donations lost the level of boosting to either donation frequency or recruitment looks challenging but is of a scale that has been achieved in the past. The challenge if we concentrated solely on building frequency would be to sustain that higher frequency for the long term – we do not know whether that can be achieved. Therefore the most likely success strategy would be to boost frequency for the short-term whilst building and establishing a base of replacement donors to ease the load on the existing group into the medium and long term.

7.2 Alternative exclusion approach - exclude those answering "yes" or don't know / maybe when asked if they have received blood

Under this scenario 6.3% donors and 6.5% donations would be excluded. The analysis above is repeated and it can be seen that the impact on the availability of blood is dramatically worse than if we only exclude those who are sure of having had a transfusion.

Stock Effects

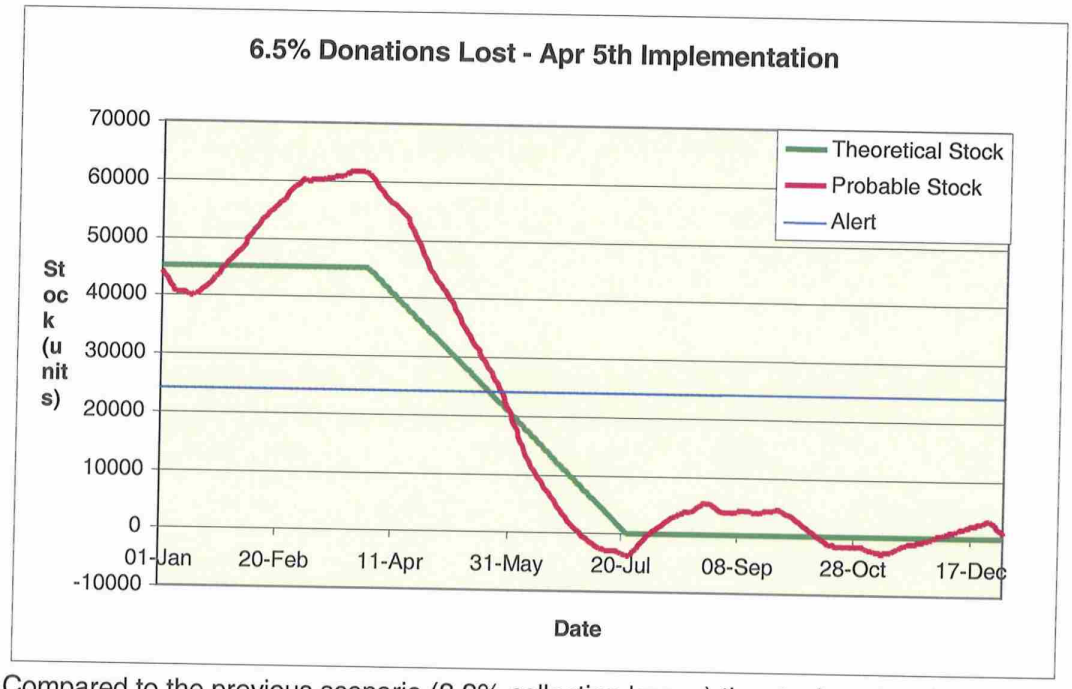
The analysis assumes a straight 6.5% reduction in collection rates from the first day of exclusion. The analysis in this section assumes that there will be no compensatory promotion to offset losses. These factors are analysed in the next section.



The chart (right) shows a theoretical model of how stock and issues would be impacted by a 6.5% reduction in collections starting (on the chart) on day number 32. This shows that, assuming a previous steady state (in which collections and issues are exactly matched to hold a steady stock of 45,000 units) exclusion would cause an immediate and significant under-collection resulting in a steady decline in stock levels – in which stock would be exhausted within about 115 days of exclusion commencing.

In practice the effect on stock will be superimposed on the typical stock cycle which can be highly variable. In this context the timing of the exclusion will be critical – if it starts when the stock cycle is rising this will delay (but not mitigate) the impact of exclusion. If it occurs at a time when the cycle is falling this will accelerate the impact and bring forward the start of supply problems (assuming no compensatory promotion).

The following chart shows what the effect of exclusion might be on stock[3] if it is implemented on 5th April 2004.



Compared to the previous scenario (3.3% collection losses) the stock pattern is qualitatively similar, but the declining phases are sharper and the steadying/recovery phases less marked. Consequently under a 6.5% collection loss scenario the critical points (below target, below alert and zero stock) are reached more quickly following exclusion.

The 50,000 stock target is breached on 22nd April just 6 days earlier than under 3.3% collection loss. Thereafter the speed with which stock falls through the various thresholds is much more accelerated with 6.5% collection losses. If exclusion occurs of April 5th the 3.5 day threshold is reached on 28th May, a month and a half earlier than if exclusion is restricted to those who answer 'yes' only.

The gap between reaching 3.5 days stock and zero stock is also greatly shortened – being reached in early July (about 4 months earlier. There is a brief recovery above zero-stock during the summer, but to very low levels which would not prevent significant shortages.

The critical dates are summarised in the table below:

	Apr 5th
Start of Stock Decline	28/3/2004
Date Stock Falls Below 50k units	22/04/2004
Date Stock Hits Stock Alert (3.5 days)	28/05/2004
Date Stock Hit Zero	2/7/2004

[3] The 'probable' stock line is estimated by superimposing the theoretical stock line on an average stock cycle based on stock information from January 2000 to December 2003

The modelled impact on stocks following a 6.5% loss of collections is much more significant than that following 3.3% losses. The outcomes in final stock terms are very similar (rapid decline and depletion); however the speed of decline is faster and duration during which stock is below the alert level longer. This would certainly mean a much greater impact on NBS' ability to meet demand for red blood cells.

Compensating for Donors Lost

Increasing Frequency

To replace the 6.5% of donations lost would require an increase in donation frequency from remaining donors of **7.0%**[4]

During financial year 2003/04 (to date) average monthly frequency has varied between 1.28 and 1.46 (annualised figures) – or nearly 12%. These values were achieved in successive months (October and November 2003), showing that short-term variations of the magnitude required can be achieved. Whether this rate of increase can be sustained is less clear.

Recruitment

The average value of a new recruit in the first 12 months after recruitment is currently 0.92 donations – down from 1.17 in 1999. The loss of 6.5% of donations is approximately 154,000 units (collected). This would imply that recruitment would need to be boosted by around **168,000** during the first 12 months following implementation of exclusion above the level of recruitment needed to replace other attrition and lapsing. This would need to be phased over the year as much of the value of a new recruit is gained shortly after recruitment, when the first donation is made (because return rates are poor many never make a second donation). This would suggest a short-term requirement to register well in excess of half a million new recruits in the 12 months following exclusion. This level of recruitment has no precedence in NBS history.

There would also be a need for ongoing elevated recruitment into the second and subsequent year following exclusion because of the high drop out rate of new donors following recruitment.

Conclusions

Based on an assumption of 6.5% loss of donations (3.3% of donors) the impact of deferring previously transfused donors under the conditions considered is very dramatically worse than deferring 3.2% of donors. The speed of stock decline is very much faster and the critical stock thresholds are reached in a much shorter time frame. Without very significant compensatory promotion, for which there is likely to be very little time to prepare, stock would be completely depleted approximately 3 months after exclusion commences and overall supply to hospitals would run consistently 6.5% below demand.

Under this more severe scenario the critical period which will affect our ability to ensure supply continuity remains April to June 2004. The rate of decline during this period is much faster than in a 3.3% collection loss situation and therefore the intensity of activity needed to prevent stock depletion would be much greater.

In terms of compensating for the donors and donations lost the level of boosting to either donation frequency or recruitment looks extremely challenging given the very

[4] 6.5 / 93.5

short period during which planning and preparation can take place. It is highly unlikely that sufficient activity could be initiated and take effect quickly enough to prevent significant stock decline occurring. The level of promotional activity that would be required is not without precedent but there is no history of sustaining activity of this intensity for anything other than short periods of time.

8. Implementation approach

8.1 Supply

i) Donor Recruitment and increasing donation frequency

The additional donations required would be achieved through a combination of recruiting new donors and through increasing the productivity of the existing donor base.

This paper contains a top-line response. It does not consider the implications of losses greater than those stated, since it is thought unlikely that such sustained losses could be met through higher collections in the time available. Such losses would need to be met through reduced use in hospitals.

Response Strategy

Previous NBS papers on related issues (RP0030 and RP0031) have considered a response to higher order degradation of the donor base. The response presented at that time relied heavily on marketing activity to stimulate the non-donating public to "backfill" the void left by donors excluded under the new criteria.

Whilst marketing activity continues to have an extremely significant roll to play in this new scenario, it is not in itself considered sufficient. PP00031 (page 9) describes the difficult operating environment existing in 2001 which is even more in evidence 32 months later.

Key elements

The introduction of mini (3 and 4 bed) bloodmobiles (BMs) into the collection regime since the publication of these earlier papers offers an alternative strategy.

The proposed response involves the deployment of a greater number of these mini bloodmobiles or min-hall teams to offset the loss of donations. The rationale for this approach is that regions have many pockets of opportunity that do not lend themselves to cost effective exploitation by larger vehicles or full mobile collection. Whilst the NBS is re-balancing its resources to allow for cost effective collection from these communities, there is the opportunity to broaden and hasten this approach to meet the challenge of an immediate and significant loss of donors. The collection response is subject to further NBS planning.

This core collection strategy would be complimented and supported by a marketing campaign that would ensure that key messages are received and understood by the various stakeholder audiences.

Costs

The top-line costs/contribution of the various elements of the strategy are as follows.

It is assumed that 80% of collection shortfall will be made up through deployment of mini (3 bed) BMs and 20% of shortfall will be recovered through general public response to the marketing programme, both new donors coming forward and existing donors giving more regularly.

BLOODMOBILES	Year 1	Years 2 plus
Capital	£94,000 x 10	
Revenue	£93,000 x 10	£93,000 X 10
Total	**£1,870,000**	**£930,000**

In order to support the marketing and planning efforts associated with this additional resource within each of the nine regions, it will be necessary to recruit an additional member to each marketing team and an additional member to each planning team. Costs for this are shown below and assume a business cost of £20K for each post.

SUPPORT STAFF	Year 1	Years 2 plus
Marketing/Planning	**£360,000**	**£360,000**

Marketing
The marketing approach will have three key aims

- It must deal effectively with the donors to be excluded. It is anticipated that approximately 55,000 donors will be affected. They will receive two mailings and a certificate at a unit cost of £3 per donor.
- It must communicate the nature of the issue to the existing donor base. This is particularly critical in the early phases of the scenario, when existing donors will be required to increase their average frequency whilst the new mini-BM resources are secured and a programme established. This will be achieved through three mailings; one informing donors of the scenario, one advising them of how they can help and one subsequently offering them thanks and an update. Each mailing has a target audience of 1.7 million and is budgeted at a pack price of £0.60.
- It must stimulate non-donors to come forward to both existing sessions and to support the new mini BM programme. This will involve a series of newspaper advertisements (costed on 8 national titles, one full-page placement on a weekday, one at weekend at a cost of £40K per insertion but this is subject to media strategy review). There will also be a new television & radio execution budgeted at £500K production cost and a 2 burst media strategy (£1.5 million media cost per burst) in both years one and two. However, it is considered that a contribution of £1M could be made to these costs in each year from the existing above-the-line budget.

Marketing costs, applying to years one and two only, can be summarised as:

MARKETING	Year 1	Year 2 only
Excluded donors	£165,000	Nil
Existing donors	£2,000,000	£1,000,000
Public	£2,640,000	£2,000,000
Total	**£4,805,000**	**£3,000,000**

Summary
The cost of responding to the loss donors in early 2004 is estimated at £7,000,000 year one, £4,229,000 in year two and £1,290,000 in each subsequent year. These costs are in the right ballpark but will be firmed up as the implementation plans are

themselves firmed up. In reality full – year effects wouldn't coincide with financial years.

ii) WNV & anti-core Hepatitis B testing.
The opportunity to recover lost donations through Hepatitis B anti –core testing of "piercers" and West Nile Virus testing on North American travellers is being considered. Feasibility and costs are yet to be determined. Such testing may provide some 8,000 –15,000 donations from WNV and 10, 000 donations from Anti-core testing.

8.2 Demand

i) Appropriate Use
There is a separate paper on appropriate use for the MSBT to consider. However, unless hospitals have a clear policy on appropriate use and this is resourced and measured in performance management terms at the top of the organisation it will continue to be difficult for advocates to make in-roads into reducing demand where appropriate.

ii) Contingency planning
This section is taken from a report on contingency planning written on behalf of the National Blood Transfusion Committee (NBTC), by its contingency planning sub-group.

The National Blood Transfusion Committee (NBTC) has developed a contingency plan for chronic shortages. This has been reviewed by clinical experts and a number of actions identified to make it operational. The plan involves a different way of working to that previously experienced in shortages. The NBTC recognise that to be effective the plan would need to ensure that:

- The national "pool" of blood is available to all hospitals so it can be targeted at those who need it most
- Usage is reduced so that the most urgent need is met.

The plan contains three stages:

Green – normal circumstances where supply meets demand
Amber – reduced availability of blood (such as in a loss of 10% of donations)
Red – severe, prolonged shortage (such as a loss of 50% of donations)

The plan contains actions for hospitals and the NBS at each stage. Each hospital will have a set of actions defined within an Emergency Blood Management Plan.

In order to ensure the maximum availability of the general "pool" of blood to all, hospitals will be expected to reduce their stockholding at each of the shortage levels (to 67% in amber and to 40% in red.) Stockholding figures will be based on the average stockholding for different groups of hospitals as defined by the Blood Stocks Management Scheme.

A number of actions were identified by the expert clinical group as being required for the plan to be successful, these can be divided into three areas.

i) Resource.
Resource MUST be provided to enable Trusts to implement the recommendations of the HCS 2002/009 Better Blood Transfusion. In particular Blood Transfusion practitioners and dedicated Consultant sessions are required to establish a hospital

transfusion team. Audit tools must be available to the Hospital transfusion team to enable them to identify where blood usage can be reduced. Funding needs to be made available for blood conservation measures such as cell salvage, use of aprotonin etc. Implementation of the reasons for transfusion as defined in the hospital codes for transfusion recommended by the NBTC are a good framework for these strategies.

If successful, this strategy may avert the requirement for the plan to be activated for a shortage caused by exclusion of previously transfused donors.

ii) Extending the plan.
The combined plan is to be adapted to include clinical guidance on which groups of patients should receive blood transfusions at each stage. Patients will initially be divided into three broad categories. Further work will need to be undertaken to refine and expand on these categories.

Category 1	Category 2	Category 3
Active Major Bleeding	Cancer Surgery	Elective Surgery
Emergency Surgery	Urgent Cardiac Surgery	Post op top up transfusion
Life threatening anaemia	Anaemia with Major Symptoms	Elective top up for anaemia

In an "amber" shortage situation attention will initially be to reduce hospital stockholding. In a more prolonged shortage hospitals will be expected to reduce usage by 20%. Patients in category 3 would be identified and transfusions/ operations suspended to achieve this reduction. Higher reductions in usage would be expected in private hospitals where a higher percentage of the workload is in category 3. In a prolonged shortage this could have a significant effect on waiting list initiatives.
In a "red" shortage situation hospitals would be asked to reduce usage by a % set by the NBS. In a red shortage situation it is unlikely that patients other than those in category 1 could be supported.

It is planned that the NBS will monitor and provide feedback on hospital usage in times of shortage. Hospitals which are not achieving the target reduction in usage will be contacted and will not be able to receive additional supplies unless actions have been taken to reduce usage. This monitoring will require DH support to be effective.

iii) Communications.
It is planned to produce a generic hospital Emergency Blood Management Plan which hospitals can use as a framework for individual plans.

Once published the NBS will need to co-ordinate activity to communicate information to all areas of the hospital on the existence of the plan, the workshop recommended use of the relevant clinical journals as the preferred route for these communications.

In addition it would be critical for the plan to be communicated directly from the DoH to CEO of Trusts, with a responsibility placed on Strategic Health authorities and PCT's to ensure that an effective local plan is in place.

Recommendation on Timescales.
There are a significant number of actions which need to be undertaken to ensure the effective integration of the plan in the NBS and within hospitals. These include:

1. Produce a combined plan to distribute to all hospitals
2. Further expand the categories of patients in the three broad categories and identify other measures that can be introduced to reduce blood usage in specialist areas (E.g. cardiac surgery.)
3. Establish procedures to enable blood usage at hospitals to be monitored on a weekly basis and feedback/ corrective action to be implemented. This may require an independent review outside of the NBS.
4. Gain assurance that hospitals have understood the need for a plan and have adapted plans to manage a shortage.

Although the full impact of the exclusion of donors is unlikely be felt by hospitals for approximately 3 months from the time the exclusion is implemented, the complex nature of the arrangements which need to be made with over 300 hospitals will require a significant lead-time.

9. Blood Component Withdrawal / Recall

Frozen components donated by donors who have subsequently been identified as previously transfused could be withdrawn / recalled if this was considered appropriate. Red cells and platelets would not be impacted by this decision due to their shelf life. For plasma components this is a difficult process to manage for two reasons:-

1. The NBS has limited product availability from male-only donors (following the recent implementation of this TRALI risk reduction measure).
2. There are significant operational difficulties in asking hospitals to look only for that plasma from previously transfused.

The NBS will give further consideration to the practicality of a withdrawal / recall when the stock position is clearer.

10. Look-back exercises

Regardless of the decision taken on product recall there is a separate consideration around donor look-back. Look-back exercises have been conducted in the past when it has been demonstrated that donors have evidence of infection with an agent which is capable of transmission by blood transfusion. Donors who identify themselves as previously having been transfused would not fulfil that criterion. A look-back exercise in relation to a precautionary measure would be a major new departure. A look-back exercise including all donations from previously transfused donors would be a major programme both for the NBS and hospital records departments, covering more than 55k donors who might have multiple patient records. We have not allocated any resources to such an exercise and would have to recruit medical and administrative resource to carry it out. This has not been costed. This is because of the cost–benefit is likely to be weighted in favour of not doing a look-back for a precautionary exclusion. However, the CJD Incident Panel may wish to express a view on this.

11. Risks and mitigating actions

This section looks at the risks and mitigating actions associated with implementing the proposed exclusion policy. The risks considered are

i) Estimates of Donor & Donation Loss are wrong
ii) Not sure / maybe donors are excluded
iii) Exclusion date
iv) Announcement date
v) Non-transfused donors self-defer
vi) Impact on NBS plans
vii) Adverse effect on NBS reputation
viii) Adverse effect on NHS reputation
ix) Contingency plan to manage shortages to hospitals not in place
x) There is another possible transmission of vCJD through blood transfusion before the exclusion policy is implemented.

The first four risks are considered to be the greatest threat.

i) Estimates of Donor & Donation Loss are wrong

Risk	Mitigating action
The accuracy of the estimates of donor and donation loss will depend on the question wording and the context in which it is answered. Anecdotal evidence has emerged since the 2000 survey that donors associate the term 'blood transfusion' with receiving a significant quantity of blood. When a donor has received a small quantity of blood in transfusion they tend to deem that as receiving 'a little bit of blood'. This emerged in qualitative research to develop TV adverts to mitigate loss of donors resulting from exclusion of transfused donors.	If the exclusion criteria adopted is 'have you received a blood transfusion since 1st January 1980?' then the above estimates should be reasonably accurate. If however an alternative wording is used (e.g. have you ever been given blood in surgery or as part of medical treatment) it is possible the rates will be higher. However at this stage we cannot estimate what those rates might be. Those who have had many units of blood components are the ones who are at greatest risk of transmission and they are more likely to know they have received blood.
Another factor which may impact the rate is the context of the question. The transfusion history survey was deployed as a stand-alone questionnaire at collection sessions. Donors were specifically asked to complete the form which contained only 5 simple questions. There may be a proportion of donors who have received a transfusion in the past will skim-over the question and answer 'no'. This may reduce the rate of exclusion – though again, it is not possible to estimate the scale of this effect.	Implement an exclusion date of 5th April to enable NBS to send new Donor Health Check Questionnaire's (DHCQ) with exclusion questions and explanatory leaflets to donors' homes, encouraging them to read the information carefully. The DHCQ has been completely redesigned to overcome the problems of donors skimming over the questions. In addition mailing the DHCQ to donor's

	homes gives them more time to read them carefully and complete correctly.

ii) Not sure / maybe donors are excluded

Risk	Mitigating action
3.1% donors and 3.2% donations fall into this group. The 'not sure' group is almost identical in size and importance as the group having received a transfusion since 1st Jan 1980. Indeed the higher frequency of these donors mean they would be more difficult to replace if excluded. Men are less likely to be certain of their transfusion history than women.	Very careful training of Health Care Professionals to avoid deferring this group of donors. Marketing material carefully worded to emphasise the need for these donors to continue to donate.

iii) Exclusion date

Risk	Mitigating action
It is apparent that the critical period which will affect our ability to ensure supply continuity will initially be April to June 2004. It is during this period that stock typically falls and under an uncorrected exclusion scenario that fall will be very steep and take us below the alert level of 3.5 days. In fact West Nile Virus deferrals will bring make this worse	Implement an exclusion date of 5th April to enable NBS to send new DHCQ's with exclusion questions and explanatory leaflets to donors' homes.

iv) Announcement date

Risk	Mitigating action
The earlier the announcement date, the more likely it is that the risks associated with a February implementation date will be realised. Once announced donors will contact the NBS and begin to self defer. So the NBS needs to be able to deal with the consequences. Of particular issue is the fragility of the IT link with the contact centres.	Provide NBS with at least 1 week's notice of announcement date. Keep the announcement date to within 2-3 weeks of the implementation date to enable invitation letters to be used Announce no sooner than 8th March to enable NBS to send new DHCQ's and explanatory leaflets to donors' homes.

v) Non-transfused donors self-defer

Risk	Mitigating action
Non-transfused donors may self-defer. This may be because they • are disenchanted with the process perhaps if a family member or friend is excluded • unsure if they have had a transfusion and don't want to risk infecting someone else	In marketing material emphasise patients' constant need for blood and the benefits of a significantly enhanced quality of life and lives saved. Monitor self – exclusions and confirm that the reason for exclusion was appropriate.

vi) Impact on NBS plans

Risk	Mitigating action
The NBS business plan is already extremely stretching reflecting critical developments driven by wider NHS priorities. This includes • Agenda for Change • Other prioritised safety initiatives • Modernising the donor-facing programme to improve donor loyalty • Improving customer satisfaction of hospital partners and colleagues	Re-prioritise workload delaying other initiatives previously seen as critical.

vii) Adverse effect on NBS reputation

The reputation of the NBS could be tarnished through being seen to reject donors whose blood had previously been used in transfusions. The message being that there have been potential infections through blood transfusions.	Careful messaging of risk –reduction activity, drawing on experience in previous donor exclusions driven by changing donor selection criteria.

viii) Adverse effect on NHS reputation

Shortage of blood components later in the year will impact on Government waiting list targets and treatment priorities (e.g. cancer and heart programmes)	Government to give more teeth to BBT2 and to look for ways to make appropriate use a real priority of NHS hospital Trust CEOs – perhaps through SHA performance measurement frameworks. Marketing and customer service activity focussed on replacing lost donations prior to a shortage arising. This could lead to a further risk because if particularly successful it might result in higher stocks of older blood and more outdating!

ix) Contingency plan to manage shortages to hospitals not in place

Shortages will have a greater impact if hospitals are not able to operate the contingency plan.	Government support is given to ensure contingency plan mechanisms can be implemented and are operational if needed. No consideration has been given to importing labile blood components in this paper. As a short-term response this is considered impractical.

x) There is another possible transmission of vCJD through blood transfusion before the exclusion policy is implemented.

There is another possible transmission of vCJD through blood transfusion before the exclusion policy is implemented	To date there has been one possible case. A number of those still alive who received blood from people who subsequently developed vCJD had their transfusions several years ago. EOR can advise, but it is thought that the risk of a further transmission through blood in this time window is small. This must be balanced against other risks. The risk of screening mistakes through rushed implementation and subsequent transmission of viruses to patients, the risk to donor health together with the adverse impact on blood stocks and patient health are thought to be much greater.

Liz Reynolds
Director of Public & Customer Services
National Blood Service
16th January 2004

Appendix 1:

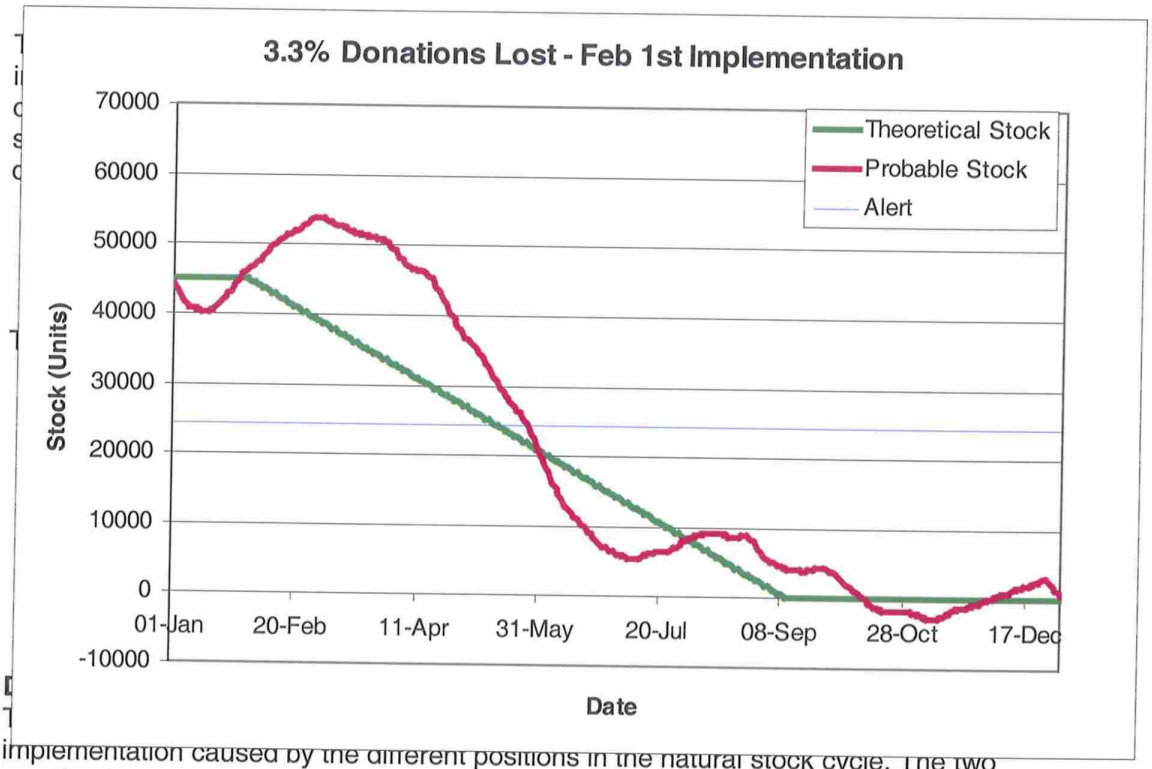
Impact on stock and adequacy of supply of applying exclusion criteria from 1st February 2004.

1) Impact for donors who answer "yes" when questioned about having received blood.

Under this scenario only donors who answer "yes when questioned about having had a blood transfusion are excluded from 1st February 2004.

Stock Effects

The following chart shows what the effect of exclusion might be on stock[5] if it is implemented on 1st February 2004.



implementation caused by the different positions in the natural stock cycle. The two months that separate the dates become reduced to around a month's difference for reaching each of the critical stock points (stock below target; stock below alert; stock depleted).

The critical period which will affect our ability to ensure supply continuity will be April to June 2004. It is during this period that stock typically falls, and under an uncorrected exclusion scenario that fall will be very steep and take us below the alert level of 3.5 days. In the February implementation scenario there will be no immediate stock fall (assuming the 3.3% estimate is correct) for almost 2 months after implementation. In this situation we should not be lulled into a false sense that we have avoided a negative impact.

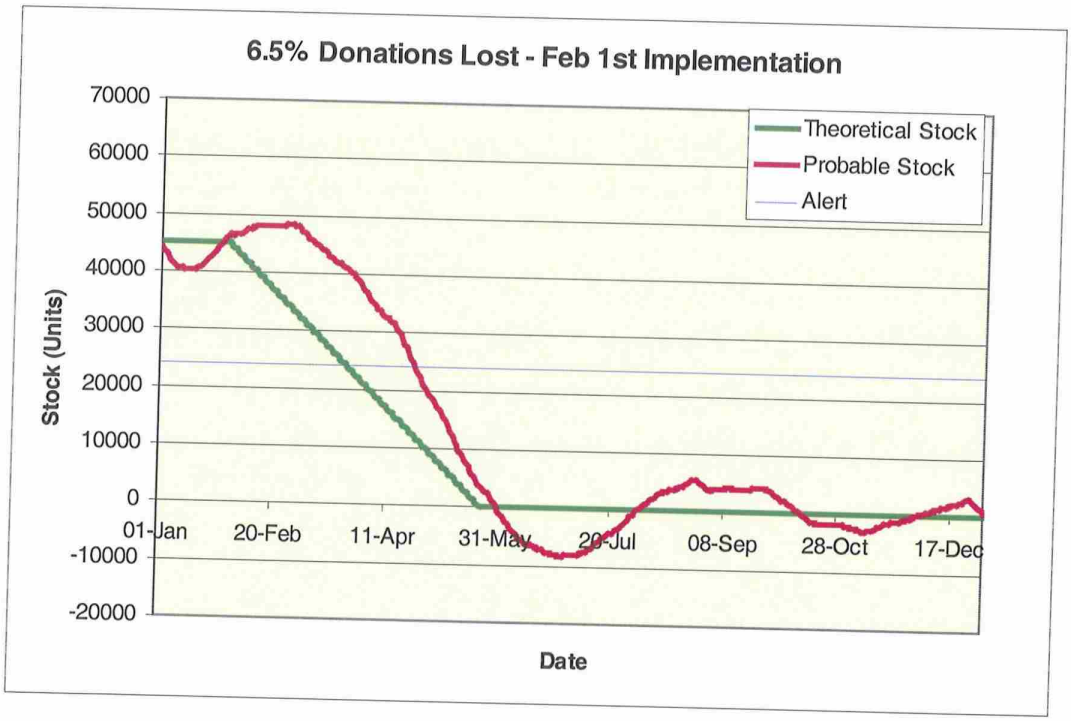
[5] The 'probable' stock line in both charts is estimated by superimposing the theoretical stock line on an average stock cycle based on stock information from January 2000 to December 2003

2) Impact for donors who aren't sure if they have had a transfusion.

Under this scenario donors who answer "yes" and those who answer "don't know" / "not sure" when questioned about having had a blood transfusion are excluded from 1st February 2004.

Stock Effects

The chart below shows what the effect of exclusion might be on stock[6] if it is implemented on 1st February.



Under this scenario with February implementation stock levels never recover to 50,000 target level following the early January dip. Under 3.3% loss scenario, stock remained above 50,000 units until early March. Thereafter the speed with which stock falls through the various thresholds is much more accelerated with 6.5% collection losses. With February 1st implementation the 3.5 day alert is reached on 24th April, more than a month earlier than with 3.3% losses.

The gap between reaching 3.5 days stock and zero stock is also greatly shortened – being reached at the end of May (more than 4 months earlier) than it would be if only those answering yes were excluded. There is a brief recovery above zero-stock during the summer, but to very low levels which would not prevent significant shortages.

The critical dates are summarised in the table below:

	Feb 1st
Start of Stock Decline	04/03/2004

[6] The 'probable' stock line is estimated by superimposing the theoretical stock line on an average stock cycle based on stock information from January 2000 to December 2003

Date Stock Falls Below 50k units	*
Date Stock Hits Stock Alert (3.5 days)	24/04/2004
Date Stock Hit Zero	31/059/2004
* stock never reaches 50,000 units following early January dip	