Vox Sanguinis International Forum on donor notification and counselling strategies for markers of transfusion-transmissible infections

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Canada, Canadian Blood Services

Question 1

Canadian government Food and Drugs Act, Blood Regulations (s. 43) require donor notification in person or in writing, if a donor is found unsuitable for donation. Canadian Standards Association (CSA) standards for blood and blood components (Z902-15 s. 5.1.6 and 5.1.9) state that a donor be told that blood donations are tested and that abnormal results will be communicated to the donor. Although not mandatory, CSA Standards are followed by Canadian Blood Services.

Question 2

Donors are notified by letter of any repeat-reactive serologic or positive nucleic acid test result; a letter is sent within 10 working days of receiving supplemental/confirmatory test results. In addition, a donor with positive supplemental/confirmatory test results for West Nile virus or Chagas (*T. cruzi* antibody) will also be contacted directly by phone, while donors with positive supplemental/confirmatory HIV test results will also generally be contacted by a Medical Officer. Donors with hepatitis B virus results possibly related to recent hepatitis B vaccination are also often contacted directly by phone by a Canadian Blood Services Medical Officer.

Question 3

Yes, all positive test results for reportable diseases under provincial legislation, must be sent to the regional Medical Health Officer where the donor resides. Reportable diseases in all provinces include: HIV, Hepatitis B and C, and syphilis. Some (but not all) provinces also require reporting of transfusion transmissible or rare/serious/uncommon diseases, including: HTLV, West Nile virus, or Chagas. Positive Cytomegalovirus or bacterial test results are not reportable in any province.

Question 4

Donor letters are sent out by two regional Medical Offices under the review of a nurse or Medical Officer. Donors who call for counselling or advice speak to either a trained nurse or to a Medical Officer.

Question 5

Donors are informed by letter of their test results and also receive a copy of a physician letter to bring to their family doctor. They are advised to follow up directly with their family doctor. Canadian Blood Services does not perform diagnostic testing for blood donors.

Question 6

Donors with repeat-reactive transmissible disease markers, whether subsequently interpreted to be false-reactive, indeterminate or confirmed positive, are encouraged to follow up with their family doctor for further testing if indicated. Repeat testing by the donor's family doctor, through a diagnostic laboratory, is specifically recommended for positive supplemental/confirmatory donor test results. Donors may also contact a Canadian Blood Services Medical Officer to discuss their results if desired.

Question 7

Except for the province of Québec, served by Héma-Québec, there is no regional/national blood donor registry external to Canadian Blood Services. Canadian Blood Services' national electronic donor information system automatically updates all donor screening test results in real time.

Question 8

Donors who test repeat-reactive on initial screening but negative/indeterminate on confirmatory testing for HBsAg, anti-HCV, anti-HIV are eligible for re-entry after a 6 month deferral period. If the donor again tests repeat reactive for the same or a different marker, he/she is then permanently deferred, even if the final interpretation is not 'confirmed positive'. The current donor re-entry program does not include repeat-reactive, confirmatory-negative HTLV. Donors who test repeat-reactive on initial screening but negative/indeterminate on confirmatory testing for any marker are acceptable for autologous donation.

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France

Question 1

Blood donors are always informed of any biological abnormalities (positive infectious markers, abnormal count of hemoglobin or platelet...) discovered on their initial blood donation. This information is based on screening tests (serological or genomic ones) and additional analysis if necessary (eg: immunoblot, IFI). The result of these tests can be positive or indeterminate.

When an infectious marker is discovered (HIV-NAT/antibodies, HCV-NAT/antibodies, HBV-NAT/HBsAg/ anti-HBc, Syphilis, trypanosoma cruzi and malaria antibodies), the donor is invited by letter to an interview including information about the detected infection and investigation about potential risk factors.

A questionnaire is completed by the blood bank physician who has performed the interview. The donor is then addressed to a specialist clinician for a therapeutic management. A new sample is collected to confirm the previous results. The results of biological abnormalities are given to the donor by the authorized qualified physician of the EFS (i.e., the French National Blood Services).

Question 2

In case of a biological abnormality, a letter is sent to the donor by an EFS physician. This letter only mentions that a biological abnormality has been found and that an additional biological control needs to be performed. At this stage, the donation biological results or the infectious marker are not communicated. This notification period does not exceed 10 days but its duration may depend on the achievement of confirmatory testing. Thus, this period may be reduced to a few days (or 48 h after the donation) in the case of HIV-1 pre-seroconversion profile that requires quick information and therapeutic support. In such a case, a physician will contact the donor by phone for an appointment without delay. For donor who does not respond, internal procedures set the conditions as per which a registered letter may be sent and/or a follow-up phone call may be made. As soon as the results of the biological control are available and confirmed, donors are referred to a specialized center.

Question 3

Yes since 1992, the report of every confirmed positive markers (HIV, HCV, HTLV, HBV, syphilis) detected in French blood donors is mandatory. This information is reported to the French Institute for Public Health Surveillance (InVS). InVS performs epidemiological monitoring of blood donors and based on these data assesses the residual risk of transfusion transmissible infections. The biological data corresponding to each positive marker discovered are recorded in the EFS national database and electronically transmitted to InVS. In addition, a second independent institution, the National Institute of Transfusion Sanguine (INTS) is informed and biological samples are sent in order to performs surveillance of viral diversity of major transmissible viruses (HIV, HCV, HTLV, HBV) identified among blood donors.

Question 4

In each regional blood center, an EFS physician is trained to interview and to provide information in order to become qualified to perform donor notification. A procedure describes the qualification conditions of this

physician, as well as the time required for the information of the donor and the nature of information collected, the data privacy rules applicable the information exchanged. When the donor refuses the interview by an EFS physician and prefers to see another practitioner, the procedure also describes the way the epidemiological information is communicated. The physician is also trained to advice the donor on prevention of secondary transmission. Definitive or temporally deferrals period (according to the regulation) is allowed to the donor and recorded by a specific code in the national software.

Question 5

The control sample (blood sample collected but without new blood donation) is analyzed in order to confirm the detection of the presence of the infectious marker previously detected. The same serological and/or genomic technics, than those used to find a positive result on the blood donation, are carried out. The physician in charge of blood collection and donor monitoring will send the results of these new testing by letter.

Question 6

Blood donors with confirmed infection for HIV, HTLV-I, HCV, Chagas disease and Malaria, are permanently deferred for blood donation. In case of positivity for HBsAg (and/or HBV DNA), the donor is temporarily deferred. Plasma for fractionation from the donor with HBsAg (and HBV DNA) negative and anti-HBc positive can be used if anti-HBs rate is higher than 0·5 IU/ml.

Question 7

Each notification of positive donor for transmissible infectious markers are centralized in an EFS national database and reported to InVS. A national specific software has been implemented within EFS database since 2010 collecting all information on positive donations available (epidemiological, biological. . .) and activity data (number of candidates, first time and repeat donors, deferred donors, rejected donations. . .).

Question 8

Donors tested non reactive on repeat testing may be accepted for re-entry in donor pool.

Return to donation after blood sample control could be permitted only if biological interpretation of all results concerning the implicated pathogen indicates that the donors is not infectious and after a sufficient delay permitting to observe a seroconversion profile.

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Hong Kong

Question 1

In Hong Kong, donors with confirmed positive results of testing for infectious markers (HIV, HBV, HCV, HTLV and syphilis) will be notified, counselled and referred to specialist clinics for follow up.

Question 2

Once the results are available, donor notification will be initiated. Donors with confirmed hepatitis B will be notified by post with information on hepatitis B and follow up. For other infectious diseases, donors will be contacted by phone and invited to come back for counselling. If they are not contactable by phone, a letter/email will be sent to the donors' corresponding address/email address and ask them to contact the Blood Transfusion Service for further information.

Question 3

Reporting is on a voluntary basis. However, if hepatitis B is confirmed as recent infection, the Blood Transfusion Service is required to notify the Department of Health.

Question 4

The medical staff of the Blood Transfusion Service is responsible for donor notification and counselling.

Question 5

Usually no further testing is required in confirmed sero-conversion cases. For NAT yield cases or suspected window donations, follow up samples are taken for demonstration of sero-conversion or for alternative molecular procedures as confirmation testing for reactive NAT screening results.

Question 6

See response to Q1.

Question 7

No.

Question 8

Donors with confirmed positive results of testing for infectious markers including HIV, HCV, HTLV and syphilis will be deferred permanently and after counselling, referred to specialist clinics for follow up. Neither repeat testing nor re-entry program will be arranged for them.

However, for donors whose had confirmed positive HBsAg results in their previous blood donation records but found to be non reactive by their own doctors and come forward for blood donation, a repeat testing will then be arranged for them. Re-entry will be considered if the testing results showed negative results for HBsAg and HBV NAT together with anti-HBs > 100 mIU/ml.

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India

Question 1

The Action Plan for Blood Safety, National AIDS Control Organisation (NACO), Ministry of Health and Family Welfare (MOHFW), Government of India (GOI), is the key document which addresses the operational strategies for objectives listed in the National Blood Policy [1]. It is mandatory to test each unit of donated blood for five infectious markers; hepatitis B surface antigen (HBsAg), antibodies to hepatitis C virus (anti HCV), antibodies to HIV 1 and 2 (anti HIV 1 & 2), VDRL test for syphilis and test for malarial parasite [2]. As per subsections 4·16–4·19 of the objective 4 of the Action Plan for Blood Safety, specific consent of the donor should be taken in respect of disclosing the result of the tests. Hence only if the donor has given the consent of knowing the TTI test result at the time of filling the donor questionnaire, he/she is requested to visit the blood bank personally 'as some of the immediate test results are not conclusive and need to be confirmed'. If the blood sample of the donor has been found to be reactive for anti HCV or HBsAg, the donor is counselled and a fresh sample is drawn in the blood bank. If the second test confirms sero-reactivity to hepatitis B or C, the blood donor is to be referred to a physician. In case the donor unit tests reactive for syphilis or is positive for malarial parasite, the donor is to be referred to a physician without any second test in the blood bank.

A blood donor sero-reactive for HIV is referred to linked Integrated Counselling and Testing Centres (ICTCs) as notified by NACO, MOHFW, Government of India. In the ICTC, comprehensive counselling is provided to the donor, a fresh sample is drawn for confirmatory tests and if the donor is confirmed positive then further management, referral for, care and support is organised through the ICTCs. There are over 4000 ICTCs in the country and largely located in government hospitals.

Since NAT testing is not mandatory in India, there is no policy/guideline on notification of blood donors who

are NAT reactive but serologically non-reactive. NAT testing however has been implemented in some of the blood centres in the country but there is no uniformity in practice regarding notification of NAT only reactive blood donors.

Question 2

Communication to the donor for purposes of notification is performed through telephone. The contact number of the donor's mobile phone is noted on the donor questionnaire at the time of donor screening. At least three telephonic calls are made within 1 month of the donation to those who tested reactive. For those donors who do not respond to the calls, messages (SMS) are sent to the donors on their mobile phones. For those donors who do not respond/return a reminder call/message is sent again after 3 months. The attempts to call the donor are documented.

Question 3

All blood centres are required to send a detailed monthly report of total blood collection, component preparation, TTI testing and seroprevalence of HBsAg, anti-HCV, anti-HIV and 2, VDRL reactivity and malaria positivity to National AIDS Control Organisation where the national database related to blood centres is maintained. In the Union Territory (UT) of Chandigarh, where our institute is located, malaria has been declared as a notifiable disease with effect from January 2016, under the National Vector Borne Disease Control Programme [3]. A weekly report of malaria testing results in blood donors is submitted to the office of the Director Health and Family Welfare, UT, Chandigarh.

Question 4

Our blood centre is actually an academic department of transfusion medicine within a super-speciality medical institute. The transfusion transmissible infection screening laboratory of the department is directly supervised by a consultant of the designation of assistant professor. The technologists perform the tests; the test results are verified by the senior resident and finally approved by the consultant. For sero-reactive donors, the donor details and specific consent for revealing TTI test results are checked from the blood donor history and consent questionnaire (adapted from the template approved by the National Blood Transfusion Council, NACO). The relevant donor details and TTI test results are documented in the donor notification register. The consultant/senior resident then contacts the donor for the further notification and counselling.

Question 5

When the blood donor reports back after notification he/she is counselled by the consultant and consent is obtained for repeating the test on a fresh sample in case of sero-reactivity for hepatitis B and/or hepatitis C, HIV 1 and/or 2. The test on the fresh sample is performed using ELISA/rapid kits from two different manufacturers or if from the same manufacturer, from two different lots. In our departmental policy for procurement of TTI testing kits, both ELISA and rapid kits for each infectious marker are procured from two different manufacturers. If the results of the initial test from the pilot sample tube and the donor are concordant, the donor is labelled in the records as repeat reactive. A structured risk assessment form is filled up for the information on risk factors that may have contributed to the infection. For syphilis and malaria no repeat testing is done in the department.

Question 6

Our institute is a tertiary healthcare academic centre with several clinical specialities and superspecialilties and we have implemented a well co-ordinated reactive donor referral strategy with the clinical services. Donors testing repeat reactive are referred on a structured referral format to the consultant of the concerned clinical speciality to aid the blood donor to be seen on priority at the outpatient clinic. The donor sero-reactive for hepatitis B and/or hepatitis C is referred to the outpatient clinic of the Department of Hepatology of our institute. The donor sero-reactive for anti HIV 1 and/or 2 is referred to the ICTC managed by the Departments of Immunopathology and Internal Medicine. The HIV reactive donor is accompanied in person to the ICTC by the medical social worker in our department. The donor reactive for VDRL/RPR test is referred to the STI (Sexually Transmitted Infections) clinic of the Department of Dermatology and Venereology. The donor positive for malarial parasite test is referred to the Internal Medicine outpatient services for treatment.

Question 7

No, there is no Regional/National centralized registry of blood donors positive for the TTI markers, where we have to report the case. As mentioned previously a TTI seroprevalence report and donor recall data is sent to NACO on a monthly basis.

Question 8

As per the national Action Plan for Blood Safety, a blood unit that is once reactive on TTI testing has to be discarded in accordance with the existing biomedical waste management and handling rules. There are no national guidelines in our country for follow up plan and advise for the donors found to be non reactive on repeat testing. After review of the literature on the topic our department has adopted the policy to keep such a donor on follow up for repeat testing at intervals of 3 months up to a period of 1 year. During each visit a fresh sample is drawn for serology and NAT testing after obtaining donor's consent. The sample is tested with three different ELISA/EIA kits and ID-NAT. If the serology and NAT are non-reactive on all follow-up samples then the initial result is interpreted as false positive and no further recall of the donor is done. However since there is no national policy/guidelines for donor return to donation, we do not advise these donors of any future donations on the precautionary approach. In the event of a repeat reactive result obtained with kit from only one manufacturer the reactivity status is labelled as inconclusive. In these circumstances the donor is referred to the clinical services for further investigation and follow-up.

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3 National Vector Borne Disease Control Programme, Directorate General of Health Services, Ministry of Health & Family Welfare. Available at: http://nvbdcp.gov.in/Doc/Strategic-Action-Plan-Malaria-2012-17-Co.pdf. [Last accessed 22 April 2016]

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Japan

Question 1

A Law for securing stable supply of safe blood enacted in 2003 asks blood collectors (Japanese Red Cross Blood Service, JRCBS, is an only one licensed blood collector in Japan) to protect donors. However, there is no specific regulation nor a national guideline for notification of donors whose blood were positive for infectious disease screening tests. JRCBS notifies donors according to its own SOP and manual.

Question 2

Donors are notified by mail soon after the testing procedures for notification are completed.

Question 3

We are not mandated to report a private donor test result to any public authority. We only report the trend of donor HIV-positivity to the AIDS Trend Committee of the Japan Foundation for AIDS Prevention every 3 months.

Question 4

Mails for notification are sent from each Block Blood Center where the tests are conducted under the responsibility of Block Blood Center Director. In the Block Blood Center, the Donor Registry Division is responsible for notifying the donor by mail and the Blood Examination Division is responsible for donor counselling (mainly over the phone).

Question 5

Donors are recommended to consult physicians of medical institutions in the notification mails. They are also welcomed to call back to the Blood Examination Division when they have any questions to the notification.

We usually do not repeat the test or follow up the disease unless there is special need and request from the donors.

Question 6

As mentioned above, we inform the donors of positive test results with a letter advising them to go to the clinic and asking them not to donate blood any more.

We refer donors to the specialists on request from donors.

Question 7

JRCBS is the only one blood service in Japan. All the data of donors, collection, testing, processing, and distribution are registered in our national IT system.

There is no Regional/National centralized system to which we have to report positive cases.

Question 8

As we inform the donors of positive test results with a letter advising them to go to the clinic and asking them not to donate blood any more, those donors usually do not come to donate. However, some donors may come again and their test results might be non-reactive. In those cases, we do not use the blood for processing nor notify.

For these donors, we have a formal re-entry program in which donors can resume donating blood if their test results are repeatedly found to be non-reactive at least twice at a certain interval.

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Russia, Sverdlovsk Region

Question 1

Guidelines ‘Algorithms of donor survey, blood components culling and removal donors from the donation by the results of research on infectious markers’ approved by the Ministry of Health of Sverdlovsk region from 01·10·2010 are in use now. The algorithm and the tactics of each department after receiving the results of research from the laboratory are provided for every transfusion-transmissible infection with methodical recommendations.

The sequence of actions and measures of culling products are defined in the guidelines:

1 Blood components subject to be in quarantine.
2 Blood components being in quarantine.
3 Blood components not subject to be in quarantine.

It’s planned to update the document to make additions according to the current sanitary rules of Russian Federation.

In case of receiving a positive result of primary screening a mark ‘delayed’ is put into Automated Information System of Transfusions (‘AIST’). The donor doesn’t get the information about the positive result of the screening. In case of receiving a negative result of the confirmatory test, the procedure is defined for every infection with the guidelines.

In case of reactive serological re-examination the blood components are rejected. The donor will be suggested just to be surveyed next time. Donors, whose primary screening was positive, but all the secondary (not less than three examinations) were negative and the negative result was verified with the confirmatory test, are informed of the results of non-specific serological reaction and removed from the donation.

Question 2

Time periods are different and regulated with the ‘AIST’ program. Specifically, there is no reference to the situation. The problem is solved by experts of laboratory together with the transfusiologist. The time of appearance of new infection markers is taken into consideration.

Question 3

We inform the regional AIDS center about positive result of primary HIV examination. After receiving positive results of primary screening test we give the

information about the donor and about the number of his donation. After getting a positive result of the confirmatory test we issue a 'Notice of identification of human donors in HIV, hepatitis B, hepatitis C. Information about the donor'. The form of the document is approved by the Russian Federal Consumer Rights Protection and Human Health Control Service. We upload the information from 'AIST' via MS Excel.

The form contains information about the donations in the last 12 months (the date of the donation, what was prepared, the number of donation, barcode, information of giving the component: waybill number, the date, the name of the recipient.) This form is sent to the Russian Federal Consumer Rights Protection and Human Health Control Service and to Sverdlovsk regional AIDS center.

Question 4

According to the order, the specialist of donor department is responsible in the center, but a chief of a brigade is responsible in exit conditions.

Question 5

If a donor was recommended to repeat the test in a regular 1 or 3 months' period, the blood is taken only in a test tube. After conducting research and obtaining results the problem is solved by the transfusiologist.

Question 6

The algorithm is defined. The donor is rejected from donations. The components are being destroyed.

Question 7

Regional register is conducted by a Blood banking service itself. All information from Russian Federal Consumer Rights Protection and Human Health Control Service and Sverdlovsk regional AIDS center is updated on a time basis at least once a month and the specialists of a donors' compilation department put it into 'AIST'.

Question 8

Here in a Facility after re-examination and getting a negative result the examination is surveyed according to the guidelines. A donor will be allowed to participate in a donation. There is also a sequence of actions of restoration in a donation even if the donor is put in a 'Constant rejection from donation' status column. A donor will be referred to examination in scheduled period. The specialists of a donors' compilation department make an analysis of circumstances, the reasons of a 'Constant rejection from donation' column, then they ask the laboratory of a possibility of donorship's restoration. The laboratory a nalyses the history of re-examination and the reason of the enquiry itself. On a basis of negative (at least in 1 month's period) re-examinations (at least twice), which were gotten in the Blood banking's laboratory. The laboratory's specialist (manager) counsels – *recommended to restore in donorship* – the decision is made collectively.

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Russia

Question 1, 2

In case of positive result of a screening test (serological reexamination or detection of nucleic acid in a separate donation) donor has to be invited to blood establishment for counseling as soon as possible.

Question 3

We inform the regional AIDS center about positive result for HIV and regional health authority about HBV, HCV and syphilis.

Question 4

Specially trained physician of blood donor center.

Questions 5, 6

Each region has specially designated clinic (AIDS center, infection hospital, venereal dispensary etc.) for thorough

medical examination (and treatment if necessary) of deferred donor.

Question 7

Yes, all our blood establishments has to send information to web-based protected blood donor database with register for deferred donors.

Question 8

If donor did not appear to have markers and clinical signs of transfusion-transmissible infections in a re-examination in above-mentioned designated clinic, he (or she) may return to blood establishment. After evaluation of the donor documents commission of blood establishment may allow the donor to donate again.

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Saudi Arabia

In Saudi Arabia the blood transfusion services is fragmented hospital based services and nationally Ministry of Health is responsible for these services nationally.

Question 1

To do confirmatory testing if positive to inform donors through electronic message (mobile phone text message) or phone call to come for review of their results with BTS physician then do counselling for the donor by BTS physician and refer to Speciality physician for management and follow up.

If testing is indeterminate the donor will be deferred temporarily and asked to revisit the donation room to recheck the investigation after 2–3 months, if the results including confirmatory tests are negative the donor will be considered for donation after counselling with the BTS director or designee doctor.

Unit will be considered as positive in both scenarios and the unit will be discarded.

Question 2

As soon as donor results confirmed there is a *message* to be send to the donor asking him to come for getting his results.

The staff *call* donors to ask them to come for getting their results, if they not answer they try again.

This usually done in 1–3 days after donation and results confirmed.

Question 3

Yes, all Confirmed serology positive donors will be reviewed (Counselled) by Medical Director or his/her designee then their results will be sent every week (Sunday) to the infection control department along with a copy of their id and questionnaire form to be referred through *Infection Control Department* to the proper channel (*Ministry of Health*) and all confirmed positive donor results will be referred to Infectious Disease clinic for further Counselling and treatment if needed.

For HIV Confirmed positive donors will be informed to the Infection control department immediately same day after confirmatory results is out for their further process of counselling and treatment.

Quesiton 4

The responsibility is for Supervisor of donation services or his designee to notify the Donors and asked him/her to visit the Counseling clinic to be counseled by physician in charge of donor center, the Medical Director or his/her Designee.

Question 5

Usually any Donors/Units found to be positive for any of the serological investigation will be repeated in duplicate. If any one of them or both are positive, the Donor/Unit will be considered as positive and sample send for confirmatory testing. If testing confirmed positive from first time donor is deferred permanently and the unit will be discarded. If both are found to be negative and the confirmatory test are negative the unit should be discarded and the donor will be deferred temporarily and asked to revisit the donation room to recheck the investigation after 2–3 months, if the results including confirmatory tests are negative the donor will be considered for donation after consultation with the BTS director or designee doctor.

If Donor comes after notification all tests are repeated and counselling is done.

Donors will be either deferred as temporarily or permanent and reported in the system that in case donor return his status will be shown in the system for staff as deferral that they can not accept as active donor but his results will be confidential not shown except to Authorised personnel.

Question 6

Donors after counselling and report all information into the donor notification form in a strictly confidential manner are referred to specialised physician for management and follow up.

Question 7

There is no national registry of blood donors positive for TTI yet but all cases are reported to Ministry of health as mandatory requirement and MOH keep records of all positive donors.

Question 8

If any donors found to be positive for any transfusion transmissible infectious testing will be repeated in duplicate. If both are found to be negative and the confirmatory tests are negative the unit should be discarded and the donor will be deferred temporarily and asked to revisit the donation room to recheck the investigation after 2–3 months, if the results including confirmatory tests are negative the donor will be considered for donation after consultation with the BTS director or designee doctor and, re-entry program in the IT system is there to return donor (change status) from temporary deferral to active donation.

The program of re-entry is not unified in the country for all hospitals (it could be manual or electronic) but the deferral policy, mandatory reports to Ministry of health and testing algorithm (policy) are unified in the whole country.

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Singapore

Question 1

Currently there is no regulatory requirement for donor notification in event of a positive screening test in Singapore provided that the supplementary or confirmatory test is non-reactive or inconclusive.

Nonetheless notification of donors with a positive screening test is standard practice and part of the Standard Operating Procedure at Blood Services Group.

Question 2

Donors with a positive screening test are notified formally by post within a month, followed by a formal counselling session with one of our physicians at the blood centre.

The exception would be donors with a positive HIV screening test; these donors are contacted by phone within a week and a formal confidential interview arranged with a senior blood bank medical doctor within 2 weeks. The test results would only be informed to the donor during the private interview session.

Question 3

Currently there is no mandatory requirement to report positive donor screening test results to our public health agency (Ministry of Health). It is only mandatory to report confirmatory diagnostic test results.

Donation samples that are positive on donor screening tests at the blood bank are sent for confirmatory testing at an external laboratory; positive results on confirmatory tests are reported by the external laboratory directly to the Ministry of Health.

Donors with positive HIV screening results are the exception. Once the blood bank receives a positive confirmatory HIV test result (Western Blot) from the external laboratory, we would report these cases, along with all HIV screening and confirmatory results, to the Ministry of Health.

Question 4

Designated senior blood bank physicians are responsible for notifying and counselling affected donors.

Question 5

Donors with clear-cut, conclusive positive results (screening and supplementary/confirmatory tests results are

concordant) would be permanently deferred from blood donation. They would also be advised on the significance of their test results and referred for further medical assessment and treatment.

Donors with inconclusive results on screening tests and a negative result on confirmatory testing are usually deferred for a period of time (example, 6 months), after which they may resume donation if the subsequent test becomes negative. These donors would be similarly informed about their results and advised on when they may resume donation.

Question 6

These donors are referred to the appropriate medical specialist clinic for further testing and follow-up management. For example, donors who test positive for viral hepatitis markers would be referred to a liver specialist, whilst donors testing positive for malaria or HIV would be referred to an infectious diseases physician for further care.

Question 7

Blood Services Group assumes the role of the central registry of blood donors positive for transfusion transmissible infectious markers. In addition, the blood bank also regularly updates the Ministry of Health with collated data of donors testing positive for these markers.

Question 8

Repeat donor testing is usually not offered if the test results on the donation sample were conclusive. These donors are deferred permanently.

In cases where the test results are ambiguous or there is discordance between screening tests and confirmatory test results, donors would be reviewed on a case-by-case basis for retesting and/or re-entry as donors after a specified deferral period.

For example, donors who are weakly positive for viral hepatitis NAT, but negative on all serological markers and confirmatory/supplementary tests may be offered repeat testing on request. The donor would be considered for possible re-entry if repeat NAT testing was negative and all serological tests are negative.

Donors who are positive on HBs Ag screening tests but negative on HBV NAT as well as repeat HBs Ag testing with neutralisation are deferred for 6 months, after which they may resume blood donation if all the repeat tests are negative. Similarly for donors who are positive on the Anti-HCV screening test, but negative on HCV NAT and Anti-HCV supplementary tests (LIA or RIBA).

Donors who are reactive on the Anti-HIV screening test, but negative on HIV NAT, along with a negative or indeterminate Western Blot result, would also be eligible to resume blood donation after a 6 month deferral if all the repeat tests are negatives.

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South Africa

Question 1

The South African National Blood Service is enabled in legislation in South Africa, specifically the National Health Act (No. 61 of 2003) [1]. This is effected through the granting of a license for the establishment of a national co-ordinated blood transfusion service. The National Health Act is subject to the Constitution of South Africa (Act 108 of 1996) and the Bill of Rights.

The National Health Act stipulates that the licensed blood transfusion service must comply with the provisions of Standards of Practice. The Standards of Practice for Blood Transfusion in South Africa (6th edition, 2013) [2] is approved and endorsed by the medical directors and executive committees of the licensed blood transfusion service. Standard 20 – Notifying donors of abnormal test results – states;

'20·1 The establishment shall send a letter or notify donors verbally of any medically significant abnormality detected during the pre-donation evaluation or as a result of subsequent laboratory tests and advise them to seek counselling and/or treatment.

20·2 All putative HIV positive donors should be requested to return to the establishment for confirmation and counselling where possible and a record shall be kept.'

The relevant standard is interpreted within SANBS through a standard operating procedure (SOP-MLD-006 and SOP-MLD-015). The above Notification and counselling is performed on donations that test concordantly serology and NAT repeat reactive. Donations that are repeat reactive but discordant between NAT and Serology are requested to return for follow up confirmatory testing (see below in INF-DTD-001).

Question 2

The Medical Liaison Officer (MLO) contacts the donor telephonically immediately after the results have been verified and confirmed with Donation Testing Department. The MLO during the call will also confirm with the donor if the contact details on the system are correct to send a letter and how they would prefer it to be done i.e. postal, email etc.

Based on standard operating procedures, donors are informed of the above scenarios through a standard letter sent to the donor's postal address or email as recorded on the SANBS donor database. For all other testing markers excluding HIV, the letter includes the test results, possible interpretations of test results, donor status and recommendations to have the test results analysed by a physician of the donor's choice. The letter must be sent within 3 weeks of the donation date.

There is no stipulated time-frame for communicating the result to donors telephonically; however the donor status is recorded on the internal donor database at the release of the test results.

Question 3

No. The donor is provided with post-test counselling and written notification for follow up of test result with a physician of the donor's choice. The physician is then only given the results provided the donor has given consent for us to do so.

Question 4

This function is performed by medical liaison officers (MLO) who are registered nurses with HIV counselling certificates and experience. These MLOs report and are supported by Medical Managers/ Officers who will also assist as and when required.

Question 5

This is located within donation testing algorithms (INF-DTD-004 Virology Supplementary algorithm for discordant results).

At the time of counselling the MLO performs an HIV rapid test to confirm that the donor presenting is HIV positive. Positive donors are deferred permanently form donating blood thereafter.

Question 6

Donors found to be reactive on repeat testing are counselled on the effects of the infectious agent by the blood establishment, advised to follow-up the test result in consultation with a physician of the donor's choice and the donor is permanently deferred from blood donation on our systems. The latter is effected through a marker indicating the result of the positive test linked to the donor's unique identification parameters on a SANBS IT database.

Question 7

The internal, national SANBS donor database routinely records the data of all test results in donors post-donation. This database is however not available to third parties, e.g. a public health agency. A National Blood Committee chaired by the national department of health has not been functioning since 2008 and an independent regulatory body has not been established.

Question 8

Donors with these testing results are marked as 'evaluate' on the SANBS donor database, telephonically contacted and sent a standard letter indicating the need for retesting. On the donor returning for the relevant confirmatory test and being found negative, the donor is sent another letter discussing the test result indicating the donor is eligible to donate. (SOP-MLD-017).

References

1 National Health Act (No. 61 of 2003)

2 *The Standards of Practice for Blood Transfusion in South Africa*, 6th edn. South Africa, 2013

NAT AND SEROLOGY ALGORITHM

SANBS

Registration No. 2000/025910/07

KEY: PSY = Possible Serology Yield; BF = Biological False; CF = Confirmed, PNY = Possible Nat Yield; UY = Untyped Yield; LO = Liaison Officer; ML = Medical Officer

INDEX DONATION													CONTACT DONOR		FOLLOW-UP SAMPLES		Comments
No	ID NAT				SEROLOGY			Meditech Classification	Additional Testing	Donor Status	Unit Status	RCC / Buffy Coat	Plasma	Contact - Donor	Time & Number of contacts	Tests on Follow-up Samples	Look Back	
	Initial	Rep 1	Rep 2	dHxV	Initial	Repeat	Conf											
1	NR	N/D	N/D	N/D	NR	N/D	N/D	None	No further testing	Active	Available	Available	Double tested system	None	None	Not done	No	
2	R	NR	NR	NR	NR	N/D	N/D	NRR	No further testing	Active – add HBc Marker for HBV	Contaminate	Destroy	1 Aliquot	None	None	Not done	No	
3	R	NR	NR	NR	R	NR	N/D	NRR	No further testing	Active – add HBc Marker for HBV	Contaminate	Destroy	1 Aliquot	None	None	Not done	No	
15	NR	NR	NR	NR	R	NR	N/D	None	No further testing	Active	Available	Available	Double tested system	None	None	Not done	No	
4	R	NR	NR	NR	R	R	R	HIV PSY HCV PSY HBV PSY	Serology Yield - Refer to INF-DTD-004	Evaluate	Contaminate	Destroy	Aliquot into 3-5ml tubes (entire unit)	HIV-FRM-MLD-005 HBV-FRM-MLD-003 HCV-FRM-MLD-004	ASAP a = 3; b = 1; c = 1	Refer to INF-DTD-004	Hold look back for 6 weeks so that donor can be retested. LO to consult with LC or MO	
12	NR	N/D	N/D	N/D	R	R	R	HIV PSY HCV PSY HBV PSY	Serology Yield Refer to INF-DTD-004	Evaluate	Contaminate	Destroy	Aliquot into 3-5ml tubes (entire unit)	HIV- FRM-MLD-005 HBV-FRM-MLD-003HCV-FRM-MLD-004	ASAP a = 3; b = 1; c = 1	Refer to INF-DTD-004	HIV & HBV perform look back immed. HCV hold look back for 6 weeks so that donor can be retested	
16	N/D	N/D	N/D	N/D	R	R	R	HIV PSY HCV PSY HBV PSY	Serology Yield Refer to INF-DTD-004	Evaluate	Contaminate	Destroy	Aliquot into 3-5ml tubes (entire unit)	HIV- FRM-MLD-032 HCV-FRM-MLD-028 HBV-FRM-MLD-023	ASAP a = 3; b = 1; c = 1	Not done	HIV & HBV perform look back immed. HCV hold look back for 6 weeks so that donor can be retested	

No	ID-NAT Initial	ID-NAT Rep 1	ID-NAT Rep 2	dHxV	Serology Initial	Serology Repeat	Serology Conf	Meditech Classification	Additional Testing	Donor Status	Unit Status	RCC / Buffy Coat	Plasma	Contact - Donor	Time & Number of contacts	Tests on Follow-up samples	Look Back	Comments
5	R	NR	NR	NR	R	R	NR	HIV BF HCV BF HBV BF	Biological False Pos - No further testing	Active - add HBc Marker for HBV	Contaminate	Destroy	Aliquot 3x 3.5ml - Store remaining tubes	None	NA	Not done	No	IF DTD for 2, 3 or 4+ tests, refer to SOP for Donor Follow-up
13	NR	N/D	N/D	N/D	R	R	NR	HIV BF HCV BF HBV BF	Biological False Pos - No further testing	Active - add HBc Marker for HBV	Contaminate	Destroy	Aliquot (1) - store unit	None	None	Not done	No	
6	R	R	R /NR	NR	R	R	R	HIV CF HCV CF HBV CF	No further testing	Permanent inactiv	Contaminate	Destroy	Aliquot (1) - store unit	HIV-FRM-MLD-032 HCV-FRM-MLD-028 HBV-FRM-MLD-023	ASAP a=3; b=1; c=1	Not done	Yes	Check for dual positives prior to finalising outcome
7	R	R	R/NR	R	R	R	N/D	HIV CF HCV CF HBV CF	No further testing	Permanent inactiv	Contaminate	Destroy	Aliquot (1) - store unit	HIV-FRM-MLD-032 HCV-FRM-MLD-028 HBV-FRM-MLD-023	ASAP a=3; b=1; c=1	Not done	Yes	
8	R	R	R	R	R	R	R	HIV CF HCV CF HBV CF	No further testing	Permanent inactiv	Contaminate	Destroy	Aliquot (1) - store unit	HIV-FRM-MLD-032 HCV-FRM-MLD-028 HBV-FRM-MLD-023	ASAP a=3; b=1; c=1	Not done	Yes	
14	R	R	R	R	R	R	N/D	HIV CF HCV CF HBV CF	Refer to INF-DTD-004	Permanent inactiv	Contaminate	Destroy	Aliquot into 3.5ml tubes (entire unit)	HIV- FRM-MLD-032 HCV-FRM-MLD-028 HBV-FRM-MLD-023	ASAP a=3; b=1; c=1	Not done	Yes	
9	R	R	NR	NR	NR	N/D	N/D	NAT UY	Untyped NAT Yield - Refer to INF-DTD-004	Evaluate	Contaminate	Destroy	Aliquot into 3.5ml tubes (entire unit)	Phone for recall and send Retest letter FRM-MLD-033	ASAP Contact - At least 2	Refer to INF-DTD-004	Hold look back for 6 weeks so that donor can be retested. LO to consult with LC or MO	
10	R	R	R	NR	NR	N/D	N/D	NAT UY	Untyped NAT Yield - Refer to INF-DTD-004	Evaluate	Contaminate	Destroy	Aliquot into 3.5ml tubes (entire unit)	Phone for recall and send Retest letter FRM-MLD-033	ASAP Contact - At least 2	Refer to INF-DTD-004	Hold look back for 6 weeks so that donor can be retested. LO to consult with LC or MO	
11	R	RJ NR	RJ NR	R	NR	N/D	N/D	HIV PNY HCV PNY HBV PNY	NAT yield - Refer to INF-DTD-004	Evaluate	Contaminate	Destroy	Aliquot into 3.5ml tubes (entire unit)	Phone for recall and send Retest letter FRM-MLD-033	ASAP Contact - At least 2	Refer to INF-DTD-004	Hold look back for 6 weeks so that donor can be retested	

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Spain

Question 1

We, basically, follow CoE recommendations (1), but due to spanish transposicion text in RD 1088/2005 (2) of Directive 2002/ 98/CE (3) there are differences in its interpretation. It is mandatory to recall repeatedly reactive (RR) serological results of the donors at the initial sample and proceed with a second one, in order to do confirmatory test. Discrepancies arose based on the kind of test we perform on rutin (CMIA, QLMIA) and that we make now, high sensibility NAT technics in each sample or pool ($\leq \times 6$). The RR serological samples with NAT negative are retested by mean of different technical principle (WB or inmunoblot) in HIV or HCV cases and neutralization test in HBV.

All donors positive confirmed with results RR plus NAT positive and/or second kind serological test, are requested for a second sample. The cases of HBV and HCV can recieve a brief information and they are invited to come for new tests or go to their general practitioner, been asked for communicate the results to Blood Establishment (BE), if they are not confirmed. Most of donors involved come to BE. Donors related with HIV or syphilis received a letter without information with an appointment to come for a second sample. Once results are confirmed they are derived to general practitioner or infectious diseases specialist. Writing notifications are sent, we all legal requirements in order to assure the reception of it, specially HIV or Syphilis cases, in these one, there is another notification if donor does not attend the first one.

1 Guide to the Preparation, Use and Quality Assurance of Blood Components (18th Edition).
2 REAL DECRETO 1088/2005, de 16 de septiembre, por el que se establecen los requisitos técnicos y condiciones mínimas de la hemodonación y de los centros y servicios de transfusión. ANEXO IV: Criterios de interpretación de las pruebas de detección de agentes infecciosos en las donaciones.
3 Directive 2002/98/CE of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive2001/83/EC.

Question 2

In a 7 day period we are impeled to notify to industry in cases of donor seroconvertion but we have not legal time frame for donor communication. The HIV and Syphilis cases are notified as soon as possible (included phone citation); until they come back they do not received any kind of specific information. Usually they are dated no longer than 10 days.

Question 3

In Spain it is not mandatory to comunicate this situation to any governamental nor epidemiological instances. There is an annual stadistical data communication to regional and state health authorities.

Question 4

Donor notification and counseling is carried out by BE medical staff responsible for the detection area of blood transmitted diseases.

Question 5

In a second sample we repeat all the routine test included genomic one, in order to confirm results and that one else we consider necessary for a definitive diagnostic. In HBV and HCV cases results are sent by letter been sent the donor to general practiotioner or to specialist. In HIV and Syphilis cases, the donor is notified personally in a second interview, a report is delivered them by analytical detected results and sends them to a specialist doctor.

Question 6

For RR donor in screening tests and genomic and complementary tests negative there is an optional request. My opinion is that RR with NAT and complemetary test negative can be understood, as a non infeccious donor and this RR reactivity is a false positive or inespecific reactivity so I am not agree with notificate this reaction, that only create alarm to donor. The majority of these donors (more of 50%) they will be negative in the following donation. Nevertheless, a trace of this reactivity remains

on the record of the donor and if this situation is repeated, donors are recalled to explain this anomalous reactivity and kindly requested to give up in blood donation in 2 years or at least, make them know that if this anomalous reactivity persist their blood will be discarded.

Question 7

There is not a centralized register of any kind of blood donors and there is not a mandatory report of positives donors. As we lack of an unique Spanish donor data base, there is not a register of these donors. Every one of the 17 autonomous region of Spain has its own donor register, not related among them.

Question 8

If a RR donor in prior donations, comes back to donate is analytical treated routinely as a every donor, but components are not validated if there is not a confirmatory or complementary negative test in a second prior sample; if there is not this sample, donation is interpreted second sample if all results are negative, blood components are accepted.

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Sri Lanka

To understand the Sri Lankan scenario, I feel that it is essential to provide you some background information about the National Blood Transfusion Service (NBTS) of Sri Lanka.

The NBTS is a centrally coordinated specialized campaign coming under the Ministry of Healthcare & Nutrition of Sri Lanka. The National Blood Centre is the operational headquarters of the NBTS and there are 94 hospital based blood banks (HBB) providing transfusion facilities to the patients. Based on the geographical location, HBBs are divided into 20 clusters. Activities within the clusters are coordinated by a 'Cluster Blood Centre' (usually the largest blood bank within the cluster), Activities such as blood collection, processing and screening for transfusion transmissible infections are done only at the cluster blood centres and a few larger HBBs. Each cluster blood centre has Consultant Transfusion Physician who is a specialist in Transfusion Medicine & Immunohematology.

The answers provided here are for the entire NBTS to a large extent and not only for the National Blood Centre where I work.

Question 1

The National Blood Transfusion Service of Sri Lanka has a set of guidelines on how to manage a blood donor with a repeat reactive serological test or a positive NAT result. The management differs according to the marker for which the individual is tested positive.

- HIV – currently the serological test that is being done is a combined antigen-antibody test. All repeat reactive samples are sent to the National STD/AIDS Control Programme (NSACP) for confirmation through the National Blood Centre. If the confirmatory test is positive, the donor is contacted, counselled and referred to NSACP for management.
- Hepatitis B and Hepatitis C – Repeat reactive donors are contacted, counselled and referred to a physician for confirmation and further management.
- Syphilis – All positive samples are tested with a TPPA test and if positive, the donor is contacted, counselled and referred to NSACP for management.

Question 2

There is no strict time frame, but the donor is contacted as soon as possible (usually within 1–2 weeks. Initially, contact is attempted using the telephone number provided at the time of registration. If this fails, the donor is sent a letter by registered post and asked to come to the respective blood centre. The specific reason for the request is not divulged in the letter.

Question 3

In case of HIV, as stated above, confirmed positive donors are contacted, counselled and referred to NSACP for management.

Malaria is reported to the Epidemiology unit of the Ministry of Healthcare & Nutrition.

In case of other disease markers, there is no mandatory reporting by NBTS as confirmatory testing is done elsewhere.

Question 4

The Consultant Transfusion Physician in charge of the blood centre is responsible for notification and counselling. (At the National Blood Centre, the Consultant in charge of the donor department is responsible)

Question 5

- HIV – As the donors are called after confirmatory testing, there are counselled and directly referred for management.
- Hepatitis B and Hepatitis C – The donors are referred to a physician with the screening test results. The physician is responsible for the confirmation of diagnosis.

Question 6

Donors who are confirmed positive for HIV and Syphilis are referred to the NSACP for management.

Those who are repeat reactive for other markers are referred to the relevant physicians.

Question 7

The National Blood Centre maintains a registry of donors who are confirmed positive for HIV. No registries are maintained for other diseases at present.

Question 8

Those donors who are found to be initially reactive but negative on repeat testing remain eligible for future donations.

Those who are repeat reactive, but are found to be negative or indeterminate on confirmatory testing, if they want to continue to donate, are re-tested after a period of 3 months. If found to be negative for the specific marker at re-testing, they are allowed to re-enter the active donor panel.

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The Netherlands

Question 1

All blood donations are screened with standard screening tests and in case of HBV, HCV and HIV also with NAT screenings tests. A repeatedly reactive screening result leads to the initiation of confirmatory tests on the same sample. A reactive NAT screening results directly in donor notification. See Table.

Question 2

In our country we have one blood establishment with a centralized screening laboratory and an independent confirmation laboratory. Donors with a reactive confirmatory test result are directly invited by the administrative staff telephonically to make an appointment for counselling by a donor physician in the donor centre. See Table.

Question 3

Yes, we report confirmed reactive test results in case of HBV and HCV to the public health agency.

Question 4

The donor physician.

Question 5

Donor with reactive confirmatory test results are counselled and test tubes are drawn for repeat testing. In case of repeat reactive confirmatory test result, as is nearly always the case, donor are referred to their general practitioner for further advice or treatment.

Question 6

Donors with reactive confirmatory test result are directly invited for counselling and repeat testing.

Question 7

We have one blood establishment in the Netherlands and these data are published in our annual report.

Question 8

We have a police and algorithm for donors with reactive test result on single and repeat occasions, see table.

Situation	Occasion	Screening	Confirmation	Conclusion/Action
A	On one occasion	Repeat reactive	Non-reactive	Product discarded No action donor 'Silent re-entry'
B	On consecutive occasion	Repeat reactive	Non-reactive	Product discarded 2 year deferral Donor receives a letter
C	On one occasion	Repeat reactive	Reactive	Product discarded Permanent deferral Donor invited for counselling
D	On one occasion	NAT reactive		Product discarded Donor invited for counselling
E	After 2 year deferral of reactive test results	Non-reactive		Product used Donor re-entry
F	After 2 year deferral of reactive test results	Repeat reactive	Non-reactive	Product discarded Permanent deferral Donor receives a letter

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P. Hewitt

United Kingdom

Question 1

There are no regulatory requirements or guidelines for notification of blood donation *screening test* results in England. No test results are notified to the donor until the blood sample has been tested in the reference laboratory and a written report has been issued confirming that the sample shows evidence of infection, with two exceptions. Donors whose blood samples have tested serology repeat reactive in HIV or HCV screening, and have also tested reactive for HIV or HCV RNA in the pooled NAT screening assay (pools of 24) are notified immediately, without waiting for a reference laboratory report, on the basis that the serology repeat reactive result has been confirmed by the (pooled) NAT result, which has been resolved to the individual sample. Screening test results for HBV are not notifed until the reference laboratory report is received, as it is not possible from screening test results (HBsAg on single sample testing and HBV DNA in a pooled NAT assay) to determine the stage of infection (acute or chronic). Screening test results for HTLV, TPHA, and other non-mandatory markers (malaria antibody test, *T. cruzi* antibody test) are not notified, and all notification takes place on the basis of a reference laboratory report confirming that infection is present. HEV RNA screening will be introduced during February 2016, and results will only be notified when confirmed by the reference laboratory.

Question 2

For HIV and HCV, where notification takes place on the basis of concordant repeat reactive serology screening test result and pooled NAT result resolved to a single donation, the donor will be sent a letter once the screening test results have been entered onto the donor database. Action will therefore be taken approximately 48 h after donation, but letters are not sent out at the end of the week, to avoid them being received on a Friday or Saturday. Some notifications may therefore be delayed for 48 h, but in general donors with HIV and HCV infections will have been sent a letter within 7 days of blood donation and usually much earlier. For all other markers, letters are sent out on receipt of a reference laboratory report, but again avoiding the end of the week. In the vast majority of cases a notification letter will be sent within 21 days of the blood donation, and usually within 14 days.

All communication is by letter in the first instance. For HBV, HCV, HTLV, and active malaria infection, the donor is sent a letter naming the infection, with an accompanying information leaflet to read. The donor is invited to have a telephone discussion with a member of the blood service clinical staff, when questions can be answered and further information provided. For HIV and syphilis, the infection is not named in the letter. The donor is informed by letter that the test results need to be discussed, and is invited to telephone to speak to a member of the clinical team. Notification of the infection is given over the telephone, further information and advice given, and an information leaflet offered at this stage, but in

general the donor will be seen as a specialist clinic (see below) within 48 h.

Donors who fail to respond to the initial letter are contacted again. For donors who have provided a mobile telephone number and/ or e mail address, which is increasingly common, a bland text or email is sent, indicating that a letter has been sent and inviting the donor to respond. If neither text or email are possible, a further letter is sent. Further contacts for non-responders depend on the circumstances, but usually will involve a telephone follow-up in the first instance.

Question 3

Reporting only occurs when the reference laboratory has issued a report for confirmed positive test results. There is no reporting of screening test results. There is mandatory reporting of confirmed positive HBV and HCV test results to the local Public Health Team, because hepatitis B and hepatitis C are included in the list of notifiable infections which must by law be notified to Public Health. Hepatitis E is also a notifiable infection and will be notified once screening of blood donations has started. Active malaria infection also falls within this category, so any case of a donor who is malaria DNA positive, is reported. This amounts to one or two cases/year. There is no mandatory reporting of HIV, HTLV, syphilis, etc.

Question 4

In England, notification and post-test discussion (not 'counselling') is an activity which is managed nationally, and not from individual blood centres. It is under the responsibility of a Consultant in Transfusion Medicine. The team of staff who carry out the work consists of Speciality Doctors and Clinical Nurse Specialists.

Question 5

We do not routinely carry out any further testing once the donor has been notified of the test results. All screening test results are confirmed in the blood service reference laboratory. For HIV and syphilis we aim to refer the donor directly to specialist care, usually within 48 h, at the local Sexual Health or Genito-Urinary Medicine clinic. Further testing will be carried out there, with the aim of commencing treatment with minimal delay. For hepatits B and C, we refer the donor to the General Practitioner with a recommendation to repeat the tests and then refer on to specialist care. For HTLV, we refer direct to the national HTLV specialist clinic in London, or one of the three satellite clinics elsewhere in England, where further testing is carried out.

Question 6

See above.

Question 7

We have an Epidemiology Unit, which collects data on confirmed positive donors. A standardised form, giving information about test results and risk information, is completed electronically for each infected donor and the information is collated and published annually in the Epidemiology Unit Annual Report. This is not a registry, and personal information (name, address) is not collected in the database.

Question 8

Donors who have repeat reactive serology screening tests which are concluded by the reference laboratory to be not confirmed infection are considered to have non-specific test results. Donations are discarded on receipt of a first repeat reactive serology screening test result. Donors are not informed of the screening test results on the first occasion and are managed on an alternative assay algorithm. Once the reference laboratory has concluded that there is no evidence of confirmed infection, the donor's record is set to 'alternative assay' by means of a flag in the computer database. When the donor next attends, the sample is screened using the routine primary screening assay. In a proportion of cases the reactivity will have disappeared and the donation is then suitable for issue. If the sample shows reactivity in the primary screening assay, it is then tested by an alternative screening assay from a different manufacturer, which is of equal sensitivity to the primary screening assay. If the sample is non-reactive in the secondary assay, it is suitable for issue. If there is reactivity in the secondary assay, the sample is referred back to the reference laboratory for repeat testing, but we have never seen a confirmed positive result in this situation. If the sample is reactive in both the primary screening assay and the alternative screening assay, it is concluded that there is non-specific reactivity in more than one screening assay, or, most usually in the case of HCV, there could have been previous infection, which has been cleared. Whichever conclusion we have reached, we then notify the donor that his/ her donations are unsuitable for issue, and we withdraw the donor from the donor panel. We inform the donor's GP, but we do not recommend specialist referral and we emphasise that the finding is of no significance to the donor's health. We offer the opportunity for a re-test 3 years after the incident, as some antibody reactivity declines over time and the donor may become reinstateable at a later date. We

have in place alternative assays for HIV, HBV, HCV and HTLV serology.

We do not normally see reactive NAT test results which are unconfirmed in the reference laboratory. If we did have a non-confirmed NAT screen test result, we would offer the donor a re-test, and if confirmed negative we would return the donor to the donor panel for routine testing on the next occasion.

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United States

Question 1

Blood collection agencies in the United States must notify blood donors, including donors of autologous components, about any *relevant transfusion-transmitted infection* (RTTI) test results that cause the deferral of the donor. Regulations issued by the U.S. Food and Drug Administration (FDA) consider relevant two groups of transfusion-transmitted infections [1]. The first is a list of 10 infections: HIV, HBV, HCV, HTLV, syphilis, West Nile virus, Chagas disease, Creutzfeldt-Jakob disease (CJD), variant Creutzfeldt-Jakob disease (vCJD), and diseases caused by *Plasmodium species* (malaria). Blood donors are currently tested for the first seven and questioned in medical history about the remainder. In addition, infectious agents may be identified as relevant when the following conditions are met: (1) Appropriate screening (medical history questions, behaviors or tests) exist, have been cleared and are available and (2) the agent may have sufficient incidence or prevalence to affect the potential donor population, or may have been released in a manner that could place potential donors at risk of infection.

When a donor is reactive on a screening test for a RTTI, and an approved supplemental test is available, it must be performed. Donor deferrals may be temporary, indefinite or permanent [2]. For example, positive results on HIV, HBsAg, HCV, HTLV, syphilis and Chagas disease lead to permanent deferrals, i.e. the donor is not eligible for future donations. According to current FDA guidance, blood establishments defer a donor who tests reactive for anti-HBc or anti-HTLV, types I and II, on more than one occasion, or when further testing on the same donation is positive, or when a second approved screening test for HBV or HTLV has been performed on the same donation and is reactive. Travel to certain geographical areas may lead to temporary deferrals (e.g. malaria) while residence in certain geographical areas for extended periods of time (e.g. UK, Europe, vCJD) lead to indefinite deferrals. In the event that FDA determines that, under current conditions, a transfusion transmitted infection now meets the definition of a RTTI, as happened with the recent appearance of the Zika virus in the Americas, the FDA issues guidance that addresses appropriate screening measures.

Donors must be notified whenever test results lead to permanent or indefinite deferral with inclusion of the donor in a confidential deferral list that is consulted prior to every donation. Donor notification is made by letter or, for certain RTTI, in person (see below) and includes results of both initial and further testing (known as supplemental or confirmation testing) in order to provide appropriate information about the meaning of the test result, recommendations for follow up with a healthcare professional and information about the eligibility of the donor for future donations (deferral status).

Question 2

Donors are notified as soon as all testing is completed. The vast majority of notifications are done via letter and include a contact number for donors to reach our counselling staff with questions. The length of time it takes to notify donors may be impacted by the testing that is required. For example, testing for Hepatitis C includes a screening antibody test and a multiplex nucleic acid test. If the antibody test is reactive but the multiplex test is not, additional antibody testing by a different method is performed. Alternatively, because nucleic acid testing is done in pools, if the antibody test is reactive and the multiplex test is reactive as well, there must be deconstruction of the original pool for individual multiplex testing, followed by discriminatory testing if the individual sample was reactive. Typically, all testing is complete within 2–6 days. The donor notification letter explains the results, suggests that the donor see a healthcare professional if indicated, and notes the deferral status of the donor.

Every attempt is made to notify donors with HIV and HTLV confirmed positive results in person. An initial generic letter indicates that test results were abnormal and need to be discussed personally at an office visit. The letter requests a call for an appointment. In case of non-response after a week, a second letter re-emphasises the

need for the office visit. If ignored, a final letter with delivery restricted to the individual is sent. It includes tests results, counselling messages, referral to healthcare professionals, and a phone number in case the donor wants a follow up at the donor center. Most of the donors make counselling appointments.

Question 3

Reporting of confirmed relevant transfusion-transmitted infections is determined by the state in which the blood is collected. In the states of New York and New Jersey HIV, hepatitis B and C, syphilis and West Nile Virus must be reported to the respective state health departments. In addition, centers that collect blood on U.S. military bases must have a Memorandum of Understanding (MOU) that require the military authority be notified of any reactive/positive infectious disease finding on a military donor at that base.

Question 4

The department providing donor counselling at the New York Blood Center is staffed by specially trained registered nurses. Hiring requirements include experience in one or more of the fields of infectious diseases, HIV, sexually transmitted diseases or substance abuse. Nurses in all these areas have experience dealing with the relevant transfusion transmitted infections.

Question 5

All supplemental testing on donated units which are initially reactive is completed prior to donor notification and deferral. No additional testing is done after notification. Donors who are eligible for re-entry based on existing FDA guidance are invited to return for additional testing after the appropriate period of time.

Question 6

Donors who are confirmed positive for any infectious disease marker are referred to their healthcare provider for follow up. If the donor does not have a healthcare provider, referrals to community health resources are made. We have extensive referral resources for HIV positive donors, including specialized resources specific to situations such as teenage/young adult patients, gay or lesbian patients, etc.

Question 7

There is no central or national registry in the United States due to concerns about maintenance of a secure and accurate database and confidentiality of donors. Our center shares our deferral list with hospitals in our area that perform their own blood donor collections.

Question 8

Donors who are eligible for re-entry under FDA guidance or rules are offered re-entry [3]. Typically, after a FDA prescribed waiting period, donors who were reactive on serological screening for HIV or HCV and were negative on supplemental tests are retested and may be re-entered if negative. The same is true for donors who were reactive on NAT for HIV, HCV, HBV and non-reactive on antibody tests after a negative retest [4, 5]. Donors who are reactive for anti-HBc are not deferred unless this happens on two donations. Once deferred they are also eligible for re-entry with testing after a waiting period [6] . Donors with confirmed positive results for Syphilis are eligible for re-entry after meeting certain conditions of treatment [7].

References

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4 *Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry.* Available at: http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM210270.pdf (Last accessed 7 March 2016)

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6 *Guidance for Industry: Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibodies to Hepatitis B Core Antigen (Anti-HBc).* Available at: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm2008053.htm (Last accessed 7 March 2016)

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www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM340993.pdf (Last accessed 7 March 2016)

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