Informed Parental Consent for Persons Not of a Legal Majority

Information

This form must be completed by a parent or legal guardian for blood donations by any person who has not yet reached the age of legal majority as defined by the laws of the state in which the donor makes the blood donation.

Questions or concerns about the blood donation process should be directed to

Department: **Donor Health Consultants**

Phone Number: **(800) 448-3543 (Press Option 6)**

Hours of operation: **M-F: 8am-9pm, Sat: 9am-1pm, Sun 4-8pm**

Parental Consent

I have received and read a copy of "What You Must Know Before Giving Blood" describing the overall blood donation process.

I have received and read a copy of "What You Must Know About NAT- A New Blood Test" describing additional test procedures and any research-related attachments.

I understand that in the event it becomes necessary to notify my son, daughter, or ward of test results, the American Red Cross will send those results directly to my son, daughter, or ward.

I understand the information provided to me and have had an opportunity to ask questions about the information it contains. I hereby give permission for my son, daughter, or ward, to make a voluntary donation of blood to the American Red Cross during his or her legal minority.

A signed consent from the Parent/Guardian will be required for each donation until the donor reaches the age of majority.

Donor Name [son, daughter, or ward] (print) _____

Parent/Guardian Name (print) _____

Parent/Guardian ***Signature*** _____ **Date:** / /

WBN/DIN → [ ]

American Red Cross Blood Services Washington, DC 20006	American Red Cross

WHAT YOU MUST KNOW ABOUT NAT

Possible Use of Donor Information and Blood Samples in Medical Research

The American Red Cross Blood Services mission is to provide a safe and effective blood supply for patients who need blood transfusions. As part of this mission, the American Red Cross may conduct research. Some research is conducted with other institutions, such as academic centers and biomedical companies.

Some examples of the types of research are:

- Studies relating to testing, storing, collecting and processing blood to increase the safety of the blood supply.
- Studies of new test methods for infectious agents carried in the blood, like Nucleic Acid Testing (NAT).
- Studies of ways to recruit blood donors and to evaluate donor eligibility.

Participation does not require additional blood to be collected or additional time.

By signing your Blood Donation Record, you are giving consent to allow us to use a portion of your blood donation and donor information for research like that listed above. Donor information for research will not include anything that would identify you as the donor, such as your name or Social Security Number (SSN).

Confidentiality

American Red Cross policy requires protection of the confidentiality of your donor identifying information, results of tests on your blood samples and information collected at the time of donation. Strict procedures are observed at all blood collection facilities to maintain the confidentiality of donor information.

Your donor identifying information will not be released to other institutions for research purposes without your consent. Your age, gender, general geographic location, and test results may be used to evaluate important information about disease or donor recruitment, but this information is combined with information about other donors and not identified with you.

While study results may be published, donor names and other identifying information will not be revealed, except as required by law. Records are kept, as required by State and Federal Laws. The Food and Drug Administration (FDA) may need to review and copy donor records in order to verify study data. The FDA, however, is committed to protection of the confidentiality of donor identity.

Testing and Storage

Blood samples used by researchers are coded. This means that your donor identifying information, including name and SSN, is not used in connection with research. Coded samples can be linked to information about donors' identity only by authorized Red Cross personnel who are required to follow Red Cross procedures to maintain confidentiality.

Some of your sample or information may be saved for future research on viruses or other agents that may be carried in blood. Samples linked to your identifying information may be used, either

now or in the future, for infectious disease testing, as described in What You Must Know Before Giving Blood or in other information about a specific research study that is being conducted today. Your identified sample and information will not be used for genetic testing or for research unrelated to blood safety without your consent.

You will be notified in person, by phone, or by letter, about any test results that may impact your health. You will receive information about how these test results may affect your health and future eligibility as a blood donor.

Possible Participation in a Follow Up Study
If your test results are positive or unexpected, Red Cross staff may ask you to participate in a follow up study. Participation is voluntary and of no cost to you.

Benefits
By using new infectious disease tests like NAT, you may find out sooner if you are infected by one of the agents being tested. This may be important to your health.

Risks
There is a very low chance that your blood sample may give a false positive or true positive infectious disease result. If this happens, the blood that you donate will not be used for transfusion and there is the likelihood that you may not be able to donate again. If you are donating for a specific patient and have a positive test result, your blood donation will not be available for that patient. If you are donating blood for yourself and have a positive result, your blood donation may not be available to you.

Your Right Not To Participate
You may refuse to participate now or at any time during the donation process. If you decide that you do not want your donation or donor information to be used for possible research like that listed above, you will not be able to donate today. It is very important to include all donors in such research in order to provide a safe and effective blood supply.

If you decide not to participate at this time, your decision will not change your future relationship with the Red Cross.

If you begin donating and then decide that you do not want to participate, you must notify the blood collection staff before you leave the collection site. If you decide to withdraw in the future, contact the Scientific Support Office at (301) 212-2801. However, test information collected before your withdrawal may still be used or disclosed after your withdrawal.

Questions
If you have any questions about your donation, please feel free to ask the ARC staff member performing your confidential health history interview. If you have questions later, you can contact the Blood Center at 1-800-652-9742.

If you have scientific questions, you can call the Scientific Support Office at (301)212-2801. If you have any questions about your rights as a research participant, call the American Red Cross Institutional Review Board Administrator at (301)738-0630.

You have been given this information sheet to read and will be offered a copy to keep.

American Red Cross Blood Services
Washington, DC 20006

What You Must Know Before Giving Blood

Thank you for coming in today!

This information sheet explains how **YOU** can help us make the donation process safe for yourself and patients who might receive your blood. **PLEASE READ THIS INFORMATION BEFORE YOU DONATE!** You will be asked to sign a statement that says you understand and have read this information today. **If you have any questions now or anytime during the screening process, please ask blood center staff.**

Accuracy And Honesty Are Essential

Your **complete honesty** in answering all questions is very important for the safety of patients who receive your blood. We will ask you for identification each time you try to donate. Please register using the same identifying information each time you donate (name, date of birth, etc.). **All information you provide is confidential.** Although your interview will be private, it may require more than one American Red Cross employee to participate in or be present at your health history and blood donation.

What happens when you give blood

To determine if you are eligible to donate we will:

- ask questions about your health, travel, and medicines
- ask questions to see if you might be at risk for hepatitis, HIV, or AIDS
- take your blood pressure, temperature, and pulse, and
- take a small blood sample to make sure you are not anemic.

If you are able to donate we will:

- cleanse your arm with an antiseptic. **(If you are allergic to Iodine, please tell us!),** and
- use a new, sterile, disposable needle to collect your blood.

While you are donating: (the donation usually takes about 10 minutes)

- you may feel a brief "sting" from the needle at the beginning.

After donating we will give you

- a form with post-donation instructions, and
- a number to call if you have any problems or decide after you leave that your blood may not be safe to give to another person.

What to expect after donating

Although most people feel fine before and after donating blood, a small number of people may have a(n)

- lightheaded or dizzy feeling
- upset stomach
- black and blue mark, redness, or pain where the needle was, and
- very rarely, loss of consciousness, or nerve or artery damage.

We will give you a number to call to report any problems or concerns you may have following your donation.

Why we ask questions about sexual contact

Sexual contact may cause contagious diseases like HIV to get into the bloodstream and be spread through transfusions to someone else.

Definition of "sexual contact":

The words "have sexual contact with" and "sex" are used in some of the questions we will ask you, and apply to any of the following activities, whether or not a condom or other protection was used:

- vaginal sex (contact between penis and vagina)
- oral sex (mouth or tongue on someone's vagina, penis, or anus), and
- anal sex (contact between penis and anus).

Continued on back

American Red Cross Blood Services
Washington, DC 20006

What You Must Know Before Giving Blood, Continued

Persons who should not donate

You should not give blood if you

- had hepatitis on or after the age of 11
- had malaria in the past 3 years
- met any of the conditions listed in the CJD Information Sheet
- were held in a correctional facility (including jail, lock up, prison, or juvenile detention center) for more than 72 straight hours in the last 12 months.
- have had sexual contact in the past 12 months with anyone who is sick with hepatitis or AIDS
- had or were treated for syphilis or gonorrhea or tested positive for syphilis in the last 12 months
- were raped in the last 12 months
- **have AIDS or have ever had a positive HIV test**
  AIDS is caused by HIV. HIV is spread mainly through sexual contact with an infected person, or by sharing needles or syringes used for injecting drugs.
- **done something that puts you at risk for becoming infected with HIV**
  You are at risk for getting infected if you
  - have ever used needles to take drugs, steroids, or anything not prescribed by your doctor
  - are a male who has had sexual contact with another male, even once, since 1977
  - have ever taken money, drugs, or other payment for sex since 1977
  - have had sexual contact in the past 12 months with anyone described above
  - received clotting factor concentrates for a bleeding disorder such as hemophilia
  - were born in, or lived in, Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria, since 1977.
  - since 1977, received a blood transfusion or medical treatment with a blood product in any of these countries, or
  - had sex with anyone who, since 1977, was born in or lived in any of these countries.
- have any of the following conditions that can be signs or symptoms of HIV/AIDS
  - unexplained weight loss (10 pounds or more in less than 2 months)
  - night sweats
  - blue or purple spots in your mouth or skin
  - white spots or unusual sores in your mouth
  - lumps in your neck, armpits, or groin, lasting longer than one month
  - diarrhea that won't go away
  - cough that won't go away and shortness of breath, or
  - fever higher than 100.5 F lasting more than 10 days.

Ineligible donors

We maintain a confidential list of people who may be at risk for spreading transfusion-transmitted diseases. By continuing this process, you consent to be entered in this confidential list of deferred donors if you are at risk for spreading such diseases. When required, we report donor information, including test results, to health departments, military medical commands, and regulatory agencies. Donation information may also be used confidentially for medical studies.

If you decide not to give blood

If you decide that you should not give blood, you may leave now.

Testing your blood

Your blood will be tested for hepatitis, HIV (the virus that causes AIDS), syphilis, and other factors. (There are unusual circumstances in which these tests cannot be performed.) You will be notified about test results that may disqualify you from donating blood in the future or that may show you are unhealthy. Your blood will not be used if it could make someone sick. (A sample of your blood or a portion of your donation might be used now or in the future for additional tests or other medical studies. Please tell us if you object.)

Though the tests we use are very good, they are not perfect. HIV antibodies may take weeks to develop after infection with the virus. If you were infected recently, you might have a negative test result, yet be able to infect someone. That is why you must not give blood if you are at risk of getting AIDS or other infectious diseases. **If you think you may be at risk for HIV/AIDS or want an HIV/AIDS test, please ask for information about other testing facilities. Please do not donate to get tested for HIV, hepatitis, or any other infections!**

Travel to or birth in other countries	Blood donor tests may not be available for some contagious diseases that are found only in certain countries. If you were born in, have lived in, or visited certain countries, you may not be eligible to donate.

American Red Cross Biomedical Services	Doc No ARC F6628CJD	Version 05/08
Form: **CJD Information Sheet**		

What this form is about

This form explains Creutzfeldt-Jakob disease to the donor.

Who should use this form

This form applies to collections staff.

Revision History

Revision Number	Summary of Revisions
07/04	Developed and released prior to revision history requirement
05/08	• Removed watermark so sheet can be printed from eDOCs or eBinder • Revised American Red Cross Logo • Placed into System 3 Document template

CJD Information Sheet

American Red Cross

Please <u>do not</u> donate if you—

- Since January 1, 1980 through December 31, 1996—
  - -Spent a <u>total time</u> that adds up to 3 months or more in any country(ies) in the United Kingdom (UK).
  - -The UK includes any of the countries listed in Table 1 below.
- Were a member of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military that spent a total time of 6 months on or associated with a military base in any of the following areas during the specified time frames—
  - -From 1980 through 1990 - Belgium, the Netherlands (Holland), or Germany
  - -From 1980 through 1996 - Spain, Portugal, Turkey, Italy, or Greece
- Since January 1, 1980 to present—
  - -Spent a <u>total time</u> that adds up to 5 years or more in Europe (includes time spent in the UK from -1980 through 1996 and time associated with the military bases in Europe as outlined above).
  - -The European countries that are affected are listed below in **Table 1** and **Table 2**.
  - -Received a blood transfusion in any country(ies) listed in **Table 1** below.
  - -Received an injection of bovine (beef) insulin made in any of the countries listed below.
- Ever received—
  - -A dura mater (or brain covering) transplant during head or brain surgery.
  - -Human pituitary growth hormone (brain extract).
- Any blood relative has had Creutzfeldt-Jakob disease. A blood relative is your mother/father, grandparent, sibling, aunt/uncle, or children.
- Have been told that your family is at risk for Creutzfeldt-Jakob disease.

If any of these apply to you, your donation cannot be accepted. If you have any questions, please ask us. We sincerely appreciate your support.

Table 1

United Kingdom			
♦ Channel Islands	♦ Falkland Islands	♦ Isle of Man	♦ Scotland
♦ England	♦ Gibraltar	♦ Northern Ireland	♦ Wales

Table 2

Europe		
♦ Albania	♦ Hungary	♦ Poland
♦ Austria	♦ Ireland (Republic of)	♦ Portugal
♦ Belgium	♦ Italy	♦ Romania
♦ Bosnia/Herzegovina	♦ Kosovo (Federal Republic of Yugoslavia)	♦ Serbia (Federal Republic of Yugoslavia)
♦ Bulgaria		♦ Slovak Republic (Slovakia)
♦ Croatia	♦ Liechtenstein	♦ Slovenia
♦ Czech Republic	♦ Luxembourg	♦ Spain
♦ Denmark	♦ Macedonia	♦ Sweden
♦ Finland	♦ Montenegro (Federal Republic of Yugoslavia)	♦ Switzerland
♦ France		♦ Turkey
♦ Germany	♦ Netherlands (Holland)	♦ Yugoslavia (Federal Republic includes Kosovo, Montenegro, and Serbia)
♦ Greece	♦ Norway	

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American Red Cross Biomedical Services	Doc No 14.4.ja021	Version 1.1
Job Aid: **Medication Deferral List**	Approved by Quality Assurance	
	Approval date 05.04.06	

Please tell us if you are now taking or if you have EVER taken any of these medications:

- ☐ **Proscar® (finasteride) – usually given for prostate gland enlargement**
- ☐ **Avodart® (dutasteride) – usually given for prostate enlargement**
- ☐ **Propecia® (finasteride) – usually given for baldness**
- ☐ **Accutane®, Amnesteem®, Claravis®, or Sotret®, (isotretinoin) – usually given for severe acne**
- ☐ **Soriatane® (acitretin) – usually given for severe psoriasis**
- ☐ **Tegison® (etretinate) – usually given for severe psoriasis**
- ☐ **Growth Hormone from Human Pituitary Glands – used only until 1985, usually for children with delayed or impaired growth**
- ☐ **Insulin from Cows (Bovine, or Beef, Insulin) – used to treat diabetes**
- ☐ **Hepatitis B Immune Globulin – given following an exposure to hepatitis B**

  Note: This is different from the hepatitis B vaccine which is a series of 3 injections given over a 6 month period to prevent future infection from exposures to hepatitis B.
- ☐ **Unlicensed Vaccine – usually associated with a research protocol**

Please tell us if you are now taking or if you have taken any of these medications in the last 7 days:

- Clopidogrel
- Coumadin (warfarin)
- Heparin
- Plavix
- Ticlid
- Ticlopidine

IF YOU WOULD LIKE TO KNOW WHY THESE MEDICINES AFFECT YOU AS A BLOOD DONOR, PLEASE KEEP READING:

- If you have taken or are taking **Proscar, Avodart, Propecia, Accutane, Amnesteem, Claravis, Sotret, Soriatane, or Tegison**, these medications can cause birth defects. Your donated blood could contain high enough levels to damage the unborn baby if transfused to a pregnant woman. Once the medication has been cleared from your blood, you may donate again. Following the last dose, the deferral period is one month for **Proscar, Propecia, Accutane, Amnesteem, Claravis** or **Sotret**, six months for **Avodart** and three years for **Soriatane**. Tegison is a permanent deferral.
- **Growth hormone from human pituitary glands** was prescribed until 1985 for children with delayed or impaired growth. The hormone was obtained from human pituitary glands, which are found in the brain. Some people who took this hormone developed a rare nervous system condition called Creutzfeldt-Jakob Disease (CJD, for short). The deferral is permanent. CJD has not been associated with growth hormone preparations available since 1985.
- CJD has been reported in extremely rare cases in Australian women who took **gonadotropin from human pituitary glands** for treatment for infertility. Gonadotropin from human pituitary glands was manufactured and distributed outside the United States and was never marketed in the United States to treat infertility. Human chorionic gonadotropin which is used for fertility treatments in the United States is not derived from human pituitary glands and is not a cause for deferral.
- **Insulin from cows (bovine, or beef, insulin)** is an injected material used to treat diabetes. If this insulin was imported into the US from countries in which "Mad Cow Disease" has been found, it could contain material from infected cattle. There is concern that "Mad Cow Disease" is transmitted by transfusion. The deferral is indefinite.
- **Hepatitis B Immune Globulin (HBIG)** is an injected material used to prevent infection following an exposure to hepatitis B. HBIG does not prevent hepatitis B infection in every case, therefore persons who have received HBIG must wait 12 months to donate blood to be sure they were not infected since hepatitis B can be transmitted through transfusion to a patient.
- **Unlicensed Vaccine** is usually associated with a research protocol and the effect on blood transmission is unknown. The deferral is for one year.
- If you have taken **Clopidogrel, Plavix Ticlid, or Ticlopidine in the last 7 days**, these medications affect the portion of your blood called platelets. If you are donating platelets, your donated blood could contain high enough levels of the medications that it could affect the quality of the platelets that you give. Once the medication has been cleared from your blood, you may donate platelets again. Following the last dose, the deferral period is 7 days.
- If you have taken **Coumadin (Warfarin) or Heparin in the last 7 days**, these medications can affect the blood's ability to clot, which might cause excessive bruising or bleeding when you donate. Therefore, we ask that you be off of these drugs for 7 days prior to giving blood. Following the last dose, the deferral period is 7 days.

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American Red Cross Biomedical Services Washington, DC 20006	**Controlled Documents Approval**	

SECTION 1: Document Package Information

Transmittal Sheet Title: Revised health History Tables and Related Douments Number: 2522
Version: 1.0

Document Title: Time Period: May 2006

List Documents Here:	14.4.ja041, v-1.1	14.4.tbl010, v-1.4
14.3.019, v-1.3	14.4.ja049, v-1.2	14.4.tbl011, v-1.2
14.3.070, v-1.2	14.4.tbl001, v-1.3	14.4.tbl012, v-1.2
14.3.092, v-1.2	14.4.tbl002, v-1.3	14.4.tbl016, v-1.3
14.3.094, v-1.2	14.4.tbl003, v-1.4	14.4.tbl021, v-1.2
14.4.ja021, v-1.1	14.4.tbl004, v-1.4	14.4.tbl023, v-1.3
14.4.ja028, v-1.2	14.4.tbl005, v-1.2	14.4.tbl024, v-1.3
14.4.ja029, v-1.4	14.4.tbl006, v-1.3	14.4.tbl025, v-1.2
14.4.ja031, v-1.3	14.4.tbl008, v-1.2	14.4.tbl026, v-1.2
14.4.ja032, v-1.1	14.4.tbl009, v-1.3	
List Documents Here (continued):		
14.4.tbl027, v-1.2	14.4.tbl039, v-1.3	
14.4.tbl028, v-1.2	14.4.tbl044, v-1.3	
14.4.tbl029, v-1.4	14.4.tbl045, v-13.	
14.4.tbl030, v-1.2	14.4.tbl046, v-1.3	
14.4.tbl031, v-1.3	14.4.tbl047, v-1.3	
14.4.tbl033, v-1.2	14.4.tbl048, v-1.3	
14.4.tbl034, v-1.4	14.4.tbl201, v-1.1	
14.4.tbl035, v-1.2	14.4.tbl202, v-1.1	
14.4.tbl036, v-1.2	14.4.tbl208, v-1.1	

SECTION 2: Approvals

Your approval signifies that you have reviewed the documents according to the requirements for your functional area.

Signatory Name	Role	Signature	Date
Please print or type name here Pat Demaris	*Check role* Process Owner ☑ CEO/ Division VP ☐ None ☐	Pat Demaris	05/05/06
Anne Eder	Medical Office ☒ None ☐	Anne Eder	05/05/06
	Executive QA ☒ System QA ☐ BIT-QRM ☐ Testing Support QA ☐ Facility Quality Director ☐	Ira Quinley	05.05.06

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平成１５年度　厚生労働科学研究費補助金（医薬品等医療技術リスク評価研究事業）
分担研究報告書

４．採血により献血者に起こる副作用・合併症の解析

—平成 14 年の全国データから—

分担研究者
佐竹　正博　（東京都赤十字血液センター）
中村　榮一　（東京都赤十字血液センター）

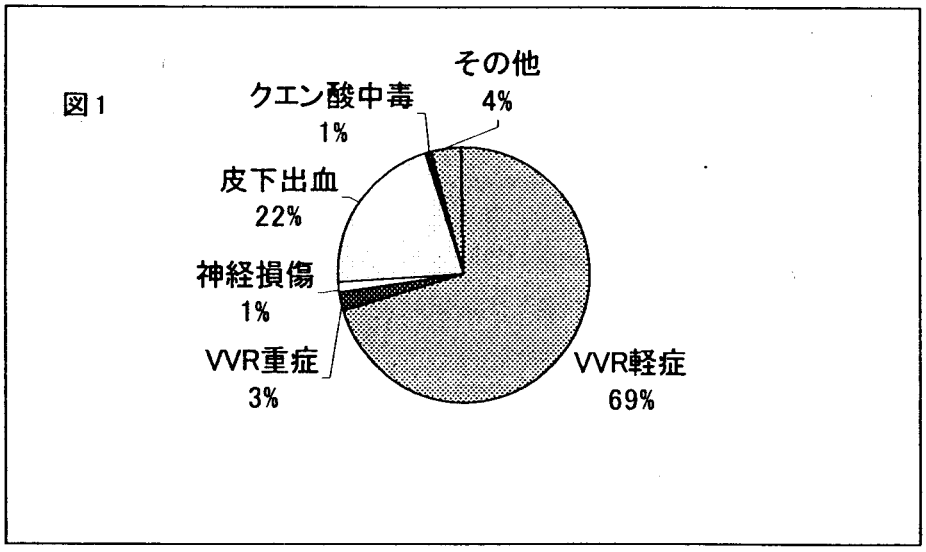
日本赤十字社では、献血時の採血によって献血者に起こる副作用や合併症のデータを集積しているが、ここでは全国の血液センターから集められた平成 14 年のデータをもとに解析を試みた。

まず、すべての採血種における全献血者の副作用の頻度を表に示した。

	VVR 軽症	VVR 重症	神経損傷	皮下出血	クエン酸中毒	その他	合計
%	0.73	0.026	0.011	0.23	0.011	0.039	1.04

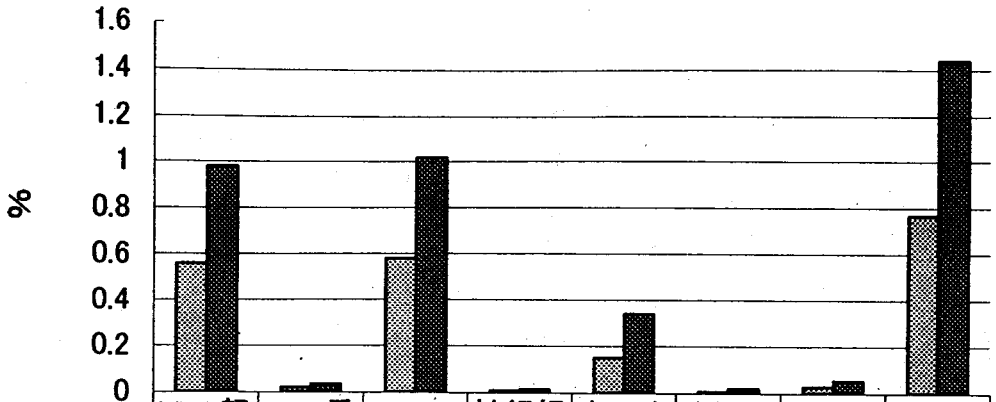
全献血者の約 1%に何らかの副作用が起こっており、その 73%は VVR（vasovagal reaction、血管迷走神経反応）である。献血者に長期にわたる愁訴・運動障害などを起こす可能性のある神経損傷が 1 万人に 1.1 人の確率で起こることは重大である。副作用の割合を示したのが図 1 である。VVR に次いで、皮下出血が 22%を占めている。

図 1



これを男女別にみたのが次の図 2 である。

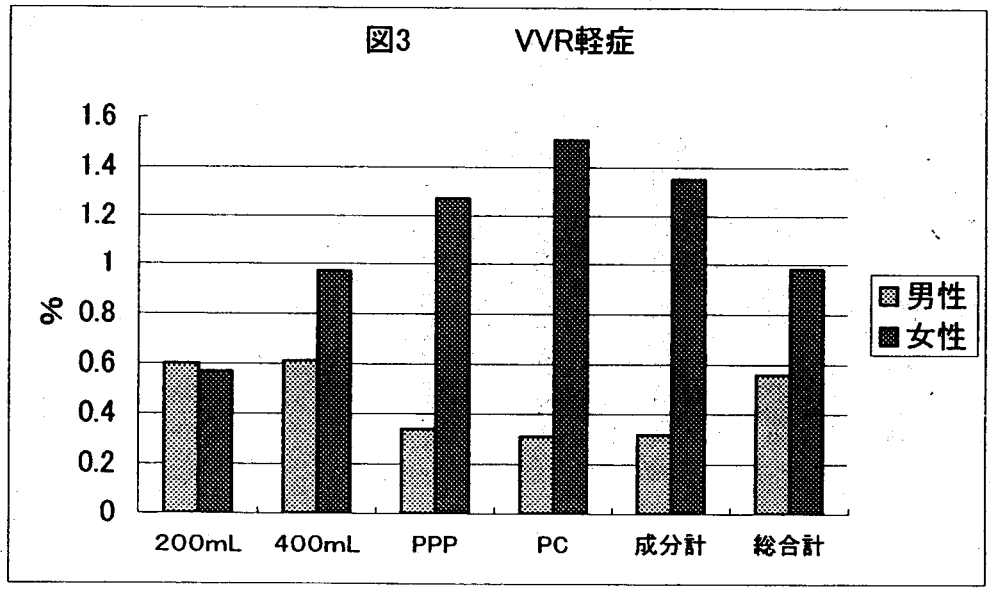
図2　　全ての採血



	VVR軽症	VVR重症	VVR計	神経損傷	皮下出血	クエン酸中毒	その他	合計
男性	0.56	0.021	0.58	0.0093	0.15	0.0051	0.029	0.77
女性	0.98	0.035	1.02	0.014	0.34	0.02	0.054	1.44

男女別でとくにパターンの大きな変化はないが、すべての副作用において女性のほうがその頻度が高い。しかしながら、これを採血種別にみていくと男女間でかなり大きな差があることがわかる。図 3 は比較的軽症の VVR の発生頻度を採血種別にみたものである。

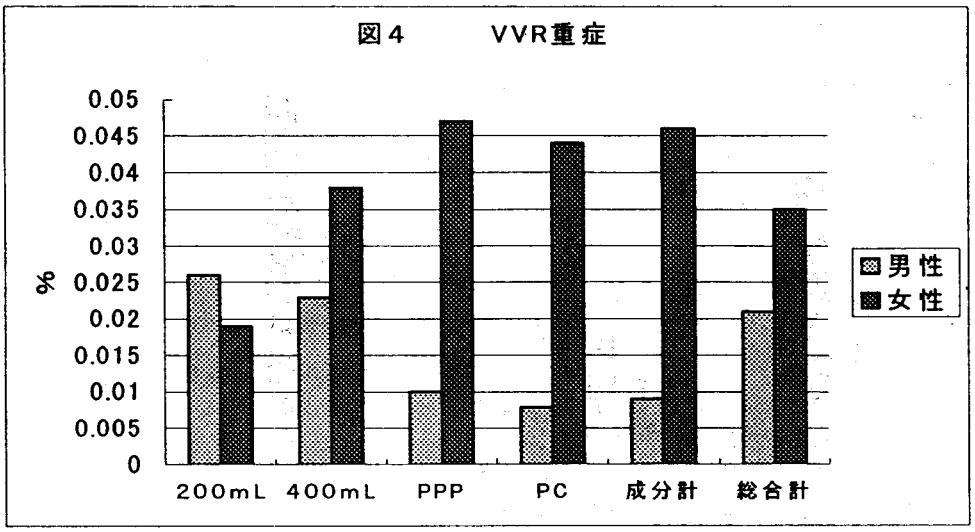
図3　　VVR軽症



200mL 採血では男女ほぼ同じ頻度で VVR が起こっているが、400mL になると女性のほうが有意に多くなる。これは、女性のほうが一般に循環血液量が少なく、血管内の volume loss による症状が現れやすく、それが VVR に加算されて頻度が高くなったものと思われる。PC や PPP の成分採血になると、男性ではむしろ VVR が少なくなっているのに対し、女性ではさらに頻度が高くなっている。女性で多くなるのは、前述のように血漿採取量の増加の影響が出ているものと思われるが、男性でかえって少なくなる理由は不明である。男性の場合、血漿採取量が循環血液量に影響を及ぼさない範囲では、専用椅子に 1 時間近くゆっくり座って採血を受ける成分採血の方が心理

的に余裕があり、VVR が起こりにくいこともあるのではないかと想像される。

重症の VVR では図 4 にように 200mL 採血ではむしろ男性の方が多い。成分採血では女性は男性の 5 倍ほど重大



な転帰をとりやすい。男女とも 200mL 採血では循環血液量に影響が出ることはほとんど考えられないので、この採血において男女の VVR の頻度がほぼ同じであることは、純粋に神経学的な機序のみで起こる VVR の頻度に性差はあまりないことを示すものといえる。図 5 は軽症と重症を合わせた全 VVR の頻度である。