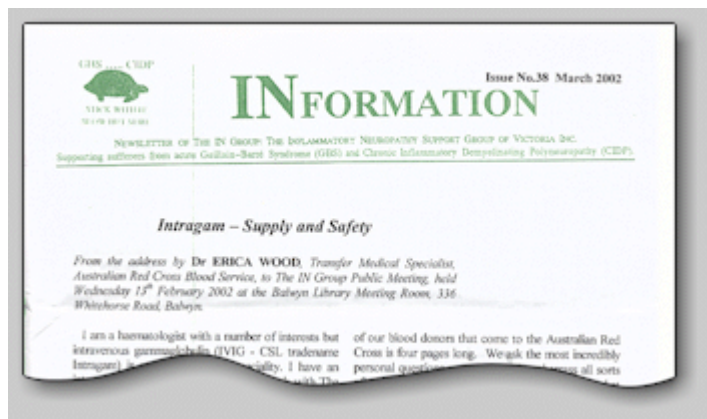


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Intragam - Supply and Safety

Newsletter No.38 - March 2002

From the address by Dr ERICA WOOD, Transfer Medical Specialist, Australian Red Cross Blood Service, to The IN Group Public Meeting, held Wednesday 13th February 2002 at the Balwyn Library Meeting Room, 336 Whitehorse Road, Balwyn.



I am a haematologist with a number of interests but intravenous gammaglobulin (IVIg - CSL tradename Intragam) is not my particular speciality. I have an interest in blood safety and I do some work with The World Health Organisation. Professor Boyce is our Intragam specialist but a lot of my work on a day-to-day basis is talking to doctors, hospitals, nurses and sometimes to patients about Intragam and its uses.

Intragam P is the current product available ? intra-venous gammaglobulin is its scientific name. Basically it is a fractionated plasma product. We collect blood plasma from blood donors and then we prepare the plasma fraction from that, using a variety of means. What we end up with is a very small amount of immunoglobulin, the antibodies from the original donations. All the Intragam comes from Australian blood donors. We don't have any synthetic way of making it, or making it from animals.

The term anion-exchange chromatographic technology platform is the term that explains how we get our Intragam. In the past we used to use a technique call-ed cone fractionation. The new method is more sophisticated, gentle and efficient ? a 10 % increase in out-put. Intragam P has two viral inactivation steps. One is a pasteurisation, heating the Intragam at 60 degrees C for 10 hours. The second step is incubation at low ph (very acidic). These steps are to inactivate viruses that could be transmitted through plasma. Intragam is an extremely safe product. Since these steps were introduced there has been no transmission of any viral infections in Australia from Intragam. Intragam is probably one of the safest IVIGs in the world.

The most important way that we ensure the safety of the Intragam that comes from CSL is to choose our blood donors carefully. The questionnaire that we ask of our blood donors that come to the Australian Red Cross is four pages long. We ask the most incredibly personal questions, some of which embarrass all sorts of people. But we need to know a lot about what people have done in their past lives which may or may not make them eligible to be a blood donor. Our blood donors are volunteers. They come because they feel a sense of altruism, a sense of community service. The blood is not going to somebody they know necessarily. Because they are not getting any personal reward, we can rely on their honesty when they answer the questionnaire. Before we had any tests for hepatitis, HIV (aids virus), this asking people the right questions about risk behaviours in their past was the way that the rate of HIV transmission through blood transfusion was decreased very dramatically. This was much more effective, surprisingly, than having a test for HIV. So we rely on those kinds of donor screening questions as the first step in the safety of our IVIG.

After collection the blood is separated into its fractions ? the red cells, the platelets, the plasma. The plasma is sent to CSL for fractionation. It goes through this anion process to end up as Intragam. When we send the blood to CSL it has already been tested by the Red Cross for Hepatitis B and C, HIV and a number of other things. CSL then tests it again after receipt. Then we know the steps involved in making Intragam remove lots of potential viruses, should there have been any that we didn't detect on testing. We go to extreme lengths to ensure the plasma we send to CSL for fractionation is safe and the Intragam for treatment that results is safe. All of this comes from a volunteer donor, so we need to rely on the screening mechanisms to make sure the blood is safe. Anything that comes from a human being has a potential to transmit disease to another human being. CSL is involved in a lot of research to work out what things could be transmitted through blood that might be of relevance to the people receiving the Intragam.

Q. Do you lose any of the plasma you collect through such processing?

A. We lose quite a lot. This new chromatographic processing has increased the yield by some 10%. We still don't get out 100% of the proteins that we put in, we get out about 40/50%.

Most of the Intragam goes to support people with immune deficiencies, either congenital ? you are born with the deficiency as a child and we can give you Intragam that contains antibodies to make up for those you can't produce. Secondary immune deficiencies are also very common, sometimes related to haematological problems that come on later in life and cause inability to produce adequate quantities of antibodies and risks of infection. A large number of people suffer from neurological disease such as GBS and CIDP and these receive some 25% of the Intragam output.

Categories of appropriateness of therapy by Intra-gam have been established by the Review of the AHMAC Working Committee. Category 1 is where there is convincing evidence that treatment by Intra-gam is likely to be beneficial. (GBS and CIDP are so categorised.) Category 2 refers to conditions where there is some evidence, but not conclusive, that it may be beneficial. Category 3 is where there is no convincing evidence.

This latter is a very vexed area. How much evidence do you need to start treating somebody with Intragam? If you treat more disorders of this last category, will you gather evidence that it may or may not be helpful. Most of the Category 1 disorders for which we now have good evidence probably started off without such evidence. It is because we gather that kind of data, not just here but internationally, about how IVIG works in different conditions that we can build up the data base of whether it is likely to be effective. For rare disorders it may take thousands of people to be treated to really know whether people benefit or not.

Q. Why have some asthma sufferers been treated with Intragam?

A. There are some case reports that some steroid resistant asthma sufferers do extremely well with Intragam. But this should be done as a clinical trial. Where there are new or emerging indications we would like to encourage clinicians to enrol their patients in a clinical trial. A problem is that Australia has a small, spread-out population. On the other hand we have a very sophisticated medical system and people are very interested in doing research. Some of the conditions are quite rare and so in Australia it can be quite difficult to get enough cases. For this reason many studies have been done overseas.

It is not only the new indications of likely benefit from Intragam; there is also the situation we have a growing, aging population. Many of the diseases are ones of later life and we don't have enough Intragam to go around. But we know that we are trying to increase the amount of plasma that goes to CSL for fractionation. Each year the Australian Red Cross has been able to increase the amount of plasma that goes to CSL to make Intragam - last year we sent nearly 250 kg of plasma.

It is important to remember that a lot of the plasma donated is needed to treat people without being fractionated ? just as raw plasma for burns victims, people with coagulation disorders. It is frozen and then released for transfusion. We have to strike a balance between CSL fractionation and transfusion. The demand for transfusions is also increasing.

Q. How many people are eligible for donating blood?

A. About 3-5%.

We have estimated that the amount of blood needed for fractionation, given the current requirements, the Australian population and international expectations, is probably 50kg of raw plasma per million of population. This works out at about 900 kg. At the moment we are sending 250 kg. It all costs money to increase the supply ? increase more blood donors, more staff to collect more blood, etc. As you know we cannot presently meet the demand, on a good day about 80% of the requests.

For every litre of donated raw plasma we get about 3gm of Intragam. Many doctors and patients would like to receive a dosage of 2gm/kg patient weight on a regular basis. So if you are the average weight of 70kg you are going to need the equivalent of 47 litres of plasma from 200 donations for the needed Intragam. We set the safe limit of 0.5litre for a blood donation (about 10% of the person's blood). We treat every donor with respect and consideration ? we also look forward to future donations! The blood donated is quickly regenerated ? to be achieved by drinking plenty of fluids before and after donation.

Blood is collected in cities and many towns throughout Australia and the plasma for fractionation goes to CSL. In Melbourne we have collection centres in Bundoora, Bourke Street and Southbank. We also go out in the community and set up in church and school halls. We have blood drives in hospitals ? hosp-ital staff are amongst our most loyal supporters. We want to make it easy for people to donate blood.

CSL, as well as processing plasma for the Australian requirements, also processes for some SE Asian countries. CSL receives the plasma from these countries and returns them the processed Intragam.

Q. Most of our members are prescribed very much less than the 2m/kg Intragam for their GBS and CIDP, usually say 30gm (and they usually only get say 24gm).

A. There are many conditions where we will try and give a very large first dose and then go to some maintenance monthly dose. We certainly can't support 2mg/kg on a regular basis for most people.

Q. What can be done to improve donations?

A. Advertising is a basic way but there are lots of other ways. Community networking and support is very powerful. Many people come to the Red Cross and say they have decided to be a blood donor. We say "Thanks very much". They have usually decided this because they know somebody who needed a blood transfusion. This is one of the most powerful ways of attracting donors. People's families can be very committed in this way, not thinking about donating until the need has become personal.

Q. Some years ago the Commonwealth Government stopped giving their staff time-off to donate blood. Is there any chance of a change of policy?

A. This may well have happened. A lot of companies will give time out to their staff to give blood but it is very hard to require that. We do endeavour to make it easier for people to come, not in the middle of their work day, can we open earlier or later, on weekends.

One of the problems is to know when people will come. So we encourage people to make appointments, particularly at our permanent locations.

Q. One recommendation by the AHMAC Working Party that the Government did not accept was to provide \$14 million extra to overcome the Intragam short fall? How important is money?

A. Money is one part of it. It would certainly be nice to have more staff, more occasions for people to donate, more places for people to go.

Q. Do you have a schools? program?

A. Yes, we do. Quite a lot of our blood comes from young people. We have a program for the last year with the "Herald-Sun" to increase the awareness and importance of blood donations in schools. Young people are very open, many are community minded but many would never have thought of being a blood donor if somebody had not put that information to them. We have also blood drives in universities. (*The In Group has taken part in the Blood Service Summer Challenge for the past two years, Ed*)

Q. My brother is a teacher at Ballarat and being aware of my condition he has encouraged kids at his school to donate blood. This year they are getting in competition with other schools.

A. It has been very successful. We have been delighted with the uptake from young people. We know the hardest thing is for somebody to become a donor for the first time. People are too busy; I don't like needles. Once you get people to come in the first time, it is not as scary as they thought, it is not as painful, they didn't feel so crummy afterwards. The first time is the hardest. We have had a campaign last year of "Bring a mate". We have encouraged people to bring a buddy with them, not only less lonely and frightening but also more friendly. It has been very successful. It is slightly less hard for them to come back provided we look after them. We don't keep them waiting for two hours, we don't give them blood bruising on their arm. Most of these are preventable.

Our blood donors give blood between 1.7 and 2.1 times per year (maximum is 4 times per year.) If we could increase the small percentage of people who donate from giving once to twice a year this would be a great increase in the supply. Plasma donors give 5 to 9 donations a year (some every few weeks). Their blood is passed through an apheresis machine to obtain the plasma with the remainder, red cells, being returned to the donor. The donors can make up their plasma quite quickly so that is why they can donate more frequently than full blood donors. Especially for women who have a tendency to get iron deficient and anaemic from loss of red cells. It is a good way to get plasma without too much concern for the donor.

Q. Have there been any studies made of why generally donors don't give more than once or twice per year?

A. We know some of the reasons but not the individual responses. Last year Sir Ninian Stephen handed down his review of the Red Cross Blood Service and suggested that more research should be done on blood donors, why people do and don't donate. Interestingly, blood donor research is one of the neglected areas of transfusion research. I spend a lot of time on transfusion research, on people who receive blood, potential benefits and hazards, but we know little about the psychology of a blood donor and what motivates a blood donor.

Q. What percentage of plasma goes into Intragam?

A. I don't know the answer. We know for each batch of Intragam it takes more than 10,000 blood donations. I don't know how many batches CSL produces each year but we collect in the order of one million donations each year. A large proportion of the plasma collected goes to CSL. I don't

know how much CSL allocates to Intragam.

Q. My Intragam was cut back a year ago. Is it likely to be cut back again? After the cut back, I got worse.

A. I don't know the answer. We don't have enough Intragam to meet all the needs. It is a balance between giving some people all the Intragam they need and some people nothing which is obviously not appropriate, and trying to give most of the people most of what they need most of the time. That is not an easy balance. At the same time the Blood Service has the need to try and work with people and their doctors to determine the minimum amount to keep people active and healthy.

Q. My doctor has communicated with the Blood Service about my not getting adequate Intragam and has received no reply.

A. I am sorry to hear that. Could I suggest you ask your doctor to write again. We are happy to review everybody's request. I spend part of my day in reviewing requests. For some people we don't hear from their doctor, for others we hear every few months, saying Mrs X is doing well or Mr Y is not doing well. This communication is very helpful.

Q. Generally, are you seeing an improvement or a decline in the situation?

A. I don't know. It is in a constant state of flux. The demand is increasing at the same time as the supply is increasing. It is very hard to see which is predominating at any time.

Q. Why do people get Intragam at different periods?

A. We know that Intragam has a long half-life, about forty days. So it is difficult to predict whether some-body would benefit from a larger dose less often or a smaller dose more often. This has to be worked out between a person and their doctor. Also it can change with time. Some people improve and need less, some can get worse and need more.

Q. I find it frustrating to go too frequently for the Intragam.

A. This is why communication is very important between the Blood Service, doctors and patients. It is very individual. Some people improve and can have the interval between Intragam treatment extended, others get worse and may need the interval reduced.

Q. If a doctor supplies some objective evidence about the treatment, what is the Blood Service response?

A. We do appreciate those who supply hard evidence but it still means we don't have enough Intragam.

Q. What has been the effect of the "Mad Cow" disease on donations?

A. We expected to lose 5,000 donors in Victoria with the CJD deferral introduced last year. In fact we have been successful in replacing most of those people but it has taken a lot of time, effort and money. We have collected more blood last year than in the previous year. The most useful donors are those who come year after year. We know the donors, and regulars will have a lower rate of hepatitis and HIV.

Q. I have a reaction to Intragam. Is it the plasma component or something added?

A. There are very few things added. There is maltose, a kind of sugar. About one percent is not

immunoglobulin and occasionally people will have reactions. Most of the reactions can be prevented or reduced by slowing down the rate of infusion.

Q. Is oral rather than intravenous provision of Intragam possible?

A. It is unlikely because antibodies circulate in the blood stream and their proteins would be destroyed if passed through the gastro/intestinal system.

Q. Do you keep up with other countries?

A. We do. I use to work in the USA Red Cross in the IVIG use. Australia has a middle ranking in the amount of IVIG used per capita. USA uses about twice as much as we do and we use about twice as much as the UK.

Q. How can we help with the blood donations?

A. Probably the most useful thing is to talk to your friends and family about what you need for your treatment and say "It is quite easy to be a blood donor. It is something most people can do."

Q. Would you welcome correspondence from nurses involved in Intragam treatment?

A. We are very interested in how people are doing as it helps us to know how we are meeting the needs.

(Dr Erica Wood most kindly replaced our scheduled speaker, Dr Neil Boyce, at very short notice. Dr Boyce unfortunately was ill and could not attend.)

STOP PRESS from NE Cluster Group

*Dear James, I had a telephone call and a visit from Robert and Nancy Wilson. Robert contracted GBS on Christmas Day ? what a present! John Ward (who is connected with the family) suggested he ring me. I gave him various pieces of literature to read including a booklet. Since then he has been in contact with Jill Grimmond. He was very pleased with our information which he says lifted him out of his depression. He said he would like to make a small donation and also join. **VILMA CLARKE.***

IN Group News

Rosemary MacQualter and James Gerrand attended a meeting of COSH (Collective of Self Help Groups) 14th February to hear Bernice Murphy of the Victorian Department of Human Resources present the government's funding for Health Self Help and Disability Services. The In Group expects to make a submission to the Department for such funding. It is hoped we may obtain a grant for this year of some \$500-\$1,000 to help our support for chronic health sufferers.

James attended the Annual General Meeting of the Chronic Illness Alliance (CIA) and took the opportunity to inform the meeting of the major problem being experienced The IN Group due to the shortage in the supply of Intragam. Many of our members are suffering because they are not receiving the full amount of their medical prescription.

The IN Group is to consider joining the Physical Disability Council of Australia Ltd (PDCA). It appears to be active throughout Australia and is planning **A National Day of Action** for September 2002 in regard to physical disability. James expects to attend the next meeting of its Victorian group on Thursday 28th February 11.30am ? 2.30pm at Para Quad 208 Wellington St Carlton.

The In Group exchanges newsletters with The Australian Reflex Sympathetic Dystrophy Support Group - "Fighting Pain Together".

An email was received from Emma Corcoran seeking stories of people living with a chronic illness or condition for a book she was collating. She had obtained our member Margaret Brew's story from The IN Group's web page. We advised that we had two booklets featuring such stories.

Support is the Name of our Game

Local Support

KEITH COLWILL has been busy visiting sufferers from GBS and CIDP. Here are two reports.

Dear James,

Since you informed me about GBS patient Paul Beardsley, I have visited him three times in the Hampton Rehab Hospital.

I am pleased to report he is making very good progress and on each visit the improvement in his condition has been quite noticeable. Throughout, his attitude has been very positive and today he was able to show me he can now stand again!

He wishes to join The In Group for which purpose, enclosed is my cheque for \$10.

Keith Colwill.

Great support, Keith, and again:

Dear James,

My visits to Paul Beardsley have prompted me to check up on the conditions of two other GBS patients I visited in June last year, viz: Mr Chris Gooch (age 52) of Wonthaggi and Mr Jim Dick (age 50) of South Caulfield.

Mrs Jenny Gooch reports her husband is much improved and pleased to be back at work although he can't do as much as he did formerly. He still tires easily. He and his wife were very grateful for my visits when he was at Hampton Rehab Hospital.

Mr Gooch asked if I knew anything about GBS effects on teeth. Apparently Chris's teeth became fairly brittle after his discharge from Hospital and since then three of his teeth have broken off! Do you have any relevant info on that problem?

Mr Jim Dick, who fortunately suffered a relatively mild GBS attack, tells me that he recovered well and returned to work with no residual ill effects. He was at the Brighton Rehab Centre.

Keith Colwill.

Seventeen year-old Keiran Weir was badly affected by GBS. After spending some weeks in Intensive Care at the Monash Medical Centre he is now in rehab there. After being informed of his plight I visited him shortly after he came out of the ICU, still pretty paralysed and not able to talk. I arranged for Julie Loncar and her son (who had GBS when aged 12 and is now a basket-ball player at 20) to visit him and also Keith Colwill visited. Keiran is a keen drama student, recently selected for a lead role in a play at his school. *James Gerrand.*

I received an email from Tasmanian member John Stanley relaying a message from a brother-in-law of a 35 year old woman, originally diagnosed with GBS but now rediagnosed as Critical Care Myopathy. This disorder has made her a paraplegic, her legs and lower body being paralysed. I visited her at North Croydon at a home run by the Paraplegic and Quadriplegic Association. While she was accommodated comfortably in her own room, the centre lacked live-in medical attention. Her lungs were also somewhat affected, resulting in her not breathing in sufficient oxygen. It seems she needs an oxygen generator (it treats the air to increase the oxygen proportion) but this is not available full-time to her. I said The IN Group would look into seeing whether there was sufficient long-term and multi-use demand for such a ventilator that would make it worthwhile for The In Group to purchase one at a cost of \$2,800. *James Gerrand*

Accommodation for the rehabilitation of GBS and CIDP is becoming very difficult at some Rehab Centres for those requiring long-term attention. I visited a Fred West (age 72) recovering from GBS at the Box Hill Hospital, following separate email advice from his two daughters. He had been sent to the Royal Talbot Rehabilitation Centre but had been returned after one day suffering from pneumonia. Recovering from that The Royal Talbot refused to have him back stating they only handled shorter-term cases. Then St George's Hospital was proposed but Fred objected because it is a centre for geriatrics. He is now at the Ferntree Gully Rehab Centre. *James Gerrand*

Overseas Support

Many overseas requests for help come via the Internet (thanks again CSL for your continued sponsorship that finances this communication avenue). Often it is for information about our relatively rare and unexpected disorder, GBS/CIDP, to which we respond with booklet/brochure newsletter..

Vineet Kapilla of New Delhi, India, advised "*My wife has recently suffered an attack of CIDP. She was treated with five day dose of IVIG and now the doctors will monitor her progress further.*" Material posted.

Malcolm Bentley, Bradford, UK, sought advice as to what may have caused his CIDP. He also mentioned "*the most difficult thing I've had to deal with has been losing my ability to play the fiddle.*" We advised that whilst some bodily invasion can usually be ascribed to an attack of GBS, no clear indicator showed up for CIDP.

Goska Wolnik emailed "*I wish to apply for membership. My father, who lives in Poland, has been recovering from GBS ?spent nearly 6 weeks in hospital. There are no support groups in Poland so there is not enough emotional support for him and my mother. ? I hope that additional information on recovery, exercises and treatment would be beneficial to him and my family.*" Material posted and Mr Wolnik is now a member.

Email from Jim Janis. "*I live in Upstate New York, USA, and am currently taking cytoxin treatments monthly with little or no change to my ? Multi-Focal Motor Neuropathy and continue to lose the use*

of my hands slowly and surely, also my legs. My treatment will end in March ? and was hoping maybe you could suggest a clinic or doctor that may be able to help me. My present doctor is very good but seems to be puzzled ?" Replied with advice to contact the GBS Foundation International (based in the USA) and the Mayo Clinic.

Curtis Vincent, Louisiana, USA, emailed "*I was diagnosed with CIDP a year and a half ago and have been reading your info on the website. It is the most helpful and up to date that I have found so far. I would like to become a member in order to receive your newsletter and support the organisation. ?" Curtis thanked for his compliments, asked for his address so material could be posted and for details on how the CIDP has affected him and what treatment. In his reply Curtis stated " My symptoms began ?with mild numbness in the tips of my fingers ? The real onset ?was ? burning sensations that have crept up my right leg ? There ? have been no motor problems yet. I have been through two, five consecutive day, treat-ments with IVIG and neither has improved symptoms in the least. ? IVIG is very expensive here ? about \$15,000 for each five day treatment."*

Rafic Moubarac, Montreal Canada emailed "*I have had a chronic GBS for the past 20 years. I am interested in joining your association and be the local chapter for Eastern Canada. ?" Material posted.*

Rosa Garcia, Idaho USA emailed "*My father? was recently diagnosed with CIDP. He is only 42 years old. He went for months without doctors knowing what was wrong. Now he can?t even walk. I would like to join so I can receive more information on CIDP."* Material posted.

Two letters have been received and replied to, from an inmate, suffering from GBS, at the Pelican Bay State Prison, Crescent City, California USA. In the later letter, John writes "*I am 42 years old and still looking for a pen-pal. I?ve had GBS two times in five years and now they say it?s CIDP. James, I?m not feeling too good today ? my feet, legs, and hand hurt bad. The weather here is cold and wet. I hate it. Hopefully you can find a female or two for me to write to. That would make my day?."* A CIDP booklet, our brochure and newsletter posted to John. Any member (female?) who would like to be a pen-pal communicate with James Gerrand 9853 6443.

Some Zen Thoughts

On the other hand, you have different fingers.

I just got lost in thought, it was unfamiliar territory.

42.7% of all statistics are made up on the spot.

Honk if you love peace and quiet.

Last Updated: 15 Oct 2007 17:49