THE UK EXPERIENCE
TREATER AND PATIENT ASSOCIATION PERSPECTIVES

P. GIANGRANDE

K. PAPPENHEIM

DHSC0006838_071_0001

Communicating Risk - The Example of vCJD
The UK Experience: The Treater Perspective

Dr. Paul Giangrande, Director, Oxford Haemophilia Centre (UK) and Vice President Medical, WFH

The purpose of this session (a joint presentation between a physician and a patient representative) is to highlight a specific example of risk assessment, and to stimulate discussion about the various practical and ethical issues involved.

In December 2000, physicians in a number of haemophilia centres in the UK were informed by BPL (Bio-Products Ltd) that a donor who had contributed to the plasma pool used to manufacture various blood products in 1996 and 1997 had recently died of vCJD. The letter specified several batches of both factor VIII and IX which were issued some time ago and had therefore been used in clinical practice. This was not the first time this problem had arisen, as batches of factor VIII were the subject of a similar recall by BPL in 1997.

The principal questions which needed to be addressed were as follows:

Should patients be informed of these events?
On this occasion, the company offered no specific advice on whether or not patients should be informed of the problem which had arisen. However, an accompanying letter from the UK National Blood Authority specifically instructed that patients should not be told of the problem. This advice was consistent with similar advice issued two years before by the Department of Health, and was based on the premise that no test was available to identify true infection with vCJD and furthermore no treatment was available. In other words, imparting the knowledge of exposure to a possible risk, which was perceived as small, could only engender anxiety.

Physicians in the UK (UKHCDO) convened an early meeting with the aim of adopting a common response. The majority of physicians expressed the view that an early and frank disclosure was required on ethical grounds, although this was not a unanimous opinion. In addition, it was recognized that the national patient organization (UK Haemophilia Society) had already been appraised of the situation and news of the problem had also leaked out to the national media and this added weight to the view that silence was not an option.

It also subsequently transpired that a number of batches of other blood products (such as albumin) implicated in this product recall had been distributed around the UK and indeed other countries round the world. To my knowledge, no attempt was made to inform the recipients of these products of the problem.

How and when should patients be told?
The preferred option would have been to have held personal discussions with individual patients at their routine six-monthly reviews. Clearly, there was no clinical need to inform patients about the problem immediately. However, the knowledge that news would break in the media required a prompt response. One view was that all patients - not just those who had received the implicated batches - should be informed

DHSC0006838_071_0002

about the problem and asked to specify whether they wished to be told if they had received any of the material. The alternative view, which ultimately prevailed, was that only those who had received the batches should be approached. This generated a tremendous amount of work for all staff at affected haemophilia centres. In my own centre, a total of 85 patients had received implicated batches and all received individual letters notifying them of the problem. Care was taken to ensure that letters went out early in the week, to ensure that they did not arrive at the start of the weekend when no-one was available for advice and support. In addition, the patients' own general practitioners needed to be informed. A second wave of letters then had to be sent out to all other patients to reassure them, in the light of media reports, that they had not received any of the batches.

What should patients be told?

Although the option of a single, common letter for all patients was considered, it was ultimately decided that individual centres would write letters to their own patients. In addition, the UK Haemophilia Society produced a letter which was sent to all members in the country. The key points made in all letters were the lack of any evidence of transmission of vCJD and the fact that BPL plasma-derived concentrates (which are still widely used in England) are now made from imported plasma.

What was the reaction of our patients?

As a general rule, the reaction was surprisingly phlegmatic. Many recognized that, in contrast to previous outbreaks of HIV and hepatitis, vCJD is an issue which faces all of us who live in the UK, and not just the recipients of blood products. However, there were several notable exceptions where real and persisting anxiety has been generated, including several patients who have consulted me because they are convinced that they are harbouring vCJD.

One common reaction, both among patients as well as physicians, was that this episode (which had generated anxiety for patients and a lot of extra work for physicians) could have been avoided if the government had adopted the unanimous view of haemophilia treaters in the UK to introduce recombinant factor VIII by the beginning of 1997. This episode has also made patients even more sceptical about switching to plasma-derived products because of the current shortage of recombinant factor VIII, and it has also resulted in our policy of using certain plasma-derived products (particularly of European origin) for the treatment of von Willebrand disease being called into question.

Were there any other consequences?

One unexpected consequence was that some patients who had received these batches were regarded as being at high risk of transmitting infection themselves. There were several instances of patients being denied surgery, dental work or endoscopy because of the implications for surgical instruments. Advice was sought from the Department of Health, and although guidelines are expected to be published these have not yet been forthcoming at the time of writing.

Summary

Although the company should be congratulated for making a full disclosure to physicians, it is regrettable that the government (Department of Health) applied

DHSC0006838_071_0003

considerable pressure for some time to specifically prevent patients being informed of the facts. The contribution of the media in this case was not at all helpful. Overall, there was good collaboration between physicians in the UK to produce a common response although this could have been more rapid. There was also consultation between physicians and the UK Haemophilia Society.

DHSC0006838_071_0004

Communicating Risk – The Example of vCJD
The UK Experience: The Patient Association Perspective

Karin Pappenheim, Chief Executive, UK Haemophilia Society

1. Introduction

In December 2000 - just before Christmas - the Society was notified by BPL that a plasma donor had been found to have variant CJD (vCJD). The Society had to decide how it should respond to this news and what actions - if any - it should take to communicate this information to members.

This was not the first such incident in the UK; in 1997 a product recall was initiated after it was found that two plasma donors had vCJD. That was the first time in the UK that this situation had arisen, and information had to be provided very quickly because product was still in use. Many – patients and treaters alike – had found that traumatic and stressful.

In the 2000/01 incident the major difference was that the affected product had either been used already or had been taken out of use already; hence there was not the same urgency as with a product recall. Nevertheless this was still important and sensitive information to convey to patients.

After urgent consultation between myself, as Chief Executive, and the Society's trustees, it was decided that the Society had a responsibility to notify its members. However, we were aware that the haemophilia centres would probably also take action to notify their patients. Having consulted with Dr Frank Hill, the UKHCDO chairman, it was decided a) not to send this information out over Christmas and b) to try to co-ordinate our actions and to wait until the UKHCDO executive had met on 15 January to decide their policy on this situation.

There were two additional concerns:

a) that the Department of Health had had a policy in place for some years that information of this kind should not be passed on to patients and therefore it was possible that the haemophilia doctors would decide to comply with that;
b) that the media might get hold of this information before patients and their families had been notified hence causing greater alarm/distress.

Overall, the Society wanted to reassure members that the risk of contracting vCJD via blood products was 'theoretical' and that latest expert opinion supports this (particularly the briefings sent out by the World Federation of Hemophilia medical/scientific experts). We were aware, though, that the lack of a test for vCJD would cause additional anxiety.

Also, in the UK, the particularly high media profile of vCJD was another factor. The four-year public inquiry into BSE had recently been concluded and there had been much press/media coverage of the suffering of vCJD victims including video footage shown on TV of a dying teenager. This meant that general public awareness of the condition was much higher than in 1997 when the previous vCJD incident occurred.

2. How was information conveyed?

People with haemophilia received information about the vCJD donor in three ways

a) via a letter from the Society if they were a member or registered on our database (not all the UK's 11,000 people with haemophilia/von Willebrand are on our database)
b) via their haemophilia centre either by letter or phone call or combination of both

DHSC0006838_071_0005

c) through the media.

Our letter went out to members in the week of 15 January, once we had learned that the UKHCDO would be communicating to patients. Unfortunately, although it was sent first class (i.e. for delivery the next day), due to problems at the time with the UK trains and postal service, some letters arrived late. This meant that some received the information over the weekend, which caused additional distress because families could not contact our helpline or their centre until Monday.

3. Practical communications problems facing the Society

The major problem for the Society as the patient organisation was our lack of detailed information about the patients who had received the implicated product. BPL as the manufacturer could not tell us which patients had received the product; only the haemophilia centres were in a position to do this and for reasons of time and patient confidentiality they could not pass on this information to the Society. This meant that we could not carry out a mailing targeted only to those people directly affected by this product.

The other practical problem for the Society was our own patient database is in the process of being updated and at that time did not permit us to easily separate children from adult members. We wished to avoid sending our letter to any under 16s as we felt the information in the letters would be too distressing and difficult to send direct to children. We also did not wish to create a situation in which a child might be notified by a letter from us but their parents might not receive a similar letter.

In order to prevent these problems, we had to manually sort our mailing which in turn delayed the mail-out.

Our other difficulty was that since we did not know which of our members might have been affected, we had to send our letter to all of them. Thus, some might take the view that they had been unnecessarily worried, although I am not aware of any comments to that effect from our members.

In order to be prepared for the response, our services team had briefing information packs containing the latest expert research. However, this was too technical to send out to many of those who contacted the helpline, especially those who were very distressed. Talia Barry, our children and families worker, therefore prepared a simplified information sheet for adolescents/parents in consultation with haemophilia specialist nurses Vicky Vidler and Kate Khair.

4. The doctors' role in conveying information

The UK haemophilia doctors decided to offer patients a choice as to whether they wanted to have this kind of information now and in the future. However, this approach was only implemented by some centres.

It seems some centres relied wholly on letters as their form of communication; others made personal phone calls. Some held meetings for patients; some offered individual counselling to those affected.

5. The media's role in conveying information

The unpredictable element was the press and media who decided to seize this issue following a parliamentary question to Lord Hunt, health minister, in the week of 29 January. The

DHSC0006838_071_0006

Society was involved in a media blitz with coverage on many radio and TV channels. Some of this was misleading and sensational implying that people with haemophilia had actually contracted vCJD.

It was after this coverage that numbers of calls to our helpline increased, and people were clearly more distressed by the press/media coverage than they had been by receiving letters from the Society.

6. What could be done better next time?

One of the important decisions for the Society is whether or not we have a role in providing this kind of information to those on our database in future. If we could achieve better co-ordination and co-operation with the UKHCDO and the centres it might be unnecessary for the Society to send out the kind of mailing in future. Letters from centres could mention the Society's helpline as another source of information/advice. In this way we would continue to have an important role in providing information/advice but we would not be taking the lead in informing individuals.

In our contact with people seeking information and advice from the helpline, the Society has inevitably had to refer individuals back to their own centre for detailed discussion/information. It may have been confusing or frustrating for some of our members to receive a letter from the Society and to then have to contact their centre to find out whether they were personally affected by one of the BPL batches.

Feedback from some centres suggests that in some ways our letter imposed more strain/distress because the Society's information mailing was not targeted only to those who were affected; e.g. one centre reported that they had had to spend much time reassuring worried parents whose children had not actually received the affected BPL batch.

Another concern expressed by Society groups was that their officers were not notified of this information before we sent out to members. This meant that some received worried phone calls from members of their own group which they were not in a position to deal with.

The other issue which we will be addressing with the Department of Health is that of their current guidance stating that patients should not be given this kind of information. Having raised this at the meeting with Lord Hunt in January, it was stated that the Society would be involved in reviewing this guidance.

In general, having discussed the situation within our staff, trustee and volunteer groups, the overall conclusion of the Society is that, whatever other agencies may do in providing information, as the patient organisation we have a responsibility to be pro-active. As the national patient organisation, we do not believe that we can leave it wholly to others to provide information and advice in this situation.

7. Lessons and outcomes for the future

The Society is in discussion with the Department of Health, which at the time of writing was reviewing the procedure to be adopted when such incidents occur. This is part of a wider discussion in the UK about handling of vCJD incidents, which is being reviewed by an expert advisory group reporting to health ministers.

DHSC0006838_071_0007

Through this we hope that

1) Advice from the Department of Health to doctors will be changed so that it is recognised that they need to inform those affected next time vCJD plasma is traced to treatment products.
2) A national protocol will be agreed to, setting out the timescale for communications and the key stakeholders to be involved, including the patient organisation.

One of the unplanned benefits of this situation has been a raised awareness among the patient group of the need to be connected with the Haemophilia Society. Inquiries about becoming a member or simply registering on our database increased substantially following the vCJD incident. The Society has also taken the opportunity to send out membership information, reminding people that if they are not on our database we will not be able to send them updates on product safety and supply in future.

Patients' and carers' reactions to this latest vCJD incident have been varied. Older patients have often tended to be more philosophic, and viewed this as 'just one more thing, first the HIV, then the hepatitis, now this....' 'It could have been the beef burgers anyway' was another reaction from those who realised that the whole UK population was potentially at risk of vCJD from eating affected meat. Strangely this was a comfort to some.

Others were very angry that as they saw it haemophilia patients had been once again exposed to risks of blood-borne infections. In effect, after HIV and hepatitis, this news about vCJD was the final straw. As a result some wished to take legal action and/or complain to their hospital authorities.

Some of the most distressed reactions have been from parents of children who have received the treatment batches traced to the vCJD donor. This was especially so for those children who had fairly recently been switched to recombinant, whose parents had been feeling less anxious – now only to realise that shortly before the switch their child had received this vCJD donor product. One very distressed father reported that he and his wife had spent all weekend watching their son for signs of vCJD.

Following media publicity, some parents also reported bullying and teasing of their son at school. Other children in one school were apparently using the nickname 'mad cow' for a boy with haemophilia.

Overall, the incident has served to strengthen the Society's campaign for recombinant for all patients. At the time of writing the provision of recombinant in the UK is very uneven – a policy of recombinant for all applies in Scotland and Wales but in England and Northern Ireland only children under 16 years are entitled to this treatment. We have put the case to government for introducing a policy of recombinant for all for the UK, and await the outcome at present.

Karin Pappenheim
Chief Executive, UK Haemophilia Society
Chesterfield House, 385 Euston Road
London NW1 3AU
Tel GRO-C
Email GRO-C

July 2001

DHSC0006838_071_0008