vCJD Donor Notification Exercise: 2005

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Abstract

The UK blood services, supported by the Health Protection Agency/Health Protection Scotland, carried out an exercise over the summer of 2005 to notify 110 donors whose blood was transfused to three recipients who later developed vCJD. These donors were to be informed that they were now considered "at risk of vCJD for public health purposes". The notification began on 20 July 2005 and was completed (barring follow-up) at the end of the first week of October 2005. Apart from 2 donors who had died, contact was attempted with all donors, including 4 who were not currently registered with a GP. The lessons learnt about the conduct of such notification have been reviewed. The limited ad hoc feedback available suggests the process and content of this notification was acceptable to donors and their GPs.

Key words: vCJD, blood donors, notification

Introduction

In December 2003 the first case of possible transmission of vCJD by blood transfusion was described[1]. Shortly afterwards, a further case of vCJD infection associated with transfusion was reported, when post mortem investigations on a transfusion recipient who showed no clinical evidence of vCJD before death and died of other causes, found evidence of vCJD infection.[2] For both these recipients, a blood donor had already been identified who had developed vCJD some time after donating blood. Following the first case of vCJD associated with transfusion, it was decided that all other (surviving) recipients of blood from donors who had later developed vCJD should be informed of their exposure and their increased risk (above that in the general population) of vCJD through transfusion. Notification of *recipients* of blood from *donors* who later developed vCJD therefore began in late 2003/early 2004. Based on recommendations from the CJD Incidents Panel[3] these individuals are considered to be 'at-risk' of vCJD for public health purposes, and are asked to take certain special precautions to reduce the risk of transmission of vCJD to others. These special public health precautions are: not to donate blood or other tissues, and healthcare staff to apply special infection control measures to certain healthcare instruments[4]. Transmission of vCJD by blood and healthcare instruments (even after current best-practice cleaning and decontamination) has the potential to cause further cases of vCJD and even, under some plausible assumptions, to sustain an ongoing epidemic of vCJD in the UK. The application of special precautions for individuals who are identified as at increased risk of harbouring vCJD infection is one component of the UK's efforts to reduce the risk of ongoing

transmission of vCJD by healthcare procedures. These precautions are for the benefit of others, hence the term 'at-risk' *for public health purposes*.

Because the incubation period for vCJD may be long, and variable between individuals, the question then arose as to whether *donors* whose blood had been transfused to *recipients* who later developed vCJD might be considered as a possible source of their recipient's infection, and therefore to have an increased risk of vCJD infection. An assessment of the risk of donors being infected – given a recipient of their blood was infected – was conducted. This assessment estimated the probability of infection, given certain assumptions: this 'probability' of infection can also be described as the 'risk' of infection. This showed that each such donor had an increased risk of being infected with vCJD, and of being the possible source of vCJD in the transfusion recipient, and the CJD Incidents Panel judged that the size of this increased risk warranted considering such donors to be 'at-risk' of vCJD for public health purposes, i.e. that special precautions against onward transmission by blood/tissues and by healthcare instruments should be taken. The notification of donors to vCJD cases, and of their general practitioners, of their increased risk of vCJD infection was planned over the early summer of 2005, and was announced by a public statement in the House of Commons on 20 July 2005.

The notification related to donors to 3 vCJD cases who had received blood transfusions prior to their onset of vCJD, where blood transfusion could not be excluded as a possible source of their vCJD infection and no infected donor had already been identified. Two of the vCJD cases had received blood transfusion in England in 1993. One case had been transfused with 3 units of blood components and the other had been transfused with 103 units of blood components. A third case had been transfused in Scotland in 1994 with 4 units of blood components. Each of

these blood components was donated by a different donor, so these three vCJD cases had been exposed to 3, 103 and 4 different donors respectively. The notification involved three blood services (England, Scotland and Wales), with the National Blood Service (NBS) (England) being responsible for the vast majority (103 [KS?? 106??] of 110) of the affected donors.

Methods

In England and Wales, "active" (current) blood donors were notified by letter on 20 July 2005, or as soon after as identification and tracing allowed. Active donors were defined as those who had donated in 2000 or later. In Scotland, where the number of donors was small, all were notified on 20 July 2005.

For donors in England who had not attended for 5 years or more, the blood service sought to confirm the donors' current situation and status before notification. Each lapsed donor's GP was identified through the Strategic Health Service Tracing system and asked to confirm the patient was still alive and under his or her care, and to provide any information which might be of relevance to the notification of their patient.

For all donors, the blood services sent a letter directly to the donor together with a comprehensive information leaflet from the Health Protection Agency (HPA)/ Health Protection Scotland (HPS). For every donor registered with a GP, the HPA/HPS sent GPs an explanatory letter providing further information, with copies of the correspondence sent to their patient (the donor). Letters were timed to arrive with GPs at least 48 hours before the donors received their notification letters. GPs were given details of further support through the local Consultant in Communicable

Disease Control (CCDC) or equivalent (CPHM in Scotland) or from staff at the HPA Centre for Infections. Relevant CCDCs/CPHMs were also sent prior warning of the notification of an individual in their area so that they could be prepared to offer support to the GP if requested, and to assist with any subsequent public health measures.

All donors were offered access to further advice and support from their GP, and invited to use a contact number, available 24 hours/day, for discussion with a senior member of the blood service medical staff. In addition, notified donors were provided with the CJD Support Network contact number. NHS Direct set up a dedicated helpline to respond to queries from the public.

In order to ensure good cover and accessibility of call-lines etc, the work in England was phased; active donors were notified on 20 July or soon after, and lapsed donors in batches thereafter. To help planning, the NBS maintained a regular timetable for management of lapsed donors. Enquiry letters to GPs were posted in two batches during August 2005. Replies from GPs were processed in weekly batches. Each Tuesday, HPA was informed of the donors to be notified the following week. HPA sent out information packs to the relevant GPs (and CCDCs) on the following day, so that the GPs should receive the communication by the end of the week; letters to the donors were sent to arrive on the following Wednesday.

For all notifications, GPs were asked to return a form to the HPA confirming that their patient had received and understood the information sent to them, and reporting any other donation history or recent healthcare that may require investigation by the CJD Incidents Panel The CJD Incidents Panel[3] is an expert committee established on behalf of the UK Chief Medical Officers in 2000. Its terms of reference include:

'To assist all those bodies responsible for the provision and delivery of healthcare to decide on the most appropriate action to take to handle incidents involving potential transmission of Creutzfeldt-Jakob Disease (CJD) and variant CJD (vCJD) between patients through clinical interventions, including via surgical instruments, tissues, organs and blood and to keep the relevant devolved administrations informed.

To consider what information should be collected on patients who may have been exposed; advise on what studies or follow-up may be needed; advise Directors of Public Health on patient tracing and notification exercises where these are indicated; and advise on whether any other measures are needed to protect the wider public health.'

Details of calls received in relation to the exercise were recorded and reviewed. Forms returned to HPA and calls to the NBS were crosschecked to identify any donors for whom no contact - either personally or through their GP – had been made. The HPA contacted the GPs of deceased donors in order to identify any medical treatment prior to death that may require investigation by the CJD Incidents Panel.

Results

Within England there were 50 "active" donors who had donated blood within the previous 5 years. One of these was known to have died without any evidence of vCJD and one had transferred to Wales. The NBS therefore sent 48 notification letters to "active" donors, SNBTS notified 6 donors (active and lapsed), and the Welsh Blood Service notified one donor. A total of 55 letters were therefore sent by

blood services to arrive with donors on 20 July, or soon after (as tracing of active donors allowed). All but 1 donor was registered with a GP. HPA/HPS sent letters to 54 GPs and to the relevant CCDCs/CPHMs for all 55 donors, timed to arrive on 18th July.

The NBS received 13 telephone calls and one letter by or on behalf of notified donors out of the 48 'active' donors notified. One call was from a GP who had mislaid the HPA letter, and one was from a GP on behalf of his patient. One was from the husband of a notified donor who was too distressed to speak in person: the GP had contacted the donor before she had received the notification letter from the NBS, and this had caused the distress. The remaining calls were from notified donors. Most were seeking clarification of certain points, in particular trying to assess individual risk. A number of notified donors who were health care workers had queries about any occupational issues, for example the need for special precautions when carrying out exposure-prone procedures (an issue not covered in the information leaflet). Only one telephone call was received by NBS outside office hours, at 19.00 on the day of the notification. One SNBTS donor reported attempting contact (which was unsuccessful) at the weekend following the announcement. This donor then contacted the CJD Support Network.

In Scotland, the blood service spoke to all 6 notified donors in the period following the notification.

The CJD Support Network received one call from a GP (who also contacted NBS) and four calls from notified donors, including the Scottish donor referred to above. Whilst some donors expressed anxiety to varying degrees, all donors were judged to

have handled the information well. The calls mainly revolved around trying to further clarify individual risk.

Only one caller (to blood services or CJD Support Network) was judged to be distressed (above). Some provided helpful suggestions for further notifications. Others were seeking assurance that they would be contacted and offered a test when one became available. The majority commented that the notification letter and information leaflet were clear and informative. Understanding of the reasons for the notification and for the public health precautions they were being asked to take was good.

The NBS had a total of 54 "lapsed" donors, including 1 deceased and 3 not readily contactable who were not registered with a GP. One was known to have moved to Spain, but two were of unknown whereabouts. This left 50 donors to be notified after response from the GP.

Many GPs responded promptly to the NBS's request for information relevant to the notification of their patient. The majority provided details of current health, and details which might be relevant to the notification (e.g. one woman had recently had a baby and would need reassurance about the health of her baby, one woman was on treatment for depression). One GP refused to provide any information without his patient's consent, and another telephoned with the same concern but was reassured by discussion that provision of relevant details was in his patient's best interest. One GP wrote to express his gratitude for the prior warning about his patient's notification, which he found "refreshing" and "unusually proactive".

Non-responding GPs were telephoned in the week of 5th September to expedite progress, but replies from 5 GPs were still outstanding by the end of September. Notification of the final 5 donors followed a telephone conversation with the GP, but without any written information. The number of notification letters sent to donors ranged from 4 to 16 per week over a period of 6 weeks.

The NBS received contact from two lapsed donors: the donor with the history of depression and the pregnant lady, illustrating the value to the NBS of having this information in advance of any contact with the donor. The GP of a third donor made contact expressing concern about the notification, which he felt would deeply distress his patient. He made suggestions for changes in the letters sent to the GP and the donor. These suggestions were noted and his concerns acknowledged. The donor subsequently wrote to the NBS and was contacted by a senior member of the medical staff. A long telephone discussion helped to address some of the donor's concerns and distress. A report was made to the GP who expressed extreme satisfaction with the NBS's response to him and his patient, and gratitude for the personal response to them both.

Follow-up

By mid-November 2005, GPs had returned 53 forms to the HPA, giving details of their patient's notification and of any healthcare procedures that may require public health precautions to be taken. Forty-eight forms confirmed the patient had received and understood the information. Many GPs had seen their patient in person. Five GPs were unable to confirm that the information had been received as they had not had any contact with their patient since the notification. Two of these five patients,

and a further 3 whose GPs have not yet returned the form, are known to have received the information because they called the NBS help-line, making a total of 53 donors who are known to have received and understood the notification information from the NBS. All six SNBTS donors were contacted proactively, and the WBS donor was confirmed by the HPA to have received the information. Follow-up of GP forms is continuing in order to confirm that all donors have received and understood the notification letter.

Other contacts

NBS Customer Services received 12 communications following the public announcement, and one letter was forwarded from CMO's office for a response. Six calls and the forwarded letter were from donors unaffected by the announcement who disagreed with the decision to notify the affected donors. These donors all received a telephone discussion or written response. None of them had seen the contents of the announcement or the communications sent to the notified donors: they were all responding to media reports. The other calls were not directly connected with the announcement, but related to other CJD precautions and donor selection. All donors received a personal response.

NHS Direct received less than 20 calls in the 48 hours after the announcement, and therefore stood-down its dedicated line and transferred further calls to the routine service. No calls required referral to HPA for further discussion, as all could be managed within the pre-prepared answers supplied to NHS Direct.

Discussion

There had been, prior to this notification, several previous notifications of groups of individuals considered to be 'at-risk' of CJD or vCJD due to an exposure associated with medical care. Individuals have been notified as a result of potential iatrogenic risk for CJD from: potentially contaminated surgical instruments; surgery possibly involving *dura mater* grafts, and much earlier, patients exposed to human pituitary extracts such as growth hormone. Previous notifications in relation to vCJD risk have involved individuals exposed to potentially contaminated healthcare instruments, blood transfusions from donors who later developed vCJD, or treatment with certain plasma-products. Since 2000, these notifications have been conducted following recommendations from the CJD Incidents Panel and have been co-ordinated by the Health Protection Agency Centre for Infections working in close collaboration with the blood services (where relevant), and the patient/recipient's clinical carers in hospital or general practice.

Lessons have been learnt with each notification. The first two major notifications involving patients potentially exposed to vCJD by blood transfusion and plasma products occurred during the winter of 2003/2004 (transfusion recipients) and the summer of 2004 (plasma-product recipients). For transfusion recipients, GPs made the notification with the aid of literature supplied by the HPA and support from the local Health Protection Unit (HPU). This notification was the first of its kind and had to be conducted in a short time frame over the Christmas holiday period, following the placing of information into the public domain in December 2003. Criticisms of this notification included the need to communicate information to patients to tight deadlines, and during a holiday period, and that General Practitioners did not always feel that they had sufficient background knowledge to be comfortable with communicating the information as requested. These lessons were applied to the next major notification exercise involving recipients of plasma products.

The majority of individuals identified as 'at-risk' of vCJD due to treatment with plasma products during the notification in September 2004 were patients with bleeding disorders, very many of whom were under ongoing care at a haemophilia centre. They were informed by haemophilia centre clinicians, by whom they were known. Staff in these centres had earlier been involved in communicating information, when this became known, about previously unknown infective risks (HIV and HCV) associated with the use of plasma products. Such information introduces great uncertainty for the patients' future health. This previous experience was invaluable, in addition to that gained with earlier CJD notifications, in planning the notification of these patients. Furthermore, there was the advantage of being able to work through clinicians who were well informed about both individual patients and the issues relating to the notification information. Also, staff likely to be involved could be identified in advance (by association with defined patient groups) and invited to attend a training session to gain background information and given opportunities to provide input into the conduct of the exercise. Because of the patients' past experience of blood-borne infections there was the potential that the notification could be complicated by arousing individuals' existing concerns for their health. For this reason the notification process was constructed so that patients would be given full information about vCJD, its risk of transmission by plasma products and then allowed to choose whether they wished to know or not know if they had received an implicated batch. The reason for allowing this choice by patients was so that they could determine the approach that would allow them to cope best with this further and new uncertainty. In addition, they were informed that health precaution measures would be taken if instruments were used to conduct certain investigations or surgery on themselves. Thus, public health measures would be invoked whether or not the patient chose to know, and the whole group are in future considered at risk

of vCJD for public health purposes. This approach has the advantage of limiting secondary spread should further patients be identified in the future as recipients of an implicated batch.

Notification of individuals considered to be 'at-risk' of CJD by the CJD Incidents Panel has primarily been motivated by concern for public health, as well as for fair and open communication with the individuals about their exposure and risk. These notifications are co-ordinated by the Health Protection Agency. In the case of blood donors, the UK blood services felt strongly that they should take responsibility for contacting the donors with the news. Indeed, it was felt that donors would think it strange if the message came from anywhere else. The notification was a direct result of donating blood, and the duty to give the "bad news" relating to their blood donation was therefore seen as a responsibility best placed with the blood service.

The blood services have a long history of communicating results/information to blood donors and the most usual method used is by letter with back-up in the form of a personal interview either by telephone or face to face according to the donor's needs/preferences. The major exception is in the case of what are conventionally recognised as sexually transmitted diseases, where the donor is invited to attend an appointment (in the case of HIV infection) or to telephone to discuss test results (in the case of treponemal infection) without any knowledge of the test results. There are obvious disadvantages to the approach of inviting donors to an appointment without any information about the nature of the concern. The donor is usually ill prepared for the news, and lacks any written information until the appointment itself. The opportunity to prepare questions and assess personal implications of the information is lacking, and this limits the value of the personal interview. In the case of both HIV and syphilis, the blood services have excellent relations with local

specialist services and can arrange rapid referral for the individual, which helps to ensure that appropriate clinical care and other support is accessible within an acceptable time frame.

In the planning of this exercise, various options were discussed : asking donors to see their GP, calling them in to be told face to face by blood service staff, or notification by letter. Consideration was given to the numbers involved, their location, when and where they could be seen, how soon they could be seen, the impact of delay, and the anxiety caused by not knowing what the call to an appointment was about. There were many proponents of the appointment/interview approach, but the blood services felt strongly that the model of calling in donors for an interview without providing any information was not acceptable for the vCJD notification exercise. It would put the donor at a disadvantage, would be bound to provoke a number of anxious telephone calls to ask for further information, and could lead to greater distress than a well planned written notification. It was decided to follow the procedure in which the blood services have most experience and expertise: notification by letter accompanied by written information, together with the availability of support from special helplines, GPs, HPA consultants and CJD experts.

Acknowledging that it was impossible to know which form of support would be used by affected donors, and recognising that some would immediately turn to their GP, the exercise was managed so that GPs always had advance notice of the notification of their patients, were provided with supporting literature, and were made aware of the support available from HPUs. In the case of lapsed donors the GP was always asked about the current health/circumstances of the ex-donor before any notification letter was sent, although it was made clear that as this was a public health exercise,

non-notification was not an option. As a precaution, GPs were reminded that they should not contact their patient in relation to the notification until the blood service had confirmed that the letter had been sent to the donor. One of the two cases of reported distress in a recipient of the notification letter was a donor who was contacted by her GP before she had received the letter from the blood services.

A great deal of time was spent in planning the content of the communication with donors. The main message was contained in a letter, which was identifiable as a communication from the blood service. The content of the letter was identical throughout the UK, differing only in the contact telephone numbers. It was important to make the letter clear, concise and relevant, and equally important not to include too much information, as this might distract from the key message. The letter was supplemented by an information document containing facts about vCJD, explanation of the rationale for the notification, questions and answers and other sources of advice. Although this document was adapted from those already used in patient notification exercises, it was "customised" for blood donors.

The blood services made their own arrangements for donor helplines. These generally took the form of a direct telephone number for the clinical staff office during normal working hours and arranging for a suitably experienced member of staff to be available to take calls during the day. After hours, the NBS transferred calls to an on-call Consultant, suitably briefed and able to deal with enquiries. In the event, this facility was not required as no donor made a call after normal office hours except for one who telephoned at 19.00 hours on the first day of the exercise. Nevertheless, the arrangement remained in place until the last donor notification letters had been sent many weeks later. Because all other calls were received during normal office hours the blood services were able to ensure that they were dealt with by a small

core of clinical staff experienced in dealing with anxious or distressed donors over the telephone. In the event, most calls involved requests for information in an effort to assess personal risk, together with helpful suggestions.

The response to the notification encouraged us to conclude that this was a workable and generally acceptable method of communicating difficult information to a large group of people, when information had already been put in the public domain. The public announcement was in many ways helpful, as some donors heard the announcement on the day they received the letter, so that the news was not exactly out of the blue. Contrary to our predictions, there were more calls from active donors who received their letter on the day of the public announcement, than from lapsed donors who heard some weeks later. Perhaps active donors were more likely to turn first to the blood service for further information, whereas lapsed donors did not naturally turn to the blood service as the first source of support. As the main implication for these healthy individuals was that they could no longer act as blood donors, it is possible that the lapsed donors saw the notification as largely irrelevant. Unlike the active donors, they were unlikely to feel disappointed and "rejected". Not surprisingly, we also received many calls from unaffected donors who heard the announcement and wanted to check whether they were "on the list" to be notified.

When the lapsed donor notification started we found it helpful to use a strict timetable. Replies from GPs were batched at weekly intervals. On a set day of each week the blood services informed the HPA of the next donors to be notified. The HPA sent letters and information to the GP/HPU on a set day at the end of that week so that information was received before the donor was notified. By using this approach, all staff at the different agencies were clear about what actions were to be taken and at what time, and the potential for confusion was minimised.

Although the outcome of the notification exercise in respect of donors' experiences has not yet been evaluated, every contact with a donor, GP, or HPU was logged. A formal evaluation is planned but the information to date indicates that the majority of donors, although anxious, understood the notification and its implications, and had received the information with equanimity. This could be a reflection of the fact that blood donors generally volunteer because of a wish to help others and they are conscientious about their responsibility to fellow citizens. We are aware of one donor who was exceedingly upset to receive the notification (as predicted by her GP) but who was better able to put the information into context following a long telephone conversation with clinical staff. Her GP expressed himself very satisfied with the blood service response to his patient and has also provided suggestions for evaluation of the notification.

This donor notification exercise was carried out in line with other notifications handled by the blood services, such as the large HCV lookback exercise, where blood transfusion recipients were notified of their risk of HCV. When the information being provided is unexpected and potentially distressing, collaboration between blood services and General Practitioners (and including in this case HPA/HPS) must be designed to ensure that the best possible service, information and support is provided for the donor/patient.

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3. CJD Incidents Panel: http://www.hpa.org.uk/infections/topics_az/cjd/incidents_panel.htm

4. Transmissible spongiform encephalopathy agents: safe working and the prevention of infection http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/Index.htm

Table 1

Advantages and disadvantages of informing patients they are considered 'at-risk' of vCJD for public health purposes

Advantages	Disadvantages
- Enables public health precautions to reduce risk of secondary transmission[1].	- May cause anxiety in a) patients considered 'at-risk', b) their relatives and c) other patients undergoing similar procedures.
- Enables vigilance for clinical signs or symptoms of disease.	- May cause problems with accessing medical or dental care for a) 'at-risk' patients, b) other patients at hospitals where instruments have been quarantined.
- (Some patients) Openness about the potential risk.	- (Some patients) Unwanted information given to patients about the potential risk.

1. Not to donate blood or other tissues, and healthcare staff to apply special infection control measures to certain healthcare instruments.

Table 2

Key lessons learnt

- Use of established methods of communication with blood donors worked well for communicating information about vCJD risk
- Considerable effort to coordinate the content and timing of communications to all involved appears (based on feedback received) to have yielded an acceptable process for all involved at both national and local levels. Where this coordination failed to work as planned, complaints and or anxiety resulted.
- Informing this group of individuals of their increased risk of vCJD directly by letter, with back-up support available to them as/if they wished, was - to our knowledge - acceptable to them.
- New queries/concerns arose, to be incorporated into information documents in future.
- Demand for help-line services was relatively low.