

Development of a patient-centred communication framework for people at risk of medically-acquired Creutzfeldt-Jakob disease (CJD): a systematic review

Data extraction tables to support thematic synthesis on notification and support (Ryan RE, Hill SJ and Lowe D).

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Study reference	TSE	Study population	Aim of study Data collection methods	Intervention	Outcomes	Results Limitations of the study Authors' recommendations/ conclusions	Other notes Other study features Reference to related papers
Callum 1999* Callum JL, Coovadia AS, Thomson A, Dewsbury F, Pinkerton PH (1999) Creutzfeldt-Jakob disease targeted lookback. Transfusion 39: 540-1.	CJD	Patients; recipients of blood products (albumin and IV immunoglobulin) recalled after a blood donor and parent of a blood donor had developed CJD. Total number identified: 970 patients transfused with 1121 blood products from recalled lots. 723 believed alive: 723 received albumin, 10 received IV immunoglobulin.	To notify patients who were recipients of blood products take from donors who later developed CJD. Letter to the editor describing approaches to lookback/ notification. Data collected from telephone information line	Notification process aimed to inform patients of possible exposure. Assessment of information needs by patients in these situations. Nurse was educated specifically to deal with questions about CJD. Total time spent counselling patients was 28 hours, mean 15 minutes (range 5 to 45 min each).	Patient numbers: of 970 total, 733 were believed alive. Of 733 registered letters posted, 67 returned unopened (no further attempt at contacting these patients), 15 because the patient was dead. Of the remaining 651 (88%), 183 (25%) phoned the hospital as requested in notification letter (to report receiving the letter). 58 (all receiving albumin) of the 183 (9%)	Number confirming receipt of notification letter = 183 (25%) Of these, number seeking counselling/ further information about the notification = 58 (32%). Of the 58 patients receiving counselling, only 3 were aware of having received blood products. Specific concerns of the 58 patients were: basic information about CJD (51); information about albumin (9); personal transfusion history (9); information about pump prime (procedure where blood products had been used) (10); information about CJD transmission to family members (6); information about symptoms of CJD (7). Six patients were reportedly	NB describes notification process occurring alongside notification in two other hospitals: that described in King 1998 (Hospital for Sick Children, Toronto) and Freedman 1997 (St Michael's Hospital, Toronto). Also describe Sullivan et al (1997) (available abstract form only): none of those identified in lookback went on to develop CJD. Also cites Sibbald (1998): notification also causes undue anxiety for people.

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		Location: Canada	provided to people notified of CJD exposure via letter. Content of letter and other intervention characteristics not described further.		called to discuss the notification with a trained nurse, who spent 28 hours in total counselling patients about different aspects of CJD.	angry about the notification. Estimated cost = CAN \$17716 (per person confirmed as contacted \$97; or per person presumed to have received notification letter \$27). Authors' conclusions: 'the following key components are critical to a lookback: computerised blood transfusion records, computerised patient demographic information, the availability of a trained individual to counsel patients on the virus or prion in question, and the ability to crosscheck blood bank records with individual charts.' (p 541).	All references obtained/ checked.
Carruthers 2001* Carruthers J, O'Hoski P, Warkentin TE, Heddle NM (2001). A survey of transfusion practice related to informed consent and	CJD	Hospitals: identifying procedures for obtaining informed consent, and for informing patients post-transfusion of associated risks (HIV, HCV, CJD). Total number of hospitals contacted: 56. Response rate 57%	To determine the degree to which hospitals comply to recommendations (arising from the Krever report) regarding the processes of obtaining informed consent for	No intervention; aim of the study was to assess informed consent processes and processes for notification of risks associated with transfusions in hospital settings.	Responses for processes of informed consent (in general and for transfusion); and processes for informing people of risk and of notification of potential risk following blood recalls (CJD).	<i>Informed consent:</i> Most hospitals did not have a separate mechanisms (form) for obtaining informed consent for blood transfusion specifically; consent was considered to be covered by the hospital's general consent form. Half of responding hospitals did not have a policy for obtaining informed consent in situations where the person was unconscious/ emergency. Informed consent procedure was conducted using a range of materials and formats (pamphlet, fact sheet, video etc).	Authors note that despite the risk of CJD transmission via blood still being regarded as theoretical, studies have shown that the majority of people would prefer to be notified of their possible exposure to this risk (citing Callum 1999).

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<p>post transfusion notification. Medical Laboratory Science 63: 179-88.</p>		<p>(32/56). 20 responding hospitals were community-based, the remainder were tertiary hospitals. An active transfusion committee existed in 66% of respondents.</p>	<p>transfusion; and the processes of notifying people post-transfusion of blood products received, the quantity they received, and any risks such as possible exposure to HIV, HCV or CJD.</p> <p>Report of survey questionnaire administered to hospitals in 1998.</p> <p>Review questions addressed:</p> <p>Q4 What issues exist around feasibility and implementation</p>			<p><i>Notifying patients about transfusion:</i> The majority of hospitals indicated there was no formal process for informing patients of blood products that had been received, post- transfusion; and there was a range of processes followed and types (and amounts) of information included among these approaches. In 8/13 hospitals the notification was performed while the person was still an inpatient; the remainder notified people after discharge. None of the hospitals has assessed their processes to determine the acceptability or usefulness of the processes, as rated by patients.</p> <p><i>Notifying people about risk of HIV and HCV:</i> Surveyed hospitals had notified approximately 40% of patients transfused between 1978 and 1985 (HIV), and approximately 30% of those transfused between 1978 and 1990 (HCV), that they should be tested. Of hospitals included, approximately 60% (HIV) and 80% (HCV) had notified all transfused patients; but others had only selectively notified certain patient groups, such as paediatric patients only or adult patients only.</p> <p><i>Notifying people about risk of CJD:</i> 50% of hospitals did not notify patients of</p>	

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			<p>of interventions to communicate with and support people in the situation of being notified of a possible CJD exposure?</p> <p>Q6 What are the barriers to people seeking support and/or follow-up after notification of CJD exposure?</p> <p>Data collected via questionnaire sent to identified hospitals.</p> <p>Questionnaire covered 5 main areas: hospital demographics;</p>			<p>the theoretical risk of CJD following blood product recall. There was no additional information provided about the process of notification by hospitals that performed it; and the notification was performed by a range of different people including family physicians (majority of responses) and physician who had ordered the product.</p> <p>Authors' conclusions: 'Although Justice Krever made a number of recommendations about informed consent and notification of transfusion, approximately 50% of hospitals responding to our survey had not implemented these recommendations. The reasons for this lack of implementation was beyond the scope of this survey and requires further investigation.'</p>	

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			informed consent process; process for informing people post-transfusion; how hospitals are attempting to inform people at risk of HIV/HCV; and patient notification for CJD following recall of blood products.				
<p>Freedman 1997*</p> <p>Freedman J, Hall A, Dey A (1997). Potential Creutzfeldt-Jakob Disease (CJD) Exposure: To notify or not to notify.</p>	CJD	<p>Patients; recipients of blood products (mostly intravenous immunoglobulin or albumin) derived from donors with suspected CJD</p> <p>Total 352 patients due for notification; no further characteristics provided.</p>	<p>To evaluate the notification process for patients informed of CJD exposure one year previously. One-year follow-up to determine people's experiences of</p>	<p>Notification process aimed to inform patients. Evaluation of the notification process.</p> <p>Questionnaire sent as letter: again emphasised the state of knowledge and theoretical nature of CJD risk. Included 2 questions:</p>	<p>Outcomes</p> <p>Proportion responding yes/no to the two questionnaire items.</p>	<p>Q1: Do you think people exposed to theoretical risk should be informed? Yes: 111 (79.9%) No: 26 (18.7%) No response: 3</p> <p>Q2: Would you have preferred not to have been notified? Yes: 31 (22.3%) No: 103 (74.1%) No response: 5.</p>	<p>Original notification procedure: Letters sent to attending physician asking them to inform patients. Included pamphlet outlining the state of knowledge at the time and emphasising that the CJD risk was theoretical.</p> <p>Physician reaction was mixed – some upset/angry; some patients</p>

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Transfusion Science 18(3): 491-2.		<p>Authors note that age did not appear to be a determinant of preferences for notification: mean \pm SD age of yes responders to Q1 64 ± 12 (range 33-83); no responders 68 ± 12 (range 42-86); not significantly different. No information available on other factors affecting whether an individual would prefer to be notified or not.</p> <p>Location: Canada</p>	<p>being informed and to determine their decision making in situations of uncertainty.</p>	<p>Q1: Do you think transfused patients should be informed of a theoretical risk of transfusion where there is no evidence showing the risk is a real one? Q2: In your case would you have preferred not to have received notification?</p> <p>Yes/no response indicated for both questions</p>		<p>Limitations: small sample size, large number responses lost/ unable to be contacted; small number of outcomes assessed.</p> <p>Authors' conclusions: '...this study does indicate that (a) almost one third of physicians did not notify their patients despite strong recommendations to do so, (b) current addresses could be obtained for most patients, (c) three-quarters were willing to answer the questionnaire, and (d) the majority (80%) advised that such information should indeed be imparted to recipients.' (p 492).</p>	<p>showed considerable anxiety following notification.</p> <p>Authors note that 101 of the total 352 patients (28.7%) intended for notification were not informed by physicians. Of remaining 251, addresses obtained for 199 (79.3%). 12 returned to sender; of 187 letters presumed to have arrived at destination, responses to 139 (74.3%).</p> <p>Authors note a large range of responses and comments were made on the questionnaire, ranging from the positive (in support of being notified) to the negative; others expressed their wish that they had been notified by their doctor, not via a letter.</p> <p>No references to follow up.</p>

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<p>Hewitt 2006b*</p> <p>Hewitt PE, Moore C, Soldan K (2006). vCJD donor notification exercise: 2005 Clinical Ethics 1: 172-8</p>	vCJD	<p>Active blood donors whose blood had been transfused to three recipients who later developed vCJD.</p> <p>110 active donors whose blood was transfused to three recipients who later developed vCJD. Donors were to be informed that they were to be considered 'at-risk' for public health purposes. Donors were considered active if they had donated blood in 2000 or later. Lapsed donors were traced and GP identified and contacted to confirm the donor was alive and still under their care, and to provide additional details relevant to</p>	<p>To examine the effects of notification of donors following recipient development of vCJD.</p>	<p>Notification letter sent directly to each donor (from blood service). A comprehensive information leaflet from the Health Protection Agency/ Health Protection Scotland accompanied the letter.</p> <p>For each donor registered with a GP, an explanatory letter was sent, providing further information and copies of the correspondence sent to their patient (donor). Letters to GPs were timed to arrive at least 48 hours before donors received notification letters. GPs were also given further details of support through a local Consultant in Communicable Disease Control (to which prior warning of</p>	<p>Numbers of active and lapsed donors in the at-risk group; notification rate (confirmed by GP responses); details of calls received in relation to the notification; details of current health and healthcare relevant to notification;</p>	<p>50 active donors identified in England (1 had died, 1 moved to Wales); 6 in Scotland; 1 in Wales, therefore a total of 55 notification letters sent out. All but one patient was registered with a GP.</p> <p>54 lapsed donors identified in England, including 1 who had died and 3 who were not readily contactable and were not registered with a GP. A total of 50 notification letters were sent to lapsed donors.</p> <p>The NBS received 13 calls and 1 letter in relation to the 48 active donors notified; most were from notified donors themselves. Most sought further information, especially in terms of trying to assess their individual risk. Some of the notified donors were healthcare workers and had specific questions about occupational issues or the need for precautions when carrying out exposure-prone procedures (not covered in the information sent to notified donors).</p> <p>The CJD Support Network received one call from a GP, and 4 from notified donors. Some expressed anxiety but all were judged to have dealt with the information well and calls focussed mostly on clarifying individual risk.</p>	<p>Authors note that previous notification exercises for people considered at risk of CJD or vCJD for public health purposes: these have been carried out and used to inform and develop the approach to each successive notification exercise.</p> <p>Two major previous notifications discussed:</p> <ol style="list-style-type: none"> 1. People potentially exposed to vCJD via blood and plasma transfusions (2003/2004): GPs made the notification with the help of information from the HPA and with support from the local Health Protection Unit (HPU). Criticisms of this exercise included: the need to communicate information to patients within tight deadlines during the Christmas holiday period; and GPs not feeling they had enough background

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		<p>notification.</p> <p>A total of 55 active donors were notified; 54 of whom were registered with a GP.</p> <p>Blood services involved were the England, Scotland and Wales blood services, with the National Blood Service responsible for the majority of the donors (103/110).</p> <p>Notification began 20 July 2005, completed early October 2005.</p> <p>Donors were notified on 20 July or as soon after as possible following identification and tracing.</p>		<p>the notification was also sent) or from staff at the Health Protection Agency Centre for Infections.</p> <p>All donors notified were offered access to further advice and support from their GP; invited to use a 24-hour contact number for discussion with a senior member of the blood service medical staff; and provided with the CJD Support Network contact number. The NHS also established a helpline to respond to queries from the general public.</p> <p>Notification was phased: active donors were notified first (20 July or soon after); lapsed donors in regular timetabled batches after.</p>		<p>Only 1 caller (to the NBS of CJD Support Network) was judged to be distressed upon receiving notification. Other callers suggested improvements for future notifications; and most commented that the notification letter was clear and informative; understanding of the reasons for their notification and for the public health precautions they were being asked to take was judged as good overall.</p> <p>Many GPs responded to the call for further information relevant to the notification of their patient: the majority provided relevant health care details; 1 refused to disclose information without the patient's consent, and another expressed similar concerns but was reassured by discussions. One GP wrote to express gratitude for the prior warning of his patient's notification and noted that the approach was proactive.</p> <p>Two lapsed donors contacted the NBS directly (one with a history of depression, one who was pregnant): this showed the value of the NBS having access to the additional patient information ahead of donor contact with the agency.</p> <p>One GP of a third donor contacted the</p>	<p>knowledge to be able to adequately communicate the required information to patients.</p> <p>2. People with bleeding disorders potentially exposed to vCJD via plasma products (September 2004): Patients were informed by haemophilia centre clinicians, who were known to them. Staff had been previously involved in communication to patients about previous infective risks such as HIV. Because of their ongoing involvement in patient care, staff could be identified in advance, offered training to provide the necessary background information, and given the chance to provide input about how the notification should be conducted. Because of the serious implications for the patient's ongoing health and wellbeing, patients</p>

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				<p>GPs were asked to return a form to the HPA for each notification, confirming that their patient had received and understood the information sent to them and reporting any health care details that could require investigation by the CJD Incidents Panel.</p> <p>Non-responding GPs were actively followed up; 5 replies were outstanding by the end of September.</p> <p>Authors note the following about planning for the notification exercise:</p> <ul style="list-style-type: none"> The usual method used for communicating with blood donors is via letter with backup personal interview 		<p>NBS due to concerns about the possible distress of notification on his patient. He suggested changes to the notification letter, which were noted. The donor later wrote to the NBS and was contacted by a senior member of the medical staff who undertook to address some of the donor's concerns and distress. This was reported back to the GP, who expressed satisfaction with the approach and with the personalised response to his and his patient's concerns.</p> <p>By mid November 2005, 53 GP forms had been returned; 48 of which confirmed that their patient had received and understood the notification information. Five GPs were unable to confirm this as they had not had contact with the patient since notification. Two of these 5 patients, and another 3 who's GPs had not returned forms had contact with the NBS directly; confirming that they had received and understood the information.</p> <p>The NBS received 12 communications following the public announcement: 6 calls and a letter expressed disagreement with the decision to notify affected donors but were all in response to media reports (ie they had not seen the communications with notified donors). The remaining 6</p>	<p>were provided with information about vCJD and its risk of transmission via blood products. To best allow patients to cope with the new uncertainty regarding vCJD, patients were then given a choice about whether they wished to know, or not, whether they had received blood products from the implicated batch. Patients were also informed about precautions for public health purposes.</p> <p>The blood services have long experience of communicating with blood donors and the most usual method is by letter including information, with backup in the form of personal interview, either face-to-face or via telephone, according to the donor's needs and preferences.</p> <p>GP advance notification is seen as important; as well</p>

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				<p>(telephone or face-to-face), depending on the needs and preferences of the donor. Disadvantages of notifying people directly via appointment or telephone call are noted: people may be ill-prepared for the news; have no written information until the appointment; have no opportunity to prepare questions or to assess the personal implications of the information.</p> <ul style="list-style-type: none"> The decision to notify people via letter with backup was made in preference to other possible approaches (eg interview/ appointment) as it 		<p>were unrelated to the announcement and notification exercise.</p> <p>NHS Direct received fewer than 20 calls in the 48 hours following the public announcement and so stood down the dedicated phone line, with routine referrals for calls following this. No referrals to the HPA were needed as all calls were managed with the answers prepared for the NHS Direct line.</p> <p>Authors also note that the public announcement was helpful in many ways. More active donors who received letters on the day of the announcement called helplines than lapsed donors who were notified some weeks later.</p> <p>Authors also note that the majority of donors, although anxious about the notification, understood the information and the implications of it.</p> <p>Authors conclude that where information is unexpected and potentially distressing, collaboration between agencies (in this case GPs and blood services) must be designed to ensure that the best possible information, service and support is provided to the patient.</p>	<p>as clear communication of the fact that the notification was a public health exercise and non-notification of donors was not an option.</p> <p>A lot of planning went into the content of communication with donors: importance of clear, concise, relevant messages; avoidance of too much information that would detract from the key messages of the letter; supplementary information provided containing the facts about vCJD, explanation and rationale for the notification exercises, questions and answers and other sources of information.</p> <p>Authors note the following key lessons learnt from the notification:</p> <ul style="list-style-type: none"> Use of established methods for communicating with blood donors was seen

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				<p>was thought to be less disadvantaging to donors, and potentially provoke less anxiety and distress. The letter notification approach was also that with which the blood services had the most experience and had been seen to work well previously (letter plus information, with backup support from special helplines, HPA consultants and CJD experts).</p> <ul style="list-style-type: none"> Recognising that some patients would consult their GP for advice, the exercise was structured and managed so that GPs always had advance notice; had supporting 			<p>as an effective way of communicating about vCJD risk.</p> <ul style="list-style-type: none"> A focus on coordination of the timing and content of information appeared to produce an acceptable process for those involved, both locally and internationally. Complaints and anxiety were noted as occurring in cases where coordination failed. Informing people of increased risk directly via letter, with backup support as needed, appeared acceptable to those involved. New concerns and queries arising from the exercise were noted for consideration/ incorporation into future exercises. Demand for helpline

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				<p>literature provided; and were aware of the support available from HPUs. GPs were instructed not to contact patients until the blood service confirmed that the letter had been sent to the donor. Authors note that one of the two cases of distress following notification letter receipt was by a donor contacted by her GP before she had received the letter.</p> <ul style="list-style-type: none"> Content of the communication with donors was planned, with main message contained in the letter, supplemented by an information document on vCJD. 			<p>services was relatively low.</p>

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				<ul style="list-style-type: none"> Donor helplines were established: usually as a direct helpline, staffed by experienced clinical staff during office hours; and after hours to an NHS on-call consultant who had been briefed. 			
<p>King 1998*</p> <p>King SM, Watson H, Heurter H, Ricketts M, Elsaadany S (1998). Notifying patients exposed to blood products associated with Creutzfeldt-Jakob disease: theoretical risk for real people.</p>	<p>CJD (theoretical risk of)</p>	<p>Transfusion recipients, notified of the CJD blood recalls (patient and parents of patients) in 1995 and 1996.</p> <p>Families who had been notified that they/ their child had received a blood product at the Hospital for Sick Children that had been recalled because of the potential risk of</p>	<p>To determine the views of patients and parents of patients (under 16 years of age) about being notified that they/their child had received blood products potentially contaminated with CJD.</p> <p>Questionnaire used to collect</p>	<p>All families who had been notified were invited to an information session; attendees were asked for one member of the family to complete the self-administered questionnaire. Families not attending the sessions were selected randomly and interviewed (telephone) using the questionnaire.</p> <p>Mean interval between notification</p>	<p>Knowledge of transfusions and risks; preferred methods of notification; preferences to be notified or not to be notified; emotional response to notification</p>	<p>Representative of 100 families attended the information session (group 1); 93 of whom agreed to complete the questionnaire; responses of 85 included enough information to be included in analysis.</p> <p>Of the 100 families contacted by telephone (group 2), 97 completed the interview (3 were not completed due to language difficulties).</p> <p>Of the total group of respondents (n = 190), 12 (6.3%) were aged 16 years or older.</p> <p>Groups did not differ in responses to questions on their knowledge of</p>	<p>Note also relevance to earlier studies by these authors with respect to HIV notification in Canada 1995. Note that questionnaire used was adapted from one used to evaluate families' responses to notification of transfusion and risk of HIV infection (King 1995).</p> <p>King 1995 King SM, Murphy T, Corey M, Newman AM, Major C, McCrindle BW et al (1995). The HIV Information Project for</p>

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Canadian Medical Association Journal 157(2): 155-7.		<p>transmission of CJD through that blood product. Recalls occurred between January 1995 and February 1996.</p> <p>Note that all transfusion recipients were children. Of the 528 recipients notified, 74 were aged 16 years or more.</p> <p>Location: Canada</p>	<p>data; designed for self-completion or administration during interview.</p> <p>Questionnaire was adapted from one used previously to evaluate families' responses to notification of the risk of HIV transmission and transfusion. King et al (2005)</p>	<p>and questionnaire responses was 4 weeks for group 1 (attending session) and 14 weeks for group 2 (phone interview).</p>		<p>transfusions and risks, or those relating to the way they had been notified.</p> <p>78% of respondents were aware of the transfusion.</p> <p>The notification methods that was most favoured was letter (40%); the least favoured, via telephone (9%). Over 50% indicated that their current physician (community physician or hospital specialist) should be involved in the notification, or should be the one to give them the information.</p> <p>Negative emotional responses were common, with approximately two thirds of respondents reporting these. Negative emotional responses were more common in group 1 than 2; and of those in group 2, 44% indicated that their fear, anxiety and anger had decreased over the time period since being notified (to interview).</p> <p>81% of families said they wanted to be notified; and 84% said they would want to be notified in the event of another recall.</p> <p>Authors note that responses consistently indicated that the majority of people wished to be notified of a child's exposure to blood products recalled because of</p>	<p>transfusion recipients a decade after transfusion. Archives of Pediatric and Adolescent Medicine 149: 680-5: Consultation with patients, parents, hospital and community-based physicians, and other healthcare workers indicated that an individualised letter would be the most acceptable way of notifying patients about the risk for HIV infection associated with transfusion. Letters were sent to patients' current community physician; the physician was requested to notify patients or parents of transfusion history; the risk for HIV infection; and to offer HIV counseling and testing. Sent with the physician letter was: a letter for patients/ parents; a laboratory requisition for HIV testing; an information sheet about HIV and transfusion; and a</p>

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						<p>CJD. However, authors also note that 9% of respondents clearly wished not to be notified in such situations (ie they did not want to be notified in the event of a future recall of blood products), and in a general notification exercise such people would be notified.</p> <p>Emotional responses to notification suggested that parents wanted all information about their child, even if the information caused anxiety.</p> <p>The authors cite research indicating that the way that 'bad news' is delivered to patients is important: and no single way to give bad news is right for all patients. The relative benefits compared with harms of notification depend on the way that notification is conducted and the ability of those involved in providing the information to be aware of the consequences (emotional) for those being notified.</p> <p>Some common themes emerging from questionnaire responses and discussions at information sessions:</p> <ul style="list-style-type: none"> • Minimise the delay in providing information; • Personalise the way in which information is given; • Provide information at a physician visit 	<p>questionnaire for physicians (17 closed-ended questions asking for views about HIV and transfusion practices). Physicians were also asked to notify the study team about the status of testing for those patients contacted.</p> <p>Patient questionnaires: 25 closed-ended and two open-ended questions; to evaluate patients'/parents' knowledge of HIV and transfusion; awareness of patient's transfusion status; and awareness of and response to the HIV Information Project. One of two nurses completed the questionnaire in a telephone interview with parents/patient.</p> <p>Note also editorial on evaluating the effectiveness of notification strategies (King 1997).</p>

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						<p>if possible, but if this means that a long delay will occur send a letter before the visit;</p> <ul style="list-style-type: none"> • Provide access to more information and to counseling, especially to help people deal with anxiety; and • Ensure that the treating physician is aware of the notification. <p>Authors note that a limitation of this study is that all transfusion recipients were children: results may not be generalisable to transfusion recipients of all ages.</p> <p>Authors conclude that most of the parents of children who have received blood products are in favour of being informed about the risk of CJD, despite the uncertainty of the risk information and the anxiety that such information causes.</p>	<p>King SM (1997). Look-back notification: how do we assess effectiveness? Journal of the Canadian Medical Association. 157(2): 155-7:</p> <p>The effectiveness of look-back programmes needs to be assessed in the context of the goals of lookback notification, which includes: informing patients of their transfusion history; providing patients with information about the risk of infection; developing and maintaining the trust of patients and their families/ carers by sharing information; sustaining community trust in public institutions by demonstrating the commitment to share information.</p> <p>The latter two goals relate to trust built at more than one level: at the individual level of patient-physician relationships, and at the societal level. At both</p>

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							<p>levels, trust is built by open and respectful partnerships.</p> <p>Also note the issues of informed consent (Hart 2004).</p> <p>Hart J, Leier B, Nahirnak S (2004). Informed consent for blood transfusion: should the possibility of prion risk be included? Transfusion Medicine Reviews, 18(3): 177-83:</p> <p>Implementing strategies to minimize or avoid potential harms may help physicians in the informed consent process (for blood transfusion).</p> <p>Authors note that little has been done to support people (eg counselling programs to help people to deal with the implications of potential infection with a prion diseases) involved as transfusion recipients of</p>

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							<p>blood potentially contaminated with CJD. There has also been no follow-up notification to inform people with a previous transfusion-related exposure to CJD that CJD is no longer thought to be transmitted via blood.</p> <p>If a more supportive infrastructure were available, physicians may feel more willing to discuss the potentially serious risks of transfusions with patients, knowing that appropriate counselling and support would be available to patients to help them to deal effectively with their fears or concerns about the safety of the blood supply.</p> <p>CJD is currently one of the unknown risks associated with transfusion. Informed consent regarding vCJD transparently recognizes</p>

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							<p>that although the blood supply may be as safe as it is possible to make it, uncertainties still remain about safety. In the context of HIV and HCV, both of which were known to exist but were not known to be blood-borne, vCJD has a similar profile at present. Disclosing the possibility of vCJD transmission to patients may help to preserve trust between patients and doctors: if vCJD is later ruled out as a risk, doctors will be seen to be acting cautiously and with their patients' interests in mind. If vCJD transmission through blood is confirmed, patients may feel confident that the decision to go ahead with transfusion was made based on the benefits outweighing the possible risks of transfusion.</p>
Pauls 1996*	CJD	Patients notified of increased CJD risk	To describe the ethical	Once the decision to notify patients was	Description of the experiences of the	A total of 153 patients were notified of at-risk status.	Exposure to risk was via albumin (screening lung,

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<p>Pauls, F., Hayes, J., Read J. (1996). "Creutzfeld-Jakob disease: the Grace General Hospital experience." Leadership in Health Services 5(6): 42-43.</p>		<p>after receiving treatment at a number of hospitals in Winnipeg.</p>	<p>reasoning behind notification; and the process used to inform hospital patients of their increased risk for CJD.</p> <p>Description of the notification process used for people exposed to the risk of CJD through hospital treatment.</p> <p>Review questions addressed:</p> <p>Q1 What are people's experiences of being notified of CJD?</p> <p>Also Q4</p>	<p>made, a two-step process for notification was decided upon: notification via letter with follow-up via public meeting.</p> <p>Stages of the notification process were as follows:</p> <ul style="list-style-type: none"> Physicians responsible of patient care were sent information on CJD; as well as information on counselling services available if required for patients. Letters were sent out: these informed people of their risk of exposure to CJD through blood products (ie from a donor who developed CJD); that there were no documented cases 	<p>Grace General Hospital; and their consultation with the ethics committee and process used to notify people of CJD risk.</p> <p>153 patients notified via letter; 90 of these attended the public meeting follow-up.</p>	<p>90 letter recipients attended the public meeting held to follow-up notification letters.</p> <p>Major concerns of patients notified:</p> <ul style="list-style-type: none"> That they had not been made fully aware of the nature of the tests they had undergone (ie that blood products were involved). Participants noted the concern they experienced as a result of being notified. Some indicated that they would rather have not known, but the majority indicated that they appreciated being informed. Two patients were considering legal action; 1 expressed gratitude for the test as it had identified a cancer that was previously undiagnosed. <p>Authors note that key to the success of the public meeting was ensuring that knowledgeable, appropriate people to participate and provide information to patients.</p>	<p>liver and bone marrow test) donated from a person who later developed CJD.</p> <p>Description of the experiences of the Grace General Hospital, one of several hospitals involved in the exposure incident; each hospital consulted own ethics committee on whether to notify patients and the process used to do so.</p> <p>Ethical considerations: In favour of notification: people have the right to be informed of anything that affects their health; anyone who has received a blood product from someone who developed CJD should not themselves donate blood or organs; and the principles of open disclosure were important to restore and maintain the public's trust after the Krever inquiry.</p>

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			(feasibility of implementation of interventions to communicate); and Q5 (harms of being notified of increased vCJD risk).	<p>of CJD acquired through blood; and informing people of the public meeting to be held 10 days later.</p> <ul style="list-style-type: none"> Public meeting was held at the hospital. Chaired by the vice president of support services. Content included: information on CJD (infectious diseases expert), on scans (medical imaging expert); and patients could sign up for psychological support services. <p>Approximately 1 week later the media were contacted by a patient; coverage of the incident was low-key and did not generate further inquiries about the incident.</p>			<p>Against notification were the following arguments: informing patients of their possible exposure to risk may cause distress and so do more harm than good (since the risk of CJD was very small); and the uncertainty of the information to be shared, as well as a lack of any way to measure the risk, or of the availability of any useful course of action for people once notified of risk.</p>

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<p>Reesink 2003*</p> <p>Reesink HW and Engelfriest CP (2003) Future counselling of donors and recipients of blood products concerning prion-related diseases. Vox Sanguinis (2003). 85: 126-48.</p>	vCJD	<p>Experts, primarily from blood services internationally.</p> <p>List of questions was sent to experts; replies were received from 17.</p>	<p>To obtain information about the future counselling of donors and recipients of blood products in relation to prion-related diseases. The study was undertaken in the context of considering the future availability of a specific and/or confirmatory test for vCJD; and the implications for notification and counselling of donors with a positive screening-test result, and or recipients of blood products from these donors.</p>	<p>List of seven questions was sent to experts internationally. These question were as follows:</p> <ol style="list-style-type: none"> 1. What information will you provide to donors before carrying out a screening test for vCJD? 2. When a donor tests positive in a screening test but no confirmatory test is available will you inform the donor? If yes, what will you tell them? 3. Regarding question 2, will the information to the donor change when a specific confirmatory test becomes available? 4. Will you consider a lookback exercise to recipients of blood products from a donor subsequently found to be positive for CJD 	<p>SUMMARY OF MAIN RESULTS</p> <p>Q1. All participants indicated that extensive information be provided to donors, as well as the significance and implications of a positive screening test. There were a range of views: some experts indicated that obtaining informed consent from the donor before testing is essential; another suggested that donor screening should not be implemented before a confirmatory test is available; and donors should be fully informed of the implications of a positive test result, before testing occurs.</p> <p>It was suggested that information might include the following: comprehensive information on the disease severity; the cause, genetic risk factors and route of infection; the long latency, symptoms and progression of the disease, lack of treatment, and the very small risk of actually being infected with vCJD. Information should also include the meaning of a positive test, and what would happen in the event of a positive result. This information will depend on the features of the test – ie sensitivity, specificity, positive and negative predictive values. Implementation of a screening test before confirmatory tests are available may present many problems. A positive result may have a huge impact on mental health, relationships, employment, insurance and other life prospects. Information should be provided in writing to individual donors, with the opportunity to attend lectures where they can ask questions.</p> <p>Q2. Most experts believed that donors should be fully informed of any positive test result, even if the test was based on a surrogate marker or had poor specificity for vCJD. One expert found it unethical and unacceptable to screen donors before a confirmatory test became available. Another suggested an opt in/out clause in the informed consent process to allow donors the choice of whether to be notified of a positive test or not.</p> <p>It was noted that people with a positive test result should receive information and counselling; and counselling should include the uncertainties of the test result and the lack of a confirmatory test (ie the limitations of the test). An honest and open approach to notifying people of a positive test will be needed; and systems put in place to support the donor. Provision of counselling and appropriate medical information would be an integral part of the</p>		

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			<p>International forum: list of questions sent to experts in the field of blood products/ services and prion-related diseases.</p>	<p>via screening? Will your decision be influenced when the donor is confirmed to be positive for CJD? 5. What kind of follow-up do you suggest for positive blood donors and recipients of their blood? 6. What do you expect the impact may be of screening on the willingness of people (current and future donors) to donate blood? 7. What legal issues do you envisage when vCJD screening tests become available? Do you think that compensation for donors and/or recipients testing positive for vCJD should be considered?</p>	<p>notification process.</p>	<p>Q3. For those experts in favour of informing donors about test results, the availability or lack thereof, of a confirmatory test would not influence their notification of donors. For others, donors would only be informed of their positive result once a positive test becomes available.</p> <p>Past instances of introduction of a screening and confirmatory test have been accompanied by information about what a positive and negative test result actually mean: the situation with vCJD is not clear eg it is not clear whether a positive results indicates future illness, especially given the long incubation period for vCJD; similarly, it is not clear whether a negative result indicates that the person is free from vCJD.</p> <p>Past instances of notifying donors of positive test results (eg for HIV) indicate that there is the possibility of profound effects and harm on donors with positive test results for vCJD. Those with true positive results will have to deal with the possibility of developing and incurable disease; those with intermediate results may be even more anxious because of the uncertainty of their risk; and those with negative confirmatory results may be angry due to the fear they have suffered and deferral from donation.</p> <p>Q4. Most experts did not support lookback activities without confirmation of a positive test result. All experts agreed that once a positive test result could be confirmed, a lookback of recipients would be necessary.</p> <p>It was suggested that prudence be shown in lookback activities; and given the long incubation period, the patient's age and clinical status should be assessed before notification of a positive result (ie lookback might be reasonably limited to younger individuals with good prognosis). The balance between the right to be informed and the right to not be harmed needs to be struck.</p> <p>Recipient groups would need to be involved in making decisions relating to notification and the notification process.</p> <p>There should be no lookback investigations until appropriate support mechanisms are in place for those notified of infection.</p>	

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						<p>Q5. For those testing positive for vCJD (either through screening or confirmatory testing), and for those recipients of test-positive blood products, experts suggested referral to neurologists and/or psychiatrists for periodic follow-up.</p> <p>Follow-up should be with appropriate, well-trained medical staff. It will need to be developed via multidisciplinary cooperation.</p> <p>Follow-up should fill a number of roles: it should support individuals and assist them to cope with the uncertainties of the results and the implications of the results; it should help to clarify the meaning of the result; and it should help to ensure that people infected are monitored and that they have access to any therapies that become available.</p> <p>Donors testing positive should receive counselling, an important aspect of which is to impart a realistic understanding of the risk to the donor and not to scare them unjustifiably.</p> <p>Q6. Most participants expect that when the prevalence of the test marker is high it will have a significantly negative impact on the willingness of donors to donate blood. Conversely, when prevalence of the marker is low most experts expected that there would be little impact on blood donation.</p> <p>Q7. Several experts expected many future claims. Most were supportive of a no-fault compensation system although it was acknowledged that implementation of this might prove difficult.</p>	
<p>Sibbald 1998*</p> <p>Sibbald B. (1998). Blood recipients and CJD: to notify or not to notify, that is the question.</p>	CJD	<p>Patients/ carers who were recipients of blood products from a person who later developed CJD.</p> <p>Descriptive study: present two</p>	<p>Conference reviewing the science and ethics of CJD transmissibility.</p> <p>Questions include: Is notification</p>	<p>Non-interventional study. Cites range of research.</p> <p>Cites views of two people notified of exposure to CJD: one in favour of having been notified; the</p>	<p>Unclear: preferences for notification; views on notification also cited.</p> <p>Examples of responses:</p>	<p>Cites the following research (from L Boshkov, University of Alberta): Of 1216 Alberta residents surveyed, 67.8% replied that they would want to be notified. 54.3% agreed that contacting blood recipients would do more harm than good; and 62.4% said that the money to notify people would be better spent on public education about risks of blood</p>	<p>Commentary on research meeting than primary research.</p> <p>Also cites research by King (1998) in same issue: covered as separate paper later.</p>

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Canadian Medical Association Journal 159(7): 829-31.		opposing views from patients/ carers on whether notification should occur where risk is theoretical. Location: Canada	justified given that the risk is only theoretical? If it is justified, why are those who have been notified allowed to donate blood?	other against notification.	Patient 1: 'I'm not afraid of it, I'm afraid of you trying to make decisions for me.' Patient 2 [notified of son's exposure]: 'Initially I was glad I was told ... and now I wish I hadn't been. Notification, I think, is an injustice, because the risk is only theoretical.' Although opposing views were expressed on many issues, there was agreement that general practitioners should be better informed about CJD.	products. Notes that opinions of patients are mixed: Researchers have suggested that results indicate that people should have more individual choice when it comes to notification. Authors cite Dr Kaegi (Red Cross Blood Centre, Calgary): 'it's not fair to notify people when there's no proof CJD is even transmitted by blood, and there's no way of diagnosing the disease, must less treating it.' At a recent meeting of the CJD Society, he 'was surrounded by a dozen people who were scared silly every time they forgot a number or a key. Many went to see a physician or psychiatrist about their fears. This notification has done a lot of harm. I think we have to take some of the blame here for notifying people about a disease that's exceedingly rare and, to our knowledge, not transmitted by blood.' (p 830).	No references to follow up.

INDIVIDUAL ACCOUNTS, ISSUES, OTHER DATA, DESCRIPTION OF ISSUES FOR THOSE AT-RISK

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<p>Anonymous 2001</p> <p>Anon (2001). "A mad, mad world: ICPs fight panic with policy for much misunderstood CJD: but patient-to-patient transmission can occur." Hospital Infection Control 28(9): 117.</p>	CJD	People being notified of CJD risk as a result of medical treatment	<p>To describe the process for notifying people exposed to CJD through neurosurgery (Colorado hospital, USA).</p> <p>Description of the reasoning behind and process for notifying patients of increased CJD risk.</p> <p>Review questions addressed:</p> <p>What is the range of strategies available for notifying people of</p>	<p>Once the patient with CJD was diagnosed, and the diagnosis confirmed, the decision to notify people of their increased CJD risk was made.</p> <p>Notification approach: decided by hospital ethics committee.</p> <p>Primary physicians conducted the notification, as patients had existing relationships with these professionals.</p> <p>Patients met with their primary physician; no further description of the notification processes or of supportive activities or information.</p>	<p>Instruments used on a patient subsequently developing CJD was tracked; 6 neurosurgical patients were identified as a result of instrument tracking (having been operated on with the same instruments) and were notified of exposure to the risk of CJD.</p>	<p>No details of the outcomes of notification were reported.</p> <p>Notification in such cases is becoming more common, may be driven by legal liability (since medically there is nothing that can be done about the at-risk status).</p> <p>There are reports of surgeons who refuse to operate on people with CJD, and of pathologists who refuse to perform autopsies on these same patients. There have been no cases where a surgeon has acquired the risk of CJD via surgery.</p> <p>Despite attempts of this hospital and others to clarify the differences between CJD, BSE and nvCJD, there is still much misinformation in the media.</p>	<p>Authors note that notification of people of CJD risk is often intertwined with media hype and attention, as well as poor or inaccurate information about CJD.</p> <p>Although the risk of CJD transmission via blood has not been proven, many blood services have notified people of this theoretical risk (blood recipients from donors later developing CJD).</p> <p>Authors note that there is often confusion among the media and among others about CJD, BSE and nvCJD. It therefore often falls to infection control practitioners to explain CJD to patients, the public and media.</p>

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			exposure to CJD risk?				
<p>Anonymous 2003</p> <p>Anon (2003). 'CJD 'nightmare' leads to routine high sterilization: a staggering 3,600 patients notified.' Hospital Infection Control 30(5): 67-68.</p>	CJD	<p>Surgical patients exposed to the risk of CJD.</p> <p>3600 patients who had received surgery with instruments used on a patient who went on to develop CJD (University of Pittsburgh Medical Centre, USA).</p>	<p>To describe the process of notifying people of risk following surgical exposure to CJD risk; and measures taken subsequently to decrease this risk among hospital patients.</p> <p>Review questions addressed:</p> <p>What is the range of strategies available for notifying people of exposure to CJD risk?</p>	<p>Patients exposed to risk through use of the same surgical instruments as the patient who went on to develop CJD were notified of the risk via letter.</p> <p>The media was also informed; and a hotline established to answer patient questions (with the stated aim of decreasing anxiety).</p>	<p>Description of the process for notifying patients and the rationale for establishing more rigorous decontamination processes for surgical instruments.</p>	<p>The hospital made the decision to adopt extremely rigorous sterilization procedures for instruments on a permanent basis (routine processing of all OR instruments at 274 [degrees] F for 18 minutes).</p>	<p>No further details of the notification method or other aspects of communication were reported.</p>

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			Data collection methods	Limitations of the study Authors' recommendations/ conclusions
<p>CJD Support Group Network (CJDSGN) 2008*</p> <p><i>Understanding CJD</i></p> <p>Educational DVD</p> <p>Produced by the CJD Support Network Group Australia, launched February 2008, Canberra</p> <p>Available from the CJD Support Group Network Australia.</p>	CJD	<p>People with CJD and their families and carers; those at risk for CJD for public health purposes, due to iatrogenic exposure to the risk of CJD or due to genetic susceptibility to CJD</p>	<p>Aims to raise awareness about CJD within Australia, particularly among the medical profession. Also aims to highlight problems in care and accessing care experienced by patients with CJD and their families/ carers, and for people at-risk for CJD.</p> <p>Includes interviews with family members of people who have died from CJD, people at risk of CJD (either genetically or due to iatrogenic exposure), and medical experts on CJD.</p>	<p><i>Problems and issues highlighted</i></p> <p><i>Personal issues:</i></p> <ul style="list-style-type: none"> • Distrust and suspicion surrounding the disease, both from the medical profession and from the public. • Stress created within families – personal problems, difficulties with behavioural problems, guilt. • ‘why me?’ – associated with a rare disease. • Responses from the medical profession and difficulties accessing medical and health services – such as delays or cancellation of procedures when the person discloses that they are at risk of CJD. • People at risk of CJD neglecting health problems to avoid confronting the negative perceptions of the medical profession. <p><i>Perceptions versus facts around CJD:</i></p> <ul style="list-style-type: none"> • CJD is often associated with mad cow disease, by both the general public and from those within the medical profession (eg nurses, others). • People’s perceptions of CJD appear to be based largely on media coverage, and this seems to account at least in part for the mistaken association with mad cow disease. <p><i>Issues around diagnosis:</i></p> <ul style="list-style-type: none"> • Delays in diagnosis are distressing for families; they can see their relative worsening, sometimes day to day, and yet have no name for the disease affecting their family member. • Early diagnosis can be difficult; other diseases must be ruled out and a number of diagnostic tests conducted. CJD is also rare and many doctors would not have encountered a case previously. <p><i>Issues around management:</i></p> <ul style="list-style-type: none"> • People related instances where they had needed to undergo surgery. Worry about the

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				<p>additional negative impact of their at-risk status on top of anxiety about the procedure was an issue.</p> <ul style="list-style-type: none"> • Hospitals, clinics and health services need to find out what they need to do before a person arrives for treatment. This information is not hard to find and can be accessed through the health department or experts contacted through the CJD Support Group Network. • Misconceptions by medical staff about the infectious nature of CJD are common: CJD is not infectious, it is transmissible, and many procedures (eg most dental procedures) do not need additional infection control procedures to be in place. The exception is surgery on the central nervous system. • Special precautions are only needed for people at risk undergoing high-risk procedures. For genetic CJD, only first-degree relatives are regarded as being at risk and may need special precautions; for sporadic cases of CJD, there are no additional measures that need to be taken (ie these people are not at higher risk than anyone else in the population). • Medical and nursing staff should treat people at risk sensitively and with the appropriate level of response (ie not to overreact to their at-risk status, or to make patients feel as though they are posing a great personal risk). <p><i>Issues of discrimination:</i></p> <ul style="list-style-type: none"> • People at risk of CJD often experience discrimination in accessing or receiving medical or health treatments. This reflects a lack of knowledge about the low risk of most procedures and the ways that risks can be effectively managed. • People at risk are often refused treatment, or experience treatment delays. • People at risk have a moral obligation, but not a legal one, to disclose their risk status when having medical or health procedures. However, the sense of fear from doctors, dentists and others in the medical profession leads some patients to neglect their health or put off going for treatment or screening. <p><i>Working towards a better understanding of CJD:</i></p> <ul style="list-style-type: none"> • In order to encourage patients to be open and honest and to disclose their risk status, it is necessary to have a healthcare workforce that is better informed about CJD. Health professionals should be informed about CJD, its rarity, and the fact that they may have

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				<p>patients with different levels of risk for CJD.</p> <ul style="list-style-type: none"> Doctors, nurses and other healthcare professionals need to be better educated about CJD in order to be able to provide information and support for patients and their families, and to be able to effectively care for patients over the course of the disease.
<p>CJD Support Group Network (CJDSGN) 2006a*</p> <p><i>Infection control issues, discrimination and refusal of treatment medical and dental – state by state</i></p> <p>Data collected 1st June 2006 to 31st December 2006</p> <p>Author: CJD Support Group Network</p>	<p>CJD</p>	<p>People at risk of CJD (genetic or iatrogenic)</p> <p>Note: for these complaints data information relating to genetic CJD/ familial patients at risk has not been included in the current review.</p>	<p>To report on the issues and problems accessing medical and health care by people at risk of CJD within Australia.</p> <p>Authors note that there has been a significant improvement in the number of infection control issues facing people at risk in the previous 6 month period. The authors attribute this to growing knowledge and awareness among hospitals, and improved knowledge about who to contact if an issue arises.</p>	<p>There are frequent infection control issues arising as people at risk attempt to access medical and health care. These may be better dealt with and problems prevented if hospitals prepare for people at risk before difficulties arise.</p> <p>Authors note an improvement in the situation in Victoria following the CJD Consensus workshop (November 2004), but that after 12 months conditions started to deteriorate again, suggesting that ongoing awareness raising may be important.</p> <p>Several individuals attempting to access surgery or other care experienced significant delays in accessing treatment, such as cataract surgery (almost 12 month delay); a delay of several months for spinal surgery; or were refused procedures including scopes.</p> <p>Several hPH recipients admitted that they have not disclosed their at-risk status when having a scope procedure. One woman who works in a hospital where a screening questionnaire is used booked into another hospital to avoid this.</p> <p>The husband of a woman with a genetic predisposition to CJD was refused dental treatment and would have to attend a different clinic to where his wife and child received dental treatment because of his CJD risk. Contact from the CJDSGN reinforced the dentist's fear of infection from the man; and although this incident was sorted out through contact with the dentist's director this caused the family considerable stress.</p>

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<p>CJD Support Group Network (CJDsgn) 2007a*</p> <p><i>Infection control issues, discrimination and refusal of treatment medical and dental – state by state</i></p> <p>Data collected 1st January 2007 to 30th June 2007</p> <p>Author: CJD Support Group Network</p>	CJD	<p>People at risk of CJD (genetic or iatrogenic)</p> <p>Note: for these complaints data information relating to genetic CJD/ familial patients at risk has not been included in the current review.</p>		<p>One family was very distressed and angry that it had taken approximately 12 months for them to receive the results of their family member's autopsy that confirmed the diagnosis of CJD.</p> <p>One hPH recipient who had lost a child to cancer and who has another sick child was told by doctors that her children's illnesses were a result of her hPH treatment. She was asked on a questionnaire at a children's hospital if she had ever received hPH treatment.</p> <p>One family affected by genetic CJD continued to have dental problems. A mother with the CJD mutation was very concerned about seeking specialist treatment for her young son, and it was decided that it would be better for the procedure to be done at a dental hospital. A quick appointment was set up with the assistance of the state health department and the care was excellent but there remains an issue of delays in getting care.</p> <p>A patient at risk was denied dental treatment by her clinic, and when she showed them her medical-in-confidence letter they explained that she would need to be treated at a dental hospital. The clinic staff discussed her at-risk status in front of a full waiting room, and again at a nearby café in front of a number of people.</p> <p>A hPH recipient due to have cataract surgery found that the clinic had a screening questionnaire asking about hPH treatment. Discussions with the clinic and doctor before admission and the state health department assisted, so that the procedure went ahead without problems.</p> <p>However, another hPH recipient refused a scope was given an alternative test but still refused the scope procedure until the revised infection control guidelines are released.</p> <p>The family of a patient with suspected CJD was upset when the patient was transferred to a nursing home and treated as though contagious. Intervention by the state health department led to a nursing home meeting to discuss the issues with the staff.</p> <p>The family of a patient with suspected CJD was treated badly and the patient refused proper tests. After contacting the CJDsgn and ANCJDR, testing took place. However when this</p>

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Study reference	TSE	Study population	Aim of study Data collection methods	Results Limitations of the study Authors' recommendations/ conclusions
				<p>suggested possible CJD the staff told the patient's wife that he had mad cow disease.</p> <p>A young woman was very concerned as she was pregnant and wanted to know if she needed to inform the doctor as she would be having an epidural. Her mother had recently been refused treatment (day surgery to remove a growth from her tongue) when she informed them that she had a family history of CJD).</p>
<p>CJD Support Group Network (CJDSGN) 2007b*</p> <p><i>Infection control issues, discrimination and refusal of treatment medical and dental – state by state</i></p> <p>Data collected 1st July 2007 to 31st December 2007</p> <p>Author: CJD Support Group Network</p>	CJD	<p>People at risk of CJD (genetic or iatrogenic)</p> <p>Note: for these complaints data information relating to genetic CJD/ familial patients at risk has not been included in the current review.</p>	<p>Authors note that awareness and knowledge of CJD is improving but that there remains a lot of room for improvement.</p> <p>Authors also note that the ANCJDR and some state health departments are now receiving regular calls in relation to infection control: this shows an improvement in clinicians' knowledge about where to seek experts advice; and that it is hoped the education and awareness campaign (by the CJD SGN) will further improve this.</p> <p>Many people at risk of CJD wish to do the right thing and notify healthcare professionals of their at-risk status, but are afraid to do so as they have</p>	<p>A hPH recipient needed neurosurgery and this was handled appropriately through the state health department contact person. Both the patient and hospital were appreciative of the support and information provided.</p> <p>Dental issues continue to be a concern for many. Some genetic family members have had assistance from their state health department and the CJDSGN to resolve issues; in other cases people cannot obtain specialist referrals for braces. In another case a person with the CJD mutation informed her dentist and he refused to pull out her tooth due to the expense of disposing of instruments.</p> <p>In another instance, a child from a genetic CJD family who had been to hospital for dental advice returned for a scheduled appointment. The family history of CJD had been disclosed at the previous meeting. However, the mother was reprimanded for failing to bring this to the attention of the staff treating her son on the day. The dental work being undertaken involved an anesthetic and the doctor asked to speak to the mother about the child's CJD risk in front of the child. The 6 year old child later asked his mother if he had CJD.</p> <p>One patient exposed iatrogenically to CJD and who needed screening for cancer was assisted to undergo a minor preliminary procedure rather than the initial planned procedure, through help from the state health department. The original procedure did go ahead at a later time point, but as cancer was detected this delay may have significant implications for the patient and their survival.</p> <p>In another case a woman with the CJD mutation and who had informed her GP of this status assumed that this information had been communicated to the hospital where she had</p>

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Study reference	TSE	Study population	Aim of study Data collection methods	Results Limitations of the study Authors' recommendations/ conclusions
			<p>had negative experiences with infection control issues, been refused treatment or made to feel 'like a leper.'</p>	<p>surgery. It was not, and after the risk was identified post-surgery the woman was told she had cost the hospital \$40,000 for equipment that needed to be destroyed since she had not disclosed her risk status. This same woman was scheduled to have a colonoscopy but received a call to say that she should realize that she was not able to have this procedure.</p> <p>Another young woman without a record of hGH in her treatment records but convinced that she had been treated was refused a colonoscopy procedure by a hospital.</p> <p>Another young patient was refused tonsil surgery at a private hospital. His grandfather had died of CJD, confirmed by autopsy, but genetic testing of the family remained to be done. There was no reason to suspect that the grandfather had died of genetic CJD; however the private hospital was concerned and confused about vCJD and transmission risks. The surgery was done instead with a public hospital, whose infection control department met with the CJDSGN and who were happy to proceed with the operation.</p> <p>Another family with genetic CJD reported problems following the death of their family member. They agree to an autopsy, but received a call from the funeral parlour to ask if they realised that they would need a bigger coffin for their relative. The reason given was that the family member's body was arriving in a bag marked contagious and that some of the hospital equipment was also left in this bag. The family was also told that they would not be able to dress their relative for the burial. After the family complained the body was taken back to the hospital to have the equipment removed from the bag.</p>
<p>CJD Support Group Network (CJDSGN) 2006b</p> <p><i>Issues for 'at risk of CJD' patients</i></p>	<p>CJD</p>	<p>People at risk of CJD (genetic or iatrogenic)</p> <p>Note: for these complaints data information relating to genetic CJD/ familial patients at risk has not been included in the current review.</p>	<p>Authors note that discrimination and difficulties in accessing care will only worsen with the expansion of screening, unless education about the risks of CJD is undertaken.</p>	<p><i>Infection control issues</i></p> <ul style="list-style-type: none"> Human pituitary hormone (hPH) recipients continue to confront Infection Control Issues when accessing health care: even as low risk patients, presenting for low infectivity tissue procedures, people often experience unnecessary delays and difficulties in accessing appropriate health care. Areas that are associated with the greatest concern includes dental work and eye surgery; for example, very long delays in accessing scope procedures; cataract surgery; or people waiting up to 20 weeks for root canal procedures despite being in pain and unable to eat or sleep. The procedure was then done in a single appointment, rather than

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Study reference	TSE	Study population	Aim of study Data collection methods	Results Limitations of the study Authors' recommendations/ conclusions
<p>30th June 2006</p> <p>Author: CJD Support Group Network</p>			<p>It is also noted that at-risk patients are often denied suitable treatment due to fears of contamination of instruments. The needs of the patients are weighed against the costs of instruments: this leads to discrimination, and by treatment being compromised by delays or alternative diagnostic or management strategies.</p>	<p>being spread over at least two as is usual.</p> <ul style="list-style-type: none"> • People at risk have been denied treatment by doctors and hospitals, including being turned away from an emergency department. <p><i>Discrimination</i></p> <ul style="list-style-type: none"> • People at risk who feel morally obliged to disclose their risk status are becoming increasingly dissatisfied with their treatment and discrimination they face. • People have treatment delays despite being in pain; have been prepared for operations but sent home even when the surgery was a low infectivity procedure; have been referred to as 'CJD patients' by doctors who refused to treat them; and have very long delays for screening scopes despite a history or risk factor for cancer. <p><i>Lack of knowledge in Australia</i></p> <ul style="list-style-type: none"> • Sensible treatment options for people at risk are possible and can often be achieved: many infection control people are educated and aware of what can and cannot be done when treating an at risk patient, and explain to the patient reasons for any changes from usual routine. Often this situation comes about via involvement from the CJDSGN and/or ANCJDR and state health departments. However, many other health care workers remain uneducated and lack adequate knowledge of the CJD infection control guidelines. • Media coverage of vCJD has increased awareness but also created confusion and this has contributed to problems faced by patients. • It is important that the problems faced by patients at risk are known and addressed. Particularly with more screening questionnaires being used in healthcare settings it is important that the facility has procedures in place and educated staff to deal with people who are identified as being at risk through such screening.
<p><i>CJDSGN Management response to Infection Control</i></p>	<p>CJD</p>	<p>People at risk of CJD (genetic or iatrogenic)</p> <p>Note: for these complaints data information relating to</p>	<p>Response to the Infection Control Guidelines for cCJD.</p>	<p>There is concern that some scopes may be unavailable for patients at risk. Those patients at risk who disclose their risk status are becoming increasingly dissatisfied with their treatment and discrimination they are exposed to when attempting to access medical treatment, despite their responsible approach to disclosure. In considering the precautions that are needed when treating people at risk, the needs of these patients</p>

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Study reference	TSE	Study population	Aim of study Data collection methods	Results Limitations of the study Authors' recommendations/ conclusions
<p><i>Guidelines for cCJD</i></p> <p>Author: Management Committee, CJD Support Group Network</p>		<p>genetic CJD/ familial patients at risk has not been included in the current review.</p>	<p>Authors note that they are pleased to see the introduction of precautions to apply for low and high risk patients, which should cause less confusion amongst health care workers and avoid the attitude often adopted of applying more rigid precautions for high risk patients to all at-risk groups.</p>	<p>also need to be considered and measures taken to ensure that these people are not denied the best available care based on their at risk status.</p> <p>Although the guidelines states that 'Alternate diagnostic and management strategies, if available, should be considered in patients at risk of cCJD, provided that the care of the patient is not compromised' the experience of the CJDSGN is that at risk patients are often denied suitable treatment. Discrimination is very common; and this is creating a situation where people at risk are not prepared to disclose their risk status when undergoing treatment.</p> <p>Consideration should be given to developing a Medical in Confidence Letter and fact sheets (to be available upon request) for those people who fall into the high infection control risk group for inherited forms of prion disease (including those who have been tested and are confirmed as carrying a mutation for CJD or another prion disease; and those in whom testing has not been done but who are at risk of a genetic prion disease or have two or more first degree relatives who have died of CJD).</p> <p>Genetic testing of patients suspected of having CJD should be encouraged – in the interests of protecting the public health.</p> <p>Some suggestions that may assist both patients and health care facilities include the following:</p> <ul style="list-style-type: none"> Introduction of a standard screening questionnaire (all states/ territories, all public and private hospital and facilities) where high infectivity tissue is involved. The appropriate screening question is 'whether a patient has two or more first degree relatives with CJD' but often this is mis-framed as 'do you know anyone with CJD?': this is not an appropriate question. That screening questionnaires be used only on procedures involving high infectivity tissues. <p>If healthcare facilities do use a screening questionnaire for CJD risk, they must have a clear action plan for instances where they encounter a positive response: this should include staff education to improve knowledge that a patient at risk of CJD is not a risk to staff or nearby patients.</p>
<p>Commonwealth Department of</p>	<p>CJD</p>	<p>People at risk of CJD acquired through pituitary</p>	<p>To survey pituitary hormone recipients about the</p>	<p><i>Survey results:</i></p> <ul style="list-style-type: none"> • Approximately 22% of people responded to the survey.

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Study reference	TSE	Study population	Aim of study Data collection methods	Results Limitations of the study Authors' recommendations/ conclusions
<p>Health and Family Services (Australia) (CDHFS) 1995*</p> <p><i>HPH Newsletter Survey of pituitary hormone recipients</i></p> <p>Outlined in March 1995 newsletter; results reported in June 1995 issue</p>		hormone therapy	<p>newsletter, recommended by the Report of the Inquiry into the Use of Pituitary-Derived Hormones in Australia and CJD. The survey aimed to gauge recipients' needs in terms of what they would like to know and the information that they would be prepared to share; and to evaluate whether translation, more frequent mail-outs, or other services were needed by recipients.</p> <p>Questions covered by the survey covered the following issues: frequency, content and understandability of the newsletter; whether additional articles on topics written by recipients or by other organisations would be useful; whether other mechanisms of providing information would be useful; and general comments.</p>	<ul style="list-style-type: none"> • Many questions indicated a strong positive response to the newsletters: <ul style="list-style-type: none"> ○ 92% of respondents found the information covered in the newsletters to be useful, in understandable English and easy to read; ○ 88% responded that there should be more response to medical questions and supported the proposed question and answer section within the newsletter; ○ Comments of respondents indicated that they were supportive of the work of the Task Force and were supportive of the type and style of the information provided in newsletters; ○ Many respondents indicated that they would like more factual information; and some indicated specific questions that they would like to be addressed. • There was some indication that a column featuring letters from recipients and/or their families about the experience of living with the risk of CJD; although others expressed concern that this information might be too emotional and might be upsetting to some readers of the newsletter. Those people who would like to access letters relating to personal information or experiences were invited to contact the CJD SGN Inc or their local support groups to discuss the inclusion of this type of column in local or national newsletters. The consensus was therefore to stay with the focus of the newsletter on providing up-to-date factual information to recipients and their families. • General articles about counselling written by Relationships Australia and counselling experts were to be included in future issues of the newsletter. • Responses on the desired frequency of newsletter provision were variable, but a majority of respondents expressed a preference for a quarterly newsletter. • The Task Force also noted that it was in the process of producing a video to provide easily accessible information about CJD and the type and range of services available to recipients and their families; and which could be distributed widely to people (ie more widely than those people who may be able to attend support group meetings).
Commonwealth	CJD	People at risk of CJD	To survey pituitary hormone	<i>Survey major results</i>

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Study reference	TSE	Study population	Aim of study	Results
			Data collection methods	Limitations of the study
				Authors' recommendations/ conclusions
<p>Department of Health and Family Services (Australia) (CDHFS) 1996*</p> <p><i>HPH Newsletter Summary report of survey of recipients</i></p> <p>Outlined in October 1995 newsletter (preliminary results); summary of main results reported March 1996 newsletter</p>		<p>acquired through pituitary hormone therapy</p>	<p>recipients, in response to the Allars Inquiry. The survey aimed to give recipients the opportunity to provide up-to-date information to the Task Force; to indicate whether they wished to share personal information about themselves with other recipients; to determine whether they were interested in participating in an epidemiological study; and to seek information on the medical information line, and on the counselling and support group services available to recipients and their families.</p> <p>Questions covered by the survey covered the following issues: issues around sharing of personal information; participation in an epidemiological study; and recipients' opinions on information and support services available to themselves and their families.</p>	<ul style="list-style-type: none"> • Surveys were sent to 1,579 recipients of human pituitary hormones; completed responses were received from 697 (44% response rate). • Regarding the provision and sharing of personal information: <ul style="list-style-type: none"> ○ Most respondents updated their personal details, and 95% asked for a copy of their updated record from the Australian Human Pituitary Hormones Program database. ○ The majority (59%) of respondents indicated that they were prepared to share personal information with other recipients in similar situations, such as their same and address. Of these respondents, most indicated that they would like to have their name and contact telephone number provided to the national and/or state support group coordinators. • Regarding possible participation in an epidemiological study: <ul style="list-style-type: none"> ○ The majority of respondents (77%) indicated that they would be willing to participate in an epidemiological study. Of these respondents, over half preferred to be contacted via letter, with fewer preferring face-to-face contact (17%) or telephone contact (16%). ○ Of those responding, 84% indicated their willingness to have personal details and details of their treatment disclosed to a researcher, as long as this information was de-identified. • Regarding information and support services: <ul style="list-style-type: none"> ○ The majority of respondents wished to receive or continue to receive information from the Pituitary Hormones Section, including the HPH newsletter, updates on factual information, and listings of the services available to them. Satisfaction with the available information was generally high, although some respondents indicated that they would like more medical or technical information to be made available. ○ Of those who used the 1800 Medical Information Line, 72% rated it as 'good' to 'excellent'. ○ Of those who rated the Information Line as 'poor' (9%), many were concerned about access to the line, and had experienced difficulties getting through to the line or were unhappy with having to leave an answering machine message. ○ A small proportion (12%) of respondents indicated that they had used the free counselling service provided by Relationships Australia. The majority of people

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Study reference	TSE	Study population	Aim of study Data collection methods	Results Limitations of the study Authors' recommendations/ conclusions
				<ul style="list-style-type: none"> ○ who had used the service rated it as 'good' to 'excellent.' ○ Of those who had rated the counselling service as 'poor', many again cited access problems, such as difficulty in accessing the service if living in rural areas. A number of respondents who had not used the counselling service noted that although they had not yet used the service, they were pleased to know of its existence, should they need to use it in the future. ○ Approximately one third (34%) of respondents indicated that they had attended a CJD Support Group meeting, or had received information from a support group. Of those who had accessed a support group, over 80% rated it as 'good' to 'excellent', with less than 3% rating it as 'poor'. Access was again raised as an issue, with people living in rural/ remote areas responding that the felt they could not take full advantage of the service because they could not readily attend meetings.

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Study reference	TSE	Study population	Aim of study Study design/ type; data collection methods	Intervention Aim/ purpose	Outcomes	Results Limitations Authors' recommendations/ conclusions
Hartley 2004 Hartley, J. (2004). "vCJD alert is 'upsetting' for	vCJD	Haemophilia nurses contacting patients to notify them of increased risk of vCJD via blood transfusion.	To describe the impact of notification of higher risk for people with haemophilia. Description of nurses' experience of the notification	No intervention; aim of the paper review was to describe some of the issues for people with hemophilia notified of elevated risk status for vCJD; as well as the experiences of	Incident identified from 9 blood donors, making 23 donations that contributed to approximately 200 plasma batches.	Nurses describe the issues for patients: that this notification represents the third time many patients with haemophilia have been notified of increased infection risks as a direct result of

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Study reference	TSE	Study population	Aim of study Study design/ type; data collection methods	Intervention Aim/ purpose	Outcomes	Results Limitations Authors' recommendations/ conclusions
all involved." Nursing Times 100(39): 3-3.			<p>process as well as the impact of the notification information upon patients.</p> <p>Review questions addressed:</p> <p>Q1 What are people's experiences of being notified of CJD?</p> <p>Also Q4 (feasibility of implementation of interventions to communicate); and Q5 (harms of being notified of increased vCJD risk).</p>	<p>the nurses conducting the notification. Notification conducted via nationwide alert from the Department of Health to 6000 patients with haemophilia and other blood disorders; notification via letter, haemophilia nurses also involved in identifying and contacting patients via letter (role not described further).</p>	<p>Account of individuals' experiences and the impact of notification.</p>	<p>treatment with blood products (previously HIV and HCV).</p> <p>Nurse responses indicate that such information might damage patients' trust. For example, many nurses involved in notifying patients were those who administered the contaminated blood products and so exposed patients to increased risk.</p> <p>Nurses note that some patients are refusing to receive treatment unless they have no choice.</p>
Sulser 2006 Sulser E (2006). A patient's perspective on hemophilia. Seminars in Hematology 43 (supplement): S13-6.	vCJD	<p>People with hemophilia (general overview of the issues for people with hemophilia).</p>	<p>To describe some of the major issues around treatment faced by people with hemophilia.</p> <p>General literature (non-systematic) review.</p> <p>Review questions addressed:</p> <p>Q1 What are people's experiences of being notified of CJD?</p>	<p>No intervention; aim of the review was to present some of the major issues for people with hemophilia and their carers, in terms of informed decision-making about treatment.</p>	<p>General overview of the literature.</p>	<p>People with hemophilia making choices about treatment need to evaluate four major areas: safety, purity, cost and convenience.</p> <p>Safety of the blood supply (in terms of pathogen infection) is an ongoing issue for people with hemophilia. Although the blood supply has never been safer, safety could also be improved with strategies such as improved education and more selective donor acceptance, as well as</p>

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Study reference	TSE	Study population	Aim of study Study design/ type; data collection methods	Intervention Aim/ purpose	Outcomes	Results Limitations Authors' recommendations/ conclusions
						<p>better viral inactivation and conservative transfusion practices.</p> <p>The effect of HIV contamination of the blood supply is still an issue for those with hemophilia. Doctors are in a position to help to address patients' fears regarding transfusion and the blood supply, and to help patients to understand the risks associated with treatment.</p> <p>The potential for infection of the blood supply with vCJD has a strong psychological impact on people with hemophilia, given the history with HIV contamination. Further research is needed before patients and their families will be able to make informed decisions about the risk of vCJD. To be able to make informed choices, there is a need for unbiased information about the risks and benefits of treatment.</p> <p>Author's conclusions: '...In order to select optimal therapy, a patient's right to information is critical...Given this history [of the HIV epidemic],</p>

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Study reference	TSE	Study population	Aim of study Study design/ type; data collection methods	Intervention Aim/ purpose	Outcomes	Results Limitations Authors' recommendations/ conclusions
						policy decisions should always be complemented by medical ethics and quality-of-life considerations.'
<p>Zekauskas 1990</p> <p>Zekauskas, S., M. B. Boggs, et al. (1990). "Human growth hormone and Creutzfeldt-Jakob disease." Journal - Oklahoma State Medical Association 83(9): 447-8.</p>	CJD	<p>Patients who had received contaminated human growth hormone for short stature (as children; mean age of treatment 10.7 years, ranging from 1.8 to 19 years of age). Period of treatment was from 1969 until withdrawal of cadaver-derived human growth hormone in 1989. Location: Oklahoma.</p> <p>A total of 60 children and adolescents were identified through retrospective review; authors note that the probably population affects was likely much higher as the hormone was available also through commercial sources (as well as the treatment programs in Oklahoma (2 university-based programs).</p>	<p>To describe the process for notification of people treated with potentially-contaminated human growth hormone.</p> <p>Description of the notification and follow-up processes, as well as long-term implications for people at risk.</p> <p>Review questions addressed:</p> <p>What is the range of strategies available for notifying people of exposure to CJD risk?</p> <p>What is the range of strategies available for supporting people notified of exposure to CJD risk?</p>	<p>Retrospective review of clinical and hospital records was used to identify those who had received injections of human growth hormones.</p> <p>Affected patients identified through review were notified and enrolled in long-term follow-up program (through the CDC, NIH and the FDA). This long-term program aims to keep individuals informed of recent developments of knowledge in the area, and also aims to document additional CJD cases.</p>	<p>Description of the notification and follow-up processes, as well as long-term implications for people at risk.</p> <p>Data extraction here focuses on issues of safety of therapy and difficulties with emerging infections.</p>	<p>People at risk are enrolled in long-term follow-up which aims to provide emerging information as well as document new cases of CJD.</p> <p>No changes to daily living routines are recommended for people at risk, although they are prevented from donating blood or tissues.</p>

POLICY DOCUMENTS, AGENCY REPORTS, CONSENSUS CONFERENCE PROCEEDINGS, OTHER LITERATURE

Study reference	TSE	Study population	Aim of study Data collection methods	Intervention	Outcomes	Results Limitations of the study Authors' recommendations/ conclusions	Other notes Other study features Reference to related papers
<p>Blajchman 2004*</p> <p>Blajchman MA, Goldman M, Webert KE, Vamvakas EC, Hannon J, Delage G (2004). Proceedings of a consensus conference: the screening of blood donors for variant CJD. Transfusion Medicine Reviews 18 (1-2) 73-92.</p> <p>Also reported in:</p> <p>Hewitt PE (2004). Implications of notifying donors and recipients. Vox Sanguinis 87 (s2): 1-2.</p>	vCJD	<p>Those exposed to the risk of vCJD through blood transfusion.</p> <p>Regular, novice, interrupted and potential blood donors at 5 sites across England.</p>	<p>To determine the effects of vCJD testing on donor's attitudes to blood donation.</p> <p>Market research commissioned by the National Blood Service (NBS), UK.</p> <p>Participants were interviewed in group discussions (October 2001).</p>	Evaluation research.	Donors' attitudes towards screening tests for donated blood; awareness and understanding of vCJD; attitudes towards screening test for vCJD; attitudes towards being notified of positive test result for vCJD.	<p>Donors appear to give little thought to blood screening/ implications of blood screening.</p> <p>Participants had a range of knowledge of vCJD, reflecting primarily what had been presented in the mass media. Most were aware of the risk of vCJD to the general population in the UK; most were not generally aware of the likely long incubation period of vCJD.</p> <p>Before more information on vCJD was communicated to them, participants expressed little concern about the possibility of testing for vCJD, or concern over the possibility of a positive test result; and generally supported notifying donors of their results.</p> <p>Support for notifying donors of positive test results decreased as more information about vCJD was communicated to participants: when the uncertainty of screening test results (ie the possibility of false positive results, the possibility of a long incubation period if a true positive result) was communicated to</p>	See also Reesink 2003 – paper by P Hewitt and others regarding future counselling of donors and recipients related to prion diseases

POLICY DOCUMENTS, AGENCY REPORTS, CONSENSUS CONFERENCE PROCEEDINGS, OTHER LITERATURE

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						<p>participants they were generally less certain about the use of being informed of such a result, and a minority admitted they would prefer not to be notified in such a situation. The majority maintained that they would still prefer to be notified, in order to avoid passing the disease on to others, to access treatments as they became available, and to plan for the future.</p> <p>Authors note that the attitudes towards vCJD testing may change as more information becomes available and will need further research closer to the time at which a screening test becomes available.</p> <p>Authors also note that based on current knowledge, very little could be communicated to donors who screened positive to a vCJD test.</p> <p>Authors also raise the following questions: what information about the meaning of a positive test result can be communicated to those who test positive? What information about the meaning of a negative test result can be communicated to those who test negative?</p> <p>The NBS sees no alternative but to notify donors of positive test results in a future</p>	

POLICY DOCUMENTS, AGENCY REPORTS, CONSENSUS CONFERENCE PROCEEDINGS, OTHER LITERATURE

Study reference	TSE	Study population	Aim of study Data collection methods	Intervention	Outcomes	Results Limitations of the study Authors' recommendations/ conclusions	Other notes Other study features Reference to related papers
						test for vCJD; however it anticipates psychological harms and other poor outcomes associated with such a notification.	

POLICY DOCUMENTS, AGENCY REPORTS, CONSENSUS CONFERENCE PROCEEDINGS, OTHER LITERATURE

Reference and citation	TSE, additional notes	Population	Intervention features	Outcomes and results, recommendations
Allars M, June 1994* <i>Report of the inquiry into the use of pituitary derived hormones in Australia and</i>	The inquiry aimed to examine the operation of the Australian Human Pituitary Hormone Program (AHPHP), and to report on the issues arising from the program in regard to CJD.	The inquiry examined the use of human growth hormone (hGH) and human pituitary gonadotrophin (hPG) under the AHPHP, for treatment of infertility and short stature within	The report makes a number of recommendations. These include the need for further research into specific aspects of CJD (the infectious agent; genetic susceptibility to infection; epidemiological study of recipients of hormone recipients; research into developing effective therapies for CJD,	<i>Notification of recipients</i> In June 1985, the Minister gave a news release stating that the AHPHP had ceased due to a deaths of hGH recipients overseas. A small number of the recipients interviewed by this inquiry remembered reading a newspaper article, with a contact name as contact officer. Three recipients contacted the officer and left their details. One of these people was not contacted, despite telephoning again; another who was the mother of a recipient was told by the contact officer that

POLICY DOCUMENTS, AGENCY REPORTS, CONSENSUS CONFERENCE PROCEEDINGS, OTHER LITERATURE

Reference and citation	TSE, additional notes	Population	Intervention features	Outcomes and results, recommendations
<p><i>Creutzfeldt-Jakob disease</i></p> <p>Australian Government Publishing Services</p> <p>Please also refer to the following document which refers to this report extensively: Parliament of Australia, Senate</p> <p><i>Report on the CJD Settlement Offer</i> October 1997</p>		<p>Australia.</p>	<p>and for improved diagnostic methods for CJD); and the need for review of access to medical records; as well as recommendations around the support and follow-up of the recipients involved.</p> <p>Epidemiological study was used to retrospectively assess and follow-up each person treated under the AHPHP, in order to confirm the number of deaths due to CJD in recipients of human Growth Hormone (hGH) recipients, and to determine their current state of health. This study included examination of medical records and death registry records; and contact with medical practitioners to request information on any patients with CJD who had received pituitary extracts.</p> <p>A protocol was established with the aim, among others, of establishing a system for following up patients treated with hGH.</p>	<p>there was nothing to worry about and was then later upset when told by a medical practitioner that there was cause for concern; and another recipient was told that follow-up of recipients was being conducted, that it did not concern CJD and she was not recontacted despite leaving her details.</p> <p><i>Inquiry recommendations regarding tracing and counselling</i> The CJD Task Force role should include the following:</p> <ul style="list-style-type: none"> • Continue to trace recipients of pituitary-derived hormones, with staffing levels maintained until the task is close to being completed. • Continue publication of CJD News regularly. • Survey recipients involved to supplement the data already collected and contained in the database on recipients; specifically collecting data on the needs of recipients. • Conduct information evenings on pituitary hormones and CJD in each capital city at 6-monthly intervals, with a review of continuing need after 12 months. • That counselling services (provided by Marriage Guidance Australia) should continue to be funded; and that for those recipients for whom this counselling is inappropriate or inaccessible that alternative counseling should be made available. • That the National Advisory Group be replaced by an Advisory Committee with the aim of advising the Task Force on a range of issues, including the following: <ul style="list-style-type: none"> • How the needs of recipients may best be met. • How to foster support groups. • The conduct of research in which recipients are subjects.
<p>CJD Incidents Panel*</p> <p>Title: <i>CJD Incidents Panel Public summary of the</i></p>		<p>CJD, vCJD</p>	<p><i>Notification issues regarding iatrogenic CJD</i></p> <p>In cases where some members of a specific patient group have thought to have been exposed to CJD, but the at-risk individuals cannot be identified, the</p>	<p><i>Feedback on the blood components notification (December 2003)</i></p> <p>A report was made on the results of a survey conducted by the CJD Support Network. The survey included 12 patients and relative who had contacted the CJD Support Network helpline after the December 2003 notification of people receiving blood components. The main findings of the survey were that:</p>

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<p>15th meeting 11th May 2005</p> <p>(CJD IP (Public Meeting) 2005)</p> <p>Accessed October 8 2007, available at: http://www.camr.org.uk/infections/topics_az/cjd/summary05_05.pdf</p>			<p>Panel has consistently advised against patient notification. This is in the interest of preventing unnecessary alarm, in the absence of any preventative measures, when the exposure to CJD risk of individuals in the group is not certain.</p> <p><i>Follow-up and research for patients possible exposed to CJD or vCJD</i> The Panel's Framework document proposes that two groups of patients potentially exposed to CJD iatrogenically be recorded on a database: one group for those patient contacted about their risk; the other group for those patients whom the Panel has advised against contacting because of their uncertain level or risk, or low level of risk of CJD. The purpose of the database is for research and monitoring purposes; and will form an important component of the strategy for detecting secondary CJD transmission.</p> <p><i>Other issues</i> Anecdotal reports were noted that outlined delays in endoscopy (for investigations or treatment) on patients with bleeding disorders following the notification of plasma recipients of plasma products in September 2004 of their status as at-risk for public health purposes. The report notes that the risks of cross-contamination depends on the purpose of the endoscopy; and that while instruments exposed to CJD risk</p>	<ul style="list-style-type: none"> ● Where the patient had been notified by a GP they knew, and with whom they had a good existing relationship, the information had been well accepted and the patient had felt supported. ● In other cases, where the patient was informed of their risk by someone they didn't know; where the informant had little knowledge about CJD; and where the patient had to go elsewhere for support and information, and in some cases seek this out themselves; were associated with difficulties. ● The fact that patients often need a second consultation after being given this type of news was highlighted. This second consultation is necessary to give the patient the chance to receive the information again and to ask more detailed questions.

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			can be reserved for use of patients with probable CJD, the same approach cannot be used for patients with bleeding disorders who are at-risk of CJD.	
<p>CJD Incidents Panel (UK) (CJD IP (Framework Document) 2005)</p> <p><i>Management of possible exposure to CJD through medical procedures</i></p> <p>Framework Document August 2005</p> <p>Accessed October 8 2007, available at: http://www.hpa.org.uk/infections/topics/az/cjd/</p>	<p>CJD/vCJD</p> <p>The CJD Incidents Panel (CJDIP) is one component of the UK response to iatrogenic CJD risk; the other is an assessment of prevention of CJD transmission risks undertaken by the National Institute of Clinical Excellence (NICE).</p> <p>The CJDIP aims to assist all those involved in the provision of care to determine the best course of action in response to incidents involving possible transmission of CJD through clinical procedures. The Panel also advises in data collection, research required, and the need for any additional measures needed to protect the public health.</p>	<p>Technical document – outlining what is known about the risk of transmitting TSEs through medical procedures; how incidents should be identified; how public communication should be delivered.</p> <p>People undergoing invasive medical procedures are at variable risk levels – depending on the type (location) of surgery, number of instrument decontamination cycles etc. People at risk may pose a threat of infection to others: therefore need to be informed about exposure and potential implications to protect the public health (ie advised not to donate blood, organs, tissues).</p>	<p>Process for informing individuals who have been exposed to the risk of CJD: As patients who may be at risk may pose a potential threat to the safety of other patients, these patients must be notified of their possible exposure and the implications of this exposure.</p> <p>The clinician should be notified (usually a GP), who can take appropriate precautions for future medical interventions; they must also ensure confidentiality of information. The clinician should also ensure that public health advice is also provided. It may be appropriate to inform more than one medical adviser; and this may be discussed with the patient, who should be encouraged to share responsibility for protecting the public health.</p> <p>Informing people of at-risk status needs to be done with sensitivity, as the information is unlikely to be of benefit to the individuals informed and will be a burden. Notification may raise practical questions, such as those concerning</p>	<p>The Framework notes that essential to the Panel's strategy for dealing with healthcare-associated exposure to CJD is the provision of an adequate process for informing and counseling the people involved.</p> <p>The Panel is also collecting information on healthcare procedure-based CJD exposure, both on those people at risk and notified of their risk status; and on those that have not been informed of their risk exposure at present. Databases will be used to collect information for public health research and for long-term follow-up of people who may have been exposed to CJD through medical procedures.</p>

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		<p>The Framework outlines a way to manage incidents arising as a result of medical treatments, where people have undergone procedures or donated blood, tissues or organs and have then gone on to develop CJD (or have CJD suspected).</p> <p>The primary aims of the Framework and principles underpinning action include:</p> <ul style="list-style-type: none"> • To protect patients from exposure to the risk of TSEs in healthcare settings • To ensure that those who are potentially exposed to risk are informed in a manner that is appropriate to their individual level of risk. • To provide high quality information and advice to those people who may have been put at risk. • To increase 	<p>insurance. Information should be provided to help answer the patient's questions, and GPs can be assisted by experts on different aspects of CJD to help to support the GPs by providing information and answering questions.</p> <p>The following should be provided to assist in notification:</p> <ul style="list-style-type: none"> • Information should be provided on practical matters, such as insurance. • Clinician should be identified to carry out the notification; a team of experts on CJD should also be formed and available to help discuss the implications of the exposure and to support the clinician. This team should share the consultation if appropriate. • Appointments should be scheduled to allow enough time to explore issues/ concerns. Advice should be supplemented with telephone contact and/or another appointment if needed. • Written material supporting the consultation should also be prepared with the assistance of the Panel and the HPA/HPS, for people to take away from the appointment. • Patient counseling should include information on the uncertainties of risk and the limits of what is currently known about CJD. <p>People should not be informed of</p>	

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		<p>knowledge about the risks of TSE transmission in healthcare settings; and to ensure that the public is informed about the possible risks associated with healthcare, as well as the uncertainties about TSEs.</p> <ul style="list-style-type: none"> • To respect, where possible, the wishes of those people who do not wish to be informed of risk. • To protect the confidentiality of patients who are infected and those at risk of infection. • To ensure that, wherever possible, actions taken to protect the public health do not prejudice the care of individual patients. 	<p>possible exposure against their will unless measures need to be taken to protect the public health, in which case the individual should be informed.</p> <p>Public communication is also recommended. Information should be widely available and accessible on TSEs, including what is currently known about the risk of TSE exposure through healthcare procedures, and what action is being taken to minimize these risks.</p> <p>Communication should aim to provide:</p> <ul style="list-style-type: none"> • general information on TSEs and the current state of knowledge, and the measures that are being taken to minimise risk and improve knowledge in the area; • general information about specific incidents; • opportunity for individuals to discuss and obtain information/ reassurance about risk; • provide a process for individuals to establish whether they are at risk and provide care and support; • information about the current state of diagnostic tests and treatments for TSEs. <p>Where the public needs to be notified of specific incidents, the following should be provided:</p> <ul style="list-style-type: none"> • A press release which refers to general information leaflet and 	

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			<p>websites as sources of information.</p> <ul style="list-style-type: none"> The general information sources can also give the numbers (NHS Direct) that people who remain concerned can call to further discuss the issues. <p>People who ring NHS Direct for further information will speak to a Health Information Adviser in the first instance, who will note that the call is in relation to a clinical exposure to TSEs. The Health Advisor can then address these concerns using materials provided (flowchart and Q&A sheets); or can pass the call on to a smaller group of Health Information Advisors with experience in the field, who would also use the materials provided and answer the caller's questions.</p>	
<p>CJD Incidents Panel (UK)* (CJD IP (Annual Report) 2005; 2004)</p> <p><i>Fifth Annual Report 1st September 2004 to 31st December 2005 to the Advisory Committee on Dangerous Pathogens Working Group on Transmissible</i></p>	<p>CJD/ vCJD</p> <p>Report on the activities of the CJD Incidents Panel</p> <p>A CJD incident is defined as an event arising where there is potential for CJD transmission between patients via clinical procedures, including surgery, tissues, organs and/or blood.</p> <p>'The Panel gives advice</p>	<p>Between January 2000 and December 2005, 12 surgical incidents involving 65 patients for notification; plus one incident relating to donated organs.</p> <p>Describes the notification of individuals at risk of CJD/vCJD for public health purposes.</p> <p>The number of patients</p>	<p>Outlines the types of medical/ surgical incidents associated with CJD/vCJD.</p> <p>The Panel generally advises that only patients identified with certainty that they were exposed to instruments that could have been contaminated with medium or high risk (infectivity) tissues are notified of their risk.</p> <p>Donors informed about vCJD at-risk status by letter from UK Blood Services; accompanied by comprehensive information leaflet, with access to special helpline. The HPA also asked</p>	<p>Early recommendations of Panel included that patient considered at risk of CJD (over background risk in UK) should only be notified once appropriate support processes were in place. The HPA has experts to provide expertise and advice on informing and supporting contactable patients. HPA CJD section also provides toolkits for professionals to assist in the notification process for patients involved in CJD incidents.</p> <p>The HPA evaluated the notification process by surveying the GPs of at-risk blood component recipients. In general GPs did not think there had been any major problems with the notification process; and the problems that had occurred concerned the timing and speed of notification process.</p> <p>Note: see Hewitt (2006) for more on the 2003/2004 incident and notification.</p>

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<p><i>Spongiform Encephalopathies</i></p> <p>Accessed October 8 2007, available at:</p> <p>http://www.hpa.org.uk/infections/topics_az/cjd/incidents_panel.htm</p>	<p>on a case by case basis... The Panel also advises health care teams on the need to follow-up patients potentially exposed to CJD, how to conduct patient tracing and notification exercises, and how to deal with equipment that may have become contaminated with abnormal prion protein.'</p> <p>'The Panel has consistently advised against patient notification where only some members of a particular group of patients are thought to have been exposed to CJD, but the 'at risk' individuals cannot be identified.'</p>	<p>notified as being at risk of CJD/vCJD has grown: research into the impact of notification on these people needed, would inform future notification strategies.</p>	<p>GPs to support their patients, supplied an information pack, and offered support by local Health Protection Units.</p> <p>Notification was staged: first contacting current donors (given blood within 5 years); then tracing and contacting lapsed donors.</p> <p>Note that this report outlines the same incident and notification exercise described in Farrugia (2005).</p>	<p>The CJD Support Network surveyed 12 of the patients/ family members who had contacted its helpline after the 2003/2004 notification to recipients of blood components. Patients who received the notification from a GP they knew and with whom they had an established relationship, accepted the information well and felt supported. Instances associated with problems included: where patients were informed by someone that they did not know; where the informant had little knowledge about CJD; or where the patient had to go elsewhere for support and information.</p> <p>Another notification exercise performed in 2005 in donors of blood where transfusion recipients later developed vCJD and the transfusion could not be ruled out as the source of exposure. Donors were informed of their vCJD risk status via letter, which was accompanied by a comprehensive information leaflet and contact details for a dedicated helpline. The HPA contacted GPs and asked them to support their patients; provided an information pack to GPs and offered additional support by the local Health Protection Units. The notification was staged; with current donors contacted first, and lapsed donors traced and contacted later.</p> <p>NB See Hewitt (2006) for detailed description of this notification exercise.</p> <p>The report notes that the group of patients notified of their 'at-risk' status has grown, and research into the impact of notification is needed and would be used to further inform future notification exercises.</p> <p><i>Additional information from the 4th Annual Report (1st September 2003 to 31st August 2004)* (available at http://www.hpa.org.uk/infections/topics_az/cjd/incidents_panel.htm; accessed March 13 2008.</i></p> <ul style="list-style-type: none"> • In November 2003 the Panel met with key stakeholder groups to discuss how health professionals involved in notifying patients of

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				<p>their increased risk of developing CJD could be best supported in this role. A 'cadre of experts' was formed to fill this role, including individuals with experience in patient counselling and clinical care; and accessible via the HPA CJD Section.</p> <ul style="list-style-type: none"> The Panel has helped the HPA to develop several communication toolkits to assist local incident management teams in notifying and supporting patients contacted on the basis of the advice of the Panel. This includes toolkits for notifying patients and families involved in surgical, blood component and plasma product incidents.
<p>CJD Incidents Panel (UK)* (CJD IP 2006)</p> <p><i>Sixth Annual Report 1st January to 31st December 2006 to the Advisory Committee on Dangerous Pathogens Working Group on Transmissible Spongiform Encephalopathies</i></p> <p>Accessed March 4 2008, available at: http://www.hpa.org.uk/infections/topics_az/cjd/incidents_panel.htm</p>	<p>CJD/ vCJD</p> <p>Report on the activities of the CJD Incidents Panel</p> <p>A CJD incident is defined as an event arising where there is potential for CJD transmission between patients via clinical procedures, including surgery, tissues, organs and/or blood.</p> <p>'The Panel gives advice on a case by case basis... The Panel also advises health care teams on the need to follow-up patients potentially exposed to CJD, how to conduct patient tracing and notification exercises, and how to deal with</p>	<p>The report notes that there are 4 patient groups considered to be at risk of vCJD, based on Panel advice, as a result of having received or donated blood:</p> <ul style="list-style-type: none"> Recipients of blood components from people with vCJD Recipients of plasma products from people with vCJD Donors of blood components to people who develop vCJD Other recipients of blood components from donors to people who develop 	<p>Outlines the types of medical/ surgical incidents associated with CJD/vCJD, and the responses to these incidents.</p> <p>The Panel generally advises that only patients identified with certainty that they were exposed to instruments that could have been contaminated with medium or high risk (infectivity) tissues.</p> <p>The Panel notes that there needs to be balance between public health protection and prevention and the possible harms to individuals' quality of life and possible harms associated with notification and precautionary management of CJD.</p> <p>The report outlines follow-up research activities for people at risk for vCJD based on Panel advice. The first set of activities focuses on follow-up of at-risk individuals: monitoring of people implicated via</p>	<p>Early recommendations of Panel included that patients considered at increased risk of CJD (over background risk in UK) should only be notified once appropriate support processes were in place. The Panel has an ongoing role in overseeing this advice, including a cadre of experts to provide expertise and experience in managing CJD incidents, and whom local health professionals can access. The HPA CJD Section also provides toolkits for professionals to assist in notifying patients involved in CJD incidents.</p> <p>The report also notes that as a result of re-classification of tissue infectivity and changes in the advice regarding precautionary public health steps to be taken after surgical incidents, the Panel advised that in 2006 14 at-risk patients should be notified that they were no longer considered to be at risk.</p> <p><i>Information to be given to at-risk patients</i></p> <p>A local incident management team had requested advice about a specific patient. One of the two patients notified of exposure following a surgical incident had asked whether the index patient had developed vCJD; and had been informed that they had not, and that it was an area of uncertainty. It was later found that the index patient had developed vCJD, and the Panel was asked to advise whether this new information should be given to the patient at risk, as there was concern about preserving the index patient's confidentiality.</p>

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	<p>equipment that may have become contaminated with abnormal prion protein.'</p> <p>'The Panel has consistently advised against patient notification where only some members of a particular group of patients are thought to have been exposed to CJD, but the at-risk individuals cannot be identified.'</p>	<p>vCJD.</p>	<p>blood transfusions (following three probable cases of transfusion-transmitted vCJD), to ensure they receive appropriate support and for research purposes (eg post-mortem examination for vCJD infection).</p> <p>The report notes that qualitative research on the impact of notification for people at-risk of CJD is also ongoing and is a priority. Research to assess the psychological impact of notification is needed, in order to inform the development and conduct of future notifications. By the end of 2006, it was decided to study two groups of people at risk: those at risk due to surgical incidents, and those who had donated blood to people who later developed vCJD.</p>	<p>The Panel advised that the person at risk should be notified that the index patient had developed vCJD; but that this case should not be treated as a precedent. When the at-risk patient did not respond to approaches from the local incident management team, the Panel agreed that the patient had the right to refuse to discuss the issue further, even if this was based on incomplete information, as long as the patient was able to be contacted by the local team in the future if needed.</p> <p>The Panel agreed to the principle that, depending on individual cases, or if at-risk patients in the future ask about the status of the index patient, they should be given this information; and where appropriate, the index patient and/or their family should be told that anonymised information was being shared with the individual at risk.</p> <p><i>Management of cases where patients with/ at risk of inherited prion disease do not wish to inform family members</i> An issue identified in developing the guidance for public health management of prion incidents were those instances where patients with, or at risk of, inherited prion diseases did not wish their family members to be informed of this, due to personal reasons.</p> <p>It was decided that, the wishes of these individuals should be respected and their confidentiality respected, in line with genetic counselling practices. This approach however ran counter to the usual precautionary approach adopted by the Panel, which advises that all people at risk are notified and asked to take precautionary public health measures.</p> <p><i>Access to dental care</i> In 2006, the Panel approved an advice note for use when people (or their families) at risk of CJD for public health purposes, have difficulty accessing dental care. The aim of this advice was to clarify issues around the introduction of new NHS general dental services; and was not initially intended as a reactive document responding to problems</p>

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				<p>in accessing dental care by people at risk or their families.</p> <p>Note: see also documents on dental advice/ dental advice note (from CJDIP, HPA and Chief Dental Officer (2006) UK).</p>
<p>Prepared by the CJD IP, HPA, with advice from the Chief Dental Officer (Department of Health)</p> <p>(CJD IP/ HPA/ CDO advice 2006)</p> <p><i>Advice note concerning problems with dental care for individuals 'at-risk' of CJD for public health purposes (2006)</i></p> <p>Available at: http://www.hpa.org.uk/webw/HPAweb&Page&HPAwebAutoListName/Page/1191942152869?p=1191942152869</p> <p>Accessed March 17 2008.</p>	<p>CJD/ vCJD (people with disease and those at risk of disease for public health purposes) – disclosing their risk status to dentists when receiving routine or other dental treatment.</p> <p>The aim of the letter is to provide advice to dentists with patients who have been diagnosed with CJD, or are at risk for public health purposes.</p> <p>The clinical care, including dental care, of these patients should not be compromised in any way. Appropriate decontamination measures are needed; and if head or neck surgery is required precautionary measures may be needed to reduce any potential risk of CJD transmission.</p>	<p>This advice refers to the Chief Dental Officer's letter to dentists, requesting that people with CJD, or at risk of CJD for public health purposes, or their relative, not be refused routine dental treatment based on their risk status.</p> <p>Several groups of patients have been identified as being at an increased risk of CJD: ie above the 1 per million risk level for CJD; the background risk level for vCJD is not known.</p> <p>There has recently been an increase in the numbers of patients classified as being at risk of vCJD following confirmation of vCJD transmission via blood and notification of patients considered to</p>		<p>An important principle of the CJD Incident Panel's advice for people with CJD or at risk of CJD, is that infection control measures that need to be in place should not prejudice individual patient care. This letter outlines advice for dentists on infection control practices and also emphasizes their duty to provide dental care to people who have disclosed their CJD risk status.</p> <p><i>Key messages</i></p> <ul style="list-style-type: none"> • Patients with CJD, or at risk of CJD for public health purposes (or their relatives), should not be refused routine dental treatment. • Satisfactory decontamination standards must be observed: routine dentistry is considered low-risk, therefore no special infection control measures are needed for instruments used on people who are symptomatic or at risk for CJD. • Information about the patient's at-risk status must be included in any referrals for surgery, and entered in patient records: head/ neck surgery may involve contact with tissues that are considered to be of medium to high infectivity for CJD, and for which special infection control procedures are recommended.

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<p>Chief Dental Officer, Department of Health</p> <p>Information for dentists about the management of patients with, or 'at-risk' of, Creutzfeldt-Jakob Disease (CJD) including variant CJD (vCJD) (2005)</p> <p>Available at http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1195733840924</p> <p>Accessed March 17 2008</p>	<p>This letter and enclosed annex includes information about appropriate clinical management of these patients, as well as source of further information.</p>	<p>be at vCJD risk due to the receipt of blood products.</p> <p>Healthcare professionals involved in notifying these patients of their risk have been asked to arrange for this information to be recorded in patients' medical records; the responsibility for informing primary dental carers lies with the patient themselves.</p>		
<p><i>Farrell vs CSL Limited and Commonwealth of Australia*</i> (Farrell 2004)</p>			<p>This case concerns a recipient of human pituitary gonadotrophin (HPG) under the Australian Human Pituitary Hormone Programme (AHPHP), claiming for psychiatric injury as a result of being</p>	<p>The recipient's case is based on the fact that since June 1993, when she was informed of deaths of other hormone recipients from CJD, that she has suffered severe psychiatric illness manifesting as anxiety and depression, which has caused profound disability. The recipient's claim states that she has been unable to work and has suffered severely in all aspects of her life.</p>

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<p>At Supreme Court of Melbourne, at Common Law Division'</p> <p>Date of judgment: 26 August 2004</p>			<p>exposed to the risk of contracting CJD.</p> <p>The case rests largely on what the recipient was told about her risk of contracting CJD as a result of her treatment; from whom she received information; when she received it; and the effects it had upon her.</p>	<p>The recipient's treating doctor, upon learning of deaths from CJD among recipients of HPG (which had not yet been reported), began trying to contact the patients he had treated. He wished to inform these patients but also to help them to deal with the information, and so developed a checklist of issues to cover when he contacted each of his patients, on which he also took notes when he talked with each patient.</p> <p>After attempting to contact this recipient a number of times via letter, the doctor eventually spoke to her by telephone in June 1993. From the notes on his checklist, the doctor informed the patient that there had been four known deaths from CJD from approximately 2,100 pituitary-derived hormone recipients; outlined information on CJD; noted that the patient was not a blood or organ donor; and that she did not seem introspective about the news. He also informed her that she could contact him for follow-up at any time if she so wished. The doctor also wrote to the recipient two days later, invited her to contact him if she had further questions; enclosed a document entitled 'Plain facts about CJD' provided to him by the Commonwealth Department of Health; invited her to keep his office informed of her current address; and concluded by telling her that he had also written to her other treating doctors.</p> <p>The patient's memory of the conversation with the doctor was that she was told she may have CJD. She said that she was devastated by this news and decided to take her own life. She denied having been told anything about the non-transmissibility of CJD; and said that she did not remember what she had been told.</p> <p>The court documents outline the judge's satisfaction with the evidence provided by the doctor; that the patient's account was unreliable and that she was confused about the notification; and there are many inconsistencies between the two accounts of events.</p> <p>The patient was informed at a later contact date (approximately one</p>

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				<p>year later) that she had not received hormone treatments from the same batch as the women who had died from CJD; and the doctor again wrote to the patient to inform her of the batch numbers which had been implicated as contaminated. It was noted that this information could have been provided to the patient one year earlier if she had requested it then.</p> <p>The patient appears to have misinterpreted the information given to her; and a letter that was sent to her from the Department of Health, which she incorrectly interpreted as telling her that she had in fact received a batch of hormone implicated in the deaths from CJD of other patients.</p> <p>The court outlined a number of the circumstances which may have contributed to the patient's psychiatric illness arising from this incident; including her apparent misunderstanding of treatment batch numbers and Health Department files numbers:</p> <ul style="list-style-type: none"> o 'her refusal to accept Dr Giles' assurance that she had only been treated with batch 57, a batch with which no one who contracted CJD and died was also treated; and/or o her misreading of Dr Maynard's letter of 13 May 1994 as informing her that she was treated with batches 57 and 67, the latter of which was also used to treat a woman who died; and/or o her misinterpretation of the file cover at folio 43 of her Health Department file as meaning that she had been treated with batch 25, another batch which, Dr Maynard said, had been used to treat a woman who died.'
<p>Farrugia 2005</p> <p>Farrugia A, Ironside JW, Giangrande P (2005). Variant Creutzfeldt-Jakob disease</p>	<p>vCJD</p> <p>Patients who had received clotting factor concentrates (people with haemophilia) from UK-sourced plasma 1998 to</p>	<p>Patient notification scheme: intended to inform all people of their increased risk of 1% relative to the general British population of their developing vCJD –</p>	<p>Letters and information from public health agencies and clinician organizations notified clinician organizations (haemophilia centre doctors etc): used to inform patients, give them an opportunity to discuss, identify patients at risk and include</p>	<p>The notification exercise was designed to standardise the approach taken to inform patients potentially at risk.</p> <p>Authors recommend the following based on the general notification programme described:</p> <p>Communication must be honest, accurate consistent and immediate, initiated by a credible spokesman.</p>

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<p>transmission by plasma products: assessing and communicating risk in an era of uncertainty. Vox Sanguinis 89: 186-92.</p>	<p>2001 and considered 'at risk' for public health purposes.</p> <p>Discussion of UK and French approaches to managing and communicating risks of vCJD</p>	<p>in order to minimise the risk of spreading vCJD iatrogenically.</p> <p>Case study of patient notification exercise in UK – Department of Health and CJD Incidents Panel/ UK Health Protection Agency, occurred September 2004: intended to reduce the risk of iatrogenic transmission of vCJD.</p>	<p>information in treatment notes as well as notifying local infection control teams, GPs etc</p> <p>Notification of all haemophiliacs at risk of vCJD based on receiving clotting factor concentrates was undertaken to adopt a standardised approach to notification. This same standardised approach has not been used for other situations in which people potentially at-risk have been notified (eg recipients of blood transfusion).</p>	<p>Dissemination should occur through many different channels.</p> <p>Ongoing training and education of the media is needed for effective public health risk communication.</p> <p>Risk communication plans must be responsive to the needs of diverse populations.</p> <p>Authors note also that the possible repercussions of risk assessment for CJD and notification, both for individuals and for public health more generally, can be significant; for example, the World Federation of Haemophilia (WFH) has reported that patient stigmatisation has followed the notification exercise in the UK. There are also implications for the use of surgical instruments exposed to patients at risk of vCJD.</p> <p>Authors conclude that 'authorities should recognise that adequate communication is an integral part of good risk-management practices.'</p> <p>Outlines also the parameters used to calculate risk of vCJD – based on numbers of transfusions, volume of plasma/blood donation etc</p> <p>NB Dolan 2006 complements this paper:</p> <p>Dolan G (2006)*. Clinical implication of emerging pathogens in haemophilia: the variant Creutzfeldt-Jakob disease experience. Haemophilia 12 (suppl 1) 16-20.</p> <p>Describes the response to blood recall based on haemophiliacs' experiences of blood product use.</p> <p>Outline of the notification process: In 2004, it was decided to inform all patients about the possible risk of transfusion-transmitted vCJD infection, whether people had received treatment with batches of concentrates that had come from donors who later developed vCJD or not.</p>

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				<p>Patients were given three choices regarding notification:</p> <ul style="list-style-type: none"> • Discuss the information in person with healthcare provider in personal consultation • Be fully informed via letter • Refuse to be informed in any way. <p>Authors note that many patients chose the third option. Those who chose to be informed were given information of their potential risk of vCJD; authors note that this caused considerable concern.</p> <p>It also created considerable administrative burden for the United Kingdom Haemophilia Centre Doctors Organisation, who had to urgently review all records; contact those patients possibly at risk; and give each patient the choice of reviewing the information on vCJD known at that time. Government-mandated timelines on informing patients also increased the administrative burden in conducting this exercise.</p>
<p>Food and Drug Administration 2006a (FDA 2006a)</p> <p>Department of Health and Human Services</p> <p><i>Meeting of the Transmissible Spongiform Encephalopathies Committee</i></p> <p>September 18 2006</p>	<p>CJD/ vCJD</p>	<p>The minutes of this meeting cover a range of topics, including updates on the clearance of TSEs and infectivity of blood and plasma products; and a report on the status of the FDA's communication of the potential exposure to vCJD risk associated with blood products.</p>	<p>Agenda Item: Status of FDA Initiative on Communication of Potential Exposure (to vCJD risk) (taken from minutes from the SEAC meeting September 18 2006).</p> <p>It was noted that, except for blood transmission, there has not been any other new class of medical products associated with the transmission of CJD in the past 10 years.</p>	<ul style="list-style-type: none"> • There is the possible but unproven risk of vCJD to recipients of an investigational Factor XI product used to prevent/ treat bleeding disorders (approximately 50 people received this treatment). The product was made using plasma from donors in the UK, where vCJD has occurred. • The product was not made from plasma from anyone known to develop vCJD; and no-one receiving the product is known to have become infected with vCJD. However, it is still possible that someone receiving the factor product may contract vCJD because someone who was not symptomatic for vCJD may have donated blood. • The FDA's model risk assessment has been used to consult with a range of special government employees, including members of the haemophilia community, to obtain advice on the risk assessment, on the interpretation of the risk assessment, and for advice on the communication of risk.

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<p>Available at: http://www.fda.gov/ohrms/dockets/ac/cber06.html#TransmissibleSpongiform Accessed March 21 2008.</p>				<ul style="list-style-type: none"> • In the UK, recipients of plasma-derived coagulation products (derived from UK donors) that they may have an increased risk of CJD above the background risk of the UK population through exposure to BSE-contaminated beef. • The risk assessment has now been completed and distributed to the haemophilia community for comment. These will be incorporated into FDA advice and interpretive summary to be presented to patients. There will also be a public posting of the risk assessment and notification of the risk information to haemophilia organisations about the risk information. • The impact of the information will be assessed, as well as the numbers of patients contacted and the need for additional information or assistance from the FDA or CDC. • One participant noted the need to educate physicians treating people with haemophilia; as well as the additional people involved in their care who may fall outside of the person's treatment centre team (eg dentists, internists) and with whom it is important that the FDA formally communicate with and recognise their role in the patient's treatment. • The need for controlled, clear communication from the FDA to this small group of affected haemophilia patients was emphasised: rather than uncontrolled or leaked information that might lead to all haemophiliacs being identified at risk. • The WHO measures to revise the safety of medicinal products was discussed in detail: one goal of the WHO consultation was to update risk assessments and to provide advice to national regulatory authorities with limited resources ie. In countries with limited resources and where comprehensive approaches to TSEs do not exist (unlike the USA, Canada, UK, Australia and New Zealand), advice on TSEs may not have the same weight. Also, these countries may not be able to undertake the same steps that have been implemented in other countries; however, an awareness of the risk and the nature of the risk of CJD is believed to be important. • The WHO consultation also acknowledged that the risk of CJD has now become a global one, for example, the risk and spread

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				<p>of vCJD from the UK via travellers. CJD is now seen as a global risk or disease and one that all countries should at least be aware of. The risk of vCJD in particular is uncertain: there is the possibility that there remain many undiagnosed cases of vCJD, and the risk to the blood supply and the spread of the disease is unclear.</p> <ul style="list-style-type: none"> It was noted that there is an ongoing need to ensure that all regulatory authorities with limited resources have access to reliable and up to date information regarding TSE risks and the safety of medicinal products, and when assessing these risks within their own country; it was also emphasised that the communication of risks is very difficult, due to all of the uncertainties around CJD and the transmission of CJD through medical procedures and products.
<p>Food and Drug Administration 2006b (FDA 2006b)</p> <p>Department of Health and Human Services</p> <p><i>Meeting of the Transmissible Spongiform Encephalopathies Committee</i></p> <p>September 19 2006</p> <p>Available at: http://www.fda.gov/ohrms/dockets/ac/cb</p>	<p>CJD/ vCJD</p>	<p>The minutes of this meeting cover a range of topics, including the issues of screening tests and donor screening for vCJD.</p>		<ul style="list-style-type: none"> Issues around the introduction of a screening test for vCJD were discussed in detail. The issue of the availability of a confirmatory test for those people who test positive was raised; and the problems of false positive results in particular for TSEs, due to the very long incubation period and the lack of effective treatments for TSEs once symptoms emerge. In this context, notification of people with unconfirmed positive tests would be likely to lead to significant negative consequences: the adverse public health effects of notifying a large number of people with repeatedly reactive false positive tests would also be very problematic. A reliable and sensitive confirmatory test is needed, but one is not yet available. Counselling of donors deferred from donating blood due to positive screening tests for vCJD was raised as an issue, and would need to be carefully considered in advance of introducing any screening tests for vCJD. The impact of introduction of a screening test for vCJD for blood donors needs to consider both the rate of false positives that are likely to affect people; as well as the impact of the blood supply of the introduction of such a test.

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<p>er06.html#TransmissibleSpongiform</p> <p>Accessed March 21 2008.</p>				<ul style="list-style-type: none"> • The implications of a positive test result for vCJD also needs consideration: what would a positive result mean (since not all people with positive test results will go on to develop vCJD)? That is, what is the prognostic significance of a reactive test for donors both with and without risk factors for vCJD? The blood collection facility may be the main source of information on vCJD for blood donors, as medical practitioners may not be well informed about prion diseases. A similar issue arises when products are recalled based on reactive test results: what information needs to be provided to people notified of these activities? • The social and psychological impact of notification and the indirect effects on donor recruitment and retention may be very profound: studies on the impact of presymptomatic testing for Huntington's disease (in Wales) indicate that the majority of people at familial risk choose not to be tested. Research also indicates that those people who do undergo testing and who have a positive result have catastrophic attempts, defined as: an attempted suicide or serious psychiatric breakdown requiring hospitalisation. A larger proportion of those tested are alright, but a significant proportion go on to develop significant levels of personal problems, including psychological stress, social problems, family breakdowns and problems with insurance. • For Huntington's disease testing, there is a well-established international protocol for counselling people prior to screening for those at risk; and this includes detailed consideration of the implications of a positive test might for them and for their families. • The efforts put into prescreening and counselling seem to be beneficial; but this is done for a fairly small number of patients at risk, and a similar level of effort may not be practical if talking in the order of millions of blood donors per year.
<p>Compiled by the HPA Centre for Infections, CJD Section 2005*</p>	<p>This reports on a two-day seminar conducted in March 2005. The seminar involved a range of</p>	<p>vCJD – in relation to blood donation</p>	<p>Note that the NBS study on how blood donors might respond to vCJD testing: for details see Hewitt (2004) papers. The results of this study suggest that</p>	<p>Recommendations arising from the seminar include the following for blood donors in relation to the introduction of a possible test for vCJD:</p> <p><i>Informing donors of vCJD test results</i></p>

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<p>(HPA 2005)</p> <p>Chairman: Professor A Weale</p> <p><i>Report of seminar on ethical and social aspects of testing for vCJD</i></p> <p>October 2005</p> <p>Available at: www.hpa.org.uk/infections/topics_az/cjd/ethicalsocialetesting.pdf</p> <p>Accessed March 12 2008.</p>	<p>experts and stakeholders; aimed to identify the social and ethical issues arising in the case of a test for vCJD becoming available.</p>		<p>blood donors were initially relatively unconcerned by the prospect of their blood being screened for vCJD; however as they were provided with more information, the less certain they were about wanting to be informed of their risk status based on screening.</p> <p>Authors of the current report that there are possible analogies between screening for vCJD and screening for other diseases such as hereditary neurodegenerative diseases such as Huntington's disease; these may provide some useful models for considering some of the issues associated with vCJD testing. However, authors note that even with Huntington's disease, there is considerable certainty around the test results, what a positive result means; and that the situation is not likely to be comparable with vCJD testing when it is introduced.</p>	<ul style="list-style-type: none"> • That the practice of informing donors of positive test results be maintained, with no option for donors to choose not to receive the information. • Donors should be fully informed ahead of time that their donated blood will be tested for vCJD; the likelihood of their blood testing positive (ie they should be provided with as accurate an estimate as is possible); that they will be informed in the case of a positive test result; and the implications of this. Authors note that this may require awareness-raising about vCJD as a disease and consequence of donation. • The duty of care to donors and to the general public should include preparation for bad news arising from testing for vCJD. Expert advice and consultation with donors should be used to determine how best this should be done. <p><i>Communication of blood donors' vCJD test results</i></p> <ul style="list-style-type: none"> • Current communications to blood donors testing positive for a range of infectious diseases are currently of high quality and could serve as a basis for future communications. The quality of the communications is promoted by notification letters being produced by a small number of highly experienced staff, working in a limited number of sites. • For donors testing positive, communication usually recommends that the donor consent to their GP being informed by UKBS; with donors intensively followed up to give consent. In very rare cases the UKBS may break their confidentiality agreement with the donor in the interest of public health protection, and inform the GP. Further consideration needs to be given to how this situation might be handled, if donors not consenting to vCJD information being given to their GP are likely to occur more frequently. • As public perception of the risks of vCJD may influence how donor testing affects those who test positive; and this might be dependent on media coverage around the time of the introduction of the test. The media should be systematically informed, in advance of test introduction. • Donors who test positive to vCJD should be offered long-term

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				<p>monitoring and should be assured of being informed of developments.</p> <p><i>Information to be given to donors</i></p> <ul style="list-style-type: none"> • The knowledge, attitudes and values of donors regarding vCJD testing should be elicited via surveys closer to the time when a test becomes available. Such studies should be planned in advance, and processes for re-conducting the surveys should be in place in the event that public perceptions undergo a rapid change. Survey results should be carefully considered to prepare appropriately for the test introduction. • Donors should be consulted to explore the best ways to manage the notification of people of positive test results in the interests of protecting the public health. • The range and types of psychological effects of test results for donors, and knowledge of iatrogenic CJD transmission among patients, need to be studied. Depending on what this research indicates, it should be used to inform the implementation of measures to protect donors and patients from avoidable psychological harms. It should also be used to develop and provide care for those who experience unavoidable psychological harms. • The knowledge and attitudes of healthcare staff who will be involved in communicating with donors before and after testing needs research. All staff involved in communication need training and information <p><i>Insurance issues</i></p> <ul style="list-style-type: none"> • Consultation with the insurance industry is needed to determine how testing might affect insurance premiums and coverage, and existing policies. • It may be necessary to consider a social insurance scheme for donors. <p><i>Ongoing healthcare</i></p> <ul style="list-style-type: none"> • Donors testing positive for vCJD should have suitable referral options made available to them, eg, through referral to specialist

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				<p>clinics; and should be provided with further information and referral for further testing and care, if and when it is needed or wanted.</p> <p><i>Other issues</i></p> <ul style="list-style-type: none"> • It is ethically imperative for research to be undertaken with the aim of reducing the uncertainty of test results, both positive and negative, and to improve understanding of the prognosis for people who test positive. Studies should also aim to determine how anxiety for those testing positive might be minimised. • Information provided to transplant recipients should be reviewed and revised to ensure that they are appropriately informed of potential implications of the transplantation and of the implications of test results after transplantation. • Consideration should be given to providing information about and setting standards for the testing of people at risk of vCJD, or with other reasons to request testing for vCJD, eg for people involved in a geographically-associated cluster of cases. Guidelines for testing may need to specify criteria that must be met for testing to be provided; and further consultation should be conducted to determine the appropriate level of access to vCJD testing for general members of the public. • The promotion of vCJD testing through non-NHS services should be regulated to prevent possible harm arising from patient testing without the provision of appropriate information, support and follow-up.
<p>Health Protection Agency and Health Protection Scotland 2006 (HPA/HPS 2006) <i>Creutzfeldt-Jakob disease (CJD) and</i></p>	<p>All CJD types -sporadic and variant CJD</p> <p>The document aims to provide information for clinicians and other staff caring for people at risk of CJD following medical procedures, including</p>	<p>Advice for patients and for clinicians and other health care workers in relation to care for people 'at risk' of CJD for public health purposes (ie where the person has had an operation of procedure</p>	<p><i>Advice for GPs and other medical staff</i></p> <ul style="list-style-type: none"> • The GP should be informed if a patient is notified that they are at risk of CJD for public health purposes. • The GP should do the following: <ul style="list-style-type: none"> ○ be informed of their patient's risk status ○ record in the patient's records that the patient is at risk for public 	<p><i>Discussing CJD risks with patients</i></p> <ul style="list-style-type: none"> • Patients may find the news that they are at risk of CJD distressing and may want definite assurances that they will not develop the disease: this is not possible. • The exact risk of CJD infection following exposure via surgery is not known. • Before informing patients of their risk status, their risks should be carefully considered, and arrangements for the patient to discuss issues with the appropriate healthcare staff after the notification

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<p><i>surgery: Clinical Information</i></p> <p>October 2006</p> <p>Source: www.hpa.org.uk/infections/topics_az/cjd/CJDsurgexpClinical.pdf</p>	<p>surgery.</p>	<p>where surgical instruments were used that had been used previously on a patient who has gone on to develop CJD).</p> <p>In practice, this means that patients at risk of CJD:</p> <ul style="list-style-type: none"> • Cannot donate blood, organs or tissues. • Need to disclose their at-risk status to whoever is treating them in any case of surgery, endoscopy or dental work. • Should probably best tell their families in case health care is needed in the future and the family could inform the healthcare staff if necessary. 	<p>health purposes</p> <ul style="list-style-type: none"> ○ include the risk information in any referral letters ○ check whether the patient has had surgery in the previous year; and notify the local Health Protection Team if so. <ul style="list-style-type: none"> • Doctors should ensure that people at risk of CJD receive the same medical and dental care that they would otherwise receive if they were not at risk. 	<p>should be made ahead of time.</p> <ul style="list-style-type: none"> • The decisions about how, and the best way, that people should be notified need to be made; and the possibility that patients will need more than one session to discuss the implications of the notification and to come to terms with the information needs to be clearly recognised. It may be helpful to consult a trained counsellor for advice on managing the process.
<p>Health Protection Agency UK 2007</p> <p>(HPA 2007)</p> <p>January 2007</p> <p>Title: vCJD and</p>	<p>vCJD</p> <p>The document aims to provide information for clinicians and other staff caring for people at risk of vCJD following treatment with plasma products.</p>	<p>Advice for patients and for clinicians and other health care workers in relation to care for people 'at risk' of vCJD for public health purposes.</p>	<p><i>Advice for GPs and other medical staff</i></p> <ul style="list-style-type: none"> • The GP should be informed if a patient is informed they are at risk of vCJD for public health purposes. • The GP should do the following: <ul style="list-style-type: none"> ○ be informed of their patient's vCJD risk status ○ record in the patient's records that 	<p><i>Discussing CJD risks with patients</i></p> <ul style="list-style-type: none"> • Patients may find the news that they are at risk of CJD distressing and may want definite assurances that they will not develop the disease: this is not possible. • The exact risk of vCJD infection following consumption of BSE-infected meat is not known; nor is the extra risk for those receiving treatment with plasma products known, but is likely to be small.

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<p>plasma products - Clinical Information</p> <p>Source: http://www.hpa.org.uk/infections/topics_az/cjd/vCJDplasma-Clinical.pdf</p> <p>Accessed: 11 January 2008</p>	<p>In 2004 all people with bleeding disorders who had been treated with UK-sourced plasma products (pooled factor concentrates or antithrombin) between 1980 and 2001 were classified as at-risk of vCJD for public health purposes.</p>	<p>In practice, this means that patients at risk of CJD:</p> <ul style="list-style-type: none"> • Cannot donate blood, organs or tissues. • Need to disclose their at-risk status to whoever is treating them in any case of surgery, endoscopy or dental work. • Should probably best tell their families in case health care is needed in the future and the family could inform the healthcare staff if necessary. 	<p>the patient is at risk for public health purposes and that infection control measures are needed</p> <ul style="list-style-type: none"> ○ include the risk information in any referral letters if the patient needs surgery (including dental surgery) or any other invasive procedure. ○ check whether the patient has had surgery in the previous year; and notify the local Health Protection Team if so. <ul style="list-style-type: none"> • Doctors caring for people at risk for vCJD should ensure that their risk status is recorded in their hospital and primary care records; this should only be done after the person has been informed of their risk status. • Doctors should ensure that people at risk of CJD receive the same medical and dental care that they would otherwise receive if they were not at risk. <p><i>Previous notification exercise for vCJD and plasma products in 2004</i></p> <p>People who received plasma products donated by people who later developed vCJD were notified in 2004; all patients with bleeding disorders, treated with UK-sourced pooled factor concentrates or antithrombin between 1980 and 2001 were informed of their at-risk status.</p> <p>Patients were:</p> <ul style="list-style-type: none"> • Informed that they had an additional vCJD risk as they may have been 	<ul style="list-style-type: none"> • In the UK, three patients have been infected with vCJD following blood transfusion, and one of these did not develop clinical disease. No cases of vCJD have been reported in people receiving plasma products from people who later developed vCJD; and vCJD does not seem to be spread via surgery. • Before informing patients of their risk status, their risks should be carefully considered, and arrangements for the patient to discuss issues with the appropriate healthcare staff after the notification should be made ahead of time. • The decisions about how, and the best way, that people should be notified need to be made; and the possibility that patients will need more than one session to discuss the implications of the notification and to come to terms with the information needs to be clearly recognised. It may be helpful to consult a trained counsellor for advice on managing the process.

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			<p>treated with plasma from individuals who later developed vCJD.</p> <ul style="list-style-type: none"> • Given the chance to find out whether they had received an implicated batch; and told that their risk assessment might change if further batches were implicated. • Informed that they were at-risk for public health purposes • Reassured that their clinical care would not be compromised in any way by their at-risk status. 	
<p>Kirkup 2003*</p> <p>Department of Health Published date: 28 February 2003</p> <p>Title: <i>Incident arising in October 2002 from a patient with Creutzfeldt-Jakob disease in Middlesbrough Report of incident review</i></p> <p>Source: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4008283</p>	<p>This report aims to review the handling and communication of the decision to contact patients deemed at risk of CJD as a result of a surgical incident.</p>	<p>Interviews with the 22 people most closely involved locally and nationally in the incident were carried out; the available documentation (including correspondence, emails, meeting notes, protocols, guidance and policy documents) were also examined.</p> <p>Patients involve 24 people exposed to the risk of CJD through surgical instruments.</p>	<p>An urgent meeting was convened in the Trust to decide how to rapidly and sensitively inform patients and the public of the incident. A draft letter from the CJD Incidents Panel was arranged; a telephone helpline was established to respond to calls from patients, relatives and others.</p> <p>Over the following 24 hours, over 150 calls were received. Many were angry, distressed and anxious, as was expected from the criticism of the Trust in the media occurring at the same time.</p> <p>All received calls were screened in order to identify the 24 patients involved in the incident (ie exposed to the risk of CJD through surgery): this was so that those who needed to be counseled individually could be informed. Authors note that this process was difficult for all people involved, and was worsened by the</p>	<p>Patients were notified of their potential exposure to CJD via surgical procedures so that precautionary measures could be taken to protect the public health. Initially 29 patients were identified as being at risk; this was later decreased to 24 people; and the CJD Incidents Panel requested that each person be assessed further to decide whether any were at a low risk of exposure. The authors note that even 10 weeks after the CJD Incidents Panel had been advised of the incident that further information had not been received to make this further assessment of risk to occur.</p> <p>The author notes that the CJD Incidents Panel held the view that the patient with CJD should have been suspected of having CJD from the outset, and that the procedures in place for surgical instrument decontamination and tracking were inadequate. These criticisms may have influenced the Department of Health's response to media enquiries.</p> <p>The Trust has worked since the incident came to light in August 2002 to improve the response to such incidents. One aspect was to openly approach the media with a statement asking for a 48 hour embargo to allow patients affected by the incident to be contacted before the story appeared in the media. This approach has been used successfully in other situations; but in this case was not possible as news of the</p>

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<p>Access date: 11 January 2008</p>			<p>perception of the public that the Trust had made a mistake which led to the exposure to CJD risk in these patients.</p> <p>Authors also note that from the following day a more sympathetic and constructive approach was adopted by the Department of Health and the Trust; and that partly as a result, media interest decreased. This in turn allowed the Trust to concentrate in its primary task of counselling those people put at risk of CJD exposure, and refining the individuals' risk assessment (which had been a request of the CJD Incidents Panel). This ongoing risk assessment has suggested that the number of patients at elevated risk of CJD is likely to be fewer than the 24 people identified on October 29 2002.</p>	<p>incident had been leaked to the media before the Trust had a chance to release a statement.</p> <p>Authors note that the process of informing people that they may be at risk of CJD through surgical instruments is difficult, made more so by the perception that the incident had arisen as a result of a mistake or the failure to implement proper procedures to prevent such exposure.</p> <p>Informing people of exposure to the risk of a disease such as CJD, done hurriedly and under difficult circumstances was very unfortunate. The authors also note that further investigations (risk assessment), if available, may have been able to spare some of these patients being informed of such bad news.</p>
<p>Chaired by: Lee, P 2004* Prepared for the Honourable Angus MacIsaac Minister of Health, Nova Scotia (Lee 2004) August 3, 2004 <i>Report of the review of events around suspected</i></p>	<p>CJD, iatrogenic exposure</p> <p>The aim of the review was to improve quality by identifying lessons learned from past experiences, and sharing these experiences in order to improve future action.</p> <p>The focus of the review included the following:</p> <ul style="list-style-type: none"> • Roles and responsibilities of individual organisations 	<p>The review outlines notification of people possibly exposed iatrogenically to CJD via two separate incidents (both patients involved were considered to be high risk patients for CJD, but in one incident medical devices came into contact with high infectivity tissues; in the other, it was not clear whether medical devices had come into</p>	<p>Organisations all faced several ethical and practical challenges when communicating publicly about possible or suspected cases of CJD. The difficulties of protecting patient information when communicating publicly were acknowledged; the difficulties of educating the public about a disease for which so much uncertainty exists were also highlighted in the review process.</p> <p>There is a strong commitment to open disclosure of the risks to public health, but a balance is needed between the</p>	<p><i>Infection control</i> <u>Strengths:</u> rapid response by the health services in isolating affected equipment and communicating publicly to respond to the community's reaction to perception of risk.</p> <p><i>Communication</i> <u>Strengths:</u> Inter-organisational sharing of protocols for notifying patients; coordination by the Department of Health; the availability of experts. <u>Weaknesses:</u> Lack of system-wide organizational leadership available for contact at all times. <u>Recommendations:</u> Process for accessing staff of health care agencies outside normal working hours should be in place and shared across health systems.</p>

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<p><i>Creutzfeldt-Jakob Disease (CJD) in Nova Scotia</i></p> <p>http://www.gov.ns.ca/health/downloads/final_CJD_Report.pdf</p> <p>Accessed 18 March 2008.</p>	<p>regarding infection control for CJD.</p> <ul style="list-style-type: none"> The interactions between organisations needed to fulfil their roles Strategies and processes for communicating within the health system and to the public. Basic requirements for organisations in order to manage prevention, containment and post-exposure management; and how these roles were met, and where gaps lie, in current practice. 	<p>contact with low infectivity tissue).</p>	<p>public's right to know about risks and the privacy of individuals involved, as well as the need to ensure the accuracy of information communicated.</p> <p>A national guideline on notification of potential contacts and public communication of risks does not exist, and practices within Canada are variable.</p> <p>Ethical issues regarding notification is that individuals are entitled to full information about their own medical conditions or risk to health and safety. This information must be conveyed accurately and in a sensitive manner. Another ethical principle is that those who are most directly affected should be informed first, and this should be done directly by clinicians or by the health care organisation, not through the media.</p> <p>For these cases, potential transmission risk was only to those patients with direct contact with the equipment implicated; there was therefore no general public health threat requiring public announcements. The first priority was therefore to inform those patients exposed to the risk of CJD through the health system, and to ensure that no further patients were exposed to risk through medical devices.</p>	<p><i>Notification of patients and the public</i></p> <p>Strengths: The presence of notification strategies to inform exposed patients of possible CJD risk; and the use of an ethical framework for decision-making about notification of potentially exposed patients.</p> <p>Weaknesses: The absence of system-wide notification policies and/or protocols for conveying the risk of exposure/ transmission for CJD. Lack of clear process for the local medical officer to require an autopsy in cases of probable or possible CJD, in order to protect the public health.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> A process for collaborative communication planning when informing the public about real or theoretical risk of exposure within the health care system. Processes for safeguarding patient confidentiality in public communications should be clearly outlined in organizational communication protocols. Disclosure policies should incorporate an ethical framework for decision-making. Promote collaboration between public health, the medical examiner and neuropathology to share timely autopsy information to enable accurate risk information about possible exposures to be determined in the interests of protecting the public health. <p><i>Surveillance</i></p> <p>Strengths: National and local tracking systems; and the existence of Health Canada CJD Infection Control Guidelines.</p> <p>Weaknesses: Lack of clear thresholds for reporting possible CJD cases; lack of use of standardised terminology regarding CJD risk.</p> <p>Recommendations:</p> <p>Clear thresholds for reporting possible risk of CJD should be stated and communicated to the range of agencies involved.</p> <p>A process of mandatory reporting communicated to the health system.</p> <p>Policy should explore opportunities to link communications and share information across surveillance systems.</p> <p>Consistent terminology should be used when referring to CJD cases as confirmed, probable or possible.</p>

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			<p>As there was no immediate urgency to notify patients, and the notification was likely to cause distress to those involved, both health authorities established further the features of the exposure (tissue types etc) before contacting patients.</p> <p>Once public information was released through the media it was critical to provide accurate factual information about the nature and size of the risk. As there was a larger number of patients potentially involved, risk assessment was fast tracked and patients potentially exposed to risk were notified in the absence of definitive risk information.</p> <p>Although difficult for families, the review also noted that it is important for the purposes of tracking cases and protecting public health to diagnose CJD through post-mortem examination.</p>	<p><i>Guidelines</i> <u>Strengths:</u> Adherence to Health Canada's Infection Control Guidelines for CJD (2002). <u>Weaknesses:</u> Lack of system guidelines for situations where a patient with possible, probable or confirmed CJD is transferred from one facility to another. <u>Recommendations:</u></p> <ul style="list-style-type: none"> • Guidelines should be reviewed for feasibility and applicability across Nova Scotia; they should also be regularly updated to reflect the most recent knowledge on CJD. • A checklist should be developed for use when multi-stakeholder teams are mobilized, in order to assign responsibility for the appropriate notifications and procedures outlined in the guidelines. Guidelines should be developed describing the information to be provided when patients are transferred between facilities. <p><i>Safety culture</i> <u>Strengths:</u> Critical and open analysis of organizations to facilitate the review. <u>Weaknesses:</u> Lack of clear process or system to share information on the lessons learned from incidents with local and national organizations. <u>Recommendations:</u></p> <ul style="list-style-type: none"> • Processes to share lessons learned and access expertise should be developed for local and national systems. <p><i>Recommendations for Health Canada</i></p> <ul style="list-style-type: none"> • Opportunities to share or link information between surveillance systems should be explored and policy developed or amended to support this. • A process for regular updating of the national CJD guidelines to reflect most recent knowledge should be a priority. • Processes for accessing infection control expertise outside normal working hours should be developed and shared across

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				<p>the health system.</p> <ul style="list-style-type: none"> The process for clinical consultation with Health Canada's expertise on CJD should be outlined and differentiated from the voluntary reporting of cases to the CJD surveillance system.
<p>McCullough 2004*</p> <p>McCullough J, Anderson D, Brookie D, Bouchard J-P, Fergusson D, Joly J, Kenny N, Lee D, Megann H, Page D, Reinharz D, Williams JR, Wilson K (2004). Consensus conferece on vCJD screening of blood donors: report of the panel. Transfusion 44: 675-83.</p>	<p>Focus on vCJD.</p> <p>The report of this consensus conference aims to highlight the issues surrounding the introduction of a screening test for vCJD in blood donors (should one become available); the ethical implications of text introduction; and some of the practical issues associated with donor screening and the required features of a screening test (sensitivity, specificity, presence of an adequate confirmatory test).</p> <p>Review questions addressed: Q4 What issues exist around feasibility and implementation of interventions to</p>	<p>Conference panel from meeting sponsored by HEMA-QUEBEC and the Canadian Blood Services.</p> <p>The report highlights a number of major issues around the development and introduction of a screening test for vCJD in blood donors, including the implications of notifying people of a positive result; the need for adequate communication and counselling with people involved, and especially those who return a positive test result; and including the possible effects on the blood supply.</p>	<p>There is a need for a rapid, sensitive and specific vCJD test in order to effectively screen blood and to protect the public health.</p> <p>The report emphasises that recipients might be harmed if the test has a high false-negative rate; while donors might be harmed if the test has a high false-positive rate. To prevent high levels of fear and anxiety among people who are not really at risk, a test with high sensitivity and specificity is therefore needed before widespread screening can be introduced. A highly specific confirmatory test to complement a highly sensitive initial test may reduce the number of indeterminate test results and reduce anxiety among donors.</p> <p>The report also notes that any screening test may not be able to detect blood donated from people in a preclinical vCJD stage, even though their blood donations may be capable of transmitting the infection.</p>	<p>Consensus conference.</p> <p>The panel recommended that two different tests be used to screen blood for vCJD: a highly sensitive and reasonably specific initial test, followed by a confirmatory test with high specificity and sensitivity. This would allow notification of donors of their positive first test and the results of their confirmatory test, which would serve to minimise anxiety among this group of people.</p> <p>The report highlights several ethical implications of introducing a screening test for vCJD. This includes the following:</p> <ul style="list-style-type: none"> The introduction of any screening test needs to be linked to appropriate counselling about the nature of the test and the meaning of a positive (or other) result. Participation of donors in a screening test should include disclosure to donors of: the nature of vCJD and the fact that there is no cure for the disease; the fact that false-positive and indeterminate test results do occur and that follow-up tests would then be needed to confirm results; and the potential for genetic testing for themselves and members of their family. All possible efforts should be made to minimise the effects of false-positive results. Confidentiality needs to be protected – especially as concerns false- or true- positive test results. <p>The above principles and others should be used to guide decision-making about introducing a screening test; but further consideration of the ethical implications of a test will be needed when a test becomes</p>

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	<p>communicate with and support people in the situation of being notified of a possible CJD exposure?</p>		<p>The report also highlights the need for transparency with the public and to maintain the public's confidence and trust in the blood supply system.</p>	<p>available.</p> <p><i>Information and counselling for donors</i></p> <ul style="list-style-type: none"> • The impact of a positive test result, given the uncertainties about its meaning and the lack of any clear prevention or treatment measures that can be taken for vCJD, will be very profound for those involved. • Blood services will need effective communication strategies to deal with these situations. As large amounts of information are already provided to people donating blood, other means of communication, and making sure the information is understood, will be needed when the possibility of screening donations for vCJD becomes a possibility. • Counselling services for blood donors and recipients will need to be expanded; with previous experiences showing that counselling needs to be provided in a number of ways, and over a long time period, to be effective. • Blood services should also conduct research on the impact of the introduction of vCJD screening on blood donation.
<p>New South Wales Government Department of Health 2004 (NSW DoH 2004)</p> <p><i>Response protocol for NSW Public Health Units</i></p> <p>Last updated: 06 September 2004</p> <p>Available at:</p>	<p>Classic CJD and vCJD</p>	<p>Reasons for surveillance include the following:</p> <ul style="list-style-type: none"> • To monitor the epidemiology of CJD and enable prompt recognition of any cases in NSW. • To facilitate collection of information on potential risk factors for infection. 	<p>Healthcare workers caring for the patient must be aware of the relevant infection control guidelines.</p>	<p>Any decision to trace and disclose potential CJD exposure should be made in consultation with Communicable Diseases Branch and after a careful risk assessment and consultation with an expert panel.</p> <p>The risk of psychiatric injury due to the disclosure of a possible risk of contracting a fatal disease with a long incubation period and no cure must be considered, along with other issues.</p> <p>Contacts should not donate blood or body parts. The patient or their carer should be informed about the ways that CJD is transmitted and informed that the patient should not donate blood or body parts.</p> <p>Contacts should alert health care workers (including medical and dental workers) to their increased risk of CJD and health care workers should refer to the Commonwealth Infection control guidelines.</p>

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<p>http://www.health.gov.au/factsheets/guideline/cjd.html</p> <p>Accessed 18 March 2008.</p>		<ul style="list-style-type: none"> To ensure that carers and clinicians are aware of infection control guidelines, in order to minimise the risks of further transmission. 		<p>Appropriate counselling should be offered, and the person informed of relevant support groups.</p>
<p>Parliament of Australia, Senate 1997*</p> <p><i>Report on the CJD Settlement Offer</i></p> <p>October 1997</p> <p>Available at: http://202.14.81.34/senate/committee/clac_ctte/completed_inquiries/1996-99/cjd/report/index.htm</p> <p>Accessed April 4 2008.</p>	<p>CJD (iatrogenic)</p>		<p>The first definite link between pituitary hormone therapy and CJD was made in November 1984; the AHPHP was suspended in May 1985.</p> <p>The first Australian death from CJD of an hPG recipient occurred in August 1988; with the Allars Inquiry reporting that this did not become widely known in the medical community until it was published in a medical journal (August 1990). Three more deaths occurred between May 1989 and January 1991; in only the last two cases were news releases made by the Department in early 1993.</p>	<p><i>Suspension of the AHPHP</i></p> <ul style="list-style-type: none"> Patients were not directly contacted by the Department following suspension of the program. Medical practitioners participating in the AHPHP were written to and asked to inform patients currently receiving pituitary hormone extracts of the potential risks associated with their use (1985); these requests were repeated in 1990 and 1992. In early 1993 a media advertising campaign was mounted and people thought to have been treated were asked to contact the Department; later the Department used Medicare records to trace recipients. The Allars report found that the Department had 'a moral duty to take steps to ensure that recipients were made aware of the risk when the AHPHP was suspended in 1985' and that they should not have been 'left in the dark because they did not request information'. The Inquiry also found that the Department 'should have provided assistance in 1985 to medical practitioners through a coordinated program of tracing recipients in connection with the epidemiological study'; and that Departmental officers were overly guarded in their responses to recipients who were seeking information about their treatment under the AHPHP. A CJD Unit was set up within the Department (1992) in response to growing inquiries from recipients and media attention; and the Pituitary Hormones Task Force (PHTF) (1993) to monitor research internationally to ensure that research developments

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				<p>could be rapidly applied locally.</p> <p><i>The Allars Inquiry</i></p> <ul style="list-style-type: none"> • The Inquiry was established to conduct a public inquiry into the AHPHP; it made a wide range of recommendations concerning the operation of the AHPHP and the issues identified from this process. • This included a desire for factual information by recipients, which had been missing during treatment, upon discovery of the link with CJD, and in the government response that subsequently followed. • In 1994, substantial funding was announced to implement the recommendations of the Allars Inquiry; including a Trust Fund established to cover the cost of medical and other expenses for those recipients who developed CJD, and to contribute to counselling and support groups; funding allocated to research and to tracing of recipients; <p>Recommendation 2 of the current committee report concerns the findings and implementation of the Allars Inquiry, including the following:</p> <ul style="list-style-type: none"> • To ensure that arrangements to assist recipients and their families to access counselling are in place and effective. • That further efforts be undertaken to sensitively identify and trace any approved and unapproved recipients. • That treatment records and other information requested by recipients be provided to them directly. • That an index to the Allars report be developed and made available to all recipients and to all other interested groups. • That NPHAC processes are open and flexible to allow input from recipients on issues under consideration, and that recipients are informed of decisions made. <p><i>Impact of the AHPHP on the lives of recipients and their families</i></p> <ul style="list-style-type: none"> • The impact that the AHPHP has had personally on recipients and on their families should not be overlooked.

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				<ul style="list-style-type: none"> • The knowledge of being placed at risk dying from a rare disease that cannot be diagnosed; the often accidental way in which recipients discovered of the risks associated with their treatment; and the lack of information available may all have contributed to the experiences of recipients and their families. • Responses of the individuals involved have been variable, ranging from those who have been able to put the issue of their possible risk to one side to those who feel that they are living with a time bomb, and who have been very significantly affected by the notification. • Very significant effects on families have been noted, including the following: disruption and break up of families; older children leaving home due to parental stress and anxiety; couples deciding not to have children to avoid any possible risks; a sense of guilt developing in some children born as a result of hormone treatment, or among parents who had consented to their child having hormone treatment; fear of CJD which prohibits people talking about the issue with family, or with friends and others has led to some people 'bottling up' their anxiety; although there are also many cases where problems within families have been helped by strong family support and commitment, or through counselling and other support. • Effects on the quality of life of individuals have also been noted: these included feeling that their right to privacy had been compromised through their names being provided to blood banks and by being excluded from blood or organ donation. Some recipients expressed a feeling of being an outcast from society, and embarrassment and shame at having to produce a medical-in-confidence letter whenever they access medical or health care; and these feelings were worsened by refusal or deferral of procedures. Some recipients indicated that they neglect their health problems rather than face this confrontation; and a number indicated that they have grown to distrust the medical profession, the law and the government. • Recipients noted feelings of discrimination centring on the perception that only women and children were treated under the

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				<p>AHPHP.</p> <ul style="list-style-type: none"> Other recipients mentioned problems in keeping employment (mostly due to anxiety and stress levels); financial costs (indirect and direct); and being unable to obtain insurance. <p><i>Recommendations regarding the activities of the Pituitary Hormones Task Force</i></p> <p>The Allars report recommended a number of activities for the CJD Pituitary Hormones Task Force, including the tracing of recipients; and provision of information to recipients.</p> <ul style="list-style-type: none"> Tracing: Doctors participating in the AHPHP were asked to contact all hormone recipients (Nov 1990); advise them of the association between their treatment with pituitary derived hormones and CJD and counsel them not to donate tissue organs and blood. A follow-up letter was sent to original treating doctors (after confirmation of the second CJD death). By November 1992 only a third of former recipients had been traced. A range of additional strategies were used to contact recipients, including placing advertisements in the <i>Australian Women's Weekly</i>, <i>New Idea</i> and <i>Who</i> magazines from 1992 to 1994; matching names against the Medicare records in (March 1993); data matching with the Australian Electoral Commission (Oct/Nov 1994). As of July 1997, 90.2% of all recipients treated through the AHPHP had been traced (not including unapproved recipients). <p>The Committee concluded that the Department tracing of hormone recipients had been inadequate. The anecdotal evidence is that rather than being `traced' by the Department's actions, many recipients only learnt of the risk resulting from their participation on the AHPHP through TV and print media. For many recipients discovering their risk in such a manner caused considerable shock, anxiety and distress.</p> <ul style="list-style-type: none"> CJD News (HPH Newsletter), produced quarterly during 1995,

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				<p>was reduced to a biannual publication following a recommendation by NPHAC, alternating with the production of <i>National Network News</i> by the CJDSGN.</p> <ul style="list-style-type: none"> • Special edition newsletters or flyers are produced for events for which recipients need immediate notification. • AHPHP Patient Database was developed as a resource for recipients as recommended in the Allars report; and was designed to be user friendly; present patient records in clearer, accessible manner; and have improved reporting capacity. • The database holds data relating to people who applied for or received treatment with human pituitary derived hormones under the AHPHP; as well as people who are known to have received treatment with human pituitary derived hormones outside the program; the names and addresses of treating doctors; and of general practitioners nominated by recipients. • Some recipients have concerns about the database, especially regarding the type of information retained on the database and its potential use. • Information provision: 11 information sessions were held throughout Australia during 1994. • A communication strategy to improve information dissemination for recipients and their families was implemented in February 1995. This involved the release of the information brochure <i>Treatment with Human Pituitary Hormones and the risk of Creutzfeldt-Jakob Disease</i>; and <i>Understanding CJD</i> (an information video designed to target recipients unable to attend support group meetings or information sessions, particularly those in rural/remote areas); translating the information brochure and Allars report executive summary into seven languages; transcription into talking tapes for recipients who have difficulty reading or have a visual impairment; the addition of an information homepage to the Department's Homepage on the Internet. • An index for the Executive Summary of the Allars Report was

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				<p>produced in July 1995 to assist people in finding information contained in the Report.</p> <ul style="list-style-type: none"> • Information sessions were often problematic, often with recipients airing their problems to Departmental representatives for past grievances (including being systematically prevented from gaining information). Information sessions were scaled back in 1995, as they were considered expensive, with little new information to provide. • Support Group meetings which are regularly held were considered better venues for information sharing. However, many recipients choose not to participate in the Support Groups and as such are potentially being deprived of a source of information. • Access to medical records: Allars recommended that the Commonwealth Department of Health initiate and coordinate the development of a uniform Federal/State approach to access to medical records and their disposal, which: applies to records held in public hospitals, private hospitals and by private medical practitioners; and creates legally enforceable rights of patients with regard to access and disposal of such records, either through the extension of freedom of information legislation in each jurisdiction or through the application of conditions to providers under the Medicare scheme. • Recipients continue to experience difficulties in gaining access to their records of treatment by their medical practitioners and hospitals. • According to DHFS this recommendation led the Department to the conclusion that it was desirable to maintain s.135A as the provision did not prevent access by individuals to their own records. The Department submitted that: release of their own information under s.135A has been made available to all hormone recipients on request; the Department prefers that this is mediated through a medical practitioner as it provides better quality information to the recipient, through explanations, context and counselling. The sensitivity of the records and the anxiety

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				<p>and concern that may be quite unnecessarily exacerbated by inadequate information on the face of the record, or by conflicting information coming from other sources such as the media. According to the Department, forwarding medical information directly to hormone recipients is an option provided that the person has been positively identified as the hormone recipient to whom the information relates.</p> <ul style="list-style-type: none"> • The CJDSGN suggests that despite many representations from the Support Groups and from NPHAC it is still the case that initial confirmation that you were a participant of the AHPHP is required before information is provided to patients. This process is unacceptable to many recipients, who feel they have a right to receive such information directly and to choose for themselves whether they need to share it with their medical practitioner. <p>The Committee concluded that the part of this recommendation to facilitate the release of information directly to recipients has not been satisfactorily addressed. The Committee feels that renewed pressure will be put on the Department to provide individual information, particularly batch number and treatment information, following the notification of a further probable CJD case. Proposed amendment to s.135A should await the outcome a review by the Attorney-General's Department on existing secrecy provisions, with a view to coordinating them and promoting a consistent approach.</p> <ul style="list-style-type: none"> • Counselling service: • <i>Allars recommended that continuing counselling for recipients be provided by Marriage Guidance Australia continue to be funded, and suitable provisions be made for those where these services are inaccessible or unsuitable</i> • The Department chose to give a national contract to one organization rather than have a series of State specific providers. Marriage Guidance Australia (later Relationships Australia) was contracted in October 1993. In 1994 ongoing funding for free counselling services through Relationships Australia was allocated until the year 2002-03.

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				<ul style="list-style-type: none"> • Private counselling was allowed for in a small number of cases where a therapeutic relationship had developed before October. However, the Committee received evidence that the procedure for reimbursement was 'cumbersome and difficult'. • Support Groups received more and more complaints about limited access (for some telephone, or travelling great distances at considerable cost) to counselling and the CJDSGN became concerned that less than one hundred people across Australia were receiving counselling for the \$500,000 per annum being paid to Relationships Australia. • Some recipients found the service inappropriate for their circumstances and continued private counselling at considerable personal financial cost. • The Human Pituitary Hormone Counselling Service provided a network of organisations and individuals certified to offer appropriate and free counselling to recipients and their families (October 1996). This provided recipients the choice of their own counsellor or an already accredited provider, who were suitably qualified professionals. Recipients provide their names but these are kept confidential. Payment is on an agreed scale and made directly to the providers. All recipients and family members are entitled to fifteen counselling sessions, after which a panel of clinical psychology experts assess their ongoing needs. • The Counselling Panel's role is to: certify providers; and broadly, to provide recommendations to the Department on exceptions to length of counselling or other advice; including dispute resolution processes. • Since the implementation of the new arrangement, no one had been refused approval for counselling; approval is given either on the basis of the counsellor's credentials or on the basis of an ongoing counselling relationship with a recipient. • Additional effort may be required to ensure that the new counselling arrangements are widely understood and are able to be accessed by all recipients requiring such a service. Emphasis should be given that these arrangements are distinct from, and specifically overcome the difficulties associated with, the

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				<p>previous monopolistic counselling arrangements.</p> <ul style="list-style-type: none"> • The news of another probable case of CJD may increase need and use of counselling services. • Establishment of Advisory Committee: <i>The Allars report recommended that: the National Advisory Group be replaced by an Advisory Committee with the functions of providing advice to the Task Force on: meeting the needs of recipients; fostering support groups; operation of the database; conducting surveys; and the conduct of research in which recipients are subjects.</i> • The National Pituitary Hormones Advisory Council (NPHAC) (established in December 1994) provides independent, expert advice to the Minister on: how the Pituitary Hormones Section may meet the needs of recipients; including the ongoing needs for treatment and care and counselling, development and fostering of self-help support groups; conduct of the survey of hormone recipients and their information needs; and public health issues relating to people who have received treatment with pituitary derived hormones. • NPHAC provides advice on the welfare of hormone recipients and their families, including current medical, legal, scientific and social issues. • NPHAC includes expert membership and members of the recipient community, and is responsible for advising the Minister. The CJDSGN has indicated that the composition of the NPHAC differs to that envisaged in the Allars report, which was comprised of a purely recipient group advising the Task Force. • The CJDSGN reports that recipients generally were satisfied with the process and the results of NPHAC and find the members of NPHAC very open to recipient concerns and attitudes. • Some recipients noted that there are difficulties for recipients to be able to convey their views and opinions on various issues to NPHAC if they were not linked with Support Groups. <p><i>Guidelines relating to human experimentation – include the following:</i></p>

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				<ul style="list-style-type: none"> • The NHMRC emphasised the need for information about the possibility of long-term effects of new treatments and the importance of informed decision making about any proposed treatment in a report <i>Long-term effects on women from assisted conception</i> (1995). • The report also recommends that the outcomes for HPH recipients should be included in general studies of the outcomes of assisted ovulation, including ovarian and breast cancer as outcome measures in a broader epidemiological study of the health of HPH recipients. It is the type of information sought in this proposal which is the basis of the Committee's recommendation to reconsider undertaking an epidemiological survey. <p>Guidelines for medical practitioners on providing information to patients <i>Allars recommended that the NHMRC review the adequacy of the 'General guidelines for medical practitioners on providing information to patients'.</i></p> <ul style="list-style-type: none"> • A working party was set up by the National Health Advisory Committee (NHAC) made three recommendations: 1) that the <i>General guidelines for medical practitioners on providing information to patients</i> not be revised in light of recommendation 11 of the Allars Report; 2) that NHAC consider preparing a stand-alone statement on providing information to patients who may no longer be a patient, when a risk becomes apparent some time after the intervention; and 3) that NHAC consider relaunching the guidelines. • NHMRC released <i>Creutzfeldt-Jakob Disease and Other Human Transmissible Spongiform Encephalopathies: Guidelines on patient management and infection control</i> (December 1995). This was sent to a range of medical and scientific individuals and organisations, as well as advertised in <i>HPH Newsletter</i> in March 1996. The document provides infection control guidelines for the management of, and for medical surgical procedures including autopsies on, patients with or at risk of developing CJD. • NPHAC noted (July 1996) that there were continued problems

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				<p>among some members of the recipient community regarding the guidelines, particularly regarding individual dentists' problems with the infection control guidelines. The Scientific Research Subcommittee of NPHAC noted (Sept 1996) the concerns and agreed that it would write to the NHMRC indicating the need for revision of the infection control guidelines (July 1997).</p> <p>Conclusions The Committee concluded that:</p> <ul style="list-style-type: none"> • Generally the actions taken by government in response to the Allars Inquiry recommendations have been fair and adequate. The funding commitments to State-based support groups until 2010 and counselling services until 2002-03 (subject to an evaluation by PHTF this financial year) should be re-affirmed, in order to allay recipient concerns, especially in view of the probable new case of CJD. The Government should also include the possibility of extending counselling services for a longer time period. • There also remain a number of reservations which need to be addressed before the Allars recommendations can be regarded as fully and equitably implemented. These include: • Ensuring that revised arrangements (introduced October 1996) to assist recipients and their families who need counselling, are understood and are able to be accessed by all recipients. This includes provision for cases where counsellors providing a service to the satisfaction of particular recipients are not precluded from assistance under the revised arrangements. • Efforts to trace remaining (approved and unapproved) recipients be renewed, with appropriate sensitivity given the time elapsed since the AHPHP ceased. • That treatment records and other information requested by recipients be provided directly to them. • That an index to the Allars Report be prepared and made readily accessible for all recipients and others. • That NPHAC's processes and procedures are sufficiently open and flexible to enable it to receive views and opinions from all members of the recipient community on issues under consideration; and that

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				<p>recipients are kept informed of decisions taken by NPHAC and their outcome;</p> <p>Committee comments</p> <ul style="list-style-type: none"> • The Committee considers that a course least likely to highlight the risks of the AHPHP was adopted in the first instance. • From 1985 to 1990 no effort was made by the Department to contact recipients directly; or to ensure that practitioners had contacted those who had been current patients in 1985. The Committee considers that three events were significant and should have, at the very least, caused the Department to reconsider its policy on contacting recipients, these being: the decision to defer blood donation from individuals who had received human pituitary-derived growth hormone; advice to state health departments to ensure that pituitary-derived treatment recipients were excluded from organ and blood donation; and the appearance of a patient with signs of CJD, who had been treated under the AHPHP. • The Allars report highlighted problems in communication and responsibility between committees and the Department. The committee expressed concern that events didn't trigger the Department's concerns about recipients 'right to know', the impact on recipients who did find out about the risk of CJD when trying to donate blood, or public safety concerns arising from those recipients who may, inadvertently, not have relayed to Blood Banks or organ donation agencies that they had been treated under the AHPHP. • The committee expressed concern over the Department's failure to explore other avenues for tracing recipients prior to further letters to practitioners being sent out in 1992. • The approach to notification contrasted with a similar situation in the US: following the death of three hGH recipients in the USA in early 1985, an interagency committee (May 1985) decided that an extensive epidemiological study be undertaken. By June 1986, a private company was contracted and had started a systematic epidemiological study of the entire recipient

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				<p>population; with the primary goal of identifying and determining the health status of every individual treated with growth hormone. To identify recipients, a thorough tracing system was developed: this used a combination of telephone and postal records, credit and driver's license record searches.</p> <ul style="list-style-type: none"> • Between November 1992 and October 1993, the percentage of recipients traced and notified reached 78% (from 33%). Many recipients however discovered they were at risk of CJD not through the hospital department or their treating practitioner but through the media, when they attended to donate blood or through magazine articles. <p>Recommendation 12: The Committee recommends that the Department review all possible tracing methods in an attempt to identify the remaining 190 or so untraced approved recipients.</p> <p><i>Information provided to recipients</i></p> <ul style="list-style-type: none"> • Recipients noted that there was initially very little information available to them about CJD, and that provided by practitioners was variable, some providing information about risks and CJD, others glossing over the importance of it as a risk, and some not being able to provide much information about CJD. • The notification system was poorly organised and the Commonwealth was reluctant to ensure that recipients received the information directly, fearing mistakenly that this would contravene the s.135A of the National Health Act. <p>The committee considers:</p> <ul style="list-style-type: none"> • That recipients need quick, easy access to the information they require: this removes a potential source of stress and ensures that recipients have access to information concerning their treatment in order to make informed decisions about their health and any future medical treatment, but also in determining whether to accept the settlement offer. ○ The Department's efforts in tracing unapproved recipients have been inadequate; and that efforts to rectify this situation have also been inadequate.

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				<ul style="list-style-type: none"> ○ Resources should continue to be devoted to tracing, until tracing of both approved and unapproved recipients is complete. Recommendation 14: The Committee recommends that the Department continue to devote resources to tracing unapproved recipients. Recommendation 15: Once it is established that a person did receive hPG or hGH from the AHPHP, the recipient's status should be differentiated from those who were approved recipients; and where a dispute between the Department and a person who claims to have received treatment exists an independent arbitrator should resolve the conflict. <p><i>New cases of CJD</i></p> <ul style="list-style-type: none"> • Very late in this Committee's inquiry, evidence of a probable further case of CJD emerged: this information had been circulated on the Internet and throughout the recipient community since July 1997. The Committee acknowledges the ramifications this evidence has for the recipient community. • As of August 1997, the Department had not formally received any clinical information on this possible further case. Initially the CJD Case Registry would be notified and they would evaluate whether to include this case in their register. The Department would also receive the information officially to consider the person's eligibility for access to the trust fund; the process for which involves referral to an independent panel, which provides an assessment and advice. <p>The Committee considers:</p> <ul style="list-style-type: none"> • That confirmation of the probable further CJD case will renew anxiety among recipients, and especially so as the recipient was treated early in the program. • The Committee is concerned that the Department has not responded adequately to a situation that has profound implications for the individual recipients and for the broader recipient community. • Although an edition of the HPH Newsletter was produced,

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				<p>following reports in the media, that outlined some details of the probable further case of CJD, including the batch numbers implicated and the dates of treatment the woman received.</p> <ul style="list-style-type: none"> • The Department did not inform recipients of the possibility of a further CJD case before the matter was raised in the media; and learning of such news via the media may have increased the anxiety of many of the recipients, and the Department could have informed recipients about the new probable case and of her treatment circumstances before the media reported these details, and have provided as much information to recipients as possible. <p>Recommendation 16: The Committee recommends that the Department implement protocols to ensure sympathetic early intervention in order that information and assistance be provided to recipients suspected of having CJD as soon as their condition becomes known, rather than awaiting official confirmation.</p> <p>Recommendation 17: The Committee recommends that the Department inform the recipient community about the required steps in making an application for assistance in the event that a person contracts CJD.</p> <p>Recommendation 18 and conclusions: The Committee concludes the following regarding the Health Department:</p> <ul style="list-style-type: none"> • It seems to lack an understanding of the ethical matters and accountability issues raised in the Allars Inquiry; • Its failure to respond to developments (1985 to 1988) raise questions about the decision-making processes within the Department; • The Department did not adequately respond to the AHPHP suspension by tracing and contacting recipients; • The Department failed to plan and understand the needs of recipients, and this is shown in the lack of information concerning the risk of CJD being provided to recipients in a consistent, comprehensive and organised manner; • Recipients continue to experience problems accessing information held by the Department; • 'The Department's failure to act promptly to minimize the

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				<p>possibility that a person treated with human pituitary-derived hormone may have donated blood and organs calls into questions its commitment to maintaining the highest levels of public safety in Australia; and</p> <ul style="list-style-type: none"> • The Department failed to inform recipients that their names had been supplied to Blood Banks and organ donation agencies. ' <p><i>Legal issues and considerations'</i></p> <p>Recommendation 5: That the settlement offer should not prevent a future claim relating to other physical illnesses proven to be related to long term side effects of HPH treatment; or liability if CJD transmission or other illnesses relating to HPH treatment be proven.</p> <p>Recommendation 6: That the Commonwealth:</p> <ul style="list-style-type: none"> • Allocate additional funds to the existing Trust Account in order that its purpose be widened. • Widen the Trust Account scope to permit one-off payments to be made to recipients providing evidence of psychiatric injury as a result of AHPHP treatment. • Consider extending the payment offer to those recipients who have suffered psychological stress or significant life disturbance; and • Appoint an independent governing Board to assess applications and to authorise payments from the Trust. <p>Recommendation 7: That those recipients who have already accepted the settlement offer would also be eligible for the additional offer (Recommendation 6), providing they have evidence of psychiatric injury, psychological stress or significant life disturbance.</p> <p>Recommendation 8: That unapproved recipients also be eligible for the settlement arrangements.</p> <p>Recommendation 9: That the Commonwealth formally acknowledge:</p> <ul style="list-style-type: none"> • Problems with the processes and regulation of the AHPHP; • The experimental nature of some aspects of treatment under the

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				<p>AHPHP; and</p> <ul style="list-style-type: none"> • The anxiety and stress recipients have experienced. <p>The adequacy of the offer whether a plaintiff must choose between damages for nervous shock and damages for physical harm</p> <ul style="list-style-type: none"> • Damages awarded in nervous shock cases are often less than generous. • As such if a plaintiff was successful in their claim for nervous shock, and then developed CJD, the (smaller) amount received in compensation for nervous shock will inhibit the plaintiff from a claim for a greater amount of damages for physical injury. • Client succeeds at trial for psychiatric injury; neither that client nor that client's family would have any further claim for compensation in the instance that the client falls ill with CJD thereafter. • Clients who settled their claim, rather than sought the court result, would ensure that their medical expenses etc are covered if they contract CJD, (as such, it might be argued that the Commonwealth's offer is reasonable). <p>Level of damages in nervous shock cases</p> <p>The level of damages recoverable in actions for psychiatric damage is also relevant in assessing the Commonwealth's offer of settlement, since psychiatric injury suits usually have small payouts the few successful litigants who might go on to develop CJD would be financially disadvantaged.</p> <p>The adequacy of the offer failure to recognise psychiatric injury</p> <ul style="list-style-type: none"> ○ It might be argued that the Commonwealth's offer was fair, even though it failed to compensate for psychiatric injury, because (on one view of the law) the prospects of a plaintiff recovering for psychiatric injury were poor. ○ Alternatively, it could be argued that the Commonwealth is morally, even if not legally, obliged to compensate recipients for psychiatric damage. ○ Many recipients felt it was inappropriate that the offer did not

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				<p>include damages for psychiatric damage, perceiving it as a failure of the system to recognise and understand the ongoing traumatic impact that the CJD episode has on the recipients.</p> <ul style="list-style-type: none"> ○ The CJD Support Group Network was particularly concerned that, in addition to the benefits promised under the Commonwealth's offer, recipients be given 'compensation and some expression of regret on the part of the government for the distress and anxiety they have suffered and continue to suffer'. ○ The Committee heard graphic evidence from a number of witnesses on the suffering of recipients ○ The offer may seem reasonable for recipients who have not suffered psychiatric injury and whose major concern is how they will be taken care of if they develop CJD (difficulty in assessing how many fall into this category). ○ The CJD Support Group Network stated that the impact on some people's lives has been huge, where others have put it to the back of their minds and carried on much as before. Many people would feel uncomfortable about consulting a psychiatrist and even less comfortable about documenting their psychiatric health. <p>The argument that the Commonwealth had already undertaken to compensate CJD sufferers Given that the commonwealth had paid damages to the four original victims of AHPHP, there was strongly held belief among pituitary hormone recipients that, irrespective of the settlement offer, the Commonwealth was obliged to pay compensation to recipients who actually contracted CJD.</p> <p>Liability for other physical diseases The offer of settlement does not take into account other long term side effects (apart from the CJD risk) allegedly associated with assisted conception and the possibility of cancer. The release in favour of the Commonwealth in the offer of settlement appears to be very broad and it may extend to physical illnesses other than CJD. However, the Committee did not receive any detailed evidence on this point.</p>

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				<p>The deadlines set by the Commonwealth and Rennick Briggs</p> <ul style="list-style-type: none"> ▪ the offer in APQ's case was made about a week and a half before APQ's cases was due to begin; ▪ due to an oversight the AGS's offer to Rennick Briggs' other clients made on 4 April 1997 did not impose a deadline, although Rennick Briggs imposed its own deadline of 24 April; ▪ Rennick Briggs advised clients on 28 April that it proposed to cease to act on their behalf after 14 May if they did not settle; ▪ the AGS gave clients of Macedones 14 days to accept the offer on 30 April 1997, although this was extended to 30 June; ▪ the AGS wrote to former clients of Rennick Briggs imposing a deadline of 30 May on 21 and 23 May 1997; ▪ The option for hormone recipients to accept the Commonwealth's current settlement offer has been left open until they have had the opportunity to consider the Government's response to this report. • There is evidence that the members of The CJD Support Group Network were largely unaware of details of preparations for APQ's trial and that the settlement of APQ's case came as a shock • There were concerns related to the conduct of Rennick Briggs. In response Rennick Briggs states that the information contained in the letter of 4 April could hardly be considered as bullying or intimidatory tactics and that all their clients had the choice to accept or reject the offer. <p>The threat to enforce costs against plaintiffs</p> <ul style="list-style-type: none"> • The Commonwealth threatened to enforce costs against plaintiffs in the event that they should seek to discontinue without accepting the Commonwealth's offer, or should proceed with their action and fail. • The CJD Support Group Network gave evidence to the Committee arguing that the AGS letter to Rennick Briggs dated 18 April 1997, which Rennick Briggs passed on to its clients, was 'obviously not intended for a general audience, and the commentary provided by Rennick created great fear among litigants'. • There was also concern that clients felt abandoned by Rennick

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				<p>Briggs when he stopped acting on behalf of those who did not settle.</p> <ul style="list-style-type: none"> • These themes of the intimidating power and authority of the Commonwealth, the feeling of having no real alternative but to accept the settlement offer, and that the perception that legal avenues to pursue the case had been shut recurred through a number of submissions. • The Network's submission criticised Rennick Briggs for not outlining the processes by which costs could or would be recovered from plaintiffs. It was suggested that Rennick Briggs had exaggerated the costs threat to induce clients to settle. It may have been in the financial interests of Rennick Briggs to induce clients to settle thus ensuring that their costs were paid. <p>The refusal of legal aid</p> <ul style="list-style-type: none"> • The lack of legal aid in APQ's case was may have been an important factor influencing the settlement of that case and appears to be a major reason why many others accepted the settlement offer. <p>The offer was not made to off program - unapproved recipients</p> <ul style="list-style-type: none"> • A small number of "off program" recipients of the pituitary hormone treatment (approximately 200, of which five were litigants for the psychiatric injury court proceedings) are currently not included in the guarantee of damages, nor the offer to pay legal costs • The decision on extending the offer to unapproved recipients will be taken by the Minister. The Department considered that, given that litigation in relation to those who had not accepted the offer was being held in abeyance until after the Committee reported, it would be appropriate to await the outcome of this inquiry. <p>Non-litigants</p> <ul style="list-style-type: none"> • The majority of recipients were not involved in litigation for one reason or another. • For a large number of recipients the concept of litigation would have been daunting and foreign. In reaching a decision not to

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				<p>litigate, some recipients apparently considered the impact of litigating on their employment status and careers, and the impact that a court case would have on their families, and the recipients were concerned that they may not be able to prove psychiatric injury because they had never seen a psychologist or counsellor.</p> <ul style="list-style-type: none"> • This does not mean that they may not have suffered significant psychiatric injury. • The same outcome must be available to all recipients regardless of their current legal circumstances, litigants and non-litigants, those who have accepted the offer and those who have not. <p>Conclusions Whether the Commonwealth's offer was fair and adequate The legal perspective</p> <ul style="list-style-type: none"> • It difficult (for the Committee) to assess the fairness of the Commonwealth's offer in a global sense. Viewed against the strict legal rights of the parties, the offer may be generous in relation to some plaintiffs and unfair in relation to others. • Some plaintiffs, especially those treated in the early years of the program, may not have established a duty of care. Others may have failed in their nervous shock claims if nervous shock is not compensable in the relevant circumstances. Alternatively, a plaintiff might have succeeded, but found that the damages awarded were minimal and the judgement in their favour prevented them from bringing an action for physical injury if they subsequently contracted CJD. • The weight to be given to these factors is not a matter which the Committee can determine in individual cases. These are matters upon which a recipient should seek legal advice. (NB Mr Jack Rush, QC, Mr John Philbrick of Counsel, and Rennick Briggs strongly recommended that its clients accept the proposal.) • It is difficult for the Committee to assess the Commonwealth's offer from a legal perspective without making a judgment on the likely outcome of the nervous shock claims. On such a matter, only a court can make a judgment.

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				<p>Was the offer 'fair and adequate?'</p> <ul style="list-style-type: none"> • The National Pituitary Hormones Advisory Council argues that the issue of fairness should be judged in a wider moral context, and that any such assessment must take into account both: fairness to the plaintiffs and fairness to the taxpayer. • The psychiatric injury plaintiffs have suffered as a result of their possible exposure to CJD through the hormone program may have been exacerbated by the feeling that this kind of injury is seen by the Commonwealth as exaggerated or illegitimate. • The assistance is being provided to recipients though the Trust Account may have been seen by some recipients as insufficient and that there should be a payment of general damages in respect of psychiatric distress as well as compensation for out of pocket expenses. • The financial cost to a plaintiff, and possibly the plaintiff's legal and other advisers, resulting from a nervous shock claim through a court hearing and any appeal, has resulted in some plaintiffs feeling pressured to accept the offer even though they might have rejected it if they had the financial resources to litigate. The costs and pressures of litigation have the potential to add to the psychiatric stresses on recipients. • The implications that a settlement payment for nervous shock would have by way of precedent for other situations where people may suffer psychologically under the threat of contracting a disease need to be taken into account. • The Committee is persuaded that the settlement offer was fair and adequate. However, the Committee acknowledges the concerns that have been expressed that the settlement does not go to the original basis of the litigation - psychiatric injury as a result of participation in the AHPHP. The Committee believes that in addition to the settlement now being offered in relation to possible contraction of CJD in the future, the Government should recognise that psychiatric injury has occurred in some cases. • Many original litigants have not and will not accept the settlement offer. At least one, and possibly more, legal firms will continue with their actions to court. As such, the Commonwealth is most likely to

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				<p>be involved in protracted and expensive litigation.</p> <p>Whether the Commonwealths offer gave recipients sufficient time and information</p> <ul style="list-style-type: none"> • The imposition of a deadline on acceptance of the Commonwealth's offer is defensible as without the deadline, the AGS would not know which particular cases it should be preparing to defend. The Committee also notes that the Commonwealth's offer remains open, albeit as a result of the establishment of this inquiry. • Some of Rennick Briggs' clients may have felt pressured and compelled to settle between 4 April 1997 and 24 April, given the deadline stated in Rennick Briggs' letter of 4 April. As such each individual case would need to be considered on its merits, which is strictly a judicial function. • There may have been telephone conversations between Rennick Briggs and clients, which may have clarified the fact that the deadline was not imposed by the AGS • The Committee is of the view that Rennick Briggs was probably justified in bringing the threat concerning costs to the attention of its clients. However, it is difficult for the Committee to assess whether adequate information was given by Rennick Briggs to their clients, especially on the question of whether the Commonwealth would pursue them for costs. This could vary in individual cases where clients made telephone contact with Rennick Briggs. The Commonwealth's intentions would probably vary depending on the financial position of particular plaintiffs and the extent of costs run up by the Commonwealth in individual cases. • The Committee also noted the view of many recipients who believed that access to information included in their treatment records, such as the batch numbers of the hormone they were treated with, was required before they could make an informed determination on whether to accept the settlement offer. Given the difficulties encountered by many in accessing this information, these recipients believed the time was insufficient to gain this information and reach an informed decision.

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				<p>Unapproved recipients</p> <ul style="list-style-type: none"> • The Committee finds it difficult to see any sound basis for not making the offer of settlement to those who can satisfy that on the balance of probabilities they were an unapproved recipient. • Unapproved recipients should be regarded in the same manner and provided the same offer as approved recipients on the AHPHP (once confirmed that they were a recipient). This is particularly so given the failure in their duty of care to the unapproved recipients by the Department and HPAC through deficiencies in the Program's formal approval process and the monitoring of doctors conducting the fertility and growth treatments. <p><i>Tracing of recipients</i></p> <ul style="list-style-type: none"> • Contact with recipients was never made directly but rather was made through medical practitioners. • Practitioners were provided with information to assist their patients in counselling. After each new CJD death associated with pituitary hormone extracts, the Chief Medical Adviser wrote to practitioners and emphasizing the necessity of informing their patients and of counselling around the risks. • The recipient notification was therefore gradual, occurring over years, despite recommendations from the Department and the CJD Unit (established 1992) that all recipients be traced and counselled about the risks of pituitary hormone treatment and CJD. • The Allars Report notes that responses to trace recipients by practitioners was variable: some doctors informed their patients of the problems overseas and advising them not to donate blood or organs; other practitioners were reluctant to notify recipients with some citing the rarity of CJD and lack of diagnostic test as reasons for not informing their patients. • The response by practitioners was therefore slow, mainly due to a lack of resources and the necessity of developing ways to trace and contact patients. The Inquiry noted that the Department should have assisted practitioners by developing a coordinated

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				<p>tracing program</p> <ul style="list-style-type: none"> The Allars Inquiry also noted that recipients should have been informed and made aware of the risk when the AHPHP was suspended in 1985, and that it was the duty of the Department to ensure that this was done. <p>APPENDIX 5 - NPHAC REPORT ON THE FUTURE DIRECTION OF COUNSELLING SERVICES FOR HUMAN PITUITARY HORMONE RECIPIENTS AND THEIR FAMILIES (SEPTEMBER 1996)</p> <p>This report aims to document and identify problems with existing services; to outline the counselling needs and expectations of human pituitary hormone recipients and their families; and to propose ways in which these services may best meet the needs and expectations of recipients and their families, including considerations of duration and frequency of counselling, access and use issues, and quality control of the services.</p> <p><i>Examples of problems with existing services, including case studies.</i></p> <ul style="list-style-type: none"> Cost of services (previous two years) appears approximately \$300-\$450 per contact. Mechanism for subcontracting was developed (after a long delay), but the arrangement required agreement with a highly restrictive legal contract that most professionals refused to sign. Of the 87 people who indicated that they had used the counselling services provided by Relationships Australia, 86% rated the services as 'satisfactory' to 'excellent'; with 14% rating the service as 'poor'. In comparison, of those (240 respondents) receiving information or attending a CJD Support group, 96% rated the experience as 'satisfactory' to 'excellent' with 3% rating the group as 'poor'. Another survey (Pituitary Hormones Section, 1996) reporting responses from 17 people who had used the Relationships Australia counselling services indicated that 11 rated the services very highly, 1 was neutral and 5 were negative. There has been a lack of clarity about the expectations of

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				<p>consumers in terms of appropriate counselling; and concern exists about over-servicing for a small number of recipients.</p> <ul style="list-style-type: none"> Group sessions in one state suggested that no changes be sought. Some recipients have found the group sessions to raise their level of anxiety rather than alleviate it. <p><i>Clearly define the nature and expectations of the counselling</i></p> <p>Context Most recipients have been able to adapt to the risk of CJD; with a minority using counselling to alleviate their fear and uncertainty about the future.</p> <p>'Any future cost-effective counselling service would complement the already well established hormone recipient community support and education network. To promote stability and confidence within the recipient community, established counselling arrangements could be maintained if they are found to meet approved standards.'</p> <p>Assumptions The knowledge about the possible risk of contracting CJD, or that one's child may be at risk, can be a life-threatening traumatic event.</p> <p>The actual or suspected death of a recipient from CJD is another traumatic event for recipients; such an event can add to the potency of the original knowledge about CJD risk; and there may be many issues in such an instance, including grief, bereavement and survival guilt.</p> <p>It is not possible to predict how any individual or family will react to the possibility of developing CJD at some time in the future; but research suggests that selected variables can influence adjustment.</p> <p>Types of counselling issues Informal feedback from Support Group Coordinators, others in the network and HPH Counsellors has suggested the following as issue for recipients:</p> <ul style="list-style-type: none"> uncertainly about what CJD is, and medical treatment received,

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				<ul style="list-style-type: none"> • living with the threat of CJD, • anger towards the medical profession, • anger about the loss of control and the inadequacy of information provided, • anxiety about other medical conditions, • lifestyle issues such as insurance or organ donation problems, • feelings of isolation, uncertainty or disagreement about what to tell children, • family and relationship problems resulting from the knowledge of CJD risk • parental guilt about growth hormone programs, • grief and bereavement, and • stress management. <p>Preferred counselling services CJD Task Force surveys and feedback from recipients and Support Group Coordinators have suggested the following preferences when seeking counselling:</p> <ul style="list-style-type: none"> • Some freedom in choosing a counsellor • The counsellor understands CJD and the implications of CJD • The service is available in rural/remote areas • Flexible hours • Availability of Group counselling • Appointments are possible within seven days • Telephone response within 24 hours of contact • The ability to provide for expanded services in an emergency; that is, episodic needs. • Knowledge of the community for possible referral services, such as psychiatric consultations. <p>Length of counselling In general, research supports the use of brief, focused interventions rather than long-term general approaches for most clients. Exceptions include people with significant psychopathology; those with serious, chronic medical problems; people who experience difficulties forming</p>

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				<p>relationships; and those who encounter incompetent therapists.</p> <p>Cost of Counselling Services Quotes indicate that the necessary services can be provided at a cost from \$80-\$120 per hour. Agencies might provide a pool of appropriately trained counsellors, and the consumer would have some choice about who was consulted. The government would be charged for the actual services provided, with no fixed costs.</p> <p>Recommendations</p> <ul style="list-style-type: none"> • ‘Establish a network of organisations and individuals that are certified to provide appropriate counselling services to recipients and their families. • Develop a system that enables Counselling Providers to be paid directly by the Health Department. However this system requires that those receiving counselling services be identified by name. • As much as possible develop a process that requires the counselling recipient to take responsibility for selecting an appropriate Counselling Provider. • Establish a Counselling Panel to oversee the provision of counselling services and the certification of Counselling Providers.’ <p>Parameters of the counselling service</p> <ul style="list-style-type: none"> • Counselling should be based on a brief, problem-solving model. As the risk of CJD is a chronic condition, the possibility of exacerbations/ crisis periods where more intensive support or intervention is needed must be recognised. • Phone counselling is an option; however this system requires that those receiving counselling services be identified by name so that fees may be paid by the Health Department.

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<p>Populus for the Health Protection Agency and the Department of Health 2007* (Populus for HPA and DoH 2007)</p> <p>Publication Date: 28th March 2007</p> <p>Title: <i>Populus study: Opinion-former attitudes towards the possible introduction of a vCJD test for blood donations</i></p> <p>Source: Department of Health UK http://www.dh.gov.uk/en/Publicationsan</p>	<p>This report was commissioned on behalf of the Department of Health by the Health Protection Agency, to examines attitudes of key stakeholders towards the possible future introduction of a vCJD test for blood donations</p>	<p>Key stakeholders and opinion leaders with a professional interest in the introduction of a blood test for vCJD.</p> <p>The findings highlight a number of issues around the potential introduction of such a test, particularly the level of accuracy that would be required; whether and how to notify those who have been tested of the results; extending the test beyond blood donors; and whether testing might affect people's willingness to donate blood.</p>	<p>PATIENT NOTIFICATION</p> <ul style="list-style-type: none"> • Those with direct links with blood donation were more likely than any other group to say that a donor should always be notified of a positive vCJD test result. • All patient representatives and ethicists and most of Surgical Patient Testing group respondents felt that donors should be given the choice of being informed of a positive result. • Only participants in the vCJD expert group were aware that it would be illegal for the UK Blood Supply to continue to take donations from an individual who had tested positive for vCJD with the intention of not using the donated blood. <p>EXTENDING TESTING BEYOND BLOOD DONORS</p> <ul style="list-style-type: none"> • Those working in tissue/ organ 	<p>PATIENT NOTIFICATION</p> <ul style="list-style-type: none"> • Those with direct links with blood donation were more likely than any other group to say that a donor should always be notified of a positive vCJD test result. • Respondents with experience with tissues and organs were less clear about notification but several thought that donors should be offered a choice of not knowing about the result. This group was also more likely than others to cite the need to protect the public health as the reason to notify donors. • More participants responded that GPs should always be notified of a positive vCJD test result, although the most thought that GPS should only be told with consent, and that donors should not be prevented from donating blood if they did not give their consent. • People working in the area of tissues/organs were least likely to respond that donors should be tested for vCJD if a test is introduced, due to the limited supply and storage life of organs. • Those participants working with blood were more likely to respond that the public understanding of vCJD and the implications of any introduced test needed to be improved before the introduction of any test. <p><i>Key findings:</i></p>

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<p>dstatistics/Publications/PublicationsPolicyAndGuidance/DH_073487</p> <p>Accessed: 17 December 2007</p>		<p>Location: UK</p>	<p>donations were least likely to respond that donors should be tested for vCJD because of limited 'shelf-life' and scarcity of organs.</p> <ul style="list-style-type: none"> The Surgical Patient Testing group did not think that a vCJD test should be introduced for surgical patients at present, although did not rule out the possibility in future. Most respondents in most other groups also agreed that there was no scientific or ethical imperative to test patients pre-surgery. Most participants were uncertain about whether the public should be given access to a test; but some patient representatives suggested that public access should be allowed so that those with relatives who had suffered vCJD could be tested. The members of the Surgical Patient Testing group were more likely than other participants to agree that the public should have access to a vCJD test. 	<ul style="list-style-type: none"> The major differences raised by participants regarding a test for vCJD in comparison with other tests in existence were: the lack of information or understanding about what a positive test result would mean; the lack of any treatment options for vCJD at present; and the lack of a confirmatory test. There were concerns about procedures for blood tests, including the process for consent; the sensitivity and specificity of tests for vCJD should they become available; and there was some confusion about the transmissibility of vCJD via blood and via other routes. Participants expressed concern that donors with a positive test for vCJD should receive adequate support.
<p>Shamrock Marketing 2002* (Shamrock for DoH 2002)</p> <p><i>Interim Report for CJD Consultation Process prepared for the</i></p>	<p>CJD/ vCJD</p>	<p>This paper is a consultation paper on the Department of Health's CJD consultation process.</p> <p>A consultation paper and response document was mailed to members</p>	<p>A total of 3,009 contacts were mailed; of these, 2,897 were potentially contactable.</p> <p>The total number of responses was 336 (12%of total contacts). Of these NHS Trusts were the highest responders, with 199 responding; one of the most responsive groups was 'individuals'</p>	<p><i>General comments - key themes and findings included the following:</i></p> <ul style="list-style-type: none"> Processes for informing patients about CJD had to be thoroughly considered and planned with consideration of the impact on patients, families and health care professionals in primary care services. The challenge of striking the right balance between openness and the impact of notification and the relatively small public health risk. In general, respondents were supportive of the proposals, although many were concerned that existing processes, resources or skills

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<p><i>Department of Health</i></p> <p>20th March 2002</p> <p>Available at: http://www.dh.gov.uk/en/Publichealth/Communicablediseases/CJD/CJDgeneralinformation/DH_4031023</p> <p>Accessed 18 March 2008.</p>		<p>on a database of health and allied health professionals. The document provided information about the Department's proposed responses to key issues and questions, and requested feedback on these items.</p> <p>The consultation document included 16 questions, grouped in 7 sections; and each item giving the responder the chance to agree, disagree or enter a comment of 'don't know.' There was space for comments provided.</p> <p>Consultation questions included the following:</p> <p><i>Investigations of incidents</i> A system for identifying surgical incidents involving people who later develop CJD has been developed, and would build on existing public health systems (local and national). Q1-3: questions on</p>	<p>(mostly families of patients with nvCJD) accounted for a total of 26 responses (this was equivalent to 50% of those contacted).</p> <p>Responses were analysed and key themes identified; with a key theme defined as one in which 10% of the respondents giving the same answer to a question made the same, or similar, comment.</p>	<p>within the NHS would limit the success of the proposal, for examples, with the impact on resources of notifying people about the existence of the database. It was widely felt that a number of the proposals would impact substantially on the resources within the health services, as well as on those in the community.</p> <ul style="list-style-type: none"> • Lack of evidence was a concern with many of the questions: reactions ranged from the wish to exercise extreme caution in the absence of evidence, to queries about the usefulness of implementing controls in the absence of evidence. • Many viewed CJD as a relatively small public health risk that did not need national publicity campaigns, although many felt there should be some public communication to counteract the information in the media. <p><i>Other responses and key themes:</i> The contactable group –</p> <ul style="list-style-type: none"> • Notification of the contactable group of people at risk for CJD was seen to be likely to place considerable strain on existing skills and resources; and the impact of this additional work on GPs, and whether GPs or trained counsellors would be best trained to provide this advice. • Possible impacts on people's ability to get life insurance was identified as a problem of notification of those at risk. Respondents also expressed concern about the effects on people's job prospects, and potentially, which surgical procedures people were advised to undergo. • The burden of knowledge placed on people as a result of notification of exposure, when there is unclear evidence about how big a risk CJD is. • For notification of people, good support and information processes need to be in place: one theme identified the potentially devastating effects on notification on individuals' lives, and the need for adequate information and support processes to allow people to cope with this information. <p>The possibly exposed group -</p>

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		<p>managing surgical incidents, including decontamination of surgical instruments for further use.</p> <p><i>The 'contactable' group</i> Precautionary measures to protect the public health may be necessary for patients exposed to CJD. It is proposed that these patients are notified about their exposure by their doctor, and given appropriate counselling and support. Q4 Do you agree with our proposals to reduce the risk of further CJD infection via surgery and donated blood/ organs? Q5 Do you agree with our proposals to contact exposed patients so that the appropriate public health measures can be taken to protect others?</p> <p><i>The 'possibly exposed' group</i> Establishment of a database to enable</p>		<ul style="list-style-type: none"> • Legal and ethical concerns over the establishment of the database were consistently expressed; confidentiality issues were also raised. • The possibility that a case control study, rather than a cohort study (as the database would provide) may be more informative/ aid management of infection risks was also raised. • Respondents also raised the issue that as the risks of CJD transmission are not yet well understood, and the public tends to worry about poorly understood risks, that setting up the database and not informing people that they are on the database was a good idea. There were however some disagreements with this proposal on the basis of informed consent. • Respondents were positive about the establishment of the database with the aim of increasing knowledge about CJD and transmission risks; reservations expressed focussed on data protection and informed consent issues, although one issue that arose was about the expected benefits of the database versus the possible harms to patients. • Issues of informed consent were raised as a major theme; with legal and ethical implications of holding information on people without their knowledge raised as problems. • People being able to find out whether they were listed on the database or not was seen to raise several issues, including: the practicalities of being able to protect confidentiality; the need for support for those finding out that they are listed on the database, and the skill and resource implications of this. • People being able to remove their names from the database without finding out if they were at risk was largely thought to invalidate the database. <p>Investigating and managing blood donation incidents –</p> <ul style="list-style-type: none"> • Themes raised included the necessity of counselling in these instances; the need for a single point of contact in the case of incidents; and the possible negative impact on blood donations. • Lack of evidence was also raised as a key theme.

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		<p>follow-up of all potentially exposed patients is proposed. This would allow identification of any people at risk who develop CJD; and would improve knowledge about the risks of CJD associated with medical procedures.</p> <p>Q6 Do you agree with our proposals not to inform possibly exposed people (except those in the contactable group) of their exposure?</p> <p>Q7 Do you agree with the proposed database to follow up all possibly exposed people?</p> <p>Q8 Do you agree with the proposal that informed consent should not be sought from individuals before recording their details on the database?</p> <p>Q9 Do you agree with our proposal that the database should be publicised so that the individuals can find out whether they are on it, and about their possible</p>		<p>Public awareness –</p> <ul style="list-style-type: none"> • Uncertainty about risks and a lack of possible action by individuals may mean too much anxiety, balanced against the benefits that a campaign may deliver. • There was also the opinion expressed that there was a need for information to be disseminated that would counteract the information contained in the press. • CJD as a small public health risk not warranting a national campaign. • Another theme was the local resource (costs and resources) implications for local campaigns and whether they would be able to cope. • Many respondents were worried about the way a campaign would be handled; in particular whether enough support would be provided. The possibility of linking a sensitive and careful campaign with national support networks was raised as possibility. • For people accessing information to determine whether they are on the database, the impact of the burden of knowledge was a theme; as was the need for training for those that would be providing information and/or counselling.

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		<p>exposures? Q10 Do you agree with our proposal that individuals (except for those in the contactable group) should be able to remove their names from the database, without having to find out whether they have been put at risk?</p> <p><i>Investigating and managing blood donation incidents</i> Q11-13: questions around the proposed systems for investigating and managing blood-associated incidents.</p> <p><i>Public awareness</i> Q14 Do you agree with the proposed national publicity campaign to raise public knowledge and awareness about CJD risks? Q15 Do you agree with the proposed local publicity campaigns for each incident? Q16 Do you agree with the proposal for enabling individuals to</p>		

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		find out about their possible exposures and whether they are on the database?		
<p>Department of Health and Aged Care (2001)* (DHAC 2001)</p> <p>Report prepared by V. Tippett and Associates Pty Ltd Brisbane</p> <p>Surveillance and Management Section National Centre for Disease Control</p> <p><i>Evaluation of the CJD Support Group Network Inc</i></p> <p>Final report, March 2001</p>	<p>CJD (people at risk and their families; patients)</p> <p>Evaluation of the CJD Support Group Network Incorporated (CJDSGNI, Australia).</p>	<p>Evaluation, primarily in hGH and hPG recipients.</p> <p>Opinions and responses were sought through surveys, focus groups and through telephone interviews with recipients of the Pituitary Hormone Program.</p>	<p>Surveys (mailed) sought the opinions of recipients of the Pituitary Hormone Program on different aspects of the CJD Support Group Network Inc. Opinions were sought from a range of people: those who were active users of the CJDSGN, or who had used the support group in the past; and those with little contact with the CJDSGNI.</p> <p>The survey included questions that were common for both groups; as well as separate questions the two groups.</p> <p>Focus groups were conducted in all states and the ACT (but not NT). Recipients (potential participants) were notified of the details of the focus groups through the information sheet accompanying the survey. Attendance was limited but provided valuable information for the evaluation.</p> <p>The final page of the survey contained an invitation to nominate themselves for a telephone interview with the consultants; and requested details such as appropriate time for contact and telephone number.</p>	<p>In 1985 the Federal Department of Health became aware of the possibility of exposure of patients to CJD through human pituitary growth hormone and sent letters to treating doctors. However this information appears not to have been consistently conveyed to recipients.</p> <p>In late 1991, it was suggested in Federal Parliament that the Government compensate the families of those women who had died of CJD following their treatment on the AHPHP. At this time, notification of potential exposure of all women who had received treatment through this Program was attempted; and that provision for counselling and support of these people and their families should be provided. This Parliamentary speech and the resulting media coverage was the first time that many of the recipient involved learned that they may be at risk of CJD.</p> <p>In 1994, support for the CJDSGN was announced, with the aim of ensuring <i>'that pituitary hormone recipients and their families receive ongoing medical, counselling and support services'</i>.¹</p> <p><i>Survey results</i> There was a response rate of 25% to surveys (578/2300). 50 were returned with no response.</p> <p>Overall, 37% of respondents had used the CJDSGNI, with a slightly higher proportion of relatives (44%) than recipients (38%) reporting use.</p> <p>Of those who had never used the CJDSGNI 37% cited obtaining</p>

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			<p>Response to telephone contact was much greater than that to focus groups: in total 193 interviews were requested.</p> <p>The evaluation collected information about the use and experiences of the CJDSGNI; but has also collected information about the additional support required and needed by people, collecting this information from a range of sources including GPs, the Commonwealth Department of Health and Aged Care and Counselling Services.</p>	<p>support elsewhere as the reason for not accessing the group; 9% got information elsewhere and 15% responded that they had no need to use the group.</p> <p>Over half of respondents (58%) gave other reasons for not contacting the CJDSGNI, including: they did not want to worry or think about CJDSGNI (6% of the total group); the newsletters provided them with adequate information (6%); the lack of a group near their home (4%) or lack of awareness of the group (3%).</p> <p>Of those respondents who had used the CJDSGNI (213), 64% were 'past but not current' users; 22% were 'current but occasional' users; and 12% were 'current and regular' users.</p> <p>The respondents found out about the CJDSGNI group through various sources, including the Commonwealth (48.6%); GP or specialist (10%) another recipient (10%), media (16%), website (1%) and through other means (13%) (including Relationships Australia; could not remember; from hospital where treated; Support Networks overseas; lawyer; counsellor; from flyers at the hospital and from the Support Group leader directly).</p> <p>The respondents who used the group typically had first contact with the group 3-6 years ago (52.2%), 7 or more years ago (37.3%), 1 to 3 years ago (10%) and only 1 person had contacted the Group for the first time less than 12 months ago.</p> <p>The majority of respondents were seeking information (90%), advice (36.2%) or support (36.6%) when they first contacted the Support Group. The first contact with the group was through phone (76.2%), letter (7.1%), or by other means (mostly through a meeting) (15.7%). Most of those who had used the Support Group had used the newsletter (89.7%), attended a meeting (66%), while very few (7%) had used the web site. Other findings are also reported.</p> <p>The key findings of the Evaluation were that although the CJDSGNI</p>

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				<p>provides an important peer-based support network were that: 1) the Network requires refreshing and improvement of its national service coverage; 2) the responsiveness of existing complementary support systems such as the Counselling Services, general practitioners and medical specialists be improved to meet the needs of recipients; 3) access to research based information and advances in testing and treatment and international experience with blood and tissue donation be improved.</p> <p>Overarching recommendations were that the:</p> <ul style="list-style-type: none"> • Commonwealth funding of support services for recipients be sustained to 2010 and closely monitored to ensure that meets the expressed requirements of the recipient community. • Commonwealth continue to fund the activities of the CJDSGNI (support group meetings, provision of Newsletters, phone support etc) • Commonwealth examines opportunities for provision of complementary support services for the recipient community. • Commonwealth implement an information campaign targeted to the recipient community to explain the full range of support services available. • Commonwealth ensures information about CJD policy and other relevant notifications continues to be provided to the recipient community through the "HPH Newsletter". • Commonwealth negotiate to re-brief and resource the CJD Case Registry to provide an independent source of summary updates on CJD research and relevant testing and treatment initiatives to recipients. • appropriate Commonwealth Committee or Reference Group continues to assure the recipient community of representation and information related to the ongoing monitoring of CJD and management issues for recipients. • Commonwealth, with relevant professional bodies and the recipient community, develop and implement a program of regular training and information updates on CJD for general practitioners and medical specialists. Including clear explication of the health and

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				<p>social/emotional implications of exposure of recipients to CJD through human derived pituitary hormones, blood and tissue donation, and requirements for reporting and notification.</p> <ul style="list-style-type: none"> • Commonwealth develop and implement an on-going in-service training module for Counsellors on CJD and the social/emotional issues for the AHPHP recipient community in consultation with the Counselling Service. • using the Commonwealth's recipient mailing list, the Support Group re-contact the full recipient community with a view to contacting recipients who do not currently seem to be aware of the purpose or activities of the CJDSGN Inc. The information provided prepared in close consultation with the Commonwealth. • Support Group re-canvass the membership in States and Territories where there is currently no State-based Coordinator to seek expressions of interest in re-filling those positions. • That in the state/territories where the position of Coordinator continues to be unfilled, the CJDSGNI secure a suitable strategic partnership with an appropriate existing organization to ensure timely support for these recipients. This recommendation predicates the need for the selected organization to be adequately informed and resourced to provide information and support which is relevant to the experience and needs of recipients. • Support Group Newsletter, "The National Network News", continue to be produced and distributed to recipients. • independent status and source of "The National Network News" be more clearly identified to avoid confusion between this and the Commonwealth Newsletter ("HPH Newsletter"). • It is further recommended that the disclaimer provided by the Commonwealth for this purpose is consistently posted in all electronic and paper based products of the CJDSGNI. • Support Group re-canvass the membership regarding the frequency of Support Group meetings and/or other activities, with a view to increasing the number of meetings/activities held annually to more than one. • Support Group seek input to the agendas for meetings from Members and ensure that the timely agenda and notification of

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				<p>meeting times and places is distributed to all Members.</p> <ul style="list-style-type: none"> • That the Support Group up-date the Network web-site and 'refresh' hyper-links to international CJD Support Groups with a similar brief, especially those in the United States and United Kingdom, to facilitate access to research and other information relevant to their experience. • Support Group establish and trial the use of electronic "chat rooms" to facilitate access to discussion and support for recipients in non-Metropolitan centres. (Ideally trialled in NSW where Support Group activity is strongest.) • Support Group establishes and facilitates special meetings/activities in order to respond specifically to the expressed needs of families of recipients. • Support Group determine the interest in establishing a special interest group for the parents of children who received human derived pituitary hormones under the AHPHP and • Support Group determines the interest in establishing a special interest group for men who received human derived pituitary hormones under the AHPHP. • That the CJDSGNI (in consultation with its membership) review its constitution to ensure its responsiveness to the needs of the full recipient community and that it is able to absorb the recommendations of the evaluation. Commonwealth review the conditions of Grant at the end of the current financial period in consultation with the CJDSGNI and update any components of the Grant agreement to ensure that the Group is able to absorb and act on the recommendations of the Evaluation. • Commonwealth continue to fund all reasonable costs of recommended improvements to the CJDSGNI. • Support Group constitution to be re-drafted to require that the position of National Coordinator be time-limited to two consecutive terms. • That a statistical summary of the results of voting for coordinators and the National Coordinators position be provided to the Commonwealth as part of the annual reporting process. • That the Support Group complies with the quarterly reporting

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				<p>arrangements required by the Grant Agreement.</p> <ul style="list-style-type: none"> • That the Commonwealth provide the Support Group with a brief proforma for quarterly reports.
<p>vCJD Clinical Governance Advisory Group 2007*</p> <p>(vCJD CGAG, 2007)</p> <p><i>Report of the vCJD Clinical governance advisory group</i> Published: 28 March 2007</p> <p>Source: Department of Health UK http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_073486 Accessed 17 December 2007</p>	<p>Focus on vCJD in the context of other forms of CJD.</p> <p>The CJD Incidents Panel (CJDIP) has experience in considering the public health risks of potential transmission of CJD between patients through invasive clinical procedures.</p> <p>The 'at-risk' threshold for public health purposes, based on expert opinion and risk assessment is defined as: the possibility of being exposed to a 1% or higher possible risk of infection with BSE than that risk from dietary exposure alone.</p> <p>This report aimed 'to advise the UK Chief Medical Officers of the appropriate clinical governance arrangements, including</p>	<p>'People at Risk' are defined as:</p> <ul style="list-style-type: none"> • Recipients of blood components donated by people who later developed vCJD; currently approximately 24 people. • Recipients of clotting factors; currently approximately 5,000 people. • Blood donors to patients who later developed vCJD; approximately 100 people. <p>It is currently unclear exactly how many people may be at risk of vCJD, due to uncertainty about the disease and a lack of simple and accurate diagnostic tests. The extent to which non-symptomatic people may be carriers for vCJD is unknown; and</p>	<p>Aims: to consider to whom people at risk can turn and be assured that their best clinical needs are being met; and to ensure that people at risk can be appropriately informed and supported over time, for example, as more information about vCJD, or a screening test becomes available.</p> <p>In this Report, clinical governance is described as 'the arrangements that optimally provide the best clinical needs and welfare of persons at risk, set against a backdrop of the public health needs of the population at large'. It represents the system through which NHS organisations are accountable for continuously improving service quality and ensuring high standards of care.</p> <p>The World Health Organization describes four main features of good clinical governance: professional performance (technical quality); resource use (efficiency); risk management (risk of injury/ illness associated with the service); and patients' satisfaction with the service provided.</p>	<p>Arrangements for dealing with people with CJD or at known or suspected risk have been developed over time with input from many different people and groups. However, as information about CJD is updated and changes over time, it is appropriate to reassess the key needs of people at risk, and information must be kept up-to-date and communicated in a timely way to people at risk.</p> <p>New clinical governance arrangements for people at risk should include a clinical care partnership involving the general practitioner (the primary doctor for the person at risk); a local/ regional neurologist (with specialist interest in dementia and able to provide on-site advice); and the national CJD specialist centres (NPC and NCJDSU).</p> <p>Being informed of potential risk can be worrying to individuals and their families and friends. As new evidence emerges about vCJD, and recognizing that the needs of people at risk may change over time, there must be systems in place to ensure that people at risk are appropriately informed and supported at all times.</p> <p>The following are identified as essential:</p> <ul style="list-style-type: none"> • At all times, people at risk must be given good care and sensitive support. Their individual needs should be fully considered and should generally take priority over other factors. • People at risk must receive the best professional advice and support; and this should be tailored to the individual's needs, and to the possibility that their needs may change over time. A staged approach to notification of risk may be most appropriate, and this should take into account their individual circumstances. • People at risk must be given adequate information to enable them,

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	<p>follow-up care and support, for individuals identified as 'at risk' from developing vCJD. To advise further on the appropriate monitoring of individuals, taking account of their views, and to better understand the disease and the potential for secondary transmission.'</p>	<p>the risk to individuals via surgery may vary depending on several factors (such as surgery type, tissue involved in the index case and subsequent patients). The government's approach has therefore been a precautionary one to protect the public health.</p> <p>Given the recent probable confirmation that vCJD may be transmitted via blood transfusion (either from clinical or asymptomatic individuals), it seems likely that further cases of vCJD will be identified in the future.</p> <p>Authors note that recommendations about vCJD will need to be regularly reviewed and updated as new evidence becomes available about vCJD.</p>	<p>Practically, good clinical governance depends on an integrated approach to meeting the clinical needs of people at risk. Such an approach builds on previous work for dealing with CJD patients and their families, developed with input from several groups (including the National CJD Surveillance Unit (NCJDSU); National Prion Clinic (NPC); CJD Incidents Panel (CJDIP); Health Protection Agency (HPA); Health Protection Scotland (HPS); HPA-Consultants in Communicable Disease and their equivalents in Scotland; NHS Blood and Transplant (NHSBT); UK Haemophilia Centre Doctors Organisation (UKHCDO); Great Ormond Street Hospital); and with support from patient groups, particularly the CJD Support Network and the Human BSE Foundation.</p> <p>Considering best arrangements for informing people at risk and their support can be useful in the context of the approach used for people at risk via the use of pituitary-derived hGH. The approach to supporting people was established in May 1992 after a successful pilot: a full contact and counselling centre was set up; the system identified a local neurologist to be the point of contact for monitoring, assessment and investigation. The team actively intervenes to ensure rapid access to expert diagnosis where CJD is</p>	<p>or their carer, to make informed choices about their condition, the available options, and the potential impact of actions that they may wish to take (such as recognising that donating blood would not be appropriate due to the risk of potentially spreading the disease).</p> <p>A clear clinical partnership is needed to ensure that people at risk are able to make informed choices, and that their best clinical needs are met. A partnership involving the general practitioner, consultant neurologist and specialist centres is recommended; and that the following clinical governance arrangement should give priority to those people at highest risk.</p> <p><i>The HPA's role:</i> In the proposed arrangements, the HPA should coordinate information for the person at risk and with the CJDIP be advised of any people considered at risk. The HPA/CJDIP should make a judgement about the individual's potential risk; inform the GP as a matter of priority; and provide an up-to-date HPA vCJD Information Pack. The pack should be user-friendly and include information on vCJD and all other contact details, including those for the NPC and the NCJDSU. The HPA should also update vCJD information to be available on-line; alert all GPs to this site; provide a list of appropriate neurologists (local/regional); as well as a list of people suitable for counselling of PAR, such as those with experience of counselling people with genetic risk for inherited dementias.</p> <p><i>The GP's role:</i></p> <ul style="list-style-type: none"> • The GP should be the usual guardian of the patient's needs; and that where specialist care is needed; this should be centred on the GP working closely with specialists to ensure the best possible patient care for the person at risk. • Since CJD is rare, GPs will need professional support in dealing the issues associated with CJD, and this may be achieved as follows: <ul style="list-style-type: none"> ○ The GP should be fully briefed, in all cases by a Designated Consultant Neurologist, before raising the issue with the person

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			<p>suspected; and to ensure that local support services are informed and rapidly mobilized to provide support.</p> <p>The approach to the risk of inherited genetic diseases was also taken into account.</p>	<p>at risk and to decide how best to inform the individual. The GP needs also to be aware of the possible impact on the person at risk and to adopt specialist advice if needed.</p> <ul style="list-style-type: none"> ○ The consultation to inform the person of risk should be via a consultation in a placed convenient for the individual. The person at risk should be given personally (by the GP or Designated Neurologist) the up-to-date HPA Information Pack, with any additional relevant information. The person at risk should have ready access to the GP whenever they feel that this would be useful; and once the person at risk has been given adequate information to make an informed choice they could request to see the Designated Neurologist or to seek specialist advice from the NPC and NCJDSU. ○ Information about the person at risk should be documented by the GP and provided to the HPA annually. <p><i>The Designated Neurologist's role:</i></p> <ul style="list-style-type: none"> • Following the GP's discussion with the person at risk, the Designated Neurologist should take the local clinical vCJD lead in assessing and providing advice for the person at risk and making contact, as needed, with specialist services, and by working closely with the GP at all stages. • Following an initial assessment of the person at risk, their condition should be monitored and reviewed annually or sooner if symptoms develop or tests become available. <p><i>The specialist centre's role:</i></p> <ul style="list-style-type: none"> • For people at risk who would like it, the NPC and NCJDSU can offer additional testing and support. People at risk should be offered access to the services at both centres via their GP or Designated Neurologist; and information on these centres should be provided to people at risk as part of the HPA information pack for people at risk, and online. <p><i>Support for people with clinical CJD</i></p> <ul style="list-style-type: none"> • The NHS care fund established to support patients and provide

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				<p>additional care aims to ensure that there is a rapid response following CJD diagnosis and to help to ensure that quality care is available to patients; and supplements existing local health and social care.</p> <ul style="list-style-type: none"> Care packages vary from person to person; and should provide appropriate care to the patient and their family at home. <p><i>Coordination of databases</i></p> <ul style="list-style-type: none"> Recommendations include that the Department of Health review current practices for collecting and managing information. This would help to coordinate data, access and provision across the UK dealing with people with CJD. <p>Recommendations include more coordination of research on the distribution, extent and impact of CJD; including the social impact of notification of risk of vCJD on people at risk and their communities.</p>
<p>Victorian Government Department of Human Services 2006* (DHS, 2006)</p> <p><i>Report of the consensus workshop Creutzfeldt-Jakob disease: preventing transmission in the health care setting. Implementing the Infection Control Guidelines.</i></p> <p>June 2005, (revised</p>	<p>CJD associated with healthcare procedures</p>	<p>The workshop aimed to develop a clear and achievable approach to implementing the infection control guidelines for CJD. It also aimed to build community confidence that all possible measures are being taken to prevent exposures and that the risk of exposure to CJD within Victoria is extremely low.</p> <p>The workshop covered 3 main areas: risk assessment and</p>	<p>Authors note that guidelines will need to be regularly updated as the evidence around CJD builds.</p> <p>The workshop covered 3 main areas: risk assessment and screening; cleaning, disinfection and sterilisation of instruments and equipment; and adverse event management. The first two areas are not the focus of this review but included detailed presentations and discussions of the technical aspects of screening, disinfection and sterilisation, and other related issues. This review focussed on some of the major relevant issues arising from the area of adverse event management and the recommendations arising from the workshop</p>	<p>Concerns were raised by participants involving the possibility of people identified as being 'at risk' of CJD for public health purposes experiencing discrimination and difficulty accessing health services. The report notes that discrimination will be an issue that needs ongoing attention.</p> <p>The report notes that the difficulty in assessing the degree of risk of individuals exposed to the risk of CJD through a range of medical procedures makes lookback exercises difficult (eg it is not known what the risk of CJD is when the instruments were used on a patient who is later identified as having CJD, and retrospective tracing identifies instruments that may have been used and processed many times in the interim). The extent of the lookback (ie the numbers of people traced and notified or their exposure) will depend on many factors that need to be assessed on a case-by-case basis; and as this is an area of uncertainties the best approach may change over time.</p> <p>The Australian CJD Incident Panel was established in 2004; modelled on the UK Incident Panel. This panel has responsibility and</p>

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<p>2006)</p> <p>Available at: http://www.health.vic.gov.au/ideas/infcon</p> <p>Accessed February 5 2008.</p>		<p>screening; cleaning, disinfection and sterilisation of instruments and equipment; and adverse event management.</p> <p>Participants included a large range of stakeholders, including: clinicians, researchers, policy makers and consumers.</p> <p>Consensus development workshop: aiming to evaluate the available scientific evidence on a particular subject and to develop a statement about that subject or question that advances understanding in the area and which is useful to healthcare professionals and to the public. Note that the report of the consensus workshop is not a government policy statement.</p>		<p>accountability for determining what action is to be taken following an incident, as well as the scope of a lookback activity (see below for more details on recommendations on the role of the panel). An account of an incident (Royal Melbourne Hospital, September 2004). The incident involved a patient who had undergone neurosurgery twice in 2003; and who died in mid-2004 after being diagnosed with CJD.</p> <p>The National CJD Incident Panel was notified immediately; it met the following day and held discussions with the hospital and the DHS. It was decided to notify all neurosurgery patients operated on following the two operations of the person with CJD; with more specific notification to follow later.</p> <p>Patients and the media were notified on the same day; and an 1800 telephone line established to take calls. A media conference was also held.</p> <p>The next step was to stratify people notified according to their risk level: patients then received further letters and phone calls to notifying them of their updated risk status. Patients who were identified as being at higher risk were interviewed, and received a 'medical in confidence' letter outlining the risks.</p> <p>The psychological aspects of notification was discussed: it was noted that the possible harms of notifying so many people of a possible exposure to CJD risk needs to be carefully thought of, and that such information has the potential to very profoundly affect the people involved.</p> <p>RECOMMENDATIONS – ADVERSE EVENT MANAGEMENT <i>Recommendation one:</i> That a state adverse event management group be formed to liaise with the National Incident Panel and to develop a policy that takes into account the ethical implications of lookback investigations. Participants noted that there would need to be good communication</p>

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				<p>between the groups involved and between national, state and hospital levels.</p> <p><i>Recommendation two:</i> That the expectations of the National Incident Panel be clearly defined. The limited discussion of this recommendation produced the following list of expectations: a timely response; multidisciplinary approach; technical and scientific expertise, including assessment of risk to consumers and the provision of evidence-based advice; advice on risk management; and recognition of the views and the wellbeing of a range of people, including consumers, institutions and clinicians.</p> <p><i>Recommendation three:</i> That an information and management kit on CJD risk management for consumers and health care workers be produced by the DHS. There was unanimous agreement on this recommendation.</p> <p><i>Advice on lookback investigations:</i> The workshop identified the need for the following:</p> <ul style="list-style-type: none"> • Consideration of the ethical implications of lookback activities: there is a clear need to balance the consumer's right to know or not to know of their risk, and the public health risk. Consumers raised the need for consumer input into the process of lookback activities and this could be achieved via consumer advisory committees at individual hospitals. • Evaluation of the impact on the people involved in lookback investigations (ie those notified of exposure risk): this would be undertaken to inform future actions in such situations. • Consistent advice on lookback investigations: in order to ensure that when CJD-related events occur people know what to do. • There was agreement on the following aspects of notification in relation to CJD-related incidents: <ul style="list-style-type: none"> ○ Standardised advice should be available for notifying people. ○ Patients should be informed by personal telephone call that follows a standard script, followed by a letter and/or

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				<p>a face-to-face consultation; although there was concern that standard advice would not be effective, as each patient is an individual, and particularly in those who are at a higher risk of CJD will need an individualised approach.</p> <ul style="list-style-type: none"> ○ Communication should come from the involved hospital, rather than the DHS, as they have a pre-existing relationship with the patient. ○ An 1800 number should be established, with trained staff. ○ Community education is also needed, including an information pamphlet written in plain English.
<p>Report of a WHO Expert Consultation Meeting* (WHO, 2006a)</p> <p><i>Risk Perception and Communication Setting the agenda for the 5th Ministerial Conference on Environment and Health, 2009</i></p> <p>May 2006.</p> <p>Available at: http://www.euro.who.int/Document/Hms/RiskPercep_Comms.pdf</p>	<p>BSE/ vCJD (in the public health arena)</p>	<p>This report summarises an expert meeting dedicated to risk perception and communication. Risk perception and communication of risk; with BSE/CJD as an example.</p>	<p>The case of BSE is an important example that illustrates the limitations of risk communication as a one-way process where risk information is conveyed to the public after policy decisions have already been made. In relation to BSE, communication problems have been identified as one of the major difficulties which led to a loss of trust in governmental processes throughout Europe.</p> <p>Analysis of communication strategies used in Europe at the time of the BSE crisis (including the interactions between the media, policy and public perceptions) highlight the need to create links and mechanisms for exchange between stakeholders and policymakers at early stages, and at all stage of policy making, for risk communication to be</p>	<p><i>Lessons from the BSE/CJV saga</i></p> <p>There were seven key lessons identified, including the following:</p> <ul style="list-style-type: none"> ● Avoid the perception of conflicts of interest among public agencies by separating consumer protection from other interests. ● Avoid restricting policy options, especially regarding early reassurance as this may prevent further investigation of risk or responding to new evidence as it emerges, ● Better understandings of public attitudes are needed; and assumptions should not be made about the public wanting simple answers, zero risk and complete certainty. ● The media should be considered as having a dual role: both reflecting and contributing to public perception, and considering both roles may inform assessment of public perceptions of risks for the purposes of policy-making. ● Public opinion should be viewed as an input to policy, rather than something to be separately managed. A framework is needed to effectively engage the public's perception at different stages of policy making. A suggested framework includes involving public upstream of policy making (framing assumptions about risk); midstream (risk assessment); and downstream (assessing the costs and benefits of the risks).

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<p>Accessed March 18 2008.</p>			<p>effective. Some of the most central problems identified included understatement and concealment about the BSE problem; efforts to reassure consumers about the safety of beef the uncertainty of risks to humans were often communicated as 'no risk to humans' (rather than the possibility of risk to humans; and messages to the public from the Ministry of Agriculture, Fisheries and Food were perceived as having a conflict of interest (ie regarding their dual role to promote beef and to protect food safety).</p> <p>These and other problems led to a loss of public trust, considerable anxiety among the public, and economic and political repercussions.</p>	<ul style="list-style-type: none"> • Deliberative and participatory methods hold great potential, and there are many ways to involve the public in decision-making. • Provide information before decisions are made; and interactions should be encouraged whereby there is a two-way dialogue about how the decisions will affect people. This should occur when framing the risks, and when deliberating about possible options for the management of the risk.
<p>WHO 2006b*</p> <p><i>WHO guidelines on tissue infectivity distribution in transmissible spongiform encephalopathies.</i></p> <p>Available at: http://www.who.int/bloodproducts/cs/TSE_PUBLISHEDREP_ORF.pdf</p>	<p>CJD and vCJD</p>	<p>The report discusses issues of transmissibility and implications for human health; primarily on a policy level.</p>	<p>The 2003 WHO Guidelines encouraged authorities to introduce precautionary approaches to minimise the potential risk of vCJD transmission by blood, while maintaining an adequate blood supply. These recommendations were made while the risk of vCJD transmission via blood was still theoretical. These recommendations were reiterated in the 2005 WHO Consultation, with authorities encouraged to consider the risk of vCJD in the context of their own country's situation; and to weigh the benefits of a precautionary approach against the</p>	<p><i>Policy considerations for risk management and risk communication</i></p> <ul style="list-style-type: none"> • Risk management needs to consider actions in the context of historical and current risks, which may need different approaches. • Risk communication is an aspect of policy that is particularly important, and has been highlighted by work in Canada and elsewhere. Of note, there is the need to develop risk communication statements for those (doctors and regulators) communicating with the public about their likelihood of being infected with CJD via medical treatments, including through blood products. • A threshold estimated risk level must be decided upon, above which people may be considered at an increased risk of CJD. • As important is the decision about how the risk should be communicated to people, including what the message should contain, who should notify the person, and how it should be done.

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<p>Accessed: 20 March 2008</p>			<p>possible impact on the blood supply.</p> <p>At this time there have been at least 362 recognised cases of healthcare-acquired CJD, following use of: contaminated human-pituitary-derived growth hormone (180 cases) and gonadotropin (four cases), human dura mater allografts (168 cases), corneal transplants (at least three probable or possible cases), neurosurgical instruments (possibly five cases) and stereotactic cortical-probe EEG electrode (two cases).</p> <p>With the exception of the 3 transfusion-transmitted cases of vCJD documented, no new products transmitting CJD have been identified in the last 9 years, although the number of cases arising from past exposures to identified risk products has increased.</p> <p>Since 1996 when the first report of vCJD was made, to June 2006, there have been 161 vCJD cases in the UK, 17 in France, four in Ireland, two in the USA and in the Netherlands and single cases in Canada, Italy, Japan, Portugal, Saudi Arabia and Spain.</p>	<ul style="list-style-type: none"> • The implications of notifying people of an elevated risk of CJD need to be fully appreciated, particularly in the context that the majority of the people notified will not become ill with CJD. This means that the decision to notify people must be considered carefully. • The balance between protection of the public health and the potential for individual harm from notification of elevated risk of CJD needs to be carefully considered: there is the possibility of significant harm, not least of which is anxiety, for individuals and their families. This may be particularly distressing as there is no practical action that can be taken by people to determine whether they will develop CJD; and no preventative steps possible to avoid illness.