Including CJD Test Kits in Annex IIA of the EU IVD directive: Legal Issues.

Question	Answer	EU Law	National Law
If a test kit is CE marked is the NBS or the NHS required to introduce it?	No, if a test kit is CE marked the NBS or the NHS it not required to introduce it. The IVD Directive does not oblige the NBS or NHS to use CE marked kit. The NBS choosing not to use the test on the basis of clear specification criteria is arguably permissible depending on the circumstances surrounding the choice not to use the test. The issue is whether any restriction imposed on its use or refusal to adopt a test amounts to an obstacle to placing on the market or putting in to service, (see second question). The Blood Safety and Quality Regulations 2005 do not require donations to be tested for vCJD. If the SoS were to issue guidance on such testing, blood establishments would be obliged to have regard to the guidance. It would not be a breach of duty under the NHS Act, because the evidence is that current tests will lead to many more false positives than true positives, and even true positives will not reflect the number of people who go on to develop clinical disease. Refusal to introduce a test would not amount to intentional killing under Article 2. But there is insufficient evidence to provide advice on whether it would break the duty to take steps to safeguard life, because the cost of introducing a vCJD test is not yet known, therefore it is not possible to	The In-vitro Diagnostic Medical Devices Directive 98/79/EC Directive 2002/98/EC	Section 1, NHS Act 1977. Human Rights Act 1998 gives further effect to rights contained in the European Convention on Human Rights (ECHR) and makes them enforceable in domestic courts. References to Articles in this table are to Articles of the ECHR unless otherwise stated . Article 2 - Right to life. Article 3 - Prohibition of Torture. Article 8 - Right to respect for private and family life. Blood Safety and Quality Regulations 2005. Medical Devices Regulations 2002 (which implement the EC Directives on medical devices)

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	weight up the cost in relation to the benefit obtained by testing. Nevertheless, providing warning of the potential risk of infection may meet this duty. Article 3 is not strictly relevant. Article 8 will not pose a problem as long as medical practitioners are advised of the risks so that they can advise their patients accordingly.		
Would refusal by the NBS to use a CE marked test constitute an obstacle to placing on the market or putting into service.	The NBS choosing not to use the test on the basis of clear specification criteria is arguably permissible depending on the circumstances surrounding the choice not to use the test. Relevant issues are the transparency of the specification criteria, how the NBS assesses the tests, and whether the rejection of the test questions the CE mark as a mark of safety and fitness for intended purpose. It is arguable that such a choice does not question the CE mark as a mark of safety and fitness for intended purpose, rather the choice would be based on the fact that the CE mark does not attest to an appropriate specificity for the purposes of blood screening. The argument that it would not pose an 'obstacle' would be bolstered if GPs were free to use the test at the request of patients.	The In-vitro Diagnostic Medical Devices Directive 98/79/EC	Medical Devices Regulations 2002
Is there is a legal compulsion to inform donors of an abnormal test result, rather than allowing donors to exercise choice in "whether or not to know"?	The safest legal option is to require that all donors be informed of a positive test result. It is not legally justifiable to selectively report positive results to donors. It is possible to argue (relying upon Article 8) that a donor has the right not to know of a positive test result. However, whether this right exists is legally uncertain.	Directive 2002/98/EC Commission Directive 2004/33/EC	Blood Safety and Quality Regulations 2005. Article 8.
Are medical practitioners required to inform patients	Yes. It is imperative as a matter of medical law that healthcare providers warn patients of the risk of vCJD		Article 2.

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of the potential risks of becoming infected with vCJD through blood transfusion? - [DN: All procedures?]	transmission through transfusion. However, it is not possible to advise with any certainty that the provision of sufficient information to patients would avoid potential liability under the CPA.		Consumer Protection Act 1987 – the 'Burton Judgement'. Medical Law. **[DN: names of Acts ??]**.
Is it appropriate to delay the use of a screening test until the tests have been properly evaluated. **How long could it be delay?**	NHSBT would be liable at present under the Consumer Protection Act 1987 if a person was infected with vCJD through transfused blood because this is a known risk. It is possible that NHSBT or doctors could be found liable in negligence if a person was infected with vCJD. Whether or not it would be negligent not to use an available vCJD test would depend on a number of factors – for example, how great the risk of infection is, whether the cost of using the test is prohibitive and in particular whether the patient has been warned of the risk of infection and consented in any event. Given that people who are infected through transfusion can bring a claim under the Consumer Protection Act it is perhaps unlikely that any claim would be brought in negligence which requires proof of fault. It is difficult to reach a conclusion about whether a successful judicial review could be brought of any decision made by the Government to not use the test, especially without knowing what measures will be taken in this regard. However, as long as the decision to not use the testing is taken on the basis of a robust analysis of the issue and on full consideration of the relevant factors, it is very	The In-Vitro Diagnostic Medical Devices Directive 98/79/EC.	The Consumer Protection Act 1987. The law of negligence, Judicial review (if a decision is taken to delay the testing) Human Rights Act 1998 NHS Legislation **[DN: which Act?]** Medical Devices Regulations 2002

	unlikely that the decision could be successfully challenged on the basis of irrationality or on the basis that the Secretary of State has failed to discharge her duties under the NHS legislation. It is also unlikely that any human rights case could be brought if sufficient warning of the risks of infection is given to the medical profession.		
If the introduction of a test is delayed until its evaluation is completed and it is shown to meet the necessary sensitivity requirements, and a case of vCJD transmission occurred in that period, who would be liable?			
Can DH prevent the NBS/NHS organisations using CE marked kit if they want to do so?	Yes. Article 13 of the IVD Directive enables Member States to take interim measures to prohibit or restrict devices being placed on the market or put into service. The public health concerns around the introduction of a test that was not sufficiently sensitive would probably be found by the Commission to fulfil the requirements of Article 13.	The In-vitro Diagnostic Medical Devices Directive 98/79/EC.	Medical Devices Regulations 2002
What would DH's liability be if there was a case of vCJD transmission in the period before an Article 13 restriction could be put in place?			
Would refusal to introduce a CE marked test leave	The Burton Judgement classes infected blood as a "defective product". This makes the blood services liable		Consumer Protection Act 1987.

NHSBT liable if a person became infected with vCJD through a blood transfusion?	in civil law for damage caused by *any* infection acquired from transfusion, once the existence of that infection in blood donations was known, even in the absence of a test for detecting infection in individual cases. However, the Burton Judgement does not amount to a compulsion to introduce every available test regardless of the consequences.		Liability in negligence. (Unlikely that claims will be brought in negligence, more likely to be under CPA).
Are there any steps which can be taken to avoid a future judgement under the Consumer Protection Act. 1987, by warning the public that blood for transfusion may not be 1005 safe.	It is not possible to say with any certainty that warning the public would enable the provider of infected blood to avoid liability under the CPA. If the court did decide that warnings could lower the public's expectation sufficiently so that liability does not arise, it also not possible to say how such warnings should be given and who to, but it would appear to be necessary at the very least for publicity to be made widely available, and not only given to the medical profession.		Consumer Protection Act 1987.
Would a decision to include CJD test kits in Annex IIA be likely to affect the rights of citizens in other EU countries.			