Supplementary Statement from Dr Vivienne Nathanson to the Penrose Inquiry

As indicated in my first statement to the inquiry advice on consent to testing, pre or post test counselling, communication with patients and other core elements of the ethical practice of medicine have undergone significant developments over the period in question.

While some doctors and some practices worked in ways which would fit with current day expectations, this was far from always the case.

It is fair to say that the change from an essentially paternalistic, doctor-knows-best culture to one in which the patient is at the centre of medical practice and his/her empowerment an essential element of the relationship between patient and doctor, has evolved at different rates in the practice of different doctors. The earlier the time frame under consideration the commoner an essentially paternalistic approach would have been.

Changes have occurred following clear expositions of good ethics, and supported by case law, education, and in particular training in communication skills to enable doctors to communicate with patients and their relatives in a sensitive and nuanced manner.

The development of key elements of ethical practice, and of ethics teaching is outlined in more detail in the introduction to my first statement.

(1) What is the current approach to testing for HCV? In particular what information should a clinician provide to his/her patients about the disease and the implications of a positive diagnosis? What is the current GMC/BMA guidance on this point?

The approach to consent to treatment, including testing, is set out in the General Medical Council's booklet *Good Medical Practice* and the supplement *Consent: patients and doctors making decisions together.*[i] The relevant section is set out in full in my earlier evidence, but the key paragraph states

> (b) The doctor uses specialist knowledge and experience and clinical judgement, and the patient's views and understanding of their condition, to identify which investigations or treatments are likely to result in overall benefit for the patient. The doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side-effects of each option, including the option to have no treatment. The doctor may recommend a particular option which they believe to be best for the patient, but they must not put pressure on the patient to accept this advice.

Today doctors are expected to offer the patient all the elements of information identified in this guidance. It is essential that it is understood that the information is offered; no patient can or should be forced to listen to the full set of information. It is open to the patient to make his decision based upon partial information, or even theoretically on no information at all.

In terms of patients effectively refusing to receive information the GMC guidance on consent emphasises the importance that the patient understands any significant risks and at paragraph 14 states:-

> "…But you must still give them the information they need in order to give their consent to a proposed investigation or treatment. This is likely to include what the investigation or treatment aims to achieve and what it will involve, for example whether the procedure is invasive…"

What matters is the offering being made, and the doctor being sensitive to what the patient wants to know. While the doctor may have a relatively standard "package" of information to offer in relation to specific tests or treatments, s/he must also seek to understand how the patient wishes to receive information, make it clear that the option to ask questions or to learn more never ends, and recognise that patients who are stressed, afraid or distressed may have little recollection of the information that has been shared with them.

Many doctors today back up their information sharing with leaflets, or web links, so that patients and relatives are better able to make sure they have all the information they want and can test their recollections of the conversation with the doctor.

When seeking agreement to tests one element of the information offered will be to explain what the test might show, why it is being performed, and what decisions will be made in respect of the results. Where the tests are routine monitoring tests doctors may need to add further information to that given on earlier occasions, as the implications of the test results may change over time. Such change may be due to emerging knowledge about the natural course of the illness, or of different treatment options becoming available, or ceasing to be available.

Another element that is relevant when testing for medical conditions with specific non-medical consequences, such as social stigma, or employment and financial consequences is that these should be part of the discussion. It should again be noted that such stigma or financial consequences emerge over time.

(2) What was the correct approach to testing for HCV between 1991 and 2000? In particular what information should a clinician have provided to his/her patients about the disease and the implications of a positive diagnosis? What was the current GMC/BMA guidance on this point and how did it evolve? Were there any circumstances in which testing could be done without obtaining a patient's consent?

The correct approach to testing for HCV, or any other condition, between 1991 and 2000 can most easily be summarised by the introduction to the chapter on consent in the BMA publication *Philosophy and Practice of Medical Ethics.*[ii] This was first published in 1988 and states

> "The basis for any discussion about consent is that a patient gives consent before any investigation and treatment proposed by the doctor. Doctors offer advice, but the patient decides whether to accept it."

That chapter goes on argue against the concept which remained fairly common at that time, that patients do not want to be bothered with the information, or that they would prefer to let the doctor make the decision.

While at this time the GMC advice was far less detailed, the relevant section is contained within the 1988 advice *HIV Infection & AIDS: the ethical considerations.*[iii] Paragraph 12 starts:

> "It has long been accepted, and is well understood within the profession, that a doctor should treat a patient only on the basis of the patient's informed consent."

Again the emphasis is upon the requirement for consent from the patient. The GMC advice on Serious Communicable Diseases, dated October 1997, falls within the period in question and again states the primacy of consent from the patient before testing other than in exceptional circumstances. Those exceptions are detailed. Children who are not competent cannot consent for themselves, so parents or others with parental responsibility should give consent. The true exception here is in parents who are suspected of abusing their children; this exception seems to have no relevance to the terms of this inquiry.

It is important to note that in paragraph 4 this guidance[iv] states:-

> "…Some conditions, such as HIV, have serious social and financial, as well as medical, implications. In such cases you must make sure that the patient is given appropriate information about the implications of the test, and appropriate time to consider and discuss them."

It is clear and explicit that in 1997 the GMC required doctors seeking consent to have regard to the implications of the test result. This is more explicit than the earlier advice on testing for HIV, but is in accord with it. While the advice relates to HIV it is important to note that it identifies "some conditions such as HIV" and is not, therefore limited only to testing for HIV.

Given that in the 9 years from the production of advice on testing for HIV to this advice on Serious Communicable Diseases more and more doctors have had to test for HIV, and therefore had to consider how to advise on testing for conditions with serious non-medical consequences, the GMC was almost certainly reflecting best practice and a recognition that not all practitioners were as yet practising at this level.

(3) What is the current approach to communicating the results of a test for HCV? What is the current GMC/BMA guidance on this point?

The advice from the BMA and GMC to communicating test results with patients is set out in the answer to question 5 in my first written evidence. The situation with regard to HCV would be exactly the same as for HIV.

(4) What was the correct approach to communicating the results of a test for HCV between 1991 and 2000? What was the GMC/BMA guidance on this point? How did that guidance evolve? Were there any circumstances in which a positive diagnosis for HCV could appropriately have been withheld from a patient?

The correct approach to communicating results to patients within this time period is set out in the answer referred to above. The evolution during that period has also been referred to; doctors were increasingly expected to conform to best practice, and best practice is set out in current guidance.

While the theoretical approach was the same between 1991 and 2000 as it is today it is recognised that medicine was still evolving in that period from the paternalistic basis of earlier in the 20th Century to the patient centred model embraced today. Doctors adapted to this at different rates; not always related to their own age. An inspirational exemplar could persuade, guide, teach and lead groups of doctors to gain the confidence to embrace the modern approach. Guidance from the BMA and GMC helped; lectures, workshops and toolkits gave the practical help and support to change practice.

It is also important to recognise that there was great uncertainty throughout this period about what a diagnosis of infection with HCV meant. With the experience of hindsight we can be increasingly certain of the likelihood of the development of serious or fatal liver

disease, and of the chance of success with optimum interferon-based treatment. But we should also remember that that knowledge has been developed over a period of time, alongside other information which better allows clinicians to relate the known data to the patient in front of them. The preliminary report of the Inquiry sets out the history of developing knowledge on NANB Hepatitis, later HCV, in detail and demonstrates the slow emergence of understanding of this disease, and in particular of the very long natural history of the illness. In the early period of making a diagnosis of HCV this natural history was still emerging and uncertain; while doctors are used to dealing with uncertainty, including risks, many patients and relatives find that very difficult.

Vivienne Nathanson 4 November 2011

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[i] General Medical Council (2008) *Consent: Patients and Doctors Making Decisions Together,* GMC, London.
[ii] British Medical Association (1988), *Philosophy and Practice if Medical Ethics,* p29
[iii] General Medical Council (1988), *HIV Infection and AIDS: the ethical considerations.*
[iv] General Medical Council (1997), *Serious Communicable Diseases*