Medical Report to the Inquiry:

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Commentary on the report to the Penrose Inquiry from Professor Vivienne Nathanson.

Prepared at the request of: The Penrose Inquiry, 44 Drumsheugh Gardens, Edinburgh EH3 7SW.

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CURRICULUM VITAE

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QUALIFICATIONS:

MB ChB	1976 (Sheff).	MD	1990
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DATE APPOINTED: 1/12/94

Following General Medical Training posts in Sheffield and London Teaching Hospitals and MRCP I embarked on Higher National Training in Haematology in Sheffield Teaching Hospitals. This focused latterly on Thrombosis and Haemostasis in The University Dept of Haematology in the Royal Hallamshire Hospital, the main research interest of the Department. I became a Senior Lecturer in Haematology in The University Dept of Haematology, Liverpool University in May 1987. I have been a director of a Thrombosis and Haemostasis Centre since that time. I have published more than 60 papers in Thrombosis and Haemostasis. I have been involved as an expert witness since the early nineteen nineties.

Introduction:

1. I have been asked to comment upon the supplementary statement of Professor V Nathanson, which relates to the issue of consent to hepatitis C testing and ethical issues surrounding this. I have presumably been asked to comment on this because her statement appears to contradict, to some degree, my own written evidence.

2. When preparing this report, I had access to photocopies of the following documents:-

    a. Professor Nathanson's supplementary statement, dated 4/11/11, (but not her original statement.
    b. Professor Nathanson's 4 references, namely: GMC *Guidance on HIV Infection and AIDS: Ethical Considerations* (1988); BMA *Philosophy and Practice of Medical Ethics* p 29 (1988); GMC *Guidance on Serious Communicable Diseases* (1997). GMC *Consent: Patients and Doctors Making Decisions Together* (2008).
    c. I also discussed the issues thrown up with the Head of Our Sexual Health Department, with whom I do a monthly clinic and the Hepatologist who jointly manages our patients with HCV infection.

3. Professor Nathanson qualified at the Middlesex Hospital in 1978, and after 5.5 years in clinical practice, joined the BMA in 1984. Since that time, she has worked for the BMA in various capacities and is currently Director of Professional Activities at the BMA. Although this is a broad-ranging role, her particular interest is Medical Ethics.

4. Professor Nathanson has, therefore approached the questions put to her by the Inquiry from a general medical ethics perspective. She has supported her conclusions with four references, none of which are specific to hepatitis C and two of which are not contemporaneous. Hepatitis C is mentioned once in seven pages of the 1997 guidance and not at all in any of the other 3 references.

5. There has never been any specific advice from either the BMA or the GMC or any other body about consent or counselling for HCV testing.

6. Although, Professor Nathanson acknowledges that the approach to consent for testing would be tempered by knowledge of the condition at the time, this important point is not explored in her commentary and she offers no specific opinion on the way in which the changing state of knowledge would have affected consent at specific times. Furthermore, although she acknowledges that the GMC 1997 Guidance, upon which she relies, may reflect "best practice", she is unable to offer any evidence of the extent to which this guidance has ever been applied to consent for HCV testing either then or now. Indeed, the inclusion of hepatitis C in the GMC *Serious Communicable Diseases Guidance* of 1997 is extremely dubious. Most Hepatologists would not categorise hepatitis C as a serious communicable disease. Its infectivity is at least an order of magnitude less than HIV and hepatitis B. It is more amenable to curative treatment than either HBV or HIV and its prognosis is generally very good, even without treatment. I note that this guidance mentions hepatitis C only once in seven pages and offers specific advice on HIV only. The most relevant paragraph in this document is paragraph 4 which reads: -

7. "*You must obtain consent from patients before testing for serious communicable disease, except in the rare circumstances described in paragraphs 6, 7, 9, 11 and 17 below* [relating to vulnerable adults and children and unconscious patients, etc]. *The information you provide when seeking consent should be appropriate to the circumstances and to the nature of the condition or conditions being tested for. Some condition, such as HIV, has 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."* This guidance reflects normal rather than good practice for HIV infection, probably from the late eighties onwards, but since the implications of HCV infection was and is considered very different, the approach to consent was also different.

8. Most haemophilia centres counselled patients both at the time of HIV testing, in 1985, and when they communicated the result in a face-to face interview. Much of what the patients were told at that time turned out to be incorrect, but it was the best information or opinion available at the time. In one or two centres, (e.g. Liverpool and Manchester) the HIV result was communicated to the patient by letter. This practice was widely considered reprehensible, even at the time, and left an understandable and enduring legacy of anger and bitterness in the affected families. There was no agreed policy about this at the time, however. Counselling for HIV testing became more formalised and universal in the later eighties.

9. The situation for HCV was different in a number of respects. Firstly, most patients with haemophilia had their liver function tests monitored from the late nineteen seventies and, if these were abnormal will usually have been told they had non-A, non-B hepatitis. In such individuals a hepatitis C test would be a confirmatory test and, if discussed, may well have been presented as such. Once the HCV virus had been isolated in 1989, it was assumed to be the cause of most of the abnormal liver biochemistry observed in this group of patients.

10. Secondly, at the time of original testing, mainly in 1992/3, treatment was available and the prognosis even without treatment for HCV was regarded as generally very good. This was in marked contrast to HIV for which treatment was then relatively ineffective. In the early nineties all patients with HIV were expected to die sooner or later from AIDS, an assessment dramatically transformed by the introduction of HAART in 1995.

11. It is likely that in most cases HCV testing during the very early nineties would have been mentioned in passing, probably with a short exposition on the condition as described in my earlier report. The result would have been communicated at the next clinic visit. Formal consent for testing would not have been sought, though the patient

would have been informed and therefore had the opportunity to refuse testing. Some patients and more particularly their relatives refused HIV testing.

12. I should also point out that hepatologists have never had a policy of taking specific consent for HCV testing. I have discussed this with our current Hepatologist and his two predecessors all of whom told me that it would be just one of a battery of [perhaps 15-20] tests conducted as part of the investigation of every patient they investigated for abnormal liver function tests and that each of these tests would not be discussed with the patient individually. As our current Hepatologist said *"Everyone checks the Creatinine [test of kidney function] all the time and that is never discussed with the patient in advance and yet the prognosis of a patient with an elevated Creatinine is very much worse than the prognosis of a patient with HCV"*. He re-iterated the point that HCV is potentially curable and even untreated has a generally very good prognosis and that there is no specific guidance.

13. Haematologists tend always to tell the patient they are testing for HCV and to discuss the condition prior to testing. Certainly, that is my invariable practice. This practice has been influenced by experience with HIV but counselling for HCV testing is never as involved or as prolonged as for HIV testing.

14. Most such tests (HIV and HCV) are currently conducted in the community or STD clinics where counselling is, even now, perfunctory. It will often take the form of being given an information leaflet and being asked if they have any questions arising out of their reading of the leaflet prior to being tested. Consent for such routine testing of blood donors follows this pattern as does testing in STD clinics.

15. After producing the draft, above, I was also provided with Professor Nathanson's first report, dated 9/5/11. I have the following comments on her first report: -

16. I would generally agree with most of her first report, as far as it goes. Her history of the development of consent for HIV testing appears accurate to me. In contrast to

HCV, however, there was much discussion and a plethora of guidelines issued over the years to cover HIV-testing. After the very early period, in which some patients may have been tested without their consent, in some cases to test the newly developed test (reported anonymously), consent was almost invariably obtained. With exceptions mentioned above, the result was generally communicated face to face to enable the patient to be counselled about the implications of the test result and to have an opportunity to ask questions.

17. Very few haemophilia patients refused to be tested. I have encountered non-haemophilic patients who have refused testing and a number of spouses of patients with haemophilia. That this refusal reflects the complex family dynamics is suggested by the fact that almost all of these spouses consent to testing when their relationship breaks down or their husband dies. Patients will also commonly forbid their doctor from discussing the result even with close relatives and occasionally with the GP. In the latter situation, special arrangements have to be made since the GP could inadvertently place him/herself at risk or make an incorrect diagnosis if they are not informed of the patient's HIV status.

18. There is very little mention of HCV in the first report. Presumably that is why the second commentary was requested. My comments about HCV testing above, therefore stand.

19. Professor Nathanson makes the very valuable point that: *"In general the UK, unlike the USA, does not have a legal requirement for treatment to require fully informed consent. Ethics advice over three decades has been that the patient must have sufficient information to understand the choice they are making and to make that choice freely."* We tell patients about common complications, not every possible thing that could possibly happen, however unlikely. By the same token, we do not go into chapter and verse about every single test we do. If we did, we would do nothing else. There are practical limitations to informed consent. These are: -

a.) There is not time to consent for every test. Every visit from a patient co-infected with HCV and HIV generates about 20+ blood tests and sometimes an x-ray or ultrasound. The blood count alone involves tests for at least 10 parameters. The patient generally asks and is told about two or three of these. They would obviously be informed of any abnormal results. To take full consent for everything would take two or three hours for each patient and would then be incomplete.

b.) For which tests should one obtain specific consent? Certainly, unpleasant or hazardous tests. Prof Nathanson's reports imply that one should obtain specific consent for tests for which the result may be life-changing and which may have fatal consequences. How one defines such a test is not straightforward however. Biochemistry may reveal evidence of kidney failure or malignancy but is done so routinely consent is never taken to do it. Similarly, a full blood count may reveal acute leukaemia or aplastic anaemia, but again is never consented for. Even the two tests upon which we are currently focusing will have varied in their status with time. HIV was initially thought to affect only the minority of those affected and was initially sometimes tested for without consent. Soon after this, it was realised that it would be perceived as a death sentence and so an elaborate consent process was put in place. Since 1995, however, most patients are well controlled and few die and so the consent process for this infection has actually been relatively downgraded (see UK National Guidelines on HIV testing. BASHH 2008.

20. I would also like to comment on Professor Nathanson's comments on consent for research by way of clarification. Her comments largely concern consent for interventional research. These ultimately derive, though they have subsequently been greatly elaborated, from the Nurenberg Code and later Helsinki Declaration. The Nuremberg Code was formulated after the war to prevent a repetition of the sort of unethical human experimentation conducted on inmates of the concentration camps by the Nazi Regime. These principles would apply to any interventional clinical trial

in which a patient was given an investigational drug or subjected to an investigational procedure or operation. Full informed consent is required for such research. These principles were applied to clinical trials of clotting factor concentrates throughout the period with the product monitored as seemed appropriate at the time and as directed by the regulatory authorities.

21. Consent is not required for anonymised epidemiological research, that is reporting of the incidence and natural history of a condition based on observations derived from routine clinical care e.g. reporting of the incidence and natural history of HIV where chance circumstance or the storage of routine samples make it possible to determine the time of infection. (Virology routinely store all samples for three years, throughout the UK.) Indeed, such data reported from Edinburgh was of such enormous importance that an ethical issue would have arisen had it *not* been reported. Doctors have a duty to report new observations which will advance the understanding of disease and its management.

22. So long as the tests requested and observations made are those which would have been requested and conducted in the normal way for the purpose of clinical management, then no ethical issue arises and neither consent nor ethics approval would have been required in the eighties. It would be normal to test all such patients for HIV and where stored samples existed to test these to determine the approximate time of infection.

23. An ethical issue would arise if the patient's management was changed as a consequence of participation in such an observational study, indeed that would make it an interventional study.

24. Research reports do not identify individual patients because there is no need to do so and because to do so would infringe their right to privacy and would, without consent, be contrary to the Data Protection Act. It is worth pointing out, however, that the current Act dates from 1998 and the previous Act came into force after the mid to late

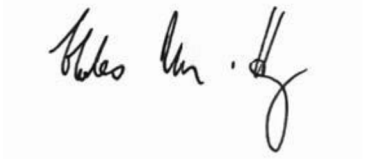
eighties. Data Protection Legislation was less well developed in the mid eighties than it is now and did not then stipulate the need for consent to use routine named observational data to produce anonymous research reports. Even now, implied consent is acceptable for this purpose.

Differences between HIV and HCV relevant to counselling are listed below: -

HIV	HCV
Incurable, even now	Curable in 40-100%
70% Mortality prior to 1995	Mortality <2% prior to 1995
Prior to 1995 expected 100% mortality	Good prognosis, slow or no progression
Treatment ineffective prior to 1995	No treatment until late eighties
Ready sexual transmission	Low infectivity
Symptomatic when advanced	Generally asymptomatic until end-stage
Causes AIDS	30% cirrhosis, eventually
	5% hepatocellular carcinoma
Uninsurable	May have an adverse effect on premium.

Declaration:

1. I understand that my overriding duty is to assist the Inquiry on matters within my expertise. I have mentioned all matters which I regard as relevant to the opinion that I have expressed. All the matters which I have expressed an opinion lie within my field of expertise. I have drawn to the attention of the court all matters of which I am aware which might adversely affect my opinion. I have indicated the source of factual information wherever I have no personal knowledge. I have not included anything in this report which has been suggested to me by anyone without forming my own, independent, view of the matter.
2. Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in my report. At the time of signing of this report, I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification. I understand that this report will be evidence that I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.
3. I confirm that I have made clear which facts and matters referred to in this report are within my own knowledge and which are not. Those that are within my own knowledge are confirmed to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which they refer.



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