Report to the Penrose Enquiry by Vivienne Nathanson

Introduction.

Medical ethics has developed over the past three decades alongside the other developments in clinical medicine. In 1979 the publication of Ian Kennedy's Reith lectures "The unmasking of medicine" had a profound impact, galvanising the movement to a more patient centred approach to medicine in which doctors did not do things to patients but with them, and in which patients were seen as partners in decisions about their investigation, management and treatment decisions. This process has taken time, and is, in many ways, still on-going. Different practitioners adapted to or adopted new ways of working at different speeds. As a generalisation older practitioners approaching retirement were often, although not always, the slowest to adopt new approaches and practices.

The UK has no central committee on health care ethics; it is rich in academic departments, but clinical advice to practising doctors comes from the BMA and, to a lesser extent, the GMC.

Medical ethics is taught in every medical school in the UK, and was at the period in question. There was then, and remains, concern about the consistency and quality of ethics teaching; it relies too often on the willingness of interested clinicians who will add the teaching of ethics to their responsibilities on teaching within a clinical discipline. In some schools there are many such interested and knowledgeable clinicians, in others far fewer. The BMA and the Institute of Medical Ethics have surveyed UK medical schools. In 1987 the IME produced the Pond Report on the teaching of medical ethics and in 1998 produced a core curriculum for ethics, to which the BMA is a signatory. A repeat IME and BMA study in 2006 demonstrated that the amount of teaching remains patchy, depending in large part upon the knowledge and enthusiasm of individual clinicians. Although it is a course requirement for there to be some teaching it is rarely a part of final examinations; and no two medical schools have the same approach to the level of teaching a student is expected to attend. In the 1970s this was certainly the case; in London most medical students got their ethics education by attending the lectures given at various schools by members of the London Medical Group.

While the BMA has had a committee on medical ethics throughout most of its history, for the last 50 years the advice it has given to members has varied widely, reflecting the ethical mores and standards of the times. In the 1974 it produced a booklet of some 50 pages which included a full reprint of the GMC rules of that time, and all the relevant ethical codes including the Declaration of Helsinki. That booklet mentioned the views of a former chair of the central ethics committee of the BMA, who between the wars stated that:

> "In the relations of the practitioner to his fellows, while certain established customs and even rules are written and must be written the principal influence to be cultivated is that of good fellowship. Most men know what is meant by 'cricket' and the spirit of the game. Difficulties and differences will arise, but most of them can be successfully met by mutual goodwill and recognition of the other fellow's point of view."[1]

In that book the only mention of consent is in relation to organ donation. Although the academic texts of the time talked about consent it was rare in the experience of doctors for their patients to question their advice, or to refuse treatment, so consent was seen to be a non-contentious issue.

By 1980 the BMA was producing a book which gave more situation-specific advice. The development of a series of three editions included advice that could be quoted to doctors seeking advice on specific clinical scenarios. The book was written by a subcommittee of the BMA's medical ethics committee, then a committee wholly of doctors. By the end of the 1980's

the books had extended and increasingly also referred to the relevant major legal cases, and increasingly gave a framework from which readers could discover their own solutions to ethical dilemmas. The advice today is far more detailed than in the 1970's, not least because the dilemmas are more complex and nuanced, in part because the relationship between patient and doctor has changed so fundamentally.

In addition the BMA has always produced specific advice sheets and guidance notes on a variety of areas. The areas on which specific advice is seen as necessary are spotted either by clusters of requests for advice or because the ethics staff observe a clinical development that might lead to ethical questions. Such guidance can be on broad issues, including how ethical constraints should apply to a new scientific development, or on the very specific ethical elements applied to individual care and the individual patient/doctor relationship.

Throughout the period under consideration the BMA has given advice to practitioners who contact its ethics advice services by telephone, letter, and increasingly by email. In 1993 it produced *Medical Ethics Today: Its philosophy and practice*[2], summarising the ethical and legal background to its advice, as well as the advice itself. In 2004 its general ethics advice book was published as the second edition of *Medical Ethics Today*[3]. This book is now over 800 pages. The latest edition goes to press in spring 2011 and amounts to around 1000 pages. The new book will be available as a free on-line resource to all BMA members; this is part of the BMA's work in reinforcing the teaching of medical ethics.

The development of advice to doctors has gone alongside an increasing dialogue with the public on the principles of medical ethics. Medicine was historically paternalistic, with doctors feeling they knew best and limiting the information given to patients or the work undertaken to help patients validly consent to medical investigation or treatment. That position was beginning to break down and be replaced by the concept of patient centred care ad patient/doctor partnership.

In 1980 the advisory book from the General Medical Council was predominantly a list of the things that might give rise to a charge of serious professional misconduct. Today the GMC produces *Good Medical Practice* and a series of other guidance on specific areas of clinical practice. The aim is to give practitioners more advice about what is good practice. Three of the current specific advice booklets are on consent, confidentiality and on end of life care.

In the 1980s the GMC advice was written by its committee on standards and ethics. They were beginning to consider advice on what constituted good practice rather than just what was bad practice. Staff members would prepare papers for the consideration of the committee, who would then effectively rewrite or edit depending upon the agreed views of the committee.

In 1987 the Committee on Standards and Ethics was considering the advice the GMC would give on testing for HIV, and treating patients. Debate in the committee included consideration of the benefits of routine testing without patient consent in prevention of cross infection of health care personnel, as well as the general ethical constraint that nothing should be done to patients without their consent.

Advice from the GMC has not changed in the intervening period, with the exception that its general advice on consent has evolved to further develop the advice on patient autonomy. The GMC now produces more advice to doctors on what constitutes good practice, rather than just a list of the major offences that could lead to disciplinary action. .

Medical ethics is recognised as a balance between different principles, rights and values. While there are no absolutes most commentators would agree that concepts of patient autonomy have risen in importance over the last two decades. Against measures of respect for such

autonomy are counterbalances such as protecting the public health or the health, safety and wellbeing of others. This gives, for example, an ethical justification for sharing information to protect others, such as telling the DVLA of someone who continues to drive against medical advice, or informing the sexual contacts of an individual of their infection with a sexually transmissible agent. In every case where a breach of confidentiality is being considered doctors will first encourage and attempt to persuade the patient to disclose on a voluntary basis. If the patient does not agree to disclose the doctor will tell them that s/he may disclose without consent. Such breaches of confidentiality must be necessary and proportionate; that is the amount of information shared must be as little as possible, the risk to others considerable, and the number of people with whom the information is shared must be as few as possible, and they must be those able to take the necessary action to reduce risk to others.

The period in question in this case is of particular interest as it represents a period of significant change in terms of medical ethics, of transition from a paternalistic pattern to one of increasing recognition of patient autonomy and patient partnership.

1. What is the current approach to consent to treatment? In particular what information should a clinician provide to his/her patients about the risk of a particular kind of treatment? Is there a difference between drug treatment and invasive treatment such as surgery? What is the current GMC guidance on this point?

In general the UK, unlike the USA, does not have a legal requirement for treatment to require fully informed consent. Ethics advice for 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. What is "sufficient" is not a simple metric and will vary from patient to patient, depending upon what the patient wants to know as well as what the major risks, benefits and alternatives are. These factors themselves vary between patients facing the same decision.

The requirement to have the necessary information is referred to in documents from the eighteenth century.

In 1767 before the use of anaesthesia it was thought

> "reasonable that a patient should be told what is about to be done to him, that he may take courage and put himself in such a situation as to enable him to undergo the operation."[4]

The right to say no to the suggested treatment is an essential element of free and valid consent. Clearly if the consequences of the decision might be significant, or even life-threatening, then that information should be made available. This was described in the BMA publication *Medical Ethics Today; Its philosophy and practice* (1993) in the following terms:-

> "As a prerequisite to choosing treatment, patients have the right to receive information from doctors and to discuss the benefits and risks of appropriate treatment options."[5]

Those seeking to help the patient make his/her choice must help the patient make their choice by offering information in a way that ensures the patient understands the relevance of the information to their decision, and feels able to ask questions. The skilled practitioner will work with the patient to find out what the patient would consider important and to form a relationship which helps the patient to see that this individual discussion is part of a process and is not their only opportunity to make a decision.

There is no ethical or legal requirement on a patient to know anything before making his/her decision about treatment. While the vast majority of patients want to know the major factors that can affect their treatment decision, including likely side effects, contraindications and alternative treatments, a few will opt not to know. Provided these patients are encouraged to learn more, and it is clear that they understand that they can at any stage receive more information, a patient asking the doctor to decide for them is giving valid consent. It is equally clear that a patient being told by his/her doctor that something is the only option, and being denied access to information about the treatment, can not give valid consent.

If patients are unconscious or otherwise unable to make a decision, and where the treatment decision is urgent and essential, doctors can start treatment in the absence of consent, unless a legal proxy has been appointed to provide authorisation. In these cases the doctor must explain what was done, and why, to the patient as soon as the patients condition allows. In 1993 this was described in the following terms.

> "In an emergency, however, the doctor should not exceed the treatments necessary to sustain life and health."[6]

In emergencies the doctor can do whatever is necessary to preserve the life of the patient; no consent is necessary. When a patient is unconscious or otherwise cognitively impaired and unable to give consent but the situation is not an emergency then a proxy decision maker may be needed.

In sharing information with the patient the doctor must him/herself first be clear what the options are. Increasingly, good practice is that consent is sought by the most experienced member of the health care team, who have the knowledge not only to answer all questions but to ensure that the patient is offered all the most important facts. Medical students and young doctors learn about the process of making a treatment plan with the patient by observation as well as from theory.

Today the General Medical Council produces a booklet on consent supplementing its basic guidance *Good Medical Practice*[7]. This booklet is called *Consent: patients and doctors making decisions together*[8] which itself established the basic premise. It describes the basic model of consent in the following way:

(a) "the doctor and patient make an assessment of the patient's condition taking into account the patient's medical history, views, experience and knowledge.

(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 options 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.

(c) The patient weighs up the potential benefits, risks, and burdens of the various options as well as any non-clinical issues that are relevant to them. The patient decides whether to accept any of the options and, if so, which one. They also have the right to accept or refuse an option for a reason that may seem irrational to the doctor, or for any reason at all.

(d) If the patient asks for a treatment that the doctor considers would not be of overall benefit to them, the doctor should discuss the issues with the patient and explore the reasons for their request. If, after discussion, the doctor still considers that the treatment would not be of overall benefit to the patient, they do not have to provide the treatment. But they should explain their reasons to the patient, and

explain any other options that are available, including the option to seek a second opinion."

There is no difference between different types of treatment, including between surgery and drug treatment, with the exception that certain irreversible treatments are held to require a higher that usual level of proof of the patient's understanding. Examples of such treatment are psychosurgery and sterilisation, because of the irreversible nature of the treatments.

In modern medical treatment prescriptions for drug treatment available to patients outside the hospital setting lead to the dispensing of drugs with associated medical information sheets. While such sheets can be available to hospital in-patients they are not routinely offered in these circumstances.

2. What was the equivalent approach to consent to treatment between 1974 and 1990? In particular what information would a clinician have been expected to provide to his/her patients about the risk of a particular kind of treatment? What was the GMC guidance during this period and how did it evolve?

Following the Nuremberg trials legal rules on medical research were put in place. While these were not then well known to doctors throughout the world the following was the first explicit modern statement of the right of every patient to consent to, and hence also to refuse, any medical treatment.

> *Nuremberg Code Rule 1*
> "the person involved should have the legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the subject matter involved as to enable him to make an understanding and enlightened decision." [9]

In 1974 the BMA published a brief ethics booklet which reflected the attitudes of doctors and patients. Much is concerned with the rules, regulations and restrictions upon those establishing a medical practice. There is no section on consent to treatment; it was inconceivable to patients or doctors that the former would ignore the advice of the latter, or indeed decide to refuse medical treatment.

In 1981 the World Medical Association adopted a statement on the rights of the patient, known as the *Declaration of Lisbon*. Amongst other things it states that;

> "(c) The patient has the right to accept or refuse treatment after receiving adequate information."[10]

In 1974 a paternalistic approach to medicine was commonplace. In this approach many doctors would have told patients what they intended to do as treatment rather than offering them information and enabling them to make choices. By 1990 that approach was rarer. Between those dates doctors adopted the patient-centred and patient-empowered approach at a variety of rates; different doctors would exhibit very variable approaches. It is, however, reasonable to say that the changing approach became increasingly common with time.

In terms of BMA advice to doctors this is reflected by an evolution in the language as follows. In 1980 we stated that;

> "The patient's trust that his consent to treatment will not be misused is an essential part of his relationship with his doctor."[11]

By 1988 the equivalent passage started;

> "The basis of 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."[12]

By 1993 the advice was as cited above; clearly there was increasing comfort is using formal ethics language and concepts in describing the basic principle.

All these quotes show that there was an understanding throughout this period that consent was important, required the patient to make a free and sufficiently informed decision, and that doctors could do nothing to a conscious and competent patient without consent.

The development in information giving came at a time when the amount of information available to practitioners was starting to increase substantially. General developments in medicine and in the research and evidence base of investigations and treatment made predictions about outcomes more evidence based. At the same time there was a very substantial increase in the treatment options available, both because of the development of new therapeutic agents and also because of the developments within surgery of new techniques, and also the development of new anaesthetic agents allowing safe anaesthetics to people with increasingly complex pre-surgical medical problems.

During this period Lord Scarman in the Sidaway case gave legal clarity about the application of consent.

> "If one considers the scope of the doctor's duty by beginning with the right of the patient to make his own decision whether he will or will not undergo the treatment proposed, the right to be informed of significant risk and the doctor's corresponding duty are easy to understand; for the proper implementation of the right requires that the doctor be under a duty to inform his patient of the material risks inherent in the treatment." [13]

This demonstrates a gradual change in emphasis about the process of gaining consent, against a recognition that all treatment requires consent.

3. What is the current approach to testing for diseases such as HIV and Hepatitis C? in particular what information should a clinician provide to his/her patients about the diseases which is being tested for and the implications of a positive diagnosis? What is the current GMC guidance on this point?

As with consent to treatment the current approach expects clinicians to offer full information to patients about all tests.

It should be recognised that the purpose of medical testing is to make a diagnosis from a list of differential possibilities. Tests can be diagnostic in and of themselves or they may contribute to a pattern of signs that lead to a specific diagnosis.

The General Medical Council advice on consent cited above applies to testing as much as it does to treatment decisions.

The clear advice from the BMA, as stated in the former GMC specific advice on HIV and AIDS, is that testing requires specific consent. HIV/AIDS is now considered a mainstream condition with a great reduction in the social stigma previously associated with a diagnosis. But the GMC remains clear that all tests and treatment require consent, and the more complex or significant the implications of a test result, the more pre-test "counselling" or discussion is required. The implications for other testing and treatment were often the subject of questions to those lecturing on ethics with doctors wanting to explore how to establish which information should be shared with patients before other types of tests.

4. What was the approach to testing for HIV between 1984 and 1990? 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 GMC guidance on this point and how did it evolve? Were there any circumstances in which a named sample from a patient could appropriately have been tested without the patient's consent?

Behind the discussion of communication of the results is an important concern about consent to testing. Put simply testing requires consent, and the concept of necessarily implied consent cannot be held to apply to testing for HIV.

> "Such implied consent can only be held to apply to the procedure in hand and not necessarily to subsequent treatments which flow from it."[14]

If patients are aware that they are routinely and regularly being tested for a panel of infections, for example blood borne viruses, it was certainly arguable that testing for hepatitis C was no different from other such routine tests. Many would then have considered testing for HIV in the same way, given that there was at the beginning of the period considerable doubt as to its nature, transmissibility, and relevance to the newly emerging medical condition of acquired immune deficiency.

When the first diagnostic test for HIV disease (in fact a test for antibodies for what was then called HTLV III) became available in 1984 there was considerable debate over whether those for whom a test might be considered clinically relevant needed to be asked to consent to the test. The attitude to testing changed over a brief period, reflecting the fact that it was rapidly seen to be clinically relevant, that there was emerging evidence on cross infection/transmission of the virus and very soon the first treatment options. This made the test not simply academically of interest but relevant to the clinical management of the patient, and the protection of others.

In the early days of testing many believed that tests could and should be carried out without consent, and that taking blood for the test at the same time as other routine medical tests would mean that necessarily implied consent had been given. Some doctors felt that health care practitioners should be able to test all patients, to ensure that treating health care staff knew the HIV status of every patient. In doing so they were contemplating breaching existing ethical advice, and often basing that decision on a misunderstanding of the nature of HIV infection and the test for HIV antibodies.

Arguments against this approach made it clear that the law would be likely to reject it, not least because the test was not "standard" or routine at that time. Ethical arguments were less persuasive; the advice published by the GMC in 1988 helped to close the argument. The GMC emphasised not only the legal and ethical arguments but the unusual nature of the test, in particular the social and financial implications of a positive test result. That advice followed

discussions within the GMC's committee on standards and ethics, and reflected the questions that were being asked about testing and treating patients with HIV/AIDS.

The lack of knowledge of HIV at this time led the BMA to establish a charity, the BMA Foundation for AIDS, and through that body to produce a short series of videos designed to help General Practitioners see how to counsel patients before testing for HIV about the issues they should consider in making their decision.

In 1993 there was still sufficient currency for a freedom to test without consent that the BMA included the following in its book *Medical Ethics Today*;

> "Even nowadays doctors are often reluctant to mention medicine's ubiquitous uncertainties and arguments are made for restricting information in certain circumstances on the grounds that autonomy is not the only ethical imperative. It is sometimes argued that an exaggerated regard for this single ethical principle puts at risk the whole concept of the doctor-patient relationship."[15]

> "it is sometimes argued that doctor should be able to carry out procedures they consider to be appropriate without specifically informing the patient, thus sparing the patient anxiety..... . "The Association does not consider it appropriate to carry out HIV-testing, for example, without patient consent."[16]

The approach to medical testing underwent the same sea change as consent to treatment. It is notable that this happened universally in large part due to the debate on testing for HIV.

5. What is the approach to communicating the results of a test for a disease such as HIV or results which suggest that a patient has a terminal disease? What is the current GMC guidance on this point?

While patients have an absolute right to know information about them that does not mean that doctors should simply hand over the information, including test results. There is a counterbalancing ethical requirement on doctors to ensure that the information is given to or shared with the patient in an appropriate way. This means that the information must be contextualised, and the doctor sharing the information is expected to also share information about what this information means to the patient and what will be done with the result. In practical terms this means telling the patient where this places him/her in terms of a differential diagnosis, and what further tests are necessary, or what treatment now seems to be indicated. In the early days of testing for HIV this placed doctors in a very difficult position as there was limited evidence on available treatment, and what evidence existed suggested a short and invariably fatal illness for some and uncertainty about the percentage of antibody–positive patients who would go on to develop a clinical illness.

As with earlier in the process this does not mean that doctors must force patients to hear the results, whether they indicate a terminal illness or not, but that the practitioner should use his/her communication skills to help the patient understand the implications and to agree with the patient a plan of action. The treatment and care plan may not always be aiming for a cure, but for management of the medical condition and of the patient's symptoms. Part of developing that plan is developing an understanding of the patient, and his/her preferences in terms of treatment and symptom control. In terminal illness, for example, pain control is of absolute importance to some patients whilst others prefer to be alert and aware for as long as possible, even when this means tolerating some pain.

Families of competent adult patients have no right to know the diagnosis. It is clearly normally in the interest of the patient for their family to know; doctors work with patients to help them

understand the benefits of sharing their diagnosis with others, especially their closest family members, and often communicate the information on behalf of the patient. Occasionally patients refuse to tell anyone else the diagnosis and doctors cannot force them to share the information.

Guidance from the GMC emphasises the importance of seeking to persuade the patient to understand enough to be an active participant or partner in decision making.

In its current guidance on consent the GMC states

"You must give patients the information they want or need about:

(a) the diagnosis and prognosis
(b) any uncertainties about the diagnosis or prognosis, including options for further investigations
(c) options for treating or managing the condition, including the option not to treat
(d) the purpose of any proposed investigation or treatment and what it will involve
(e) the potential benefits, risks and burdens, and the likelihood of success, for each option; this should include information, if available, about whether the benefits or risks are affected by which organisation or doctor is chosen to care
(f) whether a proposed investigation or treatment is part of a research programme or is an innovative treatment designed specifically for their benefit
(g) the people who will be mainly responsible for and involved in their care, what their roles are, and to what extent students may be involved
(h) their right to refuse to take part in research
(i) their right to seek a second opinion
(j) any bills they will have to pay
(k) any conflicts of interest that you, or your organisation, may have
(l) any treatments that you believe have greater potential benefit for the patient than those you or your organisation can offer."

This, especially paragraphs (a) to (e), make it clear that there are no limits to the information you should be prepared to make available.

In terms of communicating information of particular sensitivity or which might be especially distressing it is clear that doctors are expected to do this carefully, empathetically and openly. In medical education the communication of bad news is usually dealt with as a specific part of education in communication skills. Not only do medical students and young doctors practice in role play, often with actors playing the role of patients, but they are taught to review their communication critically.

It is well known that when individuals are told difficult or bad news they may not remember the conversation, and are unlikely to remember in full the detail. Research has shown that patients may deny ever discussing critical factors, and be astonished when shown a video-recording of the interview in which not only were they told the information but engaged in some discussion about its implications. Understanding this has led doctors to increasingly routinely check the understanding and memory of the patient, and to support the discussion with information sheets and suggestions for further reading. In addition doctors will reinforce the point that this is just one opportunity for discussion and the patient will be encouraged to ask questions at further meetings.

6. What was the correct approach to communicating the results of a diagnosis of HIV between 1984 and 1990 what was the GMC guidance on this point? How did that guidance evolve?

In its 1988 guidance the GMC states that

"The Council takes the view that any doctor who discovers that a patient is HIV positive or suffering from AIDS has a duty to discuss these matters fully with the patient."

At that time the GMC did not go into the level of detail that is in current guidance, but the use of the phrase "a duty to discuss these matters fully.." makes it clear that the intent is the same.

It is important to remember that at that time the majority of doctors in clinical practice in the UK had never seen a patient who was HIV positive or who had AIDS. The spread of the virus was limited, not least because of an effective public health campaign and significant behaviour change within certain high risk communities. Doctors in London and certain other cities might have case clusters, but HIV remained a relatively rare condition. Doctors in Genito-Urinary Medicine and some infectious diseases specialists gained the highest levels of knowledge and experience in managing the condition and in communicating test results with patients. Doctors treating patients with haemophilia gained comparable experience.

In the late 1970's many doctors did not tell patients the whole truth, especially where that truth was of a diagnosis of an incurable illness. This was the well intentioned legacy of Thomas Percival's influential text on medical ethics.[17] The intent was to shield patients from disturbing information. The duty of beneficence was interpreted as an obligation to be reassuring rather than honest. But many doctors had begun to move away from this benign paternalism to a more equal relationship with patients.

Following the 1979 Reith lectures by Ian Kennedy[18] doctors had begun to recognise the paternalistic nature of medicine and its impact on their relationships with patients and with society. Even benign paternalism was seen often to be less than benign. Many, but not all, doctors were increasingly thinking more about how to communicate better with patients and to shed the paternalistic stance. As stated earlier this movement took some considerable time.

It is true that at the beginning of the period in question doctors might first speak to the patient's family and tell them the truth, especially about diagnoses of terminal illness. Patients were often denied the truth, frequently because families agreed with doctors, and with Percival, that the truth would be intolerable to them. Families worried that patients would "turn their faces to the wall", give up and die, because of the diagnosis. Practice was beginning to change with many doctors becoming increasingly comfortable with communicating bad news, and recognising that it was the patient who decided whether or not their family should be told.

7. What is the current ethical position in relation to the use of patient information in medical studies and reports in medical journals? Does a doctor require to obtain a patient's consent before including a patient's medical data in a study?

Involvement of patients in research is covered by the *Declaration of Helsinki* from the World Medical Association. The document was first produced in 1964 as a way of communicating research ethics standards to doctors in a manner which would make more sense to doctors than the Nuremberg Code. It is based upon medical ethics rather than a legal definition of patients' rights. The current version is the 2008 revision. At clause 24 it states inter alia;

> "In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of he study and the discomfort it may entail, and any other relevant

> aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. ...."

Given that all research requires patient consent it follows that the process of sharing information with the patient for the purpose of getting valid consent will include permission for the publication of the results, in a manner that, as far as possible guarantees the anonymity of the patient.

If the information used is anonymised before use it follows that it will remain anonymous at the time of publication and may be used without specific consent. This applies to epidemiological studies. Best practice gives the information to all patients that their anonymised information might be used in research, and thus an opportunity to opt out of even this level of involvement in research.

Where data is extracted from the files of a limited number of patients, where the researchers know the identity of the research subjects, and especially if they are a small, defined and potentially identifiable group, the researcher is obliged to obtain the consent of the patient to the inclusion of their data in the research. The GMC considers such cases in its supplementary guidance on research ethics and makes it clear that identifiable data requires either patient consent or, where that cannot be obtained, a separate independent permission to use such data.

There is a separate point about the use of material obtained for one purpose (the clinical care of the patient) then being used for research. The ethics advice on this is explicit that this is unacceptable.

> ".... Patients should be specifically informed when material excised during the course of investigation or treatment is to be used for any purpose, including research or commercial development. The wishes of patients who object for cultural, religious or other reasons should be respected."[19]

Regardless of its nature all research requires clearance by a local research ethics committee. Today there are standard rules and formats for such committees; in the 1970's they were essentially voluntary groups of varying structure. Their role remains the same; to ensure that the research protocol conforms with ethical standards and norms, including in its approach to consent and confidentiality.

Today none of the major medical journals will publish medical research without confirmation that the research has appropriate research ethical clearance. Reputable journals, such as the BMJ, will not normally accept non-research case histories, even anonymised, if the patient has not consented to publication.[20]

8. What was the ethical position in relation to the use of patient information in medical studies and reports in medical journals in the period between 1984 and 1990? Did a doctor require to obtain a patient's consent before including medical data about them in a study?

Advice on human experimentation was available to doctors in the *Nuremberg Code* and in the World Medical Association's *Declaration of Helsinki*, first published in 1964. This last has been amended a number of times, initially to include new areas of concern and more recently to rewrite in more modern terms.

Participation in research has always required the consent of the patient. In our 1993 book the BMA advised;

> "Research brings the risk of causing harm, in the practical sense of possibly damaging or disadvantaging a patient, and of doing wrong, in the moral sense of ignoring the autonomy of that individual. People are wronged if they are deprived of choice or their values are transgressed on the assumption that the best clinical outcome is necessarily what is best for them."[21]

Although the Declaration of Helsinki[22] was designed to manage research that involved direct interventions upon the patient it applies equally to all research on human subjects. This is evidenced by the quote below from clause 9. It is clear that any research requires consent, and does not state that, for example, only research that involves physical risk or discomfort requires consent. There is no countervailing ethical code or declaration of which I am aware, although it is clear that research involving no interventions to the patient was often seen at this time as not requiring consent. Thus research that involved, for example, the use of stored blood or tissue samples, and arguably not directly involving the patient, might have been performed without such consent, contrary to the spirit of the Declaration. Throughout the development of BMA advice on ethics the Declaration of Helsinki has been the touchstone of good practice. The 1983 version, reprinted in the BMA's 1988 ethics text, deals with the ethics of recruitment of research subjects in a number of clauses. Amongst others clause 9 identifies the importance of gaining consent to be involved in trials.

> "In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing."

The Declaration also included at clause 8 the following:

> "In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in the Declaration should not be accepted for publication."

Given that the Declaration stresses the essential nature of consent to participate in research it follows that publication should not occur if the research participants did not give consent, but in practice this was not always implemented on the grounds that the information was in the public interest.

There was then, and remains, an exception to the requirement for consent which relates to epidemiological research on anonymised information. In these cases research subjects may not know that their data is being used. Where data is either readily identifiable or where the source data is named data the consent of the patient is required.

9. What is the duty of a treating doctor with regard to keeping a record of a patient's medical condition and treatment? In particular what information about treatment and diagnosis should be kept on a record by a treating clinician? Are there any circumstances in which a doctor can legitimately fail to record that a patient has been diagnosed with an infectious disease such as HIV?

Doctors have an ethical and a legal duty to keep records that are fit for purpose. Given that the purpose of medical records is to ensure the safe and effective treatment of patients it is clear

that failing to record significant information, if the doctor is aware of it, would breach good ethical practice. As far as I am aware there has never been a detailed analysis of what must and what need not be stored in the record. It should be noted that some patients do not agree to their doctor knowing the results of an HIV test obtained in a different healthcare setting.

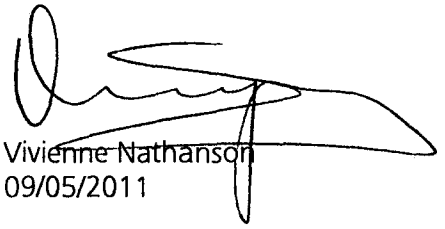
As we move into an era where medical records will increasingly be written and stored electronically the separation out of information which the patient feels is especially sensitive becomes possible using so-called "sealed envelopes" within the electronic record. This will be information which the patient does not want to be seen by those health care professionals who have routine access to his/her medical records. But there can be no question of information not being recorded.

Doctors have an obligation to record any information that they know or believe to be true; where this is reported information they may well record that fact as well. There is often then a negotiation with the patient about the manner in which it is recorded.

10. What was a treating clinician's duty with regard to keeping a record of a patient's medical condition and treatment between 1984 and 1990? At that time were there any circumstances in which a doctor could legitimately fail to record that a patient had been diagnosed with HIV?

The requirement to keep records that are sufficiently detailed for therapeutic purposes has always existed, although it is not referred to specifically in historical ethical codes. Given that they require doctors to practise conscientiously and to do their best for each patient, there is an implied duty to maintain accurate and detailed medical records, as without such records the quality of care is threatened.

Doctors have always faced requests from patients not to record information that the patient believes to be sensitive, so that others legitimately accessing their records will not see that information. For some patients sensitive information will relate to mental health, for others sexually transmitted diseases. Other patients are especially sensitive about information about family members which impact upon their own health.



Vivienne Nathanson
09/05/2011

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