

CONSENT IN CARDIOLOGY: THERE MAY BE TROUBLE AHEAD?

Nick Curzen, Sally Smith

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The number of invasive investigations and therapeutic procedures undertaken by cardiologists across the UK is expanding rapidly. The speciality has seen major advances in the technological armoury that can be deployed to investigate and treat our patients, and our awareness of the need to maintain high standards of clinical training and expertise is generally robust. Furthermore, the evidence base expands and provides us with a mandate to investigate and intervene in ever increasing numbers of clinical settings. Despite all of this, cardiologists receive no formal training in the process of consent. In addition, few consultants personally obtain consent from their patients for the majority of the procedures that they are responsible for. In fact, it is often the case that the patients who are at the very highest end of the risk spectrum, by virtue of their need for emergency treatment (cardiogenic shock or rescue angioplasty, for example), are consented by the most junior members of the medical team.

▶ CONSENT: TWO ASPECTS

Consent is a process that can be seen to consist of two intertwined agenda. First, there is the clinical priority to provide the patients (and often their relatives) with an adequate amount of information about the proposed procedure so that they are in a position to make an informed decision as to whether they want to go ahead with it. Fundamental to this is that they understand the procedure itself and the risks that are associated with it, as well as the options that are available apart from that particular choice. Done properly this has the potential to be a time consuming process. How do we know that we have done it “properly”? How can we be sure that what has been said to or read by the patient has been understood?

The second aspect of consent is the increasing need to protect ourselves from the potential for complaint or legal action in the event of an actual or perceived problem arising from the procedure. Are we taking appropriate measures to ensure that we have minimised the risk that such complaint is upheld? However unpalatable this concept may seem, it lurks in the background of every case in modern healthcare delivery. Does the patient’s signature on the consent form act as a receipt for the cardiologist to confirm that everything was done to truly inform the patient?

It is against this background that our aim in this paper is to explore the medicolegal boundaries within which we work. In a series of carefully constructed clinical scenarios, all of which are derived from real life clinical practice, there will be an analysis of the case from the expert legal standpoint. Two typefaces are used throughout: one from the “medical” author and the italicised from the “legal” author.

In considering these scenarios, a number of general matters are relevant:

- ▶ There is no difference in law between seeking the patient’s consent for cardiological procedures and for any other form of medical procedure. However, it is always striking that cardiological procedures attract an unusual degree of jargon. To the initiated jargon very quickly becomes everyday language and it is easy to forget how incomprehensible it may seem to the patient. Obtaining consent to a procedure entails making every effort to explain clearly all the terms which are used both in the doctor’s explanation and in the consent form. Particular care should be taken to use terminology consistently. The initiated frequently use different technical words which mean the same thing without realising the confusion that can cause.
- ▶ While it is helpful, as we have sought to do, to analyse the correct approach to theoretical scenarios, the reality is that the obtaining of consent must always be tailored to the individual requirements of the patient. The risk: benefit analysis of the procedure is different depending on the medical circumstances of the patient; but it must also be borne in mind that even the two patients with identical medical circumstances, and hence where the risk: benefit analysis is also identical, have to have information imparted in a way which is appropriate to their individual social, intellectual, and emotional needs.
- ▶ There is no substitute for accurate (which need not mean lengthy and time consuming) note keeping of the content of the consenting consultation. The fact of the existence of a signed

See end of article for authors’ affiliations

Correspondence to:
Dr Nick Curzen, Wessex
Cardiac Unit, Southampton
University Hospital,
Southampton SO16 6YD, UK;
nick.curzen@suht.swest.nhs.uk

consent form specifying simply the nature of the procedure, though a good starting point, is on its own insufficient evidence of appropriately informed consent having been given. Of course the more detailed the information on the form the stronger the evidence that the patient was properly informed.

A doctor should always have in mind not only the basic requirements of the law relating to consent but also the guidance documents published by the General Medical Council, since both legal requirements and professional practice requirements must be adhered to. The former provides the basic position but the latter frequently adds a gloss to the standard with which a doctor must comply.

CASE 1

A 54 year old businessman is referred from a non-interventional cardiologist to an interventional cardiologist for angioplasty following a diagnostic cardiac catheter. Upon reviewing the films, the interventionist is comfortable that there is a long segment of important stenosis in the dominant right coronary artery that would be amenable to percutaneous coronary intervention (PCI), but is also concerned that there is an important ostial stenosis of the left anterior descending (LAD) coronary artery that is not clearly visualised on the diagnostic film (that does not contain a left anterior oblique (LAO) caudal view). The interventionist arranges to meet the patient in a preadmission clinic and explains to him that more information is required about one of the coronaries before he is happy to commit to PCI and stenting. The patient is therefore consented for "coronary angiogram \pm coronary stenting" and signs the form. Four weeks later, the patient is admitted for the elective procedure and upon taking more detailed pictures (including a steep LAO caudal view) the cardiologist demonstrates, as suspected, a tight ostial LAD lesion. He recommends to the patient that he may be better off having coronary bypass graft (CABG) surgery and does not proceed to angioplasty. Later on in the afternoon, the consultant is called by the ward because the patient and his wife are angry that no PCI was undertaken. The consultant is in a meeting outside the hospital, so a registrar is asked to go and explain the management plan again. A referral is subsequently dictated to a cardiac surgeon as an outpatient.

Two months later, the trust received a formal complaint, written by the patient's solicitor, claiming that he was "shocked" that the PCI did not go ahead and that he was not made properly aware that this was a possibility.

This scenario arises quite simply from a misunderstanding; the patient should have been told clearly that the angiogram was a test to enable the doctor to decide whether or not to go onto an angioplasty, what information the test would provide to enable that further decision to be made, and upon what criteria the further decision would be made. He should have been told of the benefits and risks of each of the procedures and should have been asked to consider and consent to each. If that exercise is undertaken he should clearly understand that he may, or may not, undergo an angioplasty. The consent form was in appropriate terms and suggests he was told all he should be, provided of course that the terms "angiogram" and "stenting" were explained before signing and he was told that the "plus or minus" was put there to reflect the uncertainty of the ultimate nature of the procedure he was to undergo. In circumstances where he subsequently complains, he must have misunderstood. Is that the doctor's fault? The law imposes an obligation on the doctor to disclose the information in a reasonably comprehensible way; he

should take reasonable care to ensure his explanation is intelligible to his patient. However, intelligibility means that the information is in a form capable of being understood; it is not critical that the patient does understand. Provided the doctor has given clear information, which must of course be tailored to the social, emotional, and intellectual abilities of the patient, insofar as it is reasonably possible for the doctor to judge them, it will not be his fault if the patient misunderstands. Having said that, this question is a good example of the dangerous use of interchangeable terms; remember the patient will not know that in this context "PCI" means the same as angioplasty and/or stenting. It is unfortunate that when the patient first became aggrieved a registrar had to be called to explain the management plan again; it would have been preferable for that explanation to be given by the consultant who had performed the procedure as that might have averted the subsequent solicitor's letter. In the circumstances as they arose, another meeting with the consultant to underline the registrar's explanation would be ideal.

CASE 2

A 43 year old patient from an inner city estate is referred by a colleague to an interventionist for a stent to his dominant circumflex artery. He has a clear history of angina and an abnormal exercise test. He is unemployed but previously had worked as a bus driver. At preadmission clinic, the patient makes it explicitly clear that he does not want to know how an angioplasty is performed or what the risks of the procedure are. He is happy to sign a consent form containing a list of potential complications without reading it. "You just do what you gotta do, doc," he says. If the procedure goes wrong in some way, the nurse practitioner and consultant are concerned that he has not provided truly informed consent.

This raises some difficult questions though in practice I suspect it is not an uncommon scenario. The usual process of obtaining agreement to a medical procedure entails the giving of sufficient information to enable the patient to come to a valid decision, the decision (usually but not essentially) being evidenced by his signed consent. If the patient chooses to agree to the procedure without sufficient information then it could be argued that there is no reason why he should not do so but such a choice has somewhat alarming implications for both patient and doctor. Insofar as the patient is concerned, he may say he does not want to know what the complications are but if he did know them they might change his decision and if they ultimately materialise he may well, retrospectively, feel that his decision would have been different and feel aggrieved accordingly. Insofar as the doctor is concerned, on the one hand it may be felt to be at worst potentially psychologically harmful and at best simply unkind to force information on someone who doesn't want it; on the other hand he will be performing a procedure with a known and possibly unpleasant risk which is completely unknown to the patient, which will be a very nasty shock if it materialises and may lead to suggestions that the procedure was performed without consent.

The doctor must deal with this dilemma in a way that is both sensitive to the patient and protective of himself. He should firstly make every attempt to encourage the patient to listen to the essential information as to risks; how gently and how much information he tries to provide obviously depends on his perception of the sensibilities of the patient, on the gravity of the possible complication, and the probability of the risk materialising. Properly handled, the next stage should not be reached, but if the patient is adamant in his refusal to receive information the doctor must decide whether it is nonetheless appropriate to go ahead; if the procedure is an elective one and the risks were grave and great he would be entitled to tell the patient that he could not undertake it unless he was satisfied the patient

understood them. If exceptionally he does decide to undertake it he should still provide basic information about the treatment and he should write a precise note (either in the records or on the consent form) indicating the stance taken by the patient, his attempts to dissuade him from that stance, and his reasons for nonetheless going ahead and ask the patient to sign it.

CASE 3

A 76 year old female patient with failed thrombolysis is sent to a revascularisation centre in an ambulance as an emergency for rescue angioplasty. When she arrives the on call consultant is in the lab performing an angioplasty on a different patient. The patient is seen and clerked by a senior house officer (SHO) in the catheter lab as follows: "angiogram ± stent ± CABG". An angiogram is then taken by a registrar who then calls the consultant in to supervise the subsequent intervention. The consultant assists at the angioplasty but unfortunately this is associated with poor flow at the end and the patient completes a sizeable infarct. She goes up to the cardiac care unit and 24 hours later dies of myocardial rupture. The family complains that the patient never met the consultant or realised the risks that were being taken. They claim that she did not know what "stent" or "CABG" meant.

No patient can be properly consented by a doctor who does not himself have understanding and experience of the procedure to be undertaken; in law, his seniority is not material save insofar as that reflects on his understanding. Equally in law it is not essential that the doctor who is performing the procedure does the consulting though again he may be the one who understands it best. In practice, however, the General Medical Council guidelines make it clear that it is the doctor performing the procedure who is responsible for the discussion and the obtaining of consent or, if that is not practicable, for its delegation to someone suitably qualified with sufficient knowledge of the investigation to understand it and who does it appropriately. The doctor performing the procedure remains responsible for ensuring the patient is able to give a valid consent. In the example given, an SHO is unlikely to be sufficiently senior to undertake the consenting task appropriately and if the consultant was unavailable, the registrar is likely to be more suitable. In any event the ultimate responsibility remains with the consultant.

CASE 4

A 56 year old man is brought to accident and emergency department following an out-of-hospital cardiac arrest. He was resuscitated several times, first by a passer-by and then by the ambulance crew who needed to shock him out of ventricular fibrillation twice. On arrival he was haemodynamically stable but complaining of severe cardiac chest pain and had 12 mm ST elevation across the chest leads. Urgent arrangements were made for him to go to the catheter lab and he was given a total of 10 mg diamorphine to relieve his pain. On arrival at the lab his conscious level was reduced and, although he signed a consent form, it is clear that, because of his medical treatment, he is not able to understand what he is signing. The consultant and catheter lab staff are concerned that the consent is meaningless.

This scenario is one to which the principle of necessity would apply—that is, treatment given to meet an emergency may be given even though the patient is unable to consent to it. It should be confined to procedures that it would be unreasonable to delay because of the inherent danger to the life or health of the patient. If relatives are present, it is prudent to ensure that they understand what is being

done; although they cannot give consent to treatment on behalf of an adult, their understanding may nonetheless avert complaints later.

CASE 5

A patient is seen in a specially designed preadmission clinic to prepare for a routine angioplasty. He is consented by a cardiology registrar in the clinic but when the patient arrives, as planned, four weeks later for the procedure, the sister on the ward says that it is trust policy that the consent must be re-done because the original is no longer valid.

As stated above, the process of consenting is one in which what is important is not the form but the substance, and the fact of obtaining a signed consent form is not adequate if the full consenting process has not been gone through. There is nothing inherently wrong in taking consent, either oral or written or both, in a clinic in advance of the procedure taking place and of course there are some advantages to it in that a specially designated clinic will provide more time for the patient's questions. However, the problem is that if the time lapse between the taking of the consent and the carrying out of the procedure is significant (as, given some waiting lists, it may well be) there is a danger that the patient will not recall in detail what he was told and also that his circumstances may change such that the information he should have been given would be different. If, as in this case, the time lapse is a short one, the danger may be less but nevertheless the trust's precaution is a wise one. There is no reason why the day of procedure should not form the second part of a two part procedure. At the original clinic consultation, a careful note should be made of the information given to the patient. Before the procedure is carried out, a check should be made to ensure there is no change in circumstances and that the basic information as to risk: benefit has been understood and the form can be signed at this stage.

CASE 6

A 50 year old solicitor with stable angina and a positive exercise test is admitted for a coronary angiogram with a view to proceeding to angioplasty. The consent states "coronary angiogram with a view to proceeding to coronary angioplasty and stent". Included in the listed risks are "femoral haematoma, death, stroke, heart attack, emergency CABG, stent thrombosis, restenosis". During the procedure, the interventionist finds a tight stenosis in a dominant right coronary artery. The vessel is subsequently treated by direct stenting. Unfortunately the stent does not look fully expanded, so a non-compliant balloon, 0.5 mm larger in diameter than the stent size, is inflated within the stent. Subsequent angiography demonstrates a coronary rupture that is difficult to control and requires pericardiocentesis and two covered stents. The patient recovers well but has a significant enzyme rise on the following day. The consultant told him the following morning that coronary rupture was a recognised, but rare, complication that he had seen several times previously in his career. The patient subsequently makes a formal complaint to the trust on the basis that coronary rupture was a recognised complication and had not been mentioned before the procedure.

Obtaining informed consent to a procedure does not require a detailed description of each and every aspect of it, nor does the patient have to be informed of absolutely every risk, however remote. In this case, inadequate deployment of the stent led to other procedures which led to the coronary rupture. Whether or not the patient should have been warned of this (or indeed any other) risk depends on the degree and severity of consequence of the risk. Broadly speaking most doctors should always warn of risks which are greater than in the order of 1%, though this is not a hard and fast rule and the need to warn of a

particular risk less than 1% (in the absence of an express inquiry which should **always** be responded to) is influenced by all the circumstances which include in particular the severity of the risk; if it is sufficiently catastrophic (for example, death) many doctors will warn even if it is far smaller than 1%.

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CASE 7

A 60 year old headmaster is admitted for elective PCI to his left anterior descending coronary artery. His symptoms are typical of angina but an exercise test had recently been unequivocally negative to eight minutes, both electrically and symptomatically. During the procedure, the interventionist feels that the LAD lesion is only of moderate severity after routine administration of intracoronary nitrate. Given its equivocal angiographic appearance, he elects to assess it further using a pressure wire. This suggests that there is no haemodynamically important stenosis in the vessel (fractional flow reserve after adenosine consistently greater than 0.9). The interventionalist does not therefore proceed to stent the vessel but tells the patient, while he is still on the catheter lab table, that the narrowing no longer looks worth treating with a stent. The patient subsequently issues a formal complaint to the trust that the procedure that he had consented for (angioplasty and stenting) was not carried out, but that this decision was made on the basis of a second procedure (pressure wire) that he had not been informed may occur and for which he had definitely not consented. His pain continues.

The significant point about this case is that the initial discrepancy between symptoms and exercise test meant that from the outset the procedure was to be investigative and what happened during it was dependant upon the findings. In those circumstances it should have been made clear to the patient that the procedure would give more information upon the basis of which the decision whether or not to stent would be made. It is not satisfactory to give this information when the patient is actually undergoing the procedure since it is a bit late then to be asking for consent! The patient is entitled to complain if it was not made clear to him that he might or might not be stented. Insofar as the use of the pressure wire is concerned, again if the procedure was anticipated as a possibility because of the equivocal picture and there are extra risks associated with it, it would have been wise, when seeking the initial consent, to make reference to it. The

situation might be different if its use arose in unanticipated circumstances when it could be argued that it was simply an integral part of the normal procedure for which the patient had been consented.

SUMMARY

In summary, when approaching issues of consent, the doctor should:

- ▶ ensure that he is clear in his own mind what the options for the patient are and the way in which he wishes to impart them
- ▶ bear in mind that what is important is that the consent is *informed*—that is, the patient is provided with information in a form which enables him to understand the nature of the decision he has to make
- ▶ consider, in particular for the standard procedures, the provision of a background information leaflet that the patient can take away to read
- ▶ try to develop a formula for conveying the basic information that he always follows, albeit that he adapts it to the understanding of the particular patient
- ▶ allow sufficient time for the patient to ask questions
- ▶ ensure that either the consent form is itself in detailed terms or that it is supplemented by a note in the clinical records of the information given; *always* keep the latter if there are any concerns as to the patient's understanding/interpretation of what he has been told
- ▶ remember that the provision of information that leads to consent is not necessarily a one-off event—for example, an information sheet could be provided at the first outpatient appointment and followed up on a later occasion.

Doctors should remember that their defence unions are there to help; if a formal complaint is made with regard to consent (or indeed other) issues, it is wise to telephone them before responding. They will also check the written statement of response that is prepared by a consultant before it is submitted.

Authors' affiliations

N Curzen, Wessex Cardiac Unit, Southampton University Hospital, Southampton, UK
S Smith, Crown Office Row, Temple, London, UK