

# Proving Informed Consent: Some Lessons from Two High Court Decisions

**(EKW v SMC [2011] SGHC 68 and LCH v SMC [2008] 3 SLR(R) 612)**

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In the recent High Court case of EKW v Singapore Medical Council [2011] SGHC 68 (“EKW’s case”), a medical practitioner was suspended for three months for the failure to obtain informed consent from a patient in respect of an invasive procedure. The writers understand that this case has generated concerns in the medical community regarding the threshold of informed consent required in the wider context of increasing assertion of patient autonomy. How much of risks and complications should a doctor communicate to patients without deterring patients from invasive procedures? Who is ultimately responsible for taking consent in a team management scenario? What manner and extent of proof is required when informed consent is called into question in a court of law or a disciplinary tribunal? Will videotaping the consultation process help to deter or disprove a patient’s allegations of lack of consent?

As this commentary will show, EKW’s case does not offer the answers to all the above questions. In an eight-paragraph grounds of decision, the High Court essentially set out the relevant facts in one paragraph, the Disciplinary Committee (“DC”) of the Singapore Medical Council’s (“SMC”) findings of fact in another paragraph, and its conclusion on these findings in a further paragraph, with the remaining paragraphs devoted to the issue of sentencing. The brevity of these grounds does not permit any in-depth analysis of the prevailing judicial attitude on what constitutes sufficient consent. Nevertheless, the High Court’s statement of the DC’s findings of fact, which it accepted, sheds some light on the court’s considerations in the proof of informed consent.



This article will first state the salient facts and reasoning in EKW's case. A comparison will then be made with the previous High Court decision in *LCH v SMC* [2008] 3 SLR(R) 612 ("LCH's case") which also dealt with the issue of informed consent. Some lessons will then be drawn from both cases to hopefully provide some guidance to doctors in an increasingly challenging area of practice.

## EKW's case

This High Court decision involves EKW's appeal against the DC's finding that he failed to obtain informed consent from a patient for a staple haemorrhoidectomy ("the Procedure"). EKW also appealed against the three-month suspension imposed by the DC.

The facts are relatively straightforward. On 10 July 2006, the patient consulted EKW who diagnosed him with fourth degree piles. On 13 July 2006, the patient underwent the Procedure. It was not disputed that the patient signed an informed consent form prior to the Procedure.

Before the DC, the patient alleged that the only treatment options EKW discussed were a colonoscopy and the Procedure. He further alleged that EKW was very dismissive, and did not mention the risks and complications of the Procedure. EKW disputed these allegations, stating that he discussed with the patient the option of conventional haemorrhoidectomy, and the risks and common complications of the Procedure.

The DC believed substantially the complainant's testimony, and found that the evidence contemporaneous with the material events did not support EKW's defence that informed consent was obtained. In particular, the DC:

1. found that the case notes do not record any discussion of treatment options, apart from EKW's recommendation of a colonoscopy (patient's refusal of the treatment was recorded) and the Procedure.
2. found no evidence to support EKW's claim that there was a discussion of the risks and complications involved in the Procedure. There was no record in the Patient and Family Education Record dated 10 July 2006 of such a discussion being conducted based on pamphlets.
3. took into account the inconsistencies in EKW's evidence with respect to the signing of the informed consent form in the Day Surgery Centre. EKW initially claimed that this was a standard operating procedure in the hospital. When pressed to adduce supporting evidence, he re-characterised it as mere guidelines or common practice.

4. found that the evidence was consistent with the patient's initial complaint to SMC where he stated that the only treatment options he was informed of were a colonoscopy and the Procedure.

In dismissing the appeal, the High Court accepted the DC's findings of fact on the basis that they were supported by the relevant records. The High Court also held that a suspension term is warranted in this case having regard to the importance of obtaining informed consent from a patient before performing invasive surgery on him, and the SMC's mission to raise the standard of medical treatment of patients in Singapore.

It is clear that the High Court and the DC placed substantial reliance on the contemporaneous case notes, and other documentary evidence such as the Family Education Record and the patient's complaint to SMC, and examined the consistency in the doctor's and the patient's documentary and oral evidence, in arriving at their decisions. This approach is not different from the High Court's approach in *LCH's case*, which was decided in 2008.

## LCH's case

In *LCH's case*, LCH contended that the DC erred in finding that he failed to obtain his patient's informed consent by:

1. failing to inform the patient of other treatment options; and
2. failing to explain the risks, side effects and nature of the trabeculectomy with a Molteno implant ("the Surgery").

On issue 1, SMC relied primarily on the testimony of the patient's son and daughter who had accompanied the patient during his first consultation with LCH. The patient's son gave testimony to the effect that no options were offered by LCH. The patient's daughter, who admitted in the DC hearing that her memory of the events was hazy, produced a contemporaneous email to her siblings after the first consultation with LCH, in which no reference was made to any options offered by LCH.

The High Court, based on the overall impression gathered from the testimonies of these witnesses, concluded that LCH did not provide other treatment options. It further examined the discrepancies between LCH's explanation to the Complaints Committee and his evidence under cross-examination, and proceeded to assess the credibility of his entire testimony. In particular, the High Court observed that LCH's case notes made no mention of any of the other options allegedly offered, and found that such lack of documentation did not assist his assertion of having discussed other treatment options with the patient and/or his family members.

On issue 2, the SMC's expert testified that in order to obtain informed consent, it was incumbent on the doctor to explain the risks, side effects, nature of the Surgery involved and the medications required. The patient and his son testified that LCH proffered none of these during the consultation. According to the High Court, LCH's entire defence was predicated on the phrase "guarded prognosis" which he wrote in his case notes. During examination-in-chief, LCH explained that "guarded prognosis" was his code word to say that he discussed all the problems with the patient. Under cross-examination on the discussion of treatment options, LCH asserted he had "put a summary" of the discussions in his case notes, and relied on the same phrase "guarded prognosis" as an implication that he had discussed options available to the patient.

The High Court, having regard to guideline 4.1.2 of the SMC Ethical Code and Ethical Guidelines, which requires the documentation of, amongst others, treatment options and informed consent, took the view that the lone phrase "guarded prognosis" was woefully inadequate. It endorsed the DC's emphasis on the critical importance of patients understanding all options available, and the risks and benefits of these options, especially when treatment is elective.

LCH had also produced a consent form signed by the patient which attested that "I ... have been fully informed of the possible risks of operation or infection". This form was only partially complete. Save for his signature, the patient did not fill up his name and NRIC number. The counsel for SMC also pointed out that LCH had failed to produce this form when earlier queried by the Complaints Committee more than two years ago. Further, a nurse at LCH's clinic who attested to witnessing the patient's signing of the consent form was not called to give evidence. An adverse inference could be drawn against LCH for failing to have done so.

## Lessons from EKW's case and LCH's case

From both cases, one can reasonably draw the following lessons:

1. Informed consent is not a matter of form but substance. Consent forms by themselves cannot substitute actual discussion of the relevant issues where the patient participates in decisions about the treatment. Such discussion should also be adequately and contemporaneously documented in case notes. It is generally advisable to have the patient sign any consent form only after the relevant discussions and case note documentation, so that the form acts as a means of reinforcing the points discussed and carries corroborative weight when consent is later in dispute.
2. The use of vague code words or phrases in case notes as a summary of the discussion with the patient or advice to the patient is inadequate and not encouraged. It stands to reason that the lengthier the discussion, the more entries one would expect to see in the case notes. The case notes should clearly reflect all the treatment options discussed and why a particular option is recommended.
3. Medical records of patients, including consent forms, should be as accurate and complete as possible. Consent forms should not only bear the patient's signature but also contain the relevant particulars that can identify the patient. Important points in the form should be specifically drawn to the patient's attention and clearly indicated on the form itself (e.g., have the patient countersign against the points). The form should also be correctly dated, and where appropriate the time should also be clearly indicated (e.g., when consent taking is before the procedure on the same day).
4. Medical records, including consent forms, should also be kept in a manner that allows easy access and retrieval. The inability, especially in a medico-legal event, to produce such records when called upon until much later in time, may diminish the weight to be attached to such records if good reasons cannot be proffered for the delay.
5. It is advisable to indicate the full name of the witness to the consent taking (e.g. nursing staff) in the case notes or consent form so that in case of dispute as to what was explained to or discussed with the patient, the witness can be efficiently traced to ascertain if he can offer supportive evidence.
6. Documents used as aids to illustrate to the patient the nature, benefits, risks and complications of a procedure and other treatment options should be kept with the case notes. Likewise for any written correspondence with the patient (such as emails) or any other records that may evidence such discussions. When informed consent is disputed, these documentary evidence will be helpful to corroborate the doctor's position that such discussions indeed took place.
7. While the question of whether informed consent was obtained is largely one of fact, the questions of what risks, side effects, nature of procedure, and alternative treatment options need to be explained to a patient so as to constitute valid consent is a matter of expert opinion in each case. As the law currently stands in Singapore, expert opinion in this regard will be subject to the Bolam-Bolitho test (the current accepted practice must satisfy the threshold of logic) which is applicable to medical advice.

8. When responding to allegations of failure to obtain informed consent, it is important for a doctor to show consistency in his response at all stages. For example, in the context of an SMC complaint, a doctor's written explanation to the Complaints Committee should be consistent with his oral testimony before the Disciplinary Tribunal, and preferably be supported by contemporaneous documentary evidence. During the hearing before the Disciplinary Tribunal, the doctor's oral evidence in examination-in-chief and in cross-examination should likewise maintain consistency (for a simple explanation of examination-in-chief and cross-examination, please refer to "Medical Negligence – Understanding the Litigation Process", *SMA News* March 2011 pages 12 and 13 or <http://news.sma.org.sg/4303/Negligence.pdf>).
9. As the cases of EKW and LCH show, in a factual dispute over whether informed consent was obtained, oral and documentary evidence will be intensely scrutinised before the Disciplinary Tribunals and the courts. In legal proceedings where the dispute is over who said what in a discussion, clear, comprehensible, consistent, contemporaneous and complete documentary records that can substantially corroborate a doctor's account will usually strengthen the doctor's case and add to his credibility as a witness.
10. In LCH's case, the High Court specifically mentioned and applied guidelines 4.1.2 and 4.2.2 of the SMC Ethical Code and Ethical

Guidelines in its assessment of whether informed consent was obtained. (Please see the Annex for the two guidelines.) Doctors should therefore be familiar with these two guidelines on what should be discussed during consultations and what should be documented in case notes. It is perhaps prudent to adopt a rule of thumb that if in doubt, always document more within the case notes to show the essential points discussed with the patient. **SMA**

#### *Annex*

*These are guidelines 4.1.2 and 4.2.2 of the SMC Ethical Code and Ethical Guidelines:*

#### *4.1.2 Medical records*

*Medical records kept by doctors shall be clear, accurate, legible and shall be made at the time that a consultation takes place, or not long afterwards. Medical records shall be of sufficient detail so that any other doctor reading them would be able to take over the management of a case. All clinical details, investigation results, discussion of treatment options, informed consents and treatment by drugs or procedures should be documented.*

#### *4.2.2 Informed consent*

*It is a doctor's responsibility to ensure that a patient under his care is adequately informed about his medical condition and options for treatment so that he is able to participate in decisions about his treatment. If a procedure needs to be performed, the patient shall be made aware of the benefits, risks and possible complications of the procedure and any alternatives available to him. If the patient is a minor, or of diminished ability to give consent, this information shall be explained to his parent, guardian or person responsible for him for the purpose of his consent on behalf of the patient.*