Tan Tock Seng Hospital

Consent and Documentation in Singapore
- *What's the connection, if any?*

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TTSH - Consent and Documentation

- Legal and ethical standards of consent for treatment (a quick recap)
- Legal and ethical standards of maintaining adequate documentation
- Differences and how the 2 relate to each other
- Legal significance / implications of inadequate documentation of consent

TAKING CONSENT FROM THE PATIENT

- Why does the giving of advice to and taking of a valid consent from a patient matter?
  - Respect for patient autonomy and his/her right to self-determination
  - As a matter of **law**:
    - Potential civil liability for negligence
    - Assault / battery (performing medical treatment without the patient's prior consent)
    - Potential criminal liability for performing treatment without patient's consent

TAKING CONSENT FROM THE PATIENT

- As a matter of **professional ethics**:

  Singapore Medical Council Ethical Code and Ethical Guidelines ("**SMC ECEG**") (2016 Edition)

- What constitutes a valid consent?

  - Sufficient information being given to the patient (advice);
  - Patient's understanding of the information provided;
  - Consent must be voluntarily given.

CURRENT STANDARD OF CONSENT

- As explained in the Court of Appeal decision of ***Hii Chii Kok v Ooi Peng Jin London Lucien & Anor*** [2017] 2 SLR 492
- 3-stage ***modified Montgomery*** test
- A move towards a more patient-centric approach to consent-taking

STAGE 1: SUFFICIENCY OF INFORMATION

- Patient is required to identify the exact nature of the information that he alleges was not given to him and establish why it would be regarded as relevant and material.

- Information which should be disclosed is that which:-

  - would be relevant and material to a reasonable patient situated in the particular patient's position, or
  - a doctor knows or ought reasonably to have known is important to the particular patient in question

STAGE 1: SUFFICIENCY OF INFORMATION

- What would be relevant and material information?
  - The doctor's diagnosis of the patient's condition;
  - The prognosis of that condition with and without medical treatment;
  - The nature of the proposed medical treatment;
  - The risks associated with the proposed medical treatment; and
  - The *reasonable* alternatives to the proposed medical treatment, and the advantages and risks of those alternatives.

STAGE 2: DOES THE DOCTOR POSSESS THE INFORMATION?

- Court decides if doctor possess that information
- Inquiry stops at this stage if the doctor is shown to not have the information at the material time.
  - A separate inquiry may arise in respect of any negligence in diagnosis or treatment (but not advice) if the doctor does not have the information "*because he did not conduct the test which would have discovered that information or because he lacked the factual or technical knowledge to realise that a particular risk or alternative treatment existed*".

STAGE 3: IS THE DOCTOR JUSTIFIED IN WITHHOLDING THE INFORMATION?

- The doctor has to justify why he chose to withhold the information, although material and in his possession.

- Inquiry is undertaken from the doctor's perspective – a physician-centric approach. The Court will decide if the doctor was justified to withhold the information having regard to "*the doctor's reasons for withholding the information and then considering whether this was a sound judgment having regard to the standards of a reasonable and competent doctor*".

STAGE 3: IS THE DOCTOR JUSTIFIED IN WITHHOLDING THE INFORMATION?

- Instances (not exhaustive) where withholding of information may be justified:
  - Waiver by patient (the doctor has to satisfy himself that the patient properly appreciates the seriousness of his decision);
  - Emergency situation (principle of necessity); and
  - Therapeutic privilege (whether the patient is so afflicted that he is likely to be harmed by being advised of the particular information or so impaired in his decision-making abilities).

ETHICAL STANDARD FOR CONSENT

- 2016 SMC ECEG
  - Code (3)(b) **Respect autonomy**:
    - (ii) upholding [patients'] desire to be adequately informed and (where relevant) their desire for self-determination
  - Guideline C6 **Consent**:
    - (3): the doctor must ensure that the patient is made aware of purpose [or test, treatments], benefits, significant limitations, material risks (including those that would be important to patients in their particular circumstances), possible complications and available alternatives

ETHICAL BREACH - CONSENT

- Failure to obtain an informed consent is professional misconduct

- In imposing sentence, the SMC Disciplinary Tribunal should consider:
  - The materiality of the information not explained to the patient – would the patient have taken a different course of action
  - The extent to which the patient's autonomy to make an informed decision was undermined
  - The possibility or materiality of the harm which resulted from the failure to explain the necessary information – the causation of such harm would be a "seriously aggravating factor"; the absence of such harm would generally be a "neutral consideration without any mitigating value"

Singapore High Court in the SMC decision of ***Lam Kwok Tai Leslie v Singapore Medical Council [2017] 5 SLR 116, at [90]***

ETHICAL BREACH - CONSENT

- Illustration of most recent SMC Disciplinary Tribunal case -

  SMC v Dr Ganesh Ramalingam [2018] SMCDT 6

  General surgeon did a gastroscopy, colonoscopy and biopsy on his patient. Unfortunately, the patient suffered a perforation of her colon.

- 3 charges - failure to:
  - Obtain informed consent
  - Keep proper medical records … which accurately and sufficiently set out … [doctor's] advice an explanation prior to the procedures
  - Undertake an adequate clinical assessment and evaluation of the patient before offering the procedures

Sentence imposed – suspension of 7 months (" … a suitable starting point of 12 months … [before] … mitigating factors")

ETHICAL BREACH

- Consequences of breach – penalties have become more severe

- A bit of recent history -

  Eu Kong Weng v Singapore Medical Council [2011] SGHC 68

  Failure to obtain an informed consent for staple haemorrhoidectomy – 3 months suspension. On appeal to the Court of 3 Judges ("**C3J**"):

  "*In our view, the question we have to consider is whether, having regard to the importance of obtaining informed consent from a patient before performing invasive surgery on him, and the mission of the SMC to raise the standard of medical treatment of patients in Singapore, a suspension is warranted in the present case. In this respect, we accept the approach of the SMC in determining the nature of the punishment. We agree that a suspension is called for, and if we had the discretion, we would have imposed a shorter period of suspension. However, the law does not allow us to do that as the 3-month suspension is the minimum mandated by s 45(2)(b) of the Act*."

  !!! But this is **not** the current view of the SMC or the Court.

MAINTAINING ADEQUATE DOCUMENTATION

The legal position on documentation

Is it even a legal requirement? If yes, on whom?

- Documentation of consent is part of a wider obligation to maintain clear and accurate medical records. Statutory obligation imposed on licensees governed by:
  - Private Hospitals and Medical Clinics Act (Cap. 248) and Private Hospitals and Medical Clinics Regulations (Cap 248, Section 22) ("**PHMC Regulations**").
  - 2007 guidelines issued under the PHMC Act and Regulations.

MAINTAINING ADEQUATE DOCUMENTATION

- Section 12 of the PHMC Regulations provide:
  - *(1) Every licensee of a private hospital, medical clinic or healthcare establishment shall keep and maintain proper medical records and shall in addition cause to be recorded therein in respect of each patient such particulars as may be specified in any guidelines issued by the Director from time to time*

    …
  - *(1A) Every licensee of a private hospital, medical clinic or healthcare establishment shall keep and maintain proper medical records and shall in addition cause to be recorded therein in respect of each patient such particulars as may be specified in any guidelines issued by the Director from time to time*

    …

MAINTAINING ADEQUATE DOCUMENTATION

- Chapter 4 of the PHMC guidelines state:

4.2 The medical record of each patient shall include:

a. the admission form;
b. the patient's medical history, and any referral documents;
c. clinical findings and progress notes;
d. medication, nursing care, treatment and diet notes;
e. record of allergies and other factors requiring special consideration, if any;
f. reports of all laboratory tests performed;
g. records of all Xray and other investigations performed;
h. consent forms, where applicable;
i. a discharge statement which summarises the significant findings and events of the patient's stay, condition on discharge and recommendations and arrangements for future care.

MAINTAINING ADEQUATE DOCUMENTATION

- 2016 SMC ECEG imposes a mandatory ethical obligation on doctors to maintain proper medical records and a record of documented consent:

2002 ECEG	2016 ECEG
Paragraph 4.1.2: *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.*	Guideline B3 Medical records: *(3) **Must** include all clinical details of the patients, discussions of investigation and treatment options, informed consents, results of tests and treatments and other material information. If you are delegated an aspect of care, you may confine your records to what is relevant to your portion of care.*

MAINTAINING ADEQUATE DOCUMENTATION

2002 ECEG	2016 ECEG
	Guideline B3 (continued): *(6) Medical records can only be amended to make genuine corrections or amplifications.* *(7) If medical records are made on your behalf, you **must** take reasonable steps to ensure that the quality of the records is up to the required standards.* *…*

MAINTAINING ADEQUATE DOCUMENTATION

2002 ECEG	2016 ECEG
	Guideline C6 Consent: *(2) You must take valid and adequately documented consent from patients for tests, treatments or procedures that are considered complex, invasive or have significant potential for adverse effects*

ANY DIFFERENCE

- Is there a difference?
- If yes, does it matter? Why?
- How do we relate the 2?

Legal significance / implications of inadequate documentation

- ***Lam Kwok Tai Leslie v Singapore Medical Council [2017] 5 SLR 116***

Dr Lam was convicted by the DT on a charge of failure to obtain his patient's informed consent for a conventional (coronary) angiography KIV stenting procedure. He failed to document in his clinical notes his advice to the patient of the risks and possible complications of the PCI. The patient signed a general procedure consent form for a "conventional angiogram keep in view coronary angioplasty". The consent form states "*I, the undersigned, consent to undergo the [procedure] having understood the nature, purpose, risks and alternatives which were explained to me by [Dr Lam]*".

There were 2 treatment-related charges and 1 charges of failure to obtain an informed consent. (There was no charge of failure to adequately document.)

Dr Lam appealed to the C3J against his conviction by the DT

Legal significance / implications of inadequate documentation

- ***Jen Shek Wei v Singapore Medical Council [2018] 3 SLR 943***

The patient signed a general consent form for left oophorectomy to be done by Dr Jen. Her complaint was that she was not informed by Dr Jen was going to remove her left ovary. She had understood that the surgery was to remove the mass in her left ovary.

Dr Jen appealed to the C3J against the DT's decision convicting him for, *inter alia*, failure to obtain his patient's informed consent before performing a left oophorectomy. His argument was that since the consent form was a contemporaneous document, and as the DT did not find any irregularities in the manner the consent form was signed, the form in itself is evidence of properly obtained informed consent for the surgery.

Legal significance / implications of inadequate documentation

- Singapore High Court in the civil suit of ***Rathanamalah d/o Shunmugam v Chia Kok Hoong [2017] SGHC 153***
  - The importance of the note-taking practice recommended by the Singapore Medical Council.
  - The Court may draw adverse inference from the absence of such notes.

Legal significance / implications of inadequate documentation

- Adequate documentation is an important evidentiary tool to provide *prima facie* **evidence** that valid consent was obtained:
  - Accurate and contemporaneous documentation of each and every consultation is crucial to ”*safeguard against disputes*” by patients that their consent to treatment had been obtained.
  - A guard against poor recollection by patients (highlighted by the Court of Appeal in ***Hii Chi Kok***).

(1) Signed consent form

- A patient's signed consent form is an important medical record as it shows that a procedure was done with the consent of the patient: Singapore High Court in ***Li Siu Lun v Looi Kok Poh [2015] 4 SLR 667***

- Unless there is strong evidence suggesting that the patient was well-informed, absence of a record of consent or advice can be strong indication that the advice provided was insufficient: ***Rathanamalah d/o Shunmugam v Chia Kok Hoong***

(1) Signed consent form

- ***Lam Kwok Tai Leslie v SMC***

  The C3J "recommended":

  - A doctor "*must maintain clear, legible, accurate and contemporaneous medical records of sufficient detail" …<u>we would expect that the SMC, moving forward, will consider preferring charges for failure to keep proper records</u> in cases … [such as Dr Lam's]*".

(2) Clear, accurate and contemporaneous consultation notes

- ***Jen Shek Wei v SMC***

  The C3J held:

  - The presence of a signed consent form alone is insufficient to show that valid consent was obtained until it was proven that that the patient understood she was undergoing a left oophorectomy. The presence of a signed form alone does not raise a reasonable doubt in the SMC's case against Dr Jen.
  - Little or no weight given to Dr Jen's clinical notes, which were found unclear, inaccurate, illegible and possibly less than contemporaneous.
  - Dr Jen noted "explained risks" – but this does not indicate what had already been explained to the patient and what had not. It was also not clear what these "risks" pertained to.

(3) Ultimate enquiry: Was Patient sufficiently informed of treatment?

- Inadequate documentation may not necessarily be conclusive of whether or not informed consent had been obtained.

- ***Lam Kwok Tai Leslie v SMC***

  - Patient was found to be knowledgeable about the benefits, risks, complications and alternatives to the PCI procedure.

  - A doctor's obligation under the SMC ECEG would be satisfactorily discharged if a doctor has reasonable grounds to believe that the patient was well acquainted with such information required to give valid consent

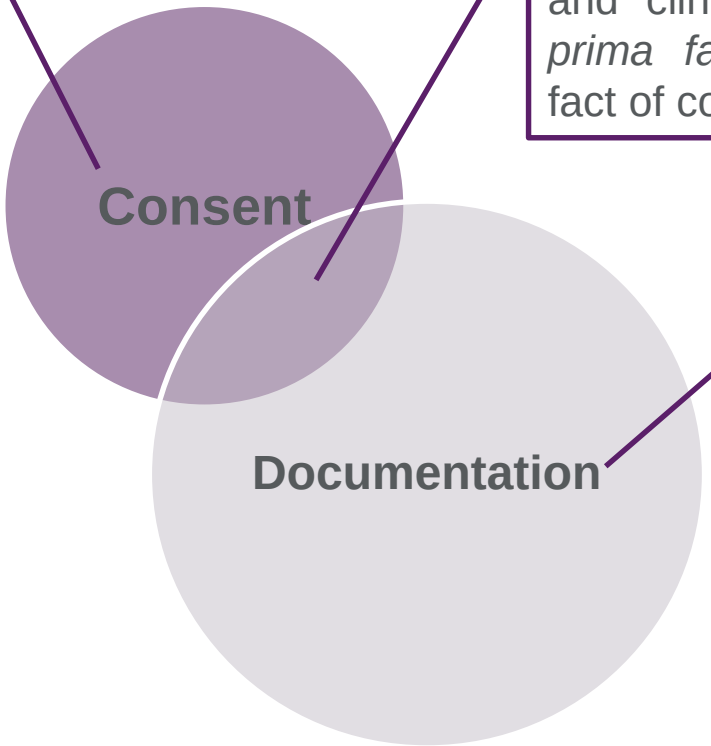
(3) Ultimate enquiry: Was Patient sufficiently informed of treatment?

- Important to assess overall credibility:
  - ***Lam Kwok Tai Leslie v SMC*** - the patient's testimony in respect of other aspects of the incident was not preferred by the Disciplinary Tribunal, and it was not satisfactorily explained by the Tribunal why the patient's testimony in respect of his allegation that informed consent was not taken should be believed.
  - ***Rathanamalah d/o Shunmugam v Chia Kok Hoong*** - the patient had signed a consent form, and she failed to explain how the form came to be signed and how it did not accurately reflect the state of affairs.

KEY TAKE-AWAY POINTS

Obtaining a valid consent

- Legal and ethical obligation
- Has patient been fully apprised of all relevant information based on:
  - Oral testimony of doctor(s), patient, witness(es)
  - Objective evidence - documentation of consent, other clinical records



Documentation (consent form and clinical records) can be *prima facie* evidence of the fact of consent.

Maintaining proper/adequate documentation

- Statutory obligation of licensees
- Ethical obligation of doctors

Speaker

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Thank you

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