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CONSENT TO MEDICAL TREATMENT

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Introduction

- **Important concept in law** – "**no wrong is done to the one who consents**"
- **Basic human right** – ***freedom to decide and act according to one's choices***
- Which makes it an **Ethical** as well as a **Legal** principle.
- Without it, a **person commits non-consensual touching amounting to trespass of battery**.

The Ethical dimensions OF CONSENT

- **Ethics is a subset of the 'concept of morality', which is** a social institution defining what is right and wrong in a society – very much influenced by religion and culture.
- Expression of **respect for patient as a person.**
- Respect patient's moral right to **bodily integrity and self-determination** of one's own life and actions.
- Ensures protection against unwanted intrusions.

PROVISION 2 – MMC GUIDELINES 2016

- Obtaining a patient's consent is an important component of **good medical practice,** and also carries specific legal requirements to do so….**Failure to do so may result in disciplinary inquiry for transgression of ethical professional codes and/or legal action for assault and battery instituted against the medical practitioner.**

CONSENT - DEFINITION

Literal meaning…*permission to do something, acceptance, approval*

Voluntary acquiescence by a person to the proposal of another; the act or result of reaching an accord; **a concurrence of minds; actual willingness** that an act or an infringement of an interest shall occur – ***Provision 1 Consent Guidelines MMC 2016.***

Provision 2 – Consent Guidelines Malaysian Medical Council 2016

- Generally, **no procedure, surgery, treatment or examination** may be undertaken on a patient **without the consent of the patient,** if he or she is a **competent person**. Such consent may be **expressed** or **implied** and may be verbal or in writing…

TYPES OF CONSENT

- **Express Consent** –
- **"permission given either verbally or in writing"**
- If given verbally, problem with oral evidence
- If in writing, usually need to sign a consent form as proof

- **Implied Consent –**
- **"giving permission without utterance of words but using gestures and voluntary action"**
- E.g.: offering one's arm for injection

CONSENT FORM – MOST COMMON METHOD TO SIGNIFY CONSENT

…**a FORM** signed by a patient prior to a medical procedure to confirm that he or she agrees to the procedure and is **aware of any risks** involved. The primary purpose of the consent form is to **provide evidence that the patient gave CONSENT to the procedure in question**.

But patient's signature on the form is not sufficient…

- **The doctor's duty is not… fulfilled by bombarding the patient with technical information, which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form –** *Montgomery v Lanarkshire (2015- UK)*
- **A signed consent form does not automatically absolve a doctor from liability and does not prove that valid consent to treatment has been truly obtained. The vital factors will always be the quality, extent and accuracy of the information given prior to the signing of the consent form. –** *Dr Milton Lum (Nov 24 The Star)*

Chatterton v Gerson [1981] 1 All ER 257

- Bristow J. stated "once the parties is informed in broad terms of the nature of the procedure which is intended, and gives her consent, that consent is real…if the information is withheld in bad faith, the consent will be vitiated by fraud…but it would be no defence to an action based on trespass to person if no explanation had in fact been given. **The consent would have been expressed in form only, not in reality."**

Therefore...
Consent Requires “Information”

- Patient needs to be informed prior to medical treatment particularly before the medical treatment.
- It requires doctors “to provide their patients with sufficient information so that the patients could assent to or withhold consent from a proffered medical treatment.”
- **The right of self-determination is to give the patient a MEANINGFUL CHOICE rather than a meaningless one.**

Provision 3 MMC Guidelines 2016

- A medical practitioner is **obliged to disclose information to the patient and to warn the patient of material risks before taking consent.** Failure to obtain a patient's consent or disclose material risks may be interpreted as a failure of the standard of care resulting in **a disciplinary inquiry by the Medical Council or may even be construed as a breach of duty of care and legal action instituted.**

Therefore . . .

Consent needs to be informed in nature

Consent SHOULD NOT BE in a Form only

To be **EFFECTIVE**, CONSENT NEEDS TO BE **LEGALLY VALID**...

- Requirements:
- a. **Mental competence** – reach the age of majority, not mentally incapacitated – able to have sufficient understanding
- b. **Own free will** – no duress, undue influence
- c. **Sufficient information** **of the proposed treatment – consent must be real, must be informed in nature not just "in a form" only**

Consent must be real – There must be Sufficient Information given

- Real consent means consent must be **INFORMED IN NATURE**
- The violation of the right to informed consent triggers a "claim" by a patient
- The law has given patient independence, autonomy and self-determination – patient has a right to determine whether or not to undergo any medical procedure.
- To do this, **patient needs to know what they are consenting to.**

The Doctrine of Informed Consent

- embodies the general principle that a person has a right to determine whether or not to undergo any medical procedure.
- It is the patient who should decide what treatment, if any, he or she should undertake.
- The violation of the right to informed consent triggers a "claim" by a patient

Re T (Adult: Refusal of Medical Treatment) (1992), *Lord Donaldson - "The law requires that an adult patient who is mentally and physically capable of exercising a choice must consent if medical treatment of him is to be lawful,…Treating him without his consent or despite a refusal of consent* ***will constitute the civil wrong of trespass*** *to the person and may constitute a crime."*

Definition of Informed Consent

- Black's Law Dictionary Abridged Tenth Edition, the term "informed consent" can be examined as "**a person's agreement to allow something to happen, made full knowledge of the risks involved and the alternatives.**" From the medical perspective, the phrase "informed consent" is defined as **"a patient's knowing choice about a medical treatment or procedure, made after a physician or other healthcare provider in the medical community would give to a patient regarding the risks involved in the proposed treatment or procedure.**

Rationale

- **to promote individual autonomy.** *Meisel* stated that the doctrine of informed consent "**protects the patient's right to determine his or her destiny in medical matters**; it guards against overreaching on the part of the physician; it protects his [the patient] physical and psychic integrity and thus his privacy; and it compensates him both for affronts to his dignity and **for the untoward consequences of medical care.**"

How much information to be given?

- The legal issues that surround provision of information centres on **how much information to impart to the patient so as to make it sufficient under the law.**

INFORMED CONSENT - HISTORICAL BACKGROUND – AN OVERVIEW

Position in the United States

- ***Schloendorff v Society of New York Hospital (1914)***- "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation **without his patient's consent commits an assault for which he is liable in damages."**
- ***Salgo v Leland Stanford Jr University Board of Trustees*** *(1960)* -[a] physician [would] violate his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment .... **full disclosure of facts [is] necessary to an informed consent – and the questions of what risks ought to be disclosed was a matter of medical judgment.**

Canterbury v Spence (1972)

- "[r]espect for the patient's right of self determination on a particular therapy demands a standard set by law for a physician rather than one which physicians may or may not impose upon themselves."
- **the doctor must disclose all "material" risks inherent in a proposed treatment**.
- the question is to be **determined by the "prudent patient" test -** "[a] risk is thus material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in determining whether or not to forego the proposed therapy." – **exception therapeutic privilege**

What is "material" risks?

What is "material" is to be determined by the **"reasonable prudent patient test"** – would reasonable prudent patient with the patient's characteristics find the risk "material"

Defence of "therapeutic privilege"

- This exception allows the doctor to withhold information from his patient concerning risks of proposed treatment if it can be established by means of medical evidence that disclosure of this information would **pose a serious threat of psychological harm to the patient.**

Position in England

- ***Sidaway v Board Governors of Bethlem (1985)*** *(a progeny of Bolam)* – House of Lords - [a] patient may make an unbalanced judgment because he is deprived of adequate information. A patient may also make an unbalanced judgment if he is provided with too much information and is made aware of possibilities which he is not capable of assessing because of his lack of medical training, his prejudices or personality.
- **Doctors need only to tell their patients what other doctors think. The standard of disclosure is to be based on medical judgment.**
- The doctrine of informed consent has no place within English law

What is “material” risks?

What is “material” is to be determined by the **“reasonable prudent doctor test”** – what other doctors think should be “material”

Sidaway Overruled

- UK Law of Consent finally embraces the prudent patient standard in…
- **Montgomery v Lanarkshire Health Board [2015] UKSC 11**

"Doctor's duty of care takes its precise content from the **needs, concerns and circumstances of the individual patient**"

"PATIENTS ARE NO LONGER PASSIVE RECIPIENTS IN MEDICAL CARE"

– LORD KERR AND LORD REID IN MONTGOMERY V LANARKSHIRE (2015)

Position in Australia

- ***Rogers v Whitaker* (1992)** -The High Court judges refused to apply the *Bolam test* and in doing so separated themselves from the leading House of Lord's case of *Sidaway.*
- Their Lordships felt that the decision in *Sidaway* was both confused and discordant. The High Court came to the conclusion that the *Bolam test* cannot be used to determine the scope of the doctor's duty of disclosure because there was a **fundamental difference between diagnosis and treatment and the provision of advice and information.**

3 features about duty to warn

- **In diagnosis and treatment, patient's role marginal as "the patient's contribution is limited to the narration of symptoms and relevant history" - he is just a recipient of the doctor's expertise.**
- The provision of information merely involves communication skills, which are not exclusive to medical practitioners and therefore, can be judged by non-medical people - doctor does not need special skill to be able to disclose the risks but rather, communicating skill that will enable the patient to apprehend his situation.
- The doctor's duty of disclosure is subjected to "the therapeutic privilege."

The Decision - *Rogers*

- The High Court concluded that, with regard to negligence, the scope of a doctor's duty of disclosure is:
- "**to warn a patient of a *material risk* inherent in the proposed treatment; a risk is material if, in the circumstances of a particular case, *a reasonable person* in the patient's position, if warned of the risk, would be *likely to attach significance*** to it or if the medical practitioner is or **should reasonably be aware that a particular patient**, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it. **This is subject to therapeutic privilege."**

What risks are material?

Reasonable Patient

What a reasonable patient would want to know and would likely attach significance to it

Particular Patient

What the particular patient you are treating would want to know and would likely attach significance to it

The Legal Developments of informed consent in Malaysia

- Courts' paternalistic approach in the majority of medical negligence cases **since 1960s…following closely English judicial decisions**.
- A change in the jurisprudential landscape on the law on informed consent when the Federal Court abandoned the *Bolam principle* in relation to doctor's duty to disclose risks in medical treatment in the case of ***Foo Foo Fio Na v Dr Soo Fook Mun & Anor*** **(2007).**
- The adoption of the reasonable prudent patient test set forth in ***Rogers v Whitaker*** has made medical practice and opinion amongst several other factors to be taken into account in setting the standard of care for duty to warn.

Bolam principle in the Federal Court (2007)

- The recent ruling of the Federal Court in ***Foo Fio Na v Dr Soo Fook Mun & Anor*** [2007] 1 MLJ 593, has decided that the *Bolam priniciple* is no longer to be applied to doctor's duty to disclose risks.
- **The test enunciated in *Rogers v Whitaker* would be "a more appropriate and a viable test of this millennium."**

Federal Court.....

- "the *Bolam Test* has no relevance to the duty and standard of care of a medical practitioner in providing advice to a patient on the inherent and material risks of the proposed treatment. **The practitioner is duty bound by law to inform his patient who is capable of understanding and appreciating such information of the risks involved in any proposed treatment so as to enable the patient to make an election of whether to proceed with the proposed treatment with knowledge of the risks involved or decline to be subjected to such treatment."**

Dr Ismail Abdullah v Poh Hui Lin (Administrator for the Estate of Tan Amoi @ Ong Ah Mauy, Deceased) (2009)

- "….in which the court affirmed that the decision of the Federal Court in *Foo Fio Na v Dr Soo Fook Mun & Anor* **represents the law in determining the standard of care for doctor's duty to disclose risks in medical treatment and the materiality or non-materiality of a risk under the test enunciated by Rogers v Whitaker** requires not just expert evidence but other factors that are relevant to the circumstances of the patient."

Zulhasnimar bt Hasan Basri & Anor v Dr Kuppu Velumani P & Ors [2017]

- Raus Sharif CJ: “Different consideration ought to apply to the duty to advise of risks as opposed to diagnosis and treatment. That duty is said to be noted in the right of self-determination. As decided by the Australian High Court in **Rogers v Whitaker and followed by this Court in Foo Fio Na, it is now the courts’ (rather than a body of respected medical practitioners) which will decide whether a patient has been properly advised of the risks associated with a proposed treatment.** The courts would no longer look to what a body of respectable members of the medical profession would do as the yardstick to govern the standard of care expected in respect of the duty to advise.”

DOCTOR needs to disclose to the patient all 'material risks' inherent in a proposed treatment. What is "material" would be determined by the "prudent patient" test which was introduced in the United States case of Canterbury v Spence (1972) 464 F. 2d 772 and later adopted in the Australian case of Rogers v Whitaker (1992) 175 CLR 479.

The Reasonable Prudent Patient Test

The Standard of Care demanded by *Rogers v Whitaker*

- The standard to be observed by medical practitioners will no longer be determined solely or even primarily by medical practice **as there will no longer be a conclusive force to medical opinion.**
- It is for the courts to judge what standard should be expected from the medical profession taking into account not only medical opinion but **other relevant factors surrounding the circumstances of the patient.**

Medical opinion no longer conclusive...other factors surrounding circumstances of the patient need to be taken into account...

- The likelihood and gravity of risks
- The desire of the patient for information
- The physical and mental health of the patient
- The need for treatment and alternatives available
- Medical practice at the time
- Nature of the procedure – whether routine or complex

PROVISION 3 – MMC GUIDELINES 2013

- The medical practitioner must inform the patient, in a manner that the patient can understand, about **the condition, investigation options, treatment options, benefits, all material risks, possible adverse effects or complications, the residual effects, if any, and the likely result if treatment is not undertaken,** to enable the patient to make his own decision whether to undergo the proposed procedure, examination, surgery, ortreatment.

Risks that were considered to be 'material' in selected Malaysian cases

- **Foo Fio Na v Hospital Assunta & Anor [2007] 1 MLJ 593** - The **risk of paralysis** in a spinal cord operation was considered to be a material risk of which the patient should have been warned.

- **Lechemanavasagar a/l S Karuppiah v Dr Thomas Yau Pak Chenk & Anor [2008] 1 MLJ 115** – The **risk of esophageal perforation** on the upper part of the esophagus is a material risk that needed to be warned before undertaking the surgery to remove the fishbone.

- **Dr Ismail Abdullah v Poh Hui Lin (Administrator for the Estate of Tan Amoi @ Ong Ah Mauy, Deceased) [2009] 2 MLJ 599** - The deceased patient needs to be informed of the **risks of acute pancreatitis and acute respiratory distress syndrome** ('ARDS') in a procedure to remove the stones by the endoscopy method (ERCP) failing which he will undertake an operation called cholecystectomy. However, the defence of therapeutic privilege in not warning the patient of any material risks in the operation can be applied in a life-saving operation.

Material Risks...Continue

- **Hasan bin Datolah v Kerajaan Malaysia [2010] 2 MLJ 646** – **Risk of paralysis** was a material risk in both surgical procedures, namely, a fenestration and a laminectomy.

- **Norizan Bte Abd Rahman v Dr Arthur Samuel (2013) MLJU 81** – The **risk of uterine rupture** if the procedure to terminate pregnancy was done simultaneously with the insertion of an intrauterine contraceptive device ('IUCD') in a single procedure was material and must be informed to the patient.

- **Abdul Razak Dato Abu Samah v Raja Badrul Raja Zeezaman [2013] 10 MLJ 34** – **The risk of aspiration** that could materialise if the surgery was undertaken without emptying the stomach content through the insertion of Ryle's tube needed to be informed to the husband of the deceased patient who would have persuaded his wife to subject herself to the Ryle's tube procedure.

Lechemanavasagar a/l S Karuppiah v Dr Thomas Yau Pak Chenk & Anor [2008]

- After accidentally swallowing a fish bone, the plaintiff went to see the first defendant, an Ear, Nose and Throat ('ENT') specialist. The first defendant recommended for an operation which was performed on the same day the plaintiff came to see him. After the operation, the plaintiff suffered esophageal perforation on the upper part of his esophagus and his lung became infected due to the perforation and almost collapsed. An emergency chest operation was performed by the first defendant to control the infection and to prevent total lung collapse.

The Claim

- That the first defendant did not warn that the operation to remove the fish bone would be a highly risky one as the plaintiff was informed that the operation was a simple one and that he would be able to return home a few hours after the operation. He agreed to undergo the surgery to remove the fish bone and did not even inform his family about it as he was under the impression that it was a simple surgery.

The Decision

- A doctor is not discharging his duties if he fails to explain the risk to the patient to enable the patient to elect to proceed with the treatment or not. As the first defendant had testified that he has explained the risks to the plaintiff which was noted in his clinical notes, the court accepted that " his evidence on the explanation to the plaintiff that the operation was a high risk tallies with the contemporaneous document in his notes when his operation note states 'watch for esophageal perforation'" – **1st def not liable.**

Dr Hari Krishnan & Anor v Megat Noor Ishak bin Megat Ibrahim & Anor and another appeal [2017]

- Pff had a giant retinal tear – recommended to Dr Hari, Klinik Pakar Mata Dr Hari – advised to undergo retinal detachment operation – after operation pff complained of continuous pain and strong pressure in his operated eye – upon inspection Dr Hari advised for a **2nd operation** as upon physical and visual inspection the retina of his right eye had folded or partially detached – Pff requested for a scan confirming this as his vision had improved but was informed that his improved vision is only temporary and will subsequently worsen – After the 2nd operation, pff experienced severe pain, continuous bleeding and total loss of vision – as his retina was badly uprooted with a lot of internal blood clotting – eye could not be saved having been drenched in blood for more than 25 days.

The Aftermath of the 2nd operation...

- Pff suffered Supra-Choroidal Haemorrhage (SCH) leading to severe injuries and loss of vision after a 2nd operation on his right eye.
- Pff claim he wrongly advised to go for the 2nd operation which was unnecessary; failing to warn of material risks; and adopted a wrong method in the procedure which aggravated the condition.
- One of the issues in the Federal Court was on the "***failure to advise and warn the patient on the risks of bucking under anaesthesia and blindness in the second operation***".
- Claim was made against the anaesthetist that he failed to interview the pff prior to the 2nd operation – failed to monitor pff closely – the wearing of the muscle relaxant drug which caused the bucking.
- The bucking could have been avoided by proper monitoring.

Judgment - The Federal Court in Dr Hari Krishnan…

- The Federal Court approved the Court of Appeal findings that "that the duty to explain risks is specific in nature; **the Consent Form, signed by the Plaintiff prior to the operation and relied upon** by Dr Hari and Dr Namazie, **only contained general precautions that the operation involves risks. "**
- Further, neither Dr Hari nor Dr Namazie warned the Plaintiff of the risks of bucking and blindness at any material time. In the circumstances, **a reasonable person in the patient's position would be likely to attach significance to it. We further note that in relation to this particular patient, given that the Plaintiff has previously requested for scans to be conducted and enquired on the need for the operation, it is apparent that the Plaintiff would attach significance to warnings of such risks**. As such, we consider such risks to be material risks in the 2nd Operation.

THE DECISION...*Dr Hari Krishnan*...

The anaesthetist, that Dr Namazie never interviewed the Plaintiff prior to the 2nd Operation, pff never heard of the word 'buck' – **pff must be interviewed when he is fully awake and not under the influence of drugs** - Based on the evidence, Dr Hari and Dr Namazie have failed to explain the risks of bucking and blindness to the Plaintiff. They were therefore negligent for not doing so, thereby **depriving the Plaintiff of the chance to make an informed decision as to whether to proceed with the operation or otherwise**.

The Importance of Individual Autonomy

….and the fact that have they been properly informed so that they can make an informed choice….has been apparent in judicial cases after 2007

Norizan v Dr Arthur Samuel (2013)

- Pff and her husband requested for termination of pregnancy and insertion of contraceptive device in a single procedure
- Defendant agreed to carry out the procedure but did not inform of the risks inherent in performing both procedures at once.
- During the procedure, def perforated her uterus…required emergency hysterectomy
- Pff and her husband claimed would not have proceeded if had known about the risks

The choice was theirs...and they needed information...

- There was an increased risk of perforation of the uterus due to pff's previous pregnancies and termination of pregnancy.
- If they had known…they would have opted for a safer method rather than going for D&C and IUD in a single procedure.
- **By failing to inform the risks, they were denied of considering other alternatives available.**

The Importance of Patient Comprehension

Gurmit Kaur a/p Jaswant Singh v Tung Shin Hospital & Anor [2012] – High Court KL

Facts of the *Gurmit*

- Plaintiff – 38 year old mother of 4…sought treatment from 1st def hospital..2nd def consultant , O & G to remove cervical polyp – agreed to the surgery to remove the polyp
- During the follow-up treatment discovered that a hysterectomy was constructed on her and she was unable to have anymore children.

The Claim

- The 2nd def failed to procure a legally valid consent for the hysterectomy – the pff did not understand the nature of the operation done and did not actually consented to the hysterectomy even though she signed the consent form.
- The 2nd def also submitted that the hysterectomy was medically indicated to treat her heavy and painful menstrual period.

The Decision

- **The fact that the pff was shocked when she was told that she can no longer have any children as hysterectomy was done on her showed that she had not fully comprehended the nature of the surgery.**
- **The plaintiff did not request for hysterectomy and there are other available options.**
- **Hysterectomy should had been offered as an option only if the pff had completed her family.**
- **Her husband was not asked to sign the consent form even though he was waiting outside.**

Continuation...the decision

- It was not enough for the 2nd def to proceed with the operation just because the pff had signed the consent form.
- Failure to call nurse who witness the signing of the form – **sec 114(g) of the Evidence Act 1950 –judgment may be decided against the 2nd def**.
- Ist def not vicariously liable as 2nd def is a freelance and independent consultant
- Pff awarded RM120,000.00 for loss of uterus, inability to conceive, injury and pain and suffering.

Going beyond individual autonomy

The Importance of Spousal Consent….***not just limited to issues affecting reproductive rights of both parties….***

Abdul Razak bin Datuk Abu Samah v Raja Badrul Hisham Raja Zezeman Shah [2013]

- Facts: Deceased 71 year old – abdominal pain..vomitting…had intestinal obstruction
- Was admitted to Temerloh Hospital but later transferred to HKL under the care of 1st Def.
- Deceased's husband knew the 1st Def personally
- 1st Def away attending conference – he requested his surgical trainee to insert Ryle's tube to pump out stomach fluid.

Abdul Razak...

- Patient refused as the insertion caused her discomfort which was recorded.
- 1st Def called deceased's husband that deceased needed immediate surgery…consented but no risks was mentioned about the importance of inserting the Ryle's tube before the anaesthesia was administered.
- After administering the anaesthetic, deceased regurgitated a large amount of stomach fluid which entered her lungs, causing respiratory failure and death the next day.

Decision

- Ist Def and 3rd & 5th Defs (Anaes)…were held liable for failing to advise the deceased adequately and sufficiently of the inherent and material risks of proceeding the surgery and anaesthesia (risk and death from aspiration) without the insertion of the tube and emptying the stomach content.
- Also liable for failing to advise the deceased's husband, the pff.

The Importance of Spousal Consent

- Although the consent form did not require the consent of the pff but the pff needed to be inform on the risks when the deceased refused the insertion of Ryle's tube.
- The pff's involvement in the decision making was obvious from the start when the 1st Def called the pff personally to inform that the deceased require immediate surgery.

The IMPORTANCE OF SPOUSAL CONSENT IN Gurmit Kaur v Tung Shin Hosp (2012) & ABDUL RAZAK V Raja badrul Zeezaman (2013)

Spousal consent was held to be necessary when…

1. **The issue concerns the reproductive rights of both parties.**
2. **The spouse was dependent on the other to make the decision as in this case the deceased was dependent on the husband to make the necessary decisions for her.**

Informed Consent is not just a principle

IT IS A PROCESS….which starts from the time which the doctor and patient discusses the proposed actions, risks, benefits and alternatives….***a process which require (i) disclosure of pertinent information, (ii)comprehension and (iii) voluntary agreement.***

There are obviously barriers to obtaining the optimal process in procuring informed consent

- Age
- Education
- Character
- Religious Background
- Cultural Influences

Efforts made by the Ministry of Health

- Upgrading of the consent form has been done by MOH recently in 2014…to take into account the legal developments
- Introduction of a new Consent Guidelines by MMC in 2013 and 2016

New Consent Form

HOSPITAL _____

CONSENT FOR OPERATION / PROCEDURE

I, _____of (address) _____
_____ hereby agree and consent
(A) *to undergo the operation(s)/ procedure(s) of _____
(B) *to the submission of my child/ ward, _____, IC/ID No. _____
to undergo the operation(s)/procedure(s) of _____
under (type of anaesthesia) _____
the nature, purpose and potential risk(s) of which (please refer to Attachment A) have been explained to me by Dr. _____ through interpretation by (if any) _____.
~~I have read additional explanatory note(s) provided (if any).~~

I also consent to any additional or alternative operative measures / procedures as may be found necessary during the course of the above mentioned operation(s) / procedure(s) and to the administration of general, local or other anaesthesia for any of these purposes.

No guarantee has been given to me that the operation / procedure / anaesthetic care will be performed by any particular practitioner.

Signed : _____
(Patient/ Parent/ Guardian)*
Relationship: _____
IC/ID No. : _____
Date : _____

Note: If ~~any other~~ the person gives his/her consent as a guardian, his/her relationship with the patient should be ~~given~~ stated below his/her signature.

Witness:
Signature : _____
Name : _____
IC/ID No. : _____
~~Post~~ Designation: _____
Date : _____

Interpreter (if needed):
Signature : _____
IC/ID No. : _____
Date : _____

I confirm that I have explained the nature, purpose and potential risk(s) of this operation(s) / procedure(s) to the *patient / parent / guardian who ~~indicated~~ has verified his/her understanding to me. I have given the patient/ parent/ guardian an opportunity to ask questions and I have answered

Patient Information Sheet

HOSPITAL _____

Name of patient: _____
IC/ID No. : _____
Date : _____

Attachment A: Explanation of operation/procedure _____

Nature:

_____
_____
_____
_____
_____

Purpose:

_____
_____
_____

Additional risk(s) (if applicable)Risk(s) :

1. _____
2. _____
3. _____
4. _____
5. _____

I have read additional explanatory note(s) provided (if any). I fully understand the explanation given and the additional explanatory notes (if any), and also ~~understand~~ the reasons, consequences and risks

Malaysian Medical Council Consent Guidelines adopted in 2016

- Example….**Provision 14**…The medical practitioner **should assist the patient to understand the material provided and, if required, explain to the patient any information that he or she finds unclear or does not understand.** The medical practitioner must afford the patient the opportunity to read the material and raise any specific issues of concern either at the time the information is given to the patient or subsequently.
- The medical practitioner must ensure that any pre-prepared material given to the patient is current, accurate and relevant to the patient.
- If such pre-prepared information material does not disclose all "material risks" either in general terms or otherwise, the medical practitioner must provide supplementary information on such "material risks" as are not disclosed, verbally. **The likelier the risk, the more specific the details should be.**

Provision 8 – MMC Guidelines 2016

- It is generally accepted that consent to be “valid” should be “informed”; the requirements for obtaining valid consent are:
- i. It must be given by a person **with legal capacity**, and of sufficient intellectual capacity to understand the implications of undergoing the proposed procedure. ii. It must be taken in a **language which the person understands**. iii. It must be given **freely and voluntarily**, and not coerced or induced by fraud or deceit. iv. It must **cover the procedure** to be undertaken. v. The person must have an awareness and understanding of the proposed procedure and its known or **potential risks.** vi. The person must be given **alternate options** to the proposed treatment or procedure. vii. The person must have sufficient opportunity to seek further details or explanations about the proposed treatment or procedure. viii. There must be a **witness/interpreter, who** may be another registered medical practitioner or a nurse, who is not directly involved in the management of the patient nor related to the patient or the medical practitioner, or any such person who can speak the language of the patient, to attest to the process during taking of the consent.
-

Patients are the ultimate rulers and they must decide whether to have a procedure when all the risks are laid out.

Dr Rollins Hanlon (former president American College of Surgeons)

Cases where consent is not necessary

- **Persons who are unable to give valid consent:**

Incompetent patients – those who are temporarily unconscious, permanently unconscious through disease, trauma, injury, mentally handicap and children (require parental consent).

****Defence of Necessity** – Violate one right to protect another right in urgent situations of imminent peril

Lord Bridge in F v West Berkshire Health Authority or Re F (Mental Patient: Sterilisation) [1990] : "treatment which is necessary to preserve life, health and well-being of the patient my lawfully be given without consent."

**Defence of “therapeutic privilege”

- This **exception to the ‘reasonable prudent patient test’ above** – it allows the doctor to withhold information from his patient concerning risks of proposed treatment if it can be established by means of medical evidence that disclosure of this information would pose a serious threat of psychological harm to the patient and **detrimental to patient’s health.**

MORE INCOMPETENT PERSONS

a. **Children**
b. **Mentally handicapped**

- CHILD/MINOR
- Age of Majority Act 1971 : Section 1: A person under the age of 18 .
- Child Act 2001: Section 2 : A Person under the age of 18.
- Legally incompetent to give consent and decide on what medical treatment, **REQUIRE PARENTAL CONSENT.**

a. CHILDREN

In the event there is a conflict between the parents…Provision 6 MMC Guidelines 2016

- The Law Reform (Marriage & Divorce) Act 1976 makes it clear that **each parent has full responsibility for each of his/her children who is under 18 years of age.** Parental responsibility is not affected by changes to relationships (i.e. if the parents separate). Each parent has the responsibility for his/her child's welfare, unless there is an agreement or a Court has made an order to the contrary.
- This means that **the consent of either parent to his/her child's medical treatment is usually sufficient.**

Provision 6 – MMC Guidelines 2016

- If a minor presents with an adult other than a parent, the attending medical practitioner should attempt to ascertain the adult's relationship to the child and whether the adult is the child's guardian. - In instances where the attending medical practitioner is unable to adopt the above attempts in ascertaining the relationship of the accompanying adult to the child, **he or she should defer the treatment unless it is an emergency life-threatening situation, or follow the procedures as for a medical emergency.**

Medical Examination and Treatment of child

Within the definition of "Child in need of Care and Protection" under Child Act 2001

Child in need of Care and Protection – Child Act 2001

- **Section 17** – meaning of child in need of care and protection includes **(f) the child needs to be examined, investigated or treated.**

(i) **for the purpose of restoring or preserving his health;**

(ii) **his parent or guardian neglects or refuses** to have him so examined, investigated or treated.

‘BEST INTERESTS OF A CHILD’

A child who is in need of medical treatment will fall within the ambit of this provision and **parental consent is not needed** if the child is in need of treatment **to restore and preserve his or her health.**

Temporary Custody

- Section 18 - if a child is believed to be on reasonable grounds, in need of care and protection (including medical examination and treatment), **a child can be taken into temporary custody by a Protector or a Police officer.**

When is Consent of 'Parent and Guardian' Not Necessary

- Where there is **an immediate risk to the health of the child certified by doctor in writing** – the consent of the parent or guardian or person with authority to consent is not necessary.
- The protector may authorize the **medical, surgical or psychiatric treatment** that is considered necessary. – Section 24(3)

Situation of Emergency

- A situation of emergency does not confer an absolute power to consent to the Protector. The protector's power to consent is subject to the following circumstances:
- (i) that the parent and guardian or person with authority to consent has **unreasonably refused to give consent or abstained from giving consent** – s24(3)(a)
- (ii) the parent or guardian or person with authority to consent **is not available or cannot be found within reasonable time** – s24(3)(b)
- (iii) the protector believes on reasonable grounds that the parent or guardian or person with authority to consent has **ill-treated, neglected, abandoned or exposed or sexually abused the child** – s 24(3)(c)

Provision 5 – MMC Guidelines 2016

- A medical emergency is defined as an injury or illness that is acute and poses an immediate risk to a person's life or long term health. Consent is not required in emergencies where immediate treatment is necessary to save an adult person's life or to prevent serious injury to an adult person's immediate and long term health where the person is unable to consent, subject to there being no unequivocal written direction by the patient to the contrary, or where there is no relative or any legal guardian available or contactable during the critical period to give consent.
- In such circumstances, a consensus of the primary surgeon (who is managing the patient) and another registered practitioner is obtained and the surgeon signs a statement stating that the delay is likely to endanger the life of the patient. The registered medical practitioner must co-sign the consent form.
-

No Liability Incurred

- Section 26 further provides that even if the medical examination or treatment of the child is made **without the consent of the parent or guardian or person with authority to consent** but instead with the consent of the protector or police officer, **all who are involved including the Protector, the Police officer, the Doctor and all persons who assist the doctor will not incur liability.**

MENTAL INCOMPETENCE

b. MENTALLY DISORDERED PATIENTS

How to assess?

- *F v West Berkshire Health Authority (1989)*, where Lord Brandon indicated that the issue is whether patients are able to understand the nature and purpose of the care. This probably involves appreciating what will be done to them if they accept treatment, the likely consequences of leaving their condition untreated and understanding the risks and side effects that the health professionals explain to them

Re MB (1997) – Test for incompetence

- First, **the patient must be able to comprehend and retain the infor**mation, which is material to the decision, especially as to the likely consequences of having or not having the treatment in question.
- Secondly, **the patient must be able to use the information and weigh it in the balance** as part of the process of arriving at the decision. The level of understanding that is required must commensurate with the gravity of the decision to be taken, more serious decisions requires greater capacity.

How to assess under MHA 2001?

- Whether or not, the patient is capable or incapable to give consent, section 77(5) requires the examining psychiatrist to consider whether, the patient understands the condition for which the treatment is proposed, the nature and the purpose of the treatment, the risks involved in undergoing and not undergoing the treatment and whether or not his ability to consent is affected by his condition.

MORE ON WHEN IS CONSENT NOT NECESSARY

Provision 5 – MMC Guidelines 2016

- Consent of the patient may not be required for any treatment that may be ordered by a court of law, for example, an order for the specific treatment of a minor, or a patient on life-support.

STATUTORY EXCEPTIONS

IF provisions of the statute require the person to submit to any intervention under the law….*he has to comply*

Examples…

Road Transport Act 1987 – Section45C. Provision of specimen for analysis

- (1) In the course of an investigation whether a person has committed an offence under section 44 or 45 involving intoxicating liquor or under section 45A a police officer may, subject to the provisions of this section and to section 45D, require him-
- (a) **to provide two specimens of breath for analysis by means of a prescribed breathanalyser; or**
- **(b) to provide a specimen of blood or urine for a laboratory test**

Section 45D. Protection of hospital patient.

(1) A person who is at a hospital as a patient shall not be required to provide a specimen for a breath test or to provide a specimen of blood or urine for a laboratory test **unless the registered medical practitioner in immediate charge of his case authorizes it and the specimen is to be provided at the hospital.**

(2) The registered medical practitioner referred to in subsection (1) shall not authorize a specimen to be taken where it would be prejudicial to the proper care and treatment of the patient.

Atomic Energy Licensing Act

- Section 58 –Compulsory examination and treatment of persons who were or might have been exposed to ionizing radiation resulting from a nuclear incident.
- A criminal offence if **a person "refuses, fails or neglects to submit for examination, treatment, detection or observation."**

The Prevention and Control of Infectious Diseases Act 1998

- Section 7(1)(b) – an authorised officer may "medically examine any person" on board a vehicle entering Malaysia.
- Section 7(1)(c) -**may take samples from such person for determining "the state of health of such person".**
- Section 7(3) –An authorised officer may order the infected person or a contact be removed to a quarantine station and detained therein for isolation or observation.

LEGAL IMPLICATIONS

- Section 22 - Any person who-

- (a) obstructs or impedes, or assists in obstructing or impeding, any authorized officer in the execution of his duty;

- (b) disobeys any lawful order issued by any authorized officer;

- (c) refuses to furnish any information required for the purposes of this Act or any regulations made under this Act; or

- (d) upon being required to furnish any information under this Act or any regulations made under this Act, gives false information,

commits an offence.

Conclusion – Future Challenges

- The doctrine of informed consent is not a mere established ideal legal theory but actually **a systematic process of a two-way communication between the doctor and the patient in order to obtain an informed decision from the patient** as per required by law. The need for….
- Constant Upgrading in Consent Form
- Comprehensive Training - Medical Education – from undergraduate onwards
- Handbooks and Toolkits

Thank you…

- If you need more details on medical law, please purchase my books on

1. Nursing Law and Ethics"

2. Medical Negligence Law in Malaysia

3.Cases and Commentary on Medical Negligence

4. Law and Ethics relating to Medical Profession

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