

CONSENT IN CLINICAL PRACTICE AND DOCUMENTATION

PROF DR PUTERI NEMIE JAHN KASSIM
AHMAD IBRAHIM KULLIYYAH OF LAWS
INTERNATIONAL ISLAMIC UNIVERSITY
MALAYSIA

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.

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...

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.



However...Consent requires Information

- ❖ Patient needs to be informed prior to medical treatment particularly before surgery.
- ❖ 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.”**
- ❖ **This 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.**

**Consent needs to be
informed in nature
Consent SHOULD NOT
BE in a Form only**

Therefore...

Legally valid consent

○ 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

ELEMENT 1 - MENTAL COMPETENCE

1. Have reached the age of majority

Age of Majority Act 1971 states: “The minority of all males and females shall cease and determine within Malaysia at **the age of eighteen years** and every such male and female attaining that age shall be of the age of majority”

Child Act 2001– a child is a person under 18 years of age

2. Not Mentally Incapacitated

Impairments to reasoning and judgment... include such factors as basic intellectual or emotional immaturity; severe mental retardation and illness, intoxication...

CHILDREN...

- ... regarded to be within the category of those **legally incompetent** to give consent and decide on what medical treatment they should have until they reach the age of majority. For children under the age of majority, it is their parents or guardians that will decide for them, and give proxy consent.





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.**



**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)
- 

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.**

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 contrary³.
- 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.



**IN THE EVENT OF ANY
CONFLICT....**

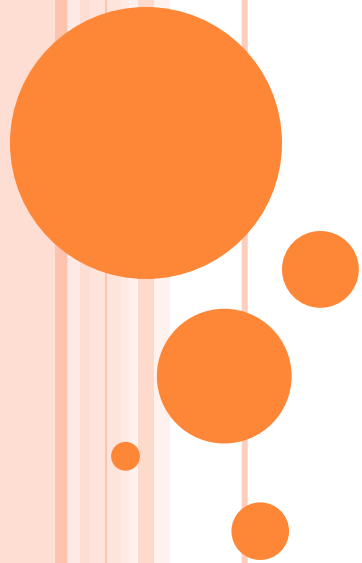
**“BEST INTERESTS OF THE
PATIENT’ SHOULD
PREVAIL...**

Provision 6 – MMC Guidelines 2016

- “Best Interest of the patient or child” is a single decision made by the medical practitioner(s), for management of a patient who is in a situation of helplessness, the decision so made being the most appropriate and fair to that patient or child under the circumstances.

1

FOR ADULTS, THEY CAN
MAKE THEIR OWN
DECISIONS IF THEY ARE
COMPETENT – **HOW TO
ASSESS THEIR MENTAL
CAPACITY...**




ASSESSMENT OF THE MENTAL CAPACITY

- This was laid out in **Re MB (1997)** -
- First, the patient must be **able to comprehend** and **retain** the information, 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.



SECTION 77 OF THE MALAYSIAN MENTAL HEALTH ACT 2001

- Subsec(1) – Where a mentally disordered person is required to undergo surgery, electroconvulsive therapy or clinical trials, consent for any of them may be given –
 - (a) **by the patient himself if he is capable of giving consent** as assessed by a psychiatrist;
 - (b) by **his guardian** in the case of a minor or a relative in the case of an adult, if the patient is incapable of giving consent;
 - (c) by **two psychiatrists**, one of whom shall be the attending psychiatrist, if there is no guardian or relative of the patient available or traceable and the patient himself is incapable of giving consent
- 

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.**



ELEMENT 2 - GIVEN BY OWN FREE WILL

Consent must be given through the patient's own free will, with no duress or undue influence

Valid consent requires the absence of any coercion from anyone.

Freeman v Home Office [1984] -A prisoner had been injected with certain drugs, apparently for the treatment of a personality disorder. Issue is whether the prisoner consented to the treatment as he could not have not given a valid consent to the prison officer as the officer was not a doctor but his disciplinarian.

ELEMENT 3 - SUFFICIENT INFORMATION GIVEN (INFORMED CONSENT)

- ❑ requires doctors “to provide their patients with sufficient information so that the patients could assent to or withhold consent from a proffered medical treatment.”
- ❑ To give the patient **a meaningful choice rather than a meaningless one.**

Provision 3 MMC Guidelines 2016

- 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, or treatment.

Consent must be real – Sufficient Information needed

- 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 patient expects the law to give him dignity, respect, independence, autonomy, information and self-determination.**
- The violation of the right to informed consent triggers a “claim” by a patient

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.**

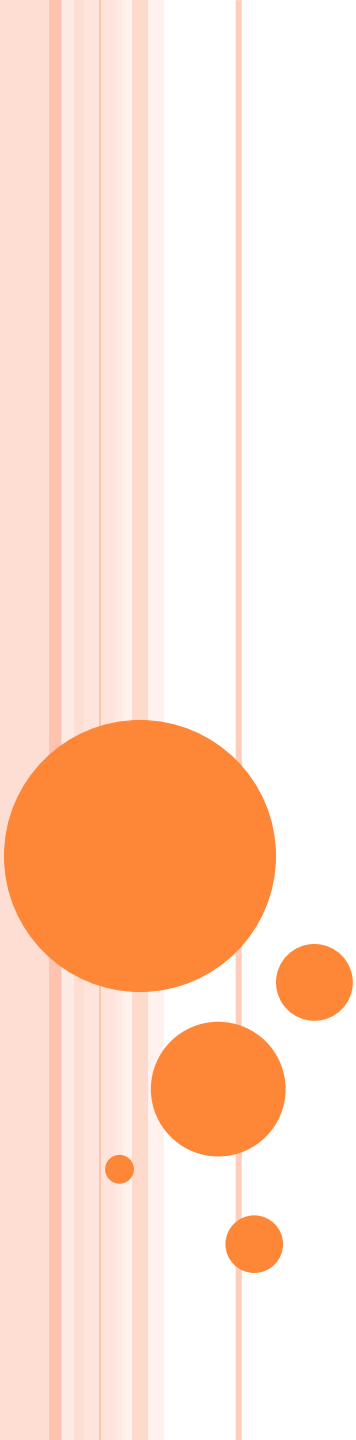


Zulhasnimar bt Hasan Basri & Anor v Dr Kuppu Velumani P & Ors [2017]

- 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.”

What is “material” risks?

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



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

Dr Ismail Abdullah v Poh Hui Lin (Administrator for the Estate of Tan Amoi @ Ong Ah Maury, 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."

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 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**

- ❖ **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 2016

- 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, or treatment.

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 Maui, 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.

Material Risks...Continue

- **Dr Hari Krishnan v Megat Noor Ishak [2018] 3 MLJ 281** – failure to advise on **risk of bucking and blindness** inherent in the surgery.
- **Ahmad Thaqif Amzar v Kuala Trengganu Specialist Hosp Sdn Bhd & Ors [2020] MLJU 2154** – Failing to advise plaintiff's parent to refer HSNZ - the **risks of large abscess can lead to obstruction** in the plaintiff's airway
- **Gurisha Taranjeet Kaur v Dr Premitha Damodoran [2020] 6 CLJ 446** – Failure to advise on **risks and benefits of the delivery options** of a 'big baby'

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.**
- 1st 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.

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 disclosure of pertinent information, comprehension and voluntary agreement...**



Key aspects of informed consent



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

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.

-

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 may 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.**

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.**

-

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 – SECTION 45C.

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**



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.**

THERE IS A
NEED TO
ENHANCE
PATIENT
SAFETY
MECHANISMS
AND ACTIVITIES



WORLD HEALTH ORGANISATION (WHO)

- World Alliance for Patient Safety's Summary of Evidence on Patient Safety: Implications for Research Report (2008) surmised that **patient safety is a pre-requisite for quality health care and unsafe medical care is a major source of morbidity and mortality around the world.**
- Thus, **a system of care delivery that emphasises on patient safety is one which (i) prevents errors; (ii) learns from the errors that do occur; and (iii) is built on a culture of safety that involves health care professionals, organizations, and patients** (Aspden & Corrigan, J., 2004)

HOW TO REDUCE CASES ON MEDICAL NEGLIGENCE?

- ▶ Be active in (i) participating in the review of clinical policies and procedures; (ii) supporting a non-punitive reporting environment; (iii) rewarding staff for reporting unsafe practices; (iv) prompt reporting of potential liability; (v) identifying potential areas of risk/liability; (vi) ensuring all staff are being educated on risk management and compliance issues (Patient Safety and Risk Management Guidelines, 2008).
- ▶ The promotion of the safety of care requires a management commitment and leadership, a collaboration and cooperation of all the professionals who are well trained not only on risk management but also on the hospital and medical practice change.



IMPORTANCE OF GOOD DOCUMENTATION

WHEN THINGS GO WRONG- THE IMPORTANCE OF GOOD AND PROPER DOCUMENTATION



**Proper
document
ation of
case notes,
lab
results, x-
ray etc.**



**In the event that they
are required to release
these documents when
the case goes for trial,
non-production will be
detrimental to the case -
court may invoked-
Section 114 (g) of the
Evidence Act 1950 -
evidence which could be
and is not produced
would if produced be
unfavourable to the
person who withholds
it.**

PROVIDES DOCUMENTARY EVIDENCE

**Written evidence
carries more
weight than oral
evidence**

**GOOD RECORD
GOOD DEFENCE**

**BAD RECORD =
BAD DEFENCE**

**NO RECORD =
NO DEFENCE**

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**
- Email: nemie@iium.edu.my