

Proposal for a Policy on Establish Guidelines on Competency and Practice and to Establish Monitoring Mechanism for Highly Specialized Procedures

A paper was presented by Dato' Dr. Mahmud bin Mohd Nor, Council Member at the Malaysian Medical Council's 253rd Meeting on 12/02/08 raising concerns about the introduction and practice of various interventional procedures and modalities in many specialities and sub-specialities. These procedures or modalities can be potentially dangerous to patients if performed by doctors who are not competent enough or do not possess the required training or knowledge to venture into these fields. Several cases of botched attempts by practitioners which had resulted in severe morbidity and even mortality had been highlighted in the press. Some cases had also been reported to MMC.

The Council subsequently decided to set up a committee headed by Dato' Mahmud to study the situation and to come out with proposals.

The Committee comprised of :-

- i) Dato' Dr. Noor Hisham Abdullah
- ii) Prof. Dr. Tan Hock Lim
- iii) Dato' Dr. Abdul Hamid Bin Abdul Kadir
- iv) Dr. Milton Lum Siew Wah
- v) Dato' Dr. Zaki Morad Bin Mohd. Zaher
- vi) Prof. Dr. Zaleha Bt. Abdullah Mahdy
- vii) Dr. Zaleha Bt. Abdul Manaf

The Secretariat comprised of:-

- i) Mr. Perumal s/o Chinaya
- ii) Miss Fazilah Bt. Mahmad Ayop

The terms of reference of the Committee are:-

- i) To make recommendations to MMC on the approaches to take to address the issue of practitioners performing highly specialised procedures without adequate training.
- ii) Define the meaning of highly specialised procedures.
- iii) Identify procedures requiring credentialing.
- iv) Identify the bodies that should develop standards and criteria for credentialing.
- v) Identify additional members to be co opted and individual to be consulted.
- vi) Propose mechanisms to ensure only competent practitioners are allowed to perform certain procedures.
- vii) Propose mechanisms to monitor individuals performing those procedures.
- viii) Propose remedial actions to be taken for practitioners who are not or no longer competent to perform such procedures.
- ix) Other proposals

The committee met 4 times over the last two months and received inputs from various quarters including a document from the Australian Council for Safety and Quality in Health

on the standards for Credentialing and Defining the Scope of Clinical Practice made available by one of the members.

The Committee took cognisance of the fact that the MMC has jurisdiction over registered practitioners only. As the Council would not be able to regulate the activities of hospitals and institutions, the committee decided to make two sets of recommendations i.e the guidelines for registered practitioners and proposals on the role of the Ministry of Health.

The Committee herewith makes the following recommendations:-

- i) The guidelines for doctors are in **Appendix A**.
- ii) The proposals for the role of Ministry of Health are as follows.
 - a. The Patient Safety Council under the Ministry of Health (MOH) be expanded to a statutory body to oversee the Credentialing, Privileging and Monitoring of Practitioners performance on a similar basis as the Australian Council for Safety and Quality in Healthcare. This body shall be entrusted with the responsibility of regulating safety standards.
 - b. The role of the Health Technology Assessment Unit under the MOH be enhanced to be the sole body to evaluate new technologies and its findings be binding on all parties concerned.
 - c. The scope of the Private Healthcare Facilities and Services Act be extended to the public hospitals and institution so as to have uniformity in responsibilities and enforcement.
 - d. The Guideline on Standard for Credentialing and defining Scope of Clinical Practice by the Australian Council for Safety and Quality in Health as attached in **Appendix B** be customised to the needs of Malaysia.

NEW CLINICAL SERVICES, PROCEDURES OR OTHER INTERVENTIONS

New clinical services, procedures or other interventions offer the promise of improved patient care. Registered medical practitioners may adopt new clinical services, procedures or other interventions, despite little evidence of either their efficacy or their superiority over existing clinical services, procedures or interventions. Some of these new clinical services, procedures or other interventions have been found to be ineffective, waste resources and endanger lives. As such, the Malaysian Medical Council issues these guidelines for the guidance of all registered medical practitioners on the usage of new clinical services, procedures or other interventions,

New clinical services, procedures or other interventions are “*clinical services, procedures or other interventions that are being introduced into a health care facility for the first time and that depend for some or all of their provision on the professional input of registered medical practitioners. They may, but will not necessarily, be innovative, complex or costly. They will, however, require more than incremental change in the way in which health care services are delivered within a health care facility.*

They may be clinical services, procedures or other interventions which:

(i) have been established in other organisational settings and are deemed by a responsible body of professional opinion to be ones that will benefit patients; or

(ii) are experimental, and therefore subject to review by a properly constituted Research Ethics Committee.

They do not include new pharmacological products.”

The safety of new clinical services, procedures or other interventions, and their potential to improve patient outcomes, are overriding considerations in determining whether to approve their introduction. In addition, cost, risks and cost-benefit have to be considered.

Patients have a right to expect that their autonomy and safety will not be compromised when new clinical services, procedures or other interventions are introduced. For this reason, all registered practitioners involved in the usage of new clinical services, procedures or other interventions shall adhere to the following principles.

1. The usage of the new clinical services, procedures or other interventions shall always be governed by respect for human rights i.e. dignity and freedom
2. The consequences of the usage of the new clinical services, procedures or other interventions shall be understood and can be controlled.
3. There shall be a favourable balance between the potential benefits and the risks of the new clinical services, procedures or other interventions.
4. There shall be an equitable distribution of the burdens and benefits of the use of the new clinical services, procedures or other interventions. Researchers shall ensure that the vulnerable are not exploited and that eligible patients who may benefit from participation shall not be excluded without good cause.
5. Valid consent shall be obtained prior to the usage of the new clinical services, procedures or other interventions. In particular, it should be informed to the extent

that is possible with the available current knowledge provided to the patient. A realistic risk assessment in view of the many knowledge gaps and the complexities involved shall be disclosed to the patient.

6. There shall not be disclosure of any personal information of patients without their permission.
7. The registered medical practitioner shall always practise within the limits of his/her competence.
8. The registered medical practitioner, who considers that he or she has the threshold credentials required, shall obtain the approval of the health care facility's governing body, prior to including the new clinical service, procedure or other intervention within his or her scope of clinical practice;
9. The registered medical practitioner in charge of the health care facility shall ensure that there is a policy, endorsed by the Malaysian Medical Council and the relevant medical specialty organization, that define:
 - a. new clinical services, procedures or other interventions;
 - b. who may request assessments of new clinical services, procedures or other interventions, and the process by which they may submit requests for the assessments;
 - c. the health care facility's requirements for assessment of the cost, risks, efficacy and cost-benefit of the proposed new clinical service, procedure or other intervention, including whether external benchmarking data should be considered;
 - d. the health care facility's requirements for consideration of the broader health care context within which the new clinical service, procedure or other intervention is proposed to be introduced;
 - e. the individuals and/or committees to whom authority is delegated by the health care facility's governing body to make decisions regarding the introduction of new clinical services, procedures or other interventions.
10. The registered medical practitioner in charge of the health care facility shall establish a committee that is responsible for advising the health care facility's governing body on the safety, efficacy and role of new clinical services, procedures or other interventions. The committee so established shall:
 - be comprised of a majority of registered medical practitioners with expertise in the relevant specialty;
 - be responsible for overseeing the assessment of a proposed new clinical service, procedure or other intervention;
 - determine whether the relevant medical specialty organization has established any guidelines or criteria relevant to the safety, efficacy or role of any proposed new clinical service, procedure or other intervention, and comply with these if available;
 - determine the threshold credentials required of registered medical practitioners to include the new clinical service, procedure or other intervention within their scope of clinical practice;
 - consider the efficacy of any proposed new clinical service, procedure or other intervention from various sources including the Health Technology Assessment Unit of the Ministry of Health, peer-reviewed medical literature, evidence-based assessments e.g. the Cochrane Collaboration, compared with

the efficacy of currently available clinical services, procedures or other interventions;

- consider the clinical risks associated with any proposed new clinical service, procedure or other intervention, compared with the clinical risks of currently available clinical services, procedures or other interventions;
- for any proposed new clinical service, procedure or other intervention which it believes is experimental, consider the recommendations of the facility's or other Research Ethics Committee, or if there are none, to seek advice from the relevant medical specialty organization or the Malaysian Medical Council;
- consider whether any proposed new clinical service, procedure or other intervention would replace existing clinical services, procedures or other interventions;
- advise the health care facility's management on the facilities as well as clinical and non-clinical support services that are necessary to ensure that any proposed new clinical service, procedure or other intervention can be provided safely and at high quality;
- formulate advice on whether a proposed new clinical service, procedure or other intervention is suitable for introduction in the health care facility based on its safety, efficacy and role, and if so, under what circumstances and with what facilities and clinical and non-clinical support services; and
- communicate its advice and decisions, regarding the introduction of new clinical services, procedures or other interventions, to the governing body, registered medical practitioner in charge and all registered medical practitioners of the health care facility.

References

1. Code of Professional Conduct, Malaysian Medical Council, 1987
2. Good Medical Practice, Malaysian Medical Council, 2001
3. Standard for Credentialling and Defining the Scope of Clinical Practice, Australian Council for Safety and Quality in Health Care, 2004