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Submission of the Hong Kong Medical Association (HKMA) to the Legislative Council Panel on Health Services (The Panel) in relation to the Review of the Human Organ Transplant Ordinance Cap 465 (The Ordinance) in response to a request in the letter from the Clerk to the Panel to HKMA dated 11th November 1998.

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The HKMA notes that the Ordinance has been put into operation for several months now. Events in these few months revealed that there were areas in the Ordinance which may need clarification and/or improvement. HKMA shall submit on three such areas herein below:

1. Section 5(4)(c) and 5(5) of the Ordinance:

These two sections provide for both the donor and recipient (in a non-genetically related live donor situation, be explained and understood of the procedure, risk and entitlement to withdraw by a medical practitioner (not involved in removing or transplanting organ in the case itself) and a suitable person respectively.

The purpose of such provisions is obvious, that is to ensure the decision made by the donor and the recipient is a properly informed one.

Difficulties (apparently unforeseen at the time of drafting of the Ordinance but is being transpired by recent events), arise when the intended recipient has, by reason of his (her) clinical condition, lapsed into a comatose state.

One strict interpretation of these sections of the Ordinance suggests that since one obviously cannot be interviewed or explained of the matters required of by the Ordinance under such circumstances, such requirement will not be fulfilled and no transplant from live donor can go ahead then.

It is indeed a painful irony that a patient is being deprived of the opportunity of the treatment of organ transplant by reason of the very condition that make him (her) so require such a treatment. One must note that organ transplant needs to be done on a comatose recipient is not at all an unusual happening. A recent event of a patient suffering from acute liver failure (which caused the patient to lapse into coma) is one obvious example.

Some views have been expressed that there is another approach to the interpretation of the Ordinance which if adopted would still make the treatment of organ transplant from a live donor for a needy patient possible under the Ordinance. The views of such interpretation approach are being put in **Appendix 1** of this HKMA submission for reference.

It is obvious that the vital moments at the time of approval decision by the Human Organ Transplant Board is not at all the best time to determine the controversy of which interpretation approach one should adopt. Since such unfortunate occurrence of denial of organ transplant from a live donor for a comatose patient will certainly repeat itself if nothing is done to clarify the situation, it is most desirable that the letters of the statue be amended to make it clear to all parties concerned.

HKMA submits that the goal of any such amendment should be to make it possible for organ transplant from a live donor to be done for a needy patient who, by reason of his

medical conditions, cannot fulfill the requirement of being interviewed and being given explanation now set out in the Ordinance, provided that:

(1) two registered medical practitioners, not involved in the removal and/or transplant of the organ, confirm that such treatment of organ transplant is needed and is in the best interest of the recipient patient concerned;

(2) the registered next of kin of the recipient patient concerned (as registered on admission to the hospital) has stood in the place of the recipient patient and fulfill the requirements of being interviewed and being given explanation now set out in the Ordinance (unless there is no registered next of kin or the registered next of kin cannot be found after reasonable effort).

The rationale and supporting law for such proposal is put forward in Appendix 2 to this HKMA submission.

2. Operation mechanism and efficacy of the Human Organ Transplant Board (The Board)

Recent events had led to concern over the operational mechanism and efficacy of the Board. Such concern is mainly over the promptness and readiness of the Board in proceeding with the consideration of applications for non-genetically related live donor organ transplant, whether it can act promptly and immediately at all times and any time of the day. This is most important because organ transplant treatment may not be an elective procedure. Both the necessity for transplant and the availability of organ may arise only at short notice and at any time of the day. Medical conditions know of no office hours or sleeping hours. If anything happens, it happens and professional staff will have to deal with it promptly at any time of the day. It also has to be dealt with promptly because every second lost may mean the loss of part of the chance of successful recovery of the patient. It may mean the difference of life and death.

A recent urgent application to the Board for approval made in the small hours of the day, has not been given an answer until more than 10 hours later. Such length of time is not acceptable at all upon the clinical setting of this matter. Review should be done in respect of how an application was being handled: whether the application was communicated to the decision makers, i.e., the Board members, promptly and immediately even at small hours of the day and whether the Board members proceed to consider the application also promptly and immediately even at small hours of the day. Lessons so learned would be important to ensure that future applications would not be handicapped by any delay arising out of adherence to office hours routines and the sanctity of sleeping hours or other human inertia in any form.

Communication in relation to the progress (or non-progress) made should preferably be made and maintained with the clinical staff looking after the patient concerned to allow them to take all factors in consideration in the management of the patient and in the consideration of alternatives.

One should note that the chain of provision of therapy to a patient has always gone through only professionals, doctors, nurses and other medical staff who understand and are prepared for providing service at all times and any time of the day. The imposition of the requirement of approval from the Board adds a new and additional factor in the chain of provision of therapy, a factor which may not understand or be prepared to act in the manner

and promptness that professionals are used to and expected to be. That would be a most detrimental hindrance to the provision of prompt and needy therapy (and/or consideration for alternatives, if necessary) to the patient. Having taken up a role in the chain of provision of therapy, the Board should understand its effect on the medical team. It is important that it will work together with the rest of medical team in saving and helping the patient (but of course without affecting its independence in coming to a decision).

The Board may have to take a more liberal approach in gathering information for determination of applications. (This point will be elaborated in discussion of Item 3 below.)

To enable future Board members not to lose sight of the importance of proceeding to consider application promptly, we suggest that amendments should be considered to add in provisions to the effect that the Board should proceed to consider promptly and immediately upon an application is being made.

3. Proof of No Commercial Dealing

Even the Board itself has expressed, in its recent statement, that they find difficulty in deciding what constitutes sufficient proof of no commercial dealing. Such difficulties are obviously real for two reasons:

(1) One is being asked to prove the negative, i.e., the non-existence of something. Logically this can be proven only by exhausting all possibilities. This is impossible in reality;

(2) The applicants are supposed to be the doctors. They can only provide matters and evidence to their own personal knowledge. This understandably is limited.

Noting (1) the above difficulties; (2) that the purpose of the Ordinance is only to avoid commercial dealing in organ transplantation but not needy treatment to patients; and (3) Organ transplant from live donors, particularly those need to be done on an urgent basis, is usually a last resort method.

It is suggested that:

(1) Decisions must err on the safe side of allowing the application so as to give the patient the opportunity of treatment.

(2) The Board should take a more active process in determining an application. They should interview the applicant, the relevant relatives and persons if it is helpful for them to gain more first hand information or impression on the matter. They should not be restricted to determining an application on papers only. A more liberal approach is better than a bureaucratic approach.

(3) The Board, after it has decided against an application, can always review its own decision on its own initiative upon production of new evidence.

(4) Affidavit evidence is acceptable for such determination.

(5) The Board may require concerned person to make or undertake to make affidavits in support of matters they alleged during the application. This may help by providing an additional deterrent of the possibility of committing perjury for making untrue allegations for an application.

All these suggestions may need amendment to the Ordinance to achieve recognition and effectiveness.

4. Background Cause - the need for promotion of cadaver donation

The plight and difficulties of organ transplant from live donors indeed arise from the sad reality that Hong Kong has failed miserably in the promotion of cadaver organ donation, i.e., organ donation from dead persons. Despite more than ten years of effort, there is little significant or persistent increase in cadaver organ donation. Consideration should be given to how to improve this situation. Possible positive action may include promotion of computerized willing organ donors registers (as now exist in the Hong Kong Medical Association Organ Donation Register) and also stimulate discussion on optional systems, e.g., opting out systems.

Further information and opinion on these two possible action will be submitted on request.

Hong Kong Medical Association

<u>Appendix 1</u>
<u>of the HKMA Submission to LegCo Panel on Health Services</u>

Alternative Interpretation of Section 5(4) and (5) of the Human Organ Transplant Ordinance, Cap 465

Before giving its approval for organ transplant from non-genetically related live donors, the Ordinance, by a literal approach, apparently requires -

Under Section 5(4)(c) registered medical practitioner, who is not the medical practitioner who will remove the organ from the donor or transplant the donor's organ to another person, has explained to the donor and the recipient, and each has understood - (i) the procedure; (ii) the risk involved; and (iii) his entitlement to withdraw consent any time;

Under Section 5(5) that the board shall ensure that the donor and the recipient have each been interviewed separately by a person whom the board considers to be suitably qualified to conduct such an interview and the person has reported to the board on the donor's and recipient's understanding of the matters contained in subsection (4)(c) and (d)."

These two requirements obviously cater for independently administered and independently proven informed consent for both the donor and recipient. The subject issue of such exercise can be said to be informed consent".

For the donor, an organ donation operation will definitely be detrimental to him (her) and of no benefit physically speaking though there are arguably the intangible benefit of mental satisfaction of helping and saving the life of others. Such exercise is of particular relevance and importance.

In the case of the recipient, the issues involved are much the same if the patient is conscious. However, if the patient is not conscious but is comatose because of his sick condition, then the circumstances on the issue of informed consent are totally different.

The issue of consent to medical treatment in a comatose patient takes on a basis totally different from that of a conscious patient. Since the law acknowledge the self determination authority of any adult person as supreme, agreement by next-of-kin, any relative, friend or any other person cannot validly substitute a consent of the patient himself and would have no real legal effect.

However, the courts have considered it to be lawful for doctors to proceed with treatment in unconscious patients without their consent if it is in the best interests of the patient and what is done is acceptable as proper by a body of skilled and experienced medical men (or sometimes said as the responsible body of "medical opinion").

The principle upon which such allowance is based range from "implied consent" to necessity".

Such principle and the attitude of the courts resolve the dilemma of consent to treatment in a patient who is unable to give consent. Treating unconscious patients is not at all an uncommon occurrence and indeed it occurs every day and hour.

There is, however, another view on how statues should be interpreted. By the "purposive approach" to statutory interpretation, the words in a statue must be interpreted according to their natural, ordinary and grammatical meaning, so far as possible, but ONLY TO THE EXTENT that such interpretation does not produce a manifestly absurd result. One well known statement of this approachis to be found in the judgment of Parke B. in Becke v Smith (1836), 2 M & W., at 195:

"It is a very useful rule in the construction of a statue to adhere to the ordinary meaning of the words used, and to the grammatical construction, unless that is at variance with the intention of the legislature to be collected from the statue itself, or leads to any manifest absurdity or repugnance, in which case the language may be varied or modified so as to avoid such inconvenience, but no further."

The purpose of the legislature in the sections now in issue surely is to provide informed consent, but not to deny those patients who are not capable of giving consent, the opportunity of treatment. A literal approach obviously produce an absurd situation as shown by the recent events. In the circumstances, by a purposive approach to interpreting the statue, the original common law position of allowing the doctors to proceed in the best interests of the patient and in accordance with acceptable medical opinion must apply. The Board should then be satisfied on the issue of the consent should there be good evidence to the effect that such procedure would be in the best interests of the patient and was in accordance with acceptable medical opinion.

Further alternatively, the literal approach indeed have not provided for the situation in which the patient is unconscious and incapable of giving consent. Then in the absence of any specific statutory provision, one again should consider that the original common law position applies, i.e., in unconscious patients, procedure done in the best interests of the patient and in accordance with acceptable medical opinion, is lawful.

Thus, either by way of the purposive approach to statutory interpretation or by arguing for the existence of a lacuna in the literal approach, the original common law position should allow the Board to feel satisfied under the circumstances of "best interests" and "acceptable medical opinion".

If these alternative views are accepted as how the Ordinance is to be interpreted, the Board would have been able to allow the application in an unconscious patient under the appropriate circumstance.

<u>Appendix 2</u>
<u>of the HKMA Submission to LegCo Panel on Health Services</u>

Rationale and Supporting law for amendment proposals

Appendix 1 of the HKMA submission to LegCo Panel on Health Services is adopted as part of this Appendix 2. Readers to this Appendix 2 should refer back to Appendix 1 first if they have not done so before.

Noting that treatment for unconscious patient may be proceeded with if it is considered to be in the best interests of the patient and in accordance with acceptable medical opinion, it is proposed that the Board may be satisfied, in the subject matter of section 5(4)(c) and 5(5), which in effect is consent, by evidence that two registered medical practitioners, unconnected with the proposed transplantation, agreed and confirmed that it is their truthful beliefs that the transplant procedure proposed is in the best interest of the patient concerned and that in their opinion, the decision to proceed with such management is acceptable to them.

Such evidence will provide two essential element: one objective evidence that such proposal is in the best interests of the patient, and the other is that the two experienced medical practitioners' view should form a valid basis that the decision is acceptable to a responsible body of "medical opinion" (formed at least by these two experienced medical men). Such is the basis for the proposal.

The suggested requirement that the registered next-of-kin should also be informed and explained to beforehand is indeed an extension of realistic and good medical practice. Even though consent from relatives or next-of-kin probably have no legal effect, it allows an element of check and balance so that alarm can be raised if objection is indeed contemplated.

It is further noted that in the World Medical Association Declaration on Human Organ Transplant adopted by the 39th World Medial Assembly in Madrid Spain, October 1987 stated, under paragraph 5 of the Declaration, that "The fullest possible discussion of the proposed procedure with the donor and recipient <u>or</u> their respective responsible relatives or legal representatives is mandatory. ......". It has thus anticipated the impossibility of seeking consent from an unconscious patient and has provided for discussion with relatives or legal representatives.

One further word of note is that the suggestion is for unconscious recipient only. The consent from live donor must remain voluntary, informed consent.

Furthermore any amendment must state explicitly that the prescribed arrangement is restricted to the matter of consent in the unconscious transplant recipients only and the common law position in other cases should not be affected.