6. BIOMEDICAL LAW AND ETHICS

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Introduction

6.1 The year under review saw the courts hand down two decisions that not only dealt with important procedural issues in relation to the prosecution of medical practitioners, but also clarified the law regarding the ethical obligations of medical practitioners in relation to the extent to which they may apply novel forms of treatment to their patients. Although these decisions were issued in the context of professional disciplinary hearings, there may be some impact on medical negligence litigation in general. A third decision was also delivered bearing on the circumstances in which a medical practitioner may delegate the post-operative care of a patient to a nurse or another medical practitioner.

Ethical obligations in relation to novel treatments

6.2 In *Gobinathan Devathasan v Singapore Medical Council* [2010] 2 SLR 926 ("*Gobinathan Devathasan*"), the medical practitioner was charged with applying two treatments – Repetitive Transcranial Magnetic Stimulation ("rTMS") and Therapeutic Ultrasound – to a 77-year-old patient who was suffering from a chronic and complicated neurological syndrome, specifically, a sub-type of chronic stroke. Previous attempts at therapy with other neurologists had been unsuccessful. Although it appears that much of the evidence led at trial related to the safety of the combined used of rTMS and Therapeutic Ultrasound, the Singapore Medical Council ("the SMC") preferred two charges, one in relation to each form of treatment, alleging that the therapy was not indicated by the patient's condition, not generally accepted by the medical profession as a form of treatment for the patient's condition, and inappropriate for the patient's condition. Dr Devathasan was eventually convicted by the disciplinary committee of only the allegations relating to the use of Therapeutic Ultrasound, though this was subsequently overturned by the Court of Three Judges. We will revisit the procedural issues relating to the prosecution and focus, presently, on the ethical obligations on medical practitioners in relation to novel treatments.

6.3 As the court explained in its judgment, there are potentially at least two different – though sometimes related – inquiries when a

medical practitioner decides to apply novel treatment in the best interests of the patient. The first relates to the extent to which a medical practitioner may prescribe such treatment when, as a matter of fact, a treatment is novel, and therefore, by definition, has not gained widespread acceptance by the medical community. The second inquiry is the extent to which such treatment, often unapproved and "off-label", should be prescribed, considering the effect that such treatment may have on the patient.

Treatments not generally accepted by the medical profession

6.4 The permissibility of prescribing treatment that is not generally accepted by the medical profession is expressly provided for in Guideline 4.1.4 of the SMC Ethical Code and Ethical Guidelines ("the SMC Ethical Guidelines"), which states:

> A doctor shall treat patients according to *generally accepted methods* and use only licensed drugs for appropriate indications. A doctor shall not offer to patients, management plans or remedies that are not *generally accepted* by the profession, except in the context of a formal and approved clinical trial.
>
> …
>
> It is not acceptable to experiment or authorise experiments or research which are not part of a formal clinical trial and which are not primarily part of treatment or in the best interest of the patient, or which could cause undue suffering or threat to the life of a patient.
>
> [emphasis added]

6.5 On a literal reading of this provision, it would appear that any treatment, unless otherwise widely approved or endorsed by one's peers, should not be prescribed except in the context of a clinical trial. Such a narrow reading of the provision, however, is ultimately counterproductive and may not be in the best interests of patients for whom conventional treatment has proven futile. Moreover, as the disciplinary committee quite rightly pointed out, a zero-tolerance policy against the use of novel treatment may hinder progress and innovation in medicine: see *Gobinathan Devathasan* at [21].

6.6 As an aside, it may be noted that, in general, the priority of clinical trials is not the interests of the patient but the protocol objectives of the trial. In this sense, there is an uneasy tension inherent in Guideline 4.1.4 of the SMC Ethical Guidelines, which requires treatments not yet generally accepted to be applied only in the context of clinical trials *and* "which are … primarily part of the treatment or in the best interests of the patient". This suggests that even when applied in the clinical trial context, the novelty of the treatment requires a further

limit – that it is in the best interests of the patient. I am grateful to Asst Prof Tracey Evans Chan for this point.

6.7 Implicit in this discussion as to whether a particular treatment is accepted by the medical community is the question – which medical community? If a treatment is not widely accepted in Singapore but widely practised in other countries, should a medical practitioner be prevented from using such treatment? The disciplinary committee appeared to take the view that just because a particular treatment was not generally accepted in the local medical community did not mean it could not be prescribed without contravening the SMC Ethical Guidelines. In this regard, the disciplinary committee did – at least in relation to the use of rTMS – have regard to the foreign medical literature supporting its use as an auxiliary treatment for the patient's condition, particularly where other treatment methods had failed: see *Gobinathan Devathasan* at [21]–[22].

6.8 In seeking to strike a pragmatic balance, the court endorsed the views of the experts who had testified before the disciplinary committee that novel treatments could be applied, provided that:

(a) there had been at least "one good study";

(b) the results of the study could be replicated and reproduced under the same sort of like treatment parameters and conditions;

(c) the study had been written up in publications and presented at meetings;

(d) the study had received peer review;

(e) the study had "clear-cut results" and the sample had been "statistically significant"; and

(f) the study had some form of controls, such as randomised double-blind trials.

The safety of "off-label" treatments

6.9 The safety of novel, unapproved or off-label treatments was considered by the court as constituting a separate analysis. Hypothetically, therefore, a medical practitioner could be guilty of prescribing novel treatment that was unsafe for the patient, and yet not have breached Guideline 4.1.4 of the SMC Ethical Guidelines, which is principally concerned with there being some scientific basis for the treatment. Of course, it is difficult to imagine a form of treatment that was *generally* unsafe being published in a recognised medical journal. But the court was quite right to point out that the two analyses did not necessarily follow each other. If the SMC was concerned about the safety

of the particular patients whom the medical practitioner had treated, or the safety of patients in general, there is no reason they could not bring a charge specifically alleging this.

6.10 The SMC Ethical Guidelines, however, do not in terms prescribe the ethical obligations of a medical practitioner thinking of embarking on such off-label treatment. Seeking guidance from the British General Medical Council and the American Food and Drug Administration, the court held that off-label treatment could be justified in circumstances where (*Gobinathan Devathasan* at [53]–[55]):

> (a) it would better serve the patient's needs than an appropriately licensed alternative;
>
> (b) there is a sufficient evidence base or experience of using the medicine to demonstrate its safety and efficacy;
>
> (c) the medical practitioner is prepared to take responsibility for prescribing the medicine, overseeing the patient's care, monitoring and following up on treatment, or arranging for another doctor to do so;
>
> (d) the medical practitioner makes a clear, accurate and legible record of all medicines prescribed and the reasons for prescribing the medicine if a common practice is not being followed; and
>
> (e) the medical practitioner keeps a record of the effect of the treatment or product used.

6.11 In short, there should be a firm scientific rationale for choosing to apply the particular treatment to the clinical situation, as well as evidence of benefit and lack of harm to the patient.

The burden of proof

6.12 The court went on to elaborate on the allocation of the burden of proof. It held that where the safety of the patient was an element of the charge, the legal burden would be on the SMC to prove, beyond reasonable doubt, that the treatment was unsafe for the patient: *Gobinathan Devathasan* at [62]. However, where the safety of the patient was not an element of the charge, and where the alleged inappropriateness of the treatment arises from the fact that the treatment was not generally accepted by the medical profession or not indicated by the patient's condition, then the evidential burden is on the practitioner to prove the safety of the treatment in order to rebut the assumption of inappropriate treatment: *Gobinathan Devathasan* at [62]. The court concluded as follows (*Gobinathan Devathasan* at [62]):

> We are of the opinion that where a doctor embarks on a treatment that is not indicated or generally accepted in the profession, but the doctor is of the view that his novel treatment may do some good, but will do no harm to the patient, placing such a burden on him to establish that no harm will come to that patient strikes a correct balance between two important considerations in medicine, *viz*, promoting innovation and progress, provided that the patient's well-being is not compromised.

6.13 There appears to be quite a few ideas condensed in this important part of the judgment. First, the court was undoubtedly correct in holding that where it is alleged that the treatment was unsafe, this has to be proven by the SMC. This is a straightforward application of the burden of proof applicable to all criminal and quasi-criminal cases.

6.14 Second, the court's view that the medical practitioner would bear the evidential burden of proving the safety of the treatment if the charge was simply that the treatment was not generally accepted or indicated by the patient's condition is, with respect, a little unclear. It seems to suggest that simply by *omitting* to allege that the treatment was unsafe, the SMC could throw the evidential burden to the medical practitioner to prove the safety of the treatment. On the other hand, by formally charging the medical practitioner with providing an unsafe treatment, the SMC bears the ultimate legal burden and at least has to adduce some *prima facie* evidence that the treatment was unsafe before the evidential burden shifts. Perhaps what the court meant was that it would be a *defence* to a charge of prescribing treatment that was not yet generally accepted or indicated by the patient's condition to nevertheless prove that the treatment was safe. In other words, no harm, no foul. This is eminently reasonable for the reasons cited by the court in the passage quoted above. But, on conventional analysis of the burdens of proof, a defendant who wishes to avail himself of a defence has the legal burden to prove his defence on a balance of probabilities. Moreover, to hold that proof of the safety of the impugned treatment is a defence seems somewhat at odds with the court's criticism of the disciplinary committee's finding that Dr Devathasan had to prove that Therapeutic Ultrasound was safe for patients. The court said that (*Gobinathan Devathasan* at [61]):

> In our view, the safety of a treatment is not a necessary facet of the inappropriateness of a treatment. Indeed, the SMC's case before the DC was that Therapeutic Ultrasound was inappropriate without any allegations that it was unsafe. [cross references omitted]

6.15 Yet, according to the passage cited above (in para 6.12), proof of the safety of the treatment is relevant as a defence even absent an allegation in the charge that the treatment is unsafe.

6.16 Third, and in any event, having to prove that no harm will be done to the patient may be asking for the impossible in many cases. It turned out, on the facts of this case, that the patient was unharmed. But this does not mean that the patient might not have been harmed. Suppose an injunction had been brought by, say, a relative or a fellow medical practitioner prior to the administration of the treatment, how would the court resolve the matter? Presumably, it would weigh the risk against the benefit, but it would ultimately have to accord significant weight to the patient's stated tolerance for the risk. The same logic should apply where disciplinary proceedings are brought after the treatment has been administered. That the treatment might have been risky should only be one part of a holistic cost-benefit analysis that takes into account the extent to which the patient had made a free and considered choice to undergo the treatment.

Impact on medical negligence litigation

6.17 Although the case concerned disciplinary proceedings, the court's willingness to accept the prescription of unconventional or novel treatment could have some impact on medical negligence litigation in general. It is well-known that a medical practitioner could defend himself from a claim in negligence by pointing to a respectable body of medical opinion supporting his actions. But what if the medical practitioner's treatment was not generally accepted (even among a minority of respectable practitioners) as standard care. Based on *Gobinathan Devathasan*, there could be an argument for saying that this alone should not mean that the medical practitioner is liable for negligence.

Delegation of post-operative care

6.18 In *Dr Eric Gan Keng Seng v Singapore Medical Council* [2011] 1 SLR 745 ("*Eric Gan*"), the court considered an appeal against a finding by the disciplinary committee that a medical practitioner, Dr Gan, ought to have been sanctioned for inappropriately managing his patient's care, and for failing to personally assess the condition of his patient in a timely manner upon the onset of symptoms and signs following an unsuccessful procedure earlier in the day. Although Dr Gan ordered various tests upon being informed on the phone that the patient was unwell, he relied solely on the assessment of junior doctors of the results of those tests, including one still in medical training. By the time Dr Gan personally visited the patient the following morning, and ordered the appropriate CT scan, which revealed the perforation of the patient's duodenum, the patient's condition had irretrievably worsened and he passed away shortly after.

6.19 The finding that Dr Gan should have personally attended to his patient sooner after the patient exhibited symptoms of being unwell breaks new legal ground; this being the first reported case of a medical practitioner being disciplined for inappropriately delegating the post-operative care of his patient. The general principles are clear enough. The court drew a distinction between the provision of treatment or care to a patient, and the clinical assessment of the condition of a patient. While a medical practitioner may, subject to the provisions of Guideline 4.1.1.4 of the SMC Ethical Guidelines, delegate the provision of treatment and care to another doctor or nurse, there is a much stricter obligation to personally visit a patient in order to assess his condition. In this regard, a medical practitioner:

> (a) is required to make necessary and timely visits or investigations (see Guideline 4.1.1.5 of the SMC Medical Guidelines); and
>
> (b) should only diagnose a patient without personal contact in exceptional or emergency circumstances (see Guideline 4.1.1.1 of the SMC Medical Guidelines).

6.20 In post-operative care, however, the line between diagnosis and care (or observation) can be challenging to tell apart in practice. The result in this case was made easier by the fact that there had been an unsuccessful procedure, the finding that Dr Gan himself had an inkling that there was something wrong with the patient, and the patient's complaints of abdominal pain coupled with bilious vomiting. In the circumstances, it is difficult to fault the disciplinary committee's (and the court's) conclusion that Dr Gan should have personally assessed the patient's condition much earlier.

Professional discipline

Procedural flaws in a prosecution

6.21 Turning to the technical aspects of the medical professional disciplinary process, the court in *Gobinathan Devathasan* (above, para 6.2) had strong words for the disciplinary committee, observing that the recent amendments to the Medical Registration Act (Cap 174, 2004 Rev Ed) permitting legally-trained persons voting membership on the disciplinary committee were timely. In brief, the court found the disciplinary committee's decision procedurally flawed for the following reasons.

6.22 First, and perhaps foremost, it misapplied the burden of proof. In so holding, the court affirmed the principle that the SMC continued to bear the legal burden of proving beyond reasonable doubt the

essential elements of the charges preferred (*Gobinathan Devathasan* at [61]).

6.23 Second, the court quite rightly found it difficult to understand why the disciplinary committee did not consider Dr Devathasan's evidence as to the safety of the Therapeutic Ultrasound when this formed the primary basis of conviction (*Gobinathan Devathasan* at [65]).

6.24 Third, the court criticised the disciplinary committee for hearing evidence, and finding such evidence relevant, that were irrelevant to the precise charges preferred. For example, the disciplinary committee appeared enamoured by the idea that Dr Devathasan had to prove the efficacy of the treatment generally even though the charges were brought in respect of treatment administered to a specific patient. Indeed, the question of safety was not, on the prosecution's own case, relevant and yet appeared to take centre stage in the eventual grounds of decision. Moreover, although separate charges were brought in respect of each modality of treatment (rTMS and Therapeutic Ultrasound), the disciplinary committee continued to hear evidence as to the soundness of administering both treatments together (*Gobinathan Devathasan* at [32]–[34]).

6.25 In *Eric Gan* (above, para 6.18), the court was again confronted by a similar submission by the medical practitioner that the disciplinary committee had traipsed beyond the confines of the charge and its particulars. As noted above, the disciplinary committee found that Dr Gan should have personally assessed the patient's condition; but, as the court frankly observed, such an allegation was not to be found in the charge presented against him. That charge focused solely on the failure to order the appropriate clinical investigation within a reasonable time. Although it affirmed the principle in *Gobinathan Devathasan*, the court held that the issue as to Dr Gan's personal attendance of the patient was a circumstance which the disciplinary committee was entitled to take into account in its overall assessment of the practitioner's gross neglect or management (*Eric Gan* at [30]). In addition, as Dr Gan had sought to call an additional witness for his views on this issue of personal attendance, he had known that "one of the issues was the post-operative care" of the patient. Indeed, his closing submissions had also dealt with the post-operative care of the patient (*Eric Gan* at [31]).

6.26 That Dr Gan should have personally assessed his patient might have been the basis for an independent charge but it was not. The SMC's case against Dr Gan was that he had failed to order a CT scan in time. This was proven and the disciplinary committee need not, and should not, have gone further. The reason for Dr Gan's failure to order the CT scan on time – that he had not personally assessed the patient's

condition – might have been interesting background but it was certainly not what the SMC had set out to prove. It may be that Dr Gan knew that this was in issue and sought to adduce evidence to the contrary; but it is not clear if this was simply an astute response to the questions being asked by the disciplinary committee or a burden Dr Gan had taken on himself (*Eric Gan* at [24]). It is equally unclear if Dr Gan managed to get the appropriate witnesses to testify on his behalf (*Eric Gan* at [24]). As *Gobinathan Devathasan* so forcefully emphasised, the requirement that disciplinary committees limit themselves to the particulars of a charge is an important procedural safeguard. In addition, a disciplinary committee has no power to act on its own motion and to expand its own jurisdiction by going beyond the confines of a charge. Nevertheless, *Eric Gan* may be confined to cases where the impugned finding is a necessary logical or chronological corollary to the charges presented and their particulars. Moreover, although not made explicit, the court might have been minded to dismiss the objection because, in its view, anything Dr Gan had to say on this score would have been futile. After all, some of Dr Gan's own witnesses testified that they would have reviewed their own patients after the procedure in question (*Eric Gan* at [34]), though it is unclear if this was directed at proving the requisite standard of care.

6.27 Returning to *Gobinathan Devathasan*, a few more observations may be made. First, the court found it significant that, after the complaint, the patient did not display an interest in the prosecution of Dr Devathasan and did not even appear before the disciplinary committee (*Gobinathan Devathasan* at [75]). There are sound reasons why in such circumstances it may be more prudent than not to discontinue the prosecution. Where the essence of the misconduct alleged centres on some injury to the patient, the patient's subsequent reluctance to testify seems to present an inescapable evidential gap. In most such cases, the extent to which the patient acquiesced or consented to the alleged wrongdoing is a critical constituent of the overall analysis as to whether the medical practitioner had acted unethically. If patient autonomy is to mean anything, a medical practitioner who provides a service in accordance with the patient's needs or desires or demands must be a relevant factor in the equation. Moreover, although the complaint once lodged technically exists, it seems artificial to operate as if there is a "real" complaint when the patient subsequently refuses to participate in the hearings. Given that the disciplinary committee has no power to act on its own motion, there is reasonable basis to contend that the disciplinary committee should not be regarded as continuing to possess jurisdiction over the matter. Equally importantly, all professional disciplinary hearings involve the disclosure of confidential patient records. If the patient does not participate in the hearings, one cannot assume that the patient consents to having his records disclosed.

6.28 Second, the way in which the charges were framed leaves much to be desired. Although not criminal proceedings *per se*, the consequences of a disciplinary hearing are serious. For that reason, our courts have long held that the same stringent standards applicable to criminal proceedings should apply to disciplinary hearings. Looking at the charges in this case, it is obvious that they were duplicitous. For example, they contained allegations both that the particular treatment in question might not have been indicated for the patient's condition and was not generally accepted by the medical profession. But these are conceptually distinct issues. More than that, the charges were also framed in ambiguous language. The scope and meaning of an allegation that a treatment is "inappropriate" is not self-evident. By allowing such wide and loose drafting of the charges, the prosecution in such cases can play fast and loose with its legal burden, leading the disciplinary committee itself into confusion as to precisely what ought to be proven and what is not relevant.

The extraterritoriality of the Traditional Chinese Medicine Practitioners Act

6.29 Finally, in *Huang Danmin v Traditional Chinese Medicine Practitioners Board* [2010] 3 SLR 1108, Tay Yong Kwang J held that professional misconduct committed overseas can be prosecuted in Singapore. In this case, the offending acts were committed in Johor. Tay J reasoned that the purpose of the Traditional Chinese Medicine Practitioners Act (Cap 333A, 2001 Rev Ed) ("the TCM Act") – being to safeguard the interests and safety of patients – was better served by an interpretation of the TCM Act as having extraterritorial effect. There is, with respect, good sense in this ruling. As a member of a professional body, there is no reason why one's professional misconduct overseas cannot be considered for the purposes of determining whether one is suitable to remain in good standing.