香 港 醫 務 委 員 會

The Medical Council of Hong Kong

DISCIPLINARY INQUIRY
MEDICAL REGISTRATION ORDINANCE, CAP. 161

Defendant: Dr LAM Kwun Lai Paul (林觀禮醫生) (Reg. No.: M03673)

Date of hearing: 14 April 2014 (Day 1), 25 September 2015 (Day 2), 26 September 2015 (Day 3), 27 September 2015 (Day 4) and 1 November 2015 (Day 5)

Present at the hearing

Council Members/Assessors: Prof. Felice LIEH-MAK, GBS CBE JP (Temporary Chairman)
Dr CHEUNG Hon Ming
Ms CHOY Hok Man Constance
Dr IP Wing Yuk
Dr WONG Yee Him John
Dr MOK Pik Tim Francis
Dr TUNG Yuk Stewart, JP

Legal Adviser: Mr Edward SHUM

Defence Counsel representing the Defendant: Mr Alfred FUNG instructed by Messrs. Mayer Brown JSM

Senior Government Counsel representing the Secretary: Mr Mark CHAN

1. The charges against the Defendant, Dr LAM Kwun Lai Paul, are:

"That, during the period of October 2006 to November 2006, he, being a registered medical practitioner, disregarded his professional responsibility to his patient [redacted] ("the Patient") in that:

(a) he misled the patient into believing that she had an increased body burden of heavy metals and that she needed a chelation therapy when in fact the patient did not have heavy metal toxicity;

(b) he unnecessarily prescribed to the patient a chelation therapy;

(c) he unnecessarily used two toxic chelating agents, namely EDTA and DMSA, to treat the patient;

(d) he unnecessarily prescribed to the patient "Ketoconazole", an antifungal drug which is potentially hepatotoxic;

(e) he unnecessarily prescribed to the patient vitamins, minerals and nutriceuticals in the treatment of the patient's eczema."

Facts of the case

2. The Defendant was at all material times a registered medical practitioner. His name has been included in the General Register from 17 August 1979 to present and in the Specialist Register under the Specialty of Paediatrics since 4 March 1998.

3. According to the Patient, she first developed skin problems in or around early 2005. She consulted a number of doctors including a dermatologist and a specialist in immunology and allergy for treatment. Despite being prescribed with antibiotics and steroids, her skin problems were never completely cured. The Patient also told us that ever since the onset of her skin problems in or around 2005, she had all along been eating seafood about twice a week.

4. There is no dispute that through the introduction of her relative, the Patient first consulted the Defendant for treatment of her skin problems on 3 October 2006. According to the Defendant's medical record notes for the first consultation, the Patient complained of impetigo (scabby eruption)-like skin lesions over her body for 18 months and there was increased itchiness at night. Physical examination then showed erythematous (reddened) roundish skin lesions with the size of a coin over the Patient's whole body and especially on her 4 limbs. Some of them were bullae (bubble-like) and covered with scabs. Brownish discolouration was also noted on her upper and lower gums.

5. According to the Defendant, he explained to the Patient during the first consultation that she was suffering from chronic eczema that was caused by allergy to environmental allergens. He also told the Patient that her skin problems were probably related to, first, an overload of toxic heavy metals, which in turn had adversely affected her body's immunity and detoxification ability; and second, a deficiency in micronutrients, which resulted in poor skin healing; and that he was

going to give her vitamins and nutriceuticals for improvement of her body's immunity. He further told the Patient that her skin problems were exacerbated by her lifestyle and dietary habits. He advised her to avoid eating seafood during treatment and she should also stop smoking and taking oral contraceptives.

6. There is conflicting evidence as to whether the Defendant had told the Patient during the first consultation that his treatment regime represented a form of complementary treatment which was not generally adopted by the medical community. There is also conflicting evidence as to whether the Defendant had actually claimed to the Patient that his treatment regime could cure her skin problems completely.

7. It is however clear from reading the Defendant's medical record notes on the first consultation that he gave the Patient an intravenous injection of "Vitamin C, Glutathione, Zinc, Choline, Inositol and Vitamin B12". He also prescribed to her, amongst others, oral vitamins (Vitamin C and E), minerals (Selenium, Magnesium and Zinc) and other nutriceuticals (Evening Primrose, Omega 3 fatty acid, Melatonin, CQ10, Chlorella, Silymarin, Bilberry, Alpha Lipoic Acid and Taurine).

8. The Patient visited the Defendant's clinic again for follow-up on her skin problems on 16 October 2006. During the second consultation, the Patient showed the Defendant the results of a skin allergy test taken a few months earlier, which revealed that she suffered mild to moderate allergy to a number of environmental allergens, including food items. According to the Defendant's medical record notes on the second consultation that he gave the Patient an intravenous injection of "Methionine Inositol Choline, Vitamin B12, Minerals and Glutathione". He also prescribed to the Patient, amongst others, oral vitamins, minerals and other nutriceuticals.

9. On 29 October 2006, the Patient visited the Defendant's clinic again for follow-up on her skin problems. According to the Defendant's medical record notes on the third consultation, he gave the Patient intramuscular injections of Vitamin B12 and Gluthathione. Apart from giving her oral vitamins, minerals and other nutriceuticals, the Defendant also prescribed to the Patient Ketoconazole 200 mg once daily, two times on the first day for 12 tablets.

10. Then on 13 November 2006, the Defendant asked the Patient to undergo a heavy metal test and she agreed. There is conflicting evidence as to whether the Defendant had explained to the Patient that this was a challenge (or provoked) urine test by

injecting chelating agent. According to the Defendant, he had previously explained to the Patient during the third consultation that the purpose of the challenge (urine) test was to investigate whether she had an overload of toxic heavy metals, especially mercury. But according to the Patient, the Defendant merely asked her during the fourth consultation whether she was willing to take the heavy metal test. The Defendant also told her that the sooner the amount of toxins in her body was determined, the earlier her disease could be cured. Therefore she agreed to do the test.

11. It is however not in dispute that no baseline urine sample was taken from the Patient. The Defendant directly performed a challenge urine test by giving DMPS 200 mg IV to the Patient and he also advised the Patient to collect urine sample during the first 6 hours after the injection.

12. Then on 28 November 2006, the Defendant explained to the Patient the results of the challenge urine test and told her that her skin problems were attributable to the high levels of toxic heavy metals, particularly, mercury, lead and arsenic, in her body. The Defendant also explained to the Patient that he was going to prescribe chelation treatment to eliminate the toxic heavy metals, especially mercury, in her body. The Defendant then gave the Patient Calcium EDTA 900 mg and Glutathione 200 mg intravenously. He also gave oral chelation including EDTA 400 mg on alternative days, and DSMA 250 mg on alternative evening, 3 days per week. In addition, Pentoxifyline 400 mg once daily for two weeks was prescribed to the Patient.

13. According to the Patient, she took the prescribed medications for a few days until 1 December 2006 when she discussed her treatment with a friend who was a nurse. Upon the advice from her nurse friend, the Patient went to the Adventist Hospital for a blood test on heavy metal toxicity on 6 December 2006. The results of her blood test were available on 15 December 2006 which showed that the lead and mercury levels in her blood were normal.

14. According to the Patient, her skin problems persisted for about half a year into the middle of 2007. In the meantime, the Patient consulted another two doctors and she took the medicines prescribed by those doctors on and off, as and when the need arose. Eventually, her skin problems were cured and she did not require further treatment since around the middle of 2007.

Burden and Standard of Proof

15. We bear in mind that the burden of proof is always on the Legal Officer and the Defendant does not have to prove his innocence. We also bear in mind that the standard of proof for disciplinary proceedings is the preponderance of probability. However, the more serious the act or omission alleged, the more inherently improbable must it be regarded. Therefore, the more inherently improbable it is regarded, the more compelling the evidence is required to prove it on the balance of probabilities.

16. There is no doubt that each of the allegations made against the Defendant here is serious. Indeed, it is always a serious matter to accuse any registered medical practitioner of misconduct in a professional respect. We need to look at all the evidence and to consider and determine each of the charges separately.

Findings of the Council

17. The Defendant admitted that he had explained to the Patient during the first consultation that the intractability of her eczema could be due to toxic heavy metals overload in her body, lack of essential nutrients, unhealthy lifestyle and dietary habits as well as medications from her previous doctors, especially steroids. The Defendant emphasized to us that the Patient was given a choice of using chelating agent(s) or change in lifestyle and dietary habits but it was the Patient's own choice to undergo speedier treatment by way of chelation therapy.

18. The Defendant sought to convince us that toxic heavy metals overload could cause or, to use the words of his expert witness, Dr SIOW, "lead up" to intractable eczema in the case of the Patient here. However, it was the evidence of Dr SIOW, that the International Board of Clinical Metal Toxicology ("IBCMT"), of which he is a fellow, had never done any research on the correlation between toxic heavy metals and eczema.

19. Our attention was drawn by Dr SIOW to an article entitled "Occupational skin disease in Finland" which was published in 1988. Dr SIOW further told us that from his study of this article, he arrived at the clinical conclusion that there is a link between increased toxic metal burden and intractable eczema. And yet, it was clear from reading this article that the statistics on toxic eczema was based on skin contact with toxic heavy metals.

20. In our view, the alleged correlation between toxic heavy metals overload and intractable eczema was mere speculation, unsupported by rigorous evidence from either clinical research or empirical studies. We agree with the Secretary's expert, Professor KUMANA, that "recourse to chelators to tackle such uncertain possibilities should only be conducted in a research context/setting".

21. In this connection, it was the unchallenged evidence of the Patient that the Defendant told her during the first consultation that he would treat her with natural remedies and avoid as far as possible the use of drugs. Indeed, the Defendant's evidence-in-chief was that the Patient consulted him several times instead of just one time because she was "confident that he could give her a chance of better cure or a remedy to her chronic problem". We accept the Patient's evidence that she had put a lot of trust in the Defendant who offered to cure the intractable eczema, which troubled her a lot in the past one and a half years.

22. The Defendant told us in his evidence-in-chief, his treatment modality, which he claimed to be the IBCMT's protocol of treatment, was to deliver safe therapy to lower the toxic load of the patients and ultimately to restore their health in a more efficient manner. The Defendant insisted that he was practising evidence-based medicine and he should not be faulted for subscribing to a minority body of medical opinion. In this connection, it was clearly stated in paragraph 22.2 of the Code of Professional Conduct (2000 edition) that:-

"A medical practitioner who utilizes complementary/alternative treatment modalities may be subject to strict review and judgement with reference to the law governing the alternative practice."

23. We need to emphasize that we are not endorsing the IBCMT's protocol of treatment. But even if there existed a responsible body of medical opinion on treatment of intractable eczema with chelation therapy, the real point is that the Defendant had departed from the IBCMT's protocol by failing to arrange for the Patient to do a baseline urine test. Protocol of treatment is meant to be a set of good practice guidelines that ensure the safety of patients and efficacy of treatment. Therefore, it is a fundamental principle in evidence-based medicine that there must be good justification(s) to depart from a protocol of treatment. Indeed, Dr SIOW also told us in his evidence-in-chief that a baseline urine test is "the gold standard protocol of the IBCMT".

24. The Defendant admitted that when he started off treating patients with his treatment modality, he would ask his patients to do blood test, baseline urine test as well as challenge urine test. However, his experience was that results of most of the baseline (unprovoked) urine tests were not above the reference ranges; and this would impose a financial burden on the patients who needed to pay for all these tests.

25. And yet, when being asked by us on what investigative tests would he use to arrive at the diagnosis that there was toxic heavy metals burden in a patient with intractable eczema like the Patient here, Dr SIOW replied that he had to do a baseline urine test and compare its results with that of a challenge urine test done with a specific provocative agent according to the protocol of a specific laboratory. Dr SIOW also told us in his evidence-in-chief that "there was no such thing as a general provocative urine test" in the IBCMT's protocol. We agree with Dr SIOW that any such test had to be specific to the provocative agent used as well as the protocol of the individual laboratory.

26. It was, in any event, never put to the Patient in cross-examination that she was concerned with the financial burden of having a baseline urine test. We accept the Patient's evidence that the Defendant had told her during the consultation on 28 November 2006 that her lead and mercury levels were very high when compared with the reference ranges stated in the laboratory test report. Indeed, the Defendant also stated in his medical report on the Patient dated 27 January 2007 that "…This test showed 6 fold increase in Mercury, 3 fold increase in Lead, and 5 fold increase in Arsenic. This has demonstrated Ms WU to have overloaded toxic heavy metals in her body responsible for her damaged immune function perpetuating her skin problem…".

27. It was however clearly stated in the laboratory test report that "Reference ranges are representative of a healthy population under non-challenge or non-provoked conditions". We agree with Professor KUMANA that challenge urine test is difficult to interpret due of lack of standardization. This is particularly true when the laboratory test report in this case did not provide any reference ranges that were representative of a healthy population under challenge or provoked conditions. We also agree with Professor KUMANA that the Defendant's interpretation of the laboratory test results to indicate that the Patient was suffering from toxic heavy metals overload (burden) was wrong and misleading.

28. Counsel for the Defendant criticized the use of the phrase "when in fact the patient did not have heavy metal toxicity" in charge (a) and he submitted charge (a) was defective as a matter of law. It is important in our view to understand at the outset that we are not talking about "acute" heavy metal toxicity here. It was the evidence of Professor KUMANA that chelation therapy might be warranted if an abnormal level of toxic heavy metals was associated with the patient having (clinical) features consistent with intoxication. Indeed, Dr SIOW also agreed in cross-examination that leaving aside the level of toxic heavy metals burden, unless the threshold of toxicity had been reached resulting in manifestation of symptoms, then a conservative approach based on remediation of personal exposure, education and monitoring via blood level would have been justified. Viewed in this light, the fact, which we accept on the evidence, that the Patient did not have any heavy metal toxicity must be relevant to charge (a).

29. The Defendant sought to water down his failure to do a baseline urine test by focusing on what he called "clinical signs" of the Patient. We agree with Professor KUMANA that "looking for the so called lead line in the [Patient's] gums … is not recommended as helpful". We also agree with Professor KUMANA that the Defendant's diagnosis of toxic heavy metals overload could not be made on non-specific clinical features that were found on his physical examination of the Patient. We do not accept on the evidence that the Patient's clinical signs were indicative of toxic heavy metals overload. In our view, the Patient's skin problems were equally consistent with a list of differential diagnoses including infection and immune-deficiency.

30. In our view, it was misleading for the Defendant to tell the Patient that her lead and mercury were very high when compared with the reference ranges stated in the laboratory test report. There is no doubt in our minds that the Defendant misled the Patient into believing that she had an increased toxic heavy metals burden in her body and that she needed a chelation therapy when in fact the Patient did not have heavy metal toxicity. In our view, the Defendant's conduct and/or omission, be it intentional or not, has clearly fallen below the standards expected of a registered medical practitioner in Hong Kong.

31. For these reasons, we find the Defendant guilty of charge (a).

32. As regards charge (b), the Secretary's case against the Defendant is that there was no clinical indication for him to prescribe chelation therapy to the Patient. As we

mentioned above, the Defendant wrongly interpreted the results of the challenge urine test to indicate that the Patient was suffering from toxic heavy metals overload. Moreover, there was no robust evidence from either clinical research or empirical studies to support the alleged correlation between toxic heavy metals overload and intractable eczema.

33. We agree with Professor KUMANA that the Patient should be managed conservatively by concerted efforts to eliminate or reduce possible source of exposure to toxic heavy metals. Indeed, Dr SIOW did not argue otherwise. We also agree with Professor KUMANA that "the Defendant should at least explain to the Patient that his "off-label" use of chelating agents as being unconventional". This was particularly true because both chelating agents that the Defendant used, EDTA and DMSA could result (though claimed to be uncommon) in a variety of significant adverse effects.

34. It was the Defendant's evidence under cross-examination that if the patients' conditions were not severe, they were not necessarily given chelating agents. Instead, they would be given nutritional supplements which could serve the purpose of a mild chelator and also [help] relieve the patients' symptoms and regain their health.

35. Initially, the Defendant sought to convince us that for the Patient's case here, 18 months of intractable eczema was quite significant and would warrant the use of chelation therapy. If this was the case, conservative treatment would not be suitable for the Patient. But then again, the Defendant told us that he had given the Patient a choice of undergoing chelation therapy or not. It was the Patient's own free will to undergo speedier treatment. However, when being challenged by the Legal Officer, the Defendant was constrained to accept that the Patient had "not emphasized that she need[ed] a speedier recovery but her intention or her attitude really impl[ied] she would like to have a speedier recovery".

36. We are firmly of the view that there was no clinical indication for the Defendant to prescribe chelation therapy to the Patient. The Defendant's suggestion that the Patient would like to have a speedier recovery is merely an afterthought. There was in any event no urgency to start chelation therapy. The Defendant should at least carry out further test(s) to rule out the differential diagnoses of infection and immune-deficiency before prescribing to the Patient a chelation therapy. We also agree with Professor KUMANA that the resort to chelation therapy could not be justified unless there was robust evidence of overall benefit for the Patient. We are

satisfied on the evidence that the Defendant unnecessarily prescribed a chelation therapy to the Patient.

37. For these reasons, we also find the Defendant guilty of charge (b).

38. Although we do not accept that charges (b) and (c) are void for duplicity, we agree that charges (b) and (c) overlap with each other. We shall treat them as alternative charges. Since we have already found the Defendant guilty of charge (b), we need not proceed to deal with charge (c).

39. As regards charge (d), Professor KUMANA fairly accepted that there was a body of recognized physicians who resorted to the prescription of Ketoconazole for treatment of intractable eczema. Therefore, leaving aside whether this drug would be potentially hepatotoxic, prescription to the Patient might not be unnecessary provided that there was clinical indication for it. In this connection, we accept on the evidence that the Patient did not respond well to conventional therapy with antibiotics or steroids. It was also the unchallenged evidence of the Defendant that he observed fungal infection on the Patient's body. In our view, the Secretary is unable to prove on the evidence that there was no clinical indication for prescription of Ketoconazole to the Patient.

40. We therefore find the Defendant not guilty of charge (d).

41. Turning to charge (e), the gravamen of the Secretary's case against the Defendant is that prescription of vitamins, minerals and nutriceuticals was not evidence based for treatment of any form of eczema. It is debatable whether some if not all of these vitamins, minerals and nutriceuticals might have therapeutic benefits for the Patient's intractable eczema. We wish to note on record our disapproval for any medical practitioner to dispense large quantity and variety of substances, health claim or not, of doubtful clinical benefit for the patient.

42. But then again, Professor KUMANA did not regard this to be a major transgression as he was aware that many competent physicians prescribed vitamins and other similar products for patients with a variety of complaints, possibly to achieve a placebo effect. Hence, regardless of whether it was evidence based or not, we do not find the Defendant's prescription of vitamins, minerals and nutriceuticals to the Patient amounts to professional misconduct.

43. We therefore find the Defendant not guilty of charge (e).

Sentencing

44. It was clearly stated in paragraph 22.1 of the Code (2000 edition) that:-

"A registered medical practitioner utilizing complementary/alternative treatment modalities should ensure that:-

(a) the modality of treatment concerned is ethical, beneficial and safe for the patient;
(b) the procedure is carried out in good faith and in the patient's best interest;
(c) informed consent has been obtained with the following:-
  (i) the benefit of the procedure;
  (ii) the risk of the procedure;
  (iii) the fact that this is a form of complementary/alternative treatment; and
  (iv) the prevailing conventional method available;
  having been explained to the patient;
(d) the practitioner himself has received relevant and adequate training such that he would be clinically competent in carrying out the treatment; if necessary, he should obtain professional support from qualified persons."

45. We are particularly concerned that the prescription of chelation therapy to the Patient had not been in her best interest. In our view, any registered practitioner, regardless of whether he is utilizing complementary/alternative treatment modalities or not, must ensure that his decision to treat the patient with any form of therapy is evidence based.

46. In this case, not only did the Defendant wrongly interpret the laboratory test report but he had actually proceeded with chelation therapy without first establishing a diagnosis based on rigorous evidence either from clinical research or empirical studies. All the more serious, the Defendant misled the Patient into believing that she had an increased body burden of heavy metals and that she needed a chelation therapy. But then again, we bear in mind that there is no evidence in this case that the Defendant deliberately or dishonestly misled the Patient.

47. Having considered the nature and gravity of the disciplinary offences for which the Defendant was convicted and what we have heard and read in mitigation, we order

that:-

(1) in respect of charge (a), the Defendant's name be removed from the General Register for a period of 12 months;
(2) in respect of charge (b), the Defendant's name be removed from the General Register for a period of 9 months;
(3) the said 2 removal orders to run concurrently, making a total of 12 months.

48. We have considered whether to suspend the operation of the said removal orders. We appreciate that the Defendant is going to put in place a system whereby he will make sure that he explains properly and adequately to his patients and obtains their written consent before embarking on any form of therapy. However, we have grave concerns whether the Defendant really understands the importance of evidence based medicine. This is particularly true when according to the Defendant his treatment modality had been used for 70,000 patient times over the past 12 years. In our view, it is not simply a matter of obtaining written consent. For the protection of the public, we need to be satisfied that the Defendant will fully address our concerns.

49. In the circumstances, we therefore order that operation of the said removal orders be suspended for 3 years subject to the condition that the Defendant shall complete during the suspension period satisfactory peer audit by a doctor to be appointed by the Medical Council with the following terms:-

(a) the appointed doctor shall conduct random audit of the Defendant's practice with particular regard to evidence based medicine, communications with patients and use of chelation agents;

(b) the peer audit should be conducted without prior notice to the Defendant;

(c) the peer audit should be conducted at least once every 6 months during the suspension period;

(d) during the peer audit, the appointed doctor should be given unrestricted access to all parts of the clinic and the relevant records which in the appointed doctor's opinion is necessary for proper discharge of his duty;

(e) the appointed doctor shall report directly to the Medical Council the finding of his peer audit at 6-monthly intervals. Where any defects are detected, such defects should be reported to the Medical Council as soon as practicable; and

(f) in the event that the Defendant does not engage in active practice at any time during the suspension period, unless otherwise ordered by the Council, the peer audit shall automatically extend until the completion of 36-month suspension period.

Remarks

50. The Defendant's name is included in the Specialist Register under the specialty of Paediatrics. It is for the Education and Accreditation Committee to consider whether any action should be taken in respect of his specialist registration.

Prof. Felice LIEH-MAK, GBS CBE JP
Temporary Chairman, Medical Council