Pang Ah San *v* Singapore Medical Council
[2013] SGHC 266

Case Number : Originating Summons No 799 of 2012

Decision Date : 29 November 2013

Tribunal/Court : High Court

Coram : Sundaresh Menon CJ; Chao Hick Tin JA; V K Rajah JA

Counsel Name(s) : Gregory Vijayendran, Lester Chua, and Jason Gabriel Chiang (Rajah & Tann LLP) for the appellant; Melanie Ho, Chang Man Phing, Sim Mei Ling, and Chang Qi-Yang (WongPartnership LLP) for the respondent.

Parties : Pang Ah San — Singapore Medical Council

PROFESSIONS – Medical profession and practice – professional conduct

29 November 2013

V K Rajah JA (delivering the grounds of decision of the court):

Introduction

1 These grounds relate to an appeal against the decision ("the DC Decision") of the Disciplinary Committee ("the DC") of the Singapore Medical Council ("the Respondent"), which found Dr Pang Ah San ("the Appellant") guilty of professional misconduct for performing a loop Percutaneous Endoscopic Gastrostomy ("loop-PEG") procedure on one Mdm Goh Lee Kheng ("the Patient"). The DC held that the treatment was not generally accepted by the profession outside the context of a formal and approved clinical trial, and that the Appellant had breached Clause 4.1.4 of the Singapore Medical Council's Ethical Code and Ethical Guidelines ("the ECEG") ("Clause 4.1.4"). We affirmed this decision.

2 This appeal raises some important issues relating to the use of innovative medical treatment in Singapore. When will offering innovative treatment without prior regulatory approval under the current regulatory regime be permissible? How does the current regulatory regime balance the need to ensure the safety of patients without stifling innovation which might benefit patients? What are the steps doctors should take to comply with the existing regulatory framework?

3 A critical challenge faced by the medical community today is the insidious trespassing of commercial priorities into the healthcare delivery system. This may sometimes give rise to an evaluative bias in favour of treatment or remedies that elevate the interests of the medical practitioner over those of the patient. Left unchecked, this may over time erode patient trust and confidence in medical practitioners. However, medical practitioners also have a legitimate right to give appropriate levels of consideration to proper business considerations. Plainly, the right balance has to be struck between professional virtues and business considerations. On the one hand, the right incentives can spur medical innovation for the common good. Yet on the other hand, processes must be in place to guard against the siren call of financial incentives which may potentially cloud the doctor-innovator's evaluation of the risks and benefits of administering an innovative treatment. Situations may arise where the interests of the doctor-innovator may even conflict with the patient's best interests. This potential pitfall is exacerbated by medical uncertainty, information asymmetry, and patient vulnerability. Clearly, technical competency alone is merely a pre-condition to maintaining the trust of patients and society. Ethical codes and guidelines marking out the boundaries of

professional practice must also be adhered to. Medical ethics benchmark professional values and standards, and thereby distinguish practices which are acceptable from those which are not. To uphold high standards of practice within the medical profession and maintain public confidence in the medical profession, the Respondent has the vital role of formulating and enforcing ethical standards on professional medical practice and standards of behaviour for the common good. In these grounds, we are concerned specifically with Clause 4.1.4 and the issue of permissible innovative treatment. We will be using the terms "doctor" and "medical practitioner" interchangeably. We use the term "treatment" in general to mean treatments which are administered solely for the benefit of the patient, administered solely for a research objective, and administered for a mixture of both purposes.

The facts

4 The Appellant is a general surgeon of 26 years' standing, and has run a surgical practice at Mount Alvernia Medical Centre for the last 18 years. He specialises in general surgery, in particular, surgery of the gastrointestinal tract, and has performed numerous gastrostomy and laparotomy procedures, including 50 standard Percutaneous Endoscopic Gastrostomy ("PEG") procedures.

5 The Respondent is constituted under the Medical Registration Act (Cap 174, 2004 Rev Ed) ("the MRA") and regulates the conduct of medical practitioners in Singapore.

6 The Patient was 84 years of age in 2008. She suffered a stroke and required permanent tube feeding. Ms Liew Swee Fong ("Ms Liew"), the Patient's daughter-in-law, sought advice from the Appellant, who recommended the use of the loop-PEG tube as a preferable alternative to the standard PEG in order to feed the Patient. After receiving the consent of the Patient's family, the Appellant then carried out the loop-PEG procedure on the Patient on 7 July 2008. The Patient was discharged two days later. Soon after, the Patient's medical condition significantly deteriorated and she passed away 20 days later.

7 On 8 August 2008, two of the Patient's children, Mr Tan Kwang Chuan and Mdm Tan Sok Hia, made a complaint to the Respondent via a joint statutory declaration. After several exchanges of letters between the Appellant and the Complaints Committee ("CC"), the CC determined that a formal inquiry should be held by a DC.

8 A Notice of Inquiry was issued against the Appellant. The Appellant was charged for providing treatment to the Patient that was not generally accepted by the profession and outside the context of a formal and approved clinical trial, in breach of Clause 4.1.4. The Notice of Inquiry served on the Appellant stated as follows:

> That you, Dr Pang Ah San, a registered medical practitioner, did between 7 July 2008 and 9 July 2008 at Mount Alvernia Hospital provide treatment to Mdm Goh Lee Kheng (the "**Patient**") that was not generally accepted by the profession outside the context of a formal and approved clinical trial, in breach of Clause 4.1.4 of the Singapore Medical Council's Ethical Code and Ethical Guidelines (the "**ECEG**").
>
> Particulars
>
> (i) Clause 4.1.4 of the ECEG provides, amongst other things, that a doctor shall not offer to a patient remedies that are not generally accepted by the profession except in the context of a formal and approved clinical trial;
>
> (ii) On or about 30 June 2008, you recommended the insertion of a "loop" percutaneous

endoscopic [gastrostomy] tube (a "**Loop PEG Tube**") for the Patient;

(iii) The Loop PEG Tube was a novel device in that it differed from the normal percutaneous endoscopic [gastrostomy] tube both in terms of design as well as in terms of the method of insertion, and was therefore not a device that was generally accepted by the profession;

(iv) Accordingly, the pre-operative procedures and protocols, the insertion of the Loop PEG Tube as well as the post-procedure treatment and protocols all ought to have been carried out only in the context of a formal and approved clinical trial;

(v) You failed to inform the Patient of the novel nature of the Loop PEG Tube prior to obtaining her consent for the surgery. In particular, you failed to inform the Patient that she would be one of the first few patients in the world to have a Loop PEG Tube inserted;

(vi) On 7 July 2008, you, together with Dr Chia Siew Cheng, performed surgery on the Patient to insert a Loop PEG Tube, and you did so outside the context of a formal and approved clinical trial;

(vii) Following the insertion of the Loop PEG Tube, you, together with Dr Chia Siew Cheng, provided post-operative care and monitoring of the Patient outside the context of a formal and approved clinical trial,

and that in relation to the facts alleged, you have been guilty of professional misconduct within the meaning of Section 45(1)(d) of the Medical Registration Act (2004 Rev Ed.) (Cap. 174, the "Act").

[emphasis in original in bold]

9 Dr Chia Siew Cheng ("Dr Chia"), the Appellant's wife, who assisted in the procedure on the Patient, was also similarly charged, but was acquitted by the DC.

10 The DC inquiry was held over eight days. The witnesses that were called to give evidence at the inquiry were as follows:

(a) For the Respondent:

(i) Mr Tan Kwang Chuan, the Patient's son;

(ii) Mdm Tan Sok Hia, the Patient's daughter;

(iii) Ms Liew, the Patient's daughter-in-law; and

(iv) Professor Ti Thiow Kong ("Prof Ti"), the Respondent's expert witness.

(b) For the Appellant:

(i) The Appellant ("Dr Pang"); and

(ii) Professor Teo Eng Kiong, an editor of the Singapore Medical Journal (in respect of whom Dr Pang issued a subpoena).

(c) For Dr Chia:

(i) Dr Chia; and

(ii) Dr Francis Seow-Choen ("Dr Seow-Choen"), Dr Chia's expert witness.

11 At this point, we think it is appropriate to elaborate on the procedures concerned. For a helpful description of the standard PEG procedure, we refer to the Appellant's article, published in Pang A S, "A new feeding tube which is secure and easy to change" Singapore Medical Journal 2009; 50(7): 740–742, at 740:

> Loss of a normal swallowing reflex as in dysphagic stroke is the commonest indication for long-term tube feeding. For this, either the nasogastric tube or the percutaneous endoscopic gastrostomy tube is used, with the former being uncomfortable. …
>
> ...
>
> Most medical and nursing societies recommend the gastrostomy (G) tube for long-term tube feeding. The G tube passes directly to the stomach through the anterior abdominal wall. ... The G tube has been in existence for more than a century. There are many insertion methods, broadly classified as surgical, laparoscopic, radiological and endoscopic. The endoscopic method is the most popular today because it is simple, safe and requires only local anaesthesia. A G tube inserted by the endoscopic method is commonly called a percutaneous endoscopic gastrostomy (PEG).
>
> ***The PEG has been in routine use, worldwide, for about 30 years . Clinical experience has found the pull-method of PEG to be safe*** , *producing a stoma that fits the tube snugly, with a low risk of leakage.* ...
>
> [emphasis added in italics and bold italics]

12 We refer to the same article for a general description of the loop-PEG procedure at p 741:

> A third-generation (3G) tube manufactured by SGN Pte Ltd, Singapore, and marketed under the brand LOOPPEG™ is now available. The LOOPPEG™ 3G tube is a 15 Fr soft silicone gastrostomy tube with all the features of an ideal feeding tube. It is placed in a loop configuration with the limbs locked together … Consequently, it cannot be pulled out even when tugged with a great force. There is a spigot at each end, and a pair of exit openings at the mid-segment which lies in the stomach. Any end may be used for feeding liquid food, reserving the other for medicines. It is inserted under local anaesthesia using the same pull-method of PEG. ... No check endoscopy or radiograph is required.

13 For a further description of the loop-PEG procedure, we refer to Prof Ti's expert report:

> The silastic loop PEG has a smaller calibre of 15F compared with 14F to 30F of standard PEG tubes. It is a straight flexible tube but assumes a loop configuration on insertion into the stomach.
>
> The "loop" PEG thus has two points of penetration of the stomach and the two ends of the loop can be inter-locked externally. There are two exit openings in the middle of the looped tube which serve as exits for feeds introduced through either ends of the tube in the unlocked position.

14 For ease of comparison, the various drawings of the loop-PEG tubes which we will be referring to are reproduced in the annex to this written grounds of decision. The drawings are:

(a) the Appellant's drawing of the actual loop-PEG tube affixed to the Patient, as recorded in the contemporaneous medical case notes ("Diagram 1");

(b) a drawing of the loop-PEG tube shown in the Appellant's article (see Pang A S, "A new feeding tube which is secure and easy to change" Singapore Medical Journal 2009; 50(7): 740–742) ("Diagram 2");

(c) a drawing submitted and relied on by the Appellant in the proceedings below ("Diagram 3"); and

(d) the diagram of the LOOPPEG3G®3G, a subsequent commercial variant of the loop-PEG, taken from SGN Pte Ltd's website (accessed on 12 October 2011) ("Diagram 4").

15 We prefer to view the treatment administered on the Patient holistically, and hence we will be using the expression "loop-PEG procedure" to mean the use of the loop-PEG tube on the Patient generally, without distinguishing the method of inserting the loop-PEG tube into the Patient, the way the loop-PEG tube was to operate inside the Patient, and the loop-PEG tube itself.

The decision below

16 The DC found that the Appellant had intentionally and deliberately ignored his ethical obligations enshrined in Clause 4.1.4 by giving treatment that was not generally accepted by the profession outside the context of a formal and approved clinical trial.

17 The DC considered that the standard PEG tube had been in use for a long time and was an established modality to feed patients, whereas the loop-PEG tube was a novel device which, while serving similar objectives, incorporated an altogether different design.

18 The DC ordered that the Appellant:

(a) be fined the sum of $10,000;

(b) be censured;

(c) provide a written undertaking to the Respondent that he would not be engaged in or offer any treatment plan or treatment which included the insertion of the loop-PEG tube or any variation thereof outside the context of a formal or approved clinical trial or unless he obtained approval to use the same on patients from the appropriate authorities; and

(d) pay 70% of all the costs and expenses of, and incidental to, these proceedings, including the costs of counsel to the Respondent and the Legal Assessor.

The issues before the court

19 The issues before this court were:

(a) whether the DC erred in law in convicting the Appellant based on the surgical "treatment" he provided, when particulars of the charge preferred only related to that part of Clause 4.1.4 on offering medicinal "remedies" ("Issue 1");

(b) whether the DC erred in law in finding that the loop-PEG procedure performed on the Patient was "not generally accepted" by the profession ("Issue 2");

(c) whether the DC erred in fact in finding that the loop-PEG procedure performed on the Patient was "not generally accepted" by the profession ("Issue 3"); and

(d) whether the DC erred in law in finding that the Appellant's breach of Clause 4.1.4 (if any) amounted to professional misconduct ("Issue 4").

20 In relation to our appellate oversight in this matter, we should explain that the High Court exercises appellate jurisdiction over the DC and can overturn the DC's findings on issues of medical ethics or standards of professional conduct if it is of the opinion that these findings are "unsafe, unreasonable or contrary to the evidence": see s 46(8) of the MRA (before the amendment on 1 December 2010).

Our analysis

Issue 1

21 The first issue is whether the DC erred in law in convicting the Appellant based on the surgical "treatment" he provided, when particulars of the charge preferred only related to that part of Clause 4.1.4 on offering medicinal "remedies".

The arguments

22 The Appellant argued that the loop-PEG procedure did not come within the meaning of "remedies" in Clause 4.1.4 because the term "remedies", as used in Clause 4.1.4, referred specifically to a medicinal product which was capable of a "clinical trial". The proviso "except in the context of a formal and approved clinical trial" suggested that the term "remedies" was used in a manner that was premised on these "remedies" being capable of a "clinical trial". At the time the loop-PEG procedure was performed on the Patient on 7 July 2008, the only two statutory regimes providing for the regulation and approval of clinical trials were the Medicines Act (Cap 176, 1985 Rev Ed) ("the MA") and the Health Products Act (Cap 122D, 2008 Rev Ed) ("the HPA"). The loop-PEG procedure did not fall under the clinical trial regulatory regimes provided for under the MA and the HPA. Therefore, the loop-PEG procedure was not capable of a "clinical trial" and hence did not fall within the meaning of "remedies" in Clause 4.1.4.

23 The Respondent, however, submitted that the loop-PEG procedure fell within the meaning of "remedies" in Clause 4.1.4. The fact that the existing statutory regime for clinical trials might not apply to the loop-PEG did not mean that clinical trials were not required. Moreover, the Appellant's interpretation was inconsistent with the spirit and purpose of the ECEG, which was to uphold the trust and confidence in the profession by setting out minimum standards of good medical practice which all doctors should apply in all areas of a doctor's clinical practice.

The applicable ethical principles

24 Clause 4.1.4 states:

4.1.4 Untested practices and clinical trials

> 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. [("paragraph 1")]
>
> A doctor who participates in clinical research must put the care and safety of patients first. If a doctor wishes to enter a patient into a clinical trial, he must ensure that the trial is approved by an ethics committee and conforms to the Good Clinical Practice Guidelines. In addition, informed consent must be obtained from the patient. [("paragraph 2")]
>
> 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. [("paragraph 3")]
>
> [emphasis added]

Our decision

25 As a starting point, we refer to the ordinary meaning of the term "remedy" in *The Oxford English Dictionary* vol 13 (J A Simpson and E S C Weiner) (Clarendon Press, 2nd Edition, 1989) at p 584:

> **1. a**. A cure for a disease or other disorder of body or mind; any medicine or treatment which alleviates pain and promotes restoration to health. …

26 Plainly, the term "remedy" embraces a very broad category of cures or treatments and includes the loop-PEG procedure, other surgical procedures, and uses of medical devices.

27 The Appellant sought to limit this board meaning of "remedies" in Clause 4.1.4 by arguing that "remedies" referred specifically to medicinal products which were capable of a "clinical trial". We found the argument strained. Adopting a contextual approach to the interpretation of Clause 4.1.4, we note that it starts with a general prescription in paragraph 1 to "treat patients according to *generally accepted methods*" [emphasis added]. What then follows is a general proscription against offering "management plans or remedies that are not generally accepted by the profession", and an exception to the proscription, namely when the remedy is offered "in the context of a formal and approved clinical trial". Reading the proscription and exception against the backdrop of the prescription, it is our view that if a particular remedy is indeed not capable of a "clinical trial", that particular remedy is still caught by the general proscription, *ie*, the offering of a particular remedy that is not generally accepted by the profession and is not capable of a "clinical trial" is still prohibited. The exception of a "formal and approved clinical trial" functions only as a limited exception to the general proscription, and does not limit the application of the proscription to only remedies that are capable of a "clinical trial". It bears mention that Clause 4.1.4 is prefaced by the caption "*Untested practices and clinical trials*" [original emphasis omitted; emphasis added in italics] which indicates that it is the safety of the remedy evidenced by general acceptance by the profession that takes centre-stage in determining permissible usage.

28 Further, the Appellant's interpretation of Clause 4.1.4 is inconsistent with the spirit and purpose of the ECEG. The spirit and purpose of the ECEG is to uphold the trust and confidence in the medical profession by setting out standards of good medical practice which all doctors should apply in all areas of a doctor's clinical practice. Specifically with regard to Clause 4.1.4, the court in *Gobinathan Devathasan v Singapore Medical Council* [2010] 2 SLR 926 ("*Gobinathan*") commented at [45] that:

Turning to para 4.1.4 which sets a standard of good medical practice, the position appears to be that whenever appropriate, patients should be treated with time tested methods where the benefits and risks have been well researched and documented. The purpose of requiring doctors to conform to generally accepted practices is to ensure that *"patients suffer no harm"*. [emphasis added]

29 This purpose is better served through a common-sense reading of Clause 4.1.4 that prohibits any form of medical practice that was not generally accepted, rather than the Appellant's unduly narrow reading of Clause 4.1.4, which does not prohibit a form of medical practice which cannot be the subject of a clinical trial under the existing statutory regimes provided by the MA and the HPA. Such an interpretation should apply with even more force, given that the loop-PEG procedure is an invasive procedure that involves the surgical insertion of a device, and hence involves a higher level of risk than a non-invasive procedure. Therefore, we found that the loop-PEG procedure, even if assumed to be incapable of a "clinical trial", is caught by the prohibition in Clause 4.1.4.

30 In any case, we found that the Appellant could have applied to conduct clinical trials on the loop-PEG procedure. The fact that the existing statutory regimes provided by the MA and the HPA for clinical trials did not apply to the loop-PEG procedure does not mean that the loop-PEG procedure was incapable of a clinical trial, or that a clinical trial was not required. The Appellant could have applied for review and approval from the relevant Institution Review Board ("IRB") or ethics committees to conduct clinical trials. We note that IRBs are synonymous with ethics committees. In our view, the term "clinical trial" in the context of Clause 4.1.4 merely means any trial which is "approved by an ethics committee", which "conforms to the Good Clinical Practice Guidelines", where applicable, and where "informed consent" has been obtained from the patient (see paragraph 2 of Clause 4.1.4). It seems that the Good Clinical Practice Guidelines were written to apply to drug-trials only. In our view, that simply means that those guidelines do not apply to clinical trials for surgical procedures or medical devices. It does not mean that Clause 4.1.4 applies to only drug trials.

31 Clinical trials are not limited to drug trials, which are required and governed by a separate statutory regime, and can be employed for assessing new medical devices and new surgical procedures. The Ministry of Health, in accepting the Ethical Guidelines on Research Involving Human Subjects of 1997 ("NMEC Guidelines") by the National Medical Ethics Committee ("NMEC"), issued a written directive dated 25 June 1998 requiring all government and restructured hospitals to set up hospital ethics committees for the ethics governance of research relating to new medical devices and new procedures which involves human subjects. This directive states among other matters (see The BAC Guidelines (see [32] below) at para 2.25) that:

> The National Medical Ethics Committee has recommended that:
>
> (i) hospital ethics committees vet for ethical considerations, all research protocols that involve
>
> - human experimentation be they clinical trials or drug trials, trials of new medical devices, new procedures and any other forms of clinical studies that require the participation of human subjects or the use of human tissues and organs ...
>
> ...
>
> The Ministry has accepted these recommendations.
>
> [original emphasis omitted; emphasis added in italics]

32 The fact that clinical trials can be conducted for new medical devices and new procedures has been confirmed by the Bioethics Advisory Committee ("BAC"), which was appointed by the Singapore Cabinet in December 2000 to examine the legal, ethical and social issues arising from research on human biology and behaviour and its application, and to develop and recommend policies on legal, ethical and social issues with the aim of protecting the rights and welfare of individuals, while allowing the life sciences to develop and realise their full potential for the benefit of the wider community. The BAC's guidelines issued in 2004, which were accepted by the Life Sciences Ministerial Committee, state (see Bioethics Advisory Committee Singapore, *Research Involving Human Subjects Guidelines for IRBs* (November 2004) (Chairman: Professor Lim Pin) ("the BAC Guidelines") at para 3.9):

> Every research programme involving Direct Human Biomedical Research should be reviewed and approved by a properly constituted ethics committee or IRB.

33 The BAC Guidelines defined "Direct Human Biomedical Research" at para 3.7:

> (a) Direct Human Biomedical Research. This comprises any kind of human biomedical research that involves *any direct interference or interaction with the physical body* of a human subject, and that involves a concomitant *risk of physical injury* or harm, however remote or minor. A research programme which involves the administration of any drug (whether it is for the purpose of testing the effects or efficacy of the drug, or whether it is a means for establishing any other objective of the research programme), the trial or use of a *medical device* on a human subject, or any test of a human subject's physiological, emotional or mental responses (not being tests conducted for diagnostic purposes with a view to the therapeutic management of a patient) all qualify as Direct Human Biomedical Research ... [emphasis in original in underline; emphasis added in italics]

34 This is in contradistinction to "Indirect Human Biomedical Research", one example of which is the reporting of individual patients' clinical results by the patients' doctors. "Indirect Human Biomedical Research" is defined at para 3.7 of the BAC Guidelines:

> (b) Indirect Human Biomedical Research. This comprises any research (not qualifying as Direct Human Biomedical Research) involving human subjects, human tissue, or medical, personal or genetic information relating to both identifiable and anonymous individuals, undertaken with a view to generating data about medical, genetic or biological processes, diseases or conditions in human subjects, or of human physiology or about the safety, efficacy, effect or function of any device, drug, diagnostic, surgical or therapeutic procedure (whether invasive, observational or otherwise) in human subjects whether as one of the objectives or the sole objective, of the research study, trial or activity, and which research, study, trial or activity has the potential to affect the safety, health, welfare, dignity or privacy of the human subjects involved in the study, or of the donors of human tissue or information used in the research, or of the family members of any of the human subjects or donors thereof, or to which such medical, personal or genetic information relates.

35 It should be noted that the Ministry of Health issued a directive to all doctors in January 2006, directing that the BAC Guidelines would be used as the standard for ethical conduct in research in the evaluations and deliberations of the Singapore Medical Council: see Ministry of Health, *Governance Framework for Human Biomedical Research* (December 2007) ("*Governance Framework for Human Biomedical Research*") at footnote 2.

36 Therefore, there is no doubt that there is general awareness within the medical community that clinical trials are not limited to drug trials, and can also be employed for new medical devices and new

procedures. We go further to note that any research on the loop-PEG procedure ought to be considered as "Direct Human Biomedical Research" and hence, a review by an IRB should be initiated before any trials can be done. This is in contrast to "Indirect Human Biomedical Research", where there is no consensus on what kinds of such research need to be formally reviewed by an IRB: para 3.10 of the BAC Guidelines. Nonetheless, an important consideration for an exemption from review is that there should be no likelihood of harm to the research subject: para 3.14 of the BAC Guidelines.

37 The IRB plays an important role in the ethical governance of research with its primary objective being to protect and assure the "safety, health, dignity, welfare and well-being of human research subjects and to safeguard against research practices and objectives that are not ethically acceptable to society at that point in time": see paras 4.4 and 5.6 of the BAC Guidelines. The BAC Guidelines further explains the responsibilities of IRBs as such:

> **The Responsibilities of Institutional Review Boards**
>
> ...
>
> 5.20. Ethics Review Gateway. The fundamental responsibility of an IRB is to act as an ethics review gateway for all Human Biomedical Research carried out under the auspices of its appointing institution, with the primary objectives of the protection and assurance of the safety, health, dignity, welfare and well-being of human research subjects. An IRB has a duty to ensure that all Human Biomedical Research carried out under the auspices of its appointing institution are ethically acceptable, and to comply with the principles outlined in Section IV.
>
> 5.21. Review of Scientific Merits. A review of the scientific merits of any proposed programme of Human Biomedical Research is an integral part of a proper assessment of the ethical acceptability of the programme. A research programme with little or no scientific merit is ethically unacceptable.
>
> 5.22. In its assessment of the ethical acceptability of any proposed research programme, an IRB will need to be satisfied that an objective review of the scientific merits of the proposed programme of research has been carried out, and that there is sufficient evidence of scientific merit before the IRB makes a decision on the ethical acceptability of the proposed research programme.
>
> 5.23. The IRB is not responsible for carrying out the scientific review of research proposals. It is for the researchers to satisfy the IRB that an objective review of scientific merit has been carried out, and that the findings (whether positive or negative) of any review of scientific merit are made available and are fully disclosed to the IRB.
>
> [emphasis in original]

38 We refer to the guidelines published by the Ministry of Health, which set out a helpful summary of the responsibilities of IRBs (see *Governance Framework for Human Biomedical Research* at para 13–14):

> 13 The IRB has a duty to ensure that all HBR [human biomedical research] carried out under the auspices of its appointing institution are ethically acceptable. The primary objective of the IRB is the protection and assurance of the safety, health, dignity, welfare and well-being of

human research subjects. IRBs are responsible for:

(i) ethics review and approval of HBR projects;

(ii) continuing review, such as the evaluation of progress updates of research projects and adverse event reports provided by researchers, to ensure the continued validity of ethical approval of projects approved by them. IRBs should have the authority to suspend or terminate their approval of research projects where there are sufficient concerns over the safety and well-being of research subjects;

(iii) reporting to their respective institutions any unusual or unexpected events arising from the research in accordance with their standard operating procedures; and

(iv) providing feedback to, and maintaining dialogue about applicable standards with, their constituent researchers.

Review of Scientific Merit

14 The IRB is not responsible for carrying out the scientific review of research projects. It is for the researchers to satisfy the IRB that an objective review of scientific merit has been carried out, and that the findings (whether positive or negative) of any review of scientific merit are made available and fully disclosed to the IRB. The IRB should be empowered to require a more extensive or rigorous review of scientific merit if deemed necessary.

39 Even though the foregoing shows that IRBs are not responsible for carrying out scientific review of research projects, this does not mean that IRBs are not at all concerned with the scientific merit of the research project. Far from that, the researcher still has to satisfy the IRB that an objective review of scientific merit has been carried out, and that the findings (whether positive or negative) of any review of scientific merit are made available and fully disclosed to the IRB. The IRB is also empowered to require a more extensive or rigorous review of scientific merit if deemed necessary.

40 Accordingly, we concluded that the expression "remedies" in Clause 4.1.4 did not only mean "remedies" which were capable of a clinical trial, and in any case, the Appellant could have applied to conduct clinical trials on the loop-PEG procedure. Therefore, we rejected the Appellant's argument that the DC erred in law.

Issue 2

41 The second issue is whether the DC erred in law in finding that the loop-PEG procedure performed on the Patient was "not generally accepted" by the profession.

The arguments

42 The Appellant argued that the DC's interpretation of the term "not generally accepted" was erroneous and inimical to patients' interests, especially when applied to the field of surgery. The DC appears to have interpreted the term "not generally accepted" to mean "not generally known" or "novel" (*ie*, different from the standard). Instead, it should be interpreted to mean "generally rejected" or "generally disapproved" as this would strike a better policy balance between the need to promote innovation and the need to ensure that patient safety was not compromised. The DC's interpretation was inconsistent with the fact that innovative treatment was part and parcel of medical practice, and would stifle all innovation unnecessarily. Moreover, given that flexibility in

varying surgical techniques was a necessary part of surgical practice, the DC's interpretation would expose surgeons to disciplinary action each time they varied a surgical technique. This was inimical to the best interests of patients.

43 Further, the Appellant argued that the test for "generally accepted" in *Gobinathan* was crafted to apply to mass-produced and standardised treatments like drugs and devices, and should not be applied to the area of surgical practice as that would lead to inappropriate requirements, such as the need for a "statistically significant study", which would be onerous in surgical practice where treatments are customised to suit the unique conditions presented by each patient. The right test for a treatment being "generally accepted" should be the same as that for determining whether a doctor has breached the tortious duty of care owed to his patient, as stated in *Khoo James v Gunapathy d/o Muniandy and another appeal* [2002] 1 SLR(R) 1024 ("*James Khoo*").

44 The Respondent submitted that there was no reason why surgical practice should be treated differently from drugs and devices. In any case, it had been the Appellant's position until a late stage of the proceedings that the loop-PEG tube was a device. It could not be the case that every insertion of a device would amount to a surgical procedure.

Our decision

45 The starting point for a proper analysis of this issue is Clause 4.1.4 (see above at [24]).

46 The questions to be answered are: (a) What does "not generally accepted by the profession" mean? (b) Does paragraph 3 of Clause 4.1.4 provide an exception to paragraph 1 such that experiments that are not part of a formal clinical trial are permissible if they are part of treatment and done in the best interest of the patient?

(1) Meaning of "not generally accepted by the profession"

47 The expression "not generally accepted by the profession" is not without ambiguity. As noted by the Appellant, the literal reading of "not generally accepted" can arguably carry a range of meanings, ranging from "not generally known" or "novel", to "generally rejected" or "generally disapproved". These possible meanings contain certain assumptions which need to be unpacked. One issue is whether there is a requirement of an acceptance of the treatment by the profession (*ie*, positive act of acceptance), or whether a lack of rejection of the treatment by the profession (*ie*, positive act of rejection) will do, or either. Another issue is when this acceptance or rejection by the profession has to occur. Does it have to occur *ex ante*, *ex post*, both, or either?

48 In *Gobinathan*, the court held at [33] that "[a] novel treatment, by its very definition, cannot be said to be generally accepted". The underlying assumptions seem to be that there has to be a positive act of acceptance by the profession, and such acceptance by the profession has to occur *ex ante*, not *ex post*. We did not elaborate on these issues, and this present case provides an opportunity for us to clarify the position.

49 In *Low Chai Ling v Singapore Medical Council* [2013] 1 SLR 83 ("*Low Chai Ling*"), we commented on Clause 4.1.4 at [42]:

> The DC rightly rejected the applicant's argument that a medical treatment was "generally accepted" for the purposes of [Clause] 4.1.4 of the ECEG if it was widely practised by a large number of medical practitioners ... . The assessment of whether or not a particular medical treatment is generally accepted must be scientific rather than empirical. *Illegitimate or unethical*

practices are not legitimised merely because large numbers of doctors engage in them. As a specialist tribunal with its own professional expertise and understanding of what the medical profession expects of its members, the DC's conclusion on this matter should be accorded a high degree of deference, especially with regards to findings of a scientific and/or medical nature. [emphasis in original in italics]

50 This clarifies that the concept of general acceptance contains a scientific aspect, rather than forming a purely empirical issue. This means that a certain treatment may be "not generally accepted by the profession" if that treatment is deemed to be unethical or illegitimate, even though a significant number of doctors may be providing such a treatment. However, we would like to highlight that the inquiry cannot be totally divorced from the empirical aspect. For instance, where the overwhelming majority of the medical profession endorses a certain treatment, this is *prima facie* evidence of general acceptance by the profession, particularly if this has been the case over a substantial period of time.

51 In *Gobinathan*, the court noted at [46] that the expert witnesses for both sides in that case broadly agreed on the test for when a particular treatment would become "generally accepted". The "factors" which were considered "crucial" were:

(a) there had to be 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 to have "clear-cut results" and the sample had to be "statistically significant"; and

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

52 It is clear that a particular treatment that satisfies (a) to (f) is definitely "generally accepted". The question then is whether this test in *Gobinathan* is an exhaustive and adequate test for all forms of medical treatments, including surgical treatments. As noted by the Appellant, the requirement for a "statistically significant study" would be onerous for surgical practice where treatments are customised to suit the unique conditions presented by each patient. However, that does not mean that the test for "generally accepted" in *Gobinathan* should not apply to surgical practice with appropriate modifications. The question to be considered now is whether the test in *Gobinathan* is adequate and exhaustive, or if the formulation of the test ought to be varied. In this regard, the Appellant argued that the right test for "not generally accepted by the profession" should be the same as that for determining whether a doctor has breached the tortious duty of care owed to his patient, as stated in *James Khoo*. In *James Khoo*, it was held that a doctor will not be found to have breached his duty of care owed to his patient if there is a respectable body of medical opinion, logically held, that supports his actions. This involves a two-stage inquiry. In the first stage, the expert has to direct his mind to all the comparative risks and benefits relating to the matter. In the second stage, the expert has to arrive at a "defensible conclusion", defined as a conclusion that is internally consistent on its face and does not fly in the face of proven extrinsic facts. Importing that to the present context of medical ethics, a particular treatment should not be considered as "not generally accepted by the profession" if there is a respectable body of medical opinion, logically held,

that supports the use of that treatment.

53 We rejected the Appellant's proposed test. As stated above at [28], the spirit and purpose of the ECEG is to uphold the trust and confidence in the medical profession by setting out minimum standards of good medical practice which all doctors should apply in all areas of a doctor's clinical practice. Specifically with regard to Clause 4.1.4, the court in *Gobinathan* commented at [45] that:

> Turning to [Clause] 4.1.4 which sets a standard of good medical practice, the position appears to be that whenever appropriate, patients should be treated with time tested methods where the benefits and risks have been well researched and documented. *The purpose of requiring doctors to conform to generally accepted practices is to ensure that "patients suffer no harm".* [emphasis added]

54 This purpose is better served if the expression "not generally accepted by the profession" is taken to mean "not generally known or used". This entails an *ex ante* acceptance of the treatment by the profession (*ie*, positive act of acceptance), rather than a lack of rejection of the treatment by the profession (*ie*, positive act of rejection) or an *ex post* acceptance. If a positive act of rejection is favoured over the positive act of acceptance, that does not adequately protect patients from the risks of innovative treatment because the profession may not even know of the existence of such innovative treatments to even consider a rejection of such treatments. Likewise, patients are not adequately protected from the risks of innovative treatment if *ex post* acceptance of an innovative treatment is favoured over the requirement for *ex ante* acceptance. This is because Clause 4.1.4 functions as a prophylactic measure, rather than a remedying measure. An *ex post* remedying and scrutiny measure is already provided by the law on medical negligence. Therefore, we affirm what was said in *Gobinathan* at [33] that "[a] novel treatment, by its very definition, cannot be said to be generally accepted", and we concluded that the DC adopted the right interpretation of "not generally accepted".

55 In addition to the factors stated in *Gobinathan* at [46], we generally agree with the approach articulated in DH Cowan, "Innovative Therapy versus Experimentation" (1985) 21 Torts & Ins LJ 619 *("Innovative Therapy versus Experimentation"*) at p 621, in determining whether there has been acceptance of a particular treatment:

> The acceptance or approval of a practice may be based on the results of activities ranging from anecdotal, uncontrolled "experiences" of numerous practitioners to highly organized, carefully conducted randomized clinical trials. *The key consideration is that the potential benefits and risks of the practice and the ability to control these are approaching a level of predictability that is acceptable to both therapists and patients.* It is acknowledged that all risks may not be known or totally absent. *However, the degree of ignorance of the risks has been sufficiently reduced in relation to the anticipated benefits as to justify the use of the practice in a setting where the sole intent is to promote the patient's well-being.* [emphasis added]

56 Therefore, quite apart from the manifestations of acceptance of a particular treatment, we note that the underlying basis and guiding principle for labelling a particular treatment as being generally accepted is that the potential benefits and risks of that treatment and the ability to control these are approaching a level of predictability that is acceptable to the medical community in general. For the purposes of the present case, standard treatments are synonymous with treatments which are "generally accepted by the profession". Nonetheless, we note that standard treatments may lose their status of being "generally accepted" if there is a rejection of the standard treatment by the profession, or if the underlying assumptions about the safety and efficacy of the standard treatment ought to be seriously questioned in the light of advances in medical knowledge, provided that there

are viable alternatives to that treatment.

57 In a similar vein, we clarify that a particular treatment will only be caught by the prohibition against offering innovative treatments in Clause 4.1.4 if that particular treatment is significantly different from the standard treatment that is generally accepted by the profession. Where the particular treatment in question is not significantly different from the standard treatment, such as where the treatment is merely a variation or adaptation of the standard treatment to suit the individual patient's circumstances, the treatment in question may be taken to be similar to the standard treatment, and hence the treatment is not caught by the prohibition against offering innovative treatments. Important factors in assessing whether a particular treatment is significantly different from the standard treatment are the increase in the amount of risks, the addition of new types of risks, and a significant increase in the degree of ignorance of the risks. Where there is no significant increase in the amount of risk that is already present in the standard treatment from which the particular treatment is varied, and no new and significant risks are introduced, that particular treatment will likely be deemed to be the same as the standard treatment. In general, once it is decided that a particular treatment departs significantly from the standard treatment, and this treatment has not been validated by reliable research methods, has not earned a firm basis of support from the clinical community, and there is simply insufficient evidence to support its safety, this treatment will constitute innovative treatment, which is generally caught by the proscription against innovative treatments in paragraph 1 of Clause 4.1.4. The factors stated in *Gobinathan* at [46] assist us in deciding whether a particular treatment constitutes innovative treatment. For our purposes, innovative treatments are synonymous with treatments that are "not generally accepted by the profession" in paragraph 1 of Clause 4.1.4. Such a treatment may only be given in the context of a clinical trial, or as part of a one-off therapy (see below at [61]–[62] on the distinction between therapy and research) before conducting a clinical trial. Given that flexibility in varying surgical techniques is a necessary part of surgical practice, and such variations should generally not be considered to be significantly different from the standard technique, it is hoped that this clarification of the scope of Clause 4.1.4 will allay any concerns that surgeons will be exposed to disciplinary action each time they vary a surgical technique. We believe that patients' access to treatment customised to suit their unique circumstances will not be so restricted, as long as the risks in the customised treatment are not significantly increased, or where there is insufficient evidence to assess the risks, the treatment is given as part of a one-off therapy (or an approved clinical trial).

58 In any case, the Appellant's argument referring to the flexibility inherent in surgical practice did not quite apply to the loop-PEG procedure. Although the loop-PEG procedure involved a surgical procedure, what took centre-stage was the employment of the loop-PEG tube, a medical device. The relevant surgical procedure was a means adopted to facilitate the insertion of this device. What was at the heart of the complaint, as will be shown below at [78]–[107], was the whole concept of how this device was to operate in the Patient's body in place of the standard PEG. Plainly, the use of the loop-PEG tube significantly increased the risks of leakage of gastric contents into the peritoneal cavity, hence rendering the loop-PEG procedure significantly different from the standard PEG procedure/tube.

59 Accordingly, we affirmed the DC's decision that the loop-PEG procedure was "not generally accepted by the profession".

(2) Exemption from the general prohibition against administering innovative treatments

60 The Appellant argued in passing that paragraph 3 of Clause 4.1.4 created an exception to the general prohibition against remedies not generally accepted by the profession in paragraph 1, such that experimental treatments not part of a formal clinical trial were permissible if they were part of

treatment and done in the best interest of the patient. This argument appears to have been based on views expressed in Tracey Evans Chan ("Asst Prof Chan"), "Legal and Regulatory Responses to Innovative Treatment" (2013) 21 Medical Law Review 92 ("*Legal and Regulatory Responses to Innovative Treatment*") at p 99:

> The conjunctive and alternate clauses confuse the meaning of the paragraph, but a contextual reading suggests two distinct situations when experiments or research are ethical: (i) if they are part of a formal clinical trial conducted in accordance with prevailing legal and ethical standards; or (ii) if they are *primarily* part of treatment administered in the best interests of the patient. If this interpretation is accepted, this clause amounts to a qualification of the first in that it expands the reach of medical practice to encompass instances of experimentation if these serve the patient's best interest. [emphasis in original]

61 We generally agree with Asst Prof Chan's observations (subject to the clarifications below) that experimental and innovative treatment which is *therapy* administered in the best interests of the patient is permissible. The distinction between research and therapy is important, and this distinction has been recognised in the BAC Guidelines at paras 3.21 to 3.23, where it adopted the definitions provided by the NMEC guidelines:

> **Therapy versus Research**
>
> 3.21 In Section 2.2.1 of the NMEC Guidelines, it is stated that:
>
> > "*Human research can be broadly defined as studies which generate data about human subjects which go beyond what is needed for the individual's well-being. The primary purpose of research activity is the generation of new information or the testing of a hypothesis. The fact that some benefit may result from the activity does not alter its status as "research". Defined in this manner, human research includes not only studies which involve human subjects directly, but also epidemiological surveys and reviews of patient records, for purposes not related to the patient's immediate health care needs*".
>
> 3.22 In its Guidelines, the NMEC also considered the relationship and distinction between research and therapy. It held that when "an activity is undertaken with the sole intention of benefiting the patient, the activity may be considered to be part of "therapy". The progressive modification of methods of diagnosis and treatment in the light of experience is a normal feature of medical practice and should not be considered as research. There could be potential conflicts between research (intended to generate new information) and therapy (intended to benefit the individual patient directly). Their resolution rests on the integrity of the physician / investigator. The patient is always entitled to the best clinical management, and research considerations must never override this." (Section 2.2.2)
>
> 3.23 We agree with these NMEC statements and adopt them.
>
> [emphasis in original]

62 Hence, research is ordinarily defined as studies which generate data about human subjects which go beyond what is needed for the individual's well-being, with the primary purpose of generating new information or the testing of a hypothesis. Therapy is not as clearly defined. It seems that therapy is defined as an activity that is undertaken with the sole intention of benefiting a particular patient. We note Asst Prof Chan's remark that such a definition for therapy may be unduly stringent because it is always possible to infer some secondary research intent in deploying innovative

treatment, even if the primary purpose is therapeutic: *Legal and Regulatory Responses to Innovative Treatment* at p 102. However, we note that the NMEC Guidelines quoted by the BAC Guidelines merely stated one instance of when an activity may be considered therapy, namely, when an activity is undertaken with the sole intention of benefiting the patient. We do not think that the NMEC Guidelines sought to give an exhaustive definition of therapy. Reading the above quotations on the whole, it is our view that therapy is defined as an activity that is undertaken with the *primary* purpose of benefiting the patient. Correspondingly, where the primary purpose of an activity is to generate new information or test a hypothesis, that activity will be considered research. This is consistent with the guidelines for IRBs issued by the Ministry of Health (see Ministry of Health, *Operational Guidelines for Institutional Review Boards* (December 2007) at paras 2.1 to 2.3), which states:

> 2.1 "Research" is defined as any investigation designed to develop or contribute to generalisable knowledge. This generalisable knowledge will benefit specific groups, or the whole, of the human population, rather than any specific individual.
>
> ...
>
> 2.3 An activity that is undertaken with the *intention* of improving the health of the patient may be considered "therapy". However, the fact that some therapeutic benefit to the patient may result from an activity that is designed to develop or contribute to generalisable knowledge does not alter its status as "research".
>
> [emphasis added]

63 Where a particular treatment is significantly different from the standard treatment (see [57] above), such treatment will be considered innovative treatment. We agree with the following elaboration of the peculiar features of innovative therapy stated in *Innovative Therapy versus Experimentation*, at p 623

> *Innovative therapies generally represent uncontrolled, often single, interventions intended to manage or solve particular clinical problems.* They are not ordinarily designed to test hypotheses. **Additionally, they are not undertaken in order to gain new knowledge beyond the needs of the patient.** ***Although the use of innovative therapies may lead to the development of new knowledge, this consequence is secondary to their primary purpose of benefiting patients*** . [emphasis added in italics, bold italics and bold italics underlined]

64 The distinction between research and therapy is significant because therapy is excluded from the regulatory regime which provides for prospective review applicable to research. This is recognised by the BAC Guidelines, which does not require therapy to undergo prospective review by IRBs (see para 3.24):

> 3.24We therefore exclude therapeutic activities undertaken with the sole intention of benefiting the patient from our definition of Human Biomedical Research. In this respect, we note that medical therapy is already subject to regulation by the MOH under the Medical Registration Act (Cap. 174) and the Private Hospitals and Medical Clinics Act (Cap. 248).

65 Therapy is patient-centric. The protection of the interests of the patient undergoing treatment under therapy instead of research is ensured largely by post hoc regulation via the law of medical negligence and disciplinary proceedings.

66 The rationales for distinguishing research from therapy are that the relationship between the doctor and his or her patient (the doctor-patient relationship) is fundamentally different from the relationship between researchers and their research subjects (the researcher-subject relationship), and the interests of the researcher may not be entirely aligned with those of the research subjects. We find helpful Assoc Prof Terry Kaan Sheung-Hung's exposition on this fundamental difference in Kaan Sheung-Hung, Terry, "Medical Research" in *Essentials of Medical Law* (Sweet & Maxwell Asia, 2004) (Yeo Khee Quan ed) ch 9 at p 313–315:

> **9.3** The most fundamental difference between the two kinds of relationships is quite simply that, in law and in ethics, the physician-patient relationship is (and must be) intended for the benefit and best interests of the patient. So, it has been held that when the condition of an unconscious patient (and therefore, by definition unable to give consent to further treatment) reaches the point that the best interests of the patient can no longer be served by further medical intervention, the very legal basis of the legal relationship of physician-patient fails, and the physician-patient relationship comes to an end as far as the law is concerned.
>
> **9.4** This object of direct benefit and best interests of the patient is the primary reason why the law has to this day given special consideration to the relationship of physician to patient: it is a professional relationship governed by rules quite different from that of most others. But the relationship between a researcher and his research subject (taken in the broadest sense as covering a person who is the direct subject of medical research in the form of experimental therapy or experimental non-therapeutical intervention, or a person from whom tissue of any kind, or medical data or information of any kind used in research originates from) is quite a different one. In the overwhelming majority of cases, there is no question of any *direct benefit* to the subject arising from the research or the relationship. To put it bluntly in another way: research subjects usually do not benefit directly from the relationship of researcher-subject in any way.
>
> **9.5** For this reason, medical researchers who are also medical practitioners must be careful not to confuse their roles (and, therefore, their obligations) when dealing with patients who may also at the same time be their research subjects. Again, this might arise in cases where they carry out experimental therapy (using new or experimental surgical procedures, medical devices or drugs) on their patients. In such cases, medical practitioners need to be aware, and need to make their patients aware, of the possibility that the imperatives of research may well conflict those of treatment; and that the objectives of the two quite different relationships (physician-patient, researcher-subject) are different, and indeed may be in conflict.
>
> **9.6** A simple example of conflict of these two kinds of relationships is in double-blind trials conducted by a medical practitioner on his patients. In such cases, even assuming that a patient gives full and informed and enthusiastic consent, there is a necessarily a conflict between the imperatives of patient care and research. If a placebo is used as a control in the double-blind trial, how is this to be justified in the context of the physician-patient relationship? Even if the control is a standard drug which the patient would be ordinarily prescribed for his condition, there is still the element of risk with the experimental drug being tested. In either case, there is a conflict of interest if the medical practitioner is at once the physician and researcher. That is not to say that such a conflict is never permissible, or that it can never be resolved or managed to the satisfaction of the law and ethics, but the point to be made here is simply that medical practitioners who are researchers should be aware of the potential for conflict of interests.
>
> [emphasis in original]

67 The objective of distinguishing research from therapy is therefore to identify an activity where

there is a deviation between serving the best interests of the patient and the interests in developing generalisable knowledge (see *Legal and Regulatory Responses to Innovative Treatment* at p 109). Where the primary purpose for offering innovative treatment is no longer to benefit the patient, but to generate new information or the testing of a hypothesis, the doctor morphs into a researcher, and there may be a conflict of interest. That is why prospective reviews for research are in place so that the researcher is not the sole judge of the ethical acceptability and scientific merit of a proposed programme of research. As we have noted above at [37]–[38], IRBs play an important role in the ethical governance of research by acting as an ethics review gateway for all human biomedical research. Even though IRBs are not responsible for carrying out scientific review of research projects, the researcher has to satisfy the IRB that an objective review of scientific merit has been carried out (see above at [39]). In the ethical assessment of the research project, the IRB will have to be satisfied that there is sufficient scientific merit in the innovative treatment to warrant its approval.

68 Having outlined the distinction between research and therapy, we now return to Clause 4.1.4. As stated at [27], paragraph 1 of Clause 4.1.4 provides a general proscription against offering "management plans or remedies that are not generally accepted by the profession", and an exception to the proscription, namely when the remedy is offered "in the context of a formal and approved clinical trial". Paragraph 3 of Clause 4.1.4 then provides that experimental treatments which are primarily part of treatment administered in the best interests of the patient are permissible. Taking a contextual reading of Clause 4.1.4, it is our view that if it can be established that the experimental or innovative treatment in question is therapy administered in the best interests of the patient, it is exempted from the general proscription against "remedies that are not generally accepted by the profession" in paragraph 1 of Clause 4.1.4. However, where it has been established that a doctor gave a treatment that was not generally accepted by the profession, the burden is on the doctor to prove on a balance of probabilities that the treatment in question is part of therapy administered in the best interests of the patient. We believe this strikes an appropriate balance between the need to protect vulnerable patients from unknown risks, and the need to allow flexibility in clinical practice to encourage innovation.

69 In our view, in the situation where the doctor has doubts as to whether an innovative treatment would constitute research or therapy, and where the standard treatment has not been shown to be ineffective or where urgent treatment is not required, it would be prudent to seek the approval of the IRBs if seeking such approval is not impracticable. We refer to *Legal and Regulatory Responses to Innovative Treatment* at pp 120–121, which helpfully discusses some of the potential problems arising from not subjecting innovative treatments to any prospective external review at all, and leaving any scrutiny to the post hoc review in a medical negligence action or disciplinary proceedings:

> ***First, the decision to offer innovative therapy is subject to an increasing potential for conflicts between the patient's best interests and the physician's personal and professional interests in profit and advancement.*** *The potential intellectual property and commercial spin-offs related to the development of new medical technologies have the potential for influencing professional judgments concerning innovative treatments, given their nascent stage of development and potential capacity, once administered, to generate valuable information in advancing the physician's interests.* Concerns over conflicts of interest are of particular concern in a system where healthcare is principally delivered through privately operated institutions and cost recovery (if not profit) is an overriding concern.
>
> ***Secondly, quite apart from financial considerations, there may also be an evaluative bias in favour of the soundness of self-produced innovation, with the risk of an overestimation of the potential benefits and underestimation of the risks.*** This may be difficult to determine,

particularly in an area where there is a lack of supporting data.

Thirdly, pressure to innovate comes not only from professional quarters, but also from patients themselves. Patients without existing alternatives, and their families, may place strong pressure on doctors to try something new in the hope of a miracle cure. They are increasingly well informed and may point physicians to the latest media-informed developments across the globe. The burden of providing a detached, objective evaluation of the innovative option currently falls on the shoulders of the individual attending physician or surgeon, which may often be an unrealistic aspiration.

[emphasis added in italics and bold italics]

70 We reiterate our earlier view at [30] that the term "clinical trial" in the context of Clause 4.1.4 merely means any trial which is "approved by an ethics committee", which "conforms to the Good Clinical Practice Guidelines", where applicable, and where "informed consent" has been obtained from the patient (see paragraph 2 of Clause 4.1.4). Accordingly, the use of a particular innovative treatment which satisfies all these requirements, and which is not therapy, would constitute a "clinical trial". We should point out that IRBs, while having a critical role in the approval process, should not be held legally responsible for any unintended consequences arising from the employment of innovative treatment. It is the researcher/doctor who should be wholly responsible. This is supported by the BAC Guidelines at paras 6.5–6.6 (see also *Governance Framework for Human Biomedical Research* at para 8):

6.5. *This responsibility of the researcher is a non-delegable and personal responsibility.* It is a responsibility that cannot be transferred or delegated to an IRB or to any party in the ethics review and governance process merely through the approval of a research proposal by an IRB.

6.6 *By the same token, researchers remain entirely responsible for ensuring that their research complies with all relevant laws and legal or regulatory obligations and requirements.* Ethics approval given by an IRB is not to be taken as an assurance or representation by the IRB of such compliance, or as an assumption of legal liabilities arising out of the proposed research by the IRB. *In short, it is unethical for researchers to treat IRBs and the review process merely as "legal insurers" or as "legal insurance*".

[emphasis added]

71 Support for such prudence in seeking the early approval of the IRBs, even though a particular innovative treatment is likely to be considered therapy, can be found in the Belmont Report (see United States National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for Protection of Human Subjects of Research* (18 April 1979), at Part A, para 3), which recognises that innovative treatments should be the object of formal research at an early stage so as to determine whether they are safe and effective:

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is "experimental," in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation

be incorporated into a formal research project.

72 Nonetheless, where the standard treatment is likely to be wanting or ineffective, then subject to the observations we have already made concerning the burden of proof falling on the doctor, it may well be that the doctor's use of innovative treatments would likely be considered to be therapy and not research, and on that basis be considered permissible, provided that it is shown to be in the best interests of the patient. This is supported by the Declaration of Helsinki (see World Medical Association, *Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects* (October 2013), para 37 <http://www.wma.net/en/30publications/10policies/b3/index.html>) (assessed on 27 November 2013), which also states that innovative treatments should be the object of formal research at an early stage:

> In the treatment of an individual patient, where *proven interventions do not exist or other known interventions have been ineffective*, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention *should subsequently be made the object of research*, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available. [emphasis added]

73 In summary, the first step of the analysis is to decide whether a particular treatment is significantly different from the standard treatment. If the treatment is significantly different from the standard treatment, the second step of the analysis is to determine if it constitutes innovative treatment, hence triggering the prohibition against innovative treatment. If the treatment constitutes innovative treatment, the third step of the analysis is to decide if the treatment constitutes therapy administered in the best interests of the patient, which is exempted from the prohibition against innovative treatment. It seems to us that these issues were not fully fleshed out in the DC's decision. We shall now examine whether the Appellant breached the general proscription and whether any exemption to this general proscription applied.

Issue 3

74 The third issue is whether the DC erred in fact in finding that the loop-PEG procedure performed on the Patient was "not generally accepted" by the profession.

The DC's findings

75 The DC concluded (at [98]–[110] of the DC Decision) that the loop-PEG procedure performed by the Appellant on the Patient was "not generally accepted by the profession" because:

(a) the DC took the view that the loop-PEG was novel and therefore a new device;

(b) all the experts were in agreement that until they were engaged as experts, they had never seen the loop-PEG device before;

(c) all the experts were in agreement that apart from the self-serving articles written by the Appellant, there was no other medical literature available on the loop-PEG;

(d) all the experts were in agreement, or at least did not dispute that even with the disadvantages of the standard PEG, the generally accepted device to be used was the standard PEG with the bolster and bumper mechanism; and

(e) all the experts were in agreement that they knew of no one else using the loop-PEG except for the Appellant.

The arguments

76 The Appellant argued that the DC's finding that the loop-PEG procedure performed on the Patient was "not generally accepted by the profession" was contrary to the evidence. As stated above, the Appellant argued that the right test for "generally accepted" should be the same as that for determining whether a doctor has breached the tortious duty of care owed to his patient, as stated in *James Khoo*. Dr Seow-Choen's expert evidence represented a respectable body of medical opinion that was logically held, and that supported the Appellant's actions. Existing medical literature, it was argued, showed that there was natural apposition between the stomach and the abdominal wall such that the "bumper-bolster" mechanism in the standard PEG tube was not necessary to ensure apposition. The Respondent, in response, submitted that the DC was entitled to find that the loop-PEG procedure was not generally accepted by the profession because it was novel, and to prefer Prof Ti's evidence over Dr Seow-Choen's evidence. The DC rightly found that Dr Seow-Choen expressed reservations in using the loop-PEG.

77 It should be noted that the Appellant did not seek to challenge reasons (b) to (e) stated above at [75]. The Appellant only argued that the DC erred in finding that the loop-PEG procedure was "not generally accepted by the profession" on the following grounds:

(a) the DC ought to have preferred Dr Seow-Choen's evidence that the loop-PEG tube should not be considered as "not generally accepted by the profession";

(b) the DC had erred in finding that Dr Seow-Choen expressed reservations in using the loop-PEG tube;

(c) Prof Ti conceded that: (i) the fact that the loop-PEG used two stomas instead of one was not a significant point of difference from the standard PEG, and (ii) a loop-PEG tube is similar in design to that of Diagram 2 and Diagram 3 would have apposition of the stomach wall to the abdominal wall and minimal risk of rotation; and

(d) the bumper-bolster mechanism in the standard PEG was not necessary as there was natural apposition between the stomach and abdominal wall.

Our decision

78 In our view, the DC was entirely correct in arriving at its conclusion that the loop-PEG procedure was "not generally accepted by the profession". First, the DC was correct to find that the loop-PEG was significantly different from the standard PEG, and was therefore new. The DC found (at [100]–[103] of the DC Decision) that the standard PEG procedure and the loop-PEG procedure were different because the loop-PEG procedure had no bumper-bolster mechanism, which ensured apposition of the stomach wall to the peritoneal surface of the abdominal wall. The general and accepted view was that apposition between the stomach wall and the peritoneal surface of the abdominal wall in the standard PEG was important to seal off the site of the stomach tube penetration and expedited the formation of a mature tract around the tube. We agreed with these findings of the DC. Further, we agreed with the DC's decision to reject the Appellant's argument that the stomach was naturally in apposition against the abdominal wall and that gastropexy was not required.

79 Second, the DC was correct to find (at [110] of the DC Decision) that the loop-PEG procedure

was "not generally accepted by the profession". Applying the factors in *Gobinathan*, the fact that there was no other medical literature available on the loop-PEG other than the articles written by the Appellant (reason (c)) is relevant. The fact that the experts had never seen (or even heard of) the loop-PEG device prior to their engagement (reason (b)) supports the finding that the profession could not have had the opportunity to accept the new procedure. The fact that the experts did not know of anyone else using the loop-PEG (reason (e)) supports the finding that the profession had yet to accept the new procedure. On the other hand, the fact that the generally accepted device was the standard PEG (reason (d)) seems to be a neutral factor because it is conceivable that the profession could accept more than one device, and the fact that the standard PEG was the generally accepted device does not ineluctably mean that the loop-PEG device could not be generally accepted as well.

80 We now set out our detailed views on the Appellant's arguments.

(1) The DC's preference for Prof Ti's evidence

81 The Appellant's argument was premised on adopting the test in *James Khoo*. Applying that test, Dr Seow-Choen's evidence represented a respectable body of medical opinion, logically held, that supported the Appellant's actions. As a result, the Appellant argued that it was not open to the DC to make the contrary finding that the loop-PEG procedure performed on the Patient was novel, not based on sound science, or in any way "wrong".

82 We rejected the Appellant's argument. As stated above at [53]–[54], the test in *James Khoo* was made in the context of medical negligence and should not be applied to decide if a particular treatment is "not generally accepted by the profession" in the context of medical ethics. The Appellant argued that Dr Seow-Choen gave evidence that the loop-PEG tube was not novel, but was merely a variant of the standard PEG tube, of which modifications had been made "*based on the experiences gained from the enormous amount of literature associated with the PEG Device*" [emphasis in original]. In our view, the DC was entitled to reject Dr Seow-Choen's evidence that the loop-PEG procedure was merely a variant of the standard PEG procedure because even though Dr Seow-Choen gave evidence that the loop-PEG was not novel in concept, he accepted that the device was novel in design, and that the loop-PEG was new in the sense that it was not used prior to 2007. Moreover, the specifications of the Appellant's patent show that the Appellant set out to invent a device for tube feeding that was different in design from the standard PEG and which resolved the problems that the Appellant perceived to be inherent in the design of the standard PEG. Further, the many articles authored or co-authored by the Appellant clearly compared the loop-PEG tube with the standard PEG and concluded that the former was significantly different. It should also be noted that the DC found that apart from the articles which were written by the Appellant, there was no other medical literature available on the loop-PEG tube.

83 The DC was also entitled to reject Dr Seow-Choen's personal view that the Appellant was not wrong to have used the loop-PEG tube outside the context of a clinical trial, as this view was not based on any clear medical basis, and an assessment of whether a particular act is unethical or constitutes professional misconduct lies within the purview of the DC. It bears reminding that the court in *Gobinathan* stated at [29] that the court should be mindful that the DC is a "specialist tribunal with its own professional expertise and understands what the medical profession expects of its members". Therefore, this court would ordinarily be slow to interfere with the findings of the DC, especially in the area of assessing expert evidence.

(2) Dr Seow-Choen's reservations

84 The Appellant argued that the DC erred in finding (at [109] of the DC Decision) that "Dr Seow-

Choen himself expressed that he would have had reservations using the loop PEG" because Dr Seow-Choen said that he would "hesitate" to use a device except in the context of a randomised or approved clinical trial, unless he himself was the inventor. Moreover, Dr Seow-Choen was clear in his evidence that the loop-PEG was much better in design compared to the standard PEG.

85 We rejected the Appellant's argument. The Appellant's reading of Dr Seow-Choen's evidence that he would "hesitate" to use a device except in the context of a randomised or approved clinical trial, unless he himself was the inventor is not inconsistent with the finding of the DC that Dr Seow-Choen expressed reservations in using the loop-PEG tube pushed to him by *another doctor*.

(3) Prof Ti's evidence

86 At the DC inquiry, Prof Ti's evidence was that the loop-PEG procedure was novel because of two risk factors that increased the risks of leakage into the peritoneal cavity, hence rendering it less safe than the standard PEG, namely:

(a) there was no mechanism to ensure apposition of the abdominal lining to the stomach wall to prevent leakage into the peritoneal cavity; and

(b) there was a real risk of rotation of the loop-PEG in such a manner that would cause leakage into the peritoneal cavity, particularly, the fenestration at the middle of the loop could be displaced from their intragastric position into the peritoneal cavity.

87 Prof Ti gave evidence that without these two risk factors, the loop-PEG procedure could be considered substantially equivalent to the standard PEG, and would no longer be considered novel.

88 At the outset, we should mention that we entirely agree with Prof Ti's approach. As stated above at [57], the important factors in assessing whether a particular treatment is significantly different from the standard treatment are the increase in the amount of risks, the addition of new types of risks, and a significant increase in the degree of ignorance of the risks. A particular treatment will only be caught by the prohibition against offering innovative treatments in Clause 4.1.4 if that particular treatment is significantly different from the standard treatment that is generally accepted by the profession.

89 The Appellant argued that the DC's findings were inconsistent with Prof Ti's evidence because Prof Ti conceded that the fact that the loop-PEG used two stomas instead of one was not a significant point of difference, and that a loop-PEG tube similar in design to that of Diagram 2 and Diagram 3 would ensure apposition of the stomach wall to the abdominal wall and have a minimal risk of rotation. We shall now examine these two arguments.

(A) Two stomas

90 The Appellant noted that in the DC's oral grounds of decision, the DC observed that one reason why the loop-PEG was different from the standard PEG was because the loop-PEG procedure involved the creation of two stomas, which was more invasive than the standard PEG. With reference to this, the Appellant argued that Prof Ti's evidence was that the fact that the loop-PEG used two stomas instead of one was not a significant point of difference from the standard PEG. Therefore, the DC was wrong to find that the loop-PEG procedure was different from the standard PEG because it involved the creation of two stomas instead of one.

91 We agreed with the Appellant that Prof Ti did give evidence that the fact that the loop-PEG

used two stomas instead of one was not a significant point of difference from the standard PEG:

> MR LIN: That will lead you to say it's novel because of these -- because it's more than one stoma and because it's --
>
> PROFESSOR TI: No, no. It -- that is a small difference.
>
> MR LIN: Small difference?
>
> PROFESSOR TI: It might lead -- lead to a higher leakage rate because it -- it's two instead of one. But, to me, it is not highly significant.

92 Although Prof Ti gave evidence that the fact that two stomas were used in the loop-PEG procedure was not *in itself* sufficient to render the loop-PEG procedure novel, and that the difference from the standard PEG was "not very significant", it is clear that Prof Ti did not mean to relegate the fact that two stomas were used as totally irrelevant to the enquiry of whether the loop-PEG procedure was novel, because it might lead to a "higher leakage rate". Moreover, two other reasons were given in the DC's oral grounds of decision, namely, that the treatment given by the Appellant did not involve a bumper-booster mechanism and did not secure apposition between the stomach and the peritoneal abdominal wall, and that there was no independent evidence of any other practitioner using the loop-PEG. Further, the DC's written grounds of decision dated 23 July 2012 did not rely on the fact that two stomas instead of one were used in the loop-PEG procedure to conclude that the loop-PEG was different from the standard PEG procedure, and the DC prefaced its oral grounds of decision by saying that the oral grounds were "merely a summary of [their] grounds of decision" and that the full written grounds of the decision would be made available to all parties. Therefore, we found the Appellant's reliance on this point to be misplaced.

(B) Risk of leakage

(I) Apposition of the stomach wall to the abdominal wall

93 The DC found that the general and accepted view was that gastropexy (*ie*, the apposition of the stomach wall to the peritoneal surface of the abdominal wall) in the standard PEG by using the bumper-bolster mechanism was important to seal off the site of the stomach tube penetration and expedite the formation of a mature tract around the tube. This is supported by Prof Ti's expert report:

> More importantly, the internal bumpers (bolsters) in standard PEG serves as a sutureless device for gastropexy, helping to seal off the gastrostomy tube tract and reducing life-threatening leakage of gastric secretion and contents into the abdominal cavity. The bumpers also serve to secure the gastrostomy tube from being propelled further down the gastro-intestinal tract or be dislodged externally.

94 The absence of the bumper-bolster mechanism or any other mechanism to provide gastropexy in the loop-PEG procedure led Prof Ti to rightly conclude that there was a higher risk of leakage and that the loop-PEG procedure was novel:

> Furthermore, without bumpers, stitches or other mechanisms to create gastropexy in "loop" gastrostomy, the sites of penetration of the loop tube are not sealed off from the peritoneal cavity. This could also have contributed to gastric leakage in [the Patient].
>
> ...

The loop PEG, in spite of two sites of penetration of the stomach lacks this precaution against leakage of gastric content.

As the "loop percutaneous endoscopic gastrostomy" (loop PEG) differ in design and inserted position from standard percutaneous endoscopic gastrostomy in significant ways, particularly in preventing stomach leaks, it is submitted that the loop PEG is "novel" in design and insertion.

95 However, the Appellant argued that Prof Ti conceded that in the case of a loop-PEG tube similar to Diagram 3, there would be apposition of the stomach wall to the abdominal wall. We rejected the Appellant's argument. Prof Ti merely stated that he agreed that there was theoretical apposition in Diagram 3, but that Diagram 3 was merely hypothetical and was unlikely to be an accurate portrayal of reality.

96 Moreover, even if it is assumed that the loop-PEG tube can be made to conform to Diagram 3, it was Prof Ti's evidence that there would be problems such as lacerations and ulcers, and hence the changes in design could not be made, or this would be another reason to regard the loop-PEG procedure as novel.

97 It should be noted that the articles which the Appellant co-authored stated that gastropexy *could be added* to the loop-PEG tube. In Pang AS, Ho ST, Maetani I, "A simple gastropexy for the loop-gastrostomy tube" Journal of Minimal Access Surgery 2012; 8(4):154, pp 154–155, it was stated:

> The percutaneous endoscopic gastrostomy has been in clinical use for more than three decades. A recent innovation, the loop-gastrostomy, is more suitable for developing countries because the tube cannot be dislodged and is easy to change. Gastropexy and gastrostomy are separate but related moieties. We describe a novel technique to *add a gastropexy* to the loop-gastrostomy, using it successfully in a man with permanent dysphagia. It involved creating a secondary loop at the mid-portion of the LOOPPEG®3G tube with absorbable ligatures.
>
> ...
>
> Gastropexy, the apposition of the anterior stomach wall to the anterior abdominal wall, *enhances the safety* of a tube gastrostomy. …
>
> ...
>
> This case proves that a *gastropexy can be added* to the loop-gastrostomy via the tube.
>
> ...
>
> It is plain to see that the secondary loop and lock are the *counterparts of the bumper and bolster of the standard PEG*.
>
> [emphasis added]

98 In AS Pang, "The Twin-stoma Gastrostomy and the LOOPPEG® 3G Tube" (2011) in *Gastrostomy* (InTech, 2011) (Pavel Kohout gen ed) ch 8 p 123, it was stated:

> Gastrostomy and gastropexy are related but separate moieties. By excluding the peritoneal cavity, the latter *enhances the safety of the former*.

For the twin-stoma gastrostomy, the *gastropexy may be effected* with T-fasteners or suturing. An alternative method is the loop-lock technique. A secondary loop is created at the midportion of the 3G tube with absorbable ligatures. Two ligatures, each comprising two square knots, are required (Figure 4). This is done before pull-through.

After pull-through, the secondary loop and lock are used *to appose the stomach wall* to the abdominal wall (Figure 5B). When the LOOPPEG® is used in this fashion, we refer to it as the LOOPPEGG™ (the additional G to represent the gastropexy).

...

Our current practice is to always insert the 3G tube with a secondary loop. Besides providing traction, the secondary loop keeps the central opening of the tube within the stomach and *away from the gastric puncture sites*.

[emphasis added]

99 It was not disputed that the loop-PEG procedure performed on the Patient *did not have a secondary loop to add gastropexy*. The above quotations from the Appellant's articles seemed to contradict his position that the loop-PEG procedure already provided for apposition of the stomach wall to the abdominal wall, and that the bumper-bolster mechanism or any other mechanism providing gastropexy was not required. If the loop-PEG procedure indeed provided for gastropexy, a secondary loop would not be required to provide for gastropexy. Similarly, the provision of the secondary loop to provide for gastropexy contradicted the Appellant's argument that there was natural apposition between the stomach and the abdominal wall.

100 It should also be noted that Diagram 3, which was only submitted by the Appellant at the start of the DC hearing in 2011, is the very first drawing in which the bottom of the loop-PEG tube is depicted as being pulled against the stomach wall to ensure apposition of the stomach wall to the peritoneal surface of the abdominal wall. All the other earlier diagrams that the Appellant had produced of the loop-PEG tube, specifically those found in the Appellant's articles (including Diagram 2), the Patient's contemporaneous medical case notes, and the Appellant's patent application, all depicted the tube as elliptical and hanging loose inside the stomach such that it did not hold up the stomach. Moreover, instructions on SGN Pte Ltd's website expressly warned users to ensure that there was sufficient length of tube inside the stomach, otherwise, "the central segment with the opening [could] escape from the stomach to the peritoneal cavity during patient movement" (see Diagram 4). This must mean that there was no proper apposition provided by a loop-PEG tube.

101 In any case, it was doubtful that the loop-PEG procedure performed on the Patient conformed to that in Diagram 3. If the loop-PEG tube used on the Patient conformed to that in Diagram 3, the lock in the middle should have rendered the loop-PEG tube immovable thereby ensuring apposition of the stomach wall to the peritoneal surface of the abdominal wall. Ms Liew testified that the loop-PEG tube used on the Patient had some space in between the tie and the two stomas.

(II) Tube rotation

102 The DC made no findings as to whether there was a risk of rotation of the loop-PEG tube in such a manner that would cause leakage into the peritoneal cavity. However, we will address the Appellant's arguments in relation to this issue for completeness.

103 In Prof Ti's expert report, he opined that there was a real risk of inadvertent rotation of the

loop-PEG in such a manner that would cause leakage into the peritoneal cavity; in particular, the fenestration at the middle of the loop could be displaced from their intragastric position into the peritoneal cavity. This was supported by his view that there was no bumper-bolster mechanism to "seal off the gastrostomy tube tract and [reduce] life-threatening leakage of gastric secretion and contents into the abdominal cavity". Prof Ti clarified how the rotation could take place in his testimony:

> MR OMAR: Okay. Now one -- three more questions. You were asked about the locking system and you were shown the locking system. And your answer was, "Yes, there's one, but this is of not much significance". You recall? Can you explain what you meant when you said that the locking was of not much significance?
>
> PROFESSOR TI: I didn't want to get into all the technicalities of the locking system, but if you look at this diagram, the same diagram ...
>
> …
>
> PROFESSOR TI: Yah, 723. You see, there's a lock there, but the whole thing, you know -- that can be lifted up like a handbag, you know. The whole thing can be lifted like a handbag and rotated around.

104 The Appellant argued that Prof Ti conceded that in the case of a loop-PEG tube similar in design to Diagram 2 with one cable tie as the lock and additional cable ties at both the left and right entries of the tube, the risk associated with tube rotation would be minimal. However, this argument was misconceived. Prof Ti's comment that the risk of rotation would be less was merely in response to a question on a hypothetical scenario where three cable ties were used in Diagram 2 instead of a lock.

105 It was doubtful that the Appellant used three cable ties on the Patient. It was Ms Liew's evidence that only one cable tie was used on the Patient:

> MR LIN: Now, at that time, I understand that the tube was locked together by a cable tie. Is that correct? Can you remember?
>
> MS LIEW: Yah, in the centre, there -- there is a lock, a cable tie, yes.
>
> MR LIN: Yes. *Now, were there any other cable ties, apart from the centre?*
>
> MS LIEW: *No.*
>
> MR LIN: And when you fed the syringe -- the milk through the syringe into the tube, did you have to remove the cable tie?
>
> MS LIEW: I don't -- I don't remember removing anything.
>
> [emphasis added]

106 In the circumstances, we rejected the Appellant's argument. In any case, it bears repeating that the DC made no findings as to whether there was a risk of rotation of the loop-PEG in such a manner that would cause leakage into the peritoneal cavity. The DC concluded that the loop-PEG procedure performed on the Patient was significantly different from the standard PEG, and was therefore new because there was no mechanism to ensure apposition of the abdominal lining to the stomach wall to prevent leakage into the peritoneal cavity. Based on the evidence before us, we are

inclined to go further to find that there was a risk of rotation of the loop-PEG in such a manner that would cause leakage into the peritoneal cavity.

107 Even if it was assumed that the loop-PEG tube inserted in the Patient was similar to that illustrated in Diagram 2, there would still be risks associated with tube rotation. While Prof Ti had commented that the risk of rotation would be less, this was in response to a specific hypothetical scenario if three cable ties were used instead of a lock. Ms Liew confirmed that only one cable tie was used on the Patient.

(4) Was the treatment given to the Patient therapy or research?

108 As stated above at [64], the distinction between therapy and research is important because therapy is excluded from the regulatory regime applicable to research, which provides for prospective review, such as the requirement for research to be approved by IRBs. Also, as stated above at [68], experimental or innovative treatment given as therapy is exempted from the general proscription against "remedies that are not generally accepted by the profession" in paragraph 1 of Clause 4.1.4, and the burden is on the doctor to prove on a balance of probabilities that the treatment in question is therapy administered in the best interests of the patient. The Appellant did not make substantive arguments on this issue of whether the treatment given to the Patient was therapy, and barely asserted in his skeletal submissions that the loop-PEG procedure given by the Appellant was therapy. Therefore, the Appellant had not established that the loop-PEG procedure was primarily part of therapy administered in the best interests of the Patient.

109 In any case, the evidence suggested that the loop-PEG procedure was given as part of research and not therapy. First, it had not been shown that the standard PEG, which was the accepted treatment, was ineffective. In fact, the above analysis on the differences between the standard PEG and loop-PEG procedure suggested that the standard PEG was safer and more established than the loop-PEG. The Appellant was not confronted with a life and death situation, and there was no compelling reason to offer the Patient (who was 84 years old) the loop-PEG when the standard PEG would have sufficed. At the very least, there was uncertainty in the safety of the loop-PEG procedure. Accordingly, this suggested that the offering of the loop-PEG procedure was not in the best interests of the Patient. Second, the procedure had purportedly been performed on two other patients before it was performed on the Patient. This suggested that it was not a situation of the Appellant customising treatment to suit the unique circumstances of the Patient. Instead, the Appellant seemed to be embarking on a research trial to establish a wider usage of a new procedure and device for general use. This inference was reinforced by the fact that when the loop-PEG procedure was performed on the Patient on 7 July 2008, the Appellant had already filed a patent application on 11 October 2007, pursuant to which the Appellant was subsequently granted Letters of Patents on 31 August 2009. Moreover, the commercial variant of the loop-PEG tube, namely the LOOPPEG® 3G Tube, showed that the invention has evolved over time. As stated above at [97]–[99], the Appellant's practice as of 2011 was to use the LOOPPEG® 3G Tube with a secondary loop to provide for gastropexy, while it was not disputed that the loop-PEG procedure performed on the Patient did not have a secondary loop to add gastropexy.

110 We accept, however, that the publication of data from the use of innovative treatments would not in itself give rise to an inference that the treatment was not undertaken with the primary purpose of benefiting the patient, but with the primary purpose of generating new information or the testing of a hypothesis. In fact, we note that the collection and publication of clinical information by a doctor is consistent with good clinical practice of sharing useful data with the medical community.

Issue 4

111 The fourth issue is whether the DC erred in law in finding that the Appellant's breach of Clause 4.1.4 amounted to professional misconduct.

The arguments

112 The Appellant argued that the DC erred in finding that the Appellant's breach of Clause 4.1.4 amounted to professional misconduct because:

(a) the DC failed to consider that no harm was alleged to have been caused to the Patient and that the Appellant was not experimenting on the Patient;

(b) it was implausible for the Appellant to have conducted a clinical trial on the loop-PEG tube;

(c) the DC wrongly enquired into the issue of whether the Appellant had obtained the Patient's informed consent, but in any case, the Appellant had informed the Patient that it was a new procedure; and

(d) the Appellant honestly believed that the loop-PEG tube was based on sound scientific principles and clearly better than the standard PEG.

113 The Respondent on its part submitted that the DC did not err in finding that the Appellant's breach of Clause 4.1.4 amounted to professional misconduct. The Appellant intentionally and deliberately ignored his ethical obligations, and the loop-PEG procedure was capable of being subjected to clinical trials.

The applicable legal principles

114 According to *Low Cze Hong v Singapore Medical Council* [2008] 3 SLR(R) 612 ("*Low Cze Hong*") at [37], professional misconduct under s 45(1)(*d*) of the MRA (before the amendment on 1 December 2010) can be made out in at least two situations:

(a) where there is an intentional, deliberate departure from standards observed or approved by members of the profession of good repute and competency; and

(b) where there had been such serious negligence that it objectively portrays an abuse of the privileges which accompany registration as a medical practitioner.

Our decision

115 Since we found at [30]–[36] that clinical trials were not only possible, but required, and that the loop-PEG procedure was administered on the Patient as part of research and not therapy, only these three issues were left to be considered:

(a) Whether the DC had failed to consider that no harm was alleged to have been caused to the Patient.

(b) Whether the DC had wrongly enquired into the issue of whether the Appellant had obtained the Patient's informed consent, and whether the Appellant had informed the Patient that it was a new procedure.

(c) Whether the Appellant had honestly believed that the loop-PEG tube was based on sound

scientific principles and clearly better than the standard PEG.

(1) Harm

116 The Appellant argued that the DC ought to have considered the fact that no harm had been caused to the Patient because *Low Chai Ling* suggested that whether harm was caused to the patient and whether the doctor experimented on the patients may well be relevant considerations in determining whether there was professional misconduct.

117 We rejected the Appellant's argument because the court in *Low Chai Ling* merely noted at [53] the DC's observation that the gravity of the departure or whether harm was caused may well be relevant, and the ultimate question was whether the level of severity or intentionality as stipulated in *Low Cze Hong* had been made out. Moreover, the court in *Low Chai Ling* did not have to proceed to determine whether the treatments were harmful to patients in determining whether there was professional misconduct. Therefore, the DC was entitled to disregard the issue of whether harm had been caused to the Patient in the present case.

118 The DC was entitled to conclude that the Appellant had intentionally and deliberately ignored his ethical obligations because:

(a) the ECEG sets out the basic standards that doctors are expected to abide by; and

(b) the Appellant had intentionally and deliberately ignored his ethical obligation in Clause 4.1.4 because:

(i) the Appellant was aware that the loop-PEG tube was different from the standard PEG;

(ii) as at July 2008, there were no published articles or any other literature on the loop-PEG tube, and there was no one else using the loop-PEG tube except for the Appellant;

(iii) the Appellant was aware that there was an ethics committee at Mount Alvernia Hospital;

(iv) the Appellant did not seek approval from any ethics committee or IRB to carry out any clinical trial; and

(v) the Appellant took the position that he did not need to or could not do a clinical trial.

(2) Informed consent

119 The DC found (at [115] of the DC Decision) that the Appellant did not have the informed consent of the Patient because the Appellant did not inform Ms Liew that her mother-in-law would be the third patient in the world to receive the loop-PEG procedure, and all the Appellant told Ms Liew was a description of the loop-PEG procedure, the costs of the procedure and that the loop-PEG procedure was better and safer. The Appellant argued that the DC ought not have inquired into whether there was informed consent because:

(a) Clause 4.1.4 did not deal with the requirement for informed consent outside of a clinical trial;

(b) the charge did not address the question of whether the Patient understood all options available as well as the risks and benefits of these options; and

(c) the Patient and her family members knew that the loop-PEG procedure was "new".

120 We rejected the Appellant's argument. It is conceivable that the existence or absence of informed consent from the patient can affect the finding of whether the breach of the ECEG was intentional and deliberate, which can establish professional misconduct. Moreover, the issue of informed consent may be relevant because informed consent is a requirement for offering innovative treatment in the context of a clinical trial. In any case, while the DC found that the Appellant did not obtain the Patient's informed consent, the DC nonetheless recognised (at [117] of the DC Decision) that it was not material to the charge, as the Appellant would still be in breach of Clause 4.1.4 because he did not obtain approval to conduct any clinical trial (see [117]–[118] of the DC Decision):

> Having found that Dr Pang did not have informed consent of the Patient or their family members, we wish to add that even if there was informed consent, it may not be material to the charge which Dr Pang faces. This is because whilst informed consent is a crucial part of any clinical trial, the clinical trial must still be an approved clinical.
>
> In other words, even if Dr Pang argued that he had conducted a clinical trial and the patient had given full informed consent, Dr Pang would still run afoul of paragraph 4.1.4 of [the ECEG] because the clinical trial was not an approved clinical trial.

(3) The Appellant's honest belief

121 The Appellant argued that the court in *Gobinathan* held at [72]–[74] that the doctor could not be said to have known that he had "overstepped the line" or "turned a blind eye" to either the appropriateness or safety considerations of the innovative treatment because:

(a) the evidence showed that the doctor honestly believed in the efficacy of his innovative treatment and that the treatment was in the interests of the patient;

(b) this honest belief was reflected in a proposal he submitted to the relevant authorities detailing his innovative treatment;

(c) the doctor stated in his proposal that further clinical trials to verify his findings might be desired, even though his personal view was that they were not necessary; and

(d) the doctor was confident that his innovative treatment would also benefit patients afflicted with conditions similar to the patient's conditions in general.

122 The Appellant argued that these four features were also present in the current case.

123 Even if it is assumed that these four features are also present in the current case, the Appellant's reliance on *Gobinathan* was misplaced. In *Gobinathan*, the court set aside the conviction on various grounds: it took issue with the way the charge was framed, the manner in which the proceedings were conducted, and the reasoning of the DC. When the court disagreed with the DC there that the doctor must have known that he had overstepped the line or at least turned a blind eye, that was in reference to the appropriateness of the innovative treatment, which in turn related to whether the treatment was generally accepted by the profession and whether it was indicated for the patient's condition, and in reference to the safety of the treatment. In our view, the reasons

given by the court in disagreeing with the findings of the DC resonated more with respect to whether the doctor's use of the treatment was indicated for the patient's condition and whether the use of the treatment was safe, rather than whether the treatment was generally accepted by the profession.

124 Further, logically speaking, in the absence of compelling reasons to administer the loop-PEG procedure on the Patient, the fact that the Appellant honestly believed in the efficacy of his innovative treatment and that the treatment was in the interest of the Patient should not be relevant to the issues of whether the treatment was generally accepted by the profession or whether the breach of the ECEG was intentional or deliberate. In fact, where the administration of an innovative treatment is considered research and not therapy, the requirement for prospective reviews by IRBs is to ensure that the researcher is not the sole judge of the ethical acceptability of a proposed programme of research, and to guard against any possible conflicts of interest: see above at [66]–[67].

125 We would like to reiterate that where a particular innovative treatment is considered therapy and not research, that will be exempted from the general proscription against "remedies that are not generally accepted by the profession" in paragraph 1 of Clause 4.1.4: see above at [61]–[72]. Where there are compelling reasons to administer an innovative treatment, such as where time is of the essence or where the standard treatment is ineffective, that can point towards an inference that the innovative treatment is given as therapy and not research. Even if the treatment is found to be given in the context of research, such factors may militate against a finding of misconduct.

126 Having rejected the Appellant's arguments, we found that the DC did not err in finding that the Appellant's breach of Clause 4.1.4 amounted to professional misconduct.

Conclusion of the appeal

127 For the above reasons, we dismissed Originating Summons No 799 of 2012, and ordered that the costs incurred be borne by the Appellant. We also varied the undertaking to be provided by the Appellant. The order for the undertaking now reads:

> [T]he 1st Respondent shall provide a written undertaking to the SMC that he will not be engaged in or offer any treatment plan or treatment which includes the insertion of the loop PEG or any variation thereof outside the context of a formal or approved clinical trial unless he obtains [a] waiver or exemption from the need to obtain such approval to use the same on patients from the appropriate authorities.

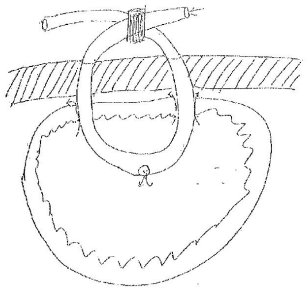
Coda

128 In the present case, the Appellant was only charged for a breach of Clause 4.1.4. Simply put, he should not have administered a treatment not generally accepted by the profession on the Patient without seeking prior review and approval from the relevant IRB, and where there were no compelling reasons for choosing such a treatment over the standard treatment. For that breach, his act was found to have amounted to professional misconduct. We would like to point out that other ethical obligations may also have been engaged. For instance, Clause 4.6.2 of the Ethical Guidelines in the ECEG provides that a doctor shall refrain from "improperly prescribing drugs or appliances in which he has a financial interest". Other ethical obligations found in the Ethical Code in the ECEG were also potentially triggered. Those include the obligations of ensuring that patients suffer no harm and of not abusing the patient-doctor relationship for personal gain. However the possible breaches of these ethical obligations were not explored.

129 On a separate note, despite having analysed Clause 4.1.4 extensively, we are of the view that Clause 4.1.4 could have been better drafted for easier understanding. We understand that the ECEG is currently undergoing revision by the Respondent, and we hope that the Respondent and the relevant regulatory authorities would take the points raised above into consideration. Finally, although we did not adopt his views entirely, we would like to express our gratitude to Asst Prof Chan for the valuable assistance provided by his article.

Annex

(1) Diagram 1: The Appellant's drawing in the Patient's contemporaneous medical case notes



(2) Diagram 2: Diagram from the Appellant's article: "A new feeding tube which is secure and easy to change" Singapore Med J 2009;50:740

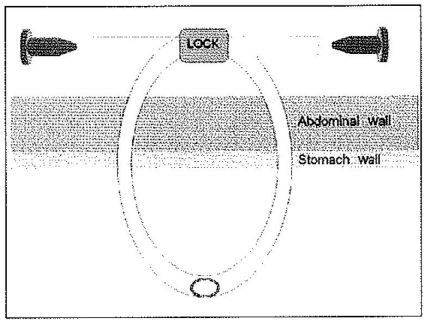
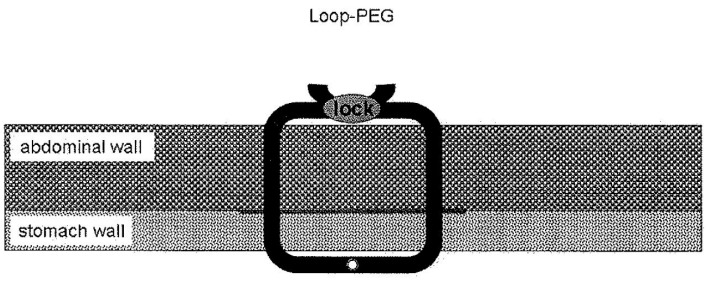


Fig. 1 Schematic diagram shows the anatomy of a third-generation feeding tube.

(3) Diagram 3: Diagram from the Appellant's bundle of documents submitted on 19 October 2011



(4) Diagram 4: The diagram of the LOOPPEG3G®3G, a commercial variant of the loop-PEG, taken from SGN Pte Ltd's website

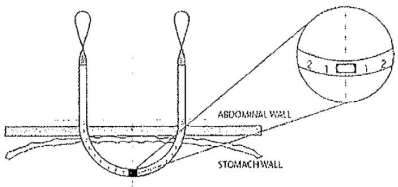


Figure 1: Centralize the TUBE between the stoma sites.

Warning: If the loop in the stomach is not long enough, the central segment with the opening can escape from the stomach to the peritoneal cavity during patient movement.