SINGAPORE MEDICAL COUNCIL DISCIPLINARY COMMITTEE INQUIRY FOR DR PANG AH SAN & DR A HELD ON 9 SEPTEMBER 2011, 24, 25, 27, 28, 31 OCTOBER 2011, 5, 6, 8 MARCH 2012 AND 23 JULY 2012

Disciplinary Committee:
Prof Ho Lai Yun (Chairman)
Dr Lim Cheok Peng
A/Prof Jacobsen Anette Sundfor
Ms Mabel Ong (Lay Member)

Legal Assessor:
Mr Joseph Liow Wang Wu
(M/s Straits Law Practice LLC)

Prosecution Counsel:
Mr Siraj Omar
Ms Joanna Chew
(M/s Premier Law LLC)

1st Respondent:
Dr Pang Ah San, acting in person

Counsel for the 2nd Respondent:
Mr Charles Lin
Mr Daniel Xu
(M/s MyintSoe & Selvaraj)

DECISION OF THE DISCIPLINARY COMMITTEE

(Note: Certain information may be redacted or anonymised to protect the identity of the parties.)

Introduction and the Notice of Inquiry

1. The 1st Respondent, Dr Pang Ah San, is a general surgeon. The 2nd Respondent, Dr A, is a X specialist. They faced similar charges of providing treatment to a patient that was alleged not to be generally accepted by the profession and outside the context of a formal and approved clinical trial, in breach of Clause 4.1.4 of the Singapore Medical Ethical Code and Ethical Guidelines ("the ECEG").

2. The Notice of Inquiry served on the Respondents states as follows:-

As for the 1st Respondent, Dr Pang Ah San

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 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 A, 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 A, 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").

As for the 2nd Respondent, Dr A

That you, Dr A, a registered medical practitioner, did between 7 July 2008 and 9 July 2008 at Mount Alvernia Hospital provide treatment to a patient that was not generally accepted by the profession outside the context of a formal and approved clinical trial, in breach of 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 7 July 2008, you, together with Dr Pang Ah San, performed surgery on the Patient to insert a "loop" percutaneous endoscopic gastrostomy tube (a "Loop PEG Tube"), and you did so outside the context of a formal and approved clinical trial;

(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 ensure that the Patient was fully informed of the novel nature of the Loop PEG Tube prior to having provided her consent for the surgery.*

(vi) *Following the insertion of the Loop PEG Tube, you, together with Dr Pang Ah San provided post-operative care and monitoring of the Patient outside the context of 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").

Undisputed Facts

3. The Patient was 84 years of age in 2008 and she had suffered a stroke and required permanent tube feeding. It is undisputed that prior to 30 June 2008, the Patient and/or her family members had received independent medical advice that the Patient should be given a permanent feeding tube and that the gastrostomy tube was preferable over a nasogastric tube.

4. The daughter-in-law of the Patient who was a Senior Staff Nurse, was the primary caregiver of the Patient. Her name is Mdm B. Sometime around 30 June 2008, at Mdm B's request for advice, the 1st Respondent had recommended to Mdm B the use of a Loop PEG Tube as a better alternative to the Percutaneous Endoscopic Gastrostomy Tube ("PEG Tube") as a method of feeding the Patient.

5. It is not disputed that the PEG Tube was a medically accepted device for feeding purpose; the other medically accepted method of feeding is through a nasogastric feeding tube.

6. It is not disputed that the pre-operative procedures and protocols, the insertion of the Loop PEG as well as the post-procedural treatment and protocol, were not carried out in the context of a formal and approved clinical trial. Neither Respondent had sought the approval of any ethics committee or any Institutional Review Board (IRB) to run any clinical trials in relation to the use of the Loop PEG.

7. On about 7th July 2008, the 1st Respondent carried out the procedure of inserting of the Loop PEG Tube at the Mount Alvernia Hospital. He was assisted by the 2nd Respondent and Dr C, the latter being an anaesthetist.

8. The surgical procedure was carried out under anaesthesia and involved gastroscopy as well as dual punctures of the stomach/ anterior abdominal wall for loop PEG placement.

The Complaint

9. On 8 August 2008, the children of the Patient, one Mr D and Mdm E made a complaint to the Singapore Medical Council via a Joint Statutory Declaration against the Respondents. The complaints made were wide

ranging but for the purposes of the Notice of Inquiry before this Disciplinary Committee, the only relevant complaint was that as stated at paragraph 6(a) of the Complaint which stated:-

"6. We hereby lodge a complaint to the Singapore Medical Council on the surgery performed by Dr Pang Ah San and Dr A at Mount Alvernia Hospital on 7th July 2008 on the following grounds:

a) Failing to inform Madam B (the daughter- in- law of the Patient) when she consulted him on 30 June 2008 that this loop tube has only been done for two patients in the whole world previously and our mother is the first in Singapore? If we had been told of this, we would not have agreed to it. …."

At paragraph 3 of the Complaint, it stated:-

"3. Our sister-in–law, Madam B, consulted Dr Pang Ah San (General Surgeon) clinic located at Mount Alvernia Medical Centre to arrange for the procedure to be performed for our mother. Dr Pang recommended a new procedure which he advised was better and safer loop tube instead of the PEG tube. He said the new procedure was a two hole loop tube, which he claimed was a much safer way as it will not come out easily unlike the PEG tube. …"

10. The Chairman of the Complaints Committee appointed by Singapore Medical Council wrote to the Respondents on 2 October 2008 and invited the Respondents to submit a written explanation on the complaint with the standard warning that if any disciplinary action was to follow, their written explanation could be used as evidence in the subsequent action.

The Explanation of the Respondent

11. The Respondents provided a written Explanation by way of a letter dated 17 October 2008. It appears that this letter was written by the 1st Respondent and the pronoun "I" was often used throughout this letter. Notwithstanding this, the 2nd Respondent signature appears at the end of the letter.

12. The 1st Respondent suggested he had warned Mdm B that a gastrostomy tube was not risk-free and that he (a) offered to insert a Loop PEG but not the standard PEG and (b) he showed her pictures of his two patients with the Loop PEG.

13. The 1st Respondent provided a description of the Loop PEG device in this letter. The explanation was as follows:-

"The loop-PEG is a gastrostomy tube which is inserted using the same pull method as the standard PEG. The incorporation of a loop and a lock prevents it from slipping, avoiding the serious complication of peritonitis and Buried Bumper Syndrome. The first two patients with the loop-PEG are shown in Figures 1 and 2. Through a competitive grant called ended 30 June 2008, Spring Singapore selected the loop-PEG for commercialization with a funding support of up to $500,000.00. The official award ceremony has been scheduled for 29 Oct 2008.

SSN B has wide experience with tube feeding. I did explain to her why I would insert the loop-PEG but not the standard PEG for the patient. With her experience she could have easily understood the explanation. I did not hide the fact from Mdm B that the patient would be the third patient with a loop-PEG. Contrary to the complainants' claim in the Joint Statutory Declaration, the patient was not the first patient with the loop-PEG."

14. On 5 February 2009, the Chairman of the Complaints Committee wrote to seek further clarification from the Respondents. The following questions were posed: -

"a) Is "loop-PEG" an established device in medical practice or a new device?

b) When and where it was first introduced?

c) How long has it been in routine use?

d) Which medical institutions or centres in Singapore and/or elsewhere use this device routinely?

e) Has this device been assessed for efficacy and safety through good quality clinical trials?

f) Please provide copies of literature of published peer reviewed trials with regards to this device."

15. In a letter of 8 February 2009, the Respondents gave a written and signed response to the Complaints Committee letter of 5 February 2009. The letter stated as follows:-

*"**(a) Is "loop-PEG" an established device in medical practice or a new device?***

Percutaneous endoscopic gastrostomy (PEG) is an established method to place a gastrostomy tube. The PEG method was used to place the gastrostomy tube in a loop configuration. The term "loop-PEG" is derived from loop and PEG.

The "loop-PEG" is an invented word. It is NOT a medical device according to the definition adopted by Health Sciences Authority of Singapore. Whether it is an established or a new device is moot.

b) When and where it was first introduced?

The established method of PEG was used to place a gastrostomy tube in a loop configuration in Singapore in 2007. The term "loop-PEG" was used publicly in a (successful) grant application in Singapore in 2008.

c) How long has it been in routine use?

The gastrostomy tube has been in use for more than a century. Many methods to place the tube, classified into four broad groups (surgical, laparoscopic, radiologic and endoscopic), have also been in use for a long time. Specifically, the PEG method started in the 1980s. Therefore, the method of loop-PEG has been in routine use for at least 2 decades.

d) Which medical institutions or centres in Singapore and/or elsewhere use this device routinely?

The gastrostomy tube is widely and routinely used all over the world. The PEG method is also widely and routinely used by medical institutions in Singapore and the world. The websites of the National Cancer Centre Singapore, Changi General Hospital and National University Hospital, and many other renowned hospitals overseas, have webpages featuring PEG.

The loop-PEG is not a medical device. It uses the same gastrostomy tube and PEG method as used by all the hospitals mentioned above.

e) Has this device been assessed for efficacy and safety through good quality clinical trials?

Searching PUBMED using percutaneous endoscopic gastrostomy as the keyword returned 1848 biomedical literature citations and abstracts, 275 free full-text journal articles and 22 online books. Searching the same keyword on GOOGLE gives 88,500 results in 0.17 seconds. Videos of the procedure are available on YOUTUBE for downloading. The method in loop-PEG is a proven and well known method.

Regarding clinical trials, Singapore's Health Sciences Authority Regulatory Guidance on Medical Device 2008 advised that "it is important to recognize that there is considerable diversity in the types and history of technologies used in medical devises and the risks posed by them. Many medical devices are developed or modified by incremental innovation, so they are not completely novel. Thus, it is often possible to draw on the clinical experience and literature reports of the safety and performance of comparable medical devices to establish the clinical evidence, thereby reducing the need for clinical data generated through clinical investigation of the medical device in question."

The loop-PEG is not a medical device. In any case, the loop-PEG does not involve a new technology, material, use, intended purpose, therapeutic claim or diagnostic value. A human trial without a valid justification is unethical.

f) Please provide copies of literature of published peer reviewed trials with regards to this device.

Firstly, the loop-PEG is not a medical device by definition.

Secondly, the gastrostomy tube is a proven device, in use for more than a century, while the PEG is a proven method, in use since the 1980s. For these, enormous amount of good quality clinical data already exists. The loop-PEG used these proven items, without adding anything new. Therefore, conducting studies on the loop-PEG has no scientific merit, and reputable journals are unlikely to accept them for publication.

Thirdly, clinical data already exists regarding the use of PEGs for gastric torsion and sigmoid volvulus. No doctor would conduct trials to study a loop configuration, when multiple configurations, in different organs too, have already been proven and widely-used.

Fourthly, the loop-PEG appeared in public in 2008. Time is needed to collect cases and large numbers are required, if significance is demanded. Several years from now, journal articles on the loop-PEG may start to appear. It is not reasonable, however, to expect any before 2013.

For the above reasons, your request of published peer reviewed trials with regards to the device cannot be met."

16. The deliberations of the Complaints Committee was not made known to this Disciplinary Committee but it suffices to say that the Complaints Committee on 14 May 2009 ordered that a formal inquiry be held by a

Disciplinary Committee to look into the complaint against both Respondents.

17. The Notice of Inquiry was issued on 11 February 2011 against both Respondents. The charges against them were already set out in paragraph 2 hereinabove.

18. The report of Prof F dated 8 November 2010 was attached with each Notice of Inquiry. The report was requested by counsel for SMC, who wrote to Prof F on 17 June 2010 to seek his view on whether the loop-PEG tube surgically inserted into the patient was a novel device, in terms of its design and well as in terms of the method of its insertion.

19. Taking into account the meaning of the word "novel" as set out in the Oxford Dictionary, Prof F formed the view that the word 'novel' meant something that was "new and strange; of a type not known before". He acknowledged that a novel device is commonly understood to carry a connotation of significant improvement over existing devices.

20. In his report, Prof F proceeded to consider the question as to whether the loop PEG was a new device and whether it was of a type not known before.

21. Prof F stated that he had reviewed literature of PEG and had described its use as one "*of which during the past 30 years has been the modality of choice for enteral access to patients who require long term enteral nutrition.*" Prof F stated in his report that as a surgeon, he was brought up on open gastrostomy, although in the past 10-15 years, he had performed 'standard' PEG on occasions at the National University Hospital.

22. Prof F, having compared the “standard” PEG and the loop-PEG at the second page of his report, concluded that the loop-PEG had deviated from the standard PEG in design and inserted positions. As such, he formed the view that the loop-PEG was ‘novel’.

23. In his report, Prof F set out the method of insertion of the standard PEG and briefly described its design. In respect of this matter before us, it appears that the two significant aspect as to how the standard PEG and the loop-PEG differed were as follows:

(a) In the standard PEG, only one point of penetration is made into the stomach compared to the loop-PEG where two penetrations are made, and

(b) In the standard PEG, the device of a bumper-bolster is used to achieve apposition of the stomach wall and the peritoneal surface of the abdominal wall. Apposition of the stomach wall and the peritoneal surface of the abdominal wall in the standard PEG is important to seal off the site of the stomach tube penetration and expedites the formation of a mature tract around the tube. Prof F’s view that any device without bumpers, stitches or other mechanisms to create gastroplexy as in “loop” gastrostomy, the sites of penetrations of the loop tube are not sealed off from the peritoneal cavity. [*see page 6 of his report at the second paragraph*]. At this juncture, we point out that the First Respondent (“Dr Pang”), during the course of the trial asserts that there loop-PEG in fact does provide for apposition between the stomach wall and the peritoneal abdominal wall. We will deal with this later on in this decision.

24. We found the illustrations as produced in Prof F’s report useful and we repeat them here for ease of reference.

Illustration 1 – standard peg in installed position

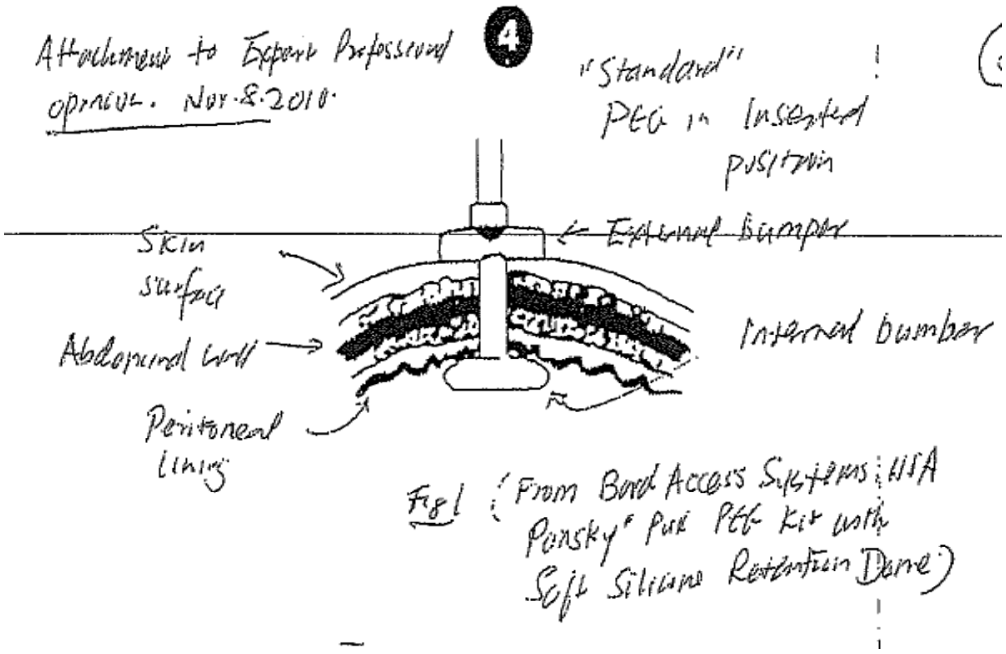


Illustration 2 – illustration by Dr G demonstrating an inadvertent rotation of the loop and that it could displace the fenestration at the middle of the loop to be displaced from intragastric position into peritoneal cavity.

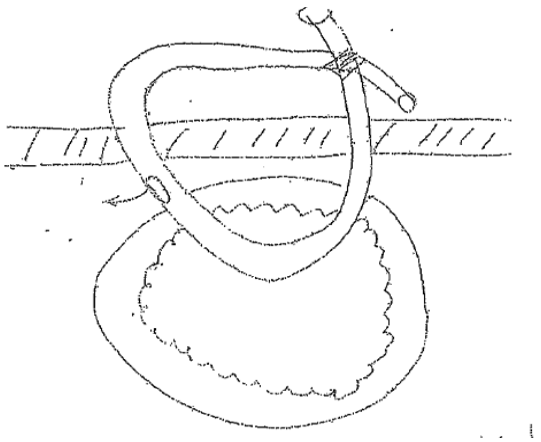


Illustration 3 – Loop PEG illustration taken from drawing from operative notes of the Patient in Mt Alvernia Hospital. (Note: this was drawn by Dr Pang)

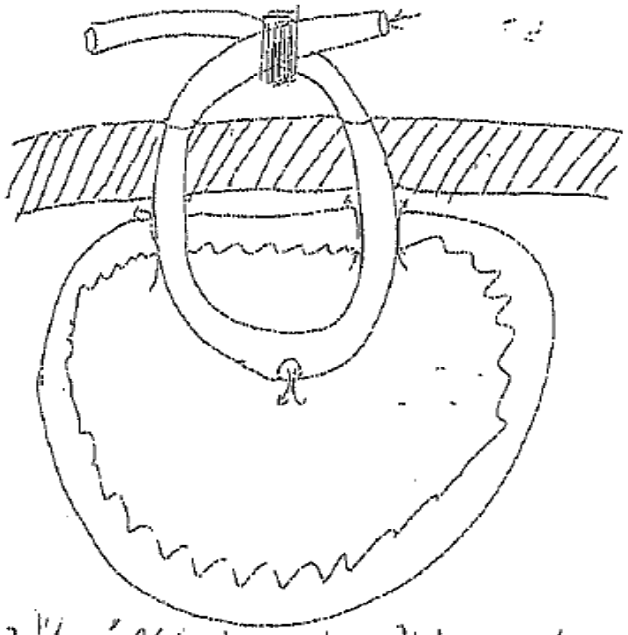


Fig 3. "Loop" PEG (Taken from drawing of from Operative notes of Medium ~~Notes~~ Cook Lee Kwong in Mt Alvernia Hospital)

25. At page 4 of his report, Prof F formed the view that it has not been well established that the apposition of the stomach to the anterior abdominal wall can be dispensed with in PEG. He also formed the view that patients requiring tube feeding, who are old and in poor health and have poor healing power are at greater significant risk of surgical complications including leakages following PEG insertion. He thought that it "seems prudent that interventional procedures such as PEG insertion should use techniques which utilize all mechanisms known to reduce complications such as leakages" and that "(it) is fortuitous to rely only on adjacent bowel and omentum, the 'policemen' of the abdomen' to move in and prevent the risk of iatrogenic (*meaning adverse condition resulting by treatment by a physician*) leakage".

26. The hearing of this matter before the Disciplinary Committee was originally fixed for 2 to 4 and from 9 to 11 May 2011. However, on 11 April 2011, the solicitors for the Second Respondent applied to have the hearing dates vacated citing the reason that their expert witness report was not ready. Counsel for SMC did not object to the application but surprisingly, the First Respondent objected to the application. The Disciplinary Committee, took into account the First Respondent's objections and inquired from the solicitors for the Second Respondent (a) why the application to vacate was made late in the day at not at least 21 days as required by Rule 19 of the Medical Registration Regulations, (b) when the expert was engaged and when the expert confirmed his willingness to act as an expert and whether he was informed of the scheduled hearing date at the time of his appointment, and (c) when the expert was expected to be able to prepare his report. At a Preliminary Inquiry Conference ("PIC") on 3 May 2011, counsel for the Second Respondent provided a satisfactory response for the vacation of the matter and the Disciplinary Committee accordingly vacated the hearing dates.

27. At this PIC of 3 May 2011, Dr Pang made an application for the production of the expert report of Dr G. The application was resisted by counsel for SMC on the basis that the documents that the Complaints Committee referred to were confidential and not relevant. Upon consideration, and on the advice of the Legal Assessor, the Chairman formed the view that the report of Dr G was relevant and directed counsel for SMC to furnish the same to the Respondents.

28. A further PIC was called on 14 June 2011 for the purpose of, among other things, setting out the dates for the hearing of this matter. Before the hearing of this next PIC, Dr Pang wrote to the Disciplinary Committee again, this time expanding his request for documents. He sought for the minutes and findings of the Complaints Committee ("CC"). This was objected to by counsel for the SMC on the basis that the documents were not relevant and since the findings of the CC should be not be placed before this Disciplinary Committee since the intention of the Act is that the principle of separation of the CC from the DC is encapsulated in section 42(2) of the Act, which provides that a member of a CC shall not sit in the same DC inquiring into the same matter. By extension of logic, the DC should not be influenced by the findings of the CC. At the PIC of 14 June 2011, Dr Pang's application for the discovery of those minutes and findings of the CC was dismissed on the grounds that the relevancy was not shown and it was not necessary for such documents to be produced. At the PIC, Dr Pang was informed by the Chairman, on the advice of the Legal Assessor that the Disciplinary Committee should come to an independent decision and not be influenced by the decision of the CC.

29. At both PICs, the Chairman of this Disciplinary Committee had directed that if Dr Pang, who throughout these proceedings was unrepresented by legal counsel, wished to engage counsel, he should do so as soon as

possible as counsel would require reasonable time to prepare for the hearing.

30. At the second PIC, the following hearing dates were fixed:-

(a) Monday 24 October to Friday 28 October 2011 from 2-8 p.m. except for the public holiday on 26 October 2011, and

(b) Monday 31 October 2011.

31. On 3 July 2011, Dr Pang wrote to the President of the Singapore Medical Council to request for the removal and for the appointment of another Chairman and Legal Assessor. The basis of his request were as follows:

(a) As against the Chairman. Dr Pang sought to base his application on the basis that the Chairman of this Disciplinary Tribunal is associated with the Singapore General Hospital and the fact that the Patient in this case died at the Singapore General Hospital ("SGH"). Dr Pang maintained that when the Patient was discharged from his care at Mount Alvernia, the Patient was well but was on the subsequent day subjected to a major surgery at SGH where she subsequently died nineteen days later. The application was grounded on "*partial or bias, whether real or imagined*".

(b) As against the Legal Assessor. Dr Pang set out four (4) grounds to seek for the Legal Assessor's removal. These were:

(i) The Legal Assessor had during the PIC of 14 June 2011 repeatedly asked the Chairman 'to let him speak'.

(ii) That when Dr Pang was presenting his grounds for the discovery of documents, and that when he asked from the Chairman to read the decision of the High Court Judge regarding the matter, the Legal Assessor had told him that he was well informed of the facts of the case and decision in Dr Susan Lim's case.

(iii) That the Legal Assessor had, as a matter of public knowledge, in communicating with a female blogger, had written: "Chocolate vs Sex? Sex wins hands down."

(iv) That the Legal Assessor had, in a disparaging remark about a neighbouring country, he had written: "…. And the Malaysian government recently announced that they can no longer afford to pay for all the scholarships for bright students… REALLY? Can't think of any friends I have who were bright AND offered scholarships from the Malaysian government. (Chuckle).

32. The President of the SMC referred the letter to this Disciplinary Committee and the Disciplinary Committee, upon the advice of the Legal Assessor, convened the full Disciplinary Committee and invited submissions to be made by parties. A special date for this hearing was fixed on 9 September 2011.

Hearing of 9 September 2011 – Application to remove the Chairman and Legal Assessor – Accusation of bias

33. At the hearing of 9 September 2011, at the start of the special hearing, the Chairman informed the parties that for the purposes of this hearing, he will not be partaking in the deliberation of the Disciplinary Committee on the application for him and the Legal Assessor to be removed.

34. Dr Pang made his submissions and largely repeated his position as set out in his letter of 3 July 2011. Counsel for the 2nd Respondent had no position with respect to the application. Counsel for SMC did not agree with Dr Pang's application and stated that in respect of the request by Dr Pang for the Chairman to recuse himself, his view was whatever happened or did not happen at SGH in respect of the Patient had nothing to do with the charge which Dr Pang faced. He submitted that there was no question of prejudice at all. Counsel for SMC left the matter to the Disciplinary Committee to decide on the matter.

35. At the request of the Chairman to advise the Disciplinary Committee on this matter, the Legal Assessor advised that the test in deciding if any member should recuse himself from the Disciplinary Committee is the "*real likelihood of bias or a reasonable suspicion that a fair trial was not possible*" test. See *Re Chuang Wei, [1993] 2 SLR (R) 357, Kay Swee Pin v Singapore Island Country Club [2008] 2 SLR(R) 802 and Haron v Singapore Athletic Association [1993] SGCA 79*. The Legal Assessor also advised that a tribunal must not only be impartial, it must appear to be impartial. A fanciful likelihood or an unsustainable suspicion would not justify the removal of a member of the tribunal.

36. At the suggestion of the Legal Assessor, the lay member of the Disciplinary Committee, Ms Mabel Ong, was asked to give her view first. She formed the view that she did not see a need for a change of the Chairman. A/Prof Anette Jacobsen formed the view that the Chairman had no conflict of interest in this matter. Dr Lim Cheok Peng, who spoke last, noted that the Chairman was appointed by SMC to sit as the Chairman and not SGH. Since A/Prof Jacobsen and Dr Lim had decided that there was no reason for the Chairman to recuse himself, it was unnecessary for the Chairman to comment on the merit of Dr Pang's application. The Disciplinary Committee thus rejected his application for the Chairman of this Disciplinary Committee to be removed.

37. In respect of Dr Pang's application for the Disciplinary Committee to remove the Legal Assessor, counsel for SMC and the 2nd Respondent took no position and left the decision to the Disciplinary Committee. The Legal Assessor advised the Disciplinary Committee that whilst there does not appear to be any express provisions for the removal of a Legal Assessor, there is no reason why a Legal Assessor cannot be disinvited from any hearing of the Disciplinary Committee. In response to an invitation from the Chairman for any further submissions, counsel for the 2nd Respondent and the SMC shared the view that the personal comments made by the Legal Assessor on a social media was a personal view and had no bearing on this matter. The Disciplinary Committee deliberated and was unanimous in their view that there was no reason to disinvite the Legal Assessor from the further hearings of this Disciplinary Committee.

38. We should add that on 20 September 2011, Dr Pang wrote to the President of the SMC and copied that letter to all the members of the Disciplinary Committee and to counsel for SMC and the 2nd Respondent expressing dissatisfaction with the decision made by the Disciplinary Committee on 9 September 2011. In that letter, he asserted that the positions taken by Ms Mabel Ong, A/Prof Jacobsen and Dr Lim were clear evidence of bias. He made the further accusation that the President of SMC had instructed counsel of SMC to "*prevent the discovery of documents (14 Jun 2011)*", which was a reference to his application for the minutes and notes of the Complaints Committee, and "*to let the DC misconduct itself*".

39. The letter was not copied to the Legal Assessor. However, despite the letter written to the President of SMC and copied to the members of the Disciplinary Committee, Dr Pang did not make any further application for the other members of the Disciplinary Committee to recuse themselves.

40. Prior to the hearing fixed to commence on 24 October 2011, Dr Pang requested for subpoenas to be issued to compel the following persons to attend the Disciplinary Hearing to give evidence. They were:-

(a) Dr H; and
(b) Dr I.

41. Dr Pang's letter dated 13 September 2011 to Dr I (which he enclosed with his application for a subpoena), it appears that he wished to call Dr I to have the latter reveal the identity of the two reviewers that rejected his manuscript to the Singapore Medical Journal. The request for the subpoena for Dr H appeared to be for similar reasons. The Disciplinary Committee was advised by the Legal Assessor, that the practice of the Supreme Court as set out in the *Singapore Civil Procedure 2007; Sweet & Maxwell* at paragraph 38/19/5 suggests that subpoenas are issued as a matter of course upon the request being made and it is for the party who objects to the issuance of the subpoena to raise this with the tribunal. If the objection relates to the relevance of the evidence, then the objection should be taken at the hearing of the matter.

42. On 18 October 2011, Dr Pang wrote to the SMC to express his dissatisfaction with the SMC Secretariat when the latter refused to assist him to serve one of the subpoenas. He then concluded that letter with the comment, "*To be honest, I would say it confirmed the bias (perceived, potential or actual) that the SMC has shown towards me for the coming Inquiry*". Having made this assertion, Dr Pang again did not take any specific application pertaining to his perception of bias by the Disciplinary Committee or SMC.

Pre-Trial Matters

43. Parties proceeded to submit their respective Opening Statements and Bundle of Documents in the week commencing 17 October 2011.

Preliminary Issue at the start of the Disciplinary Committee hearing

44. Counsel for the SMC made a preliminary application to strike out portions of Dr Pang's Opening Statement, which was marked as "**P-1**", on the basis that the Opening Statement was scandalous, frivolous and vexatious. Counsel for SMC objected to 25 portions of the said Opening Statement. The Opening Statement contained references to various persons connected or unconnected with this Disciplinary Committee. These references were not intended to be complimentary. Mr Omar was described as an "Extremist" and Ms Jauhar a "Virgin". Other personalities were called "Terrorist", "Bomb Maker" and "Suicide Bomber". Upon deliberation, the Disciplinary Committee ordered that some, but not all, of the portions of Dr Pang's Opening Statement be struck off. The Disciplinary Committee was of the view that Dr Pang could set out his case in any fashion and as vigorously as possible but it should not be scandalous or irrelevant. A copy of the 1st Respondent's Opening Statement, as allowed to stand by the Disciplinary Committee was marked as "**DC-1**".

Difference in the charges against the 1st and 2nd Respondent

45. The Notice of Inquiry was read to both Respondents, i.e. Dr Pang and Dr A. Both claimed trial. We noted that the charges as against the 2nd Respondent differs from that of those preferred against her husband, the 1st Respondent, in two aspects:-

(a) As against the 2nd Respondent, unlike the 1st Respondent, it was not alleged that she recommended to the Patient the use of the Loop PEG Tube; and

(b) As against the 2nd Respondent, unlike the 1st Respondent who was alleged to have "*failed to inform the patient of the novel nature of the Loop PEG Tube prior to obtaining her consent to the surgery*", is instead alleged that she had "*failed to ensure that the Patient was fully informed of the novel nature of the Loop PEG Tube prior to having provided her consent for the surgery*".

46. The Prosecution called three (3) witnesses of fact and one expert witness. The witnesses of fact were Mr D, Mdm E and Mdm B. Prof F was called as SMC's expert witness.

Summary of Prosecution's Evidence
Evidence of PW1 – Prof F

47. Prof F's ("Prof F") evidence in chief was largely a repetition what he had stated in his report. See paragraphs [18] to [25] hereinabove.

48. During cross-examination by Dr Pang, Prof F was asked if he agreed by reason of the fact that there were publications of the loop-PEG method in the ANZ Journal of Surgery and the Royal College of Surgeons in England, that these journals accepted his method. Prof F disagreed and expressed the view that the publication only acknowledges a contribution of the article by Dr Pang, that it did not accept the method. Prof F points out such journals typically disclaim connection to the articles published and that publication does not mean that the publication of a method makes the method an accepted practice.

49. Prof F disagreed with the suggestion made by Dr Pang during cross-examination that there was nothing novel about Dr Pang's loop-PEG due to the similarity of the method of insertion and the materials used. Prof F asserted that his use of the words "novel" was to mean that there was a deviation from the standard accepted. Where a PEG penetrates the stomach, it should be brought up to the peritoneal wall, which was not the case in the depiction of the loop-PEG diagrams which he saw in coming to his opinion in his written report. He also formed the view that the deviation from the standard PEG was that the loop-PEG could rotate that it was potentially dangerous.

Interposing of PW2- Mr D

50. In the course of the proceedings, the evidence of Mr D ("Mr D") was inter-posed before Prof F was released as a witness as Mr D had to leave for overseas the next day.

51. Mr D's evidence in chief was that he first learnt that his mother needed a feeding tube on 4 June 2008. This was the advice of one Dr J, a neurologist. She had advised him that his mother should use a PEG feeding tube instead of a nose feeding tube. After Dr J told Mr D and his family that his mother needed a feeding tube, she gave them new medication (including Plavix) for his mother. According to Mr D, his sister-in-law, Mdm B and his sister Mdm E, decided that a feeding tube was needed in June 2008 after a consultation in Mt Alvernia. He was told that there was a surgeon, Dr Pang who told them that he could insert the feeding tube but there is a much safer way to do it. He was told that it was much more comfortable, that it would not be expensive. The decision was made to accept this other method as Mr D wanted his mother be more comfortable. Mr D stated that prior to his mom being admitted, he had no conversation with Dr Pang or Dr A. He brought his mother to hospital by ambulance with help of his sister-in-law, Mdm B.

He saw to the admission requirements. He recounted that when he signed the consent form, it was signed at the Admission counter. He did not recall speaking to anyone before singing that document. He was with the staff at the counter when he signed this form. During the period before his mother went for operation, Mr D said no one spoke to her. He was waiting for her whilst she was undergoing surgery. He was there when she came out of the surgery. She went in for operation at 1 p.m. and when she came out it was 3 p.m. He stated that she was groaning in pain. He recalls seeing that when she was being transferred to bed, there was blood oozing out and there was blood under the bed sheet. The bed spread and blankets were changed immediately and he asked the attending nurses to call for doctor. Mr D said that the doctors took a while to attend to his mother and that no one attended to his mother for 30-40 minutes. The nurses had asked him what medication his mother had taken and the nurses started taking notes of all the medication she took. He recalls that he spoke to Dr Pang some time after his wife came to the hospital. This was after 5 p.m. Dr Pang explained to him that bleeding was occurring because of the blood thinners that his mother had taken. In respect of the pain, Dr Pang had said that it was because of the tube insertion. He lifted the tube and said it is very safe and said that she was the 3rd person in the world to do this. Mr D said that he was shocked to hear this and asked him if she was the first in Singapore to get this operation. Dr Pang, according to Mr D, did not answer his question. He did not have any conversation with Dr A; according to Mr D, no one in his family knew that Dr A was involved in the surgery until they saw the hospital bill.

52. In the course of cross-examination, Dr Pang questioned Mr D about his family, the nicknames that some of the family members had for one another, where and whom the mother (the Patient) stayed with, who was her favourite child. The Disciplinary Committee had on several occasions had to ask Dr Pang to state the relevance of his series of questions. On

one occasion, Dr Pang asked Mr D, who amongst his siblings, were more affected by the passing of Mr D's mother. The question was ruled irrelevant. Dr Pang then sought to elicit from Mr D whether any particular doctor had assisted Mr D in preparing his Complaint that was lodged with SMC and asked if the decision to lodge the complaint was a decision made by the whole family. Counsel for SMC objected to that line of questioning which the Disciplinary Committee agreed with as being irrelevant.

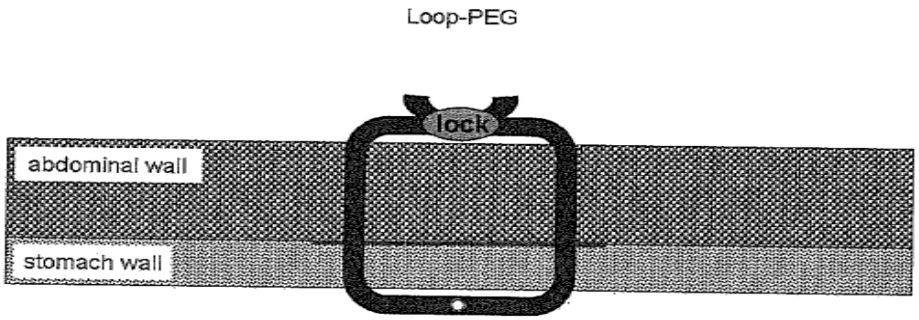
53. Dr Pang also sought to establish during his cross-examination of Mr D that Mr D's mother had global aphasia i.e. an impaired ability to comprehend or express language and therefore could not communicate whether or not she was in pain when she was at SGH. At the conclusion of his cross-examination, Dr Pang put to Mr D that he had informed Mr D's sister, Mdm B, that he had told her that Mr D's mother would be his third patient to receive the loop-PEG, an assertion which Mr D disagreed with.

54. Counsel for Dr A (the 2nd Respondent) during cross-examination sought to discover Mr D's reasons for lodging the complaint against his client, Dr A. Mr D's evidence was that the complaint was lodged, not because Dr Pang and Dr A were husband and wife respectively but because they were not informed of Dr A's involvement and because she had assisted Dr Pang in the insertion of the tube into his mother's stomach.

Continued Evidence of PW1

55. Upon continuation of Prof F's evidence (PW1), Dr Pang asked Prof F as to whether there was evidence of peritonitis in the report of Dr G. After some time, Dr Pang was asked to explain the relevance of his questions and as to why he was asking if the patient had signs of peritonitis, particularly in view of the fact that Prof F was being asked to comment on

Dr G's report. Dr Pang then asserted that peritonitis was relevant because of the allegation made that the loop-PEG rotated and there was leakage. Dr Pang then questioned Prof F's views that his device was novel. Prof F's evidence was that the loop-PEG was novel because it had no gastropexy and because it rotates. In the course of cross-examination, Dr Pang had referred to depictions of his loop-PEG device in his Respondent's Bundle of Documents. An example of such a depiction is as follows:-



56. Prof F rejected Dr Pang's suggestion to him that the configuration which Dr Pang had suggested to him would actually provide gastropexy. He was of the view that if the loop-PEG was fixed in the manner as suggested by Dr Pang, there would be problems such a bleeding gastric ulcers. Prof F's view was that the stomach wall is never used as part of a tension suture because the inner lining is very vascular and if what was depicted by Dr Pang was done, it would cause lacerations and ulcers.

57. During cross-examination by the counsel for Dr A (i.e. the 2nd Respondent), it was put to Prof F that there was no difference between the loop-PEG and the standard PEG and that the U-shaped aspect of the loop-PEG would provide apposition between the stomach and the peritoneal abdominal wall. Prof F disagreed with this. Counsel then put to Prof F that there would be no danger of rotation as 3 locks were placed on the exposed exterior side of the loop-PEG. Prof F agreed with this but stated that this did not appear to be what was done with the patient.

Evidence of PW3 – Mdm B

58. The evidence of Mdm B ("Mdm B") was that she is the daughter- in- law of the Patient and that she had approached Dr Pang to insert a PEG for the Patient. Her evidence was that when she saw Dr Pang at his clinic, he showed her a tube and said that he was not going to insert a standard PEG because this tube would have two openings and it will be easier to change and that she could even change the tube at home. At this first meeting, Dr Pang had shown Mdm B a photograph of another patient and Dr Pang also drew her a diagram to show how the tube would work. She recalls what Dr Pang drew to be something similar to that which was found at Agreed Bundle of Documents ("AB") at page 20 ("AB-20") but that it only showed the loop-PEG and the skin. She said that she was also told that this method was safer and it was not so easy to dislodge.

59. Mdm B gave evidence that just before the time when the Patient was to be discharged, a nurse told her that the Patient could go home. Mdm B then asked if she has been fed and when told that she had not been fed she decided to feed her. She feed her whilst waiting for hospital to discharge her. When she poured in milk, the Patient indicated that she was in pain by knocking on a surface. Mdm B then told nurse of what happened who then presumably told Dr Pang who came later. When Dr Pang came later, Dr Pang explained that it was actually some air in the stomach and when Mdm B poured in milk, it causes some pain. He said that she should be OK and he then poured some water into tube. The Patient seemed "okay" when that was done. Dr Pang then told Mdm B that the Patient could go back.

60. Mdm B bought the Patient home. The next day, she noticed that the Patient was passing melaena stools. She called Dr Pang who assured her that the Patient was okay and she should bring her back to Mt. Alvernia hospital if she continued to have melaena stools. However, as

the Patient's condition worsened as she had a high pulse rate of 158 and a high fever, Mdm B and Mdm E decided to send the Patient to the Singapore General Hospital ("SGH").

61. Upon admission to SGH, the attending doctor told Mdm B that the condition of the Patient was critical but they could not operate on her as yet as she was in shock. Dr Pang came to see Mdm B later and Mdm B remembered asking him why he had told her brother in law that the Patient was his "third patient in the world". Dr Pang's response was that he had told her earlier.

62. During cross-examination, Dr Pang's questions seemed to centre around the discussions that he had with Mdm B prior to the insertion of the loop-PEG, the communication between Mdm B and her brother-in-law and Mdm E and the decision to send the Patient to SGH instead of Mt. Alvernia.

63. During the cross-examination by counsel for the 2nd Respondent, Mdm B gave evidence that there was one cable tie to the tube inserted into the Patient and that when she fed the Patient, she had to lift the tube. Feeding was done via a syringe inserted into one of the two ends of the tube. There was no need to remove the cable tie to feed milk to the Patient.

Evidence of PW4 – Mdm E

64. The evidence of *Mdm E("Mdm E")* was that she was told by Mdm B (i.e. PW3) that she had met Dr Pang and that the procedure which he recommended was safer and better. An estimate of the costs was also provided. Mdm E recalls that when she went to see her mother, the Patient, she saw Dr Pang talking to her brother, Mr D, and Dr Pang told Mr D that the pain her mother was suffering from was from the two holes

made and it was normal. She recalls she stayed until quite late that evening and her mother looked to be in pain and uncomfortable throughout. Before she left the hospital that night, she recalls that her mother was pointing to her stomach and her husband had asked her if she was in pain. The mother kept pointing to her stomach and her husband assured her that it was normal.

65. Her evidence was also that when her mother's condition deteriorated as related to her by Mdm B (PW3), she and her siblings decided not to wait any further and decided to send the mother to SGH. At SGH, she was told by the doctor there that the condition of the mother was quite critical, that she may not pull through and that the family members should prepare for the worst.

66. She also stated that she had never spoken to Dr Pang or to Dr A.

67. During cross-examination by Dr Pang, Mdm E stated that she did not know if there were other incidents of melaena stools or bleeding as the mother was in the Intensive Care Unit throughout. When asked if SGH had given them any non-surgical options, she also stated that the doctors at SGH said that her mother needed surgery straightaway because of leakage of milk and blood into peritoneal cavity and because there was infection.

68. During cross-examination by counsel for Dr A, Mdm E stated that she did not know that Dr A would be involved in the surgery. She did not know that Dr C would be involved but she knew that an anaesthetist would be involved. She said that the only thing that she had asked Mdm B to check was whether the procedure was safe to which Mdm B said that Dr Pang had told her it would be safe.

Submissions at the close of the prosecution's case by the 2nd Respondent

69. At the close of the prosecutions' case, counsel for the 2nd Respondent submitted that there was no case to answer and that the charges against the 2nd Respondent should be dismissed. The thrust of the submissions made by counsel for the 2nd Respondent was that there was no evidence to show what the 2nd Respondent had done which could be said to indicate that she had 'performed surgery on the Patient to insert' the loop-PEG and that her involvement was not different from that of Dr C, the anaesthetist who like the 2nd Respondent was present throughout the surgery. Counsel submitted that there was no evidence of her being in anyway involved in the insertion of the loop-PEG.

70. Having been advised by the Legal Assessor as to the way to assess the evidence at that stage of proceedings, we came to the view that there was some evidence, if unrebutted, would warrant a finding of professional misconduct against the 2nd Respondent, Dr A.

71. The charge was one of providing treatment which is generally not accepted by the medical profession. Since it is an undisputed fact that the treatment was not given under clinical test conditions, we only had, at that stage at the close of prosecution's case, to consider the following:-

(a) Whether there is any evidence (which is not inherently incredible) of the acts of Dr A which could be considered as providing treatment, and

(b) That the treatment provided was one which was not generally accepted by the medical profession.

72. We are of the view that there is some evidence at this stage which the 2nd Respondent needs to rebut. On the issue of whether Dr A provided treatment, we form the view that there is evidence that Dr A did provide treatment. Firstly, Dr A was named as a surgeon in the Mt. Alvernia Hospital Operation Record (AB-5) as one of the surgeons. We note that there is a space in the Surgeon's notes that allows for any assistants to be named. In this case, Dr A was not named as an assistant. She was named as a Surgeon.

73. Secondly, Prof F has also stated that Dr A carried out the gastroscopy and it appears, that at that stage of proceedings, what she did was an 'integral part' of the insertion of the loop PEG.

74. At this stage, we wish to address 2nd Respondent's argument that Dr C was not charged and this procedure carried on the Patient, the late patient, could not have been carried out without the anaesthetist. In our view, this is not a matter which we have to consider since the conduct of Dr C was not a question before us.

75. On the issue whether the treatment was not generally accepted, Prof F's evidence was that the loop PEG and its use was 'novel'. Novel as he defined it was 'new' and not necessarily better. Taking into account what Prof F had said, that is to say, what Dr A did was an integral part of the treatment, we find that if this is not rebutted, a finding of misconduct would be justified. Accordingly, we ruled that the 2nd Respondent had a case to answer and as such, both Respondents in this case proceeded to enter their evidence in defence.

1st Respondent's Evidence

76. The First Respondent gave evidence that there was no need for his device of the loop-PEG to undergo clinical trial. His view that in the context of an approved and clinical trial, as set out in paragraph 4.1.4 of the SMC Ethical Code and Ethical Guidelines, the same did not apply to the treatment given to the Patient. He disagreed with Prof F's use of the words of novel. In cross-examination, he defined the loop-PEG as something which is 'new, safe and secure' to use. Dr Pang further stated that the stomach is always in apposition against the abdominal wall. He disagreed with Prof F that there was any need for gastropexy. He specifically told counsel for SMC that in the seated position, as he was during this disciplinary hearing, his stomach is in apposition to the abdominal wall. When asked why his drawings as set out in his patent application did not show the stomach being in apposition to the abdominal wall, he stated that this was probably because the patent office was not manned by doctors. Dr Pang, when referred to an article which he wrote, entitled "A Simple Gastropexy for the Loop-gastrostomy tube", stated that this article was written for "*those who believe that there must be a gastropexy*". In that article, Dr Pang described a different method for the loop-PEG in that in this new configuration, a secondary loop is created when the loop-PEG is inserted and assist in providing apposition between the stomach wall and the abdominal wall [see page 4 of 1RB3 last paragraph]. Dr Pang's new configuration for the loop-PEG was now called LOOPPEG 3G. The secondary loop within the stomach wall is transient as it fashioned using absorbable ligatures which will degrade by hydrolysis thus freeing the secondary loop leaving only one loop. This LOOPPEG 3G was different from the loop-PEG which Dr Pang inserted into the Patient and the LOOPPEG 3G provided for apposition and for gastropexy. Dr Pang then asserted that the current rules and regulations prevent him for carrying out clinical trials.

77. During the cross-examination by counsel for Dr A, Dr Pang confirmed that he was the principal surgeon and that Dr A only played a minor part i.e. that gastroscopy aspect. His evidence is that Dr A's role was minor, similar to that of the anaesthetist. He filled up Dr A's name in the forms. His evidence is that he could have done the gastroscopy himself.

78. During the cross-examination by counsel for Dr A, Dr Pang explained why he formed the view that it was not possible for him to do a clinical trial for the loop PEG. His evidence was that:-

(a) He could not do clinical trial because clinical trials have its peculiar sets of ethics.

(b) That the Ethics Committee would have found him unethical and guilty of misconduct if he had submitted a proposal to the IRB for approval.

(c) He said clinical trial basically meant human experiments. He said he was not experimenting on the patient. He asserts that what he did was part of therapy and there was no way it could be part of a clinical trial.

(d) You do a clinical trial on humans only when you have established the safety of the medical device and then you are allowed to conduct a clinical trial. This would mean there was a need to do animal study first.

(e) Dr Pang then stated that in his experience with animal studies, large loop PEG were already being used on animals on a regular basis.

(f) He describes the requirement of carrying out clinical trials and its rules as “totally bizarre”.

79. When asked by Counsel for the 2nd Respondent if he had ever considered that he needed to seek approval before carrying out a trial, his answer was that he “realized he could not go that way. It prevented us from proceeding with a clinical trial”.

Evidence of 2nd Respondent

80. The 2nd Respondent elected to give evidence and also called an expert witness, one Dr J.

81. The evidence of the 2nd Respondent was essentially that she had only assisted in the gastroscopy and she did not know about the loop PEG. Her evidence is that post-operation, on the morning after the surgery relating to the Patient, she received a telephone call from Ward Nurses of Mt. Alvernia Hospital looking for Dr Pang. Dr A picked up the call as she shares a clinic with Dr Pang. The nurse told her that the patient was passing out melaena stools. She stated that in her view that if you are in private practice, you are in charge of patient from beginning to end, since she was aware of the Patient, she decided to help Dr Pang look at the Patient and that why she was involved. She said that when she saw the Patient, she did a per-rectal examination. She noted that the Patient’s pulse rate was high and that her sugar level was also high. She ordered for an x-ray of the chest and after that, she passed the information to Dr Pang after he came out of surgery. She said that had he been available at that material time, she would not have gone to see the Patient. She states that she did not see the patient again after that incident.

82. Her evidence was that she was not aware what was entered into the case notes. It was Dr Pang who entered the notes. With regards to the

complaint and the joint-explanation signed by her and Dr Pang, she stated that she signed the joint explanation with Dr Pang. She felt that she had to answer all of the questions that were raised. However, when she saw the complaint she thought that Dr Pang would be in a better position to answer the questions from SMC since she only helped with the gastroscopy and Dr Pang was the principal doctor. She stated that in respect of all questions relating to the loop PEG, at that point in time, she had no knowledge of the loop PEG. She could not answer all the queries of SMC. She stated that she left it to Dr Pang to answer and after he prepared the explanation, she just signed because she felt that she had to answer to SMC.

83. During cross-examination, Dr A agreed with counsel of SMC that it was open to her to write a separate letter of reply to the queries of the Complaints Committee and that by signing the joint – explanation, she would appear to have agreed with what Dr Pang stated. She agreed that the endoscopy was an integral part of the procedure carried out on the Patient.

84. Dr A agreed with counsel for SMC that she did not speak to the Patient or their family members and she did not do anything to advise them of the risk involved. Dr A confirmed that she had no idea if they had been warned of the risks because she assumed that Dr Pang had done so as the primary doctor. She also agreed that she did not check if Dr Pang had advised the Patient or their family members as to such risks.

85. From evidence obtained during cross-examination, it appears that Dr A had assisted Dr Pang in two earlier surgeries involving the loop PEG and that she knew that the Patient was Dr Pang's third patient to receive the loop PEG. She also agreed that the loop PEG was not generally known or used in Singapore as of July 2008.

Evidence of Dr J

86. Dr J was called by the 2nd Respondent as an independent witness. He had prepared an expert report for the purposes of this Disciplinary Hearing which was dated 13 September 2011. Dr J's view was that the loop PEG was not a novel device. His view was that the device is novel in design but not novel in concept. His view is that the loop PEG is a variant of the PEG and is not an entirely novel device. His view was that the principles of its design and usages are based on experiences gained from the enormous amounts of literature associated with the PEG device. He pointed out that a literature search now conducted at the time of his report indicated at least 5 papers related to loop PEG which have been accepted by peer reviewed medical journals both locally and internationally.

87. During cross-examination, Dr J confirmed that he became aware only subsequent to the writing of his report that Dr Pang was the inventor of the loop PEG. It was only after the writing of his report that he became aware that the articles which he referred his report was written by the inventor of the loop PEG. Dr J confirmed that he could not find any other literature apart from those written by Dr Pang.

88. Dr J stated that if he had seen Dr Pang's device, he would have hesitated in using it but in practice, he has come across many instances where medical practitioners fashion devices which they believe are better than the prevailing techniques at that time. He gave the example of the original inventor of the PEG who used the PEG on patients as he saw it as an advancement over prevailing treatment at that time. However, Dr J agreed that the patient should be told of the treatment that was different from generally accepted treatment. He agreed that the guidelines at paragraph 4.1.4 of the SMC Ethical Code was designed to protect the

patients from the subjective views of a doctor that his treatment was safe when it could be, in fact not.

89. Dr J, during cross-examination, disagreed that the loop PEG had to be tested before it could be used on patients. His view was that when a doctor comes up with a new device which is a conglomeration of old established procedures, the doctor is entitled to use the device without a clinical trial. He formed the view that a clinical trial can only take place where there is a group of patients who agree. His view was that the requirement of clinical trial discourages inventions for medical devices.

90. Dr J accepted the suggestion made by counsel for SMC, that if a doctor wanted to use a medical device, which was not new but, in a manner that was never used before, that the doctor should make this fact known to the patient. He agreed that if the doctor did not do so, then he would have fallen short of the standard expected of him.

91. Dr J confirmed that until 2009 he had not used or heard of the loop PEG. He accepts that it was new in design but not in concept. Counsel for SMC then suggested to Dr J that paragraph 4.1.4 of the SMC Ethical Code makes no distinction between new in design and new in concept and suggested the distinction is not relevant in determining if any particular treatment was "*generally accepted by the profession*". Dr J's answer as "yes and no". He pointed out that medical devices are required to be sent to Health and Sciences Authority ("HSA") before they are approved for clinical trials. However, there are also circumstances where doctors come up with their own devices and use them on patients. Dr J referred to the article "*Jeffrey L Ponsky: The Development of PEG: How it was: Journal of Interventional Gastroenterology; 2011 April*" to demonstrate how doctors came up with innovative treatment. Counsel to SMC suggested to Dr J that at the penultimate paragraph of Ponsky's article, that Ponsky himself admits that '*such a progression would be*

unlikely to occur today' was a reference to carrying out such procedure without a clinical trial. Dr J disagreed and thought that Ponsky was bemoaning the fact that treatment could not be carried out unless animal testing was conducted.

92. During cross-examination by Dr Pang, Dr J gave his view that there is not much difference between the relative position of the stomach in a paediatric patient and an adult patient.

93. To the questions from the members of the Disciplinary Committee, Dr J formed the views that it would take between 10 days to 2 weeks for a mature tract to form, that the stomach is a movable organ and it moves in relation to the abdominal wall, that the figure as depicted in Dr Pang's article (Fig.1 AB page 796) would be accurate if the stomach had achieved adhesion with the abdominal wall.

94. When asked what his own position would be if whilst he was working in hospital environment, and if he wanted to carry any procedure or use any machine for first time, even if not new in concept but new in design, whether he would inform the Ethics Committee, Dr J's answer was that it would depend. He would do so if he was planning to use the device in the context of the clinical trial and this would be when there was a need for publication as he would need a statement of IRB approval. In a big clinical trial, the hospital would need to know what clinical trial he is performing. His view was that if he was using a small device, it would be a matter that is between him and his patient. His view is that he may carry out a clinical study on his client to consolidate what he knows about the device and he does not need to inform the IRB. In that sense, that was not viewed by him as a clinical trial as such. He added that his answer is based on his past training.

95. When asked if his evidence was that clinical validation of new medical devices was not required, Dr J stated that if he had thought of new method of helping patients, he would speak to the patient first and tell them that the device is new. He would tell them how it could help them and, if he was able to convince the patient, he would not have hesitated to use it on the patient.

Issues to be considered

96. This Disciplinary Committee considered the following to be the relevant issues:-

(a) What was the 'treatment' provided to the Patient?

(b) Whether the treatment provided was one that could be said to be "*not generally accepted by the profession*"? In particular, referring to the words as set out in the charge against the Respondents, the question is whether the "loop PEG *was a novel device which differed from the normal percutaneous endoscopic gastrostomy tube both in terms of design as well as in terms of method of insertion, and was therefore not a device that was generally accepted by the medical profession*". (emphasis ours)

(c) Whether it can it be said, in the circumstances of this case that, the 2nd Respondent provided treatment to the Patient and if so, whether it could be said that the treatment by the two respondents were 'one and the same' or that each of them provided a different treatment that was capable of being treated as distinct?

(d) Whether, for the purposes of the charges which the respondents faced, whether it mattered if the Patient was fully informed of the novel nature of the loop PEG and whether she was aware that she

would be one of the first few patients in the world to have a loop PEG inserted; and if it did matter, whether the Patient was fully informed by the 1st Respondent.

(e) Subject to the answer to issue (e) above and if relevant, whether there was any obligation on the part of the 2nd Respondent to ensure that the Patient was fully informed of the novel nature of the Loop PEG Tube?

(f) And in the circumstances, whether either or both respondents are guilty of professional misconduct?

Findings of this Disciplinary Committee

The Treatment

97. The treatment was the insertion of device called a loop percutaneous endoscopic gastrostomy (PEG). The insertion of this loop PEG device was achieved by first performing a gastroscopy to first look for contraindication to the feeding tube. Insufflation and transillumination would then be done. Under local anaesthesia, the guide wire would be inserted through the mouth and a pull through of the feeding tube would be done using the guide wire. Unlike the insertion of a standard PEG, instead of one stoma, the use of the loop PEG would require two penetration sites.

Was the treatment one which was "generally accepted by the profession"?

98. In determining this question, we had to consider the differences between the standard PEG treatment and the loop PEG treatment. If there were differences, then the next logical step would be to consider whether

these differences would make the treatment one which was not generally accepted by the medical profession.

99. We first considered the similarities between the standard PEG treatment and the loop PEG treatment. We accept that the method of inserting a standard PEG tube and a loop PEG are similar.

100. We find that what is different in the two treatments is found in the device itself. The loop PEG has no bumper-bolster mechanism. The standard PEG uses the bumper-bolster mechanism to ensure apposition of the stomach wall to the peritoneal surface of the abdominal wall.

101. We accept that the general and accepted view is that apposition of the stomach wall and the peritoneal surface of the abdominal wall in the standard PEG is important to seal off the site of the stomach tube penetration and expedites the formation of a mature tract around the tube.

102. The position which both Respondents take in respect of the question of treatment appears to be one where they assert that there is no novelty in the loop PEG and that it is not dissimilar to the standard PEG which is a generally accepted treatment.

103. With regards to this argument, the evidence does not support the Respondents' contention and overwhelmingly point the other way.

104. In the patent application made by Dr Pang which was filed on 11 October 2007, which was subsequently granted Letters of Patent on 31 August 2009, the prior art was described as the pull-through percutaneous endoscopic gastrostomy (pull through PEG) being the most widely used method. The application described the prior art as causing problems, such as ulceration and the buried bumper syndrome. It describes the

standard PEG as an ‘obstacle’ when the gastrostomy tube has to be changed percutaneously after wear and tear or blockage. Trauma is said to be caused when the PEG is removed since considerable force is required to pull the large bumper through a small hole. At page 3 of the description of the patented device, the current invention is said, in contrast to the standard PEG, to allow removal of the feeding tube without causing trauma.

105. What this indicates to us is that in filing the Patent, the critical inventive step in Dr Pang’s device was the ease in which the feeding tube could be replaced. The Patent of Dr Pang asserts that his device is better and its advantage is because of the absence of a bolster and bumper. Clearly, the device of the loop PEG is different from the standard PEG.

106. Apposition of the stomach wall against the peritoneal abdominal wall was not mentioned in the patent. Diagrams and illustrations in the patent appear to assume apposition to be a given state.

107. In the course of his cross-examination, Dr Pang suggested that one’s stomach is naturally in apposition against the abdominal wall. At this juncture, we will point out that Dr Pang’s evidence, on many instances, were irrational or contrived. On one hand, he would claim that one’s stomach is naturally apposite the abdominal wall and that gastropexy is not required but on the other hand, he then suggests that loose PEG is an acceptable treatment (loose PEG does not require apposition of the stomach wall to the peritoneal abdominal wall). We hasten to add that there is no credible evidence that loose PEG is a generally accepted treatment. His irrational and contrived arguments that his device was not novel flew in the face of the fact that he had applied for and obtained a patent for his invention, which would necessarily must mean that there was novelty or an inventive step in his medical device.

108. We note that counsel for the 2nd Respondent only limited the argument that the device was not novel, in the sense that it was not novel in terms of concept but in its design only. The counsel for the 2nd Respondent did not wholly adopt the arguments of the 1st Respondent, Dr Pang.

109. All experts are in agreement that until they were engaged as experts, they have never seen the loop PEG device before. They were also in agreement that apart from the self-serving articles written by Dr Pang, there were no other medical literature available on the loop PEG. Dr J himself expressed that he would have had reservations using the loop PEG. They were all in agreement, or at least not disputing, that even with the disadvantages of the standard PEG, the generally accepted device to be used is the standard PEG with the bolster and bumper mechanism. All experts were in agreement that they knew of no one else using the loop PEG except for Dr Pang.

110. Whilst we are of the view that the loop PEG was a novel and therefore a new device, we think that the crux of the matter is whether the use of a loop PEG is a "generally accepted treatment". Given our findings in the preceding paragraph, we have no doubt in finding beyond reasonable doubt that the treatment recommended and carried out by Dr Pang on the Patient was not generally accepted by the profession.

Did the 2nd Respondent provide treatment? Was her treatment of the Patient 'one and the same' with that of the 1st Respondent?

111. We find that the 2nd Respondent's treatment of the Patient was limited to the endoscopic aspect of the surgery to insert the loop PEG. She would have clearly known at that material time that a loop PEG was being inserted as she had assisted Dr Pang in two prior surgeries where loop PEG were performed.

112. We also find that the 2nd Respondent's treatment rendered was also in respect of the post-operative attendance to the Patient's complaint of pain post-operation.

113. However, although we have found that there was a prima facie case to answer on the part of the 2nd Respondent, we do not consider the evidence safe to merit a finding of professional misconduct. We would therefore hold that the prosecution has not been able to prove beyond a reasonable doubt that Dr A had given treatment that was not generally accepted by the profession. Although we have found that Dr A knew that Dr Pang was inserting a loop PEG for the Patient, we cannot say that the treatment that she provided was 'one and the same' with that of Dr Pang.

114. The worst that could be said of Dr A's conduct would be that she had allowed another doctor to carry out a treatment which was not generally accepted by the profession. However, the charge that she faced was quite different and we express no views as to whether a failure to stop another doctor from carrying out a treatment that is not generally accepted to be professional misconduct.

Patient not informed of novel nature of the treatment

115. We accept the evidence of Mdm B (PW4) that Dr Pang did not inform her that her mother-in-law would be the third patient in the world to receive the loop PEG. We accept her testimony that all Dr Pang told her was a description of the loop PEG, the costs of the procedure and that the loop PEG was better and safer. We find Mdm B to be straightforward and direct in giving evidence.

116. In this regard, we should comment on our views of the burden of proof on this particular point of the need to obtain 'informed consent'. It is not for the Patient to prove that he had not been given full information about any

procedure that he is about to go through. It is for the doctor to prove that he had obtained proper and informed consent from the patient. In this case, where the choice between a standard PEG and a loop PEG was an *elective* one, it would have been important for Dr Pang to show that the Patient or her family understood all options available as well as the risks and benefits of these options. In **Low Cze Hong v SMC [2008] 3 SLR (R) 612**, the High Court endorsed the view of that Disciplinary Committee, when the latter stated (see paragraph 83 of that decision) :-

> *The Committee also stresses the* critical *importance of patients* understanding *all options available, and the risks and benefits of these options, especially when treatment is elective. [emphasis added]*

117. 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 in any clinical trial, the clinical trial must still be an approved clinical trial.

118. 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 SMC Ethical Code because the clinical trial was not an approved clinical trial.

119. In this case, there is no dispute that Dr Pang did not seek to obtain approval from the Institutional Review Board ("IRB") of Mt. Alvernia to carry out any clinical trial. Indeed, Dr Pang's position in this matter has all along been that he does not need to or could not do a clinical trial.

120. We wish to comment further on the position taken by Dr Pang. He asserts repeatedly in his evidence that he did not need to do a clinical trial because the device was not novel and that concept of his treatment

is generally accepted. We have dealt with this point. He has also said that he could not do a clinical trial because it would be unlawful for him to do so and that no IRB would approve clinical trials for his device. We note that he did not elaborate why he formed the view that an Ethic Committee or IRB would not approve clinical trials of his device. Our view is that if an Ethic Committee or IRB does not approve any device for clinical trial, then it would mean that the device cannot be used. What Dr Pang seems to say is that he would, and did use the device even if the same was not approved for clinical trials.

121. Given our findings above, we do not need to deal with the issue of whether there was any obligation on the part of the 2nd Respondent to ensure that the Patient was fully informed of the novel nature of the Loop PEG Tube. As stated, we do not think that the 2nd Respondent had provided treatment to the Patient and as such it follows that she does not have the obligation to obtain informed consent in respect of the insertion of the loop PEG.

Is there professional misconduct?

122. Applying the test in **Low Cze Hong v SMC [2008] 3 SLR (R) 612**, we note that mere negligence does not amount to professional misconduct. At paragraph 37 of that decision, the High Court stated:-

"The SMC Ethical Code therefore serves a crucial role in providing an ethical "compass" to guide doctors on what the acceptable standards are from which a departure may constitute professional misconduct. In summary, we accept Kirby P's suggestion in Pillai *… that professional misconduct can be made out in at least two situations: first, where there is an intentional, deliberate departure from standards observed or approved by members of the profession of good repute and competency; and second, where there has been such serious negligence that it*

objectively portrays an abuse of the privileges which accompany registration as a medical practitioner…"

123. Given our findings above, we have no difficulty whatsoever in finding that Dr Pang had intentionally and deliberately ignored his ethical obligations as enshrined in paragraph 4.1.4 of the SMC Ethical Code. We find, beyond reasonable doubt, that he had given treatment that was not generally accepted by the profession outside the context of a formal and approved clinical trial.

Application to amend Notice of Inquiry

124. We should add that prior to us delivering the decision of this Disciplinary Committee as to our finding of whether the Respondents have been guilty of professional misconduct, we pointed out to the counsel for SMC that there appears to be a typographical error in the Notice of Inquiry against the Respondent in that the word "gastronomy" was used.

125. Counsel for SMC applied to amend the word "gastronomy" to "gastrostomy" where they appear in the Notice of Inquiry against the Respondents. Dr Pang, the 1st Respondent, objected to the amendment on the basis that he is prejudiced because he had defended the case on the basis that he understood the words to mean the 'art or science of eating or cooking'. He said that he thought that prosecution meant that or perhaps they meant to refer to 'gastrostomy' or 'gastrotomy'. Counsel for SMC submitted that the evidence of the experts made it clear that parties were dealing with 'gastrostomy'. The device which this case was concerned with is known as the Percutaneous Endoscopic Gastrostomy tube (PEG Tube).

126. Counsel for the 2nd Respondent made it clear that the 2nd Respondent was not aligning with the position of the 1st Respondent. The position of

the 2nd Respondent with regards to this application to amend the Notice of Inquiry was that it was clear to them that the case was about *gastrostomy*.

127. The Disciplinary Committee allowed the amendment sought for by the counsel for the SMC. In doing so, the Disciplinary Committee took into account that there was no prejudice to either Respondent (particularly in view that the 1st Respondent says that he prepared his defence on the basis that the words intended was all three words i.e. 'gastronomy', 'gastrostomy' or 'gastrotomy'). We also formed the view that the evidence dealt with in the entire hearing was on the basis that we were dealing with 'gastrostomy'.

Sentencing

128. Dr Pang chose not to offer any submission in mitigation.

129. We have taken into account that the standard PEG tube has been in use for a long time and is a modality of feeding patients. The loop PEG is a new device based on similar objectives but is of new and different design. When considering innovation in our profession we have to be mindful of conflicting public interests. Firstly, there is public interest in encouraging innovation. On the other hand, there is the equally important public interest in ensuring that no new (meaning not yet accepted) treatment or devices are used on patients unless they have been approved by the profession.

130. This is a case where the 1st Respondent, knowing that he has a new device that could be used in a treatment, went ahead to provide treatment not generally accepted by the profession, without any formal or approved clinical trial.

131. Notwithstanding the 1st Respondent's unreasonable and offensive behaviour throughout these proceedings, we have chosen not take this into consideration.

132. We had also asked counsel for SMC and Dr Pang to address us on the issue of costs of these proceedings. Counsel for SMC submitted that the hearing had become protracted largely due to the irrelevant course of cross-examinations and the various applications that the 1st Respondent choose to make and made the point that whilst the 1st Respondent can conduct his defence in any manner he deems fit, he must however be prepared to bear the consequences of his actions. Dr Pang submitted that he should pay no costs. We were of the view that Dr Pang should pay a substantial portion of the costs and expenses of these proceedings since we agree with counsel for SMC a large portion of the time taken in this matter were occasioned by the position taken by Dr Pang. We thought that an order for him to pay 70% of such costs and expenses to be fair.

133. Taking into account the nature of the charge and our findings, we are of the view that the appropriate punishment is as follows:

(a) that the 1st Respondent be fined the sum of S$10,000.00;

(b) that the 1st Respondent shall be censured;

(c) that the 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 or unless he obtains approval to use the same on patients from the appropriate authorities

(d) that the 1st Respondent shall pay the seventy percent (70%) of all the costs and expenses of, and incidental to, these proceedings including the costs of the counsel to the SMC and the Legal Assessor.

134. We also order that the grounds of decision and outcome of this inquiry be published.

135. The hearing is hereby concluded.

Dated this 23rd day of July 2012.