#### IN THE HIGH COURT OF THE REPUBLIC OF SINGAPORE

# [2016] SGHC 168

Suit No 714 of 2014

Between

Koo Quay Keong (Administrator of the Estate of Lee Lee Chan, Deceased)

... Plaintiff

And

Ooi Peng Jin London Lucien

... Defendant

# JUDGMENT

[Tort] — [Negligence] — [Breach of duty] — [Doctors]

# **TABLE OF CONTENTS**

INTRODUCTION	4
BACKGROUND	5
WHIPPLE OPERATION	6
ALLEGATIONS AND ISSUES	7
THE LAW ON NEGLIGENCE	9
THE PARTIES AND THEIR WITNESSES	10
SUSPICION OF ANASTOMOTIC DEHISCENCE: 7 TO 16 JULY	13
POST-OPERATIVE PANCREATIC FISTULA	13
POST-OPERATIVE MANAGEMENT	25
7 to 10 July: initial recovery	27
11 TO 13 JULY: PLEURAL EFFUSION, FREE FLUID IN ABDOMEN, AND C FACTORS	
Pleural effusion	33
Acidosis	35
Free fluids in abdomen	38
Haemoserous fluid, persistent low albumin, and abdominal distension	on39
Management	41
14 to 16 July: abdominal pain	42
Abdominal disquiet on 14 July	45
Chylous fluid on 14 July	49
Yellowish fluid on 15 July	51
Continued abdominal pain on 16 July	53
Management	54

MANAGEMENT OF ANASTOMOTIC DEHISCENCE: 17 TO	
17 то 19 July	66
20 to 23 July	70
24 to 28 July	77
CAUSATION: HYPOTHETICAL INTERMEDIATE EVENTS	79
Before 2300hrs on 16 July	82
AFTER 2300HRS ON 16 JULY	85
FEEDS	86
11 JULY TO 1900HRS ON 13 JULY	86
1900hrs on 13 July to 1900hrs on 14 July	88
1900hrs on 14 July to 2300hrs on 16 July	89
CONCLUSION	92
ANNEX	95

# DIAGNOSIS OF ANASTOMOTIC DEHISCENCE: 16 TO 17 JULY ....57

This judgment is subject to final editorial corrections approved by the court and/or redaction pursuant to the publisher's duty in compliance with the law, for publication in LawNet and/or the Singapore Law Reports.

# Koo Quay Keong (Administrator of the Estate of Lee Lee Chan, Deceased) V Ooi Peng Jin London Lucien

#### [2016] SGHC 168

High Court — Suit No 714 of 2014 Woo Bih Li J 14–15, 19–22, 26, 28–29 January; 10–12 February; 14, 30 March; 11 April 2016.

24 August 2016

Judgment reserved.

Woo Bih Li J:

#### Introduction

1 This is a claim in negligence regarding the post-operative care of a patient who underwent a surgical procedure known as a Whipple operation. Unfortunately, the patient encountered post-operative complications and eventually passed away. The Defendant was the surgeon who performed the operation, and was in charge of the patient's post-operative care.

2 The Plaintiff alleges that the Defendant ought to have, at various timepoints after the operation, suspected or diagnosed a post-operative complication and performed a Computed Tomography ("CT") scan of the patient's chest, abdomen, and pelvis (an "abdominal CT scan"). This would have led the Defendant to perform certain interventional procedures earlier than was in fact done. Those procedures would have saved the patient's life.

3 The Defendant submits that there was no reason, at the time-points put forward by the Plaintiff, to suspect or diagnose the complication, and, in any event, it was reasonable not to have performed the abdominal CT scan earlier. Moreover, the Defendant denies that an earlier CT scan would have altered the course of the patient's post-operative management.

## Background

The deceased, Mdm Lee Lee Chan ("Mdm Lee"), was 59 years of age at her passing on 28 July 2011. The Plaintiff is the widower of Mdm Lee and is also the administrator of her estate. The Defendant, Dr London Lucien Ooi Peng Jin, is a Senior Consultant Surgeon at Singapore General Hospital ("SGH") specializing in hepato-pancreato-biliary ("HPB") surgery,<sup>1</sup> *ie*, surgeries involving the liver, pancreas, and bile ducts.

5 On 4 July 2011, Mdm Lee underwent a Whipple operation performed by the Defendant to remove a tumour on the head of her pancreas. While under post-operative care, she suffered several complications, and passed away on 28 July 2011.<sup>2</sup> Her final cause of death was as follows:<sup>3</sup>

IA) ACUTE HAEMORRHAGE FROM THE PORTAL VEIN IN A CASE OF SEPTICAEMIA DUE TO

<sup>&</sup>lt;sup>1</sup> DAEIC at [9]–[13]

<sup>&</sup>lt;sup>2</sup> PAEIC at [127]

<sup>&</sup>lt;sup>3</sup> 4AB1306

IB) *DEHISCENCE* OF THE *ANASTOMOTIC SITES* OF A WHIPPLE OPERATION

[Emphasis added]

6 The Plaintiff now claims against the Defendant in negligence in his capacity as the administrator of Mdm Lee's estate.

All material events took place in July 2011. For brevity, I will omit the year in subsequent descriptions of Mdm Lee's treatment, and will where appropriate identify treatment dates by their post-operative day ("POD") numbers, *ie*, POD1 (4 July) through POD25 (28 July).

#### Whipple operation

8 The pancreas is an organ located behind the stomach. At its head is the duodenum (*ie*, the first section of the small intestines) and the bile duct (*ie*, the tube joining the liver to the pancreas).<sup>4</sup>

9 In a Whipple operation, the pancreatic head, the gallbladder, and part of the bile duct, stomach, and small intestines are removed. The remnants of the pancreas, bile duct, and stomach are then anastomosed (*ie*, reconnected) to the gastrointestinal tract to facilitate normal digestion and absorption of food.<sup>5</sup>

10 Mdm Lee had three anastomoses during her Whipple operation:

(a) a hepaticojejunostomy, which joined her bile duct to her small intestines;

<sup>&</sup>lt;sup>4</sup> DAEIC at [15]

<sup>&</sup>lt;sup>5</sup> DAEIC at [16]

- (b) a gastrojejunostomy, which joined her stomach to her small intestines; and
- (c) a pancreaticogastrostomy (a "PG"), which joined her pancreas to her stomach.

#### Allegations and issues

11 In his Statement of Claim (Amendment No 2) (the "SOC"), the Plaintiff alleged that the Defendant:<sup>6</sup>

- (a) failed to obtain the informed consent of Mdm Lee to the Whipple operation;
- (b) failed to perform the Whipple operation and two subsequent surgeries in the manner required of an HPB specialist; and
- (c) failed to deliver timely and appropriate post-operative care.

12 At or around the beginning of the trial, the Plaintiff narrowed his claim to a single allegation, *ie*, that the Defendant failed to offer timely and appropriate care between the Whipple operation and two subsequent surgeries.<sup>7</sup>

13 The Plaintiff submitted that by 7 July (POD3), Mdm Lee had suffered "an anastomotic leak of the anastomotic sites of the Whipple Operation",<sup>8</sup> which the Defendant failed to investigate, diagnose, and treat timeously. By the time the anastomotic leak was diagnosed on 17 July, it had deteriorated

<sup>&</sup>lt;sup>6</sup> SOC at [13]–[19]

<sup>&</sup>lt;sup>7</sup> PCS at [30]; JPTC Minute 4/1

<sup>&</sup>lt;sup>8</sup> PCS at [3], [57], [61]

severely. Thereafter, despite knowing of the anastomotic leak, the Defendant failed to manage Mdm Lee appropriately. Up until 24 July, he failed to investigate whether her fluid collections were adequately drained by the existing abdominal drains, and to intervene via a percutaneous drainage procedure (*ie*, inserting a small tube through the skin to drain fluid in the abdomen) into any undrained fluid collections. By the time the Defendant decided to perform a percutaneous drainage procedure on 24 July, Mdm Lee's condition had become unsalvageable.

14 The Defendant submitted that Mdm Lee did not have an anastomotic leak until 2300hrs on 16 July, and was managed appropriately both before and after that time:

(a) Before 2300hrs on 16 July, it sufficed for the Defendant to have simply suspected, but neither investigated nor diagnosed, an anastomotic leak. In any event, his management and treatment of Mdm Lee would have been substantially the same even if she had been diagnosed with an anastomotic leak.

(b) Following the occurrence of an anastomotic leak at 2300hrs on 16 July, it was appropriate for the Defendant to have managed Mdm Lee with non-surgical measures.<sup>9</sup> She was too unstable for invasive intervention, whether in the form of a laparotomy (*ie*, opening up the abdomen to wash it out and close the disrupted anastomosis), or a percutaneous drainage procedure to remove the undrained fluids in

<sup>9</sup> DCS at [439]–[440]

the abdomen.<sup>10</sup> Hence, she was managed non-surgically to optimise her condition for the definitive intervention of a laparotomy.

#### The law on negligence

15 The applicable legal principles are not in dispute. In Singapore, the leading authority on medical negligence is *Khoo James and another v Gunapathy d/o Muniandy and another appeal* [2002] 1 SLR(R) 1024 ("*Gunapathy*"). The test is as stated in *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582 ("*Bolam*") at 587:

[A doctor] is not guilty of negligence if he has acted in accordance with a *practice accepted as proper by a responsible body of medical men skilled in that particular act* ... Putting it the other way round, a [doctor] is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion who would take a contrary view.

[Emphasis added]

16 The Court of Appeal in *Gunapathy* added (at [59]) that the *Bolam* test has been supplemented by the House of Lords decision in *Bolitho v City and Hackney Health Authority* [1998] AC 232 ("*Bolitho*"). Since *Bolitho*, a defendant-doctor will not be exonerated simply because a body of experts testifies in his favour. An expert view must satisfy the "threshold test of logic" in order to constitute, in the words of *Bolam*, "a practice accepted as proper by a responsible body of medical men skilled in that particular act." The expert must have directed his mind to the comparative risks and benefits of each possible course of action, and reached a "defensible conclusion" after balancing these risks and benefits. The conclusion must be internally

<sup>10</sup> DCS at [443]

consistent on its face, and must not ignore or controvert known medical facts and advances in medical knowledge (*Gunapathy* at [63]–[65] and [109]). Further, as Tay Yong Kwang J (as he then was) stated in *D'Conceicao Jeanie Doris (administratrix of the estate of Milakov Steven, deceased) v Tong Ming Chuan* [2011] SGHC 193 at [109]:

The fact that a doctor acknowledges the practice of one group of doctors while stating that he would have opted for a different course does not of itself cause his opinion to become inconsistent. ... an expert can provide evidence of what practices are accepted as proper by a responsible body of medical men by stating his view of what he believes other doctors would have done (even if he would not himself have adopted that course).

17 An allegation that a doctor was negligent in failing to order a postoperative diagnostic test must be positively proved, and the medical basis for ordering the test must be affirmatively established. A doctor would not be negligent simply because there was no harm in ordering the test (*Chua Thong Jiang Andrew v Yue Wai Mun and another* [2015] SGHC 119 at [66]–[69]).

#### The parties and their witnesses

- 18 The Plaintiff called four witnesses:
  - (a) Mr Koo Quay Keong, the Plaintiff himself.
  - (b) Ms Koo Po Ping, the daughter of the Plaintiff and Mdm Lee.
  - (c) Dr Ian James Beckingham ("Dr Beckingham"), a Fellow of the Royal College of Surgeons of England. He is a Senior Consultant in HPB surgery at Queens Medical Centre in Nottingham, and heads the Nottingham University HPB Unit.<sup>11</sup>

He gave expert evidence on the standard of Mdm Lee's postoperative care.

- (d) Dr Mehrdad Nikfarjam ("Dr Nikfarjam"), a pancreatic surgeon based in the Austin Hospital, Melbourne specialising in HPB cancers. He is the President of the Australasian Pancreatic Club.<sup>12</sup> He gave expert evidence on the standard of Mdm Lee's post-operative care.
- 19 The Defendant called eight witnesses:
  - (a) Dr Ooi Peng Jin London Lucien, the Defendant himself.
  - (b) Dr Ng Shin Yi, an Associate Consultant at the Department of Anaesthesiology at SGH.<sup>13</sup> On 17 July, he was the intensivist on call at the Surgical Intensive Care Unit ("SICU") at SGH.<sup>14</sup>
  - (c) Dr Ang Sze Teng Claire ("Dr Ang"), a Visiting Consultant at the Department of Anaesthesiology at SGH sub-specialising in Intensive Care Medicine.<sup>15</sup> From 18 to 25 July, she was the Consultant on duty at the SICU at SGH.<sup>16</sup>

<sup>16</sup> AEIC of Dr Ang at pp 2–9

<sup>&</sup>lt;sup>11</sup> AEIC of Dr Beckingham at p 1

<sup>&</sup>lt;sup>12</sup> AEIC of Dr Nikfarjam at p 1

<sup>&</sup>lt;sup>13</sup> AEIC of Dr Ng Shin Yi at [2]

<sup>&</sup>lt;sup>14</sup> AEIC of Dr Ng Shin Yi at [4]

<sup>&</sup>lt;sup>15</sup> AEIC of Dr Ang at p 1

- (d) Dr Kalpana Vijaykumar ("Dr Kalpana"), a Medical Officer at the Department of Anaesthesiology at Changi General Hospital.<sup>17</sup>
  On 16 July, she was the House Officer on call at SGH.<sup>18</sup>
- (e) Dr Ng Shu Li, a Senior Resident at the Department of Orthopaedics at SGH.<sup>19</sup> On 17 July, she was a Medical Officer at the Department of General Surgery at SGH.<sup>20</sup>
- (f) Dr Yeo Shen Ann Eugene ("Dr Yeo"), an Associate Consultant at the Department of Colorectal Surgery of SGH.<sup>21</sup> On 4 July, he was a Registrar at the Department of General Surgery at SGH, and assisted the Defendant in Mdm Lee's Whipple operation.<sup>22</sup> Thereafter, he was part of the surgical team that managed her post-operatively.<sup>23</sup>
- (g) Dr Lim Boon Leng ("Dr Lim"), a Senior Consultant at the Department of Anaesthesiology at SGH sub-specialising in Intensive Care Medicine.<sup>24</sup> On 25 July, he was the Consultant on duty at the SICU at SGH.<sup>25</sup>

- <sup>18</sup> AEIC of Dr Kalpana at pp 2–4
- <sup>19</sup> AEIC of Dr Ng Shu Li at p 1
- <sup>20</sup> AEIC of Dr Ng Shu Li at p 2
- AEIC of Dr Yeo at p 1
- AEIC of Dr Yeo at p 2
- <sup>23</sup> AEIC of Dr Yeo at p 5
- AEIC of Dr Lim at p 1
- <sup>25</sup> AEIC of Dr Lim at p 2

<sup>&</sup>lt;sup>17</sup> AEIC of Dr Kalpana at p 1

(h) Dr Mak Seck Wai Kenneth ("Dr Mak"), a Senior Consultant at the Department of Surgery at Khoo Teck Puat Hospital ("KTPH") specialising in HPB surgery.<sup>26</sup> He chairs the Medical Board at KTPH and the General Surgery Residency Advisory Committee.<sup>27</sup> He gave expert evidence on the standard of Mdm Lee's post-operative care.

## Suspicion of anastomotic dehiscence: 7 to 16 July

#### Post-operative Pancreatic Fistula

20 On 7 July (POD3), Mdm Lee had amylase levels of 1,361U/L and 1,942U/L respectively in her right and left operatively-inserted drains.<sup>28</sup> These levels were respectively 7.3x and 10.4x of her normal serum amylase level of 186U/L.<sup>29</sup> Citing Claudio Bassi *et al*, "Postoperative pancreatic fistula: an international study group (ISGPF) definition" (2005) 138(1) *Surgery* 8 (the "Bassi Article"), the Plaintiff submitted that, in view of these results, the Defendant should have suspected or diagnosed an anastomotic leak. This was initially denied by the Defendant.

A patient with a POD3 drain amylase level of over 3x her normal serum amylase level has, by definition, a post-operative pancreatic fistula (a "POPF"). This authoritative test for a POPF is found in the Bassi Article at p 10 ("the ISGPF Test"):

AEIC of Dr Mak at p 1

- <sup>27</sup> AEIC of Dr Mak at p 2
- <sup>28</sup> 2AB404; DAEIC at [66(4)]

<sup>&</sup>lt;sup>29</sup> 3AB944

Output via an operatively placed drain (or a subsequently placed, percutaneous drain) of any measurable volume of drain fluid on or after postoperative day 3, with an amylase content greater than 3 times the upper normal serum value.

Because there was much argument over the meaning of the Bassi Article, I have annexed a copy of it to this Judgment.

22 Based on her drain amylase level on 7 July, Mdm Lee had a POPF. Although Dr Mak accepted this, he did not equate the POPF with an anastomotic leak. He added only that the prognosis on 7 July was that the POPF would resolve spontaneously.<sup>30</sup> The disputes between the parties were thus as follows:

(a) whether a POPF was to be equated with an anastomotic leak in the context of a Whipple operation; and

(b) if so, whether the Defendant should at least have suspected that Mdm Lee might have had such an anastomotic leak given her drain amylase levels on 7 July.

The Plaintiff submitted that in the accepted medical literature, the terms "leak" and "POPF" are synonymous and interchangeable. Accordingly, Mdm Lee had by 7 July suffered from, and should have been diagnosed with, an anastomotic leak. He referred to the following passage from the Bassi Article (at p 10) to support his contention:<sup>31</sup>

<sup>&</sup>lt;sup>30</sup> AEIC of Dr Mak at p 63

<sup>&</sup>lt;sup>31</sup> PCS at [63]–[64]

[T]here is considerable overlap of the terms fistula and leak; they appear to be contingent definitions, and the terms fistula, leak, leakage, and anastomotic insufficiency should be considered interchangeable.

24 The Defendant submitted that the terms "POPF", "anastomotic dehiscence", and "anastomotic leak" are distinct. Even if Mdm Lee had a POPF on 7 July, she did not necessarily have an anastomotic leak. I set out the Defendant's definitions of these terms:<sup>32</sup>

(a) POPF: a leakage of pancreatic fluid into the abdominal cavity that results in drain output on or after POD3 with an amylase content of over 3x the serum amylase activity, *without any indication of the mechanism* by which the leakage actually occurred.<sup>33</sup>

(b) Anastomotic dehiscence: a rupture or disruption in an anastomosis (the PG anastomosis in Mdm Lee's case) that results in a *gap in the anastomosis* through which contents of the stomach and pancreas can leak into the abdominal cavity.<sup>34</sup>

(c) Anastomotic leak: an anastomotic dehiscence that results in *leakage* of the contents of the stomach and pancreas into the abdominal cavity.<sup>35</sup>

<sup>&</sup>lt;sup>32</sup> DCS at [44]–[45]

<sup>&</sup>lt;sup>33</sup> DCS at [48]–[49]

<sup>&</sup>lt;sup>34</sup> DCS at [46]

<sup>&</sup>lt;sup>35</sup> DCS at [47]

Since a anastomotic dehiscence is the mechanism through which an anastomotic leak occurs, I will refer to both the complications of an anastomotic leak and an anastomotic dehiscence simply as a "Dehiscence".

The Defendant claimed in his closing submissions that he had from POD3 (7 July) suspected a Dehiscence based on Mdm Lee's elevated drain amylase level, even though there was no need to have documented it:<sup>36</sup>

Prof Ooi's evidence was that since reviewing Mdm Lee's POD 3 drain amylase test result up to 17 July 2011, he had kept the suspicion of the possibility of an anastomotic leak in mind during his treatment and management of Mdm Lee.

This submission stood in stark contrast to the Defendant's pleadings and evidence-in-chief. In the Defence, Mdm Lee's elevated POD3 drain amylase levels were omitted entirely from the Defendant's account of his observations and decisions from 4 to 16 July.<sup>37</sup> This was even though the SOC had described the drain fluid amylase level of 1,361U/L (for the right drain) on 7 July, as a finding that "reflected a clear possibility of a pancreatic leak."<sup>38</sup>

As chronicled in the Defence, Mdm Lee was first observed for indications of a Dehiscence late in the night of 16 July when she complained of sudden abdominal pain.<sup>39</sup> An abdominal CT scan in the morning of 17 July showed a possible Dehiscence.<sup>40</sup> Only thereafter was she "diagnosed" with "septic shock likely secondary to anastomotic leak".<sup>41</sup> The Defendant then

<sup>&</sup>lt;sup>36</sup> DCS at [129]

<sup>&</sup>lt;sup>37</sup> Defence at [19]–[22]

<sup>&</sup>lt;sup>38</sup> SOC at [24(b)]

<sup>&</sup>lt;sup>39</sup> Defence at [22]

<sup>&</sup>lt;sup>40</sup> Defence at [23]

pleaded that "[o]n 17 July 2011, an anastomotic leak was suspected."<sup>42</sup> This suggested that he did not even suspect a Dehiscence until 17 July.

The Defendant pleaded also that from 4 to 16 July, "[t]he volume of fluid drained from [Mdm Lee's] abdominal drains, the fluid amylase levels, and the occasional pain were not unusual."<sup>43</sup> He stated also in his affidavit of evidence-in-chief ("AEIC") that her drain amylase level on 7 July "was slightly elevated but was not unusual".<sup>44</sup> These were remarkable statements. The fluid amylase levels in [Mdm Lee's] right and left drains on 7 July were respectively 7.3x and 10.4x her normal serum amylase levels (see [20] above). These far exceeded the [3x] threshold for identifying the existence of a POPF under the Bassi Article. Even Dr Mak described Mdm Lee's drain amylase levels on POD3 as "high".<sup>45</sup>

29 The Defendant stated further in his AEIC that amylase-rich pancreatic fluid spilt during the Whipple surgery "may not have been totally washed away during surgery … will persist for a few days post-operatively and … therefore be measureable or detectable in the abdominal drains." It was thus "more relevant to monitor for a possible anastomotic leak through observing the colour and volume of the drain [fluids]." For Mdm Lee, "the colour of the drain fluid was not worrisome or suggestive of any form of anastomotic leak until 17 July".<sup>46</sup>

- <sup>43</sup> Defence at [33(2)(g)]
- <sup>44</sup> DAEIC at [66(4)]
- 45 AEIC of Dr Mak at p 62
- <sup>46</sup> DAEIC at [66(4)]

<sup>&</sup>lt;sup>41</sup> Defence at [24]

<sup>&</sup>lt;sup>42</sup> Defence at [33(3)]

30 In his oral evidence, the Defendant put forward two additional explanations for Mdm Lee's elevated POD3 drain amylase level: (i) seepage of pancreatic fluid through the suture holes along anastomoses, and (ii) release of amylase-rich exudate due to pancreatitis or irritation of the pancreas. In support of these contentions, the Defendant cited Vladimir D Dugalic *et al*, "Drain amylase value as an early predictor of pancreatic fistula after cephalic duodenopancreatectomy" (2014) 20(26) *World Journal of Gastroenterology* 8691 (the "Dugalic Article") at 8695.<sup>47</sup>

Hence, the Defendant offered four explanations in total for Mdm Lee's elevated POD3 drain amylase level: (i) retention of pancreatic fluid spilt during surgery; (ii) seepage of pancreatic fluid through anastomotic sutures; (iii) release of amylase-rich exudate due to pancreatitis or irritation of the pancreas, and (iv) a Dehiscence. I will refer to the first three explanations as the "benign explanations".

32 Although the Bassi Article acknowledged (at p 8) that, conceptually, a POPF describes not only a Dehiscence but also a parenchymal leak not directly related to an anastomosis, it was written with the objective of producing a universal test to identify a Dehiscence. The focus of the research was on the link between an elevated POD3 drain amylase level and the existence of a Dehiscence after pancreatic resection. In my view, the Bassi Article was written to set out an objective international biochemical test to diagnose, or at least to suspect, the existence of a Dehiscence. Although the existence of a POPF does not conclusively prove the existence of a

<sup>47</sup> NE 22/1 at pp 93–94

Dehiscence, the Bassi Article treated the two concepts synonymously. Given the undisputed authoritativeness of the Bassi Article on the post-operative management of patients after a Whipple operation, I find that the Defendant should have at a minimum suspected the existence of a Dehiscence based on the fact that Mdm Lee had, by definition, a POPF on 7 July.

33 The benign explanations for Mdm Lee's POPF put forth by the Defendant (at [31] above) did not assist him. As Dr Mak clarified, one would expect the benign explanations for an elevated drain amylase level to be "selflimited" and settle within a few days of a Whipple operation.<sup>48</sup> The Bassi Article advocated conducting the drain amylase test for identifying a POPF "on or after [POD3] simply because one hopes that by the third day, you might exclude some of the other possible causes for amylase being present in the fluid."<sup>49</sup> This was also the view of Dr Nikfarjam, who opined that "stitch holes often seal up, and they don't persist beyond day 3. Anastomotic leaks, on the other hand, of any significance would persist."<sup>50</sup>

In other words, the reason for measuring the drain amylase level on POD3, and not earlier, is precisely to exclude the benign explanations as likely causes of an elevated drain amylase level. Further, although the Defendant relied on the benign explanations to account for Mdm Lee's elevated POD3 drain amylase level, he could not exclude a Dehiscence as a possible cause of the same. Indeed, based on the Bassi Article, a Dehiscence was not simply a possible but rather a *likely* cause of her elevated POD3 drain amylase level.

<sup>&</sup>lt;sup>48</sup> NE 12/2 at p 209

<sup>&</sup>lt;sup>49</sup> NE 12/2 at p 208

<sup>&</sup>lt;sup>50</sup> NE 20/1 at p 63

Hence, the Defendant should have at least suspected that Mdm Lee had a Dehiscence.

35 Although the Defendant could not overtly deny that the Bassi Article was relevant and applicable to the circumstances at hand, he downplayed its utility during the trial and in his submissions.

First, the Defendant referred to Yi-Ming Shyr, *et al*, "Does drainage fluid amylase reflect pancreatic leakage after pancreaticoduodenectomy?" (2003) 27(5) *World Journal of Surgery* 606, which appeared to suggest that elevated drain amylase levels do not indicate a Dehiscence.<sup>51</sup> However, this article was written two years before the Bassi Article, and its findings had been considered by the authors of the Bassi Article when they formulated their definition of a POPF (at p 11, footnote 49). More importantly, the Defendant had in his submissions accepted the Bassi Article as authoritative.<sup>52</sup>

37 Secondly, the Defendant submitted that the Bassi Article was intended purely to facilitate comparative study of surgical experiences.<sup>53</sup> However, the Bassi Article "suggest[ed] that use of [the] proposed definition of POPF will confirm its clinical value and allow accurate comparison of different surgical experiences" (at p 12). I note that the Defendant's submissions quoted only the latter part of this sentence (which referred to the accurate comparison of surgical experiences),<sup>54</sup> but omitted any reference to the former part of the sentence (which confirmed the "clinical value" of the ISGPF Test).

<sup>&</sup>lt;sup>51</sup> NE 14/1 at p 58; DCS at [91]–[93]

<sup>&</sup>lt;sup>52</sup> DCS at [66]

<sup>&</sup>lt;sup>53</sup> DCS at [69]

38 Thirdly, the Defendant relied on Daniel J Moskovic, *et al*, "Drain data to predict clinically relevant pancreatic fistula" (2010) 12 *Journal of the International Hepato-Pancreato-Billary Association* 472 to show that elevated drain amylase levels are not of themselves clinically significant.<sup>55</sup> However, the Bassi Article ascribed no clinical significance to the bare fact of an elevated POD3 drain amylase level. Instead, it proposed a three-tier *ex post facto* grading of the clinical significance of a POPF, with Grade A having no clinical impact (see [46] below).

39 Finally, the Defendant suggested that the volume and colour of the drain fluids were more important indicators of a Dehiscence than an elevated POD3 drain amylase level (see [29] above). However, the Bassi Article had examined the diagnostic value of the volume and quality of drain output before formulating its objective test for a POPF/Dehiscence by reference to the POD3 drain amylase level (at p 11). This is not to say that the volume and colour of the drain fluid are unimportant, but only that the absence of drain fluid of a large volume or a sinister colour does not detract from the possibility of a Dehiscence when the requirements of the ISGPF Test (at [21] above) are satisfied.

40 As noted above, the Bassi Article did not postulate that the existence of a Dehiscence is necessarily clinically significant. It thus suggested a three-tier grading based on the clinical significance of a Dehiscence (see [46] below). The Defendant appeared to have conflated the *existence* of a Dehiscence with its *clinical significance*. Had he accepted the possible existence of a

<sup>&</sup>lt;sup>54</sup> DCS at [69]

<sup>&</sup>lt;sup>55</sup> NE 14/1 at p 107; DCS at [259]

Dehiscence from 7 July (POD3) before the trial commenced, the many questions and arguments on the Bassi Article could have been avoided. I find that the Defendant's stand and his attempts to draw a distinction between a POPF and a Dehiscence (in order to minimise the application of the ISGPF Test) contrived, especially since he did not reject the ISGPF Test outright. Indeed, it is telling that *he belatedly alleged in his closing submissions that he had suspected a Dehiscence from 7 July* (see [25] above). However, he was bound by his pleadings, which were to the effect that he did not suspect a Dehiscence until 17 July.

I would add only that the Plaintiff's oral elaboration of his opening statement added to the confusion. It conflated the criteria for identifying the *existence* of a Dehiscence with that for assessing its *severity*. I set out the statement of counsel for the Plaintiff, Mr Tan Chee Meng, SC ("Mr Tan").<sup>56</sup>

Mr Tan: [T]he universally accepted test, is the test whereby the drain amylase level exits [sic] three times the serum level. That is indicative of a leak. Your Honour, we are not saying that that is the only criteria. We are saying that the drain amylase test is universally accepted as the most objective test for any treating physician who are involved in a pancreatic surgery. . . . Court: But on the one hand you tell me it is the most objective test, and on the other hand you say it is not the only criterion? Yes. Because, your Honour, it would be wrong Mr Tan: for me to say that just because it is three times over, therefore it is a leak, because there are

<sup>56</sup> NE 14/1 a pp 6–7

other criteria that one looks at to ensure that such a possibility is minimised. This is based on the paper by Bassi, which my expert will bring your Honour through.

42 Dr Nikfarjam opined that a Dehiscence could be identified from an elevated POD3 drain amylase level alone. He took the view that Mr Tan's statement above, that "there are other criteria that one looks at to ensure that [the] possibility [of a leak] is minimised", was more accurately a statement that the severity of a leak could not be determined solely based on an elevated POD3 drain amylase level.<sup>57</sup>

43 On the other hand, Dr Beckingham accepted that Mdm Lee's elevated POD3 drain amylase level gave rise only to a suspicion, and not necessarily a diagnosis, of a Dehiscence.<sup>58</sup>

For this case, the distinction between a suspicion and a diagnosis of a Dehiscence is not material. Both of the Plaintiffs' experts testified that a Dehiscence is the most frequent major complication after pancreatic surgery.<sup>59</sup> Dr Mak acknowledged that a Dehiscence is the most severe cause of a POPF, "the one which we as surgeons are obliged to consider as our worst case scenario."<sup>60</sup> I find that it was thus unreasonable for the Defendant to fail to even suspect a Dehiscence based on Mdm Lee's elevated POD3 drain amylase level. In doing so, he fell below the standard of care expected of him.

<sup>&</sup>lt;sup>57</sup> NE 20/1 at p 79

<sup>&</sup>lt;sup>58</sup> NE 14/1 at pp 83–84

<sup>&</sup>lt;sup>59</sup> NE 14/1 at p 66; AEIC of Dr Nikfarjam at p 63

<sup>&</sup>lt;sup>60</sup> NE 10/2 at p 164

45 I note that Dr Mak opined that "the possible [POPF] that was discovered on [7 July] was not directly related to the later anastomotic dehiscence" that the Defendant eventually diagnosed on 17 July (see [121] below). What Mdm Lee had on 7 July was a "transient or biochemical pancreatic fistulae" that settled spontaneously. Hence, "there was not any dehiscence of the [PG] anastomosis before 16<sup>th</sup> July".<sup>61</sup> However, the Defendant did not mention a transient or biochemical pancreatic fistulae in his evidence. Besides, as Dr Beckingham explained (by reference to the Dugalic Article (at p 8697)), the concept of "a fistula that wasn't there to start with and then developing later ... after the 5th post-operative day" was doubtful.<sup>62</sup> In any event, Dr Mak conceded that "it [was] difficult to determine, if the fistulae had closed by 16<sup>th</sup> July".<sup>63</sup> Accordingly, I do not accept the suggestion that Mdm Lee had on 7 July a [transient] POPF that settled shortly thereafter and that was unrelated to the Dehiscence diagnosed on 17 July. Instead, she likely had a Dehiscence from 7 July. Although this Dehiscence was not clinically significant on 7 July, it deteriorated and had become much worse by 16 and 17 July.

#### Post-operative management

The Plaintiff's pleaded case was that an abdominal CT scan should have been performed before 17 July to investigate Mdm Lee's condition.<sup>64</sup> Had it been done, it would have confirmed the existence of a Dehiscence and

<sup>&</sup>lt;sup>61</sup> AEIC of Dr Mak at p 64

<sup>&</sup>lt;sup>62</sup> NE 15/1 at pp 177–178

<sup>&</sup>lt;sup>63</sup> AEIC of Dr Mak at p 64

<sup>&</sup>lt;sup>64</sup> SOC at [24]

revealed a need for intervention: specifically, a percutaneous drainage procedure to drain the collections of fluid in the abdomen that were inadequately drained by the existing operatively-inserted drains.

47 As a result, Mdm Lee did not have an abdominal CT scan until 17 July, by which time it was "too late" for any intervention to have changed her outcome:<sup>65</sup>

Mdm Lee's symptoms were indicative of anastomic [*sic*] dehiscence. Yet, the Defendant failed to order a full abdominal CT scan until 17 July 2011 by which time it was too late. Further, the Defendant failed to institute timely percutaneous drainage measures and/or conduct timely fluid amylase tests to rule out any anastomic [*sic*] dehiscence.

It bears mention that the last sentence is not an alternative plea, and therefore also refers to the same deadline of 17 July for the ordering of a full abdominal CT scan.

In my view, the mere fact that, on 7 July, Mdm Lee had a POPF shed little light on how she should have been managed thereafter. The Bassi Article cautioned that the ISGPF Test was "so inclusive that many asymptomatic patients that fit the definition of POPF may not be clinically ill". It thus proposed a three-tier grading system for POPF (Grades A, B, C), depending on the extent to which the patient deviated from the normal post-operative course. Further, the grade of severity has little predictive value because it can be determined only retrospectively, *ie*, at the end of the patient's postoperative course, whether discharge from the hospital or death (at pp 10–11).

<sup>65</sup> SOC at [24]

49 Although the Defendant fell below the standard of care expected of him in failing to even suspect a Dehiscence based on the elevated POD3 drain amylase level, he will not be liable in negligence unless it is shown that this omission caused the injuries suffered by Mdm Lee. Specifically, the Plaintiff must prove: (i) that the Defendant should have managed her differently if he had suspected a Dehiscence from 7 July, and (ii) that a different management would have changed the outcome of her case. Since the Plaintiff did not plead a loss of chance, this must be proved on a balance of probabilities.

50 Before any evidence was led on the first day of trial, the Defendant applied to amend his Defence to clarify that there would have been little change to Mdm Lee's management even if a Dehiscence had been diagnosed before 17 July:<sup>66</sup>

Even if an anastomotic leak / dehiscence had in fact been present and diagnosed earlier than on 17 July 2011, in light of her condition during [4 to 16 July], she would have been treated in substantially the same manner as she had been contemporaneously treated ...

51 I turn now to the post-operative management of Mdm Lee from 7 July according to the time-frames described in the Plaintiff's submissions.

## 7 to 10 July: initial recovery

52 Dr Beckingham testified that "the earliest point at which it would have been reasonable to consider further intervention would be 11 July, and probably the latest point at which we should have been considering it was 17 or 18 July."<sup>67</sup> Further, such intervention would have been performed only "on

<sup>66</sup> Defence at [33(4)] and [38(1)]

the assumption that you [have] do[ne] a CT scan which shows you something significant enough to warrant percutaneous drainage."<sup>68</sup> Although Dr Beckingham subsequently retracted his evidence that percutaneous drainage could have been performed as late as 17 or 18 July, he nevertheless refrained from criticising Mdm Lee's management before 11 July.<sup>69</sup>

- Court: But previously you had said earliest is the 11th, latest is 17th or 18<sup>th</sup> ... Which seemed to suggest ... that even if you did not do it on the 11th, that is not necessarily negligence because you have given a range. So can you help me on that.
- Dr Beckingham: I will, your Honour. I will retract it for a start then. So it should have been done on the 11th. My only comment for saying the 17th was that -- or 18th, was that after that time, I am not sure it was going to make a great deal of difference, so my comment of the 11th to the 18th, is that was our window of opportunity. If we didn't do it on the 11th, there were still other opportunities to do it when it probably would have made a difference. But if we left it until after the 18th, even if we had done it at that time, I don't think it would have made a difference to the outcome in this case -- 18th, 19th. So yes, it should have been the 11th. Apologies for the confusion.

53 Dr Nikfarjam did not challenge Mdm Lee's management prior to 11 July. From 7 to 8 July, despite her elevated POD3 drain amylase level, she had improved since her Whipple operation and was not unwell.<sup>70</sup> It was thus reasonable for the Defendant to have managed her the way he did.<sup>71</sup> On 9 July,

- <sup>69</sup> NE 15/1 at pp 199–200
- <sup>70</sup> NE 20/1 at p 109

<sup>&</sup>lt;sup>67</sup> NE 14/1 at p 41

<sup>&</sup>lt;sup>68</sup> NE 15/1 at p 97

Mdm Lee experienced respiratory compromise (*ie*, breathing difficulties) and shortness of breath,<sup>72</sup> and drained "haemoserous" fluid.<sup>73</sup> It was thus appropriate to have focussed on controlling these complications on 9 and 10 July.<sup>74</sup>

Accordingly, I am of the view that the Defendant did not fall below the standard of care expected of him in his management of Mdm Lee from 7 to 10 July.

## 11 to 13 July: pleural effusion, free fluid in abdomen, and other factors

<sup>55</sup> On 11 July, Mdm Lee's breathing difficulties worsened. At 1205hrs, she was acidotic with an Arterial Blood Gas ("ABG") level of pH7.290 (the "11 July ABG").<sup>75</sup> At 1600hrs, her abdomen was "slightly distended".<sup>76</sup> A chest X-ray showed bilateral basal atelectasis (*ie*, collapse of the lungs), and a right-sided pleural effusion (*ie*, shift of fluid into the chest) with free fluid around her liver.<sup>77</sup> Her hands and feet were edematous, *ie*, swollen by the accumulation of fluid in the tissues.<sup>78</sup> (I note that the British spellings of this adjective and its associated condition are respectively "oedematous" and "oedema". I will however adopt the American spellings, "edematous" and "edema", which were used in the medical notes for Mdm Lee, and in the

- <sup>72</sup> 2AB414
- <sup>73</sup> 1AB248–249; 2AB415–416
- <sup>74</sup> NE 21/1 at p 24
- <sup>75</sup> 3AB951, 954
- <sup>76</sup> 2AB430
- <sup>77</sup> 3AB1075; Exhibit D12
- <sup>78</sup> 2AB424; NE 22/1 at p 104

<sup>&</sup>lt;sup>71</sup> NE 20/1 at pp 109–110

parties' evidence and submissions.) Her heart rate fell from 106 beats per minute ("bpm") at 0900hrs to 80bpm at 1800hrs, but rose to 88bpm after 2200hrs.<sup>79</sup> Her albumin level fell to 19g/L, down from 22g/L on 9 July.<sup>80</sup> The Defendant ordered the pleural effusion to be treated with percutaneous drainage of the chest.<sup>81</sup> At about 1945hrs, a CT scan of the chest was performed to guide the insertion of a tube for that percutaneous drainage procedure (rather than to investigate Mdm Lee's condition generally). The scan revealed free fluid in the right suphrenic space (*ie*, below the right diaphragm).<sup>82</sup> Notably, this scan was ordered not by the Defendant but by the radiologist who performed the percutaneous drainage procedure.<sup>83</sup>

56 The Plaintiff argued that, in addition to the chest CT scan, the Defendant should have ordered an abdominal CT scan, which would have revealed undrained fluids in Mdm Lee's abdomen, and in turn have necessitated percutaneous drainage of the abdomen as well.

57 On 12 July, 2,360ml of abdominal fluid was drained from Mdm Lee.<sup>84</sup> Her ABG level was pH7.301 at 0213hrs (the "12 July 0213hrs ABG") and pH7.323 at 1108hrs (the "12 July 1108hrs ABG").<sup>85</sup> She was acidotic but improving.

<sup>&</sup>lt;sup>79</sup> 2AB426, 427, 429, 431, 433, 435, 441–444

<sup>&</sup>lt;sup>80</sup> 3AB944, 947

<sup>&</sup>lt;sup>81</sup> 2AB439

<sup>&</sup>lt;sup>82</sup> 3AB1075

<sup>&</sup>lt;sup>83</sup> NE 11/2 at pp 20–21

<sup>&</sup>lt;sup>84</sup> AB453–452

<sup>&</sup>lt;sup>85</sup> 3AB956, 958

58 On 13 July, 2,500ml of abdominal fluid was drained from Mdm Lee.<sup>86</sup>

59 The Plaintiff submitted that by 11 July (POD7), Mdm Lee had deviated from the usual clinical course after a Whipple operation.<sup>87</sup> The clinical signs and symptoms she displayed necessitated a CT scan of her abdomen to eliminate the possibility of a Dehiscence and to investigate whether further intervention was necessary. Additionally, the clinical indicators that emerged between 11 and 12 July should have heightened the Defendant's suspicion of a Dehiscence, and alerted him to the need for such an abdominal CT scan. The Plaintiff highlighted 10 indicators when cross-examining the Defendant and Dr Mak, but referred to a total of 12 indicators in his submissions:<sup>88</sup>

- (a) POPF based on the elevated POD3 amylase level on 7 July;
- (b) respiratory compromise on 9 July;
- (c) delayed gastric emptying;
- (d) increasingly large volume of abdominal drain fluids;
- (e) elevated heart rate persistently above 85bpm;
- (f) haemoserous drain fluid at various points from 9 to 11 July;
- (g) pleural effusion on 11 July;
- (h) persistently low albumin levels;
- (i) metabolic acidosis on 11 (and 12) July;

<sup>&</sup>lt;sup>86</sup> 2AB453–461

<sup>&</sup>lt;sup>87</sup> PCS at [174]

<sup>&</sup>lt;sup>88</sup> PCS at [175],[176]

- (j) free fluid below the diaphragm (seen on the chest CT scan);
- (k) elevated white blood cell ("WBC") count on 11 July; and
- (l) slight abdominal distension on 11 July.

The Defendant agreed, in cross-examination and in submission, that Mdm Lee had by 12 July displayed these 10 or 12 indicators.<sup>89</sup> However, he testified that not all of the indicators persisted *at the same time*. Some had resolved, while others had been attributed to causes other than a Dehiscence. Once an indicator was accounted for, it was "dropped from the equation" and "we move[d] on."<sup>90</sup> Thus, it was incorrect to manage Mdm Lee by "tak[ing] the ten [or twelve] symptoms and signs and throw[ing] them into one time frame. That is not the way you practice medicine."<sup>91</sup> I do not understand the Plaintiff's experts to have been propounding a different approach. Nevertheless, the parties disagreed on the *extent* to which each indicator had resolved.

61 The Plaintiff made detailed submissions only on the haemoserous fluid, pleural effusion, persistent low albumin, acidosis, free abdominal fluid, and abdominal distension. I will first examine these indicators individually, and then consider whether Mdm Lee's management should have been changed in the light of all the indicators, viewed globally.

<sup>&</sup>lt;sup>89</sup> NE 28/1 at pp 72–80; 91–93; DCS at [202]–[304] generally, and [257]–[260] (delayed gastric emptying) and [281]–[289] (increasing volumes of drain fluid)

<sup>&</sup>lt;sup>90</sup> NE 28/1 at pp 54, 71

<sup>&</sup>lt;sup>91</sup> NE 28/1 at p 100

#### Pleural effusion

62 The Defendant in his oral evidence-in-chief attributed the pleural effusion to Mdm Lee's low albumin level, which allowed fluid to leak out of her blood vessels and into the [third] space in her chest.<sup>92</sup> The fact that she had edema even of her extremities<sup>93</sup> (see [55] above) reinforced the conclusion that the third-spacing was so extensive as to have caused the pleural effusion.<sup>94</sup> This was exacerbated by her atelectasis, which had in turn been worsened by her lack of mobilisation.<sup>95</sup> Given the absence of abdominal complaints, all indicators pointed to the chest – and away from the abdomen – as the source of the pleural effusion.<sup>96</sup>

63 Dr Mak accepted that a Dehiscence could contribute to fluid in the abdomen, which could in turn lead to a pleural effusion.<sup>97</sup> Given Mdm Lee's highly elevated POD3 amylase level, the pleural effusion could not have been due only to her low albumin state. The possibility of a Dehiscence must also have been addressed.<sup>98</sup> However, any concerns about a Dehiscence were assuaged by the significant improvement in her clinical condition after her chest was drained.<sup>99</sup>

- <sup>95</sup> DCS at [253(2)]
- <sup>96</sup> NE 22/1 at pp 103–104
- <sup>97</sup> NE 11/2 at p 148
- <sup>98</sup> NE 11/2 at p 149
- <sup>99</sup> NE 11/2 at p 152

<sup>&</sup>lt;sup>92</sup> NE 22/1 at p 100

<sup>&</sup>lt;sup>93</sup> NE 12/1 at p 202

<sup>&</sup>lt;sup>94</sup> NE 22/1 at p 102–104

<sup>64</sup> Dr Nikfarjam opined that on 11 July, the breathing difficulties increasingly experienced by Mdm Lee, coupled with the associated development of a significant pleural effusion, should have raised concerns of a significant intra-abdominal complication. Large pleural effusions rarely occur after a Whipple operation in a patient who, like Mdm Lee, has no significant pre-existing heart failure, chronic liver disease, malnutrition, or chronic kidney disease.<sup>100</sup> However, Dr Nikfarjam then accepted that it was "reasonable to monitor what happens after 11 July to [determine] whether there might be a clinically significant anastomotic leak,"<sup>101</sup> and that on "12 and 13 July [Mdm Lee's] clinical condition had improved after the drainage of the pleural effusion on the 11th."<sup>102</sup>

Dr Beckingham testified that the pleural effusion was caused by the presence of pancreatic fluid [from a Dehiscence] within the abdominal cavity, which "irritate[d] the pleural viscera directly above the diaphragm."<sup>103</sup> He cited Mark I van Berge Henegouwen *et al*, "Incidence, Risk Factors, and Treatment of Pancreatic Leakage after Pancreaticoduodenectomy: Drainage versus Resection of the Pancreatic Remnant" (1997) 185(1) *Journal of the American College of Surgeons* 18 at pp 21–23, which found that at least 48.3% (14 of 29) of patients with a Dehiscence developed a pleural effusion, and that a pleural effusion pointed to a Dehiscence.

<sup>&</sup>lt;sup>100</sup> AEIC of Dr Nikfarjam at p 63

<sup>&</sup>lt;sup>101</sup> NE 20/1 at p 138

<sup>&</sup>lt;sup>102</sup> NE 21/1 at p 27

<sup>&</sup>lt;sup>103</sup> NE 15/1 at pp 50–52

Dr Mak explained that, statistically, the fact that 48.3% of patients with a Dehiscence developed a pleural effusion did not mean that there was a 48.3% chance that Mdm Lee had a Dehiscence by virtue of her pleural effusion.<sup>104</sup> The study (at [65] above) considered only the *incidence* but not the *cause* of the pleural effusions in the patients studied. It was unreliable since pneumonia, infections of the chest or lung, and low albumin states were more common causes of a pleural effusion than a Dehiscence.<sup>105</sup>

#### Acidosis

In his AEIC, the Defendant attributed Mdm Lee's 11 July ABG results to a "respiratory acidosis".<sup>106</sup> In his oral evidence-in-chief, however, he amended his explanation of the 11 July ABG results to a "metabolic acidosis possibly secondary to a respiratory cause".<sup>107</sup> He elaborated that while acidosis from a lung failure was "respiratory acidosis", acidosis from a lung problem that impaired the transport of oxygen to the tissues and thereby caused the tissues to produce acid was "metabolic acidosis".<sup>108</sup>

68 Dr Mak accepted that Mdm Lee had on 11 July suffered metabolic acidosis. The fluid that had accumulated in her chest from her pleural effusion made breathing difficult and prevented the lungs from getting enough oxygen to her tissues. The 11 July ABG result was "quite abnormal". He thus "ha[d] to exclude various possibilities ... for example, of infection and sepsis."

<sup>107</sup> NE 22/1 at p 75

<sup>&</sup>lt;sup>104</sup> NE 12/2 at pp 203–204

<sup>&</sup>lt;sup>105</sup> NE 10/2 at pp 179–180, 182

<sup>&</sup>lt;sup>106</sup> DAEIC at [71]

<sup>&</sup>lt;sup>108</sup> NE 22/1 at p 107

However, he remained "unsure simply on the basis of looking at this test result whether in fact that problem with breathlessness has also led and contributed to this abnormal state where her acidosis is."<sup>109</sup>

69 Dr Nikfarjam dismissed any relation between the metabolic acidosis and the lungs. He explained that Mdm Lee's partial pressure of carbon dioxide (PCO<sub>2</sub>) levels, which would have increased if her lungs had been unable to fully expel the carbon dioxide in her body, had remained normal.<sup>110</sup> Since her lungs were working normally, they could not have caused the acidosis.

The Plaintiff submitted that the Defendant's belated amendment of his evidence-in-chief (see [67] above) showed that he had "failed to apply his mind to properly evaluating the causes of the acidosis". Instead, he had "jumped to the conclusion that it must have been a result of the pleural effusion at the time."<sup>111</sup> The metabolic acidosis indicated an intra-abdominal problem, which undermined attempts to localise the clinical indicators to a chest problem.<sup>112</sup>

71 However, the significance of the 11 July ABG result was not fully borne out in the evidence of the Plaintiff's experts. Dr Beckingham did not mention the 11 July ABG result in his evidence-in-chief or cross-examination, and discussed it only at the end of his re-examination when Mr Tan brought it to his attention.<sup>113</sup> Dr Nikfarjam agreed that Mdm Lee's management on

<sup>&</sup>lt;sup>109</sup> NE 11/2 at pp 2–3

<sup>&</sup>lt;sup>110</sup> NE 21/1 at p 52

<sup>&</sup>lt;sup>111</sup> PRS at [208]–[209]

<sup>&</sup>lt;sup>112</sup> PRS at [215]

<sup>&</sup>lt;sup>113</sup> NE 15/1 at pp 190–193

11 July was appropriate, and that any differences between how he would have managed Mdm Lee and how the Defendant had in fact managed her constituted "an acceptable standard of variation."<sup>114</sup>

It was only after counsel for the Defendant, Ms Kristy Tan ("Ms Tan"), referred Dr Nikfarjam to the 11 July ABG results that he expressed concern about them.<sup>115</sup> Dr Nikfarjam explained that "if [he] had seen this blood test, [he] would have actually been more worried that there's an intraabdominal problem," and "would have been more concerned that an imaging test should have been done on the 11th, of the abdomen."<sup>116</sup> This was not convincing. If the 11 July ABG results were as important as he was belatedly making them out to be, he would not have neglected them earlier in his evidence.

Notably, the chest CT scan was performed only around 1945hrs on 11 July. Dr Nikfarjam conceded that, if the Defendant was unaware of the chest CT scan results, it was acceptable not to have ordered an abdominal CT scan despite the 11 July ABG result.<sup>117</sup> The Defendant testified during cross-examination that he saw the chest CT scan results only at 0730hrs on 12 July.<sup>118</sup> This was accepted by the Plaintiff.<sup>119</sup> By then, the 11 July ABG results had been superseded by the 12 July 0213hrs ABG results,<sup>120</sup> which showed that the acidosis had improved *significantly*<sup>121</sup> after the chest drainage.

- <sup>116</sup> NE 21/1 at pp 32–33
- <sup>117</sup> NE 21/1 at pp 74–75
- <sup>118</sup> 2AB437
- <sup>119</sup> NE 28/1 at p 92
- <sup>120</sup> 3AB956 *cf* 3AB951

<sup>&</sup>lt;sup>114</sup> NE 21/1 at p 26

<sup>&</sup>lt;sup>115</sup> NE 21/1 at p 27
The 12 July 1108hrs ABG results showed further improvement in the acidosis,<sup>122</sup> and both of the Plaintiff's experts accepted that Mdm Lee was in a good and stable condition on 12 July.<sup>123</sup>

#### Free fluids in abdomen

The Defendant attributed the free fluid above the liver displayed by the 11 July chest CT scan to Mdm Lee's low albumin state, which facilitated third-spacing in the abdominal cavity. The free fluid was of little concern because it could be drained by her existing abdominal drains.<sup>124</sup> Dr Mak agreed with this assessment,<sup>125</sup> and added that there was in fact no significant collection of fluid shown on the [albeit limited] set of images taken in the 11 July chest CT scan.<sup>126</sup>

75 The Plaintiff did not dispute Dr Mak's opinions in his submissions.

76 Dr Beckingham referred only to a "2-to-3-cm rim of fluid around [Mdm Lee's] liver which has not been drained", but gave no evidence as to its significance.<sup>127</sup> This fell short of establishing the Plaintiff's submission that there was "significant fluid under her diaphragm",<sup>128</sup> particularly since

- <sup>124</sup> NE 22/1 at pp 114–115
- <sup>125</sup> NE 12/2 at pp 64–65
- <sup>126</sup> NE 11/2 at p 15
- <sup>127</sup> NE 14/1 at pp 41–42

<sup>128</sup> PCS at [237]

<sup>&</sup>lt;sup>121</sup> NE 21/1 at pp 32–33; 12/2 at p 67

<sup>&</sup>lt;sup>122</sup> 3AB958

<sup>&</sup>lt;sup>123</sup> NE 15/1 at p 99; 21/1 at p 34

Dr Nikfarjam had accepted that the free fluid above the liver could have been drained out by the existing abdominal drains.<sup>129</sup>

### Haemoserous fluid, persistent low albumin, and abdominal distension

The Defendant gave evidence that haemoserous fluid was a very nonspecific sign of a Dehiscence. It indicated only that blood had been mixed with serous fluid.<sup>130</sup> The observations of haemoserous fluid between 9 and 11 July were not accompanied by any abdominal signs, except for a slight abdominal distension recorded at 1600hrs on 11 July that subsequently settled.<sup>131</sup> Further, the drain fluid became serous shortly thereafter.<sup>132</sup> Dr Mak echoed these observations, and emphasised that Mdm Lee's abdomen would have exhibited signs of disquiet had there been a Dehiscence.<sup>133</sup> The Plaintiff's submissions did not refer to any evidence from his own experts on the issue of the haemoserous fluid.

The Defendant testified that low albumin was similarly a very nonspecific sign of a Dehiscence.<sup>134</sup> Although Dr Mak accepted that a suspicion of a Dehiscence had to be entertained if a low albumin state persisted,<sup>135</sup> he attributed Mdm Lee's low albumin state from 11 to 14 July to her "somewhat conservative" albumin supplementation of 100ml/day and to her continued

- <sup>134</sup> NE 28/1 at p 93
- <sup>135</sup> NE 12/2 at pp 100–101

<sup>&</sup>lt;sup>129</sup> NE 21/1 at p 15

<sup>&</sup>lt;sup>130</sup> NE 28/1 at p 3

<sup>&</sup>lt;sup>131</sup> 2AB430, 440

<sup>&</sup>lt;sup>132</sup> NE 28/1 at p 60

<sup>&</sup>lt;sup>133</sup> NE 12/2 at pp 19–20

fasting.<sup>136</sup> He added that the steady rise in her albumin levels from 11 to 14 July pointed further away from a Dehiscence, which would have affected them adversely.<sup>137</sup> Dr Beckingham accepted that a low albumin state was common after a Whipple operation because a patient would not have been fed for three to four days.<sup>138</sup> Dr Nikfarjam testified only that low albumin was "a reflection of a patient becoming unwell ... rather than a true cause",<sup>139</sup> and was "indicative of an inflammatory process that's going on."<sup>140</sup>

The Defendant explained that the slight abdominal distension would have been worrying only if it was accompanied by impaired bowel function, which could have suggested a collection of fluid in the space behind the lining of the abdominal cavity.<sup>141</sup> Mdm Lee had normal bowel functions, which Dr Nikfarjam accepted was reassuring.<sup>142</sup> Once again, the Plaintiff's submissions did not refer to any evidence from his own experts on the issue of the abdominal distension.

#### Management

80 Despite all the indicators relied upon by the Plaintiff to submit that the Defendant should have ordered an abdominal CT scan on 11 July (or soon

<sup>141</sup> NE 28/1 at p 134

<sup>&</sup>lt;sup>136</sup> NE 12/2 at pp 100–101

<sup>&</sup>lt;sup>137</sup> NE 12/2 at pp 191–192

<sup>&</sup>lt;sup>138</sup> NE 14/1 at p 29

<sup>&</sup>lt;sup>139</sup> NE 20/1 at p 14

<sup>&</sup>lt;sup>140</sup> NE 20/1 at pp 145–146

<sup>&</sup>lt;sup>142</sup> NE 20/1 at p 126

thereafter), the short point is that this was not the initial position taken by his experts.

Dr Nikfarjam agreed that the Defendant's management of Mdm Lee on 11 July was appropriate. He also agreed that her clinical condition had improved on 12 and 13 July. However, he then backtracked and emphasised the 11 July ABG results (see [71] and [72] above).

As for Dr Beckingham, he had initially testified that it would have been reasonable to have performed percutaneous drainage – after a CT scan of the abdomen<sup>143</sup> – as late as 17 or 18 July. Although he would have ordered an abdominal CT scan and percutaneous drainage on 11 July,<sup>144</sup> it was reasonable not to have done so since Mdm Lee was getting better. Notably, this remained Dr Beckingham's position even "assuming she has an anastomotic leak".<sup>145</sup>

It was only at the close of his re-examination that Dr Beckingham retracted this evidence and asserted that an abdominal CT scan should have been done on 11 July (see [52] above). I place little weight on this late retraction and assertion.

On balance, I am of the view that the Defendant did not fall below the standard of care expected of him in his management of Mdm Lee from 11 to 13 July.

<sup>&</sup>lt;sup>143</sup> NE 14/1 at p 42

<sup>&</sup>lt;sup>144</sup> NE 15/1 at p 94

<sup>&</sup>lt;sup>145</sup> NE 15/1 at pp 98–99

# 14 to 16 July: abdominal pain

So n 14 July, Mdm Lee had a low albumin level of  $22g/L^{146}$  and drained "chylous" fluid.<sup>147</sup> At 1000hrs, she complained of severe pain over a wound site,<sup>148</sup> and received 75mg of Pethidine, a painkiller.<sup>149</sup> At 1100hrs, she had pain with slight tenderness around her right drain site.<sup>150</sup> At 1200hrs, she had mild abdominal pain with a soft abdomen and generalised tenderness on palpitation. However, she had no guarding, rebound tenderness, or peritonitis.<sup>151</sup> At 1347hrs, her C-reactive protein ("CRP") value was 135mg/L while her WBC count was 11.53 x 10<sup>9</sup>/L.<sup>152</sup> At 1620hrs, her pain had become "much better" and she was alert and comfortable.<sup>153</sup>

86 On 15 July, the colour of Mdm Lee's drain fluid was "light haemoserous" at 0600hrs<sup>154</sup> and "yellowish" at 1520hrs.<sup>155</sup> Across the morning, she drained 1,510ml and 20ml of fluid from right and left abdominal drains respectively.<sup>156</sup> At 0810hrs, she was alert, comfortable, and had no complaints of pain, normal parameters, and a soft and non-distended abdomen.<sup>157</sup> At 1000hrs, she was well enough for physiotherapy, and performed ankle

146 3AB965 147 2AB453-461 148 2AB463 149 2AB685 150 2AB465 151 2AB466 152 3AB964-965 153 2AB470 154 1AB265 155 2AB476 156 2AB479, 481, 485 157 2AB472

pumps and marched on the spot.<sup>158</sup> When the Defendant saw her at 1320hrs, she was well and had no complaints. She took feeds and passed flatus. She drained serous fluid.<sup>159</sup> At 1530hrs, she underwent another physiotherapy session. Three further physiotherapy sessions were then planned for 16 and 17 July.<sup>160</sup>

87 On 16 July, Mdm Lee had pain scores of 6/10 at 0930hrs and 3/10 at 1430hrs, but was alert and clinically well.<sup>161</sup> She underwent physiotherapy and did not complain of pain until 2035hrs.<sup>162</sup> Her drain fluids were "yellowish".<sup>163</sup>

The Plaintiff submitted that, taken together, the clinical indicators that Mdm Lee exhibited pointed to a Dehiscence. As at 14 July, these included her elevated POD3 amylase level, her low albumin level, her elevated CRP and WBC values, her "chylous" fluid, and her abdominal disquiet.<sup>164</sup> As at 15 July, Mdm Lee also displayed an inability to tolerate the soft foods that were commenced on 13 July, an elevated heart rate, and drain fluid of a high volume and light haemoserous or yellow colour.<sup>165</sup> As at 16 July, Mdm Lee suffered from the aforementioned unexplained abdominal pain. The Plaintiff focused on the abdominal signs and "chylous" fluid on 14 July, the "yellowish" fluid on 15 July, and the unexplained abdominal pain on 16 July.

<sup>158</sup> 2AB473

- <sup>161</sup> 2AB480–481
- <sup>162</sup> DCS at [399]
- <sup>163</sup> 1AB269–270; 2AB485
- <sup>164</sup> PCS at [253]–[255]
- <sup>165</sup> PCS at [298]–[300]

<sup>&</sup>lt;sup>159</sup> 2AB474

<sup>&</sup>lt;sup>160</sup> 2AB477–479

As mentioned (at [60] above), it was not unreasonable for the Defendant to have considered only the indicators that had persisted at a given point of time. Those that had been resolved or otherwise attributed to conditions other than a Dehiscence could be "left out [of] the equation."<sup>166</sup> Accordingly, I will once again examine the indicators in question individually, and then consider whether Mdm Lee's management should have been changed in the light of all the indicators, viewed globally.

<sup>&</sup>lt;sup>166</sup> NE 29/1 at p 29

# Abdominal disquiet on 14 July

90 The primary indicator relied upon by the Plaintiff was Mdm Lee's abdominal disquiet on 14 July. I set out chronologically the observations on her abdomen, as recorded in her clinical notes.<sup>167</sup>

	<b>Clinical Notations</b>	Remarks
1000hrs	Severe pain over wound site; pain score was 8–9/10, screaming and complaining of right drain pain	75mg of Pethidine administered at 1010hrs
1030hrs	Alert; comfortable; screaming; R[ight] drain pain; [abdomen] soft, mild guarding, 0 rebound	Seen by House Officer Dr Kok Yee Onn
1100hrs	Alert; complaining of pain at drain site; just got pethidine; says much better now	Seen by the Defendant
1230hrs	Alert; comfortable; mild abdominal pain; [abdomen] soft, generalised tenderness on palpitation, 0 guarding, 0 rebound, 0 peritonism	Seen by Dr Rosalynn
1400hrs	Alert; comfortable; 0 pain; [abdomen] soft, N[on]-T[ender]	Seen by Dr Kok
1600hrs	Subjective: denies pain at present	Physiotherapy note
1620hrs	Pain much better than earlier today; alert; comfortable; [abdomen] soft, non-tender	Seen by Dr Yeo
1920hrs	Well; no complaints; happy that pain score 0 since late AM; [abdomen] soft, non-tender	Seen by the Defendant

91 The Plaintiff submitted that the progression from severe pain at 1000hrs to generalised tenderness at 1230hrs should have alerted the Defendant to the possibility of a Dehiscence and the need for an abdominal

<sup>167</sup> 2AB463–470

CT scan.<sup>168</sup> Although the pain apparently dissipated thereafter, the Plaintiff submitted that Dr Yeo's observation of "pain much better than earlier today" at 1620hrs meant that the pain had resurfaced and that the underlying abdominal problem remained unresolved.<sup>169</sup> I do not accept this contention. Those words did not mean that the pain had resurfaced, but that Mdm Lee had been getting better, not worse. The Defendant's review of Mdm Lee at 1920hrs that evening, in which he observed that Mdm Lee was well with no complaints of pain, bear this out.

92 The Defendant accepted that *unexplained* abdominal pain accompanied by tenderness and guarding could point to a Dehiscence,<sup>170</sup> but denied that Mdm Lee had such unexplained pain, generalised tenderness, or guarding.

(a) Mdm Lee's abdominal pain at around 1000hrs was attributable to tugging on the right abdominal drain stitched to her skin.<sup>171</sup> She had localised the pain to her right drain site.<sup>172</sup> At 1100hrs, the Defendant examined her and found her abdomen soft and non-tender except for slight tenderness around the right drain site.<sup>173</sup> Finally, X-rays of her chest and abdomen showed an absence of free air, which pointed away from bowel-abdominal communication.<sup>174</sup>

- <sup>170</sup> NE 29/1 at pp 58–59
- <sup>171</sup> NE 22/1 at p 127
- <sup>172</sup> NE 22/1 at p 132
- <sup>173</sup> DAEIC at [79]
- <sup>174</sup> NE 22/1 at p 131

<sup>&</sup>lt;sup>168</sup> PCS at [280]

<sup>&</sup>lt;sup>169</sup> PCS at [284]; PRS at [260]–[261]

(b) The record of "generalised tenderness" at 1230hrs was inconsistent with the contemporaneous observations that Mdm Lee's abdomen was "soft" with "0 guarding, 0 rebound, 0 peritonism".<sup>175</sup> Tenderness and guarding go together, except at the very onset of an abdominal problem. When tenderness has spread through the entire abdomen to give "generalised tenderness", guarding must have followed. The discrepancy in the clinical records made it reasonable to have held off action.<sup>176</sup> By the time the Defendant reviewed Mdm Lee at 1920hrs on 14 July, her pain issues had resolved, and her abdomen was soft and non-tender.<sup>177</sup> Her abdomen remained soft and non-tender for the remainder of 14 July, and through 15 and 16 July.

Dr Mak testified that a Dehiscence would have irritated or inflamed the abdomen. However, Mdm Lee's abdomen was soft and non-tender with no peritonism (*ie*, inflammation<sup>178</sup>).<sup>179</sup> At 1030hrs, the clinical entry of "mild guarding" was contradicted by the observation that the abdomen was "soft". The further observation of "0 rebound" reinforced the conclusion that there was no peritoneal irritation or other serious abdominal problem.<sup>180</sup> At 1230hrs, the record of "no peritonism" in particular showed that the abdomen was well.<sup>181</sup>

- <sup>178</sup> Exhibit P1 at 51–53
- <sup>179</sup> NE 11/2 at p 31
- <sup>180</sup> NE 12/2 at pp 71–73
- <sup>181</sup> NE 12/2 at pp 73–74

<sup>&</sup>lt;sup>175</sup> 2AB466

<sup>&</sup>lt;sup>176</sup> NE 29/1 at pp 19–23

<sup>&</sup>lt;sup>177</sup> 2AB470

On the other hand, Dr Nikfarjam testified that on 14 July, Mdm Lee had "no right to have generalised tenderness at this point after surgery." He stressed the importance of an observation of generalised tenderness, and concluded that in view of this, the Defendant should have ordered an abdominal CT scan. Although there was some inconsistency between the observations of "tenderness" and "0 peritonism" at 1230hrs, some of the abdominal signs could have been masked by the Pethidine that was administered at around 1000hrs. Moreover, "you would never want to be waiting for someone to develop peritonism before you act";<sup>182</sup> particularly since Mdm Lee had developed abdominal pain that she did not have before.<sup>183</sup>

95 Interestingly, Dr Beckingham gave no evidence on the significance of the abdominal signs displayed by Mdm Lee on 14 July.

<sup>96</sup> The observation of "generalised tenderness" was made by a junior doctor.<sup>184</sup> As the Defendant testified, it could have been a product of unwieldy assessment technique.<sup>185</sup> Further, it was undisputed that this observation was generally inconsistent with the contemporaneous observation, made by the same doctor, that Mdm Lee's abdomen was "soft" with "0 guarding, 0 rebound, 0 peritonism".<sup>186</sup> More importantly, the Defendant had personally reviewed Mdm Lee at 1100hrs and 1920hrs, shortly after each disputed observation was recorded, and found her abdomen soft and non-tender.<sup>187</sup> The

<sup>185</sup> NE 29/1 at pp 17, 19–23

<sup>&</sup>lt;sup>182</sup> NE 21/1 at pp 43–45

<sup>&</sup>lt;sup>183</sup> NE 21/1 at pp 56–57

<sup>&</sup>lt;sup>184</sup> NE 28/1 at pp 47–50

<sup>&</sup>lt;sup>186</sup> 2AB463, 466

<sup>&</sup>lt;sup>187</sup> 2AB465, 470

review at 1920hrs, in particular, was carried out after all the effects of the Pethidine had worn off.<sup>188</sup> The Defendant thus attributed the initial pain to tugging on the abdominal drains,<sup>189</sup> and concluded that Mdm Lee's abdominal signs showed no real cause for concern throughout 14 July.<sup>190</sup>

## Chylous fluid on 14 July

97 Abdominal fluid turns white and milky -ie, chylous - when the fat globules in the lymph vessels leak out into the abdomen.<sup>191</sup>

98 The Defendant testified that the chylous fluid was attributable to the chyle from the fats in Mdm Lee's soft diet on 13 July. If a Dehiscence had occurred at that time, Mdm Lee would have been in significant pain. Instead, she exhibited no such indicators at all.<sup>192</sup>

<sup>99</sup> However, the Plaintiff's experts opined that the amount of fat in the food that Mdm Lee had consumed on 13 and 14 July was insufficient to have produced a chyle leak. Dr Beckingham testified that chyle leaks are unheard of in pancreatic surgery.<sup>193</sup> Hence, the term "chylous" in the clinical notes described only the appearance of the fluid. There was no other evidence of a chyle leak.<sup>194</sup> Dr Nikfarjam added that the definitive test for a chyle leak is a triglycerides test for fat globules,<sup>195</sup> which was not done. Instead, the

- <sup>190</sup> NE 12/2 at pp 76–77
- <sup>191</sup> Exhibit P1 at 25
- <sup>192</sup> NE 29/1 at pp 55–56
- <sup>193</sup> NE 15/1 at p 28
- <sup>194</sup> NE 15/1 at p 23

<sup>&</sup>lt;sup>188</sup> NE 29/1 at p 6

<sup>&</sup>lt;sup>189</sup> NE 22/1 at p 127

Defendant simply diagnosed and treated the chylous fluid based on what he believed to be the characteristic appearance of chyle in the abdominal drains.<sup>196</sup> This was misguided. The chylous fluid could in fact have been pancreatic fluid, which could present a similar appearance to the white colouration of chyle.<sup>197</sup> The Defendant also conceded that the white colouration could have concealed pure pancreatic fluid, which was colourless.<sup>198</sup>

100 Two senior HPB surgeons separately recorded the observations of chylous fluid: Dr Wong Jen San at 0810hrs and the Defendant himself at 1100hrs. The former added that a dissection of a lymph node could have caused the increased chylous output.<sup>199</sup> Dr Mak and Dr Ng Shin Yi testified that chyle has a distinctive appearance that experienced specialists can immediately identify.<sup>200</sup> As observed by the Plaintiff, 14 July was the only time when Mdm Lee's drain fluid had a chylous appearance.<sup>201</sup> Both parties agreed in the Glossary of Medical Terms that the Plaintiff tendered to the court that "chylous fluid" meant "*[f]atty fluids* with a white, creamy or milky colour *from the lymphatic system*<sup>202</sup> [emphasis added]". The Plaintiff could have put forward his own interpretations of term "chylous", as he did for other entries in the Glossary. The fact that he did not do so reinforced the conclusion that Mdm Lee had only chyle in her drains.

- <sup>198</sup> NE 29/1 at pp 56–59
- <sup>199</sup> 2AB462, 465; NE 29/1 at p 163
- <sup>200</sup> NE 10/2 at p 14; 11/2 at p 27; 12/2 at p 14

<sup>201</sup> PCS at [164]: "Indicator Trend Chart from 7 – 17 July 2011"

Exhibit P1 at 25

<sup>&</sup>lt;sup>195</sup> NE 21/1 at pp 71–72

<sup>&</sup>lt;sup>196</sup> NE 11/2 at p 30

<sup>&</sup>lt;sup>197</sup> NE 21/1 at pp 70–72

101 It was thus not unreasonable to have attributed Mdm Lee's chylous fluid to a chyle leak, particularly when her drain fluid became serous again shortly after her diet was changed to manage the chyle leakage.<sup>203</sup>

## Yellowish fluid on 15 July

102 The Plaintiff submitted that the "light haemoserous"<sup>204</sup> and "yellowish"<sup>205</sup> colours of Mdm Lee's drain fluid on 15 July "should have rang alarm bells."<sup>206</sup> He referred to the Defendant's evidence that "[a]ny time we see something that has been described differently, we will check",<sup>207</sup> and to Dr Mak's evidence that bile is yellowish and that a "mixture of bile and serous fluid can also turn yellowish."<sup>208</sup>

103 The Defendant testified that the change in the colour of drain fluid from "chylous" to "light haemoserous" at 0600hrs on 15 July was not in itself of concern. Only if the haemoserous colour had persisted would he have been worried.<sup>209</sup> By 0950hrs, however, the drain fluid had become "serous".<sup>210</sup> Similarly, concerns about the "yellowish" fluid observed at 1520hrs had been assuaged following Dr Yeo's review of Mdm Lee that evening. The fluid had become "serous" and was of no concern. Dr Yeo did not see fit to record it.<sup>211</sup>

203	2AB470
204	1AB265
205	2AB476
206	PCS at [315]
207	NE 29/1 at p 77
208	NE 12/2 at p 109
209	NE 28/1 at p 35
210	1AB265
211	NE 29/1 at p 82

104 Dr Mak added that bile is "golden yellow" or "intensely yellow", rather than the "straw coloured faint yellow tinge" of normal serous fluid.<sup>212</sup> The absence of observations about the *quality* of the fluid (in particular, that the fluid was bilious), as opposed to simply the colour of the fluid, suggested that Mdm Lee did not have a Dehiscence.<sup>213</sup>

105 Importantly, neither of the Plaintiff's experts took issue with the "yellowish" and "haemoserous" observations, whether in their expert reports or their oral testimony.

## Continued abdominal pain on 16 July

106 The Plaintiff submitted that the Defendant would have diagnosed a Dehiscence based on the significant abdominal pain in the morning of 16 July if he had been suspecting a Dehiscence. It was "blinkered" to have attributed the pain to "faecal loading".<sup>214</sup> The Plaintiff added in his reply submissions that the Defendant should have been alarmed because the residual pain (pain score 3/10) after Mdm Lee passed motion was "unexplained".<sup>215</sup>

107 The Defendant testified that Mdm Lee's pain score fell from 6/10 to 3/10 after she passed motion.<sup>216</sup> The abdominal X-ray on 14 July had showed faecal loading.<sup>217</sup> He thus concluded that faecal loading had caused the

<sup>&</sup>lt;sup>212</sup> NE 11/2 at p 104

<sup>&</sup>lt;sup>213</sup> NE 12/2 at pp 107–109

<sup>&</sup>lt;sup>214</sup> PCS at [304]–[306]

<sup>&</sup>lt;sup>215</sup> PRS at [261]

<sup>&</sup>lt;sup>216</sup> NE 26/1 at p 12

<sup>&</sup>lt;sup>217</sup> 3AB1086

abdominal pain at 0625hrs.<sup>218</sup> Dr Mak agreed that the passing of motion substantially resolved what appeared to have been severe abdominal pain. This suggested that the pain had not been caused by a Dehiscence or by significant inflammation or infection within the abdominal cavity.<sup>219</sup>

108 However, Dr Nikfarjam opined that faecal loading could not explain Mdm Lee's abdominal concerns.<sup>220</sup> Further, it was worrying that she kept developing abdominal pain even while on antibiotics.<sup>221</sup> Even so, Dr Beckingham accepted that faecal loading could have caused the pain, which was resolved upon the passing of motion. Mdm Lee had not passed motion from 14 to 16 July, and faecal loading was seen on the abdominal Xray that was performed on 14 July.<sup>222</sup>

### Management

109 The Defendant testified that Mdm Lee improved on 12, 13, and 14 July. This was incompatible with her having suffered a Dehiscence.<sup>223</sup> X-rays of her abdomen and chest showed that the operatively-inserted abdominal drains were in place and that there was no free air in the abdomen, which would have indicated a Dehiscence.<sup>224</sup> The fall in her WBC count from 26.26 x 10<sup>9</sup>/L on 11 July to a near-normal 11.53 x 10<sup>9</sup>/L on 14 July suggested

- <sup>222</sup> NE 15/1 at pp 153–154
- <sup>223</sup> DAEIC at [82]
- <sup>224</sup> DAEIC at [80]

<sup>&</sup>lt;sup>218</sup> DAEIC at [84]; NE 26/1 at p 14

<sup>&</sup>lt;sup>219</sup> NE 12/2 at p 111

<sup>&</sup>lt;sup>220</sup> NE 22/1 at p 16

<sup>&</sup>lt;sup>221</sup> NE 22/1 at p 17

an absence of on-going sepsis and infection in the abdomen. The maintenance of that WBC level from 14 to 16 July suggested further that Mdm Lee was quite well.<sup>225</sup>

110 Dr Mak found that Mdm Lee's stable global condition on 14 July was incompatible with that of a patient with a Dehiscence, who would have deteriorated.<sup>226</sup> Less risk-tolerant doctors might have considered an abdominal CT scan, but it was acceptable to have continued to observe Mdm Lee.<sup>227</sup> An abdominal CT scan was necessary only if she had had a fever, worsening abdominal pain associated with rebound tenderness and guarding, or drain fluid that was bilious or purulent.<sup>228</sup>

111 Dr Nikfarjam opined that he would have ordered an abdominal CT scan in anticipation of performing percutaneous drainage, given the earlier abdominal pain and the observation of generalised tenderness on 14 July. It was unacceptable for the Defendant to have waited until Mdm Lee became unstable before conducting a CT scan, especially given her elevated POD3 drain amylase level.<sup>229</sup> However, Dr Nikfarjam then appeared to accept that the improvement in the pain on 15 and 16 July *reduced* the need for an abdominal CT scan.<sup>230</sup>

Ms Tan:

I wasn't suggesting that after the 11 pm episode, you don't do the CT scan. If I were to

- <sup>228</sup> NE 12/2 at p 120
- <sup>229</sup> NE 21/1 at pp 60–62
- <sup>230</sup> NE 22/1 at pp 19–20

<sup>&</sup>lt;sup>225</sup> NE 26/1 at p 2

<sup>&</sup>lt;sup>226</sup> NE 12/2 at p 90

<sup>&</sup>lt;sup>227</sup> NE 12/2 at p 90

cut it off before then, before that episode, would you agree that it would be reasonable, given what happened in the course of the daytime of the 16th, not to have ordered the CT abdomen scan immediately, in the daytime?

- Dr Nikfarjam: I have given you my answer. With everything considered, I don't agree. I don't agree. It should have been done, whether you want to say should have been done on the 14th, 15th, 16th, on all those days, I actually believe there should have been done, and it's not reasonable to have left them and not performed them.
- Ms Tan: Leaving out the 16th night --
- Dr Nikfarjam: *If you forget what we knew in the past*, and you just want to base it on the patient's pain improving, justifying not doing a CT scan, *if you want to say the pain is the only thing you want to consider, and because the pain is better we won't do a CT scan, yes*; you didn't have to do a CT scan because the pain is better.

[Emphasis added]

112 Having testified that Mdm Lee should have had an abdominal CT scan on 11 July, Dr Beckingham did not give evidence that an abdominal CT scan should have been performed on 14 July.

113 The abdominal pain that Mdm Lee suffered initially in the morning of 14 July did not persist. The effect of the Pethidine that she had received at around 1000hrs that morning would have worn out after six hours.<sup>231</sup> Yet she did not complain of further pain thereafter. The observation of generalised tenderness was inconsistent with the observation of "0 guarding, 0 rebound, 0 peritonism" (see [96] above). In any event, the Defendant in his subsequent review that evening did not observe any tenderness of the abdomen. Indeed,

<sup>&</sup>lt;sup>231</sup> NE 29/1 at p 6

there was no subsequent observation of generalised tenderness on 14, 15, or 16 July.

As Dr Mak testified, a scan should be ordered only if there was a good reason for doing so, and not "just to look to see what things were like".<sup>232</sup> Moreover, as noted in Emmanuel Melloul *et al*, "Poor level of agreement on the management of postoperative pancreatic fistula: results of an international survey" (2013) 15 *Journal of the International Hepato-Pancreato-Billary Association* 307 at 312, there is "poor or no agreement" between HPB centres around the world as to the use of imaging strategies like CT scans in the management of POPF. Accordingly, I am of the view that the Defendant did not fall below the standard of care expected of him in his management of Mdm Lee from 14 to 16 July.

#### Diagnosis of anastomotic dehiscence: 16 to 17 July

115 At 2300hrs on 16 July, Mdm Lee complained of a sudden intense pain over her abdominal region (pain score 8/10).<sup>233</sup> She was "screaming" in pain.<sup>234</sup> Her right and left abdominal drains drained 2,775ml and 330ml of fluid respectively. She received 50mg of Pethidine, but continued to describe pain "everywhere in the abdomen" (pain score 8/10).<sup>235</sup>

116 At 0050hrs on 17 July, Mdm Lee exhibited abdominal "tenderness". At 0130hrs, she complained of abdominal pain and a tender lower abdomen.

<sup>&</sup>lt;sup>232</sup> NE 11/2 at p 37

<sup>&</sup>lt;sup>233</sup> 2AB485

<sup>&</sup>lt;sup>234</sup> 4AB1391

<sup>&</sup>lt;sup>235</sup> 2AB485, 487, 715

Believing that a Dehiscence had occurred, Dr Ng Shu Li made an order to "KIV CT Abdo[men] if symptoms persist" in respect of a Dehiscence.<sup>236</sup>

117 At 0900hrs, Dr Yeo observed that Mdm Lee had deteriorated and that her abdominal tenderness had persisted. An ABG test showed severe metabolic acidosis of pH7.187 requiring correction by bicarbonate infusion.<sup>237</sup> As the Defendant was not at work on 17 July (Sunday), Dr Yeo informed him of these findings over the telephone.<sup>238</sup> Given that Mdm Lee was in severe abdominal pain but had no severe kidney problems or breathing difficulties, the Defendant believed that the acidosis was likely due to an intra-abdominal cause. He thus "instructed Dr Yeo to arrange for an urgent [abdominal] CT scan to investigate if there was any anastomotic leak which may be the cause of a suspected intra-abdominal sepsis."<sup>239</sup>

118 At 1230hrs, a CT scan of Mdm Lee's chest, abdomen, and pelvis (the "17 July Abdominal CT Scan") was performed. It confirmed a Dehiscence and revealed collections of fluid. The scan report stated:<sup>240</sup>

There is a possible mural defect in the region of prior gastrojejunostomy with adjacent extraluminal pockets of pneumoperitoneum ... A moderate to large amount of free low density peritoneal fluid is visualised, mainly in the perihepatic and left subhepatic regions where air fluid levels are visualised. Free low density peritoneal fluid is also visualised along the pericolic gutters and within the pelvis.

- <sup>238</sup> DAEIC at [85]
- <sup>239</sup> DAEIC at [86]
- <sup>240</sup> 3AB1076

<sup>&</sup>lt;sup>236</sup> 2AB489

<sup>&</sup>lt;sup>237</sup> 2AB492

119 At 1300hrs, Mdm Lee was moved to the High Dependency Unit ("HDU") for monitoring and for stabilisation via correction of her acidosis.<sup>241</sup>

By 1320hrs, the Defendant had arrived at SGH, reviewed Mdm Lee, and diagnosed her with a "delayed pancreatic dehiscence".<sup>242</sup> After a discussion with Dr Ng Shin Yi, the consultant intensivist at the SICU on 17 July, the Defendant moved her to the SICU for resuscitation at 1530hrs.<sup>243</sup>

121 There is no dispute that Mdm Lee had a Dehiscence on and after 2300hrs on 16 July, if not earlier. The Plaintiff did not challenge the Defendant's actions on 17 July, save that the diagnosis should have been of a subsisting and not a new Dehiscence.

122 Every case must be decided on the issues raised by the pleadings, which bind the parties. If other issues are desired to be raised or come to light during the trial, they must be pleaded by way of amendment (*Deans Property Pte Ltd v Land Estates Apartments Pte Ltd and another* [1994] 3 SLR(R) 804 at [15]). Although evidence at trial can overcome omissions in a party's pleadings where the opponent is not taken by surprise (*Holland Leedon Pte Ltd (in liquidation) v C & P Transport Pte Ltd* [2013] SGHC 281 at [150]), it may not establish facts radically different from those pleaded that more than simply vary, modify, or develop what has been alleged (*John G Stein & Co Ltd v O'Hanlon* [1965] AC 890 at 909).

<sup>&</sup>lt;sup>241</sup> DAEIC at [86]

<sup>&</sup>lt;sup>242</sup> 2AB497

<sup>&</sup>lt;sup>243</sup> 2AB497, 502

123 I reiterate that the Plaintiff's pleaded case was that by 17 July, it was too late to have performed an abdominal CT scan on Mdm Lee (see [47] above). Accordingly, the Plaintiff's submission that, after 17 July, the Defendant should have ordered yet another abdominal CT scan with a view to performing percutaneous drainage on Mdm Lee's abdomen, was strictly speaking immaterial to his case. However, for completeness, I will address the Plaintiff's allegations about what the Defendant should have done on and after 17 July.

124 As an aside, I will first address the Plaintiff's submission that the Defendant should, in line with his approach of managing Mdm Lee conservatively, have performed a repeat drain amylase test to "track the 'improvement'" of her POPF.<sup>244</sup> This must have referred to the period from 8 to 16 July, *ie*, between the emergence of the POPF on 7 July and the 17 July Abdominal CT Scan that confirmed a Dehiscence. Relying on the opinions of Dr Nikfarjam and Dr Mak, the Plaintiff contended that the Defendant should have performed a repeat drain amylase test to assess "whether [the POPF on 7 July] had resolved spontaneously or if alternative management was required."245 However, the evidence of Dr Nikfarjam and Dr Mak did not go that far. Dr Nikfarjam opined that a repeat drain amylase test should have been performed only if the Defendant believed that the POPF had resolved and intended to remove the existing drains.<sup>246</sup> Similarly, Dr Mak observed that "there are no recommendations for routine follow-up evaluation of the amylase" of a patient with a POPF in order to determine the existence of a

<sup>&</sup>lt;sup>244</sup> PCS at [113]

<sup>&</sup>lt;sup>245</sup> PCS at [114]

<sup>&</sup>lt;sup>246</sup> NE 20/1 at pp 83–84, 138

Dehiscence.<sup>247</sup> I note that Dr Beckingham did not appear to have given any evidence on the subject. In my view, since the Defendant did not intend to remove Mdm Lee's abdominal drains, there was no need for him to have performed a repeat drain fluid amylase test.

### Management of anastomotic dehiscence: 17 to 28 July

125 I set out the relevant portions of the Defendant's AEIC on his plan for Mdm Lee from 17 July:<sup>248</sup>

89. The intensivists were consulted and saw the Patient at about 1.30 pm [on 17 July], and a joint decision was taken for the Patient to be transferred to the Surgical Intensive Care Unit ("SICU") for haemodynamic support. IV fluids and other resuscitation drugs were administered to provide her with support, and as she was in a poor state, she required inotropes to sustain her parameters. Presently, as the Patient's surgical drains were still functioning well, and the Patient was haemodynamically unstable, the plan was for non-surgical intervention at that stage to allow for resuscitation to take priority with a possibility of exploratory laparotomy at a later date should that become essential.

90. The surgical option would allow external drainage and lavage of the bowel contents that were leaked into the abdominal cavity and repair or closure of the anastomotic leak to minimise the leaking of bowel contents through the anastomosis. However, as the Patient's surgical drains are still in place, such abdominal contents are able to drain out through these drains. Further, her NG tube would also reduce the amount of bowel contents crossing the anastomosis into the abdominal cavity. Therefore, the fact that these tubes/drains were still in place and functioning reduced the benefit of surgery, especially in the circumstances whereby the patient is ill, haemodynamically unstable and requiring inotropic support. Surgery can be an option subsequently if the Patient's condition does not improve or deteriorates.

<sup>&</sup>lt;sup>247</sup> NE 11/2 at p 118

<sup>&</sup>lt;sup>248</sup> DAEIC at [89]–[92]

91. In discussions with the intensivists, it was clear that if the Patient was brought to surgery now in her current condition, her mortality rate would be very high, and she would most likely perish (possibly even on the operating table).

92. Primary care was handed over to the intensivists at the SICU as they worked to resuscitate the Patient and stabilise her condition.

126 The Defendant submitted that it was reasonable and appropriate to have managed Mdm Lee non-surgically on and after 17 July, and such management did in fact improve her sepsis.<sup>249</sup> From 17 to 19 July, he held off a laparotomy, a further abdominal CT scan, and a percutaneous drainage procedure because of Mdm Lee's unstable condition and because her existing drains were managing the free fluid collections seen on the 17 July Abdominal CT Scan.<sup>250</sup> From 20 to 23 July, he held off a laparotomy because non-surgical management was continuing to improve Mdm Lee's condition, and he held off an abdominal CT scan and percutaneous drainage because the additional benefits that they promised were outweighed by the risks involved.<sup>251</sup> On 24 July, however, he ordered an abdominal CT scan because of the increase in Mdm Lee's WBC count and the appearance of feculent matter in her abdominal drains, and then decided to perform percutaneous drainage of the loculated collections revealed on the scan.252 Nevertheless, before the percutaneous drainage could be performed, it was superseded by a decision to operate on Mdm Lee, on which I will elaborate later (at [156]–[159] below).

<sup>&</sup>lt;sup>249</sup> DCS at [440] and [442]

<sup>&</sup>lt;sup>250</sup> DCS at [443]

<sup>&</sup>lt;sup>251</sup> DCS at [447]

<sup>&</sup>lt;sup>252</sup> DCS at [448]

127 It is clear to me from the Defendant's AEIC and oral evidence at trial<sup>253</sup> that, from 17 July, he had wanted to perform a laparotomy but could not do so because Mdm Lee was haemodynamically unstable. The intensivists had to resuscitate and stabilise her first. This was also the evidence of Dr Ng Shin Yi<sup>254</sup> and Dr Ang,<sup>255</sup> who were the consultant intensivists at the SICU on 17 July and from 18 to 25 July respectively. However, it was less clear whether, after Mdm Lee's condition had improved by 19 July, the Defendant had been continuing to wait for an opportune time to perform the laparotomy, or had changed his mind and had been deferring the laparotomy to see whether her condition would improve to such an extent as to render a laparotomy unnecessary. As it turned out, this lack of clarity was not material, as I will explain later.

128 As for the Plaintiff's case, I reiterate that it was Dr Beckingham's evidence that 17 or 18 July was the latest time for intervention via a percutaneous drainage procedure (after an abdominal CT scan) or a laparotomy (see [52] above). Thereafter, any such intervention would not have "made a difference to the outcome in [Mdm Lee's] case." Dr Beckingham maintained this position throughout the trial.<sup>256</sup>

As for Dr Nikfarjam, he opined that if percutaneous drainage was not performed on 17 July, it should have been performed "on the 18th, 19th, 20th, 21st, 22nd, 23rd, till the day [Mdm Lee] had surgery."<sup>257</sup>

<sup>253</sup> NE 26/1 at pp 27–29

<sup>&</sup>lt;sup>254</sup> AEIC of Dr Ng Shin Yi at [8]

<sup>&</sup>lt;sup>255</sup> NE 10/2 at pp 61–62

<sup>&</sup>lt;sup>256</sup> NE 14/1 at p 41;15/1 at pp 93–94 and 199–200

- Ms Tan: You see, for the period from 17 to 25 July, your report does not identify what it is you say would have been done differently or when you would have done it. So can you please tell us now, since you think that there is falling below a reasonable standard of care, what it is you would have done differently, and when, since you have not stated it in your report?
- Dr Nikfarjam: So I have mentioned in my report that as of the 17th, I would have looked at radiological drainage. From 17th onwards that's what I would -- would consider as an initial step. So if that hasn't been performed, that's what I'm referring to. The fact that no intervention was undertaken to address this patient's intraabdominal sepsis, that is my point, and that is the only point that I'm referring to, which I stated on the 17th, and I have not repeated it every day after.

I have mentioned it on the 17th, but in my report, I haven't rediscussed on the 18th, 19th, 20th, 21st, 22nd, 23rd, till the day the patient had surgery. So that is what I'm saying.

[Emphasis added]

Ms Tan pressed Dr Nikfarjam to give a more specific time-frame for the performance of percutaneous drainage. However, he maintained that the time-frame was simply after Mdm Lee "had gone into the intensive care, was intubated, was given some inotropic supports and was having blood pressure maintained" in the afternoon of 17 July.<sup>258</sup> This was vague.

130 The Plaintiff's submissions were no better. He first alleged that the Defendant should have "included [as part of his treatment plan], a plan for percutaneous drainage to drain the source of [Mdm Lee's] abdominal sepsis as

<sup>&</sup>lt;sup>257</sup> NE 22/1 at pp 30–31

<sup>&</sup>lt;sup>258</sup> NE 22/1 p 31

soon as she was resuscitated and stabilised."<sup>259</sup> Since Mdm Lee was undergoing resuscitation and stabilisation from 17 to 19 July, the earliest opportunity for percutaneous drainage was 20 July. Yet, in the very next paragraph of his submissions, the Plaintiff criticised the Defendant for not ordering a CT scan, in order to perform percutaneous drainage, "prior to 24 July".<sup>260</sup> This was too sweeping an allegation as it ignored the fact that Mdm Lee was undergoing resuscitation and stabilisation from 17 to 19 July.

Another sweeping submission made by the Plaintiff was his criticism of "[t]he Defendant's inaction for more than a week between 17 July 2011 and 26 July 2011" as "inexcusable."<sup>261</sup> At risk of belabouring the point, Mdm Lee was haemodynamically unstable and had to be resuscitated and stabilised from 17 to 19 July. Moreover, a further abdominal CT scan was in fact performed at 1430hrs on 24 July<sup>262</sup> (the "24 July Abdominal CT Scan"), following which the Defendant ordered a percutaneous drainage procedure (see [156] below). It was thus incorrect for the Plaintiff to allege that the Defendant had been inactive between 17 and 26 July.

132 These sweeping submissions served only to distract from the real issues in question. The pertinent timeframe was 20 to 23 July, rather than the longer period of 17 to 26 July. I will explain this later (at [141]–[155] below), after describing the period from 17 to 19 July in order to contextualise the

<sup>&</sup>lt;sup>259</sup> PCS at [323]

<sup>&</sup>lt;sup>260</sup> PCS at [324]

<sup>&</sup>lt;sup>261</sup> PCS at [327]

<sup>&</sup>lt;sup>262</sup> 2AB586; 3AB1078–1079

actions that were taken by the Defendant and to explain the state that Mdm Lee was in during that time.

#### 17 to 19 July

133 When Mdm Lee arrived at the SICU at 1530hrs on 17 July (see [120] above), Dr Ng Shin Yi, the consultant-in-charge of the SICU, observed that she was "acutely ill".<sup>263</sup> Besides a Dehiscence, she suffered from septic shock, a low and unstable blood pressure, and an acute kidney injury.<sup>264</sup> She was put on active non-surgical management to control the flow of fluids to the dehisced anastomosis in order to allow it to seal off naturally.<sup>265</sup>

- (a) First, a Nasogastric Tube (an "NGT") was inserted through her nose to evacuate her stomach contents.<sup>266</sup>
- (b) Secondly, she was placed Nil-by-Mouth.<sup>267</sup> From 19 July, she received intravenous nutritional support.<sup>268</sup>
- (c) Thirdly, her antibiotics were "escalate[d]" to intravenous Tazocin.<sup>269</sup> Intravenous Vancomycin was added on 21 July.<sup>270</sup>
- (d) Fourthly, her operatively-inserted drains were put on wall suction to increase the rate of drainage of abdominal fluids.<sup>271</sup>

<sup>269</sup> 2AB498; NE 26/1 at p 25

<sup>&</sup>lt;sup>263</sup> AEIC of Dr Ng Shin Yi at [8]

<sup>&</sup>lt;sup>264</sup> 2AB506

<sup>&</sup>lt;sup>265</sup> NE 26/1 at p 37

<sup>&</sup>lt;sup>266</sup> 1AB79; 2AB498, 500; NE 26/1 at p 24

<sup>&</sup>lt;sup>267</sup> 2AB498; NE 26/1 at p 26

<sup>&</sup>lt;sup>268</sup> 2AB709

<sup>&</sup>lt;sup>270</sup> 2AB688–697

- (e) Fifthly, she was administered three different inotropes to support her blood pressure.<sup>272</sup>
- (f) Finally, she was put on dialysis to mitigate the effects of her acute kidney injury.<sup>273</sup>

By 2100hrs on 17 July, Mdm Lee had become more stable. However, she remained on two inotropes. Her abdomen was slightly more distended than earlier in the day but was still soft. Her NGT drained bilious fluid, and both her abdominal drains drained turbid fluid. Her urine output was fair.<sup>274</sup> She had an elevated intra-abdominal pressure due to an accumulation of fluid in her abdomen. Across the day, she experienced severe coagulopathy and acidosis, and had low oxygen saturation that required intubation for ventilation.<sup>275</sup>

135 On 18 July, Dr Ang assumed the role of consultant-in-charge of the SICU from Dr Ng Shin Yi, and with it, the care of Mdm Lee.<sup>276</sup> At 0830hrs, Mdm Lee remained "very unwell". In her condition on 18 July, surgery carried a 70–80% risk of death. Accordingly, the objective was to continue resuscitation to improve her condition.<sup>277</sup> By 2020hrs however, Mdm Lee had gradually stabilised. She displayed good drainage from her right drain of 800ml. Her intra-abdominal pressure had fallen further, and her abdomen had

- AEIC of Dr Ang at p 5
- <sup>274</sup> DAEIC at [97(1)]
- <sup>275</sup> AEIC of Dr Ng Shin Yi at [11]–[13]
- AEIC of Dr Ang at p 4
- AEIC of Dr Ang at p 5

<sup>&</sup>lt;sup>271</sup> NE 26/1 at pp 109, 148

<sup>&</sup>lt;sup>272</sup> NE 26/1 at p 26; AEIC of Dr Ng Shin Yi at [11]

become less tense and distended.<sup>278</sup> However, various issues persisted, including low blood pressure, severe coagulopathy, poor oxygen saturation, acidosis, acute kidney injury, raised intra-abdominal pressure, and septic shock.<sup>279</sup>

By 0930hrs on 19 July, Mdm Lee had improved even further. Her oxygen saturation had increased, and a single inotrope sufficed to support her blood pressure. Her lungs were clear and she was able to obey commands. However, her coagulopathy, acute kidney injury, and raised intra-abdominal pressure remained unresolved. The Defendant consulted Dr Ang and concluded that Mdm Lee was in no condition for surgical intervention.<sup>280</sup>

137 The Defendant testified that he had monitored Mdm Lee's drainage and abdominal signs at all times, and would have intervened via percutaneous drainage or even surgery had she failed to progress as expected.<sup>281</sup> However, Mdm Lee was from 17 to 19 July too ill for any intervention.<sup>282</sup>

138 Dr Mak agreed that from 17 to 19 July, Mdm Lee was "not stable or in any fit condition to be transferred out of the [S]ICU for any length of time". Any consideration of "the possibility of these various interventions, whether surgery or drainage … would have been academic because she was not fit at all for any of these procedures to be done."<sup>283</sup>

<sup>&</sup>lt;sup>278</sup> DAEIC at [97(2)]

AEIC of Dr Ang at pp 4–5

<sup>&</sup>lt;sup>280</sup> DAEIC at [97(3)]; AEIC of Dr Ang at pp 5–6

<sup>&</sup>lt;sup>281</sup> NE 26/1 at pp 25–26

<sup>&</sup>lt;sup>282</sup> NE 26/1 at p 27

<sup>&</sup>lt;sup>283</sup> NE 11/2 at pp 63–64

Dr Beckingham observed that up until 18 July, Mdm Lee was "as sick as a dog". While a laparotomy was theoretically possible, his first choice would have been a percutaneous drainage procedure.<sup>284</sup> Nevertheless, Mdm Lee needed to be stabilised before any such percutaneous drainage could be performed.<sup>285</sup> Given her condition, he would have been cautious, and would have "th[ought] carefully about whether to do a radiological guided drainage" at all.<sup>286</sup> Since Dr Beckingham had observed that any intervention after 18 July would have been "too late" (see [52] above), he did not comment on her management thereafter.

140 Dr Nikfarjam accepted that the plan from 17 July to stabilise Mdm Lee for surgery was reasonable.<sup>287</sup> He disputed only the *delay* in intervening, specifically via a percutaneous drainage procedure. He contended that "after 24 hours, if [she] did not improve rapidly enough for surgery ... there shouldn't have been any further time waiting for surgery."<sup>288</sup> Nevertheless, he accepted that even after this 24-hour period, insofar as there was no risk of deterioration, "[i]f the SICU team and the surgeon are still saying that 'Maybe this is not the best window for surgery; we can get her to a better window', then it would be reasonable to wait till the best possible window."<sup>289</sup> Since Dr Nikfarjam accepted that "from the septic point of view, there was improvement" with the non-surgical measures implemented from 17 July, I

- <sup>288</sup> NE 22/1 at p 40
- <sup>289</sup> NE 22/1 at pp 43–44

<sup>&</sup>lt;sup>284</sup> NE 15/1 at p 162

<sup>&</sup>lt;sup>285</sup> NE 15/1 at p 163

<sup>&</sup>lt;sup>286</sup> NE 15/1 at p 164

<sup>&</sup>lt;sup>287</sup> NE 22/1 at p 37

am of the view that the Defendant did not fall below the standard of care expected of him in holding off surgery or even percutaneous drainage, between 17 and 19 July.

## 20 to 23 July

141 On 20 July, Mdm Lee had been stable overnight, and her inotrope support had been decreased to a minimum. Her NGT and abdominal drains continued to drain well. She was, however, still coagulopathic with a low platelet count, and still needed dialysis for her kidneys. The Defendant decided to continue with non-surgical management, and to perform a laparotomy if there was no further improvement.<sup>290</sup>

By 21 July, Mdm Lee had improved further even though she remained on the Dangerously Ill List. Her blood pressure had stabilised and she was taken off inotropes. Her bilateral basal atelectasis and oxygen saturation had improved further. Her acute kidney injury was healing, even though she remained on dialysis. However, she drained bilious fluid and had septic shock, a low albumin level, and coagulopathy. After consulting Dr Ang, the Defendant decided against a laparotomy. Mdm Lee's NGT and abdominal drains were effectively draining the site of her Dehiscence. The risks of a laparotomy outweighed any potential benefits involved.<sup>291</sup>

143 At 0435hrs on 22 July, Mdm Lee was unable to focus her eyes, and her level of consciousness had deteriorated.<sup>292</sup> However, she could move all her

<sup>&</sup>lt;sup>290</sup> DAEIC at [97(4)]

<sup>&</sup>lt;sup>291</sup> DAEIC at [97(5)]; AEIC of Dr Ang at pp 7–8

<sup>&</sup>lt;sup>292</sup> 2AB560

limbs, and continued to maintain her blood pressure without inotropic support. Her lungs were clear and her oxygen saturation was at 100%. However, her coagulopathy persisted.<sup>293</sup> At 1510hrs, Mdm Lee was sent for a brain CT scan because her lack of consciousness pointed to the existence of a life-threatening bleed of the brain.<sup>294</sup> However, the scan revealed the absence of any such bleed.<sup>295</sup>

144 On 23 July, Mdm Lee maintained a similar clinical state to that which she was in on 22 July. Bilious fluid continued to be noted in her NGT, and her surgical drains drained clear brownish fluid. She continued to require blood products to support her coagulopathy,<sup>296</sup> which had worsened.<sup>297</sup>

145 The Defendant testified that by 20 July, the focus had shifted away from optimising Mdm Lee for surgery to "using the conservative [nonsurgical] management to get her well".<sup>298</sup> Surgery was maintained as a consideration only "if [Mdm Lee was] not improving further."<sup>299</sup> The effectiveness of these non-surgical measures was demonstrated by the "dramatic drop in the [WBC] count, from 28.14 x 10<sup>9</sup>/L to 11.58 x 10<sup>9</sup>/L, by 20 July", as well as the general clinical improvements of a reduction in her need for inotropes and continued active drainage of fluid.<sup>300</sup> On 21 July, she

- AEIC of Dr Ang at p 9
- <sup>298</sup> NE 26/1 at p 30
- <sup>299</sup> DAEIC at [97(4)]; 2AB543
- <sup>300</sup> NE 26/1 at pp 30–31

AEIC of Dr Ang at p 8

<sup>&</sup>lt;sup>294</sup> NE 10/2 at p 97

<sup>&</sup>lt;sup>295</sup> 3AB1078

<sup>&</sup>lt;sup>296</sup> DAEIC at [97(6)

was well enough to have her remaining inotrope removed, her WBC count had fallen further to  $10.3 \times 10^{9}$ /L, and she was afebrile.<sup>301</sup>

Dr Mak appeared to accept that there was an opportunity from the morning of 21 July, given that Mdm Lee was sufficiently stable without inotropic support to be brought out of the SICU, for percutaneous drainage to have been performed.<sup>302</sup> The 17 July Abdominal CT Scan had revealed collections of fluid on the left side of her abdomen and in her pelvis that were not easily drained by her existing operatively-inserted drains.<sup>303</sup> Moreover, Mdm Lee had uncontrolled sepsis on 21 July (as evinced by her organ failure, renal failure, and on-going bleeding) even if she had improved from a septic point of view from 17 July.<sup>304</sup> The only collection of fluid that remained undrained was that in her pelvis, which needed to be "sorted out."<sup>305</sup> Since, Mdm Lee was on 21 July in a very similar state of clinical stability as she was in at 24 July (when the Defendant eventually decided to perform a percutaneous drainage procedure),<sup>306</sup> Dr Mak would have considered performing percutaneous drainage on 21 July.

147 However, Dr Mak pointed out that percutaneous drainage should only be performed after an abdominal CT scan had been carried out and then only if the scan revealed undrained fluid collections necessitating such intervention.<sup>307</sup>

<sup>306</sup> NE 12/2 at pp 141, 143

<sup>&</sup>lt;sup>301</sup> NE 26/1 at pp 31–32

<sup>&</sup>lt;sup>302</sup> NE 12/2 at pp 138–139

<sup>&</sup>lt;sup>303</sup> NE 12/2 at p 137

<sup>&</sup>lt;sup>304</sup> NE 12/2 at p 145

<sup>&</sup>lt;sup>305</sup> NE 12/2 at pp 147–149

<sup>&</sup>lt;sup>307</sup> NE 12/2 at p 140

Also, Mdm Lee's coagulopathy had to be corrected before percutaneous drainage could have been undertaken.<sup>308</sup> This was the case on 24 July. Moreover, even though Dr Mak would have considered percutaneous drainage, he would have taken Dr Ang's guidance as to whether and when it would have been safe to bring Mdm Lee out of the SICU.<sup>309</sup> Although 21 July was the first available opportunity for percutaneous drainage, Dr Mak testified that he would have waited another day had Dr Ang told him to do so. In Dr Mak's opinion, Mdm Lee did not appear to have been so unstable that he would have lost all opportunities to intervene simply by waiting an additional day.<sup>310</sup>

148 Dr Ang gave evidence that on 21 July, Mdm Lee had been "slowly improving" and remained on track for the definitive intervention of surgery. Hence, Dr Ang would not have recommended even an abdominal CT scan – much less the consequential measure of percutaneous drainage – because "there's really no point to do a scan to see where the loculation is, if our intention is to open up the patient."<sup>311</sup>

149 It is not disputed that the Defendant, as the lead surgeon, made the decision whether to order percutaneous drainage or a laparotomy (or neither). However, Dr Ang candidly admitted that because Mdm Lee was in intensive care, any such decision involved a "collaborative discussion"<sup>312</sup> with her.

<sup>&</sup>lt;sup>308</sup> NE 12/2 at p 140

<sup>&</sup>lt;sup>309</sup> NE 12/2 at p 144

<sup>&</sup>lt;sup>310</sup> NE 12/2 at p 148

<sup>&</sup>lt;sup>311</sup> NE 10/2 at pp 95–96

<sup>&</sup>lt;sup>312</sup> NE 10/2 at pp 71–72

Dr Ang would have been prepared to suggest percutaneous drainage had she thought it advisable.<sup>313</sup> Yet, she did not suggest that percutaneous drainage be performed on 20 or 21 July. Notably, Mr Tan assured Dr Ang during cross-examination that he was "not suggesting any shortcoming on [her] part."<sup>314</sup>

150 Dr Nikfarjam's opinion that percutaneous drainage should have been performed at some point in time on or after 17 July gave the impression that Mdm Lee was deteriorating from 17 July onwards, and that the Defendant's non-surgical management of her was inadequate. It appears that, initially at least, Dr Nikfarjam did not appreciate that although Mdm Lee had deteriorated from 17 to 19 July, she had improved on 20 and 21 July. Hence the Plaintiff's present focus, in his submissions, on 20 July and particularly 21 July (leaving aside the other sweeping allegations in his submissions). I thus hesitate to rely on Dr Nikfarjam's evidence on the timing for the performance of a percutaneous drainage procedure.

151 The Defendant's position was that given Mdm Lee's condition from 17 to 22 July, there were grave risks in moving her out of the SICU and into the radiology suite. She was so moved on 22 July *only* because of the graver concern about a life-threatening bleed of the brain.<sup>315</sup> Given the grave risks of keeping Mdm Lee outside the SICU, the Defendant did not tag on a further abdominal CT scan while she was in the radiology suite.<sup>316</sup> Dr Ang and Dr Mak agreed with this assessment.<sup>317</sup> Notably, neither of the Plaintiff's

<sup>313</sup> NE 10/2 at pp 72–73

<sup>&</sup>lt;sup>314</sup> NE 10/2 at p 71

<sup>&</sup>lt;sup>315</sup> NE 29/1 at p 125

<sup>&</sup>lt;sup>316</sup> NE 29/1 at pp 171–172
experts gave evidence on whether Mdm Lee should have had a further abdominal CT scan on 22 July when she was sent for a brain CT scan.

152 On the other hand, the Defendant's evidence on why he did not order a further abdominal CT scan soon after the 17 July Abdominal CT Scan was given in a rather roundabout fashion. During his cross-examination of the Plaintiff's experts, Ms Tan emphasised the risks of moving the Plaintiff away from the support at the SICU in order to carry out such a scan, but did not compare the risks of such a movement against the benefit of a further abdominal CT scan. It was only subsequently, when the Defendant was crossexamined, that he explained that he had held off a further abdominal CT scan because was no need for it (until 24 July).

153 Notwithstanding the roundabout manner in which the Defendant gave his evidence, I accept that he did not consider the question of whether to perform a further abdominal CT scan in isolation but as part of his overall risk-benefit assessment of moving Mdm Lee out of the SICU. I also accept that the brain CT scan was performed on 22 July because of the overriding concern about a life-threatening bleed of the brain, which was not disputed by the Plaintiff. However, the fact that this brain CT scan was performed did not mean that a further abdominal CT scan should have been tagged on thereafter, and the evidence did not go so far as to establish that.

154 On 23 July, Mdm Lee remained in a similar state as she was in on 22 July. In his submissions, the Plaintiff did not take issue with her

<sup>&</sup>lt;sup>317</sup> NE 10/2 at pp 96–97, 135–136; 11/2 at pp 68–71

management on 23 July. Similarly, neither of the Plaintiff's experts specifically challenged her management on 23 July, beyond Dr Nikfarjam's assertion that percutaneous drainage should have been performed on or after 17 July. There is thus no need for me to examine Mdm Lee's management on 23 July.

155 Hence, I am of the view that the Defendant did not fall below the standard of care expected of him in his management of Mdm Lee from 20 to 23 July.

## 24 to 28 July

156 On 24 July, in consultation with Dr Ang, the Defendant ordered a CT scan of Mdm Lee's abdomen and pelvis to check her abdominal condition and healing potential.<sup>318</sup> This was performed at 1430hrs, and it revealed a loculated fluid collection in the left suphrenic space and another along the stomach wall. Free intraperitoneal fluid was also seen in the pelvis.<sup>319</sup> At 1730hrs, the Defendant ordered a percutaneous drainage procedure, and consent for this was obtained.<sup>320</sup>

157 The Defendant testified that he had ordered the 24 July Abdominal CT Scan because the increase in Mdm Lee's WBC count and the emergence of feculent matter in her abdominal drains indicated a new sinister development.<sup>321</sup> Although, as the Plaintiff observed, these reasons were not mentioned in the

<sup>&</sup>lt;sup>318</sup> DAEIC at [97(7)]

<sup>&</sup>lt;sup>319</sup> 2AB586; 3AB1078–1079

<sup>&</sup>lt;sup>320</sup> DAEIC at [97(7)]

<sup>&</sup>lt;sup>321</sup> NE 26/1 at pp 32–33; 29/1 at pp 168–169

AEICs of the Defendant and Dr Ang,<sup>322</sup> they were recorded in Mdm Lee's contemporaneous clinical notes:<sup>323</sup>

**TWC** = **14.79** [*ie*, Total WBC Count = 14.79 x 10<sup>9</sup>/L]

Dr Claire Ang S/T [ie, spoke to] Prof London Ooi re: ? faculent [sic] SMD output [ie, feculent small measure drain output] & worsening GCS [ie, worsening consciousness] → Prof London Ooi agreeable for CT Abdo pelvis

[Emphasis added in italics and bold]

Thereafter, the Defendant ordered that a percutaneous drainage procedure be performed to drain the loculated fluid collections that were revealed on the 24 July Abdominal CT Scan.<sup>324</sup> However, the procedure was not performed on 24 July because the radiologist asked that Mdm Lee's coagulopathy be corrected first.<sup>325</sup>

158 The Plaintiff's position was that by 24 July, it was "too late" for a further abdominal CT scan.<sup>326</sup> Similarly, neither of his experts specifically challenged Mdm Lee's management on 24 July, save for Dr Nikfarjam's broader assertion that percutaneous drainage should have been performed on or after 17 July.

159 On 25 July, Dr Lim assumed the role of consultant-in-charge of the SICU from Dr Ang. At 0720hrs on 25 July, the Defendant reviewed Mdm Lee

...

- <sup>324</sup> NE 26/1 at pp 33–34
- <sup>325</sup> DAEIC at [99]
- <sup>326</sup> PCS at [336]–[390]

<sup>&</sup>lt;sup>322</sup> PCS at [492]

<sup>&</sup>lt;sup>323</sup> 2AB582

together with Dr Ang and Dr Lim.<sup>327</sup> Dr Lim was of the opinion that any improvement in Mdm Lee's condition had plateaued.<sup>328</sup> The clinical view of both the surgical team and the intensivist team was that she was in the best possible state for any intervention. The Defendant therefore decided to perform a laparotomy instead of a percutaneous drainage procedure.<sup>329</sup> This laparotomy was eventually performed on 26 July.<sup>330</sup>

160 On 27 July, Mdm Lee appeared to improve.<sup>331</sup>

161 At 0445hrs on 28 July, Mdm Lee took a sudden turn for the worse.<sup>332</sup> At 0730hrs, a second laparotomy was performed.<sup>333</sup> Yet, Mdm Lee continued to deteriorate, and passed away that evening.

162 The Plaintiff also did not appear to take issue with the Defendant's management of Mdm Lee from 25 to 28 July. Although the Plaintiff challenged the performance of the two laparotomies (on 26 and 28 July) in his SOC, he did not pursue this allegation at trial or in submissions (see [12] above). I am thus of the view that the Defendant did not fall below the standard of care expected of him in his management of Mdm Lee from 25 to 28 July.

<sup>&</sup>lt;sup>327</sup> 2AB592

<sup>&</sup>lt;sup>328</sup> AEIC of Dr Lim at [5]–[6]

<sup>&</sup>lt;sup>329</sup> DAEIC at [99]; AEIC of Dr Ang at [11]; AEIC of Dr Lim at [6]

<sup>&</sup>lt;sup>330</sup> DAEIC at [101]

<sup>&</sup>lt;sup>331</sup> DAEIC at [106]

<sup>&</sup>lt;sup>332</sup> DAEIC at [107]

<sup>&</sup>lt;sup>333</sup> DAEIC at [108]

## **Causation: hypothetical intermediate events**

163 Even if there was a negligent omission, no liability lies unless the negligence *caused* or *materially contributed* to the injuries suffered (*Yeo Peng Hock Henry v Pai Lily* [2001] 3 SLR(R) 555 at [52]).

164 Given that the Plaintiff did not plead a loss of chance – that the omission of an abdominal CT scan had deprived Mdm Lee of a better chance to live – he bore the burden of proving on a balance of probabilities:

(a) what an abdominal CT scan performed before 2300hrs on16 July would have revealed;

(b) that the results of such an abdominal CT scan would have led to earlier clinical intervention; and

(c) that such earlier clinical intervention would have prevented the demise of Mdm Lee.

165 The Plaintiff submitted that where the loss stemming from a negligent omission could have been avoided if all of several hypothetical intermediate events had occurred, causation is established if the occurrence of *each* intermediate event – assessed individually – is proved on a balance of probabilities. It was immaterial that the entire series of intermediate events, on a cumulative probability, was less likely than not to have occurred.<sup>334</sup>

<sup>334</sup> PRS at [428]

In Brodie McCoy (A Minor by her Mother and Litigation Friend Joanne Jones) v East Midlands Strategic Health Authority [2011] EWHC 38 (QB) ("McCoy"), the plaintiff's mother underwent a cardiotocograph ("CTG") trace scan. The defendant-doctor concluded that the CTG trace results were normal and sent the plaintiff's mother home. The plaintiff was subsequently born with brain damage. The plaintiff alleged that the CTG trace was suspicious and that a further CTG trace should have been ordered. The High Court framed the issue as whether, "had a further scan been carried out on 17<sup>th</sup> March 1993, on a balance of probabilities would it have led to delivery before hypoxia caused brain damage to [the plaintiff]" (at [8(iii)]). Having found that "the [initial] trace is insufficient evidence upon which to conclude that a continued or further trace would have been suspicious", the High Court held (at [81]):

I find on a balance of probabilities that the Claimant has not established that a second or resumed CTG on  $17^{\text{th}}$  March 1993 would have been suspicious or pathological so as to lead her obstetrician to decide that Ms Jones' baby should be delivered on  $18^{\text{th}}$  March 1993 or at any time before  $21^{\text{st}}$  March 1993.

167 Similarly, in *Bright (Billy-Joe Marie) (by her father and litigation friend Peter Bright) v Barnsley District General Hospital NHS Trust* [2005] Lloyd's Rep Med 449 (QB) ("*Bright*"), a doctor negligently omitted to carry out an ultrasound scan to check foetal growth at 32 weeks' gestation. A scan at 32 weeks' gestation had a 60% chance of revealing foetal distress, which would have necessitated a further scan. Such a further scan had an 80% chance of showing a growth restricted foetus, which would have necessitated a careful controlled delivery, which had in turn an 80% chance of delivering an undamaged child. The defendant argued that the cumulative probability of

delivering an undamaged child was thus  $60\% \times 80\% \times 80\% = 38\%$ , which fell short of proof on a balance of probabilities. The English High Court rejected the argument, and held that each probabilistic event was a separate hypothetical fact to be decided on the balance of probabilities (at [35]).

[W]hat would the reasonable radiographer at this hospital have found at the first 32-week scan which should have been carried out? In my judgment, it is settled and conventional law that this is to be answered on the balance of probabilities and it is agreed that on balance that such a scan would probably have revealed a [distressed foetus]. This is a *question of (hypothetical) fact to be decided on a balance of probability. Thereafter*, for the purposes of deciding what would then have happened (ie 32 weeks' scanning revealing [distressed foetus]) is something which is to be *treated as though it would have occurred in fact.* 

[Emphasis added]

168 I agree with this approach. As the English High Court explained, "there should be no difference in approach in ... deciding on what would have happened as opposed to deciding whether something had or had not actually happened" (at [41]). Moreover, the alternative of examining the cumulative probability of a chain of hypothetical events would open the causation inquiry to abuse, for one could formulate an infinite number of intermediate events the occurrence of each of which involves a degree of uncertainty.

## Before 2300hrs on 16 July

169 I have found no breach of duty in the Defendant's omission to perform an abdominal CT scan (and percutaneous drainage) before 2300hrs on 16 July (see [54], [84], and [117] above). This suffices to dispose of the claims in negligence in respect of Mdm Lee's post-operative management before 2300hrs on 16 July. For completeness, I will nevertheless address the point of whether an omission to perform an abdominal CT scan before 2300hrs on 16 July caused Mdm Lee's demise.

170 Dr Beckingham asserted only that an abdominal CT scan performed between 11 July and 2300hrs on 16 July "may well have identified further collections in the abdomen", and that there "may well have been a collection in the pelvis on the 11th which has not yet been drained".<sup>335</sup> This was vague, and did not prove on a balance of probabilities that an abdominal CT scan before 2300hrs on 16 July would have revealed such collections.

171 Dr Mak opined that the images of Mdm Lee's abdomen produced by the 11 July chest CT scan did not show the presence of fluid beyond the right suphrenic space. Accordingly, an abdominal CT scan done on 11 July would have shown only the same fluid in the right suphrenic space revealed on the chest CT scan and no other abnormal features beyond that.<sup>336</sup> Since there were no signs of tenderness, guarding, or rebound tenderness, there would likely have been no evidence of a Dehiscence.

172 Dr Nikfarjam initially gave evidence that an abdominal CT scan performed on 14 July would have revealed the same features shown on the abdominal CT scan that was performed on 17 July (see [118] below). The improvements that Mdm Lee displayed on 15 and 16 July were due to her good organs compensating for the deficiencies in the organs that had failed. By 2300hrs on 16 July, however, she had become so unwell that she was unable to support her vital signs.<sup>337</sup> However, Dr Nikfarjam subsequently

<sup>&</sup>lt;sup>335</sup> NE 15/1 at p 84

<sup>&</sup>lt;sup>336</sup> NE 11/2 at p 25

conceded that the *extent* of the fluid collections revealed would differ between an abdominal CT scan performed on 14 July and the 17 July Abdominal CT Scan. The fluid was building up within Mdm Lee's abdomen between 14 and 17 July.<sup>338</sup>

- Ms Tan: I'm just taking you hypothetically on what you are saying, okay? If the fluid is building up from the 14th to the 17th, are you saying that what you will see on the CT scan on the 14th then will not be what -- be the same as what you see on the CT scan on the 17th?
- Dr Nikfarjam: I will clarify. What I mean is that the patient, if they had an oral contrast, like they did with the CT on the 14th, you would see oral contrast leaving the stomach into the peritoneal cavity; you would see free gas into the peritoneal cavity. The extent of fluid builds up with time, and some of it on the 17th was leaving the abdomen through the drain.

So the amount of fluid, the exact amount wouldn't be exactly the same on the 14th. There would be a buildup to the 17th.

[Emphasis added]

173 On balance, it remained unclear what an abdominal CT scan performed after the 11 July chest CT scan, but before the 17 July Abdominal CT Scan, would have revealed. Hence, the Plaintiff has not established that Mdm Lee would have been managed differently had the Defendant ordered an abdominal CT scan between 11 July and 2300hrs on 16 July. In consequence, I am unable to find on the balance of probabilities that carrying out such a CT scan would have saved her life.

<sup>&</sup>lt;sup>337</sup> NE 21/1 at pp 62–63

<sup>&</sup>lt;sup>338</sup> NE 21/1 at pp 64, 67–68

#### After 2300hrs on 16 July

174 The Plaintiff made no submissions on the question of causation in relation to the events after 2300hrs on 16 July.<sup>339</sup> I reiterate that Mdm Lee was in no condition for percutaneous drainage from 17 to 19 July (see [137]–[140] above), while percutaneous drainage was in fact ordered on 24 July (see [156] above). This leaves only the period from 20 to 23 July.

In my view, even if the Defendant had ordered a percutaneous drainage procedure between 20 and 23 July, it was unlikely that the procedure would have been performed immediately. Mdm Lee was in no better a coagulopathic state from 20 to 23 July than she was in on 24 July.<sup>340</sup> At 1730hrs on 24 July, the radiologist tasked with performing the percutaneous drainage ordered by the Defendant had directed that the coagulopathy be corrected first (see [157] above), and the correction had not been completed by 0720hrs the following morning.<sup>341</sup>

176 Accordingly, the Plaintiff has not established that the Defendant's omission to order a further abdominal CT scan (and a percutaneous drainage procedure) between 2300hrs on 16 July and the 24 July Abdominal CT Scan caused Mdm Lee's demise.

<sup>&</sup>lt;sup>339</sup> PRS at [432]

<sup>&</sup>lt;sup>340</sup> 3AB898 (20 July); 902 (21 July); 907 (22 July)

<sup>&</sup>lt;sup>341</sup> DAEIC at [99]

## Feeds

177 It was not part of the Plaintiff's pleaded case that Mdm Lee's postoperative feeding between 11 July and 2300hrs on 16 July was inappropriate.<sup>342</sup> However, the question of feeding was raised by the Plaintiff at trial and in submission. For completeness, I will consider the feeds provided to Mdm Lee that have been raised by the Plaintiff.

178 The Plaintiff submitted that "the major disruption late on 16 July 2011 was likely the result of the Defendant's failure to cease oral feeding and on the contrary increasing Mdm Lee's feeding to full liquid feeds and soft feeds thereafter."<sup>343</sup>

### 11 July to 1900hrs on 13 July

179 From 11 July until 1900hrs on 13 July, Mdm Lee had small liquid feeds.

180 The Plaintiff submitted that "it was imperative to be certain that a patient did not have a Leak prior to commencing them on feeding."<sup>344</sup> Hence, the only prudent course from 11 July was to keep Mdm Lee Nil-by-Mouth (*ie*, no oral feeding).<sup>345</sup> He relied on Dr Mak's opinion that oral feeds may aggravate a Dehiscence,<sup>346</sup> on Dr Beckingham's assertion that "pouring fluid into her mouth [without eliminating the possibility of a Dehiscence] may

<sup>&</sup>lt;sup>342</sup> PCS at [35]–[43]

<sup>&</sup>lt;sup>343</sup> PCS at [428]

<sup>&</sup>lt;sup>344</sup> PCS at [109]

<sup>&</sup>lt;sup>345</sup> PRS at [129]

<sup>&</sup>lt;sup>346</sup> NE 12/2 at pp 49–50

cause infection or irritation and cause a SIRS response"<sup>347</sup> [see [190] below], and on Dr Nikfarjam's evidence that "[i]n patients with a PG [anastomosis], once a major anastomotic leak occurs food and fluid that is taken orally is likely to leak out the stomach, exacerbating the problem."<sup>348</sup>

181 However, Dr Beckingham testified that the small liquid feeds were "insignificant",<sup>349</sup> did not do any harm,<sup>350</sup> and were "reasonable" *whether or not Mdm Lee had a Dehiscence*.<sup>351</sup> Dr Nikfarjam agreed that there was "no established restriction against giving oral intake after a POPF, by definition, is present",<sup>352</sup> and that it was appropriate that she was "put progressively on liquids" from 8 to 13 July.<sup>353</sup>

182 Given that the Defendant had observed that Mdm Lee had tolerated her liquid feeds well, the Plaintiff has not established that the feeds from 11 July to 1900hrs on 13 July were inappropriate.

### 1900hrs on 13 July to 1900hrs on 14 July

183 From 1900hrs on 13 July until the morning of 14 July, Mdm Lee had a soft *food*<sup>354</sup> diet.<sup>355</sup> However, after her bout of abdominal pain at 1000hrs on 14 July (at [85] above), she was kept Nil-by-Mouth.<sup>356</sup>

<sup>&</sup>lt;sup>347</sup> NE 15/1 at pp 115–116

<sup>&</sup>lt;sup>348</sup> AEIC of Dr Nikfarjam at p 65

<sup>&</sup>lt;sup>349</sup> NE 15/1 at p 132

<sup>&</sup>lt;sup>350</sup> NE 15/1 at p 134

<sup>&</sup>lt;sup>351</sup> NE 15/1 at p 134

<sup>&</sup>lt;sup>352</sup> NE 21/1 at p 114

<sup>&</sup>lt;sup>353</sup> NE 21/1 at p 120

<sup>&</sup>lt;sup>354</sup> Exhibit P1 at 65

184 The Plaintiff submitted that the signs and symptoms exhibited by Mdm Lee on and after 14 July (at [85]–[87] above]) "started surfacing almost immediately after Mdm Lee was commenced on soft foods in the evening of 13 July".<sup>357</sup> He concluded that "[a]s evident from the final outcome, the result of commencing soft foods was truly disastrous and could have been avoided."<sup>358</sup>

185 However, neither of the Plaintiff's experts took issue with this soft food diet and the placing of Mdm Lee Nil-by-Mouth thereafter. Dr Nikfarjam found the soft food diet reasonable and "the correct order to make", even if there was a POPF by definition.<sup>359</sup> Dr Beckingham testified that the soft food diet was reasonable only if there was no Dehiscence,<sup>360</sup> but conceded that there was no evidence that it produced sufficient gastric fluid to cause pain, and that any such increase in gastric fluid could in any event have been controlled by the abdominal drains.<sup>361</sup>

186 Accordingly, the Plaintiff has not established that the feeds from 1900hrs on 13 July to 1900hrs on 14 July were inappropriate.

## 1900hrs on 14 July to 2300hrs on 16 July

187 Around 1900hrs on 14 July, when the pain had subsided, Mdm Lee was given 250ml of small *liquid*<sup>362</sup> feeds.<sup>363</sup>

- <sup>358</sup> PCS at [259]–[260]
- <sup>359</sup> NE 21/1 at pp 121, 131–132
- <sup>360</sup> NE 15/1 at p 135
- <sup>361</sup> NE 15/1 at pp 149, 151

<sup>&</sup>lt;sup>355</sup> 1AB133–134, 345–346

<sup>&</sup>lt;sup>356</sup> 2AB465, 467

<sup>&</sup>lt;sup>357</sup> PCS at [259]

188 At 0810hrs on 15 July, the surgical team increased Mdm Lee's liquid feeds to 500ml/day after reviewing her and finding no complaints of pain. At 1320hrs, she had taken her liquid feeds well, continued to have no complaints, and was cheerful, mobilising, and hungry. Her abdominal signs were normal, soft and non-distended, and she was passing flatus. The Defendant thus increased her liquid feeds to 1L/day.<sup>364</sup> At 2130hrs, she had tolerated these full or unrestricted<sup>365</sup> liquid feeds well.<sup>366</sup>

189 On 16 July, Mdm Lee was continued on full liquid feeds. At 0903hrs, she had 200ml of coffee.<sup>367</sup> At 0930hrs, the Defendant ordered that a soft food diet be kept in view if there was no more pain (although Mdm Lee never did progress to the soft food diet).<sup>368</sup> At 1300hrs, Mdm Lee had 100ml of Milo.<sup>369</sup> Thereafter, she continued to be clinically well despite her abdominal pain, which was localised to faecal loading and which resolved once she passed motion. The full liquid feeds were thus maintained.370

190 The Plaintiff submitted that the major disruption late on 16 July 2011 stemmed from the Defendant's failure to cease oral feeding. Instead, the

362	Exhibit P1 at 64
363	2AB471
364	DAEIC at [83]
365	Exhibit P1 at 34
366	2AB479
367	1AB142
368	2AB481
369	1AB143

370 DAEIC at [84] Defendant put Mdm Lee on full liquid feeds.<sup>371</sup> The Plaintiff cited the oral evidence-in-chief of Dr Beckingham:<sup>372</sup>

Well, we know that we already have a pancreatic leak, by definition; but something has changed on the 16th. And I think what has happened is that from the period from the 4th to 16th there has obviously been a pancreatic fistula present, but on the 16th, either with the *introduction* of **food** on the two days -- *which starts two days before*, that that has enlarged the fistula. The fistula is a hole between the stomach and the peritoneal cavity. So whether that has enlarged it or it's become a secondary infection, one of these two features has introduced what we call a Systemic Inflammatory Response Syndrome, a SIRS attack, which is where the body basically starts to react against itself and causes breakdown of various organs, which we see evident in Mdm Lee later on.

[Emphasis added in italics and bold]

191 I make three observations.

192 First, Dr Beckingham's opinion above had to be viewed with circumspection. It was unclear whether his reference to "food" on 14 July was to the soft food diet that morning or the small liquid feeds that evening: the Plaintiff could not prove that the soft food diet that morning was unreasonable (see [184] above), while Dr Beckingham accepted that the small liquid feeds that evening were appropriate.<sup>373</sup> It was also unclear whether Dr Beckingham had mistakenly believed that Mdm Lee had consumed *solid* foods rather than *liquid* feeds from 1900hrs on 14 July. I thus hesitate to conclude that the liquid feeds on 15 July exacerbated the POPF. Dr Beckingham's subsequent comment in cross-examination that "the thing that I would not want to do is

<sup>&</sup>lt;sup>371</sup> PCS at [428]

<sup>&</sup>lt;sup>372</sup> NE 14/1 at p 33

<sup>&</sup>lt;sup>373</sup> NE 15/1 at p 142

*start* pouring fluid into her mouth ... which may cause infection or irritation and cause a SIRS response [emphasis added]"<sup>374</sup> was, with respect, unconsidered, given his earlier acceptance that small fluid feeds would be insignificant and not cause any harm (see [181] above). Indeed, the Plaintiff relied on the comment not to show that the liquid feeds had in themselves caused or materially contributed to Mdm Lee's condition at 2300hrs on 16 July, but only to establish that there was already a Dehiscence.<sup>375</sup>

193 Secondly, although Dr Mak said that he would not have given small liquid feeds of up to 1L/day from 15 July, he added that there was no evidence that the Dehiscence was aggravated by the liquid feeds that Mdm Lee had from the evening of 15 July.<sup>376</sup>

194 Thirdly, Dr Nikfarjam, who took the position that Mdm Lee had a Dehiscence by 7 July, nevertheless agreed that the "continuation of liquids from 14th night to 16<sup>th</sup> [was] reasonable."<sup>377</sup>

195 In the interests of completeness, I note also that Dr Mak accepted in cross-examination that he would not have ordered liquid feeds of 1L/day on 15 July if he had suspected that Mdm Lee had a Dehiscence.<sup>378</sup> However, the questions put to him in cross-examination were limited to what he himself would have done on 15 July, and not whether what the Defendant in fact did

<sup>378</sup> NE 12/2 at pp 103–104

<sup>&</sup>lt;sup>374</sup> NE 15/1 at p 115

<sup>&</sup>lt;sup>375</sup> PCS at [109]

<sup>&</sup>lt;sup>376</sup> NE 12/2 at p 131

<sup>&</sup>lt;sup>377</sup> NE 21/1 p 133

on 15 July was negligent. Neither party addressed this aspect of Dr Mak's evidence in its submissions.

196 Accordingly, I find on a balance of probabilities that the Plaintiff has failed to establish that Mdm Lee's feeds caused or materially contributed to the injuries suffered by her.

#### Conclusion

197 The Plaintiff has taken a machine-gun approach with his allegations in the hope that one of the bullets fired would find its target. In his SOC, he alleged that the Defendant (a) failed to obtain the informed consent of Mdm Lee to the Whipple operation; (b) failed to perform the Whipple operation and two subsequent surgeries in the manner required of an HPB specialist; and (c) failed to deliver timely and appropriate post-operative care (see [11] above). It was only before the trial commenced that he narrowed his allegation to the post-operative management of Mdm Lee, which was limited to the period between the Whipple operation on 4 July and 17 July (although he subsequently attempted to extend it up to 24 or 26 July) (see [12] and [47] above). Even then, many of his allegations of negligence were not borne out by the evidence of his experts.

198 Unfortunately, the Defendant also muddied the waters by his attempts to downplay the possibility that Mdm Lee had suffered a Dehiscence, which included the tenuous distinctions between a POPF and a Dehiscence, and between suspecting and diagnosing each condition. These assertions were contrived, particularly in view of the Defendant's belated submission that he had suspected a Dehiscence from 7 July (see [40] above). Even so, the burden remains on the Plaintiff to prove his case on a balance of probabilities.

199 The Plaintiff has not shown that the Defendant was negligent in omitting to order an abdominal CT scan before 2300hrs on 16 July. Even if it was open to him to argue that a further abdominal CT scan should have been performed before 1430hrs on 24 July, he has also been unable to establish that the Defendant was negligent in failing to do so. Further, he has not established that such an abdominal CT scan or further abdominal CT scan would have led the Defendant to have managed Mdm Lee differently. Finally, he has not proven that such a different management of Mdm Lee would have saved her life.

200 Accordingly, I find that the Plaintiff has failed to discharge his burden of proof. I dismiss his claim against the Defendant.

201 I will hear the parties on costs.

I record my appreciation for the assistance rendered by Dr Winston Woon, Senior Consultant, HPB Surgery Service, at Tan Tock Seng Hospital. He was an assessor appointed by the court and gave as much of his time as he could.

90

[2016] SGHC 168

Woo Bih Li Judge

> Tan Chee Meng SC, Sngeeta Rai, Tang Shangwei, Chan Soh Lei Kerry (WongPartnership LLP) for the plaintiff; Kristy Tan, Tham Chuen Min Jasmine, Tham Hsu Hsien (Allen & Gledhill LLP) for the defendant.

#### Annex

## Special article

# Postoperative pancreatic fistula: An international study group (ISGPF) definition

Claudio Bassi, MD,<sup>a</sup> Christos Dervenis, MD,<sup>b</sup> Giovanni Butturini, MD,<sup>a</sup> Abe Fingerhut, MD,<sup>c</sup> Charles Yeo, MD,<sup>d</sup> Jakob Izbicki, MD,<sup>c</sup> John Neoptolemos, MD,<sup>f</sup> Michael Sarr, MD,<sup>g</sup> William Traverso, MD,<sup>b</sup> and Marcus Buchler, MD,<sup>i</sup> for the International Study Group on Pancreatic Fistula Definition,\*Vorona, Italy; Athens, Graece; Poissy, France; Baltimore, Md; Liverpool, United Kingdom;

Hamburg, Germany; Rochester, NY; Seattle, Wash; and Heidelberg, Germany

**Background.** Postoperative pancreatic fistula (POPF) is still regarded as a major complication. The incidence of POPF varies greatly in different reports, depending on the definition applied at each surgical center. Our aim was to agree upon an objective and internationally accepted definition to allow comparison of different surgical experiences.

comparison of different surgical experiences. Methods. An international panel of pancreatic surgeons, working in well-known, high-volume centers, reviewed the literature on the topic and worked together to develop a simple, objective, reliable, and easyto-apply definition of POPF, graded primarily on clinical impact.

**Results**. A POPF represents a failure of healing/sealing of a pancreatic-enteric anastomosis or a parenchymal leak not directly related to an anastomosis. An all-inclusive definition is a drain output of any measurable volume of fluid on or after postoperative day 3 with an amylase content greater than 3 times the serum amylase activity. Three different grades of POPF (grades A, B, C) are defined according to the clinical impact on the patient's hospital course.

to the clinical impact on the patient's hospital course. Conclusions. The present definition and clinical grading of POPF should allow realistic comparisons of surgical experiences in the future when new techniques, new operations, or new pharmacologic agents that may impact surgical treatment of pancreatic disorders are addressed. (Surgery 2005;138:8-13.)

From the Surgical and Gastroenterological Department, Haspital "G.B. Rossi"<sup>a</sup> University of Verona; the Surgical Department, Agia Olga Hospital,<sup>b</sup> Athens; the General and Digestive Surgery Unit, Centre Haspitalier Intercommunal,<sup>c</sup> Poissy; the Surgical Department, Johns Hopkins, Hospital,<sup>d</sup> Baltimon, Md; the Surgical Department,<sup>e</sup> University Hospital, Hamburg the Surgical Department,<sup>f</sup> Royal University Hospital, Liverpool; the Surgical Department, Mayo Clinic,<sup>e</sup> Rochester; the Surgical Department, Virginia Mason Clinic,<sup>h</sup> Seattle; the Surgical Department,<sup>f</sup> University Hospital, Heidelberg

Accepted for publication May 9, 2005.

Reprint requests: Claudio Bassi, MD, Surgical and Gastroenterological Department, Hospital "G.B. Rossi,\* University of Verona, 37134-Verona, Italy. E-mail: claudio.bassi@univr.it.

\*Members of the International Study Group on Pancreatic Fistula Definition (ISGPF): Claudio Bassi (Verona, Italy), Christos Dervenis (Athens, Greece), Abe Fingerhut (Poissy, France), Charles Yeo (Baltimore, Maryland, USA), John Neoptolemos MD (Liverpool, UK), Masayuki Imamura (Kyoto, Japan), Michael Sarr (Rochester, NY, USA), William Traverso (Seattle, Washington, USA), Marcus Buchler (Heidelberg, Germany), Keith Lillemoe (Indianapolis, Indiana, USA), Carlos Femandez de Castillo (Boston, Massachusetts, USA), Laureano Fernanadez Cruz (Barcelona, Spain), Clem Imrie (Glasgow, UK), Roland Andersson (Lund, Sweden), Dirk Gouma (Amsterdam, Netherland), Milicevic Miroslaw and Lijli Pettijonevic (Belgrade, Yugoslavia), Andren Ake Sandberg (Gothemburg, Sweden), Tadahiro Takada (Tokio, Japan), Valerio Di Carlo (Milan, Italy), Joè Eduardo Cunha (San Paulo, Brasil), Rob Petbury (Adelaide, Australia), Helmut Friess (Heidelberg, Germany), Krzysztof Bielecki (Warsaw, Pohand), Effhimios Chatzitheolitos (Thessaloniki, Greece), Gregor Tsiotos (Athens, Greece), Colin Johnson (Southampton, UK), Mike Mac Mahon (Leeds, UK), John Branis (Athers, Greece), Attila Olah (Gyor, Hungary), Tibor Tihani (Budapest, Hungary), Robin Williamson (London, UK), Jakob Izbicki (Hamburg, Germany), Giovanni Butturini (Verona, Italy), Roberto Salvia (Verona, Italy), Nora Sartori (Verona, Italy), Massimo Falconi (Verona, Italy), Paolo Pederzoli (Verona, Italy).

0039-6060/\$ - see front matter

© 2005 Mosby, Inc. All rights reserved. doi:10.1016/j.surg.2005.05.001

8 SURGERY

Surgery Volume 138, Number 1

A UNIVERSALLY ACCEPTED, objective definition of a pancreatic anastomotic leak is absent in the gastrointestinal surgical literature, leading to an inability to compare objectively the surgical experiences with different operations, techniques, or pharmacologic adjuvants in pancreatic surgery.<sup>151</sup> Currently among high-volume centers, the mortality rate after pancreatic resection has decreased to less than 5%, but the morbidity remains high, ranging from 30% to 50%.<sup>351</sup> Postoperative pancreatic fistula (POPF) has been regarded traditionally as the most frequent major complication and is a potentially serious, life-threatening event that may prolong hospital stay and increase costs.

With the advent of innovative techniques in many different aspects of pancreatic surgery, an objective and uniform definition of POPF should be developed to allow accurate comparison of different surgical experiences.<sup>1,3,55</sup> After pancreaticoduodenectomy, the reported rate of POPF is highly variable, ranging from 2%<sup>4</sup> to more than 20%.<sup>5,22,23,30,39,40,43,47,51</sup> These differences might be related to the variability of the definitions used. In a recent study,3 a Medline search of the last 10 years for definitions of POPF was performed. A score was assigned to the definitions used for POPF on the basis of 2 basic parameters: daily output (milliliters) and duration of the fistula. Among the 26 different definitions of POPF used, only 14 were found suitable to apply a score on the basis of these 2 basic parameters. Four final definitions summarizing the various aspects of POPF were formulated (Table I) and then applied to a group of 242 patients in a single center who underwent proximal or central pancreatectomy with a pancreatic-enteric anastomosis. The incidence of POPF ranged from 10% to 29% according to the different definitions applied. Interestingly, there were marked differences in the "incidence" of POPF, depending on the definition used.3 On the basis of this study, an international consensus was reached that a common, objective definition of POPF was necessary. Our aim was to formulate an acceptable and objective definition of POPF that decreases interobserver variability.

#### METHODS

An international working group of 37 pancreatic surgeons from Europe, Japan, Australia, North America, and South America was convened. All the involved surgeons work in well-known international, high-volume centers, and their clinical experiences are well documented in scientific papers. They reviewed both the literature and their institutional experience. Draft definitions Bassi et al 9

Table I. Four final definitions summarizing the current pancreatic fistula concept according to the literature\*

- Output > 10 mL/d of amylase-rich fluid postoperative (postop) day 5 or for > 5 days.
- Output > 10 mL/d of amylase-rich fluid after postop day 8 or for > 8 days.
- Output between 25 mL/d and 100 mL/d of amylase-rich fluid after postop day 8 or for > 8 days.
- Output > than 50 mL/d of amylase-rich fluid after postop day 11 or for > 11 days.

\*Source: Bassi C et al<sup>8</sup>.

and severity grades of fistula were circulated to all participants for comment. Revised definitions were circulated for approval or further comment. After more than 1 year of electronic mail or, on occasion, face-to-face discussions, the final version of the POPF definition reported here was discussed during the International Postgraduate Course "HPB Marathon" held in Athens, Greece, on March 2004 and then updated during the "Pancreas Cancer Conference" held in Tirrenia, Italy, on April 2004, the 6th World Congress of the International Hepato Pancreatic Biliary Association held in Washington DC, USA, on June 2004, and during the European Pancreatic Club held in Padova, Italy, in the same month.

#### RESULTS

Terminology. The most commonly used terms to identify the complication are as follows: fistula, leak, leakage, focal postoperative pancreatitis, and anastomotic failure or anastomotic insufficiency.151 The Heidelberg and Johns Hopkins groups used a similar definition of POPF: drainage of more than 50 mL of fluid in 24 hours, with an amylase content of more than 3 times the serum amylase activity for more than 10 days after operation.<sup>4,15</sup> German and Italian studies<sup>8,10</sup> used a definition of POPF as drainage fluid of more than 10 mL in 24 hours with the amylase at least 3 times the normal serum activity 3 or 4 days postoperatively. A less-strict definition was used by a Japanese group45: fluid drainage for more than 7 days postoperatively containing amylase activity of more than 3 times the serum activity. Others suggested that radiologic imaging is necessary for a definitive diagnosis.<sup>5,11,21,23,29,30</sup> In 1997, Lowy et al19 introduced the concept of a "clinically significant leak" defined as fever (>38°C), leukocyte count of greater than 10,000 cells/mm<sup>8</sup>, sepsis, and/or the need for drainage.

Surgery July 2005

#### 10 Bassi et al

It is clear from these and other definitions used and from a general review of the related literature<sup>1-51</sup> that there is considerable overlap of the terms *fistula* and *leak*; they appear to be contingent definitions, and the terms *fistula*, *leak*, *leakage*, and *anastomotic insufficiency* should be considered interchangeable. The vast majority of the surgeons involved in the ISGPF currently prefer to use the term *fistula*.

**Definition of POPF.** A general definition of pancreatic fistula is an abnormal communication between the pancreatic ductal epithelium and another epithelial surface containing pancreasderived, enzyme-rich fluid. However, a POPF represents failure of healing/sealing of a pancreatic-enteric anastomosis, or it may represent a parenchymal leak not directly related to an anastomosis such as one originating from the raw pancreatic surface (eg, left or central pancreatectomy, enucleation, and/or trauma). In this case, there is a leak from the pancreatic ductal system into and around the pancreas and not necessarily to another epithelialized surface (eg, via a surgical drain).

Suspicion and diagnosis. The diagnosis of POPF may be suspected on the basis of the many clinical or biochemical findings. A broad definition begins with the following criteria: Output via an operatively placed drain (or a subsequently placed, percutaneous drain) of any measurable volume of drain fluid on or after postoperative day 3, with an amylase content greater than 3 times the upper normal serum value.

Drain fluid could have a "sinister appearance" that may vary from a dark brown to greenish bilious fluid (provided the anastomosis is near or aborad to a bilioenteric anastomosis) to milky water to clear "spring water" that looks like pancreatic juice. Associated clinical findings may include abdominal pain and distention with impaired bowel function, delayed gastric emptying; fever (>38°C), serum leukocyte count greater than 10,000 cells/mm<sup>3</sup>, and increased C-reactive protein may also be present.

Radiologic documentation is neither mandatory nor necessarily recommended for diagnosis.<sup>38</sup> However, imaging may be useful by identifying erosion or migration of the drain into an enteric viscus and thus the need for drain withdrawal to allow healing of the site of erosion.

**Grading.** Since the broad definition may be so inclusive that many asymptomatic patients that fit the definition of POPF may not be clinically ill, we also propose a clinical grading system for POPF (grades A, B, C). Table II is an attempt to summa-

Table II. Main parameters for POPF gra	ding
--	------

Grade	Α	В	C
Clinical conditions	Well	Often well	Ill appearing/ bad
Specific teatment*	No	Yes/no	Yes
US/CT (if obtained)	Negative	Negative/ positive	Positive
Persistent drainage (after 3 weeks)†	No	Usually yes	Yes
Reoperation	No	No	Yes
Death related to POPF	No	No	Possibly yes
Signs of infections	No	Yes	Yes
Sepsis	No	No	Yes
Readmission	No	Yes/no	Yes/no

US, Ultrasonography; CT, computed tomographic scan; POPF, postoperative pancreatic fistula.

\*Paraal (peripheral) or total parenteral nutrition, antibiotics, enteral nutrition, somatostatin analogue and/or minimal invasive drainage. †With or without a drain in situ.

rize the main features of each POPF grade. The grade of severity may only be decided after complete follow-up, including discharge from the hospital or death, when the ultimate effect of the POPF on outcome can be determined.

POPF grade A: This grade of POPF is the most common; called "transient fistula," it has no clinical impact. Grade A POPF requires little change in management or deviation from the normal clinical pathway. The patient is fed orally and remains clinically well, and the use of total parenteral nutrition, antibiotics, or somatostatin analogues are not indicated. A computed tomographic (CT) scan typically shows no peripancreatic fluid collections. Grade A POPF is not associated with a delay in hospital discharge and is managed frequently by slow removal of the operatively placed drains.

POPF grade B: This POPF grade requires a change in management or adjustment in the clinical pathway. Often the patient is kept with nothing by mouth (NPO) and is supported with partial or total parenteral or enteral nutrition. The peripancreatic drains are usually maintained in place, but if the drains are not functioning to fully drain the fistula, a CT scan may show peripancreatic collection(s) requiring repositioning of the drains. When associated with abdominal pain, fever, and/or leukocytosis, antibiotics are usually required; somatostatin analogues may also be used. Grade B POPF usually leads to a delay in discharge, or readmission after a previous discharge may be required. Many patients with grade B POPF can be discharged with drains in situ and observed in the outpatient setting. If an invasive

Bassi et al 11

Surgery Volume 138, Number 1

procedure is needed, the POPF shifts into grade C (see below).

POPF grade C: In a grade C POPF, a major change in clinical management or deviation from the normal clinical pathway occurs. Clinical stability may be border line. Clinical intervention is aggressive with the patient kept NPO and total parenteral nutrition or enteral nutrition, intravenous antibiotics, and somatostatin analogues instituted, often in an intensive care unit setting. A CT scan usually shows worrisome, peripancreatic fluid collection(s) that require percutaneous drainage. The patient typically requires an extended hospital stay with a major delay in hospital discharge.

A deteriorating clinical status with a grade C POPF, together with sepsis and organ dysfunction, may require re-exploration for 1 of 3 options: (1) an attempt to repair the site of leakage with wide peripancreatic drainage, (2) conversion to alternative means of pancreatic-enteric anastomosis (eg, conversion of pancreatic-enteric anastomosis (eg, conversion of pancreatic-option pancreaticogastrostomy), or (3) completion pancreatectomy. In patients with grade C POPF, there are often associated complications and the possibility of postoperative mortality.

#### DISCUSSION

The word *fistula* (according to Stedman's Concise Dictionary) is "an abnormal passage from one epithelialized surface to another, congenital or created surgically." *Leak* and *leakage* are more common words that relate to the escape of fluid: *leak* means "to let out" or "to escape through a hole, crevice or other opening," while *leakage* is the "act, process, or instance of leaking of fluid"; indeed, *fistula* seems to be the more appropriate term for the common complication after pancreatic surgery.

In the pancreatic surgery literature, it is almost impossible to find the same definition of POPF in any 2 papers.<sup>5</sup> Even authors highly specialized in pancreatic surgery do not provide a simple and reliable definition but still report surprisingly high rates of "collections," "abscesses," "re-operation," and "mortality rates," in many cases related to anastomotic failure. Yet, they report a simultaneous low incidence of POPF.<sup>\$1,35,34</sup> Since these different definitions could lead to misleading discrepancies on the basis of only differences in terminology, and since intra-abdominal collections and abscesses may be a manifestation of pancreatic anastomotic failure,<sup>8,58</sup> we suggest the need to propose a unifying definition of POPF.

Clinically, POPF may be suspected early (after postoperative day 3) on the basis of the quality rather than the amount of drain output, but only a long-standing observation will confirm the diagnosis because many patients will have an inflammatory serous output not related to anastomotic leak. Indeed, only after clinical recovery is complete, is it possible to ultimately distinguish and to grade the POPF as grades A, B, and C with respect to the clinical impact.

The volume of fluid output on any one day is relative, as demonstrated by the wide range reported in the literature.<sup>5,2,2,2,3,30,39,40-45,47-51</sup> Also, one must consider the duration of the complication. In some cases, as in left resections,<sup>7,27,32-34</sup> POPF may be characterized by an output of a few drops of "sinister fluid," frequently appearing as pus, leading to hesitation in removing the drain. With the present definition, these situations are graded as group A as long as the patient is asymptomatic or as grade B if there are related symptoms or an in situ drain with management in the outpatient setting for more than 3 weeks postoperatively.

As further emphasis of the confusing definitions that are based strictly on the quantitative drain output, it is interesting to note that some authors have modified their definition of *fistula* during the last few years, increasing the daily output value from 10 to 50 mL.<sup>4,30</sup> Also, one must consider that currently the clinical impact of complications in pancreatic surgery is less than that in the past.<sup>29,50,35,36,39</sup>

The amylase content is well recognized as an integral and unavoidable biochemical definition of POPF, but the amylase activity can range from hundreds to thousands of International Units depending on pancreatic glandular function and dilution by inflammatory scrous fluid: There do not seem to be any data suggesting a reliable cutoff value for absolute amylase activity.<sup>46,47</sup> The surgeons participating in our consensus agreed to a broadly inclusive value of more than 3 times the normal serum value to denote when the POPF is first "suspected." Only later can the POPF be graded.

The routine use of imaging for staging POPF was reported in only 7 of the 26 definitions collected.<sup>5,11,21,25,29,50,47,50,51</sup> As already stressed, sinography should not be considered mandatory or recommended for diagnosis, but, in selected patients, it may be useful for management. For example, the retrospective analysis of the postoperative complications occurring in the Verona patients showed that several of the recorded POPFs were, in fact, enterocutaneous fistulas caused by the drainage tube having eroded into

Surgery July 2005

#### 12 Bassi et al

the jejunum.<sup>30</sup> These enteric fistulas closed quickly on withdrawal of the drain.

Finally, among the clinical parameters to be considered, the duration (and delay) of hospital stay should be addressed. After collecting and analyzing these data among different centers in different countries, it seems reasonable to limit the definition of duration of hospital stay to 1 standard deviation beyond the mean length of stay for all personal cases, as suggested recently by Traverso et al.<sup>37</sup> We decided not to use this parameter in the suggested grading because other, more simple parameters appear to be able to distinguish between grades A, B, and C. Moreover, because delay in hospital stay is variable between countries, it would require an institution to calculate its own average duration of stay, which places an extra constraint on defining and grading POPF. Should the term POPF itself be reviewed in some way? For example, do we need to add to our definition the concept of perianastomotic collections or abscess that, when percutaneously drained, do not prolong the hospital discharge? Should percutaneous drainage place the patient into a lesser category than those of patients who require reoperation for complication of an anastomotic leak? Using our criteria, we capture these conditions into POPF grade C.

The usefulness of the clinical grading system becomes apparent with the following 2 examples. The all-inclusive broad definition using drain volume or amylase concentration cannot be used by those surgeons who do not place drains intraoperatively.<sup>26,42</sup> Also, even if drains are used, they may not be located near the collection from the leaking anastomosis, and the drain would not indicate a leak. These 2 examples would escape our broad definition until an invasive procedure was required but then would be included in the POPF clinical grading (grade C).

Moreover, one also could include in grade B a patient who had no drains but had postoperative mild fever, leukocytosis, and ileus, and a small amount of peripancreatic fluid collection detected on ultrasonography or CT scan, and who was treated with a course of antibiotics and recovered without invasive procedures.

We suggest that use of our proposed definition of POPF will confirm its clinical value and allow accurate comparison of different surgical experiences.

#### REFERENCES

 Bruce J, Krukowski ZH, Al-Khairy G, Russel EM, Park KG. Systematic review of the definition and measurement of anastomotic leak after gastrointestinal surgery. Br J Surg 2001;88:1157-68.

- Martin RC 2nd, Brennan MF, Jaques DP. Quality of complication reporting in the surgical literature. Ann Surg 2009-295-803-13.
- Bassi C, Butturini G, Molinari E, et al. Pancreatic fistola rate after pancreatic resection: the importance of definitions. Dig Surg 2004:21:54-9.
- Buchler MW, Friess H, Wagner M, Kulli C, Wagener V, Z'Graggen K. Pancreatic fistula after pancreatic head resection. Br J Surg 2000;87:883-9.
- Sato N, Yamaguchi K, Chijiwa K, Tanaka M. Risk analysis of pancreatic fistula after pancreatic head resection. Arch Surg 1998;33:1094-8.
- Ishikawa O, Ohigashi H, Imaoka S, et al. Concomitant benefit of preoperative irradiation in preventing pancreas fistula formation after pancreatoduodenectomy. Arch Surg 1991;126:885-9.
- Cogbill TH, Moore EE, Morris JA, et al. Distal pancreatectomy for trauma: a multicenter experience. J Trauma 1991; 31:1600-6.
- Buchler M, Friess H, Klempa I, et al. Role of octreotide in the prevention of postoperative complications following pancreatic resection. Am J Surg 1992;163:125-30.
- Ihse I, Lansson J, Lindstrom E. Surgical management of pure pancreatic fistulas. Hepatogastroenterology 1994;41: 271-5.
- Pederzoli P, Bassi C, Falconi M, Camboni MG. Efficacy of octreotide in the prevention of complications of elective pancreatic surgery. Br J Surg 1994;81:265-9.
- Cullen JJ, Sarr MG, Ilstrup DM. Pancreatic anastomotic leak after pancreaticoduodenectomy: incidence, significance and management. Am J Surg 1994;168:295-8.
- Fernandez-del Castillo C, Ratiner DW, Warshaw AL. Standards for pancreatic resection in the 1990s. Arch Surg 1995; 130:295-9.
- Yeo CJ, Cameron JL, Maher MM, et al. A prospective randomized trial of pancreaticogastrostomy versus pancreaticojejunostomy after pancreaticoduodenectomy. Ann Surg 1995;222:580-8.
- Nwariaku FE, Terracina A, Mileski WJ, Minei JP, Carrico CJ. Is octreotide beneficial following pancreatic injury? Am J Surg 1995;170:582-5.
- Parviainen MC, Sand JA, Nordback IH. Coincidence of pancreatic and biliary leakages after pancreaticoduodenal resections. Hepatogastroenterology 1996;43: 1246-9.
- Ridgeway MG, Stabile BE. Surgical management and treatment of pancreatic fistulas. Surg Clin North Am 1996;76: 1159-73.
- Andivot T, Cardoso J, Dousset B, Soubrane O, Bonnichon P, Chapuis Y. Complications of two types of pancreatic anastomosis after pancreaticoduodenectomy. Ann Chir 1996;50: 431-7.
- Howard JM. Pancreatojejunostomy: leakage is a preventable complication of the Whipple resection. J Am Coll Surg 1997;184:454-7.
- Lowy AM, Lee JE, Pisters PW, et al. Prospective, randomized trial of octreotide to prevent pancreatic fistula after pancreaticoduodenectomy for malignant disease. Ann Surg 1997;226:632-41.
- Akhrass R, Yaffe MB, Brandt CP, Reigle M, Fallon VF Jr, Malangoni MA. Pancreatic trauma: a ten-year multi-institutional experience. Am Surg 1997;63:598-604.
- Chew DKW, Attiyeh FF. Experience with the Whipple procedure (Pancreaticoduodenectomy) in a Universityaffiliated community hospital. Am J Surg 1997;174: 312-5.

Bassi et al 13

Surgery Volume 138, Number 1

- Howard TJ, Stonerock CE, Sarkar J, et al. Contemporary treatment strategies for external pancreatic fistulas. Surgery 1998;124:627-32.
- Cunningham JD, Weyant MT, Levitt M, Brower ST, Aufses AH Jr. Complications requiring reoperation following pancreatectomy. Int J Pancreatol 1998;24:23-9.
- Young PR Jr, Meredith JW, Baker CC, Thomason MH, Chang MC. Pancreatic injuries resulting from penetrating trauma: a multi-institution review. Am Surg 1998;64: 838-43.
- Park BJ, Alexander HR, Libutti SK, et al. Operative management of islet-cell tumors arising in the head of the pancreas. Surgery 1998;124:1056-61.
- Heslin MJ, Harrison LE, Brooks AD, Hochwald SN, Coit DG, Brennan MF. Is intra-abdominal drainage necessary after pancreatic odu ode nectomy? J Gastrointest Surg 1998;2: 373-8.
- Suzuky Y, Fujino Y, Tanioka Y. Randomized clinical trial of ultrasonic dissector or conventional division in distal pancreatectomy for non-fibrotic pancreas. Br J Surg 1999;86: 608-11.
- Slim K, Buc F, Lescure G, Chanudet G, Pezet D, Chipponi J. Use of lanreotide in the prevention of pancreatic fistula after cephalic duodeno-pancreatectomy. Preliminary study. Chirurgie 1999;124:661-5.
- Takano S, Ito Y, Watanabe Y, Yokoyama T, Kubota N, Iwai S. Pancreaticojejunostomy versus pancreaticogastrostomy in reconstruction following pancreaticoduodenectomy. Br J Surg 2000;87:423-7.
- Bassi C, Falconi M, Salvia R, Mascetta G, Molinari E, Pederzoli P. Management of complications after pancreaticoduodenenctomy in a high volume centre: results on 150 consecutive patients. Dig Surg 2001;18:453-8.
- Berdah S, Panis Y, Gleizes V, Sastre B, Valleur P. Reappraisal of pancreaticojejunostomy after pancreaticoduodenenctomy: a report of 86 cases with particular reference to the rate of pancreatic fistulation. Eur J Surg 1997;163: 365-9.
- Bassi C, Butturini G, Falconi M, et al. Prospective randomised pilot study of management of the pancreatic stump following distal resection. HPB 1999;1:203-7.
- Brennan MF, Moccia RD, Klimstra D. Management of adenocarcinoma of the body and tail of the pancreas. Ann Surg 1996;223:506-12.
- Fabre JM, Houry S, Manderscheid JC, Huguier M, Baumel H. Surgery for left-sided pancreatic cancer. Br J Surg 1996; 83:1065-70.
- 35. Li-Ling J, Irving M. Somatostatin and octreotide in the prevention of postoperative pancreatic complications and the treatment of enterocutaneous pancreatic fistulas: a systematic review of randomized controlled trials. Br J Surg 2001;88:190-9.
- Bruce J, Krukowski ZH, Al-Khairy, Russell EM, Park KGM. Systematic review of the definition and measurement of anastomotic leak after gastrointestinal surgery. Br J Surg 2001;88:1157-68.

 Traverso LW, Wada K, Shinchi H. A clinically-relevant definition of pancreatic anastomotic leak after pancreaticoduodenectomy. Gastroenterology 2004;56:7.

- Strasberg SM, Debrin JA, Mokadam NA, et al. Prospective trial of a blood supply-based yechnique of pancreaticojejunostomy: effect on anastomotic failure in the Whipple procedure. J AM Coll Surg 2002;194:746-60.
- Halloran C, Ghaneh P, Bossonet C, Hartley M, Sutton R, Neoptolemos J. Complications of pancreatic cancer resection. Dig Surg 2002;19:138-46.
- Yeo CJ, Cameron JL, Lillemoe KD, et al. Pancreaticoduodenectomy with or whitout distal gastrectomy and extended retroperitoneal lymphadenectomy for periampullary adenocarcinoma (Part 2). Ann Surg 2002;236:355-68.
- Balcom J, Rattner D, Watshaw A, Chang Y, Fernandez del Castillo C. Ten year experience with 733 pancreatic resection: changing indications, older patients and decreasing length of hospitalization. Arch Surg 2001;136:391-8.
- Conlon K, Labow D, Leung D, et al. Prospective randomized clinical trial of the value of intraperitoneal drainage after pancreatic resection. Ann Surg 2001;234:295-8.
- Yeo C, Cameron J, Sohn T, Lillemoe K, Pitt H, Talamini M. Six hundred and fifty consecutive pancreaticoduodenectomies in the 1990s. Ann Surg 1977;226:248-60.
- Talamini MA, Moesinger MD, Pitt HA, et al. Adenocarcinoma of ampulla of Vater. A 28 year experience. Ann Surg 1997;255:590-600.
- Suzuki Y, Kuroda Y, Morita A, Pujino Y, Ykawamura T, Saitoh Y. Fibrin glue sealing for the prevention of pancreatic fistula following distal pancreatectomy. Arch Surg 1995; 130:952-5.
- Yamaguchi M, Nakano H, Midorikawa T, Yoshizawa Y, Sarada Y, Kumada K. Prediction of pancreatic fistula by amylase levels of drainage fluid on the first day after pancreatectomy. Hepatogastroenterology 2003;50:1155-8.
- Shyr YM, Su CH, Wu CW, Lui WJ. Does drainage fluid amylase reflect pancreatic leakage after pancreaticoduodenectomy? World J Surg 2008;27:606-10.
- Suc B, Msika S, Piccinini M, et al. Octreotide in the prevention of intraabdominal complications following elective pancreatic resection. A prospective, multicenter, randomized clinical trial. Arch Surg 2004;139:288-94.
- Suc B, Msika S, Fingerhut A, et al. Temporary fibrin glue occlusion of the main pancreatic duct in the prevention of intra-abdominal complications after pancreatic resection: prospective randomized trial. Ann Surg 2003;23:75-66.
- Buchler MW, Wagner M, Schmeid BM, Uhl W, Friess H, Z'graggen. Changes in morbidity after pancreatic resection: toward the end of completion pancreatectomy. Arch Surg 2003;138:1310-4.
- 51. Sarr MG for the Pancreatic Surgery Group. The potent somatostain analogue Valeopride does not decrease pancreas-specific complications after elective pancreatectomy: a prospective, multicenter, double blind, randomized, placebo controlled trial. J Am Coll Surg 2003;196: 556-65.

Version No 2: 27 Oct 2020 (22:40 hrs)