COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

MAY 20, 2008

Appearances:

Bernard Coffey, Q.C. . . . . Commission Co-counsel
Sandra Chaytor, Q.C. . . . . Commission Co-counsel

Rolf Pritchard/Megan Collins . . . . Her Majesty in Right of NL

Peter Browne . . . . . Doctors Kara Laing et al

Daniel Simmons/Sarah Learmonth . . . Eastern Regional Integrated
. . . . . Health Authority

Pamela Taylor . . . . . Members of the Breast Cancer
. . . . . Testing Class Action

Mark Pike . . . . . NL Medical Association
Jennifer Newbury . . . . . Canadian Cancer Society (NL Division)
Stacey O'Dea. . . . . Central, Western and Labrador-Grenfell
Regional Integrated Health Authorities

LIST OF EXHIBITS

TABLE OF CONTENTS

COMMISSIONER:
Q. Please be seated. Mr. Coffey.
COFFEY, Q.C.:
Q. Yes, Commissioner, before I begin with, I resume with Dr. Williams, I want to let you know that myself and Ms. Chaytor and the other counsel involved here received an e-mail from Jackie Brazil dated Monday, May 19th, 2008 at 11:01 p.m., that's last night. The subject is "Reply of brief." And I'm just going to read it to you, please?
COMMISSIONER:
Q. Um-hm.
COFFEY, Q.C.:
Q. It says, "Ladies/Gentlemen, I plan to file a reply brief before 5 p.m. tomorrow. I had hoped to have an electronic copy of the brief for you this evening, but I have run out of time. I trust the Commission counsel will advise the Commissioner accordingly. Yours Truly, Jacqueline Brazil." And, Commissioner, you are so advised.
COMMISSIONER:
Q. Thank you. What time did you say that was being -

Page 5

COFFEY, Q.C.:
Q. At 11:01 p.m. last night.
COMMISSIONER:
Q. No, I meant what time does Ms. Brazil intend to file that reply brief?
COFFEY, Q.C.:
Q. Before 5 p.m. tomorrow, which would be presumably today.
COMMISSIONER:
Q. Today?
COFFEY, Q.C.:
Q. Yes.
COMMISSIONER:
Q. Mr. Pritchard, I regret having to make you a messenger in this, but I have no difficulty with Ms. Brazil filing a reply brief, if indeed she wishes to do so. I just wish to indicate that in light of the timing and our schedule of witnesses, I had indicated that I would make a decision and communicate that to everybody before the next government witness took the stand. And on the timing I'm not confident I can keep that promise but I will endeavour to do so. If I can't, I'll make the decision and communicate it as quickly as I

Page 6

can, even if the next government witness is in the middle of being examined.
MR. PRITCHARD:
Q. (Inaudible).
COMMISSIONER:
Q. Thank you, very much. Now, Mr. Coffey.
DR. ROBERT WILLIAMS, EXAMINATION-IN-CHIEF BY BERNARD COFFEY, Q.C.
COFFEY, Q.C.:
Q. Thank you, Commissioner. Now, Doctor, we had asked in 2006, I--if we could, please, if we could go, please, to Exhibit 1397, please? I'm sorry, oh, I have to enter those, actually. If I could, please, Commissioner, there are two exhibits, I believe, I'd like to move to have entered. 1397 and 1398?
COMMISSIONER:
Q. Entered.
EXHIBIT P-1397 ENTERED INTO EVIDENCE.
EXHIBIT P-1398 ENTERED INTO EVIDENCE.
COFFEY, Q.C.:
Q. And, Doctor, these are--well, this is a, I gather it's a note from Dr. Cook. I want to refer you to its contents and ask you about that. It's dated March 6th, 2006 and Dr. Cook

Page 7

has apparently written, "Spoke to Dr. B.B. Nagihily (phonetic)?
DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. "About why Clarenville discontinued ER and PR slides. Dr. Nagihily replied this was due to poor quality and lack of external controls, plus the fact they were paying for this. As far as she knows they discontinued without notify people in St. John's." Now, Doctor, did Dr. Cook ever speak to you in March or April of '06 about Clarenville?
DR. WILLIAMS:
A. Dr. Cook would have spoken earlier than that about Clarenville to me.
COFFEY, Q.C.:
Q. Okay.
DR. WILLIAMS:
A. He was going to try to find out why Clarenville wasn't using our lab.
COFFEY, Q.C.:
Q. Um-hm.
DR. WILLIAMS:
A. But I've never seen this, you know, before

Page 8

this.
COFFEY, Q.C.:
Q. Oh, I appreciate you've never seen the note.
DR. WILLIAMS:
A. But I knew he was trying to find out. And at the end trying to remember exactly what he said, but I don't remember him saying he found out for sure, he wasn't really sure, but they did stop using our service.
COFFEY, Q.C.:
Q. Yeah.
DR. WILLIAMS:
A. And he was trying to find out. Dr. B.B. was actually working for us at this time.
COFFEY, Q.C.:
Q. Yeah.
DR. WILLIAMS:
A. She transferred in from Clarenville.
COFFEY, Q.C.:
Q. Did he ever report to you what's -
COMMISSIONER:
Q. This particular doctor was not working in Clarenville at the time?
DR. WILLIAMS:
A. No, she had transferred in from Clarenville.

Page 9

COMMISSIONER:
Q. Oh, okay.
DR. WILLIAMS:
A. Was working now for us. And he was trying to find out why Clarenville wasn't using our service.
COFFEY, Q.C.:
Q. In fact, last week you had indicated that at one point, yes, you had understood he was going off to do that?
DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. Does this--with the contents of what I just read you, had you ever heard that before?
DR. WILLIAMS:
A. I'm not sure, Mr. Coffey, if--I certainly haven't seen this before.
COFFEY, Q.C.:
Q. Oh, I know. But how about the contents?
DR. WILLIAMS:
A. Don, I seem to recall that Don wasn't totally sure why, but he had talked to Dr. B.B. about it.
COFFEY, Q.C.:

Page 10

Q. Did he report what Dr. B.B. had told him to you?
DR. WILLIAMS:
A. I can't remember that, Mr. Coffey, him reporting that, but I knew he was gone off to find that out.
COFFEY, Q.C.:
Q. If we could, please, Exhibit P-1398? now, and I gather this is a note that Dr. Cook had written. I want to refer you to its contents and then I have a question for you. "Spoke to Dr. Ejeckam with Terry Gulliver morning of March 7, 2006 re the hold on certain stains in 2003. I asked him what he meant by erratic. Dr. Ejeckam reported that it meant some stains worked some days and didn't work on others. I asked him if he should have recommended a review of stains at that time. He replied to me that it wasn't his place to initiate or recommend a review." And do you recall if Dr. Cook ever reported to you about the fact that he had spoken to Dr. Ejeckam and concerning the 2003 matter and, if so, what did Dr. Cook tell you about what Dr. Ejeckam said?
DR. WILLIAMS:

Page 11

A. I subsequently found out after I'd left the organization about this particular issue. I hadn't seen that note at the time.
COFFEY, Q.C.:
Q. Oh.
DR. WILLIAMS:
A. But I knew that Dr. Cook had talked to Dr. Ejeckam earlier in 2005, actually, at the time that he brought the memos to our attention. And it was nothing new to report at that time. There was some adjustments done to the pH and the antibodies and was felt at that time, according to Dr. Cook's discussion with Dr. Ejeckam, that the situation had been rectified.
COFFEY, Q.C.:
Q. And this note suggests that Dr. Cook spoke to Dr. Ejeckam again in '06?
DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. Were you aware that he had done so?
DR. WILLIAMS:
A. I'm aware now that he had done so because I talked to Dr. Cook, but at the time I was with

Page 12

the organization, it was some time after I had left that I was aware of that.
COFFEY, Q.C.:
Q. Yeah. Well, what, since you've left the organization what did Dr. Cook tell you about that?
DR. WILLIAMS:
A. He just told me that he talked to Dr. Ejeckam on a number of occasions and his response seemed to be a little different than the last time he'd talked to him. He felt that he didn't have the authority to recommend anything on this.
COFFEY, Q.C.:
Q. Okay, so and so what Dr. Cook has told you since you left Eastern Health accords with -
DR. WILLIAMS:
A. Yes, correct.
COFFEY, Q.C.:
Q. - this kind of -
DR. WILLIAMS:
A. Yes, Mr. Coffey, that's correct.
DR. WILLIAMS:
A. - the note itself?
DR. WILLIAMS:

Page 13

A. Yes.
COMMISSIONER:
Q. Can we go back to the one, 1397 for just a moment? A lack of external--"Plus the fact that they were paying for this." Does Clarenville pay a cost to -
DR. WILLIAMS:
A. Yes.
COMMISSIONER:
Q. - the General for doing -
DR. WILLIAMS:
A. Other--my understanding is -
COMMISSIONER:
Q. - these things or, for that matter, other organizations, as well?
DR. WILLIAMS:
A. Yes. From my understanding there's certain tests that we perform in the lab that we incur a cost on that's not funded in our budget that we charge other health care organizations in the province. There's always some discussion about that. At one stage we went to the Department of Health to try to get a budget adjustment so that we wouldn't have to charge these organizations.

Page 14

COMMISSIONER:
Q. Um-hm.
DR. WILLIAMS:
A. But we weren't successful. It's not about the ER and PR, it's about some other charges that we made.
COMMISSIONER:
Q. Um-hm.
DR. WILLIAMS:
A. And we were trying to, in fact, probably in the mid 2002, 2003 year looking at sort of abolishing that. It was a lot--it was work for us to do that and if we got an adjustment from the department in our budget, then we wouldn't have to charge these other boards.
COMMISSIONER:
Q. Well, it would just seem that the mere paperwork of going -
DR. WILLIAMS:
A. Yes, that's right. We wanted -
COMMISSIONER:
Q. - to look for the money might -
DR. WILLIAMS:
A. Correct. We wanted to avoid all the paperwork. Why do all this paperwork if we could just have--adjustment to our budget for costs?
COMMISSIONER:
Q. The source of the payment, presumably comes from the same place?
DR. WILLIAMS:
A. Yeah, because it's all the same source, that's right. That was our concern, it's all the same source, it's the Provincial Government funding, so why not just get an adjustment to our budget and then we wouldn't have to charge for those.
COMMISSIONER:
Q. Okay.
DR. WILLIAMS:
A. But it wasn't related to this, it was related to some other tests, as well.
COMMISSIONER:
Q. So, are there tests that you actually get payment--that you don't get payment for from other authorities or -
DR. WILLIAMS:
A. Yeah, there's things that historically we've never got payment for, but some things, when they were set up, they were set up that they would pay.
COMMISSIONER:
Q. Okay.
DR. WILLIAMS:
A. And we tried to get that abolished. Make more sense to us just to have an adjustment to our budget to cover that cost, and then we wouldn't have to incur all this paperwork to bill.
COMMISSIONER:
Q. Okay.
COFFEY, Q.C.:
Q. Commissioner, thank you. Exhibit P-0778, please? Now, sir, a couple of e-mails, Dr. Williams. The first of them at the bottom of the page, page 1 of the exhibit is from Rick Singleton, Friday, May 19th, 2006, 11:20 a.m. to yourself, Louise Jones, Heather Predham, Dr. Laing, Nash Denic and D. Pullman. The subject is "Ethics consult re disclosure of info on deceased patients." And this ethics consult re disclosure of info on deceased patients, did you have any part to play in this?
DR. WILLIAMS:

Page 17

A. No, other than to request it. And I requested it really probably through Louise Jones, who was the vice president who had a lot of experience in the whole issue of ethics. She--with the former Health Care Corporation she was a lead person on that area, and so when we moved into Eastern Health, she was the lead person, so I contacted her. That's who I actually asked.

COFFEY, Q.C.:

Q. And why did you ask for one?

DR. WILLIAMS:

A. Well, we had the deceased patients issue here. We had some reports come back and that spurred me on, Dr. Cook sent me an e-mail and that spurred me on to ask for the ethics consult, because we would have to deal with that group of individuals anyway, Mr. Coffey.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-0780? Now, this is an e-mail from Rick Singleton, Friday, June 9th, 2006 at 9:47 a.m. It's again to the same group of people, but as well, Bandrau?

DR. WILLIAMS:

A. Natalie Bandrau, I think.

Page 18

COFFEY, Q.C.:

Q. Yes. And McCarthy, Dr. McCarthy?

DR. WILLIAMS:

A. Um-hm.

COFFEY, Q.C.:

Q. And it says, "Hi, We will have to again reschedule our meeting to discuss the disclosure of information regarding deceased patients. We've had difficulty getting a time with the lawyer who has been handling the case. He is in court almost every day this month. We are now rescheduled to Monday, June 19th at 5 p.m. Mr. Dan Boone, the lawyer, will join us a bit late. The new time is," and they set it out. "We have cancelled the meeting previously scheduled for June 19th." Now, sir, can you tell us, please, what at the time you understood, as you had requested this ethics consult, the role of Mr. Boone might be?

DR. WILLIAMS:

A. I didn't think of what the role of Mr. Boone might be, Mr. Coffey. I just asked for the ethics consult and to have people who had ethics experience review the issues and make a recommendation.

Page 19

COFFEY, Q.C.:

Q. Exhibit P-0781, please?

COMMISSIONER:

Q. Just before we leave that point, did you have any input into who was going to be a member of the group?

DR. WILLIAMS:

A. No, I did not.

COMMISSIONER:

Q. Okay.

DR. WILLIAMS:

A. I just asked for the ethics consult to be done.

COMMISSIONER:

Q. You just asked, I presume, you asked, as I understood it, Ms. Jones?

DR. WILLIAMS:

A. I think I went through Ms. Jones.

COMMISSIONER:

Q. To set one up?

DR. WILLIAMS:

A. Yes.

COMMISSIONER:

Q. And did you have any--and I'm understanding you to say that the content of the--the nature of the expertise of those involved and who was to be involved in that consult was outside of your control?

Page 20

DR. WILLIAMS:

A. I would leave that to the people who had experience in these things.

COMMISSIONER:

Q. Okay. Thank you.

DR. WILLIAMS:

A. I didn't have a lot of experience in the whole issue of ethics consults. Probably the first one I'd asked for.

COMMISSIONER:

Q. All right. Thank you.

COFFEY, Q.C.:

Q. Now, but in asking for it, I take it, you would have understood it was coming back to you?

DR. WILLIAMS:

A. Yes, I would receive a report, yes.

COFFEY, Q.C.:

Q. If we could, Exhibit P-0781, it's here on the screen. It's from Rick Singleton, Tuesday, June 20th, 2006 at 10:20 a.m. It's to

Page 21

yourself, Doctor, but this one is just to you, Dr. Robert Williams. It says, "Hi, Bob, yesterday we had the ethics consult on ER/PR. Very good discussion and outcome. I will forward the summary later. In the meantime, an issue can up that I want to give you a heads up on. Dr. Denic had a document, a report from an external reviewer of the lab processes, etcetera, here. He read from it and mentioned that he would use the report as part of information he was sharing with others. It seems the reporter opinion had been done for Dan Boone and he did not want the information shared as at this time it is privileged. Dr. Denic understood from you that he was not to copy it, but Dan seemed to be a bit concerns that it was being quoted, the expert being referred to. Dan's concerns seems to be about the privilege status of the report which he may need in a proceeding later on. Anyway, just thought you might want to know there was a bit of fuss about this." Signed, "Rick." And sir, and I think you've written--I take it, because you use this "KIV"?

Page 22

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. June 28th, 2006?

DR. WILLIAMS:

A. Um-hm.

COFFEY, Q.C.:

Q. So why were you--first of all, what was your understanding as to why this was sent to you and what you were to do about it and why you had it brought forward for June 28th?

DR. WILLIAMS:

A. I would have thought that if I KIVed it, it might be for a get together I was probably having with Dr. Denic around that time and I was just going to bring it to his attention that that was privileged information and it shouldn't be used. That would be the only thing I can think of, Mr. Coffey.

COFFEY, Q.C.:

Q. Now, is this report one of Banerjee or Wegrynowski's reports?

DR. WILLIAMS:

A. No, it was not.

COFFEY, Q.C.:

Page 23

Q. Okay. Exhibit, please, P-0783? This is an e-mail from Mr. Singleton to yourself and Louise Jones, June 22nd, 2006 at 3:04 p.m. The subject is "Ethics consult" it says, "Hi, Bob, Attached is the report from the ethics consult re ER/PR. Thanks."

DR. WILLIAMS:

A. Rick.

COFFEY, Q.C.:

Q. And we go to--this particular report is dated June 23rd, 2006. It's to yourself from Rick Singleton and "RE: Ethics consult, ER/PR." And this apparently, these documents apparently came from your office as VP medical.

DR. WILLIAMS:

A. Um-hm.

COFFEY, Q.C.:

Q. This handwriting, is that yours?

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. Okay. So you've actually spelled Dr. Natalie -

DR. WILLIAMS:

Page 24

A. Bandrauk, I spelled -

COFFEY, Q.C.:

Q. - Bandrauk's name correctly.

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. Now, sir, looking at this, they've written here, "Important" in the third paragraph, "Important facts to the history and understand of this case include the following: There were no mistakes or technical errors at the root of this problem. It is impossible to know in any specific case if the outcome for any individual patient would have been different. Intervention for post-menopausal women had positive impact by lengthening life in 47 percent of patients treated." Now, the second like, what I just read to you, "There were no mistakes or technical errors at the root of this problem."

DR. WILLIAMS:

A. Um-hm.

COFFEY, Q.C.:

Q. When you received this in June, 2006, did you think that that was true or accurate?

Page 25

DR. WILLIAMS:
A. Mr. Coffey, I didn't remember having this report until we went back in the files. And -
COFFEY, Q.C.:
Q. I'm sorry, you didn't remember?
DR. WILLIAMS:
A. Having received this report until we were reviewing it here for -
COFFEY, Q.C.:
Q. Oh, for the -
DR. WILLIAMS:
A. - testimony, yeah. Because I think what happened is that I looked at the people who were involved there, saw that we had a recommendation and probably filed it away for future reference, because at that time I was still--another issue had come up with the DCISs and the retro converters and I was trying to work through that and would have come back to this report when we were dealing with the deceased. So I can't remember, Mr. Coffey, really, twigging to that issue. But that is an issue that needs to be clarified with the author of the report, why that statement was there.

Page 26

COFFEY, Q.C.:
Q. yes.
DR. WILLIAMS:
A. I can see that in retrospect.
COFFEY, Q.C.:
Q. Because from your perspective, I take it, that's not accurate, is it, based upon what you -
DR. WILLIAMS:
A. The way it's, the way it's worded there. I'd have to see what the context was and how the person who authored it explained it, but the people around the table would have all the information on what particularly happened. We had our oncologists and our laboratory personnel, they would have the background information and Dr. Bandrauk and Mr. Singleton would be able to provide the ethical input into the decision making process.
COFFEY, Q.C.:
Q. Based upon what Dr. Banerjee and Trish Wegrynowski had told you in the reports in the fall of 2005, though, you would not at the time have said, in June of '06, that there were no mistakes or technical errors at the root of this problem?
DR. WILLIAMS:
A. No, we didn't get the right results, so there had to be something at the root of the problem.
COFFEY, Q.C.:
Q. Sure.
DR. WILLIAMS:
A. But you'd have to ask the author specifically what that statement means and what context it's said in.
COFFEY, Q.C.:
Q. Here Mr. Singleton has couched this in terms of "Important facts to the history and understanding," I presume he should have written the word "understanding" "of this case include the following". And the first of them is "There are no mistakes or technical errors."
DR. WILLIAMS:
A. Um-hm.
COFFEY, Q.C.:
Q. At the time did it occur to you that that's--your understanding at the time would be that would not be accurate, based upon what you

Page 27

Page 28

knew, that that might effect the outcome, the ethical outcome?
DR. WILLIAMS:
A. It may now, in retrospect, yeah. Like I say, when I reviewed it, I think I just went and looked at the people who were there and went right to the recommendations, realized that we had recommendations to deal with this and filed it until we got to the issue, because we had a lot of issues that we still had to straighten up at the time, that I had to follow up in detail.
COFFEY, Q.C.:
Q. If we could--so you just took it, looked at who was there, changed Dr. Bandrauk's name.
DR. WILLIAMS:
A. Yeah.
COFFEY, Q.C.:
Q. And filed it away for future reference?
DR. WILLIAMS:
A. Yes, so that when we dealt with the issue, when we had--we really had a lot of issues that arose as a result of this review that weren't related to ER and PR, but had a lot of issues, had some significance that had to be

Page 29

worked through and had some serious, potential serious impact that I wanted to make sure that we dealt with first.

COFFEY, Q.C.:

Q. On that point, Exhibit P-0411 please? So Doctor, this is a memo dated July 4, 2006. The subject is estrogen progesterone receptor testing DCIS and retro converters. It's addressed to yourself, Mr. Tilley, Ms. Pilgrim and Ms. Elliott. It's from Heather Predham and she says "I need to bring your attention to two situations that have developed during our ER/PR review. One is ductal carcinoma in situ," and if I could, I'm just going to--and two is retro converters, and now sir, I take it then that--were you aware of the DCIS and retro converter issue before you got this memo, July 4th? Would you have been aware of that?

DR. WILLIAMS:

A. I may have been, yes. I'd have to go back in the documents, but I may have been aware of that. What's the date on that?

COFFEY, Q.C.:

Q. This is July 4th, 2006.

Page 30

DR. WILLIAMS:

A. I think I may have been. I think I was aware of that before.

COFFEY, Q.C.:

Q. And could you tell the Commissioner, you indicated this was a new issue that had come up.

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. Tell her, from your perspective as VP Medical, how the issue presented to you and what you did about it.

DR. WILLIAMS:

A. Yes. Well, ductal carcinoma in situ really means that the tumour cells--the duct is like a pipe and outside, on the outside lining of a pipe there's a membrane in the ducts of the breast. The ductal carcinoma in situ would be a tumour that's confined to the duct. It doesn't invade through the membrane. And then there's ductal carcinoma in situ with minimal invasive and then of course, there's invasive breast cancer when it goes beyond. There's two schools of thought, and I'm not sure if

Page 31

that's been resolved as yet. Some individuals test people with ductal carcinoma in situ and other individuals don't test people with ductal carcinoma in situ.

THE COMMISSIONER:

Q. Test for ER/PR?

DR. WILLIAMS:

A. For ER/PR, yes, receptors. I don't know if those two schools of thought have been resolved as yet in the oncology and pathology community. The issue is if somebody had--was thought to have ductal carcinoma in situ, that's one thing. But if they were sent in for ER and PR testing because a pathologist had interpreted they weren't ductal carcinoma in situ but minimally invasive or invasive breast cancer, then that would entail a different course of treatment than just ductal carcinoma in situ, a more aggressive type of treatment with chemotherapy, this type of thing.

THE COMMISSIONER:

Q. Wait now. Are you suggesting that because you did the ER/PR testing with DCIS -

DR. WILLIAMS:

Page 32

A. That some of the -

THE COMMISSIONER:

Q. - that might result in more invasive--more treatment than had traditionally been used for DCIS?

DR. WILLIAMS:

A. No, I'm sorry, Commissioner. What I meant to say is that--what I'm trying to get across is that if somebody sent in a case to be tested for ER and PR, they may have thought that it was an invasive breast cancer, and if it turned out to be ductal carcinoma in situ, then that person would have got a more aggressive treatment than they needed.

THE COMMISSIONER:

Q. Yes, yes. Oh, okay.

DR. WILLIAMS:

A. So it was important that every case of ductal carcinoma in situ be thoroughly reviewed and what we did set in place, I think, was Dr. Cook and Dr. Carter as a panel of pathologists would review each case. Some of these cases were from outside our region, so I think if you go through the notes that I took at the time, I did contact Dr. Alteen and Dr. Jenkins

Page 33

because some of those cases were from their regions and I wanted to make sure that those cases were followed up and did they want our pathologists to do the panelling or were they going to have their pathologists in Corner Brook and Grand Falls do the panelling.

THE COMMISSIONER:

Q. Okay, just to make sure I know the substance of what you're saying. The concern was that if you discovered during the retesting that a diagnosis which had hitherto thought to be applicable to somebody -

DR. WILLIAMS:

A. Yes.

THE COMMISSIONER:

Q. - and turned out in fact to be DCIS, then the question was whether or not these individuals would have received treatment which, in the normal course of treatment of DCIS, would not have been offered?

DR. WILLIAMS:

A. Correct.

THE COMMISSIONER:

Q. Okay, and you may--as I understand it, you wanted all those particular persons to be

Page 34

reviewed in light of that?

DR. WILLIAMS:

A. Yes.

THE COMMISSIONER:

Q. Okay.

COFFEY, Q.C.:

Q. And Doctor, do you recall how many were thought to fall into this category, at least initially?

DR. WILLIAMS:

A. Oh initially, I think there was around 50, Mr. Coffey, something--a fairly large number.

COFFEY, Q.C.:

Q. Approximately 50 or so?

DR. WILLIAMS:

A. Yes, that's my understanding. I have to go back and look through notes, but there was a fairly large number which was pretty worrisome at the time.

COFFEY, Q.C.:

Q. And as time went on then, this was handled by having each of those cases looked at?

DR. WILLIAMS:

A. Thoroughly reviewed by a panel, you know, Dr. Carter who would have the expertise and Dr.

Page 35

Cook, to give a second opinion, and we also contacted--I think my notes show that we contacted Dr. Alteen and Dr. Jenkins, the medical directors in Western and Central, to ask them how they wanted to handle the cases from those areas.

COFFEY, Q.C.:

Q. To assist you in that regard, and I won't forget the retro converters, I'll come back to that, Exhibit P-1378 please? It's a couple of e-mails of July 11th and 12th 2006, July 10th in fact, all the way back actually to July 9th. There's an e-mail from Heather Predham to Lorraine Woolgar and then from Lorraine Woolgar to Ken Jenkins on July 10th, 2006, 10:40 a.m. "Please see attached from Heather Predham," and then there's an e-mail from Ken Jenkins to Dr. Paul Neil. He says "Hi, Paul. Could you please provide your recommendation? Thanks, Ken" and then from Paul Neil, July 11th 2006, 11:26 a.m. to Ken Jenkins. He says "Ken, I have no problem with Eastern doing this. However, I would like Western to have the opportunity to review as well. I am unclear as to what the problem really entails.

Page 36

If Mount Sinai says DCIS, they may only have reviewed the slide in block we sent them. There may indeed be only DCIS left on the slide, but other blocks they did not review may show invasive. Only review of the entire case would show this. Therefore, I would like to have the original pathology reviewed here as well. Thanks, Paul."

So does that kind of fairly summarize, in fact, how the 50 cases were gone through?

DR. WILLIAMS:

A. Yes, because, you know, he's right there. On one section, you might have the tumour confined to the duct, but in another section, you might have it invasive. So yes, they would need to be involved. I can't remember this last e-mail. It's not in my package, but I'm pretty sure I talked to Dr. Jenkins and Dr. Alteen and to make them aware that this was an issue and to make sure that they had it followed up properly in their regions.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-1380? Now this is a letter of July 14th 2006 addressed to Doctors Cook and Carter. It's from yourself,

Page 37

and you say "as a result of the ongoing quality review process, could you please review the following cases?" and there are a number of them.

DR. WILLIAMS:

A. Um-hm.

COFFEY, Q.C.:

Q. Do you recall what this was about?

DR. WILLIAMS:

A. No, I looked at my file and I don't know why I would ask Heather that question, and then if you look over three or four more days, there's a letter signed by me to them saying there's a number of patients that needed a review. Could you please make sure that that's done, and the reports put in their file?

COFFEY, Q.C.:

Q. What does your handwriting there say?

DR. WILLIAMS:

A. "Heather, any problems with me signing this." That's all. I don't know why I would ask her that question.

COFFEY, Q.C.:

Q. Okay, and -

DR. WILLIAMS:

Page 38

A. But when you look farther along, a week or so later, or ten days later, there is a letter from me to Dr. Cook or Dr. Carter sort of encompassing that, and I think that's how I handled it, but I can't be sure why I would have asked why I should sign it or not sign it.

COFFEY, Q.C.:

Q. Oh, no, I understand that, Doctor. I'm just -

DR. WILLIAMS:

A. I can't remember that.

COFFEY, Q.C.:

Q. But do you recall what the subject matter of the--like why you were looking for these to be looked at at all?

DR. WILLIAMS:

A. Because Mount Sinai raised an issue.

COFFEY, Q.C.:

Q. Oh, this is--and that's what I'm getting at.

DR. WILLIAMS:

A. This is these cases.

COFFEY, Q.C.:

Q. Oh, okay, that's what I was asking about, Doctor. Okay.

DR. WILLIAMS:

Page 39

A. These are to do with the DCIS type of thing.

COFFEY, Q.C.:

Q. And these would be, I take it, the local DCIS?

DR. WILLIAMS:

A. I would say they were, yes.

COFFEY, Q.C.:

Q. And as the e-mail we just looked at, for example, Dr. Jenkins is on the west coast of Newfoundland?

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. And Dr. Neil, they would have wanted to look at DCIS from their area?

DR. WILLIAMS:

A. Yes, that was--Paul Neil was chief of pathology at Western and Ken Jenkins was my counterpart, and in Central Newfoundland, it was Dr. Alteen, my counterpart, and Dr. Maurice Dalton, who was Dr. Cook's counterpart.

COFFEY, Q.C.:

Q. And I take it a similar arrangement was made with Central Newfoundland as well, in terms of the review of the DCIS?

Page 40

DR. WILLIAMS:

A. Yes. I phoned Dr. Alteen, and my notes say that I did, and I phoned Dr. Jenkins. Now I don't have a follow-up e-mail on that. My last recollection of this was about an August 15th note that I had on discussion with Dr. Denic. I know that because I was looking at it in preparation for the hearings, and there's a whole list of individuals there. I went down through them one by one, I think, with Dr. Denic to make sure that things were under control. I wanted to make sure before Dr. Howell got there that this issue had been dealt with. That's my recollection.

COFFEY, Q.C.:

Q. Okay, and this really occupied, I take it, when we look at the materials, a fair amount of your attention, probably in June when it first verbally came to your attention and then through July, into August, trying to see -

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. - how many of this approximately 50 were in fact originally truly DCIS?

Page 41

DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. And do you recall how many it ended up being reduced to?
DR. WILLIAMS:
A. I know there was three in Eastern and all those three people were notified personally with a--a meeting was held, I think, between an oncologist, Dr. Denic who was clinical chief at the time, and probably Heather Predham from quality. There was three people met with each patient. That's my recollection, and there was three from our region and all three were met with. That's my understanding.
COFFEY, Q.C.:
Q. If we could then, P-0411? No, the next page please. The retro converters, because we were dealing first of all with the DCIS. Perhaps you could tell the Commissioner again what the retro converters, from your perspective, represented and how it was dealt with?
DR. WILLIAMS:
A. These were individuals who would have, to some

Page 42

level, had some positivity interpreted for ER and PR, but when they were retested at Mount Sinai, the test came back negative. My understanding of these retro converters was that these were individuals who, on reading the slides, the pathologist read background staining and interpreted that as positive. That was my understanding.
COFFEY, Q.C.:
Q. Okay, you would have gotten that from whom?
DR. WILLIAMS:
A. Probably Dr. Denic at the time or Dr. Carter, I'm not sure. I know I was at meetings at St. Clare's, one meeting to discuss retro converters and DCIS with Dr. Carter and Dr. Denic, Ms. Predham, Ms. Elliott, myself and probably Dr. Cook at the time.
COFFEY, Q.C.:
Q. So they explained to you that the original readings for these retro--what are now retro converters, looking at the original slides -
DR. WILLIAMS:
A. That's my understanding of it.
COFFEY, Q.C.:
Q. - that they told you it was probably

Page 43

background staining that was misinterpreted?
DR. WILLIAMS:
A. Yes, that's my understanding. I tried to find out if there's such a thing as a false positive where there's nuclear staining and even when the--prior to this when the Ventana chief scientific officer--sometime in the spring of 2006, Ventana came up with some of their senior people from Arizona to present the new VIA system to us, which was a computerized technique which could scan slides for ER and PR, and the computer then would interpret what degree of positivity was in those slides. It would be another recheck on a eyeball view by the pathologist.
COFFEY, Q.C.:
Q. It's a visual imager?
DR. WILLIAMS:
A. Yes, and I remember asking their chief scientific officer, their Ph.D. person, the question, you know, and the answer I got was pretty well not possible, and I didn't get a good explanation how it could ever happen really.
COFFEY, Q.C.:

Page 44

Q. How a false positive could occur?
DR. WILLIAMS:
A. You could get actually nuclear staining.
COFFEY, Q.C.:
Q. But in terms of -
DR. WILLIAMS:
A. But I stand to be corrected. Somebody else might be able to--whose an expert, might be able to answer that question.
COFFEY, Q.C.:
Q. And I appreciate that. I'm asking you simply from the perspective of what you, as VP Medical, what occurred to you and what inquiries you made, and you're telling us that.
DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. But in terms of the retro converters referred to here in 0411, they were explained to you, as you recall, by your local, some of your local pathologists as probably misinterpretation of background staining?
DR. WILLIAMS:
A. That's my understanding. You'd have to ask

Page 45

those people if that was their explanation to me or if I got it wrong.

COFFEY, Q.C.:

Q. If we could, please--so what was done with them then?

DR. WILLIAMS:

A. There was four, my understanding. Two from outside our region and two from within our region. They would have been notified. One, I'm not sure--Heather was having difficulty. One patient went back quite a number of years and was having difficulty tracking that patient down. I can't tell you specifically what the other regions did, but I did contact the medical directors and asked them to follow up on that. One, I know one was contacted and one was, when I left, was probably still in the process of being contacted. That's my understanding, Mr. Coffey.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P--while I'm at it, and in terms of the contact, it was made by, your understanding, by what sorts of individuals?

DR. WILLIAMS:

Page 46

A. I'm not sure on that.

COFFEY, Q.C.:

Q. Okay.

DR. WILLIAMS:

A. I know well how the contact was made for the DCIS, but I would expect for the retro converters, it probably would involve a physician contact, because there would need to be an explanation.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-0413? This is a letter from Dr. Joy McCarthy and Dr. Beverley Carter, co-chairs of the Breast Disease Site Group. It's carboned to a number of people, including Dr. Laing, George Tilley, Sharon Smith and Ms. Pilgrim, but it's addressed to yourself as VP Medical Services and it says "at a recent ad-hoc meeting, great enthusiasm is expressed by many specialty groups for creating a Breast Disease Site Group at Eastern Health. As you recall, the impetus for this came from your office as a result of multiple meetings concerning ER and PR laboratory testing and the care of patients with breast cancer in this province. Please

Page 47

see attached proposal for the development and staffing needs for the BDSG. We look forward to your prompt reply and are available for a meeting at your convenience."

The doctors' assertion there that the impetus came from your office, is that correct?

DR. WILLIAMS:

A. I certainly supported it.

COFFEY, Q.C.:

Q. Okay.

DR. WILLIAMS:

A. Now I don't see any paper trail as to what I did when I got this, but I certainly would have supported it and tried to get resource for it. I thought it was actually working or had been set up.

COFFEY, Q.C.:

Q. To actually implement it?

DR. WILLIAMS:

A. Yes, I would have supported implementing it, Mr. Coffey, but I can't find, in the documentation, what I would have done about it, but I certainly would have supported it, because it made a lot of sense to get together

Page 48

people from oncology and pathology around that particular diagnosis and disease, develop some expertise, exchange information. Hopefully that would result in a better quality of care.

COFFEY, Q.C.:

Q. And if we could, please, Exhibit P-1377? Now this is an e-mail--I'm sorry, a memo to yourself from Heather Predham dated July 10th '06. It relates to DCIS and retro converters. "The following information is a follow-up to my briefing note of July 4th 2006," which I presume is that one we looked at earlier this morning, and it again deals with DCIS and retro converters. So here, I gather, Ms. Predham is reporting to you on the status of the handling of those?

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. And in terms of dealing with the DCIS issue and the retro converters issue, from the medical end of Eastern Health, were you responsible for managing it over all?

DR. WILLIAMS:

A. I wanted to make sure it was done. That's why

Page 49

I spent a lot of time and my notes, again, when I signed off on it, I think it's August 15th or some time around August with Dr. Denic, that it was--my understanding was that there was one retro converter that they had difficulty contacting.

COFFEY, Q.C.:

Q. Sure. Exhibit P-0415 please? Now this is a letter of July 19th, 2006 from yourself and it's carboned to a number of individuals, including Dr. Denic and Mr. Gulliver, Ms. Predham, Ms. Elliott. But it's addressed to Mr. Tilley and it says, "I am writing concerning the national issue we have been advocating for concerning setting up a reference lab for laboratories that do ER and PR testing in the country. I've attached a proposal from a group called the Canadian Coalition for Quality and Laboratory Medicine with a proposal with respect to immunohistochemistry. Their proposal deals with Class I tests, which does not include the important ER & PR component." And you go on to say, "Dr. Cook advises that at the weekend meeting of the Canadian Association of

Page 50

Pathologists held in St. John's this matter was discussed on their agenda. The Canadian Association of Pathologists, through their president, Dr. Diponkar Banerjee, will be writing the Canadian Coalition for Quality in Laboratory Medicine supporting the"--should be "thrust", I presume,--"of their initiative, but recommending that Class II tests also be included in their proposal." And he goes on to describe what else Dr. Banerjee was going to do, and you conclude by saying, "This is good news and, hopefully, this will lead to national standardization and assurance that labs testing in this area would be part of a national quality assurance program." If I could, please, this I take it, page two is some e-mails from Don Cook to yourself, July 12, 2006. Subject is "QC for Immunoperoxidase" and he's forwarding an e-mail from--do you know the doctor's name, Laurette Geldenhuys?

DR. WILLIAMS:

A. I only would have seen it on the--I don't know who she would be.

COFFEY, Q.C.:

Page 51

Q. And, but she is described as being an anatomical pathologists from QEII Health Sciences Centre in Halifax. And she says, "I received this documents from Ermina Torlakovic. Since we discussed this issue at an executive meeting recently, I thought you might find these interesting. I attach." Now, Doctor, at this point in time, which is the summer of '06, what is your involvement at this point in this whole area in terms of what were you hoping to accomplish?

DR. WILLIAMS:

A. Well I guess when you have a problem, a major problem like this, you read the literature and a lot of issues in Europe had been discussed, they seem to be ahead of North America in Europe, in terms of standardizing these tests, getting some quality assurance--external quality assurance programs in place. In the U.S. and Canada, that activity didn't seem to have taken place, right from, I guess, early on in this we were trying to stimulate something at a national level to ensure that something like this was in place, because we really were trying to prevent issues like this

Page 52

from continuing to happen or happen at all. So the reason I wrote Mr. Tilley was I was showing him that some, in fact, progress seemed to be being made and I also, I think, talked to Dr. Dawe at the time about this and I probably would have sent him a copy of this, I would think I was (sic.) because Mr. Dawe was, maybe by this time, through the Canadian Cancer Society, was their liaison person that was going to be working on this or having some input into this as they develop their national cancer strategy, if I'm correct on that.

COFFEY, Q.C.:

Q. Okay.

DR. WILLIAMS:

A. Now I notice in the weekend paper this whole issue in the Globe and Mail on Saturday has surfaced again with the same players involved, Dr. Torlakovic has been involved in that particular article and there's been some working going on at British Columbia and in Saskatchewan and they've developed a computerized, I guess mail-out that people can complete and then send back and get their labs rated, so I think they've made some progress

Page 53

in the, almost two years that this has happened.

COFFEY, Q.C.:

Q. And you say the weekend paper, you mean literally like Saturday's paper past?

DR. WILLIAMS:

A. Saturday's Globe and Mail, there's a big article, full-page article on this.

COFFEY, Q.C.:

Q. And Doctor, if I could please, exhibit P-0370? Now this is an e-mail of August 7th, 2006, it's to a number of--it's from Susan Bonnell, 11:19 a.m. to Ms. Pilgrim, Ms. Smith, Ms. Predham and yourself. Subject is "Communication with Family Physicians." And she writes, "Just to follow up on our conversation this morning, I just spoke with Lynn Barter, Communications Director with the NLMA. She is going to speak with the head of their GPs group, re communicating with family physicians. She agrees with me that the messages have really gotten mixed in general conversation and suspects that many family doctors may be hearing from their patients. She'll let us know if this is accurate. In

Page 54

the meantime, they will help us communicate with the GPs via letter when we are ready. It will be excellent if we were in a position to communicate where we are in the review process and to clarify what the process was about. Some of the results we are finding, generally speaking, and to address what we are doing as an organization to ensure quality control/confidence in the system. If you would like to get together in the next couple of days to strategize re: ways to reach the various groups, let us know. I am very nervous about doing any disclosures this week, the timing is very bad, especially given that we do not have a spokesperson to address this. For your information, Mark Quinn has made contact with us this morning. Mark is the CBC report who we did the Freedom of Information on ER/PR for and Leona had discussed with him setting up a briefing with our key players. I suspect he's looking for this now. We'll let you know." Now, Doctor, beginning of August, 2006, having received that e-mail from Ms. Bonnell, what was your view as the VP Medical of Eastern Health concerning the apparent

Page 55

awareness amongst physicians throughout the province concerning this matter?

DR. WILLIAMS:

A. I really can't remember--I was out of the office, I think, the first two weeks of August, so I don't remember having any discussion about this e-mail. We may well have had discussion about it, but I can't remember, Mr. Coffey. And I don't remember having any discussion with the NLMA around that time about a letter, but I may have, it doesn't appear in any of my documents.

COFFEY, Q.C.:

Q. Now, Doctor, this suggests, if we look at the media coverage, really beginning, you know, towards Christmas and before Christmas of '05 and continuing on through '06 of this issue, there are a number--the media reported on a number of concerns expressed by Mr. Dawe and others, concerning a lack of communication by Eastern Health on the issue?

DR. WILLIAMS:

A. Uh-hm.

COFFEY, Q.C.:

Q. And now, August 7th, there's an e-mail

Page 56

referencing a similar expression of concern by the NLMA's communication director.

DR. WILLIAMS:

A. Uh-hm.

COFFEY, Q.C.:

Q. Now, as the VP Medical going through the summer of '06 and into the fall of '06, were you concerned at all, I mean, by that state of affairs?

DR. WILLIAMS:

A. I'm not--Mr. Coffey, to be honest, I can't, you know, if I could tell you what discussion we had after that, I would, but I can't remember what discussion we had. I would have gotten back in the office around the middle of August, I think, because I was off for a couple of weeks and then I would have finished up at the end of August, would have taken the first week of September off when Dr. Howell came on board and then would have come back for the last three weeks of September, focusing then on really the medical staff bylaws and a few other things that I had on the agenda.

COFFEY, Q.C.:

Page 57

Q. Now, sir, -
THE COMMISSIONER:
Q. Dr. Howell came in on the 1st of September?
DR. WILLIAMS:
A. Yes, he came the day after Labour Day.
THE COMMISSIONER:
Q. Or whatever the day it was. And when he came in, I know you were there for a few weeks thereafter, but did Dr. Howell sort of take over the position immediately and you were there if he wanted to call you? Is that the arrangement? How did that work?
DR. WILLIAMS:
A. Yes, he took over the position the day he came in. I stayed out of it for four days, I took those four days off after Labour Day, just to give him a chance to get, you know, because I didn't have an office, to get them to find me a space to go and then I was available to him for briefing and a couple of other things and my main task, pretty well fulltime, was to try to develop a set of medical staff bylaws for Eastern Health in conformity to what we were trying to do at Eastern Health and what we'd-- plans we made and discussions we had with the

Page 58

six or seven organizations that made up Eastern Health, from a medical perspective, and then trying to meld that with the requirements from the Department of Health, in terms of what they wanted in the medical staff bylaws with respect to Saskatchewan and a few things like that. All the while this was going on, there would be--I had some discussions with Dr. Howell I think over the summer, he came in a couple of times just to get briefed on some things that were going on, and then I was available--there was a list of major issues that I wanted to brief him on, so I was available to brief him on those during that timeframe.
COFFEY, Q.C.:
Q. Now, Doctor, there are a couple of--if I could, again exhibit P-1081? And just to help the Commissioner put this in perspective, this is an e-mail of Friday, January 20th, '06, 11:01 from Dr. Cook to yourself, ER/PR cases from St. Anthony and he writes, "Hi, Bob. This is to let you know that we have received an additional 25 cases from St. Anthony intended for review at Mount Sinai. This time delay is

Page 59

completely unacceptable. I will have to contact Mount Sinai to see if they can handle these cases, after I indicated that we send up all cases." Signed Don. Now what was this about?
DR. WILLIAMS:
A. They come out of a number of other cases when they reviewed their files, that's my understanding. And we sent them up to Mount Sinai and they completed them pretty well expeditiously because it was only a small number. That's my understanding and they got panelled with the patients, other patients that got panelled. So in essence, there wasn't, I think at the end of the day any delay in terms of getting them panelled. They would have been put with the panelling that was done--that's my understanding anyway, they got expedited on an judicious basis because there was so many--to help us tidy things up, I think that they were done.
COFFEY, Q.C.:
Q. Sir, if I could, please, exhibit P-1108? I take it these are handwritten notes of yours? Just scroll ahead, would that be correct?

Page 60

DR. WILLIAMS:
A. That's my writing, yes, I haven't looked at this lately.
COFFEY, Q.C.:
Q. Okay, and in terms of a date, there's a reference here to Dr. Allan Gown, 27th of February, so that might help put it in some kind of temporal perspective for you.
DR. WILLIAMS:
A. That's not my writing--that's my writing on top, it's not my writing there.
COFFEY, Q.C.:
Q. No, this is not.
DR. WILLIAMS:
A. No.
COFFEY, Q.C.:
Q. That is, the reference here?
DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. Okay.
THE COMMISSIONER:
Q. I'm sorry, just to make sure I'm clear, are you saying the list of regions and results and things like that is not your handwriting?

Page 61

DR. WILLIAMS:
A. That's not my handwriting, no.
THE COMMISSIONER:
Q. What is your writing is just the notation on the top of it, with the date.
DR. WILLIAMS:
A. Yes, and some stuff on the back -
THE COMMISSIONER:
Q. All right, thank you. And the writing on the bottom, is that yours?
DR. WILLIAMS:
A. Is that comparing names to what we have received. See at that stage we were comparing names sent out to what we had received taken out of lists of results we have already received and acted upon.
COFFEY, Q.C.:
Q. So is that your handwriting?
DR. WILLIAMS:
A. Yes. Three lists, alive and negative, alive and need to be panelled, deceased and sent up with results and deceased to be tested.
COFFEY, Q.C.:
Q. Okay. How about this, is this your handwriting too?

Page 62

DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. It would be, yes. And the fourth page of the exhibit is simply a listing of ER/PR cases for retest from October 26th, '05, back in time. So, Doctor, in the third--the first bullet, well I suppose the third or fourth line down, what I read you to say here, "so far, approximately 30 percent seems to be converting"?
DR. WILLIAMS:
A. Uh-hm.
COFFEY, Q.C.:
Q. "A positivity rate for PR/ER approximately 74 percent, over years '97 to 2005 new literature says rates 80 - 82 percent positivity rate."
DR. WILLIAMS:
A. Uh-hm.
COFFEY, Q.C.:
Q. Doctor, why was that, because I gather this was probably written in February or March, probably February of '06, January/February of '06, these notes. Why would that be of concern as to whether you were 74 or 82 or--

Page 63

bearing in mind by that point in time Mount Sinai had all the results back or almost all them back.
DR. WILLIAMS:
A. Just to see if, before, as I said, we were looking, based upon our rates of 73 percent, I think at the time, and rates of up to 80 or 82 percent in the literature that we felt that overall we'd have a ten percent of tests affected, total number of tests, so that would be out of 2500, about 250, 260 tests. And I don't know if this is a calculation just to, at the time, I'd have to spend some time looking at it then, Mr. Coffey, but it looks to see if that was sort of in keeping with that kind of thing and that really, with the conversions we had, would that make sense that our rates would then be up to around 80 - 82 percent overall. I think that's what it's about, but again, I'm just seeing it now.
THE COMMISSIONER:
Q. I'm not sure I follow that, Dr. Williams, I think you're going to have to run that past me again. You're saying that--let me tell you what I took from it and you tell me whether I

Page 64

got it correct or not. You were looking at the numbers of the conversions -
DR. WILLIAMS:
A. Yes.
THE COMMISSIONER:
Q. Putting them with the percentages of positivity that you already had.
DR. WILLIAMS:
A. Yes.
THE COMMISSIONER:
Q. And seeing whether if you add the conversions to the number of positives that were already in your records, the rate of positivity overall was in the ballpark?
DR. WILLIAMS:
A. Yes, that's what--I'm just looking at it now to see if that's what I think I--that's what I think I was doing that, if it was done in February or So.
COFFEY, Q.C.:
Q. If I could, please, exhibit P-1119, now this is a fax cover sheet to Don Cook and Nash Denic, April 27th, 2006, it's from yourself, it says, "Re: letter to Peter Dawe, Don Nash for your review and comments. Thanks." Bob.

Page 65

And we have a draft letter, April 27th, 2006, addressed to Mr. Dawe, it's just over, it just goes into the second page, and here in the second paragraph you say "I've attached a dossier of the literature that we've reviewed here and Eastern Health respective methodologies and outcomes with respect to ER/PR marker testing."

DR. WILLIAMS:

A. Um-hm.

COFFEY, Q.C.:

Q. And you go on then at some length about this. If we could, please, Exhibit P-1120. This is a fax cover sheet and a letter attached. This one, the fax is to Dr. Kara Laing, May 1, 2006, it's re: a letter to Peter Dawe. And Denise, on your behalf is saying "Dr. Williams would like you to review this letter before he sends". And Exhibit P-1121, please. And this is, again, a fax of May 2, 2006 to Pam Elliot and Heather Predham, be Denise on your behalf again regarding the letter to Peter Dawe. "Dr. Williams would like both to review the attached letter and provide with comments before he sends". Now, Doctor, first of all,

Page 66

what was the purpose in sending, at that point, the letter to Mr. Dawe and the proposal to send literature to him?

DR. WILLIAMS:

A. Well, I think that at that stage, I might have had some discussion with Mr. Dawe, vis-a-vie a role that he was going to be playing. He's the--he'd be working with the Canadian Cancer Society. They were developing--we were developing a provincial cancer strategy. I think there was a national cancer strategy. And with a view to him bringing forward the issue of ER/PR as an important component of a national cancer strategy and that this is an area that needed attention, in terms of quality. So, I think that was the reason. And give him some background literature on what was happening at that time in this particular area.

COFFEY, Q.C.:

Q. If we could please, P-1123. This is an e-mail of May 4, 2006 from Mr. Tilley to Denise Dunn, saying, "Bob, the letter you are sending to Peter Dawe looks fine to me. Signed, George". And if we could, Exhibit P-1126. Now, this is

Page 67

a letter marked private and confidential and it's to Peter Dawe.

DR. WILLIAMS:

A. Um-hm.

COFFEY, Q.C.:

Q. It's from yourself copied to George Tilley and somebody has hand written here "sent May 16, '06".

DR. WILLIAMS:

A. That's what it looks like, yes.

COFFEY, Q.C.:

Q. And copied to Heather -

DR. WILLIAMS:

A. Kara Laing, I think.

COFFEY, Q.C.:

Q. Kara Laing and Heather Predman, May 16, '06.

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. And I take it this is the letter that came out of your draft.

DR. WILLIAMS:

A. Yes. I don't know if there was any changes to my draft or not; I'm not sure.

COFFEY, Q.C.:

Page 68

Q. You certainly are, at the bottom of page there, you say "any efforts your national association could offer as you move forward with the national cancer strategy to encompass enhancing quality in this important area should be pursued", so, certainly as you've pointed out to the Commissioner or trying to get his assistance in that regard. You then said, "as I advised you, our two consultants have revisited the province to review our efforts here and once we receive the reports, we will making a decision concerning re-instituting immunohistochemical testing within the laboratory services here in St. John's. Before we re-institute testing, we will be doing an update and briefing session. I would like to extend to you an opportunity to be involved in that process".

DR. WILLIAMS:

A. Um-hm.

COFFEY, Q.C.:

Q. "Again, thank you for your interest. You can be assured of Eastern Health's support in any further attempts you make in moving hormone receptor testing forward in terms of quality

Page 69

as part of the national cancer strategy for our country". And then there is attached here, page 3 is an article, "Journal of Clinical Oncology, Estrogen and Receptor testing of breast cancer in current clinic practice, what's the question", it goes on for three pages.

DR. WILLIAMS:

A. I'm sure there was probably more documents attached than that too, Mr. Coffey.

COFFEY, Q.C.:

Q. Your recollection of how much you send. Do you send him, kind of, a wad of material?

DR. WILLIAMS:

A. I do now know; you'd have to ask Mr. Dawe. I can't remember. I think there's more than one article; I may be wrong on that. And the other reason for sending it, of course, was to invite him to partake in a debriefing on this when it was held.

COFFEY, Q.C.:

Q. Now, at that point, it was envisaged that that would happen when?

DR. WILLIAMS:

A. Well, it would happen at some time before we

Page 70

re-instituted the testing. And at that time, on May 15, we needed to review, I'm not sure if both consultants had come back by then, but we needed to review their reports, develop a strategy as to when we were going to restart the testing. And then once people, I guess, from the lab primarily, but--or with oncology and put, felt that they were in a position to recommend that, then some kind of a briefing would be held with the CEO, probably that's--Mr. Dawe would be invited. That's my recollection of it. I don't think I had a time in my mind at that time, but when we did it.

COFFEY, Q.C.:

Q. If we could, please, P-1125. And these are your handwritten notes of May 12, 2006.

DR. WILLIAMS:

A. Yes,

COFFEY, Q.C.:

Q. "Meeting to discuss" -

DR. WILLIAMS:

A. Finalizing patient retesting ER and PR.

COFFEY, Q.C.:

Q. Yes and Ms. Elliot, Dr. Lain, Dr. Denic, Dr.

Page 71

Cook, Ms. Predham and yourself.

DR. WILLIAMS:

A. Um-hm.

COFFEY, Q.C.:

Q. And the topics are retro converters DCIS ER/PR and re-instituting testing.

DR. WILLIAMS:

A. Re-instituting testing, correct.

COFFEY, Q.C.:

Q. I take this was a general -

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. - matter that, internal meeting to discuss, kind of, where you were, retro converters are number one and it's marked priority number one, 17 patients. And then there's, in your handwriting, number two is DCIS priority number two.

DR. WILLIAMS:

A. Um-hm.

COFFEY, Q.C.:

Q. And that's in your hand writing, isn't it?

DR. WILLIAMS:

A. Yes.

Page 72

COFFEY, Q.C.:

Q. If we could, please, number three is ER/PR. You say "results not back, 16 out for testing. Dr. Cook to get list for Heather Predham. Contact Mount Sinai and ask for results", do you recall what that was about?

DR. WILLIAMS:

A. I don't, but it looks like maybe some late tests came in, late requests came in. I'm not sure, Mr. Coffey, I'd have to--others at the meeting recollect that, but it's not specific enough for me to say.

COFFEY, Q.C.:

Q. Number four, reports received on deceased - ethics consult.

DR. WILLIAMS:

A. Refers to getting an ethics consult, yes.

COFFEY, Q.C.:

Q. Number five is re-institution testing.

DR. WILLIAMS:

A. Need to institute all recommendations for TW, await Dr. Banerjee's report, Dr. Makarla and Dr. Elms to be in-serviced by Dr. Ejeckam. By that stage Dr. Ejeckam had left the organization at the end of April, if I'm

Page 73

correct, he came to see me and said he was submitting his resignation. He was going to retire, but before he was going to retire, he was going to go and do locum in Gander for a month. And then we hired him for a week when he finished in Gander to in-service Dr. Makarla and Dr. Elms in this area because they were going to be director and co-director of immunohistochemistry. Now subsequently, unfortunately, Dr. Makarla submitted his resignation and left to go to Calgary, I think. So, that delayed the process further because, and Dr. Elms had to get up to speed and there was nobody else, but Dr. Elms involved.

COFFEY, Q.C.:

Q. So, why was it necessary to have these two pathologists in-serviced by Dr. Ejeckam?

DR. WILLIAMS:

A. Because he had had some experience in our area and he was going to pass along his experience. They were new at this and it was early on in their learning curve. Subsequently, as you know we did send Dr. Elms, I think he went to Seattle with Dr. Allan Gown's lab to spend

Page 74

some time in the US there. That was recognized as probably the premier lab, maybe, in North America in this area. That's my recollection; I may be wrong on that. Others may be able to clarify that.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-1132? I take it these are your handwritten notes, May 25th '06?

DR. WILLIAMS:

A. Yes, "spoke to Heather Predham re: next panel meeting and retro converters--retros and DCIS's. Follow up with Dr. Denic." That would be my note there.

COFFEY, Q.C.:

Q. Yes, and then there's May 24th '06 is the actual rest of the page.

DR. WILLIAMS:

A. Yes, I don't see it there, but -

COFFEY, Q.C.:

Q. Well, actually, I'll help you. Right there, May 24th '06.

DR. WILLIAMS:

A. Okay, yes.

COFFEY, Q.C.:

Page 75

Q. And I take it this is a breakdown then of the numbers, total patients retested, total panelled, confirmed negative, deceased and outstanding.

DR. WILLIAMS:

A. Um-hm.

COFFEY, Q.C.:

Q. This was an update, I take it, on where the ER/PR was?

DR. WILLIAMS:

A. Yes, and six to be panelled and 36 require further review. That was seven retro converters and 29 DCIS. I don't know what that means "have already been panelled" in brackets. I didn't make that note, so I don't.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-1133? It's a letter of May 25th 2006. It's private and confidential to Terry Gulliver from yourself, copied to Dr. Denic.

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. You write "I'm writing concerning a number of

Page 76

issues with respect to quality issues with the laboratory medicine program. Now that we have an opportunity to review the report from TW, I wonder if you would review each of her observations and recommendations. I especially want to make significant progress in the next few weeks on completing the policies and procedure manual for the ER/PR testing service. We'll need to make a decision soon on re-instituting this testing and I want to ensure that all issues within this area have been dealt with. It would be productive to send a copy of the final manual to TW when it is completed. I realize from reviewing the report that significant progress has been made as outlined. However, we now need to finalize all issues. The other issue we need to pursue is enroling in the Ontario Laboratory Accreditation Program. I understand that you have the documentation of August 4th, 2005 that was sent to me by the managing director, Dr. Harold Richardson. I have discussed this matter with Mr. George Tilley and he's supportive of us enroling in this program. This will be one other process

Page 77

to ensure that our lab is on the leading edge in terms of quality and peer review. I would like to discuss these issues in detail at the next laboratory medicine leadership team meeting. I trust this is satisfactory."

Now Doctor, by this point, Ms. Wegrynowski and Dr. Banerjee had been back?

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. When they came back the second--in the spring of '06, who set out the terms and conditions or parameters of what they'd do?

DR. WILLIAMS:

A. I guess we just asked them to come back and review their previous report and update it and make any further comments about our lab before we'd consider re-instituting the testing.

COFFEY, Q.C.:

Q. Did you speak with Ms. Wegrynowski before she started this second review?

DR. WILLIAMS:

A. I expect I did, Mr. Coffey, but I don't have any documentation that I did.

COFFEY, Q.C.:

Page 78

Q. Okay.

DR. WILLIAMS:

A. So, I may not have, but I probably did.

COFFEY, Q.C.:

Q. Now, with respect to--the first time around in September of '05, the report that she sent certainly dealt with IHC testing at large, didn't it?

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. And not just ER/PR, but IHC testing at large.

DR. WILLIAMS:

A. Um-hm.

COFFEY, Q.C.:

Q. When she came back the second time, do you recall whether or not there was any discussion as to whether she should do the whole of the IHC again or perhaps concentrate on ER/PR?

DR. WILLIAMS:

A. I don't remember telling her just to--I don't remember, I guess, is what I'm saying. To try to say I did this or I did that, I'm not sure, but in retrospect it was just a follow-up and what they done previously, see where we were

Page 79

with the recommendations and what other things needed to be attended to before we could consider moving forward. That's my recollection.

THE COMMISSIONER:

Q. Who would be the official contact between her and the organization in any event?

DR. WILLIAMS:

A. It may have occurred at Mr. Gulliver's level the second time. I'm not sure or it may have come through my office. I think there's some e-mails there suggesting that we were in contact about a date. So, I may have talked to her on the phone as well. But my understanding would have been that she would come down and do a follow-up on her first report. That would be my understanding.

COFFEY, Q.C.:

Q. So, before her and Dr. Banerjee showed up in '06, were you given any understanding as to how many of the recommendations had actually been implemented?

DR. WILLIAMS:

A. No, we had this document done up -

COFFEY, Q.C.:

Page 80

Q. December 14, '05 spreadsheet.

DR. WILLIAMS:

A. Yes, but it was updated on occasion and it was updated just before T.W. came and Dr. Banerjee came again.

COFFEY, Q.C.:

Q. I take it you understood before they arrived that there was still a number of recommendations -

DR. WILLIAMS:

A. I understood that, yes, I understood that some other things needed to be done. I wanted to get an update on where we were and we would use that update to base our decisions on, yes. The other thing that was causing us a lot of problem at the time and took a lot of time was the fact that the pathologist, shortage of pathologists got so bad in the fall of 2005 and early in the spring of 2006 that we were sending out $30,000.00 worth of work to Gamma Dynacare in Ottawa to process and that would have taken Mr. Dyer and Mr. Gulliver a lot of time to make sure that that was done properly. You can't be sending specimens out of province without proper documentation, making sure that

Page 81

things don't get lost, all these things that had to be--because if you lose a specimen, you don't have anything else to test. So, they would have been taken off some of the things they might have been doing in this respect to tend to that, but we had no choice but to do that. Otherwise we would have people waiting for two or three or four months for pathology reports which is far from satisfactory. So, we had to send specimens out, a lot of work was sent out.

COFFEY, Q.C.:

Q. Now, what was your understanding then after Ms. Wegrynowski left and her report came in in '06., she was here in '06 and left, as to her view of the situation at that point? What -

DR. WILLIAMS:

A. There was some things that needed to be done. She was impressed, according to her report, with the quality endeavours that had taken place, through Dr. Carter's committee and this type of thing in pathology. And that we'd enrolled in the external quality assurance programs, both in Great Britain and in College of American Pathologists in the US.

Page 82

COFFEY, Q.C.:

Q. What about in terms of actually getting some manuals written?

DR. WILLIAMS:

A. Well, I knew her report said that we needed to do the manual. And as you see in my letter to Mr. Gulliver, I said it would be good if when the manual was done that they send it up to her, so we could get some feedback from her. That was my thought process, yes.

COFFEY, Q.C.:

Q. Did that ever get done while you were there?

DR. WILLIAMS:

A. I'm not sure if it got done while I was there because I wouldn't of had the follow-up meeting to talk about the institute and retesting, but I'm sure that that was something that would have been picked up then.

COFFEY, Q.C.:

Q. Do you know, to this day, if it was ever done?

DR. WILLIAMS:

A. I would not know.

COFFEY, Q.C.:

Q. Okay.

DR. WILLIAMS:

Page 83

A. But I wrote and asked it to be done and I presume it would be done.

COFFEY, Q.C.:

Q. Exhibit P-1135. Now, this is a memorandum to yourself from Terry Gulliver, June7, 2006.

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. ER/PR rates, it says, "as per your request, in light of remarks from Dr. Gown regarding our 2004/'05 Ventana ER/PR rates, I have rewrote each report and I've identified the total numbers of positives previously reported and also include specimens that were ER/PR positive, but were not breast specimens" and he's got previous results and new results.

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. And this is copied to Dr. Denic and you've written "copy given to Heather Predham on June 7".

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Page 84

Q. And under the new results, these are just the '04/'05 Ventana rates.

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. And under "new results" now it comes percentage positive 81.2 percent. Okay?

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. And that's the total from the--of the Health Sciences Centre test and then the total positive is 82.6 percent.

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. So, I take it that's the reporting by Mr. Gulliver concerning the recalculation -

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. - for the '04/'05 that you refer to before.

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Page 85

Q. If we could, please, Exhibit P-11--just a moment please--P-1139, please. These are, I take it, your handwritten notes of June 30, '06.
DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. A meeting re: start up of ER/PR testing.
DR. WILLIAMS:
A. Um-hm.
COFFEY, Q.C.:
Q. And there's a list of physicians and other personnel -
DR. WILLIAMS:
A. Um-hm.
COFFEY, Q.C.:
Q. - involved. The background decision re ER/PR testing and Dr. Denic is quoted as having given some input including where they were, I take it, with external quality reviews.
DR. WILLIAMS:
A. Um-hm.
COFFEY, Q.C.:
Q. Continue on with Dr. Denic and there's a reference Dr. Elms and Dr. Denic again, Dr.

Page 86

Cook and then finally decision. Could you just read out that, what the decision is, numbers one through five.
DR. WILLIAMS:
A. Sure. "Probably be ready to start retesting early September, 2006. Set meeting for second week of September, 2006", I guess to talk about it maybe. "Need to set out everything that needs to be done and individual assigned to do it. Accountability. Decision as to validate all our antibodies now, Dr. Makarla and Dr. Elms and start work on HER2/neu". I think the HER2/new was being sent out of province at the time.
COFFEY, Q.C.:
Q. Okay. I take it, it was being done at Mount Sinai?
DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. Now, Doctor, what was the reason for the delay in restarting it?
DR. WILLIAMS:
A. Well, we--I guess, I was gone at the time there was a delay. We had laid out from TW's

Page 87

report, 30 recommendations. You see my notes on that that needed to implemented.
COFFEY, Q.C.:
Q. That's the '06 report.
DR. WILLIAMS:
A. Yes. Dr. Makarla subsequently resigned and left the province. So, that was a delaying factor and I don't know what the other delaying factors would be because again, I knew that Dr. Makarla left before I left. Those 30 recommendations needed to be followed up and we needed to be sure that they were all implemented before we restarted the retesting. And I don't know what other factors occurred in the fall to delay the retesting, I think, until February or so, 2007?
COFFEY, Q.C.:
Q. Yes. So, if there's still 30 recommendations in TW, as you refer to, second report, did you ask anybody, like, how can we still have 30 outstanding?
DR. WILLIAMS:
A. Well, I knew that some of them, because Barry and Terry were taking off doing that. A lot of it was to do with the--there's a lot of

Page 88

work in sending out $30,000.00 worth of specimens every month to Gamma DynaCare. That's one thing. That would--I would consider that was one of the factors. Some of those 30 recommendations we were very close to implementing at the time if you see the notes, the comments that I've made. So, we've made progress, but some of them were not, we could say, finalized as yet.
COFFEY, Q.C.:
Q. Okay. If we could, please, Exhibit P-1145. These are your handwritten notes of July 12, '06, Doctor.
DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. 2:30 p.m., a conversation you had with Dr. Cook. This reads to, I take it, the DCIS issue.
DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. And information for Dr. Cook concerning again DCIS cases.
DR. WILLIAMS:

Page 89

A. Um-hm, yes. That's sort of the details on each particular situation, I think. I haven't--I'd have to scroll down through it and see that, but that's what it looks like.
COFFEY, Q.C.:
Q. Yes. And can--it refers to the breakdown of the 29, at least were, certainly the cases are and so on.
DR. WILLIAMS:
A. Um-hm.
COFFEY, Q.C.:
Q. And the first page refers to, perhaps speaking with Dr. Dalton.
DR. WILLIAMS:
A. No, I didn't speak to Dr. Dalton. If you see there, I spoke to Dr. Larry Alteen.
COFFEY, Q.C.:
Q. Larry Alteen, I'm sorry.
DR. WILLIAMS:
A. He would be my counterpart.
COFFEY, Q.C.:
Q. Yes.
DR. WILLIAMS:
A. He will speak to pathologist, Dr. Dalton, re these cases. And I presume I would have done

Page 90

the same with Dr. Jenkins, if there were any cases from there.
COFFEY, Q.C.:
Q. Okay. If we could, please, Exhibit P-1154. It's an e-mail of August 2, '06, 12:02 p.m. It's from George Butt to yourself, copied to Doris Murphy. The subject is "lawsuit against Eastern Health", and it's forwarding a media report, CBC media report which is reproduced later in the exhibit. But Mr. Butt has written, "Dr. Williams, has there been discussion with HIROC as to wether these are viewed as multiple occurrences or as a single occurrence. Insurance impact is significant to say the least. Signed, George". Well, first of all, who is Mr. Butt?
DR. WILLIAMS:
A. Mr. Butt would be the vice-president of finance and administration.
COFFEY, Q.C.:
Q. Okay. And -
DR. WILLIAMS:
A. He formerly sat on the HIROC board for a few years, I think. Each of the organizations has a seat on the HIROC board, I think that's how

Page 91

it works.
COFFEY, Q.C.:
Q. Now, had you had any involvement with HIROC?
DR. WILLIAMS:
A. Not directly, hadn't talked to HIROC directly. What we did, we had our legal counsel, Mr. Bruce, review the -
COFFEY, Q.C.:
Q. I got to be careful on this in terms of--I don't want to know anything that might be solicitor/client privileged. Mr. Simmons is nodding no.
DR. WILLIAMS:
A. Okay, sorry, okay.
COFFEY, Q.C.:
Q. So, but from your own--without--trying to get some sense for the Commissioner your involvement without being told, kind of, what it was that you were told by the lawyer.
THE COMMISSIONER:
Q. We don't need to know what the advice was.
DR. WILLIAMS:
A. Okay -
COFFEY, Q.C.:
Q. What the advice was.

Page 92

DR. WILLIAMS:
A. - was involvement, we looked at the issue and we had some legal advice on it. It seemed to satisfy our concerns about that and I don't know if Mr. Butt was aware of that. That happened earlier. My recollection it happened earlier.
COFFEY, Q.C.:
Q. So you had--within the organization, who was responsible for addressing that issue? Was it you or Mr. Tilley?
DR. WILLIAMS:
A. I would not be able to answer that. There was some discussion about it and I know we had our lawyer for Eastern Health look at the insurance policy for HIROC and make an interpretation.
COFFEY, Q.C.:
Q. Okay.
DR. WILLIAMS:
A. So, as far as we were concerned, we looked at it and had dealt with it.
COFFEY, Q.C.:
Q. Okay.
DR. WILLIAMS:

Page 93

A. Now Mr. Butt may not have been aware of that.
COFFEY, Q.C.:
Q. Okay. If we could, please, Exhibit P-1156. Now, this is an e-mail from Wayne Miller, August 3, '06 4:50 p.m. It's to Ms. Bonnell, Mr. Predham, the executive team of Eastern Health, re "seriously flawed story on CBC". He writes, "I feel that the most appropriate way of addressing the issue is to release a prepared statement that states the facts in the same manner that we would respond to a Statement of Claim. Have the lawyers work with Dr. Williams to prepared a statement" and it's signed by Wayne Miller. Now, he is the senior director of corporate strategy and research?
DR. WILLIAMS:
A. Um-hm.
COFFEY, Q.C.:
Q. Did you ever get involved in this, first of all?
DR. WILLIAMS:
A. No, I was away at the time and when I got back I don't remember this issue being bought up, bought forward to me.

Page 94

COFFEY, Q.C.:
Q. I asked you before about your involvement in communications and you'd indicated you hadn't had a whole lot. That was Mr. Tilley's -
DR. WILLIAMS:
A. Development of communications strategy, I didn't think that was my role, but I would be a spokesperson for Eastern Health on occasion.
COFFEY, Q.C.:
Q. But as to whether or not you should speak -
DR. WILLIAMS:
A. Well, I'd take my cue from communications people. I understand that some people thought I was speaking to much at one stage. But I wouldn't have been speaking if communications hadn't some and ask me to speak.
COFFEY, Q.C.:
Q. Ask you to, yes. If we could, please, Exhibit P-1170. Now, this is a letter of August 10, '06, it's addressed to Dr. Nash Denic, Clinical Chief from Dr. Bev Carter, assigns herself, quality management program.
DR. WILLIAMS:
A. Um-hm.
COFFEY, Q.C.:

Page 95

Q. And she says, "in order to implement a fixation policy, enclosed the following actions will have to be considered". And there's a listing of at least six different aspects of the matter. So, were you aware at this point in time, in the summer of '06, Doctor, that as of yet, as of that point, there still was not a fixation policy for Eastern Health?
DR. WILLIAMS:
A. I hadn't seen this, so I was not--one of the things that came out of one of the recommendations was Dr. Denic was following up on a fixation policy.
COFFEY, Q.C.:
Q. Okay. I haven't seen this until today. And Dr. Carter, in her role as head of our quality program would usually deal with Dr. Denic. It there was an issue that they couldn't resolve, I suspect she or he would have brought it to me.
COFFEY, Q.C.:
Q. P-1173, please. This is an e-mail from Denise Dunn to Dr. Denic, September 13, '06, the subject is ER/PR presentation. "Dr. Denic, I

Page 96

spoke to Dr. Williams, explained the data won't be ready for presentation until and he said okay, but he's planning to get out of the province for October". So, the data--who is in charge, from your perspective, at this point, of getting the data ready?
DR. WILLIAMS:
A. The data ready on terms of patient notify -
DR. WILLIAMS:
A. Well, presentation--well, this is -
DR. WILLIAMS:
A. Yeah, I would think that it would be a joint effort in terms of lab and in terms of quality with respect to patient data. Lab, we well, both together. Depending on--well, if the thrust was going to be from the lab, then it would be primarily lab. I think I would have been invited to this presentation as a courtesy although I hadn't had responsibility anymore, that they were going to invite me a courtesy.
COFFEY, Q.C.:
Q. And if we could, please, Exhibit P-1174. Now, this is a couple of e-mails of September 14, '06 from Ms. Bonnell. Well, the first one at

Page 97

2:51 p.m. to yourself and Dr. Howell, copied to a number. She says, "spoken to Pam Elliot about this case. She feels we should touch base tomorrow when Heather is back in the office. She is away in B.C. today. Pam does not have access to the database today. We should get back to this gentleman by tomorrow so he doesn't have the weekend to stew on a lack of response. Pam will make contact with Dr. Bob tomorrow to discuss". And this apparently, if you look at the e-mail below, at 12:49 p.m. to Ms. Bonnell, and this is from a person who is writing about a previous--"had been previously told that my late wife's ER/PR receptor was being retested as her diagnosis of breast cancer fell into the time period when inconsistencies were detected". And he goes on to say, "could you please advise who I can contact to get an answer. I don't want to be put onto a patient relations officer who is going to give me the runaround. I have been more than patient on this issue, but I know require a truthful answer to get on with my life". And he identifies his wife by her name and date of birth and date of death and

Page 98

diagnosis. "If I haven't received a reply to this e-mail by September 28, '06, I will be contacting the media with my problem". Now sir, in the middle of September of '06, how much involvement did you still have in this?

DR. WILLIAMS:

A. I was--I didn't have any responsibility, direct responsibility. Heather Predham was still keeping me in the loop until the very day I left, I think.

COFFEY, Q.C.:

Q. Okay.

DR. WILLIAMS:

A. If I recollect correctly about this, Heather got back and phoned this particular gentleman and this issue was resolved. I think Heather may have talked to him before.

COFFEY, Q.C.:

Q. Yes, there's a reference here to "woman retested, negative, negative" something "and then HP spoke to man".

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. Is this your handwriting?

Page 99

DR. WILLIAMS:

A. No.

COFFEY, Q.C.:

Q. It's not, okay. I take it that this would be the period where there was a cross over, you were still being copied on material but Dr. Howell -

DR. WILLIAMS:

A. Yes, I would have left the--the responsibility would have rested with Dr. Howell. I had really no authority at that time. I wasn't the VP Medical, but Heather, where she had, I think, been working on this all along with me, that she would let me know things.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-1180. Now this is--these your notes of October 17th '06?

DR. WILLIAMS:

A. That would be '05, I got a feeling. That's wrong. October 17th, 2005.

COFFEY, Q.C.:

Q. Okay, and so, and this would have been then, your notes of a meeting of October 17th '05. Back then, Dr. Laing, Ms. Parsons, Ms. Predham, Chris?

Page 100

DR. WILLIAMS:

A. Power.

COFFEY, Q.C.:

Q. Power.

DR. WILLIAMS:

A. She was with the Cancer Clinic.

COFFEY, Q.C.:

Q. Ms. Bonnell, Ms. Pilgrim, Dr. Cook and yourself, and here back then, you had written "one, do information for the public, Susan. Two, letter to patients." I gather Heather is supposed to do that. "Three, notify patients with results. -

DR. WILLIAMS:

A. Back as negative.

COFFEY, Q.C.:

Q. - back as negative, and four, Chris Power to get history of all patients -

DR. WILLIAMS:

A. Get listing of all patients notified.

COFFEY, Q.C.:

Q. I apologize, listing of all patients notified.

DR. WILLIAMS:

A. This is around the time a decision was made--we talked about it earlier, back in 2005.

Page 101

COFFEY, Q.C.:
Q. And on that point, because we had discussed this before, in the middle of October of what was then ’05, the letter, as of this meeting of October 17th ’05, the second point, letters to patients, a letter to patient, Heather was being tasked with preparing a letter, I take it, at the time?
DR. WILLIAMS:
A. Yes, correct. Yes, the meeting occurred on the 18th, as we talked about, I think on Friday.
COFFEY, Q.C.:
Q. But as of the meeting on the 17th, she was being tasked with doing it?
DR. WILLIAMS:
A. Yes, correct.
COFFEY, Q.C.:
Q. If we could, please, Exhibit P-1183. Now these are your handwritten notes?
DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. Of, this would be October 18th. It’s written 2006, but I gather it should be ’05? Would

Page 102

that be--you can have a look down through them and just see if you--would that be correct?
DR. WILLIAMS:
A. That was my notes, yes.
COFFEY, Q.C.:
Q. Oh yes, it should be -
DR. WILLIAMS:
A. It should be 2005, I’m sorry, yes.
COFFEY, Q.C.:
Q. Okay. Kara Laing, George Tilley, Ms. Predham, Ms. Bonnell, Dr. Cook and yourself and Ms. Pilgrim. Dr. Laing, minutes of meeting of panel. Meeting are fine, only a few suggestions to format.
DR. WILLIAMS:
A. You should have the typed report.
COFFEY, Q.C.:
Q. Yes. Here it says "two, review media releases and patient letter and suggestions made."
DR. WILLIAMS:
A. Yeah, the suggestion is that--under 3A, is that we would call all patients.
COFFEY, Q.C.:
Q. Three, suggestion is that we would call all people. What’s that?

Page 103

DR. WILLIAMS:
A. To be retested.
COFFEY, Q.C.:
Q. To be retested. B. Call all patients who have not converted. Converters will be dealt with by the physicians?
DR. WILLIAMS:
A. Physicians, yes.
COFFEY, Q.C.:
Q. And then decision. Could you read out the decision then, please?
DR. WILLIAMS:
A. "Get information to media in print," that’s what we did. "Phone patients who are retested" or to be retested, this type of thing. "Phone patients who have been retested and are not converters. Patients panelled by tumour board to be contacted by physician. Western and Central to phone their patients."
MR. SIMMONS:
Q. The typewritten version is at P-0927.
COFFEY, Q.C.:
Q. Sure.
MR. SIMMONS:
Q. Page 27.

Page 104

COFFEY, Q.C.:
Q. Thank you, Mr. Simmons. But as of the middle of October, I take it then that there was, at a meeting of October 17th, Heather was tasked with preparing a letter to patients and it’s your recollection that some time on the 18th, at that meeting, the decision was made not to send the letter?
DR. WILLIAMS:
A. Yes, according to those notes. If I didn’t have the notes, obviously I wouldn’t be able to remember back that far, but the notes do say that.
COFFEY, Q.C.:
Q. Are you able to tell what time of day this meeting occurred, on the 18th? Would you be able to--do you have a calendar that you could reconstruct that from?
DR. WILLIAMS:
A. I wish I did. My calendar was thrown out, Mr. Coffey. I went looking for it and it was thrown out, so I don’t know on what time of the day that would have taken place.
COFFEY, Q.C.:
Q. Okay. Now sir, in one of the documents we

Page 105

just looked at, there was a reference to--from your perspective, getting this under way, these recommendations in '06, implemented. Making a listing of them. You referred to accountability. In that context, what did it mean?

DR. WILLIAMS:

A. Well, we were going to have these recommendations--I have to look at them, but certain people were going to be charged with getting them implemented or moving on those.

COFFEY, Q.C.:

Q. And what would the point be then of doing that? I take it accountable would be if they're not done, you'd hold them responsible for it?

DR. WILLIAMS:

A. Well, yeah, you'd find out why they weren't done, this type of thing.

COFFEY, Q.C.:

Q. If we could bring up, please, Exhibit P-0326. Page, let me see--now sir, these are notes from the telephone log of Mr. Tilley. There's one there August 2, "follow-up conversation Bob, follow-up conversation with Allan Kwan

Page 106

re: algorithm. Get Ventana now. Meeting with oncologists, and then Bob Williams, Ventana, being sought Mount Sinai, all go forward, 500 retests, QI review. Ventana validation, who signed off? Bev Carter, letter to Don Cook re: spooked." Do you recall, you know, discussing that August 2nd letter of Dr. Carter to yourself, the one where she resigns? Do you recall discussing that with George Tilley?

DR. WILLIAMS:

A. I think that related to the August 1st meeting.

COFFEY, Q.C.:

Q. Yes.

DR. WILLIAMS:

A. Yes, I phoned him about the letter.

COFFEY, Q.C.:

Q. Did you use the word "spooked"?

DR. WILLIAMS:

A. No, I wouldn't. That's not a word I'd use, so I don't--I wouldn't have used the word "spooked."

COFFEY, Q.C.:

Q. What did you tell him, if anything, about why

Page 107

she was leaving?

DR. WILLIAMS:

A. She wasn't going to--at that time, I don't think she was going to leave.

COFFEY, Q.C.:

Q. Leaving the effort, I'm sorry.

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. I should say. She wasn't leaving the organization.

DR. WILLIAMS:

A. I started to read the letter out and asked if he wanted to see the letter, and he said no, he didn't need to see it. My interpretation of the letter, after having discussed it with Dr. Cook, and that's my interpretation, you'd have to ask Dr. Carter directly, my understanding is that there was a disagreement at one of the meetings that Mr. Gulliver was thinking that it was new technology that was at the root of this and there was a discussion that really we had some problems with how we managed the DAKO system, and so although the new technology made it easier, it wasn't just

Page 108

new technology, and that's where there was a disagreement between Mr. Gulliver and Dr. Carter. That's my recollection. And Mr. Tilley was involved in those discussions, and Dr. Carter, I think, sensed that Mr. Tilley was supporting the manager.

COFFEY, Q.C.:

Q. Okay, I'll get -

DR. WILLIAMS:

A. That's my understanding.

COFFEY, Q.C.:

Q. Mr. Tilley has used the word "spooked" in his notes concerning a conversation he had with you.

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. And I was just wondering if you recall -

DR. WILLIAMS:

A. I wouldn't have used those--I would have probably said something like I just said.

COFFEY, Q.C.:

Q. Okay. At the time, in July or August of 2005, were you ever made aware of what Dr. Carter had found in her review, the review that she

Page 109

had done?
DR. WILLIAMS:
A. Only what was written in anything she did.
COFFEY, Q.C.:
Q. So what she may--if she looked at some original slides, what she may have noticed in terms of those original slides?
DR. WILLIAMS:
A. Only what she would have put in writing at the time, Mr. Coffey.
COFFEY, Q.C.:
Q. And is there any reason why you didn't actually speak to her directly about what she was finding?
DR. WILLIAMS:
A. Again, I would have talked to Dr. Cook. He had a good relationship with Dr. Carter. I would have met with Dr. Carter and Dr. Cook on a number of occasions that summer. I can't tell you exactly when, but I was over to their office and I remember sitting in the room with both of them.
COFFEY, Q.C.:
Q. Did you ever see the spreadsheets or working papers she created?

Page 110

DR. WILLIAMS:
A. No, I don't remember seeing them.
COFFEY, Q.C.:
Q. Like ones with patient's names, MCP numbers, original ER/PR readings, Ventana retests and her observations as to what she'd seen?
DR. WILLIAMS:
A. I can't remember seeing those, no.
COFFEY, Q.C.:
Q. If we could please, Exhibit P-1347. Now sir--thank you, Registrar. This is a performance goals and objectives 2004-2005 for Dr. Don Cook as clinical chief, Laboratory Medicine program, and the headings are goals/objectives, December '04 and then there's a series of dates across the top.
DR. WILLIAMS:
A. Um-hm.
COFFEY, Q.C.:
Q. What--could you explain how this works?
DR. WILLIAMS:
A. What I would do with Dr. Cook is, starting in the fall, because he came on, I think, as clinical chief in October of 2002, if I'm correct, we would sit down each year and set

Page 111

out a series of goals and objectives that we would work on. He would work on and we'd meet on a quarterly basis to pursue.
COFFEY, Q.C.:
Q. So those goals and objectives would be like here in the left-hand column?
DR. WILLIAMS:
A. Yes, right.
COFFEY, Q.C.:
Q. And they would be set as of December '04?
DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. Goals and objectives would be: one, complete an annual review of all pathologists credentialed in the laboratory medicine program.
DR. WILLIAMS:
A. Um-hm.
COFFEY, Q.C.:
Q. And then number two, work towards filing -
DR. WILLIAMS:
A. Filling.
COFFEY, Q.C.:
Q. - filling all pathology positions.

Page 112

DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. Three, work on major quality assurance issues, developing a policies and procedures manual in the division of anatomical pathology.
DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. Four, work with the program director for the laboratory medicine program to ensure a smooth transition to the new Eastern Regional Health Authority. And five, continue to support and work on implementing recommendations of the surgical pathology review committee. And then date proposed, December 10th, 2004, and then, okay, so there would be those five things, I take it, those goals set in December of '04?
DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. Okay, tell us then--there are another series of dates throughout, April 1/05, July '05, October 7th '05 and December 9th '05.
DR. WILLIAMS:

Page 113

A. On April 1st, we'd get the first update of how far Dr. Cook had advanced that. The normal process here is that there's a document that each of the pathologists would be asked to complete as part of the annual review. So Dr. Cook would update me in April that he'd got those out, he'd asked the pathologists to complete them. There's a fair bit of detail there, and he'd received documentation on all but five of the physicians.

COFFEY, Q.C.:

Q. Okay.

DR. WILLIAMS:

A. And he'd be following up on the review process when these came in, and of course, then we got an update in July.

COFFEY, Q.C.:

Q. So you met on July 15th, according to this.

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. As scheduled, however there were other pressing issues that had to be discussed. Meeting rescheduled to August 5, but had to be cancelled.

Page 114

DR. WILLIAMS:

A. Yes, because of the ongoing issues with ER/PR.

COFFEY, Q.C.:

Q. And then October 7th '05, due to a major issue in the Lab Medicine program, this has been delayed.

DR. WILLIAMS:

A. Yes, because -

COFFEY, Q.C.:

Q. And then finally, no changes noted before. So the annual review of all pathologists credentialed in the laboratory medicine program, in late '04, that was envisaged to be done during '05 by Dr. Cook.

DR. WILLIAMS:

A. Because it had already been done a couple of years earlier, Mr. Coffey, and it was envisioned we'd do another cycle at this stage, but because of the--Dr. Cook was pretty well working full time on ER/PR issues. That's the problem.

COFFEY, Q.C.:

Q. Thank you. If I could, number two, work toward filling all pathologists positions. As of April 1/05, five positions interviewed to

Page 115

date. Four refused the offer of employment. Still awaiting the response from the fifth, and there's nothing in July of '05. October 7th '05, new physician, Dr. Makarla.

DR. WILLIAMS:

A. Makarla, yes.

COFFEY, Q.C.:

Q. Makarla, okay.

DR. WILLIAMS:

A. He came and went. He didn't last a year. He came and went to Calgary at the end of the summer, 2006.

COFFEY, Q.C.:

Q. And then December 9th, commitments for two of four residents to take up a position and two other JI visa applicants being considered.

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. Number three, work on a quality, major quality assurance issues, developing a policies and procedure manual for the division of anatomical pathology. On April 1, 2005, it's noted "quality assurance committee set up, chaired by Dr. Bev Carter." Second bullet,

Page 116

"policy and procedure manual in progress." Third bullet, "check path program, College of American Pathologists Performance Implementation, evaluation program proficiency testing programs in place and records kept of how each individual pathologist performed." Fourth bullet, "participates in cyto pathology evaluation program." Fifth bullet, "these programs are all approved by MC -

DR. WILLIAMS:

A. MCOMP.

COFFEY, Q.C.:

Q. - OMP via Royal College of Physicians and Surgeons. Next bullet, "interdepartmental consultations documented" and then final bullet, "reconcile our reports with those sent outside the province." So what was this about? I take it this is before ER/PR -

DR. WILLIAMS:

A. Yes. This is just -

COFFEY, Q.C.:

Q. - became known?

DR. WILLIAMS:

A. Yes, this is just ongoing work with respect to what's being done in terms of quality

Page 117

initiatives within Eastern Health and how Dr. Cook was moving forward on that agenda, nothing to do with ER/PR in a sense, in retrospect.

COFFEY, Q.C.:

Q. In the sense that the index case had not yet occurred.

DR. WILLIAMS:

A. Correct.

COFFEY, Q.C.:

Q. As of April 1.

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. Now the external proficiency testing was being--what was that about, do you recall?

DR. WILLIAMS:

A. Yes, our pathologists were all participating in external proficiency testing. It would rate the pathologists and also rate the lab. My understanding is that each pathologist would participate and then there'd be a group get together and the lab would--they would participate as a group. So I think the lab would be rated and the individual pathologist

Page 118

would be rated. The College of American Pathologists has that program which we subscribe to for pathologists.

COFFEY, Q.C.:

Q. So at the time, early in '05, well in fact, going back to late '04, had the idea of--had Dr. Cook raised with you any concern that he might have had about quality assurance issues and getting them documented and getting enrolled in having that anatomical pathology -

DR. WILLIAMS:

A. Not in anatomical pathology, no. He was just--I take this that he was just outlining the things that they were doing in that area. I didn't see it as an issue that he was raising, "we have a problem here." I think he was just saying look, here's the things we're doing in quality. I wanted to really get some issues on the table with respect to quality, what we were doing, how we were documenting and these type of things.

COFFEY, Q.C.:

Q. Now sir, were they doing external proficiency testing at the time?

DR. WILLIAMS:

Page 119

A. Yes, that was my understanding.

COFFEY, Q.C.:

Q. How about for IHC?

DR. WILLIAMS:

A. That issue never came up.

COFFEY, Q.C.:

Q. Did you--I take it afterward though, you asked and -

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. - when ER/PR did come up and -

DR. WILLIAMS:

A. Dr. Cook said in his first memo that they weren't doing it. That didn't come up at any of these.

COFFEY, Q.C.:

Q. Okay. Now sir, if I could please, bring up, please, Exhibit P-0467.

THE COMMISSIONER:

Q. We'll take the morning break after you're through with this exhibit, Mr. Coffey.

COFFEY, Q.C.:

Q. Thank you, Commissioner. Page 12, please. Now, sir, we have referred before to the 2003

Page 120

IHC matter. This is Dr. Ejeckam's memo to pathologists, St. Clare's--Health Sciences Centre, St. Clare's, and out of town hospitals. Subject is the immunohistochemical stains, April 4th, 2003. And it says "Thank you, Dr. G. Ejeckam," copied to Barry Dyer and all technical staff on immunohistochemistry.

So sir, your first recollection of seeing this memo was when?

DR. WILLIAMS:

A. I don't--I know Dr. Cook gave me memos from this issue back in July of 2005.

COFFEY, Q.C.:

Q. Okay.

DR. WILLIAMS:

A. I remember the two other memos, but I can't recollect that. I may have seen it, but it wasn't in my package in my binder, so I may have lost it. But the memos I was shown or what memos I saw were July 2005.

COFFEY, Q.C.:

Q. And dated back to '03?

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Page 121

Q. So in 2003, you didn't see this memo, that you recall?
DR. WILLIAMS:
A. No.
COFFEY, Q.C.:
Q. How about hear about the subject matter?
DR. WILLIAMS:
A. No, I did not.
COFFEY, Q.C.:
Q. If we could look, please, at Exhibit P-0904. Now this is an agenda of the Surgical Pathology Review Committee, April 15th 2003, "two p.m. called to order. Business arising. Terms of reference. One, the SPRC will review standardized reporting of pathology specimens. The SPRC will perform tissue audits on surgical specimens and will serve as a forum for interesting and/or difficult cases that would be reviewed on an individual basis or on specific request. It would be chaired by a pathologist, would meet once every two months. Would report directly to the vice-president of medical affairs. This committee would make recommendations, if necessary," and it's copied to yourself and Dr. Cook, the agenda.

Page 122

Now were you aware that the Surgical Pathology Review Committee was being created?
DR. WILLIAMS:
A. Yes, it was part of Dr. Cook's performance goals and objectives.
COFFEY, Q.C.:
Q. And so would you have received this agenda in April of '03?
DR. WILLIAMS:
A. Probably.
COFFEY, Q.C.:
Q. And in the normal course, how would such a committee report to you?
DR. WILLIAMS:
A. Well, they could send me copies of minutes or they could send me a report with recommendations to me that my office would need to follow up on.
COFFEY, Q.C.:
Q. Exhibit P-0467, page 26, please. Now this is--these are minutes of a meeting of April 15th 2003 for that committee. Present, Dr. Ejeckam, Dr. Battcock, Dr. Dawson, Dr. Parai, Dr. Siddiqui, Theresa Curtis is the secretary and apologies from two physicians. The call

Page 123

to order, it says "the first meeting of the Surgical Pathology Review Committee was called to order by Dr. G. Ejeckam, chairman, at two p.m. on April 15, 2003, in Room 2864 at Health Sciences Centre" and "new business, paragraph 3.1, ER and PR receptors, Dr. G. Ejeckam stated ER and PR receptors are not being performed for the next six weeks due to a technical problem. If a solution cannot be found, these tests will be sent outside St. John's. He stated it is being considered to send one or two technologists to Halifax or Toronto for training."
So Doctor, I take it then that this was never brought to your attention at the time?
DR. WILLIAMS:
A. No.
COFFEY, Q.C.:
Q. Paragraph 3.1.
DR. WILLIAMS:
A. What happened is that I came back to work on the day after Labour Day in 2003. I'd been off ill for three months.
COFFEY, Q.C.:
Q. And so you didn't go off on sick leave until

Page 124

sometime in June?
DR. WILLIAMS:
A. Yes, the 7th or 9th of June, correct.
COFFEY, Q.C.:
Q. So if this was all going on in April and May of '03, the suspension of testing and the re-institution of testing in May that you're about to see, can you tell the Commissioner how it's possible that you did not see it and didn't know about it?
DR. WILLIAMS:
A. Well, it wasn't brought to my attention.
COFFEY, Q.C.:
Q. Have you ever asked anybody why not?
DR. WILLIAMS:
A. Oh yes, yes.
COFFEY, Q.C.:
Q. Okay. Well, can you tell the Commissioner when you did that and what they told you?
DR. WILLIAMS:
A. I did that in 2005 when I got the memos or two of the three memos. I might have seen the other one.
COFFEY, Q.C.:
Q. Who did you ask?

Page 125

DR. WILLIAMS:
A. I asked Dr. Cook and I talked to Mr. Gulliver as well about the situation. Dr. Cook had followed up on the matter in the summer of 2003. He had the discussion with Dr. Ejeckam at the time. He had a discussion with Dr. Robb to seek advice, because Dr. Robb was the--in charge of the pathology program at the medical school, the discipline chair of pathology, and he'd followed up with them and Mr. Gulliver at the time and also, he'd been aware at that time that the surgical pathology review committee had looked at the issue and felt that the issue had been resolved and there was no need to bring anything forward at the time. That's my understanding.
COFFEY, Q.C.:
Q. Did you ask--I appreciate that they thought--you're being told in '05 that they had thought in '03 that it was resolved. How about the fact that it had occurred at all? Like in the period between the original suspension and the resolution, did you ask him how the clinical laboratory could shut down service for certain stains for a period of time and you, as VP

Page 126

Medical, not be informed, particularly where it involved other hospitals outside the city?
DR. WILLIAMS:
A. Well, it's a very small part of our lab, number one, it's less that two percent of the work that we do. Again, he had looked at it, reviewed it at the time and felt that the situation had been resolved and handled properly.
COFFEY, Q.C.:
Q. How about your views of it, looking back from '05?
DR. WILLIAMS:
A. Well, I guess looking at it from 2003 you'd have one set of information, looking back at it from 2005, you have an entirely different set of information, Mr. Coffey.
COFFEY, Q.C.:
Q. Um-hm.
DR. WILLIAMS:
A. So, I mean, you're looking back in a retrospective manner at the time with an understanding that certain other issues have come forward and there's some problems.
COFFEY, Q.C.:

Page 127

Q. So again, when -
COMMISSIONER:
Q. Are you saying that you didn't have a problem with their decision in light of what they knew at the time, is that the bottom line here?
DR. WILLIAMS:
A. Well, when Dr. Cook told me he'd had a good discussion and follow up with senior people and people involved and the surgical pathology review committee had reviewed it, on that basis he didn't bring it to my attention. I was concerned with the memo Dr. Ejeckam wrote to Mr. Gulliver and that there was no written response to that and I told him such that I felt we should have been replied to.
COFFEY, Q.C.:
Q. That's the June 19th memo?
DR. WILLIAMS:
A. Yes, that's correct.
COFFEY, Q.C.:
Q. And -
COMMISSIONER:
Q. But I think--I'm sorry, you haven't answered Mr. Coffey's question, really, which is even in light of what they knew at the time, in

Page 128

your position as the VP medical, was it your view that they should have, in fact, told you about it?
DR. WILLIAMS:
A. Well, I would have been saying that and it was obviously at 2005 -
COMMISSIONER:
Q. No, no, I mean -
DR. WILLIAMS:
A. Yeah. It's hard to -
COMMISSIONER:
Q. Just put yourself back in 2003, without knowing what's happening afterwards and judge it on that basis, if you will, make your assessment on the basis of not knowing about what's happening with ER/PR, would it have been your position that that was something that should have been brought to the attention of VP medical?
DR. WILLIAMS:
A. I mean, it's hard for me to answer that. Given all the information I had in 2005 the easy answer would be yes, I think that would have been -
COMMISSIONER:

Page 129

Q. Yeah, but that's not the answer I'm looking for.
DR. WILLIAMS:
A. No, no.
COMMISSIONER:
Q. I'm looking for the one that -
DR. WILLIAMS:
A. Yes.
COMMISSIONER:
Q. - what as a VP medical--really, I suppose, what I'm asking is what as a VP medical should be brought to your attention? I'm just concerned with how it goes up the line.
DR. WILLIAMS:
A. Sure. Major issues -
COMMISSIONER:
Q. And whether this made that level?
DR. WILLIAMS:
A. I guess major issues that cannot be resolved in the lab and that I need to be involved in further should come up the line to me.
COMMISSIONER:
Q. And this one, did they handle it correctly, in your view, in light of what was known at the time?

Page 130

DR. WILLIAMS:
A. Maybe based upon the discussion that Dr. Cook had with the people that were involved at the time, I can understand why he would have taken that decision. He talked to Dr. Robb, who was a senior pathologist, he talked to Dr. Ejeckam, talked to Mr. Gulliver and he'd, by that time, seen that the surgical pathology review committee would have looked at the issue and there was oncologists on that committee and surgeons on that committee and he felt at the time that he'd done due diligence to it. Now, for me to sit here in 2005, it's, the easy thing for me to say is that, you know, I think it should have been brought forward. How I would have dealt with it in 2003, had it been brought forward, I'm not, to be honest, sure exactly how I would have dealt with it.
COFFEY, Q.C.:
Q. If I could, please, Commissioner, 0467 Exhibit, please, page 12? Now the April 4th, 2003 memo, which is the first one in the chain, from Dr. Ejeckam. I mean, as VP medical do you think it's part or would you

Page 131

see it--when you were VP medical at the Health Care Corporation, as it then was, as part of your job function to be informed that a pathologist who apparently had more than a passing familiarity with IHC testing was saying that eight stains have remained unreliable, erratic and therefore unhelpful for diagnostic purposes?
DR. WILLIAMS:
A. Well, again, I wouldn't -
COFFEY, Q.C.:
Q. I take it that's really what the Commissioner is asking you. I mean, is that -
DR. WILLIAMS:
A. Yeah. I would expect to know this if there was a reason for me to know it and that we needed to resolve it and there was ongoing problems with it. So on that basis I would expect to know of these things.
COMMISSIONER:
Q. And who gets to make that determination? You see my problem here, Dr. Williams, in the sense of I know there's judgment call in these things.
DR. WILLIAMS:

Page 132

A. Yes, um-hm.
COMMISSIONER:
Q. And that's the nature of the business and somebody has to make this kind of call.
DR. WILLIAMS:
A. Sure.
COMMISSIONER:
Q. Sometimes the call is obvious, sometimes it might be open to debate.
DR. WILLIAMS:
A. Yes.
COMMISSIONER:
Q. But from the lay person, looking at what Ejeckam has written here, even if it is a small percentage of what you do in the lab, it looks like what he's saying is potentially quite serious for the service that you provide, not only to people within your area, but outside. And you're not going to provide it for a period of time, and there's potentially the--you know, he's hoping the solution is going to be found within the next four to six weeks, but, gee, maybe he won't find it.
DR. WILLIAMS:

Page 133

A. Um-hm.
COMMISSIONER:
Q. So from the person outside the organization it looks to me like that would be the kind of thing where at least you'd give your VP a heads up, listen, we may have to go to tell the people from outside our organization that we're not going to be able to stand behind the reliability of these tests which we're doing for them and maybe they got to go elsewhere to get them, that kind of stuff.
DR. WILLIAMS:
A. Um-hm.
COMMISSIONER:
Q. So -
DR. WILLIAMS:
A. Well, it could come from a variety of sources. The leadership team in laboratory medicine program or Dr. Ejeckam himself, really, could write.
COFFEY, Q.C.:
Q. But the people directly involved, your two subordinates, are recipients of these memos?
DR. WILLIAMS:
A. Yes.

Page 134

COFFEY, Q.C.:
Q. And the memo doesn't get sent to you or it's not even addressed to you, neither of them is?
DR. WILLIAMS:
A. Correct.
COFFEY, Q.C.:
Q. Can you explain why that would be? I mean, what if any process was in place to ensure that, you know, memos of any significance got sent to you, as well?
DR. WILLIAMS:
A. I don't think there was any particular process, but certainly we have a leadership team there in the lab and issues would be dealt with at that level and then brought to my attention.
COFFEY, Q.C.:
Q. So you would have had leadership team meetings in probably April, May if not June, certainly April and May -
DR. WILLIAMS:
A. I didn't have any in June or July or August.
COFFEY, Q.C.:
Q. But April and May of 2003?
DR. WILLIAMS:

Page 135

A. Yes.
COFFEY, Q.C.:
Q. And neither Dr. Cook nor Mr. Gulliver mentioned this even in passing, that you can recall?
DR. WILLIAMS:
A. No. It's not in the minutes.
COFFEY, Q.C.:
Q. And if it had been referred to, would it have been recorded in the minutes?
DR. WILLIAMS:
A. Would have been recorded in the minutes, most--yes, everything is recorded in the minutes.
COFFEY, Q.C.:
Q. If we could, please, I'll just finish this, if I could, Commissioner, this line of questioning and then--Exhibit P-0907, please? Sir, this is a memo to yourself from Dr. Ejeckam dated September 30th, 2003. Appears to be a received stamp in your office October 2nd, '03?
DR. WILLIAMS:
A. Um-hm.
COFFEY, Q.C.:
Q. And I think you've written "file", haven't

Page 136

you?
DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. Surgical pathology review committee meeting. And it says, "Please find enclosed a copy of the surgical pathology review committee meeting minutes." It's signed by Dr. Ejeckam, copied to Dr. Cook. And we look, these are surgical pathology review committee minutes of meeting September 23rd, 2003. Doctors Ejeckam, Siddiqui, Parai and Tennent are present, Mary Connors is there as secretary. Apologies from Doctors Dawson and Battcock. It's a call to order, paragraph 1, by Dr. Ejeckam. Dr. Ejeckam asked if there was anything that needed to be added or changed in the previous minutes. Dr. Siddiqui moved to accept the minutes, seconded by Dr. Parai. And then "Business arising." "2.1 Estrogen and progesterone status. Dr. Ejeckam stated that the technical problem with staining for ER and PR stains has been solved. Dr. Siddiqui asked what were the standards for performing her2/neu." And some discussion

Page 137

took place with regards to this. And it goes on from there. Now, sir, you would have seen this, I take it, in early October of 2003, I'm sorry, 3, because you wrote "file" on it?

DR. WILLIAMS:

A. Um-hm.

COFFEY, Q.C.:

Q. The reference to "Dr. Ejeckam stated that the technical problem with staining for ER and PR stains has been solved," did you notice that at the time or understand it?

DR. WILLIAMS:

A. No. As well, coming at the same time, on, I think, August, October 3rd, there was a three or four-page document with recommendations from the surgical pathology review committee. So I think I would have concentrated on that and would have worked on that series of recommendations or one big recommendation that we move forward to the clinical chief's agenda and to the MAC. So I may not have gone into the minutes, other than seeing this recommendation, unfortunately.

COFFEY, Q.C.:

Q. At the time, Doctor, would you have even

Page 138

understood what the technical problem with staining for ER and PR stains has been solved, would you have even understood what a technical problem with staining for ER and PR stains was?

DR. WILLIAMS:

A. No, I wouldn't have understood much unless I asked a question about it.

COFFEY, Q.C.:

Q. I take it at the time you didn't?

DR. WILLIAMS:

A. No, I didn't. And I don't remember if I looked through the minutes in detail because we had, I think, a three-page document come around the same time with what the surgical pathology review committee felt was important for me to deal with.

COFFEY, Q.C.:

Q. If we could, just before we break, Commissioner, P-0906, please? Thank you. Doctor, this is date stamped received by your office October the 3rd, '03. It's from Dr. Ejeckam to yourself. And he says, "Please find attached the summary and recommendations of the surgical pathology review committee

Page 139

meeting on some of the problems discussed in the meeting."

DR. WILLIAMS:

A. Um-hm.

COFFEY, Q.C.:

Q. And then at the second page is a summary of meeting of the surgical pathology review committee and recommendations to vice president medical services. Referring to the meeting held on September 23rd, 2003.

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. I take it this is the document you were referring to just then?

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Q. It goes on at some length including the fourth page of the exhibit, "Recommendation to the vice president of medical services." And this had to do with filling out the forms properly?

DR. WILLIAMS:

A. Yes.

COFFEY, Q.C.:

Page 140

Q. And trying to enforce that?

DR. WILLIAMS:

A. And that's the issue that was brought forward and that's the issue that we took the recommendations forward and eventually resolved it.

COFFEY, Q.C.:

Q. Thank you, Commissioner. Break.

COMMISSIONER:

Q. Take 15 minutes.

(RECESS)

COMMISSIONER:

Q. Please be seated. Mr. Coffey.

COFFEY, Q.C.:

Q. Thank you, Commissioner. If I could, please, actually, there are two questions, actually, I--two areas I wanted to cover. One is P-0385, please?

COMMISSIONER:

Q. I'm sorry, I didn't catch the number?

COFFEY, Q.C.:

Q. P-0385, I apologize.

COMMISSIONER:

Q. 0385?

COFFEY, Q.C.:

Page 141

Q. P-0385. This is some e-mails of October 26th, ’05?
DR. WILLIAMS:
A. Um-hm.
COFFEY, Q.C.:
Q. Actually, it’s just the one. It’s from Deborah Pennell to a number of individuals. It’s, the subject is Out of the Fog interview. And Dr., it says, "Dr. Williams is tentatively scheduled to do a one-on-one interview with Out of the Fog at Dr. William’s office at 12:15ish tomorrow. They will bring the camera to him and he will do a similar interview that he’s already done with NTV and CBC, etcetera. Dr. Williams will not be going to the studio and sitting down with," it’s a patient’s name, "and Peter Dawe. The producer is going to confirm the time with me later tonight or in the a.m. but that is 99 percent certain as of now. Deborah." Do you recall why it was that there was a concern about you going in the Out of the Fog and sitting down with Mr. Dawe and a patient?
DR. WILLIAMS:
A. I didn’t get a copy of this e-mail, so that’s

Page 142

the--number one. Number two is I’m not sure whether--what the background was to that, Mr. Coffey. I’m jus surmising it may be that there might be patient care issues come up and I wouldn’t be conversant with that. I’m not sure, Mr. Coffey. You’d have to ask somebody else. I can’t--I’m just trying to surmise now rather than recollect what happened.
COFFEY, Q.C.:
Q. Okay. If we could, please, Exhibit P-0784? Page 44, please. This is the letter of October 17th, 2005 from Dr. Banerjee to Dr. Cook as clinical chief forwarding his report. External quality review of the immunohistochemistry service. And then the second--I’m sorry, page 45 of the exhibit is another, is a copy of the cover sheet of that October 17th report. And there are then four pages of text, including more than a page of recommendations and footnotes.
DR. WILLIAMS:
A. Um-hm.
COFFEY, Q.C.:
Q. Now, sir, when you got Dr. Banerjee’s report in October of 2005, he has written here on

Page 143

page 3, at the bottom, right here, the report, under the heading "Conclusions about the reasons for test failure."
DR. WILLIAMS:
A. Um-hm.
COFFEY, Q.C.:
Q. And then on the next page he has another heading, "Other system flaws observed." And he’s listed seven. See that?
DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. Sir, at the time you read this, what, if anything, did you understand as to whether Dr. Banerjee was here summarizing his views as to why there had been a problem with the ER/PR results?
COMMISSIONER:
Q. I’m not sure I follow the question, Mr. Coffey.
COFFEY, Q.C.:
Q. I apologize.
DR. WILLIAMS:
A. - the question -
COFFEY, Q.C.:

Page 144

Q. Was this a summary, was this a summary on these two pages of Dr. Banerjee’s views as to what had caused the problems?
DR. WILLIAMS:
A. Yeah, when Dr. Banerjee did--we did an exit discussion with Dr. Banerjee.
COFFEY, Q.C.:
Q. Yeah, no, I’m just asking -
DR. WILLIAMS:
A. This would be a summary of what he found.
COFFEY, Q.C.:
Q. In terms of his conclusions about the reasons for test failure?
DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. And other system flaws he’d observed, as well?
DR. WILLIAMS:
A. Um-hm.
COFFEY, Q.C.:
Q. Subsequently is there anything that you’ve learned since you first saw this report in October of ’05 that has caused you to have any doubt about the validity of what he said here?
DR. WILLIAMS:

Page 145

A. Well, from what I've read since, the main problems you're going to get in a system in immunohistochemistry is the retrieval process, the heat treatment to tease off the antigen antibody complex so that it can stain properly. That would be one that keeps coming up in anything I've seen. So that complicated stages in that 40-step process.

COFFEY, Q.C.:

Q. Yes.

DR. WILLIAMS:

A. So that would--his comments are similar to that. The other issue he talks about was the system of checks and balances in terms of controls that's designed to detect any problem at the time. I would have to go through all of these recommendations, but that would be my -

COFFEY, Q.C.:

Q. Yes.

COMMISSIONER:

Q. Let me make sure I understood the point you're making, if you would, Dr. Williams. When you talk about the retrieval problems with are discussed in literature, then I take it you're

Page 146

saying that that confirms as a problem some of the things that Dr. Banerjee was talking about?

DR. WILLIAMS:

A. Yes.

COMMISSIONER:

Q. Not, you know, because the original question was have you learned anything since that would cause you to doubt this.

DR. WILLIAMS:

A. Yes.

COMMISSIONER:

Q. And I was taking your answer to be saying, no, but was I correct about that?

DR. WILLIAMS:

A. Yes, I haven't--I can't recollect anything I've learned since and that would cause me to doubt what his approach would suggest. Now, there's a lot of water under the bridge since he made those recommendations.

COMMISSIONER:

Q. Um-hm.

DR. WILLIAMS:

A. And had done his analysis.

COFFEY, Q.C.:

Page 147

Q. Doctor, just on that point, page 3, paragraph 1 under "Conclusions" about the reasons for test failure, after asking the question "Is the DAKO system faulty?" And "This is unlikely as there are many laboratories using the DAKO system successfully. The reason for test failure was most likely due to a lack of test optimization, including antigen retrieval method and antibody/detection system titration." So he does even there refer to antigen retrieval methods?

DR. WILLIAMS:

A. The only thing, and it jigs my memory, the only thing that's come up, and somebody else is going to have to explain this a little bit more, is that there was some issues with the DAKO system in New Brunswick from Dr. Anne O'Brien, and some suggestions that in her statement that there may have been a pump problem with that particular piece of equipment. And somebody might suggest that that may have happened here, but I haven't got any strong evidence of that. Some people, some of the pathologists have told me, Dr. Denic and Dr. Cook, but you'd have to ask them

Page 148

in more detail because I don't know how that pump works.

COFFEY, Q.C.:

Q. Um-hm.

DR. WILLIAMS:

A. And how it's supposed to pump the antibody into certain areas. So you might want to ask them a little bit more about that. That's something that's very much related to the technology and their comments.

COFFEY, Q.C.:

Q. Now, Doctor, on this point, I mean, having read Dr. Banerjee's report, were you able to draw any inferences or did you draw any inferences yourself having read his report as to how this had gone on undetected for so long?

DR. WILLIAMS:

A. Not from his report, per se. But there are issues that have come to mind, for instance, we had a high turn over of pathologists, so probably multiple people reading this. It's a subspecialized area. And a high turnover of oncologists so that the trends and this type of thing, although he didn't mention it, may

Page 149

not have been recognized.
COFFEY, Q.C.:
Q. And you were aware, though, I take it, that a number of pathologists had been there for many years?
DR. WILLIAMS:
A. A number had been there, but a number of others had come and gone. Since everybody was reading these tests, not any one pathologist or any number of pathologists would have a high number of tests that they've read and may not pick up trends if you're only reading a small number of tests. That's some of the issues that were discussed.
COFFEY, Q.C.:
Q. Now, where -
DR. WILLIAMS:
A. Not with Dr. Banerjee. The other thing that Dr. Banerjee did say when he came from our lab, and I remember this at his exit interview, because he did spend some time talking about it, was that he came out and said, "You do have a problem." I didn't take any notes on it, unfortunately, exit interview, because he said he'd have a short

Page 150

report that would be very succinct and we'd have it in short order but that he had reviewed a number of other labs in various jurisdictions and he felt that our lab was performing in the middle of the pack, that's what he said. Some labs are better and some labs are worse. He went on to give us then some information on some labs that he had seen. He didn't name them by lab, but some of the issues that had arisen in this particular area.
COFFEY, Q.C.:
Q. Sir, did you, having read this report, ever ask anyone in your organization how there could be or could have been inadequate attention paid by the grossing pathologist to the thickness of tissue slices, quality and adequacy of fixation?
DR. WILLIAMS:
A. No, I don't remember having a discussion about that.
COFFEY, Q.C.:
Q. Did you ever ask anyone within your organization as to how there could be that there was no standardized fixation protocol

Page 151

that everyone adhered to?
DR. WILLIAMS:
A. I don't remember having a discussion about that.
COFFEY, Q.C.:
Q. Did you ever ask anyone within your organization, that's within Eastern Health or the Health Care Corporation, as to how it could be that there was inadequate or no attention being paid by the reporting pathologists to the status of internal controls?
DR. WILLIAMS:
A. I did have some discussion about that, yes.
COFFEY, Q.C.:
Q. And what were you told?
DR. WILLIAMS:
A. I was told that -
COFFEY, Q.C.:
Q. Well, first of all, who did you have it with and -
DR. WILLIAMS:
A. Well Dr. Cook and maybe subsequently with Dr. Denic, I'm not sure. And that the issue of internal controls only became an issue around

Page 152

the mid 2000, 2002, 2003 area, as a--around 2002, 2003, the issue of internal controls were becoming an issue that needed to be paid attention to, that's what I was told.
COFFEY, Q.C.:
Q. So when you spoke with Dr. Cook in '05 or Dr. Denic, perhaps in '06, you were assured by one or both of them that the usage of internal controls in these sorts of tests -
DR. WILLIAMS:
A. Are becoming more of a factor written up in the literature in about 2002, 2003 and this is why you see Dr. Ejeckam in his memo paying pretty careful attention to that issue.
COFFEY, Q.C.:
Q. Did Dr. Banerjee ever say that to you, that this -
DR. WILLIAMS:
A. No, he didn't say that.
COFFEY, Q.C.:
Q. Did you ever ask Dr. Banerjee if that was--if that's accurate?
DR. WILLIAMS:
A. No, I didn't ask Dr. Banerjee if that was accurate.

Page 153

THE COMMISSIONER:
Q. And just to make sure that I have it straight, as a result of your conversations with Drs. Cook and Denic, you were given to understand that prior to 2002, 2003, one would not be using internal controls?
DR. WILLIAMS:
A. No, that the issue had been becoming more of a factor by that time, it wasn't--that's what my understanding from Dr. Cook was, but I'm not sure if it was Dr. Denic -
THE COMMISSIONER:
Q. But how did you interpret that in the sense of was Dr. Cook saying to you, look, you couldn't expect us to have internal controls before 2002, 2003? Was that the message?
DR. WILLIAMS:
A. No the issue of the importance of internal controls, people paying a lot of, you know, hanging their hat a lot on internal controls had become a factor as time went on with this particular testing, and of course, there's no absolutes in these internal controls. Sometimes I've been advised that the internal controls can be negative; nor breast tissue

Page 154

may not, I've been told, always take up stain--they've seen some cases since Dr. Cook and Dr. Carter have been doing it and it's a small group basis and sort of trying to subspecialize, that they've seen some cases where the controls were negative, yet the tests were positive.
COFFEY, Q.C.:
Q. Dr. Banerjee, I take it, was telling you in October of 2005 in this report that in his view, looking at the top of page 4, paragraph 4, "And in the event, the poor fixation resulted in an internal control failure in all available blocks. This should have been noted in the reports as an uninterpretable cases due to failure or absence of internal controls." So was it your understanding at the time that Dr. Banerjee, if I could just look back here, first page of this report, review of cases, would have understood that--as he writes here under the incident problem case, the third paragraph says, "Four other patients previously tested as negative in 2002 were also retested and all tested positive with the Ventana system. This lead to a review of

Page 155

other 57 cases reported in 2002 as negative, which on retesting on the Ventana benchmark resulted in a high conversion rate from negative to positive, 38 or 57, 67 percent." So was it your understanding in October of 2005 that Dr. Banerjee in writing this report knew he was dealing with 2002 cases. That says, doesn't it -
DR. WILLIAMS:
A. Yes, that's what it says.
COFFEY, Q.C.:
Q. Did you ever ask Dr. Cook or Dr. Denic why is it that Dr. Banerjee said that this should have been picked up in 2002 and would have, perhaps, if internal controls had been used?
DR. WILLIAMS:
A. Well again, I think Dr. Banerjee's -
COFFEY, Q.C.:
Q. If it wasn't yet known. Did you ever take that up with him?
DR. WILLIAMS:
A. No, I didn't take that up with him. What I took up with him is that really what Dr. Banerjee is basically saying is that your pathologists need to subspecialize if you're

Page 156

getting into a very detailed area, such as this, and that's what I took as his main recommendation to deal with these issues--along with some other issues. We had Trish looking at the technical aspect of it, but his main recommendation, one of his main recommendations and key ones was your pathologists should subspecialize in this area.
THE COMMISSIONER:
Q. When you say "in this area" do you mean IHC or do you mean ER/PR?
DR. WILLIAMS:
A. No, ER/PR that you should have--whether all pathologists reading ER/PR, you should get together a group of pathologists to develop expertise and subspecialization around this area, so all pathologists wouldn't be reading it, that was one of his key recommendations.
COFFEY, Q.C.:
Q. Do you recall if in his report, October 17th, 2005, Dr. Banerjee said anything about the issue of certain types of cancer should have been perhaps recognized as likely to be ER or PR positive?

Page 157

DR. WILLIAMS:
A. Well I think he references it in here, Mr. Coffey. Another thing he references in here and I guess we'll have to do some follow up on that, is utilizing different antibodies that have been used over time and recommending we take a look at the rabbit monoclonal antibody as another issue that needs to be dealt with. Now I'm not sure when the instituted the testing if we used the rabbit monoclonal antibody or not, but we indicated that has a five to ten percent higher positivity rate, then that's another issue for labs that are doing testing.
COFFEY, Q.C.:
Q. Now under the incident problem case, which is page two of his report, he numbers his cover page, page number one, he says under the incident problem case, second paragraph, "It should be noted that invasive lobular carcinomas are frequently ER positive, 92 percent."
DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:

Page 158

Q. And he footnotes it with a citation, "Thus the initial negative results should have been questioned." Did you ever ask anybody about that, either an oncologist or a pathologist within Eastern Health or the Health Care Corporation as to--take it up with them, Dr. Banerjee's assertion that the initial negative results should have been questioned?
DR. WILLIAMS:
A. Well that was discussed, I can't say with who and at what particular time, but we did have some discussion and the issue was that, well just one case by itself may not cause it to be questioned, so if you had different pathologists reading and different oncologists looking at different cases, you wouldn't get any trends established, that's, as I mentioned earlier, that was part of that discussion and follow up.
COFFEY, Q.C.:
Q. Thank you, Commissioner. Thank you.
DR. WILLIAMS:
A. Thank you, Mr. Coffey.
THE COMMISSIONER:
Q. Mr. Pritchard?

Page 159

COFFEY, Q.C.:
Q. Before you do, well I have been asked to enter two exhibits, please. I apologize.
THE COMMISSIONER:
Q. What two are they?
COFFEY, Q.C.:
Q. It's by other counsel. Exhibit P-1368 and P-1384, Commissioner?
THE COMMISSIONER:
Q. 1368 and 1384?
COFFEY, Q.C.:
Q. Yes, ma'am
THE COMMISSIONER:
Q. Entered.
EXHIBITS ENTERED AND MARKED P-1368 AND P-1384.
THE COMMISSIONER:
Q. Now, Mr. Pritchard.
MR. PRITCHARD:
Q. Thank you, Commissioner, I don't have any questions for this witness, thank you.
THE COMMISSIONER:
Q. Mr. Browne?
MR. BROWNE:
Q. Just a couple of questions, Commissioner.
THE COMMISSIONER:

Page 160

Q. Mr. Browne, did you--are those the exhibits being put in now at your behest, as it were?
MR. BROWNE:
Q. Yes.
THE COMMISSIONER:
Q. Oh, all right. I know we had a couple of requests, I just want to make sure that your particular ones were here, Mr. Browne. I think there are two more coming.
COFFEY, Q.C.
Q. There are two more, Mr. Browne, I have the actual numbers, Commissioner, it's P-1307.
THE COMMISSIONER:
Q. 1307.
COFFEY, Q.C.:
Q. And P-1317.
THE COMMISSIONER:
Q. 1317.
COFFEY, Q.C.:
Q. Yeah, it was during the break that Mr. Browne asked that these be entered, so that's just two more -
THE COMMISSIONER:
Q. Yeah, I understood that we were entering two different groups at the request of two

Page 161

different counsel.
COFFEY, Q.C.:
Q. Yes, two different lawyers.
THE COMMISSIONER:
Q. So Mr. Browne should know that the ones that he asked for are 1307 and 1317?
REGISTRAR:
Q. He said 1303.
THE COMMISSIONER:
Q. O3, all right, dyslexia again, and 1317, okay.
EXHIBITS ENTERED AND MARKED P-1307 AND P-1317
DR. ROBERT WILLIAMS, EXAMINATION BY MR. PETER BROWNE
MR. BROWNE:
Q. Thank you, Commissioner. Good morning, Dr. Williams.
DR. WILLIAMS:
A. Good morning. Registrar, are those available on the screen now?
THE COMMISSIONER:
Q. They can be, whenever you want.
MR. BROWNE:
Q. Why don't we, since those have been mentioned, deal with those right now, enter them all and I'll have some questions on those.
THE COMMISSIONER:

Page 162

Q. They're entered.
REGISTRAR:
Q. Which one would you like, Mr. Browne?
MR. BROWNE:
Q. Can we begin with 1317 please?
THE COMMISSIONER:
Q. 1317, all right.
MR. BROWNE:
Q. Dr. Williams, this is an article that I found and it refers to you, you were speaking to the Commissioner about the notion of bimodal frequency in ER/PR, you see this is an article with regard to that. And if we can--I think you have a mouse in front of you, you can scroll down, you can look at the abstract there.
DR. WILLIAMS:
A. I'll let you scroll because I'll interfere with you.
MR. BROWNE:
Q. Okay, fine. This seems to be--I don't want to get into a great degree of analysis here, but are you familiar with the classification of studies in the literature, like Class I studies, Class II studies in terms of degree

Page 163

of reliability of a particular article or journal, presentation. We have med analysis that gives it a higher classification, I don't want to get into that unless you're -
DR. WILLIAMS:
A. I'm aware of the literature that a lot of stuff gets published in the literature, when you challenge it from an epidemiological perspective, I did a couple of courses on terms of looking at, reviewing the literature, I used to know how to do it back in the early 1980s, but a lot of things get published in the literature may not stand up to some of those tests of scrutiny.
MR. BROWNE:
Q. Right.
DR. WILLIAMS:
A. So they may now, you're probably talking about different--I understand the classical epidemiology, but I don't understand what you're saying about Class I and Class II and what -
MR. BROWNE:
Q. And as I understand it, there are certain categories which are more reliable because

Page 164

what they do and we think we've heard about the term med analysis -
DR. WILLIAMS:
A. Yes, med analysis tends to bring together all the studies that have been done.
MR. BROWNE:
Q. On a particular subject matter.
DR. WILLIAMS:
A. Yes, one study in itself may give you a certain trend or some studies, but then when you--say you look at 15 studies, you might think this is the result, but when you look at all the hundred studies, you might get a different view.
MR. BROWNE:
Q. Right, and that's the important--med analysis is something that just recently developed, I think, over the past -
DR. WILLIAMS:
A. Past five or six years, maybe, yes.
MR. BROWNE:
Q. Now this particular article, as I understand it, is one particular lab's experience with and a review of their own ER/PR tumors. And if you can see there in the abstract, just

Page 165

take a moment and read that and tell me if it concords with what you understood in telling the Commissioner about this information that you received in, I think, 2005/2006 regarding the bimodal frequency? Do you see that last sentence there--last two sentences -

DR. WILLIAMS:

A. Yes, that's correct.

MR. BROWNE:

Q. "Thus the immunohistochemical method used in our lab, ER staining is essentially bimodal, the overwhelming majority of breast cancers are either completely ER negative or unambiguously ER positive and cases with weak ER immunostaining are rare." And this article, as I understand it, was published in 2005, so again, is this the literature you were referring to earlier in your evidence about -

DR. WILLIAMS:

A. Yes, it's a different article that came out in 2006, I think that I sent to Mr. Dawe as part of the package I sent to him.

MR. BROWNE:

Q. Right.

Page 166

DR. WILLIAMS:

A. And the understanding that people had sometime before that, especially when they were doing the biochemistry staining, was that there was a spectrum that's almost a normal distribution curve that you'd have some samples were one percent, two percent, 10 percent, 20 percent, and right up to 100 percent. And based upon the new detection systems and this type of thing that were coming into the forefront, probably around 2003, 2004, as we moved along with this, that concept was thrown out the window and there is now a bimodal curve that 90 percent of the patients are either totally negative or pretty well completely positive and that there is very little in the, what we thought was, you know, there's a small number at the bottom end of the spectrum that are probably difficult to detect, but they are there and so that's a bimodal curve, rather than a normal distribution curve, you now have a bimodal curve. That was the change of thought process.

MR. BROWNE:

Q. Right, and I guess the point you were trying to make to the Commissioner, and you can give me an answer, was as all this was unfolding, this new information was coming in in 2005, 2006 which affected some of the analysis as well?

Page 167

DR. WILLIAMS:

A. Yes, that would be--I know that when the Ventana system came into place, there were some concerns expressed because there was a lot of very high percentage of cells, staining positive, unlike what they'd seen before or unlike what they expected.

MR. BROWNE:

Q. Now, the next article Dr. Williams I would like to refer you to, is P-1303? Thank you, Registrar. Now this is an article, Doctor, that has actually nothing to do with ER/PR or immunohistochemistry, in fact, an article dealing with hospital responses and an article out of the United States, hospital responses to fairly severe events, bioterrorism, pandemic flus and so on.

DR. WILLIAMS:

A. Uh-hm.

MR. BROWNE:

Page 168

Q. But I want to focus on, if I could, please, if we could go to page, I think it's three of this particular--yes, thank you. And it follows in a comment that you made about having sort of lessons learned and looking back on sort of your experiences here. If you can look at the paragraph, "Despite requirements, standards and best intentions"-- and just read that for a minute.

DR. WILLIAMS:

A. I don't know what the word is in the second paragraph.

MR. BROWNE:

Q. I think it's lack of--it should be surge capacity and I'll explain what I understand the article talks about that.

DR. WILLIAMS:

A. Okay.

MR. BROWNE:

Q. Surge capacity, as I understand then this sort of dealt with somewhere in this article as well, is that when a major incident, such as bioterrorism or a pandemic happens and you have, as this paragraph reflects, contemporaneously with that, an infrastructure

Page 169

change, all these demands come upon the hospital and it identifies their short comings and inability to deal with a problem.

DR. WILLIAMS:

A. Uh-hm.

MR. BROWNE:

Q. And is that something that you sort of, looking back and reflecting on the situation here, feel may have some relevance to what happened?

DR. WILLIAMS:

A. Well certainly in terms of getting a timely response from Mount Sinai it had a problem because they didn't have, in retrospect, any capacity to increase their testing beyond a certain amount and we only got dealt with when they brought in our tests over Christmas and dealt with them, major things like that. Also really at the time, as I've said before, we were in the midst of a major reorganization that was much bigger, I think, than the organization that took place in the mid 1990s and when you're trying to do that and trying to do a lot of other things, your capacity to handle it in terms of how much are you

Page 170

expected to do and how much are you able to do, when all these things are happening around you. And by the way, this wasn't an isolated event, we were having a lot of other issues going on within St. John's and within Eastern Health. I remember at the time when I look back at my notes, we were trying to maintain a medical oncology service for the province so that people, a hematological oncology service, so that people with leukemias, lymphomas and that would continue to be treated. We had five people in the program, one was doing the transplant medicine for us, transplants for us, left the province. We were left with four. One of those four was a person who was semi-retired and the other one was on sabbatical leave, so we went down really to two fulltime and one part-time person, where we are five, four fulltime and one part-time person, and then we had to, you know, struggle to see how we were going to maintain that service and provide coverage for hematology/oncology in the province. If we had of lost that service, that would have been just as much as a problem as the ER/PR issue.

Page 171

We also, in the summer of 2006, when we were trying to deal with some of these things, had a major shortage of pharmacists. Pharmacists do a lot of work within hospitals and a lot of it relates to quality. We were back so that we lost, I think 30 percent of our pharmacists because we have a big private market out there which includes other provinces who pay a bit more, the same as the pathology issue, and the private sector, like Shoppers Drug Mart and these types of thing, were paying 20, 25,000 more per year than we could in the hospital system for a pharmacist. So we had about a year working with the Department of Health and Treasury Board and Government trying to resolve that issue. And I remember in the summer of 2006 having to deal with the media in July and August about trying to tell the pubic if we had a safe system in the hospital with respect to drugs and this type of thing. So all these things are going on at the same time as you're trying to bring together a very, very diverse organization in a diverse geographic area. So our ability to sort of just focus on this -

Page 172

MR. BROWNE:

Q. To deal with this surge in your capacity.

DR. WILLIAMS:

A. Yes, but retrospectively, you know, I'll have some comments to make later about some of these lessons learned here.

MR. BROWNE:

Q. Now, if we could just moving into the lab medicine program set up and focusing for a minute on the proficiency testing. Putting aside for a minute the division under Dr. Cook and Mr. Gulliver, other divisions in, I guess the laboratory medicine program -

DR. WILLIAMS:

A. Yes.

MR. BROWNE:

Q. Were any of those divisions involved in proficiency testing that you were aware of?

DR. WILLIAMS:

A. Yes, my understanding is that biochemistry, hematology, bacteriology and pathology were all involved in proficiency testing, standardized proficiency testing that the lab would normally participate in.

MR. BROWNE:

Page 173

Q. Okay, and were those external proficiency testing programs, were they under the auspices of the program managers for those divisions?
DR. WILLIAMS:
A. Yes, they were, that's my recollection.
MR. BROWNE:
Q. And in the lab medicine program, who was responsible for the technical aspect?
DR. WILLIAMS:
A. There was two--we had two streams and we talked about those two streams as part of the report and what we've done about them. There was a technology stream and the pathology stream.
MR. BROWNE:
Q. Correct.
DR. WILLIAMS:
A. And I would say the managers of the different sections, like biochemistry and hematology would be dealing with the proficiency testing there and the pathology would be done with Dr. Cook. That's--now you can clarify that with some other people who are closer to it than me, but that's my understanding.
MR. BROWNE:

Page 174

Q. Sure. And I think you talked about that in reference to Dr. Cook's goals in terms of the 2003, 2004 years.
DR. WILLIAMS:
A. Yes.
MR. BROWNE:
Q. And he mentioned, I think in there, some proficiency testing with the -
DR. WILLIAMS:
A. Oh in detail.
MR. BROWNE:
Q. In terms of for pathologists individually -
DR. WILLIAMS:
A. Pathologists individually and collectively, what we did was that pathologists were rated, my understanding--Dr. Cook had explained it further, College of American Pathologists was the group that subscribed to--I'm not sure if it's a different group in the U.S. on the St. Clare's site, but then pathologists were rated individually and then what Dr. Cook would do, is bring the pathologists together as a group and interpret some of the slides, so then the group would be rated too. But individually they would be rated and there was a record

Page 175

kept of those.
MR. BROWNE:
Q. But my point there being is that Dr. Cook was not responsible for proficiency testing of the technical side of that, it was only interpretation and so on of slides.
DR. WILLIAMS:
A. Yes, he was looking at the pathology side.
MR. BROWNE:
Q. Pathology side, okay. Prior to, I guess this incident, 2005, were there individuals in place for dedicated quality assurance for the lab medicine program?
DR. WILLIAMS:
A. No, there was not, of course there are now, but not arising out of this issue, but as you know that when we came together in 2005 as Eastern Health and we, we got a mandate for quality, that there was a commitment that we'd put, you know, try to put more emphasis and more resources on quality and we visited Calgary which we were told by Dr. Robson who came from Winnipeg, don't come to Winnipeg, we're just starting the process ourselves, but go to Calgary because they had a major problem

Page 176

with adverse events, an adverse event and two or three people died suddenly in Calgary in 2003 or 2004 and they had a quality audit and based upon that quality audit, they did a total reorganization of their quality program. So Pam Elliott and myself visited Calgary in early 2006, January 2006. We made contact after Ms. Elliott was appointed in the fall of 2006--wait now, I'm just trying to recollect this, 2005, yes, we made contact in the fall of 2005 with Calgary and asked if we could visit them. Contacted their vice-president responsible for quality and a site visit was arranged in early January, 2006, but we did sit in on one of their regional quality meetings that they had on a once monthly, so we did see their senior quality meeting. We met all the key players, we spent two or three days there and came back and modelled our quality program after the Calgary model, which would see attached to each of, at least the VP's portfolios, at least a minimum of one person who would be totally focused on quality within that portfolio. No other job, no other focus, just quality. So for the diagnostic

Page 177

area we were able--well it happened after I had left but it was in progress before I left, that we had one person totally dedicated to quality in that particular area of diagnostic imaging, pharmacy and laboratory medicine, the portfolio of the vice-president responsible for the areas.

MR. BROWNE:

Q. But nevertheless, was this sort of heading in this direction, did that pre-date all of what happened in terms of April and May of 2005 in terms of -

DR. WILLIAMS:

A. Well before Eastern Health came together, there was a commitment that we were going to do that, it pre-dated the ER and PR, just that ER/PR happened contemporaneously with the decision that was already made to go in this direction.

MR. BROWNE:

Q. That was my point. Now the Commissioner asked you, I think, as well this morning about the test, we saw Dr. Cook's note from Dr. Abidi about Clarenville the issues with Clarenville, one of the issues there was the fact they were

Page 178

paying for tests. Besides ER/PR, were there other tests that were being paid for by hospitals?

DR. WILLIAMS:

A. There are other tests that are being paid for or were being paid for, I don't know if they've changed that since, that required Health Care Corporation to bill other health boards and what we were trying to do in the budget process is get that money put in our budget so we wouldn't have to bill these other boards. It made a lot of sense to do it that way because there's only one payor in the province.

MR. BROWNE:

Q. But prior to that, the money that was generated for these tests, did it go back to the lab medicine program?

DR. WILLIAMS:

A. No, it did not, it went into general revenue. We tried on occasion to get that money just to go to the lab, because we wanted to do other things in the lab from time to time.

MR. BROWNE:

Q. Sure, but it nevertheless went back to general

Page 179

revenue.

DR. WILLIAMS:

A. Yes, it did.

THE COMMISSIONER:

Q. General revenue of the province.

DR. WILLIAMS:

A. General revenue for the Health Care Corporation.

THE COMMISSIONER:

Q. For health care.

DR. WILLIAMS:

A. Yes. But we weren't able to say well we, that money came into the lab, we can use that now for some laboratory initiatives. We tried that and didn't get very far with that.

MR. BROWNE:

Q. Okay, did you try that or did the lab try to have that -

DR. WILLIAMS:

A. No, we tried, I tried that on occasion, the executive team. It may be documented, but we tried it.

MR. BROWNE:

Q. Now as well you were asked about the centralization of lab services, I think this

Page 180

was raised by Mr. Gulliver in 2003 about doing that, now am I correct in understanding that his suggestion was centralization of the technical side of it, not -

DR. WILLIAMS:

A. At that point in time, it was the technical side of the operation. They had a--it was either this March of 2003 or 2002, they had a one-day planning retreat for laboratory medicine where all the leadership were there, the division managers, the people like Dr. Cook, the clinical chief and other people and I spoke to them at that time. I had an introduction of about a half hour to talk about the importance of a planning day and that's where the issue of centralizing technical processing services came up and then we tried to work through that. I think Dr. Cook's, one of his notes that was presented to me on Friday, 12 point summary after he did the reviews of the pathologists, outlined that that was one of the issues that we need to be pursing.

MR. BROWNE:

Q. Right.

Page 181

DR. WILLIAMS:
A. So, you know, it's not that he didn't support it, it's that he felt that we needed to, at that time he saw it as an issue that we needed to deal with.
MR. BROWNE:
Q. Flesh it out a bit more.
DR. WILLIAMS:
A. Yes, deal with an issue, so at the end of the day, he did support it, but some things had to be put in place.
MR. BROWNE:
Q. And he felt certain things need to be addressed before -
DR. WILLIAMS:
A. Correct.
MR. BROWNE:
Q. And I think it would be fair to say that one of the directions that he was moving in was wanting to have pathology services centralized, along with technical services?
DR. WILLIAMS:
A. Probably, I'm not sure certainly after we got the technical services centralized and after we got these reports, we did have an agreement

Page 182

in the summer of 2006 to get all the pathologists centralized on one site as well, but we would have to leave a pathologist at the St. Clare's site for frozen sections and things that came up on that site.
MR. BROWNE:
Q. Right.
DR. WILLIAMS:
A. But everybody would be working on the same site. That would foster subspecialization too, as Dr. Banerjee outlined.
MR. BROWNE:
Q. And was there any discussion with regard to the site, having a site pathologist at St. Clare's and I think possibly a technologist about the notion of any telepathology, do you recall any discussion -
DR. WILLIAMS:
A. We talked about telepathology because we use that kind of thing in radiology with the new PAX system.
MR. BROWNE:
Q. The PAX system, uh-hm.
DR. WILLIAMS:
A. My understanding is that they didn't feel that

Page 183

given that these things were slides under a microscope, we were advance enough yet to use that. There was some discussion of it, I don't think we felt--I think the answer I got was that we're not that advanced yet.
MR. BROWNE:
Q. Right.
DR. WILLIAMS:
A. But it is something that might come in the future.
MR. BROWNE:
Q. Okay. As well you were asked about the tissue auditing system and Dr. Sayid Abidi, his initiatives, I think, at the Grace in that direction, I think you mentioned that that had already been in place.
DR. WILLIAMS:
A. Yes, Dr. Abidi was probably at the General site, I think. He would have been the first chair of the surgical pathology review committee. I wouldn't have had any dealings with him or received any reports from them at that time.
MR. BROWNE:
Q. Okay, but I guess -

Page 184

DR. WILLIAMS:
A. I'm not sure who they reported to.
MR. BROWNE:
Q. Is my understanding correct that tissue auditing committee or system melded into the surgical pathology review committee?
DR. WILLIAMS:
A. Yes, that was part of their mandate, that was a big part of their mandate.
MR. BROWNE:
Q. And we saw that with one of the exhibits earlier this morning.
DR. WILLIAMS:
A. Yes, that's one of their big parts of their mandate.
MR. BROWNE:
Q. Now, can the witness be shown P-0980 please? I must have the wrong one, my apologies, I'm looking for--Mr. Simmons if you could help me, the June 19th, 2003 memo from Dr. Ejeckam to Mr. Gulliver. Maybe it's 0984--not that it's necessary, Doctor, your reason -
DR. WILLIAMS:
A. I'm familiar with -
REGISTRAR:

Page 185

Q. P-0111, page 2.
MR. BROWNE:
Q. Let's try that. Doctor, just take a moment if you need to, to refresh your -
DR. WILLIAMS:
A. No, we can go through it.
MR. BROWNE:
Q. Okay. you're reasonably familiar with this?
DR. WILLIAMS:
A. Yes.
MR. BROWNE:
Q. Now the material in this document prepared by Dr. Ejeckam, would you agree with me it's primarily technical in nature?
DR. WILLIAMS:
A. Yes, we need to move down through it, one is the location. It's talking about technical issues, yes.
MR. BROWNE:
Q. Yes, no sort of pathology issues per se?
DR. WILLIAMS:
A. He didn't bring them up in this memo, no, because he'd be dealing with Mr. Gulliver, not -
MR. BROWNE:

Page 186

Q. Right. And prior to 2005, and as you've pointed out, this was addressed to Mr. Gulliver. Did Mr. Gulliver bring this memo to your attention?
DR. WILLIAMS:
A. No, he did not.
MR. BROWNE:
Q. Now Mr. Coffey, I think, asked you on Friday as well whether you were aware of Dr. Cook met with the pathologist and explained what was going on with pathologists at any point.
DR. WILLIAMS:
A. I understood that Dr. Cook met with the pathologists arising out of Dr. Banerjee's report, I don't know the timeframe, but my understanding is he did.
MR. BROWNE:
Q. Do you know whether or not Dr. Cook also met with the technologists and explaining to the technologists anything that they knew, whether it was pre Dr. Banerjee or post Dr. Banerjee about what they understood was going on.
DR. WILLIAMS:
A. I'm not sure of that, I would not know. I might have been told, but I can't remember. I

Page 187

don't remember being told that Dr. Cook would do that.
MR. BROWNE:
Q. Because we saw at, I think it was Exhibit--if we could just--maybe this may refresh your memory. P-0559? And this is a memo from Dr. Cook to the program manager, the--Mr. Dyer, Mr. Gulliver and the other individuals, I think, are technologists. And that's dated August 8th, 2005 and it lists, if you, again, a number of things.
DR. WILLIAMS:
A. Um-hm.
MR. BROWNE:
Q. Again, mostly for the, I guess, retesting of the estrogen, progesterone receptors.
DR. WILLIAMS:
A. Yes.
MR. BROWNE:
Q. Do you know, does this help you recall whether or not there was a meeting around this time, probably the following day, between Dr. Cook and the technologists as to what was going on?
DR. WILLIAMS:
A. I would not know that. Dr. Cook sometimes

Page 188

reported on meetings to me. Ones that he didn't need any direction from me or didn't need follow up, he may not. I know Dr. Cook was very diligent around this time.
MR. BROWNE:
Q. Sure.
DR. WILLIAMS:
A. Following up on all these issues.
MR. BROWNE:
Q. And lastly, Doctor, if you could look at P-0784? Mr. Coffey showed you that this morning. And I think it's Dr. Banerjee's report, which is enveloped -
DR. WILLIAMS:
A. I have it here.
MR. BROWNE:
Q. Okay, you have it there. Doctor, Mr. Coffey asked you again, it is a reference to the fact, I think it's at page 1 in the conclusion sections and I can -
UNKNOWN SPEAKER:
Q. (Inaudible).
MR. BROWNE:
Q. Page 47, thank you. Go back to the first page, please? The incident problem case,

Page 189

Doctor.
DR. WILLIAMS:
A. Yes.
MR. BROWNE:
Q. You'll see the second paragraph there, "It should be noted that invasive lobular carcinomas are frequently ER positive." And he's got percentage there, 92 percent. "Thus the initial negative result should have been questioned." And he's referring back to the 2002 incident.
DR. WILLIAMS:
A. Yes.
MR. BROWNE:
Q. And if you could look, you'll see there very faintly somewhere around--after the 92 percent, footnote No. 1.
DR. WILLIAMS:
A. Yes.
COFFEY, Q.C.:
Q. If we go to the end of that and follow that footnote, please?
DR. WILLIAMS:
A. Um-hm.
MR. BROWNE:

Page 190

Q. And tell me what is the date on that article?
DR. WILLIAMS:
A. The date of that article is January, 2005.
MR. BROWNE:
Q. Right.
DR. WILLIAMS:
A. Yes, January, 2005.
MR. BROWNE:
Q. So Dr. Banerjee is making a statement in relation to the 2002 case using a 2005 article, is that correct?
DR. WILLIAMS:
A. That is a 2005 article, yes.
MR. BROWNE:
Q. Thank you. Thank you, Dr. Williams, that's all the questions I have.
DR. WILLIAMS:
A. Thank you.
COMMISSIONER:
Q. Thank you, Mr. Browne. Ms. Newbury. Ms. Newbury, we were a bit late having our break this morning, so may I suggest you run until about 1 and break at a convenient place around there and we'll come back then at 2:15.
DR. ROBERT WILLIAMS, EXAMINATION BY MS. JENNIFER NEWBURY

Page 191

MS. NEWBURY:
Q. Sure.
DR. WILLIAMS:
A. Good morning.
MS. NEWBURY:
Q. Morning, or afternoon now, Dr. Williams. Jennifer Newbury for the Canadian Cancer Society, Newfoundland and Labrador Division.
DR. WILLIAMS:
A. Um-hm.
MS. NEWBURY:
Q. I'm going to ask you some questions about the media that you were involved with in October of 2005. And if I could refer to Exhibit 0345, please? Now, you were shown this particular exhibit the other day.
DR. WILLIAMS:
A. Um-hm.
MS. NEWBURY:
Q. Now, on page 2 of that exhibit, in the fourth column you can see paragraphs 1 and 2 of the column No. 4. It says, "We had about 73 percent of tests that were positive, so we're only retesting the 27 percent or so that were negative." And "From the early results

Page 192

Williams said 'It appears only about 10 percent of the overall tests performed over the past seven years show different results.'"
DR. WILLIAMS:
A. It should be "will show", I was predicting.
MS. NEWBURY:
Q. You were predicting?
DR. WILLIAMS:
A. Yes.
MS. NEWBURY:
Q. Right, yeah, I understand that. So that's consistent with what you would have relayed at the time?
DR. WILLIAMS:
A. Yes. But when we, as you know, we tested more than just 27 percent because they had a very broad definition of what was negative, so we would have tested more than 27 percent -
MS. NEWBURY:
Q. Okay. And do you have any -
DR. WILLIAMS:
A. - in retrospect.
MS. NEWBURY:
Q. Do you have any idea what the rough percentage of that was?

Page 193

DR. WILLIAMS:
A. At the end of the day it looks like we had-- when I left the organization, it was 900, around 900 people.
MS. NEWBURY:
Q. Right.
DR. WILLIAMS:
A. Out of 2500, so it would have been more than that.
MS. NEWBURY:
Q. Sure, okay.
DR. WILLIAMS:
A. Yes.
MS. NEWBURY:
Q. I see your point.
DR. WILLIAMS:
A. 35 percent, maybe, something like that.
MS. NEWBURY:
Q. Okay. But other than that, other than the fact that the percentage turned out to be a bit higher, you didn't have any general criticisms about how they captured your information?
DR. WILLIAMS:
A. No. I think we needed to, there was a feeling

Page 194

that we needed to have a broad definition of what, so that we wouldn't miss anything and confuse things.
MS. NEWBURY:
Q. Okay. Now, there are other similar comments attributed to you, and I just want to show you a couple of those. It's at the same exhibit, page 4. This is an article, CTV.ca for October the 6th, the following day, I believe, 2005. And paragraph 8 of that particular article, if you can find it there, it starts with "Health care." "Health care officials say they can't be precise about the number of people affected. Mount Sinai is testing 30 percent of the hundreds of tissue samples that came up negative since 1997. So far 10 percent of results have changed to positive." So that's a similar sentiment?
DR. WILLIAMS:
A. Yeah, but it's not, it's not reflected in the same way I--it's not a quote.
MS. NEWBURY:
Q. Right.
DR. WILLIAMS:
A. And it doesn't reflect, it may not reflect

Page 195

exactly what I would have said. I was looking at 10 percent overall.
MS. NEWBURY:
Q. Overall, so -
DR. WILLIAMS:
A. Yes.
MS. NEWBURY:
Q. So that would be -
DR. WILLIAMS:
A. I was trying to keep some semblance of how I spoke. We knew that we had around 73 percent positive.
MS. NEWBURY:
Q. Right.
DR. WILLIAMS:
A. And we knew that, you know, up to 82 percent could be positive. Looking at that, I guess I was predicting at the time that about 10 percent of the overall tests would probably convert or may change.
MS. NEWBURY:
Q. Okay. So that would be not just looking at the ER negative results, but the ER positive results, as well? I mean, that's the overall group that you're talking about?

Page 196

DR. WILLIAMS:
A. Yeah, we were looking at if 73 percent of our tests are positive, and we know that we've had some conversions, especially in 2002, because that was the year when we had--we got much lower percentage of positives than on average.
MS. NEWBURY:
Q. Sure.
DR. WILLIAMS:
A. But if you look at it over those seven-year period, our average positivity rate was 73 percent.
MS. NEWBURY:
Q. Right.
DR. WILLIAMS:
A. And the rate might be up to 82 percent. One could surmise that probably we'd have it up to 10 percent overall. So that, you know, it doesn't quote me on that, but it's -
MS. NEWBURY:
Q. No, it -
DR. WILLIAMS:
A. It's not quite in the context I would have expressed it in.
MS. NEWBURY:

Page 197

Q. Right. Okay, but that's an interpretation of it. Is it consistent, though, generally, with what you said? It may not be how you phrased it, or how you saw it in your own mind, but would it still be accurate with the message that you were trying to get across?
DR. WILLIAMS:
A. Well, I guess the message I was trying to get across was we're going to have, you know, about 10 percent of overall tests -
MS. NEWBURY:
Q. Right.
DR. WILLIAMS:
A. - re--coming back, changed.
MS. NEWBURY:
Q. So, all of the ER/PR tests between 1997 and 2005, if you take all of those tests, only 10 percent would ultimately be changed?
DR. WILLIAMS:
A. Yeah, I was, at the time I was predicting based upon that, around two hundred and, up to 250 tests.
MS. NEWBURY:
Q. Okay.
DR. WILLIAMS:

Page 198

A. Could have changed. That's the best estimate I could make at the time based upon the figures we had at the time.
MS. NEWBURY:
Q. Sure, okay. And just to show you another couple, the next page, because this gets repeated across several different media outlets. This one is CBC News, this is page 5, October the 6th, 2006, paragraphs 9 through 11. And it states that, "Most of the tests performed in the Newfoundland facility were positive. Williams said, 'We are only retesting the 27 percent or so that were negative.' He said about 10 percent of tests done over the last seven years may show different results."
DR. WILLIAMS:
A. Yes.
MS. NEWBURY:
Q. And one more. Page 10 of the same exhibit, P-0345. This is an interview--I'm not sure if it's an interview or if it's a recording of a statement that you made with CBC Morning Show on the 14th of October, 2005, so about a week later.

Page 199

DR. WILLIAMS:
A. Um-hm.
MS. NEWBURY:
Q. I'll go to page 4 of that. So in the exhibit it's page 13 but it's page 4 of the transcript from the CBC Morning Show. At the very bottom paragraph it says, or Quinn says, "Health officials say that about 300 people from across Newfoundland and Labrador are given this test each year. Approximately three quarters of them test positive. So hundreds of samples are being retested and Dr. Williams say they expect that less than 10 percent of those will turn out to be false negatives."
DR. WILLIAMS:
A. I meant 10 percent of the total.
MS. NEWBURY:
Q. Of the total, right. Okay, I understand. Now, in terms of the retesting itself from the beginning, I understand that the retesting was only of those patients who were ER negative?
DR. WILLIAMS:
A. ER negative, yes. There were some patients who were PR positive, but they were retested. We wanted to make sure there was no confusion

Page 200

and we wouldn't miss anybody.
MS. NEWBURY:
Q. So there might have been some unplanned testing of ER positive patients?
DR. WILLIAMS:
A. No, there was testing of PR positive patients.
MS. NEWBURY:
Q. Oh, PR -
DR. WILLIAMS:
A. They took a definition -
MS. NEWBURY:
Q. Okay. I thought you said ER positive -
DR. WILLIAMS:
A. - of negative as they just focused on the ER and -
MS. NEWBURY:
Q. Right.
DR. WILLIAMS:
A. - and you get involved in the PR and ER, then you might start missing people so they cast a wide net to make sure that we retested a lot of people.
MS. NEWBURY:
Q. So it's ER negative, regardless of the PR status?

Page 201

DR. WILLIAMS:
A. Yes.
MS. NEWBURY:
Q. Okay. And how about ER positive patients, was there a focus on retesting ER positive patients?
DR. WILLIAMS:
A. No, there was not.
MS. NEWBURY:
Q. Okay.
COMMISSIONER:
Q. When you say ER negative, you're meaning--because we have that -
DR. WILLIAMS:
A. Yes, there -
COMMISSIONER:
Q. We have that problem of how you define negatives.
DR. WILLIAMS:
A. Yes, sure. I think it was -
COMMISSIONER:
Q. So let's figure out what they are in this context.
DR. WILLIAMS:
A. Yeah. Less than 30 percent up to December,

Page 202

2002 and after that, less than 10 percent -
COMMISSIONER:
Q. Yeah, but when you had them retested -
DR. WILLIAMS:
A. - were considered as negative.
COMMISSIONER:
Q. - what you considered positive or negative went by what?
DR. WILLIAMS:
A. Dr. Cook sent out a memo, it was discussed with the oncologists, and basically the definition of negative was anything less than 30 percent up to December, 2002 and anything less than 10 percent thereafter because those patients even though they had, some of them might have 20 percent or 25 percent would not have received any treatment at the time.
MS. NEWBURY:
Q. Right. So -
COMMISSIONER:
Q. So basically would they not be retested? Sorry, Ms. Newbury, because this is something that I had not quite the way I understood it. So when you were determining who you were going to send to Mount Sinai, did you go by

Page 203

way of the definition of positive on the date that they were originally tested or did you go by a mathematical view of what the percentages were and choose a one percent or a zero percent and those above are positive and those below are negative?
DR. WILLIAMS:
A. No, I think it was related to the changing therapeutic level cut off. So my understanding is that anybody who was less than 30 percent up until December, 2002 would be retested and after that anybody less than 10 percent. That was based upon what the treatment protocols were at the time and they changed at the end of December, 2002.
COMMISSIONER:
Q. Yes, I understood that.
DR. WILLIAMS:
A. Yes. So that's what it was based on.
COMMISSIONER:
Q. About the change, that is. I'm not sure that I understood that that was who got chosen, but in any event, I'm sure we'll resolve it.
MS. NEWBURY:
Q. If I could have Exhibit P-0539, please? Now,

Page 204

these are notes of your meeting from August the 1st, 2005, I understand. And Dr. Cook--I think there might be--there's a typed version of the notes. So the first bullet there, I believe from your earlier evidence, that those would be comments attributed to Dr. Cook?
DR. WILLIAMS:
A. Yes.
MS. NEWBURY:
Q. Okay. And in the fourth--sorry, in the third item listed under Dr. Cook's name under the first bullet, it says that "One case, 10 percent positive, came back negative."
DR. WILLIAMS:
A. Um-hm.
MS. NEWBURY:
Q. And this was referring to 11 cases sent to Mount Sinai negative and variable positives. So you were aware, as of that date, August the 1st, 2005, that there was one case that went from positive to negative? Is that, am I understanding that properly?
DR. WILLIAMS:
A. Yes.
MS. NEWBURY:

Page 205

Q. Okay.
DR. WILLIAMS:
A. That's what it looks like. And I'm not sure what cases they selected or this type of thing.
MS. NEWBURY:
Q. Sorry?
DR. WILLIAMS:
A. I'm not sure what case they selected, but I'm not sure of the details on that, so.
MS. NEWBURY:
Q. Okay.
DR. WILLIAMS:
A. You'd probably have to ask Dr. Cook about that in more detail.
MS. NEWBURY:
Q. Sure. But in terms of your understanding, at the time you would have understood that this one case, for whatever reason, had initially been tested as positive?
DR. WILLIAMS:
A. Um-hm.
MS. NEWBURY:
Q. Ten percent positive and came back negative. If I could refer to Exhibit P-1077, please?

Page 206

Okay. Now, this is a series of, I think a couple of e-mails. And I'm going to scroll down to the, actually, the original message is from Heather Predham. It's dated January the 11th, 2006, and it's addressed to Sharon Smith, Patricia Pilgrim, Pam Elliott and to yourself. Now, if you look a the fourth paragraph under the original message, there's a reference there to a group of samples that were done at on our automated Ventana system from April, 2004 to August, 2005 that were not validated by Mount Sinai. "The decision was made in the fall to send these samples up to Mount Sinai, as well. We now have a lady whose original sample showed a degree of positivity under the 10 percent level, so it was sent to Mount Sinai but came back completely negative. She has been informed and she has been taken off Arimedex. We now have two more results back with the same situation. I guess you can say that they are false positives. These two will be panelled at this Thursday's meeting." So this e-mail then for January, middle of January 2006, does that refer to what later became known as retro

Page 207

converters?
DR. WILLIAMS:
A. Probably.
MS. NEWBURY:
Q. Okay.
DR. WILLIAMS:
A. I can't be sure if these were the same ones.
MS. NEWBURY:
Q. Are there any other possible explanations for that comment there by Ms. Predham? What else could it be referring to?
DR. WILLIAMS:
A. Probably that's it, but I'm not sure.
MS. NEWBURY:
Q. Okay. So you were aware then certainly by August of 2005 that there was a possibility of samples converting from positive to negative?
DR. WILLIAMS:
A. There's a possibility, yes.
MS. NEWBURY:
Q. Okay, and in October of 2005, when you were engaged -
DR. WILLIAMS:
A. And Dr. Banerjee referenced that because that's one of the questions he was asked.

Page 208

MS. NEWBURY:
Q. Okay. Now back in October of 2005, you were, again, discussing your percentages, your expectations in terms of how many conversions there would be from negative to positive.
DR. WILLIAMS:
A. Um-hm.
MS. NEWBURY:
Q. By that time, by October of 2005, had Eastern Health taken any steps to attempt to quantify, you know, the same way that you're looking at the ER negative conversions, were there any steps by Eastern Health to attempt to quantify whether there would be any conversions from positive back to negative?
DR. WILLIAMS:
A. Not that I can recollect at the time, no.
MS. NEWBURY:
Q. So then in terms of whether or not there could possibly be any conversions from positive to negative, that would be an unknown quantity?
DR. WILLIAMS:
A. Yes, but we asked--Dr. Banerjee sort of tried to quantify that. When the people came up from Ventana in the spring of 2006, we asked

Page 209

them that question, and again, we were told that it's almost impossible, very highly unlikely that that could happen.

MS. NEWBURY:

Q. I wonder if I can refer to Exhibit P-0125, please, on page 26 of that exhibit. This is an e-mail from Marilyn McCormack to Moira Hennessey, with a briefing note for the Premier on ER/PR receptor tests and it's dated August the 18th, 2006, and this is the-- appears to be the attached briefing note, and down below, it has a chart showing a number of categories of patients and test results. Are you generally familiar with the information in that?

DR. WILLIAMS:

A. I'm not sure if I've seen that. I might be familiar with the information, but I don't know that that went through my office, that report.

MS. NEWBURY:

Q. If you look at page 28 of the exhibit, at the top, the very top row, it says "patient test results confirmed positive by Newfoundland panel" and next to it it has a number of 12.

Page 210

DR. WILLIAMS:

A. Um-hm.

MS. NEWBURY:

Q. And those were patients, the third column of that row, patients whose original test results were considered positive by treating physician and treated appropriately. There was a slight change in ER/PR status but review by Newfoundland panel confirmed positive ER/PR status.

DR. WILLIAMS:

A. Um-hm.

MS. NEWBURY:

Q. And looking down at the bottom -

DR. WILLIAMS:

A. We wouldn't be surprised with that because this is a semi-quantitative test. So it's ten percent doesn't mean ten percent, doesn't mean ten percent, doesn't mean ten percent.

MS. NEWBURY:

Q. Sure. No, I appreciate that.

DR. WILLIAMS:

A. If you have 30 percent and then ten percent or then five percent, it's semi-quantitative, subject to a lot of technical issues.

Page 211

MS. NEWBURY:

Q. But I guess, in terms of the retesting of these 12 samples, these were considered positive and ultimately confirmed positive.

DR. WILLIAMS:

A. Positive, that's what I would read it as, yeah.

MS. NEWBURY:

Q. And down at the last column on that page, there's a reference to retro converters, and there were four patients listed in that row and those are the patients considered positive at time of initial ER/PR testing. These individuals received hormonal treatment and retesting at Mount Sinai confirmed--I'm just looking, trying to gauge sort of the scope of the problem, because you indicated that the Ventana representative had basically indicated that there would be--there's very little chance of conversions from positive to negative.

DR. WILLIAMS:

A. Yes, and Dr. Banerjee would have confirmed that in his initial report.

MS. NEWBURY:

Page 212

Q. Okay. Can you explain then--it would appear to me, and again, this is my interpretation of this document, but it would appear that there were four plus 12 patients who had been considered positive that were retested.

DR. WILLIAMS:

A. Yes.

MS. NEWBURY:

Q. That was a total of 16, and out of those 16, four were converted to negative, and I understand a low number, four, the number of positive patients tested, because that wasn't the focus of the retesting by Eastern Health. So four out of 16 seems to be a fairly high proportion. Did you address that with either Dr. Banerjee or the Ventana representative?

DR. WILLIAMS:

A. That never came up in our discussion, Ms. Newbury.

MS. NEWBURY:

Q. Okay.

DR. WILLIAMS:

A. Or any discussions we had subsequent to that, no.

MS. NEWBURY:

Page 213

Q. Okay, so -
DR. WILLIAMS:
A. It did come up with the retro converters in the sense of what -
MS. NEWBURY:
Q. Right, but -
DR. WILLIAMS:
A. - there was no recommendation to go back or anything, no.
MS. NEWBURY:
Q. But there was no effort to try to find out why perhaps the percentage or the proportion of conversions from positive to negative was not consistent with perhaps what the Ventana representative or Dr. Banerjee might have anticipated?
DR. WILLIAMS:
A. No, I don't think, now looking at that, we had it in this context either.
MS. NEWBURY:
Q. Okay. Now in the media articles that I referred you to earlier, you're discussing the percentage of tests that show different results over the last seven years, and you're relating that not to the ER negative test, but

Page 214

you're relating that to all of the tests done between 1997 and 2005, and my suggestion is that if you're going to talk about the total number of the tests there, that the appropriate percentage would be ten plus X percent, and X would be the unknown quantity of conversions from ER positive to ER negative.
DR. WILLIAMS:
A. Okay, we were looking at it, at the time, of people who were negative and retesting positive.
MS. NEWBURY:
Q. Right, but when you're talking--when you're discussing this with the media, you're talking--even though you're talking about retesting of ER negative patients, you're relating that percentage wise to the entire group of retesting. So you're looking at all of the ER positive patients and all the ER negative patients.
DR. WILLIAMS:
A. I guess our focus was on the ER negative patients who would convert to positive.
MS. NEWBURY:

Page 215

Q. So did you assume that the X, you know, the-- if there are conversions from positive to negative, you don't know what that figure is? It's an unknown quantity. You'd never thought about it. It wasn't the focus.
DR. WILLIAMS:
A. No, it wasn't the focus, I'm sorry.
MS. NEWBURY:
Q. Had you assumed that that quantity would be zero?
DR. WILLIAMS:
A. No, I don't think we could assume that quantity would be zero.
MS. NEWBURY:
Q. Okay.
DR. WILLIAMS:
A. But in a sense, that was what we were thinking of at the time. We had four retro converters, so it wasn't zero, but we were thinking at the time, our problem was really missing people who were negative and not picking them up and these people were denied treatment.
MS. NEWBURY:
Q. Looking back at it now, and recognizing that there have been some conversions from positive

Page 216

to negative, do you think it would have been more appropriate when you're talking about percentages of different results that there should have been some factor taking into account by Eastern Health of the conversions from positive to negative? Either that or to restrict your percentage to the total number of ER negative tests that are going to be retested?
DR. WILLIAMS:
A. I'm not sure of that. I mean, it just wasn't a consideration at the time.
MS. NEWBURY:
Q. And why is that?
DR. WILLIAMS:
A. Because we were--as I say, we were totally focused on trying to see who we missed, in terms of negative and trying to get people panelled, get the tests done as we could, panelled and people treated.
MS. NEWBURY:
Q. I can understand that your focus -
DR. WILLIAMS:
A. It wasn't a conscious, you know, we're not going to deal with this, type of thing. I

Page 217

think just our focus was on the other issue.
MS. NEWBURY:
Q. On the ER negative patients.
DR. WILLIAMS:
A. Yes.
MS. NEWBURY:
Q. And I understand that the focus was to retest those, but in terms of your communication on the issue, why would you relate the ten percent to the overall number of ER tests done since 1997 up until 2005?
DR. WILLIAMS:
A. Because we -
MS. NEWBURY:
Q. When you're not going to test them.
DR. WILLIAMS:
A. I guess, again, we were just focused--I can only answer it the same way as I've answered. It just wasn't a consideration. It's not that we'd considered it and didn't do anything with it. It's just that we were just looking at the negative converting to positive. That's all I can say.
MS. NEWBURY:
Q. Looking back at it, do you think that there

Page 218

could be confusion from choosing the denominator in calculating your percentage of all tests done between '97 and 2005?
DR. WILLIAMS:
A. I hope that there wasn't because I tried to explain it, but again, I was focused totally on negative to positive conversions.
MS. NEWBURY:
Q. While you were VP of Medical Services at Eastern Health, was there any thought given to looking into the issue of retro converters on a broader scale, aside from those that were tested?
DR. WILLIAMS:
A. No, there was not that I can recollect.
MS. NEWBURY:
Q. And are you aware of any of the individual consequences to a patient of converting from positive to negative?
DR. WILLIAMS:
A. You'd look at the treatment profile.
MS. NEWBURY:
Q. Okay, and there could be a change in treatment?
DR. WILLIAMS:

Page 219

A. There could be a change in treatment. Now I now some people, as we looked at in follow up who were negative were already treated with Tamoxifen because the physician chose to do it, and some people may do that.
THE COMMISSIONER:
Q. Time to take the luncheon break now.
MS. NEWBURY:
Q. Sure.
THE COMMISSIONER:
Q. 20 after 2, thank you.
(LUNCH BREAK)
THE COMMISSIONER:
Q. Please be seated. Ms. Newbury.
MS. NEWBURY:
Q. Thank you. Dr. Williams, as of the summer of 2006, I understand that four retro converters were not yet notified. Is that consistent with your understanding of their -
MR. WILLIAMS:
A. My understanding that one was--my notes say one was notified.
MS. NEWBURY:
Q. Okay.
MR. WILLIAMS:

Page 220

A. The two in the other regions, the other regions were following up. I'd have to look at my notes. And one, they had difficulty contacting and they were still trying to follow up when I left the organization.
MS. NEWBURY:
Q. When you left, but in the summer of 2006, prior to that--perhaps we can pull up Exhibit P-0411, please, on page two of this exhibit. It talks about retro converters and in the third paragraph, it indicates that representatives of Eastern Health and the clinical chiefs of pathology and Cancer Care will meet with them in the next few weeks to disclose this information. So it would appear from this memo, which is dated--that's to you, dated July 4th 2006, that they had not yet, as of that date, been notified. Is that -
MR. WILLIAMS:
A. Yes, and I would have some more notes, some detailed notes that are part of this package that where I looked at all the DCIS's. I think I phoned Dr. Denic. Now I don't know what that note says because I don't have it in front of me.

Page 221

MS. NEWBURY:
Q. Sure, okay.
MR. WILLIAMS:
A. But I would have had the understanding that at least three of the four were notified sometime over the summer. I knew they had trouble contacting the fourth, and I can't answer that question. Heather Predham would have to answer that. They may not have contacted that person by the time I left.
MS. NEWBURY:
Q. Okay. I guess the point that I'm making, that as of July of 2006, that had not yet been done -
MR. WILLIAMS:
A. But it was -
MS. NEWBURY:
Q. - although some efforts were made in the next couple of months before you left to make those contacts?
MR. WILLIAMS:
A. Yes, and I expect it would have been done, and I know that the DCIS's were all notified, as far as I can understand, from Eastern Health's perspective. Again, I contacted the other

Page 222

medical directors in the other two regions to make sure that there was a process in place, and if they wanted us to help, we would help, but if they didn't, they could move forward on their own.
MS. NEWBURY:
Q. Sure, okay. Perhaps we could bring up Exhibit P-1077 again, please. This is the e-mail that I showed you earlier, and you thought that this was probably relating to the retro converters, and reading the third paragraph there--sorry, the fourth paragraph, under the original message, it would appear that three of these patients are patients who've converted from positive to negative. So if these are the same three patients that are in the group for the July 2006 memo, do you know why it would have taken so long for notification to take place?
MR. WILLIAMS:
A. No, I don't. I know that when I was notified by e-mails that I--over the months of, I think, May, June, July and August, except for the two weeks when I was away, I was fully engaged in making sure the DCIS group and

Page 223

retro converters were dealt with.
MS. NEWBURY:
Q. Okay.
MR. WILLIAMS:
A. I'm not sure.
MS. NEWBURY:
Q. Now this e-mail here is directed to you, dated January the 11th, 2006.
MR. WILLIAMS:
A. Sure.
MS. NEWBURY:
Q. Had you taken any of those steps as of January 11th 2006?
MR. WILLIAMS:
A. I would have just assumed that people were being notified as things moved forward. Then I got a specific report sometime about the DCIS's and the retro converters and I followed up on those.
MS. NEWBURY:
Q. Okay. So it wasn't until you saw it in a report form that you took -
MR. WILLIAMS:
A. Yes.
MS. NEWBURY:

Page 224

Q. - your own steps?
MR. WILLIAMS:
A. No, as we were going along in the spring, I didn't get into hands on in informing patients, but at the end of--during the summer, I did get focused in on the DCIS's because I wanted to get sure they were done and the retro converters to make sure--I understood by that time that the people had been phoned who were being retested and those who were negative had been phoned back and that those who were panelled, there was letters gone out to their physicians. That's what I understood at the time.
MS. NEWBURY:
Q. Did you ask anyone about the delay from the January 11th, 2006 -
MR. WILLIAMS:
A. No, I didn't. I didn't--so many e-mails going back and forth, to be honest, that I didn't link those two. And in fact, I had forgotten this e-mail until you just brought it to my attention.
MS. NEWBURY:
Q. And would the discovery of a conversion from

Page 225

positive to negative, as indicated in this January 11th 2006 e-mail, would that be considered an adverse event?

MR. WILLIAMS:

A. I think we considered the whole group one big adverse event, and anything around it.

MS. NEWBURY:

Q. Okay.

MR. WILLIAMS:

A. So I don't know a special event file would have been filed at that time. I wasn't aware of it.

MS. NEWBURY:

Q. And you'll note there that one of the patients referred to had actually been on a medical, Arimedex, and was taken off the medication.

MR. WILLIAMS:

A. Yes.

MS. NEWBURY:

Q. So that patient would certainly be considered an adverse group and whether it's--or an adverse event, whether or not it's a group categorization or an individual categorization, you don't know.

MR. WILLIAMS:

Page 226

A. And that patient had been notified by the looks of it, yes.

MS. NEWBURY:

Q. Yes, and do you know if any occurrence report was ever prepared regarding retro converters, either individually or collectively?

MR. WILLIAMS:

A. No, I did not see one. You'd have to ask people that did a bit more of the hands on side.

MS. NEWBURY:

Q. Dr. Williams, I'm not sure if you had a chance to reflect on the percentages over the lunch break, but if so, do you still not have any concerns with your choice of denominator, which I understand to be in the range of 2500, in calculating the percentage of results that were anticipated to be different upon retesting, even though the vast majority of the ER positive results would never be retested, according to the plan, and also, in light of your recognition that there was a possibility that there could be some conversions from ER positive to ER negative?

MR. WILLIAMS:

Page 227

A. We were totally focused, as I said earlier, before lunch, on the negatives that converted to positives.

MS. NEWBURY:

Q. But having the benefit of hindsight, looking back at it now. I realize that you were focused on that at the time, but do you still not have any concerns with using 2500 or in that range as a denominator?

MR. WILLIAMS:

A. We're talking about conversions from negative to positive. That's the number you probably would use because you were looking at that number.

MS. NEWBURY:

Q. So the denominator should have been the total number of negatives, as opposed to the total -

MR. WILLIAMS:

A. I would think the denominator, you know, we were looking at the number of negatives versus the total number of tests.

MS. NEWBURY:

Q. Okay, thank you.

MR. WILLIAMS:

A. At the time.

Page 228

MS. NEWBURY:

Q. And just for clarification, the ten percent figure quoted in the media, that wouldn't include conversions from positive back to negative? You were only focusing then on the conversions -

MR. WILLIAMS:

A. We really weren't focused at that, because I'm not aware of any literature and Dr. Banerjee didn't--we asked him about it, and there was nothing in the literature that saw that to be a problem, in the literature anyway, and from Dr. Banerjee's comments. So we were totally again focused on the conversions from negative to positive, at that time.

MS. NEWBURY:

Q. If I could bring up Exhibit P-0411. Just on the issue of who was retested, there a note in this memo from Heather Predham in the first paragraph there, it indicates that as the clinical definition of negative changed over the years, all patients with an ER of 30 percent or less were retested. Is that consistent with your understanding?

MR. WILLIAMS:

Page 229

A. Not totally consistent, no. I thought that it was ten--30 percent to a certain date and then ten percent after that date.
MS. NEWBURY:
Q. Okay. So to this day, you're not sure of whether -
MR. WILLIAMS:
A. Again, that's my understanding.
MS. NEWBURY:
Q. Okay.
MR. WILLIAMS:
A. I'd have to go back and look at the memos that were sent out by Dr. Cook, but I think that's my understanding.
MS. NEWBURY:
Q. Okay, thank you. Now Dr. Williams, are you familiar with the concept of blameless culture?
MR. WILLIAMS:
A. Yes, I saw Mr. Tilley talking about that. Probably not as familiar as he may be with it, yes.
MS. NEWBURY:
Q. Yes, he was involved with an organization that adopted that.

Page 230

MR. WILLIAMS:
A. Yes, so it wouldn't be something that I was near as familiar with. I've heard the term, terminology and this type of thing, but not in any great detail or depth. It was a concept that was, I guess, coming on nationally.
MS. NEWBURY:
Q. Okay, and was this blameless culture approach, in your view, adopted at Eastern Health or the Health Care Corporation of St. John's?
MR. WILLIAMS:
A. It was in the process of being adopted. I can't tell you specifically because at a certain stage, I was leaving the organization and I don't know exactly when that would come into effect.
MS. NEWBURY:
Q. Okay.
MR. WILLIAMS:
A. I'd have to--if I gave you an answer, I'd be guessing, to be honest with you. I'd have to go back and look at any notes I had, but I didn't see anything in these exhibits that talked about that.
MS. NEWBURY:

Page 231

Q. And would you expect to see documentation generated either by Eastern Health or its predecessor about the blameless culture approach?
MR. WILLIAMS:
A. There should be something, but it may not be in these documents. I think you'd have to ask somebody who were a little closer to it than me.
MS. NEWBURY:
Q. Okay.
MR. WILLIAMS:
A. To give you an answer, I'd be surmising, to be honest.
MS. NEWBURY:
Q. And so in say 2005-2006, when you were the VP of Medical Services and dealing with the ER/PR issue, was the blameless approach factored into any of the decision making that you were involved in?
MR. WILLIAMS:
A. It certainly would be a thought because when we were in Calgary, as I said, in 2006, there was a lot of discussion, and again, I can't really get the details, about how you'd have a

Page 232

culture that encouraged people to report things and whether it was reporting things that--adverse events that happened or near misses that hadn't caused an adverse event, but that would be useful in terms of prevention. So I think the whole focus and thrust, certainly in Calgary, so we would have been aware of it from our discussions there and there would have been some discussions I know with our executive team when we came back from Calgary, as you start to jog my memory.
MS. NEWBURY:
Q. Sure.
MR. WILLIAMS:
A. Ms. Elliott would be closer to it than me, because she's the person who's in charge of quality initiatives at that time when that system came into place, and Ms. Pilgrim, more so than me. But we did have some discussions in Calgary. A lot of the discussions in Calgary, you know, were about how they were handling things there and what we could learn from them, but there was the issue of the organization's culture and how you'd try to move that culture from, you know, maybe hiding

Page 233

things or not bringing--let's bring it out in the open, even if an adverse event hasn't occurred, so that something occurred didn't cause any harm to anybody, but it was a near miss. It could be used then to plan strategies to prevent the thing from--prevent the next time it might happen, it might cause an adverse event. So that discussion was under way.

MS. NEWBURY:

Q. Okay.

MR. WILLIAMS:

A. That's the level of my, I guess -

MS. NEWBURY:

Q. Your knowledge.

MR. WILLIAMS:

A. - detail and knowledge about time frames, you'd have to ask somebody else. I'm sorry, I can't answer that. If I can't answer it, I just shouldn't try.

MS. NEWBURY:

Q. Well, if a blameless culture approach had been adopted by Eastern Health, would you expect, as VP of Medical Services, to be aware of that?

Page 234

MR. WILLIAMS:

A. I would be aware of it in the discussion, and again, that's what emanated from our discussions in Calgary and our approach. People in the organization, because I wasn't responsible for quality prior to the fall of 2005, that people may be more knowledgeable about that than me, and that may be something that was encouraged.

MS. NEWBURY:

Q. So in your view then, this would be something restricted to the quality. It wouldn't be something known throughout the organization?

MR. WILLIAMS:

A. Well, it's something that they would be working on and try to get that out in the organization. We were working--I know, at some stage, we were working on changing the culture in the organization, yes, towards that kind of an approach.

MS. NEWBURY:

Q. Okay, and if the quality department or any other part of the organization were pursuing the blameless culture approach, and if they had conducted consultations with stakeholders,

Page 235

would you expect to be aware of this?

MR. WILLIAMS:

A. I would be aware of it, yes.

MS. NEWBURY:

Q. Okay, and are you aware that any such consultations had taken place with, say, the Board of Trustees or other regional health authorities, Department of Health, advocacy groups?

MR. WILLIAMS:

A. Again, to answer the question, I knew we were talking about that kind of a culture when we visited Calgary, and it wasn't a surprise to us that that's the approach we were taking.

MS. NEWBURY:

Q. Right.

MR. WILLIAMS:

A. Now to tell you the specifics of whether the Board was approached and when the Board was approached, I'd have to defer you to somebody else, because I might mislead you on that.

MS. NEWBURY:

Q. Okay, so -

MR. WILLIAMS:

A. And I don't want to do that.

Page 236

MS. NEWBURY:

Q. - so you don't necessarily know that it was or wasn't done?

MR. WILLIAMS:

A. No, I don't necessarily know, and I don't want to try to answer just in case I may be wrong.

MS. NEWBURY:

Q. And Mr. Tilley had indicated and acknowledged that the adoption of a blameless culture approach by an organization such as Eastern Health would be a fundamental shift in the philosophy, functioning and culture of the organization. Would you agree with that statement?

MR. WILLIAMS:

A. Well, the past there had been a different approach, and the whole issue of the patient safety agenda forward was to look at the culture and try to change the culture over time.

MS. NEWBURY:

Q. And you see it as a fundamental shift?

MR. WILLIAMS:

A. That's a fundamental shift, and--yes.

MS. NEWBURY:

Page 237

Q. And do you know, as VP of Medical Services, whether physicians were generally made aware of this new approach that was either in the works or had already been adopted by Eastern Health?

MR. WILLIAMS:

A. Well, we had started working on the whole issue of adverse events sometime before, but we had involved our physicians in the process. I think it was in the fall of 2004, September 2004, we had representatives from the Canadian Medical Protective Association come down. Dr. Martin, I think Claude Martin was their leader in risk manager and Mr. Peter Browne and they would have spoken to our clinical chiefs. I think the whole clinical chiefs meeting in September 2004 was on the whole issue of reporting of adverse events and patient disclosure, and--or it was--it may have been 2003. I think it was 2004, or one of those years anyway. It may have been--yeah, I think it was 2004. 2005, I think we had Dr. Rob Robson down to talk about clinical safety. So we were talking about clinical safety to our clinical chiefs at each annual retreat there

Page 238

for a few years in a row, but Dr. Robson, I think, was 2005 and I think the adverse events issue was either 2003, 2004. I stand to be corrected on which one it was, but it was in the September meeting, and we spent about a couple of hours talking about that with representatives. Subsequently, I had follow up with the Newfoundland--sorry, the Medical Board, and had changed themselves to the College of Physicians and Surgeons.

MS. NEWBURY:

Q. Right.

MR. WILLIAMS:

A. They'd done some work on it and we tried to meld the adverse event reporting mechanism for Eastern Health, which was applying to all staff, whether it was physicians or not, with what CMPA had recommended and with what the Newfoundland--sorry, the College of Physicians and Surgeons of Newfoundland and Labrador were looking at from other provinces. They had some drafts done up. I think that that policy was sent out before I signed it off. I heard here I signed it off in its final form in 2005, but I understand that I sent that policy

Page 239

out to all our physicians before that.

MS. NEWBURY:

Q. And that's a disclosure policy on adverse events?

MR. WILLIAMS:

A. Yes.

MS. NEWBURY:

Q. Was it discussed in the context of a blame free culture? Was that also part of your -

MR. WILLIAMS:

A. Well, probably in the sense that look, let's get this out. We don't--you have to--I think if you're going to do that, you probably have to discuss it with that background in mind.

MS. NEWBURY:

Q. Sure.

MR. WILLIAMS:

A. But like I say, to answer the question, I don't want to mislead you. I'm sure that it was probably discussed in that context. If you're going to get stuff out, you're going to report near misses, you're going to come right upfront with adverse events, I think that would probably be the background milieu you were talking about.

Page 240

MS. NEWBURY:

Q. So the incentive then would be to have the disclosure policy, but in the context of a blame free culture?

MR. WILLIAMS:

A. Well -

MS. NEWBURY:

Q. To encourage the reporting.

MR. WILLIAMS:

A. - I would think so, but again, to give you the specifics, I think you should ask somebody else, in terms of that.

THE COMMISSIONER:

Q. Would the whole rationale for the policy as well as the policy itself be written?

MR. WILLIAMS:

A. No, I don't think. I don't recall -

THE COMMISSIONER:

Q. There is a policy, is there not?

MR. WILLIAMS:

A. Yes, there is a policy on reporting of adverse events which we started to do for all our staff, nursing staff, employees basically, right, of Eastern Health. Well, the Health Care Corporation of St. John's.

Page 241

THE COMMISSIONER:
Q. Right.
DR. WILLIAMS:
A. But we also felt that the physicians should be part of that strategy of disclosing adverse events, and that's why we involved the Medical Board and that's why we invited the Canadian Medical Protective Association to join us for our clinical chiefs retreat in September, 2004. I may be wrong, it may be 2003 -
MS. NEWBURY:
Q. Sure.
DR. WILLIAMS:
A. - but it's one of those retreats.
MS. NEWBURY:
Q. Now, in terms of you wanted to include the physicians, but how about including patients in either the consultation or perhaps in an education campaign about this approach?
DR. WILLIAMS:
A. I never heard that discussed in the strategy, to be honest with you. It was the assumption that patients would like to know what happened, I presume, but I don't remember any detailed discussion. Most of my involvement

Page 242

would have been at that time was making sure that we had the physicians involved in it. And so that's why we had our clinical leaders involved in probably about a two-hour presentation, give an take. There was a presentation by CMPA and Mr. Browne here locally from the CMPA and a chance for physicians, our leaders to get involved in it to and fro with questions and this type of thing. Then I remember having some--a lot of consultation with the Newfoundland, College of Physicians and Surgeons of Newfoundland and Labrador before--and we sent something, when I sent it out, I would have sent out some reference to the College of Physicians and Surgeons that Labrador had developed a policy and if there's a problem with our policy and interpreting it along with the policy that they'd done for doctors, they could contact my office or I might have given them somebody else's name to contact just in case they had a problem with it. And so I'm pretty sure if one looked, that--I would have sent that out. But I don't know the exact date.
MS. NEWBURY:

Page 243

Q. And how would the blame-free culture compare with the traditional, the culture that preceded the blame-free culture, what would be the significant differences?
DR. WILLIAMS:
A. Well, I mean, I guess a culture of disciplining people for individual issues, looking at the individual instead of the system as a cause of the errors. And so there was some discussion around that, and I've seen some literature written on it that problems don't occur because of individual, the problem occurs because, it maybe occurs because of the system. That's some of the discussion that would have taken place. But like I say, for me to get into time frames and that type of thing with you, there's other people who would be much more conversant than me.
MS. NEWBURY:
Q. Now, if a patient or patients generally or the public generally are not involved in the consultations or educated about this new approach, would you have any concerns that perhaps if they were involved in an adverse event and then they see nothing being done and

Page 244

being completely unaware of this new blame-free culture and the potential benefits of it, might they perceive that as inaction on the part of the organization?
DR. WILLIAMS:
A. I think, you know, since I've left the organization now for almost three years there may have been something done on involving patients in the consultation process since that, I'm not sure.
MS. NEWBURY:
Q. But were there any concerns or did that perhaps arise out of concerns that patients might just see it as inaction rather than something that ultimately -
DR. WILLIAMS:
A. I can't remember, when I was there, any discussion about that, but there may have, something happen since that time to have involvement of patients in that process. I'm not sure if Calgary would have had some kind of an input as they went through with their cultural change that may have caused us to do the same thing as we move through. Because we came back from Calgary and made our

Page 245

presentation and tried to get some resources, more resources directed at quality than we've ever had in the past.

MS. NEWBURY:

Q. Now, in terms of the response by Eastern Health to the ER/PR issue, would you see that the organization was using the blame-free approach in so responding?

DR. WILLIAMS:

A. Yeah, that's the approach, I guess, we looked at as a systems approach.

MS. NEWBURY:

Q. Now, in terms of the cause of the problem, would you agree that while you were VP of medical services that there was no root cause analysis of the problem with the ER/PR testing?

DR. WILLIAMS:

A. No. We took the approach of having some outside consultants come in and look at that.

MS. NEWBURY:

Q. Okay. But -

DR. WILLIAMS:

A. As our approach we took.

MS. NEWBURY:

Page 246

Q. That's to fix the problems?

DR. WILLIAMS:

A. To identify what they felt the problems and give us a prescription for fixing that so that it wouldn't happen again. That's what I looked at them for.

MS. NEWBURY:

Q. And you wouldn't consider their reports to be a root cause analysis?

DR. WILLIAMS:

A. I wouldn't consider they'd use that. Now, I don't know a lot about root cause analysis and the technical issues involved around that. But I would have considered their approach as a look at our situation and our lab, look at what happened and develop a strategy for us that if we implement it, it would prevent it from happening in the future.

MS. NEWBURY:

Q. Okay.

DR. WILLIAMS:

A. And prevent probably other things from happening in the future. And this is what the reports that I got from Trish Wegrynowski and Dr. Banerjee, in my view, addressed in that

Page 247

sense.

MS. NEWBURY:

Q. Um-hm. Neither of their reports were directed at delving into the origin of the problems?

DR. WILLIAMS:

A. Well, Dr. Banerjee did review some slides back to 1997 and reviewed that, yes.

MS. NEWBURY:

Q. And he identified problems with, for instance, the absence of or inadequate attention paid to internal controls?

DR. WILLIAMS:

A. That's one of the things he identified. He -

MS. NEWBURY:

Q. But did he go beyond that and try to find out why there was inadequate attention paid to internal controls?

DR. WILLIAMS:

A. I'm not sure if he--what questions he would have asked at the time.

MS. NEWBURY:

Q. But did he identify it in his report?

DR. WILLIAMS:

A. No, he did not in his report, but he identified that we didn't pay attention,

Page 248

attention wasn't paid, so the approach to that would be pay attention to it in the future. And also, some of the recommendations, I think, like having a subspecializing would have dealt with a variety of that issue and some other issues that may come up from time to time.

MS. NEWBURY:

Q. Do you agree that while, certainly while you were the VP of medical services that the patients and public were not advised by Eastern Health as to the cause, the actual cause of the problems with the ER/PR testing?

DR. WILLIAMS:

A. To a large extent because we had these reports, we viewed them as a quality report and we--I felt we couldn't share them, based upon that. I did say publicly that there was a lot of problems in the, you know, the boiling the things and that we did have a system of checks and balances in place that didn't seem to work, I did say that.

MS. NEWBURY:

Q. Right.

DR. WILLIAMS:

Page 249

A. And that was referring, I guess, to the controls, that they didn't work because we--that's why we were surprised when basically the first one to find out about it, I was told there was a system of controls, so I'm thinking with a system of controls in place, how can this happen. So we found out subsequently, you know, that they didn't work and I would refer to sort of a checks and balances on it, sort of an internal quality procedure that you're undertaking.

MS. NEWBURY:

Q. But there was certainly no detail given to either the patients or the public as to the cause of the problem?

DR. WILLIAMS:

A. No, there was not.

MS. NEWBURY:

Q. Whether it was sort of a more immediate general cause of the problems or whether it dug down into the origin of all of those different issues that Dr. Banerjee or Ms. Wegrynowski found?

DR. WILLIAMS:

A. Yes.

Page 250

MS. NEWBURY:

Q. Okay.

DR. WILLIAMS:

A. I explained that earlier that that, you know, we didn't feel that we could share the detail in those because we thought they were--we were operating on the basis they were quality reports.

MS. NEWBURY:

Q. Can you see that from a patient's perspective that it might be troubling for a patient not to be told in any detail the cause of the problems with ER/PR testing, either on an individual basis or perhaps being told as a group the types of problems that were experienced?

DR. WILLIAMS:

A. And I can see that that's an issue that's been certainly identified here in proceedings. And that we're going to have to come to grips with how, if we have a situation like this in the future, that we may be able to deal with that so that we can have reports that can be disclosed publicly. I may make a few comments on that a little later.

Page 251

MS. NEWBURY:

Q. Sure, okay. And were there any steps taken while you were VP of medical services about moving towards having a type of reporting system that could address those concerns?

DR. WILLIAMS:

A. No, not when I--not before I left.

MS. NEWBURY:

Q. Okay. But you've become aware of some subsequently?

DR. WILLIAMS:

A. I may have become. I don't--I'm not aware of any, no.

MS. NEWBURY:

Q. Okay. And can you appreciate that patients may be sceptical about the ability of Eastern Health to rectify the problem if they don't know--if it's never been stated by Eastern Health what the cause is or any detail about the cause of the problem?

DR. WILLIAMS:

A. Maybe. I guess we said that we had brought in people and we did a review of the lab, I know we would have said that.

MS. NEWBURY:

Page 252

Q. So you were hoping they would just take comfort that there were recommendations made -

DR. WILLIAMS:

A. And we brought in outside people, not people inside the lab, because it's difficult for people who are working alongside of somebody else to work with them on a day-to-day basis to have--develop the necessary critique of what's being done by one of their colleagues, so that's why we went to outside people, yes.

MS. NEWBURY:

Q. Sure. Now, of course, the patients and the public and family members of deceased patients never did learn, while you were VP of medical services, the content of those reports?

DR. WILLIAMS:

A. They did not, no.

MS. NEWBURY:

Q. So they would just be asked to accept that the recommendations had been made?

DR. WILLIAMS:

A. Except that we found out what the problems were and have acted to make sure that they were prevented in the future.

MS. NEWBURY:

Page 253

Q. Do you know if anyone at Eastern Health considered the combined effect of number one, the patient being unaware of the blameless-culture approach and the potential benefits and that patient observing that no disciplinary action is being taken and perhaps interpreting that as no action being taken by Eastern Health, and number two, Eastern Health not providing an explanation in any detail as to the cause of the problem, had any attention been paid or consideration given to those issues?

DR. WILLIAMS:

A. I don't recollect anything being--that considered in that framework.

MS. NEWBURY:

Q. And would you think that if you're in the context of a blameless-culture environment, that might be particularly important to be able to explain to the patient the cause of the problem? I mean, that would be one of the benefits, presumably, of the blameless-culture approach is that there's a trade off here, we're not going to discipline people involved but ultimately you'll benefit because we're

Page 254

going to do all of these steps to improve the system. But if they're not aware of that, the latter part, certainly not aware of it in any detail, do you think that that might be a problem for those individuals?

DR. WILLIAMS:

A. And I think that you could be right there. Certainly our adverse event reporting, which was meant to deal with individual cases, one of the parts of it is that we tell the person how much we knew at the time, because sometime when you disclose individually, you may not know the full extent of the cause, so you just tell them what you knew at the time. Again, we were constrained by having these quality reports done so that people would--wanted everything, all the details done in hard hitting reports, and we did. And again, if we get into the situation again, maybe one of the lessons learned is how we might take a different approach.

MS. NEWBURY:

Q. On that point, I wonder if I could bring up Exhibit P-0161, please? Page 21. Actually, I should show you the first page, the cover page

Page 255

of this document first just so you can understand what it is. These are the Canadian disclosure guidelines which I understand were published in 2008. So I'm not sure if you're familiar with that, and I'm not -

DR. WILLIAMS:

A. No, I'm not familiar with them.

MS. NEWBURY:

Q. I'm not going to quiz you on the document itself, but I just want to know if you're familiar with some of the concepts that are in this document?

DR. WILLIAMS:

A. No, I'm not familiar.

MS. NEWBURY:

Q. With any?

DR. WILLIAMS:

A. No.

MS. NEWBURY:

Q. Well, I'll show you the concept and you can tell me now if you are aware, not of the actual written report, but whether this was a theme that you had been aware of before. And now if I could turn to page 21, please? Now, in the second column, the first paragraph,

Page 256

this is again a discussion about root cause analysis there. But it indicates, "Providers and patients should be made aware that there are explicit limitations to discussing to discussing some of the investigative information such as opinions and speculation shared as defined in legislation within each province or territories quality of care protection."

DR. WILLIAMS:

A. Where are you reading -

MS. NEWBURY:

Q. Sorry.

DR. WILLIAMS:

A. Where are you reading from now?

MS. NEWBURY:

Q. Sorry. Second column, first paragraph starting up, it's the second line.

DR. WILLIAMS:

A. Okay.

MS. NEWBURY:

Q. Thank you. Now, that's just a general statement there. Are you aware of this general statement, is this something consistent with your understanding of the

Page 257

quality assurance peer review privilege in this province back in 2005, 2006?

DR. WILLIAMS:

A. I would not be--you know, I don't even know if that was a concept that was discussed at the time.

MS. NEWBURY:

Q. Okay. So you're not aware -

DR. WILLIAMS:

A. These are 2008 guidelines.

MS. NEWBURY:

Q. No, no, no, I recognize that. But I think the guidelines -

DR. WILLIAMS:

A. I'm not sure that was a lot written nationally on this or a lot conceived nationally on this. Is this to deal with an adverse event with respect to a large number of patients or is this an individual disclosure issue here?

MS. NEWBURY:

Q. I think this is just general information. I don't think it's specifically in context -

DR. WILLIAMS:

A. But is the -

MS. NEWBURY:

Page 258

Q. - to multi-patient disclosure.

DR. WILLIAMS:

A. It's not to do with multi-patient disclosure, is it?

MS. NEWBURY:

Q. No, not -

DR. WILLIAMS:

A. It's to do with individual disclosure?

MS. NEWBURY:

Q. Yes, that's my understanding.

DR. WILLIAMS:

A. Yeah. There's some issues in our adverse event policy, and I don't have it in front of me, but that talk about some things, about the setting and things like that.

MS. NEWBURY:

Q. Um-hm. But just in terms of the privilege there, was it your view back in 2005 and 2006 that the privilege part of the peer review or quality review would be actually the opinions and speculations shared as opposed to, perhaps, you know, just straight statement of facts?

DR. WILLIAMS:

A. No, I wouldn't--I don't know if I've seen that

Page 259

before in that level of detail back in -

MS. NEWBURY:

Q. Okay. So you hadn't thought about that at all?

DR. WILLIAMS:

A. No. And I don't think there was anything written back in 2005 on it that I'm aware of.

MS. NEWBURY:

Q. Um-hm. And you, if you heard anything about this when you were in Calgary, you wouldn't recall it today?

DR. WILLIAMS:

A. No, I don't recollect any discussion about this issue in Calgary.

MS. NEWBURY:

Q. And if we can turn to page 10 of that document, please? Now, this is talking about the importance of disclosure there is the heading in the left-hand column. And at the bottom of the column, on the left-hand page under the heading, "Patient Perspective" the second paragraph there under the bullets, it says, "Patients may lose trust or become anxious or fearful when they sense that information is being withheld. This loss of

Page 260

trust can negatively affect the therapeutic relationship. Patients may be more understanding of adverse events when there has been open disclosure. Disclosure on adverse events--disclosing an adverse event to the patient shows respect, involves the patient in the clinical decision making process and facilitates future safe and appropriate clinical care." Is this concept, I know that the document was not written until 2008, but is the general concept something that you were aware of back in 2005, 2006?

DR. WILLIAMS:

A. I'm not sure, again, if I--I haven't seen anything nationally coming out on that, but in our individual adverse events report, we would have talked about issues such as those, and reporting on an individual basis to an individual patient about an event that occurred. But I haven't--I don't recollect back in 2005, 2006, anything written nationally or anything done that would deal with something like we had to deal with at the time, a major event affecting many people.

MS. NEWBURY:

Page 261

Q. But even though there weren't any documents such as this at the time that you're aware of, you must have had some discussions, enough to the point that your response to ER/PR included the blameless culture? Would that not be something -

DR. WILLIAMS:

A. I don't -

MS. NEWBURY:

Q. Would that not be something -

DR. WILLIAMS:

A. I don't remember having a lot of discussion about the blameless culture in terms of the ER and PR to be honest with you.

MS. NEWBURY:

Q. Okay, so it was more about -

DR. WILLIAMS:

A. You know, it was more about, I guess letting-- well, initially providing some information to the public so that we can let the individual patients know that there was an issue, in my mind at the time.

MS. NEWBURY:

Q. But in terms of your response to the ER/PR, I mean looking back at it, perhaps you hadn't

Page 262

focused on it at the time, but would you characterize the Eastern Health response to be one of a blameless free culture or consistent with the blameless free culture? No one was disciplined.

DR. WILLIAMS:

A. No, and we were looking at it as a system's issue and probably in that context, but to be specific about a timeframe for that, I can't recollect. And I'm not sure and I haven't seen anything, is there anything that's come out since that talks about the kind of situation we were in, in an adverse event that affects multiple people and how we would deal with it, I'm not sure if there's anything yet published on that, that I'm aware of. Anyway, there may be, but I'm not aware of it.

MS. NEWBURY:

Q. But under a traditional approach, even if you have a system's error, would you not have contemplated or look into whether or not discipline might be appropriate for some of the individuals involved?

DR. WILLIAMS:

A. I think sometime and even in a blameless

Page 263

culture if it's wanted disregard for policies and procedures and this type of thing, there would be some discipline meted out, even in those situations, if there was wanted total disregard for what happened -

MS. NEWBURY:

Q. It would have to be extreme.

DR. WILLIAMS:

A. Yes.

MS. NEWBURY:

Q. But how about if it was more ordinary?

DR. WILLIAMS:

A. No, that doesn't contemplate that, it contemplates trying to correct the system's problem, making things better so that things don't happen in the future.

MS. NEWBURY:

Q. But under the traditional approach, would the first reaction be to look and see who might need to be disciplined?

DR. WILLIAMS:

A. In some people's minds it might be, but other people's minds it's let's see what happened because there's many facets to problems that occur. It's not just one thing goes wrong; a

Page 264

number of things might have to go wrong.

MS. NEWBURY:

Q. But under the traditional approach, would there be more of an inclination to look at discipline?

DR. WILLIAMS:

A. I think it would have been more of an inclination, yes.

MS. NEWBURY:

Q. And looking back at it now, do you think that for the patients involved and the family members of deceased patients that there might have been some loss of trust as a result of patients learning for the first time from the media the problems with the ER/PR testing, as opposed to hearing about it directly from the Eastern Health?

DR. WILLIAMS:

A. Yes, I think in retrospect that's an issue that--and that's an issue that we had to deal with back in the summer in early fall of 2005.

MS. NEWBURY:

Q. And do you think that there might also have been some loss of trust when Eastern Health did not announce the cause of the problems

Page 265

with ER/PR testing?
DR. WILLIAMS:
A. I'm not sure if we did say that we had people come in and had identified issues and we were going to fix the problem.
MS. NEWBURY:
Q. But they weren't told what the cause was?
DR. WILLIAMS:
A. No, we did not.
MS. NEWBURY:
Q. Nor were they told what the corrections would be in any detail?
DR. WILLIAMS:
A. No, that's correct.
MS. NEWBURY:
Q. So do you think now, looking back at it, that maybe there might have been some loss of trust in the patients and family members?
DR. WILLIAMS:
A. I think if you're going to learn anything from this, you'd learn that there's some issues to definitely the second time around, yes, of course.
MS. NEWBURY:
Q. Okay. In terms of the concept of blame, would

Page 266

you equate finding answers to finding blame?
DR. WILLIAMS:
A. Not necessarily, no.
MS. NEWBURY:
Q. Okay, would you agree that it depends on what you do once you found the answers that would determine whether or not an organization is engaged in a blaming exercise?
DR. WILLIAMS:
A. To a certain extent, yes, depending on what you found and--it just depends on what you found at the time, right.
MS. NEWBURY:
Q. But just because you're looking for answers, it doesn't mean that you're engaged in a blaming exercise.
DR. WILLIAMS:
A. No.
MS. NEWBURY:
Q. You may ultimately decide that -
DR. WILLIAMS:
A. You're looking for answers to find out what happened and what went wrong and usually in these cases, a number of things may have went wrong.

Page 267

MS. NEWBURY:
Q. Sure.
DR. WILLIAMS:
A. It's no one person responsible, but it's broader than that, yes.
MS. NEWBURY:
Q. But even if one of the combination of factors, maybe--even if one of those factors involved human error to identify that human error in the system, would that, in your view, be considered a blaming exercise if your purpose is to make sure that it doesn't happen again, as opposed to penalizing or disciplining that individual?
DR. WILLIAMS:
A. To find out that there is human error would not mean that you are going to discipline and in fact the report that was generated, the in-home patient safety issue movement, 1999, 2000, the U.S. was entitled "To Err is Human" and that was the first--that was a seminal article on patient safety and this type of thought process and that was '99, 2000 to Dr. Leape in the U.S. started the whole issue of patient safety and this type of thing and

Page 268

things moving forward from there.
MS. NEWBURY:
Q. So the exercise would be appropriate in terms of the blame free culture and patient safety movement?
DR. WILLIAMS:
A. The exercise would be appropriate.
MS. NEWBURY:
Q. And to identify the human error, would that actually be beneficial to the organization to do so?
DR. WILLIAMS:
A. To identify any cause of error would be beneficial to the organization to do so, because then once you identify what the causes are, you can take measures to prevent them from happening again. That would be the purpose.
MS. NEWBURY:
Q. Did you observe any concern among health care workers or administrators or staff at Eastern Health that a search for answers, in their mind, might have been seen as a search for blame?
DR. WILLIAMS:

Page 269

A. You always had that issue when we--that's why we have peer review rules done up and to have peer review that has checks and balances put in because there's always that issue when they're doing a review, somebody or some thing.

MS. NEWBURY:

Q. And aside from peer review, are there any other tools that Eastern Health can use to help address that concern just to, you know, let people know that we're looking for answers, we need to identify all the factors, even if it's human error, not to blame, but to correct the problem?

DR. WILLIAMS:

A. I think that takes some time in a large organization with 12,000 people, such as Eastern Health, or 6,000 people such as the Health Care Corporation, to work on building that culture and people to buy in and that takes time and that takes experience and that takes examples over time. So that's my own view of it, I think I'm not so sure there's any set answer, but that is what I would say is that that takes time to change an

Page 270

organizational thought process and culture. It's not going to happen overnight because somebody says it's like that, that everybody says oh fine, I'll report this or I'll report that, I think it has to be built over time.

MS. NEWBURY:

Q. And do you know if there are any training workshops or trained facilitators that can assist Eastern Health in -

DR. WILLIAMS:

A. I think there's some of that has happened since I left, I -

MS. NEWBURY:

Q. Within the organization?

DR. WILLIAMS:

A. Yes, within the organization and some of it may have taken place before I left, actually.

MS. NEWBURY:

Q. Okay, and do you think that if people are going to buy into the problem, that it might be of some benefit to involve other stakeholders in the process, just for educational purposes or perhaps looking for consultation or feedback?

DR. WILLIAMS:

Page 271

A. And I think you need to ask people that are closer, because some of that might have happened by now, I'm not sure.

MS. NEWBURY:

Q. Okay, just in terms of -

DR. WILLIAMS:

A. I'm out of the organization, so if I was in the organization on a daily basis, I'd probably have some answers for you, but I'm sorry, I can't.

MS. NEWBURY:

Q. No, I'm not necessarily asking if you know it's happened, but I'm just wondering just now with the benefit of your hindsight whether you think that might help in terms of promoting that type of an approach and to maximize the benefit of it.

DR. WILLIAMS:

A. Yes, and I think that sort of thought process was something that came out in our--I'm just trying to think back in our discussions with Calgary that they may have done something along those lines and I think maybe if you looked in the organization now, because we didn't get back out of Calgary until 2006,

Page 272

that that may be moving forward in our organization, but I can't be sure of that, some people that will come behind me may be able to answer that question better than me.

MS. NEWBURY:

Q. Okay, thank you. If I could have page 30 of this exhibit, P-0161? Now this is a glossary of terms and the guidelines, the disclosure guidelines that I just referred you to earlier, and there's a definition there of system failure, "a fault, breakdown or dysfunction within an organization's operational methods, processes or infrastructure." Now, again, this is the 2008 guidelines, but is this definition consistent with your own understanding of a system failure?

DR. WILLIAMS:

A. I never thought of it, just on a cursory review of it, it looks reasonable, but I'd have to--if you wanted me to really reflect on it, I'd have to reflect on it and think about it for some time and I'd have really to look at the document and how it was used in that perspective in the document.

Page 273

MS. NEWBURY:
Q. Okay.
DR. WILLIAMS:
A. But, just looking at it, again, I haven't had any chance to think about it, so you're asking me to look at it, I haven't read the document that's embodied, so I really need to--before I got into any detailed discussion on it, I'd have to do that.
MS. NEWBURY:
Q. Sure, so it might depend on the context in which -
DR. WILLIAMS:
A. It might depend on the context and this type of thing, yes.
MS. NEWBURY:
Q. Okay. If I could have page 12 of that exhibit? And so in the first column there, on the left-hand side of the page -
DR. WILLIAMS:
A. Uh-hm.
MS. NEWBURY:
Q. "This is creating a culture of patient safety" is the heading of that section.
DR. WILLIAMS:

Page 274

A. Uh-hm.
MS. NEWBURY:
Q. And the third paragraphs says that "many adverse events in health care are now recognized as system failures where safeguards to protect patient safety were not in place or series of safeguards were not in place which resulted in harm to the patient. Adverse events often occur after recurrent patterns of failures, regardless of the dedication or experience of the health care providers involved. Systems theory emphasizes that focusing on the system, rather than on the individual, will prevent more adverse events."
DR. WILLIAMS:
A. Uh-hm.
MS. NEWBURY:
Q. Now if you want to take a moment to reflect on that -
DR. WILLIAMS:
A. That's the "swiss cheese" analogy that you're talking about there.
MS. NEWBURY:
Q. Okay. It does talk about system failure, the definition that I just referred you to and the

Page 275

recognition that "many adverse events in health care are now recognized as system failures." Is that consistent with your understanding?
DR. WILLIAMS:
A. Again, looking at it, you're asking me to pick out a paragraph in a large document and comment on it.
MS. NEWBURY:
Q. Not to comment on the document itself, but generally, you know -
DR. WILLIAMS:
A. No, but it's in the context and this type of thing, I mean a system's--it looks reasonable to me, but again, if I'm going to be dealing with it and questioned on it, it's part of a larger document which I haven't read.
MS. NEWBURY:
Q. Sure. Well just talking generally then about system failure and you alluded to it earlier in terms of why an organization may not want to discipline individuals because it's recognizing that there could be many other factors at play, you're looking at the system as a whole, as opposed to an individual's

Page 276

performance.
DR. WILLIAMS:
A. Uh-hm.
MS. NEWBURY:
Q. Is that, did I capture that correctly?
DR. WILLIAMS:
A. Yeah, well I guess we know that people have to work in the system and there's obviously a system in place, there's more, there's people working at different phases and facets of the system, so that in order for an adverse event to occur, it may occur because of one's individual issue, but it often occurs because of a number of situations that congeal around a certain event and a certain timeframe and a certain temporal relationship and you get a problem.
MS. NEWBURY:
Q. Right.
DR. WILLIAMS:
A. That's the theory.
MS. NEWBURY:
Q. Now Mr. Osborne testified that he had asked Eastern Health on a number of occasions if they had pinpointed the problem and he was

Page 277

given the understanding that the problem was a system's error and he had interpreted that to be an error with the DAKO system and that the problem was inherent in the DAKO machine and that the new Ventana, which was a more sensitive machine, did a better job. And he also indicated that he had assurances that it was not human error on the part of Eastern Health.

DR. WILLIAMS:

A. Uh-hm.

MS. NEWBURY:

Q. Now I'm not sure if you're aware of what his understanding might have been -

DR. WILLIAMS:

A. No, I wasn't--I've never met Mr. Osborne and I know he came on as minister before I left, but I've never been involved with briefing him or been involved with him, so I'm not sure -

MS. NEWBURY:

Q. Where he got that.

DR. WILLIAMS:

A. Where he got that information.

MS. NEWBURY:

Q. Do you think there might have been some

Page 278

confusion because of the, on the one hand the use, the reference by Eastern Health to the system problems, system failure, verses a layperson's understanding of what that might mean?

DR. WILLIAMS:

A. I don't know and to be honest with you, I don't want to speculate on that.

MS. NEWBURY:

Q. Okay. Ms. Dawe had also given evidence that for a considerable period of time she felt that the change in technology was a major contributing factor to the circumstance surrounding the testing and she had indicated she was disappointed not to be made aware of the inefficiencies in quality, monitoring and documentation and she testified that for a considerable period of time she felt that the change--sorry, she further stated that the minutes and the briefing material that were made public, always referenced a change in system and she wondered why this would be referenced, you know, repeatedly, if it were not an issue, and that's, I think, partly the context why she assumed that the change in

Page 279

technology was a major contributing factor. Are you aware of how she might have arrived at that conclusion?

DR. WILLIAMS:

A. No, I understand that she might have arrived at that conclusion, but I'm not aware of--I know it was always said that we, when we were retested on the new system, we had a new system in place, by that time it turned positive, that doesn't indicate that it was a problem with one system and the other system was good and the other system was bad. I don't know why--I know we did a very detailed briefing after Dr. Banerjee's visit and I know it would have mentioned some of the things he mentioned in that briefing.

MS. NEWBURY:

Q. And your briefing was a verbal briefing?

DR. WILLIAMS:

A. Yes, about a 45 minute briefing.

MS. NEWBURY:

Q. Did you think about doing a report, a document?

DR. WILLIAMS:

A. No, I didn't do a document, I would have had a

Page 280

book if I--I spent about 35, 45 minutes I'm pretty sure in going back on what ER/PR meant, how it affected treatment, I would have got that from Dr. Laing, what happened in terms of sequence and, but the first briefing of the Board would have been on the 21st of September, I wouldn't have had the debriefing, but Trish Wegrynowski at the time, because I think that happened after, but I would have had Dr. Banerjee's verbal briefing on the matter. I'm sure I would have mentioned some issues that he brought forward.

MS. NEWBURY:

Q. Can you say today whether or not you had indicated to the Board that there was a system's failure or a system's error?

DR. WILLIAMS:

A. I would have indicated to the Board what we knew and as you see some of the things that the consultants made many recommendations and we were going to be following up on them and we have a plan to deal with those.

MS. NEWBURY:

Q. But can you say whether the term, systems error, might have been used or system failure,

Page 281

something to that -
DR. WILLIAMS:
A. I don't recollect what term I used.
MS. NEWBURY:
Q. Okay. Do you think that it might have been important to have an official report just so the board could have something in hand, you know, just to aid the communication with the board as to the nature of the problems.
DR. WILLIAMS:
A. I guess in retrospect, if they feel they didn't understand the many briefings that I gave pretty well at each board meeting, yes, that might have been in retrospect.
MS. NEWBURY:
Q. But the point is, if she has taken--she might have understood it perfectly in her own mind, she might have understood it perfectly to be related to a change in technology. If she's not--she doesn't have something more official there, how can she know that what she took away from that meeting is wrong?
DR. WILLIAMS:
A. Well, I certainly spent a lot of time and I answered a lot of questions and there was a

Page 282

lot of concern on the faces of all the board members and I felt I covered every issue.
MS. NEWBURY:
Q. Do you think a report in addition to your verbal briefing might have been prudent?
DR. WILLIAMS:
A. In retrospect, now you're talking about that, yes.
MS. NEWBURY:
Q. And how -
DR. WILLIAMS:
A. I believe that's in retrospect -
MS. NEWBURY:
Q. And even if you were limited by time or other circumstances, how about submitting an official report subsequent to you meeting with the board, just to be sure that they're completely aware of all the relevant circumstances.
DR. WILLIAMS:
A. I felt at the time that I had such a detailed briefing, that people were aware, they looked very concerned and, of the issues that are brought out.
MS. NEWBURY:

Page 283

Q. These are fairly complex issues, would you agree for people hearing about ER/PR for the first time?
DR. WILLIAMS:
A. Well, I tried to make it, congeal it as simply as I could and in all honestly, I can say that I felt I did a good job on it.
MS. NEWBURY:
Q. But someone who might be more versed in, you know, medical terminology or laboratory medicine procedures might take more out of it than a member of the board who has not familiarity and might want to reflect on -
DR. WILLIAMS:
A. I try -
MS. NEWBURY:
Q. - said by reading the report a couple of times or referring back to it and -
DR. WILLIAMS:
A. I try to take the technical pieces out of it as best I could.
MS. NEWBURY:
Q. Okay. I wonder if I could have Exhibit P-0345, please, page nine, please. So, this is an article, CBC News, October 14, 2005 and

Page 284

down at paragraph 10, your attributed with the following statement, "Dr. Bob Williams, a vice-president with Eastern Health says, 'it is possible that some patients with the wrong test results may have benefited from the drug. An external review of the authorities testing equipment will be done', Williams said".
DR. WILLIAMS:
A. I don't--that's not in quotes, I would have said more than that.
MS. NEWBURY:
Q. Okay.
DR. WILLIAMS:
A. An external review of everything because we weren't just looking at the equipment.
MS. NEWBURY:
Q. So, in your view now, looking back at it, you would not have led -
DR. WILLIAMS:
A. No.
MS. NEWBURY:
Q. - the author of this to -
DR. WILLIAMS:
A. No, I would have--no, not just--we had these people come in and look at--as you'll see from

Page 285

our Terms of Reference, it wasn't limited to equipment.

MS. NEWBURY:

Q. I understand that, but just in terms of -

DR. WILLIAMS:

A. No, on -

MS. NEWBURY:

Q. - the communication with this.

DR. WILLIAMS:

A. No.

MS. NEWBURY:

Q. Was any contact made with the author of this article subsequently?

DR. WILLIAMS:

A. No, not that I'm aware of.

MS. NEWBURY:

Q. Okay. And does Eastern Health have any procedures for monitoring media?

DR. WILLIAMS:

A. They do monitor media, but I don't know if there's any procedure to correct the media or this type of thing.

MS. NEWBURY:

Q. And why would this statement here which you feel is not accurate, why would that have been

Page 286

not picked up?

DR. WILLIAMS:

A. I'm not sure.

MS. NEWBURY:

Q. And whose responsibility would that be to notice that?

DR. WILLIAMS:

A. Well, if it's--whoever, it may be mine or it may be the communications people. I certainly, our, certainly review wasn't limited to the equipment.

MS. NEWBURY:

Q. Just in terms of the handling of the ER/PR problem, aside from the communication with the board as an example, do you think it might have overwise aided Eastern Health to have official reports in place and to update them as necessary?

DR. WILLIAMS:

A. It would be something that, you know, if were doing it again, should be considered, yes. There was contact from time to time with the media over that time frame.

MS. NEWBURY:

Q. Just in terms of communicating with, you've

Page 287

got patients who are interested advocacy groups, the Department of Health -

DR. WILLIAMS:

A. Yes, I know what you're saying, yes.

MS. NEWBURY:

Q. Okay. And do you think it would be important in those reports to include all relevant background information and to provide sources of the information just to ensure accuracy? Do you think that would be something important, looking back on it now -

DR. WILLIAMS:

A. Well, looking back on it, as I say, having an adverse event of this magnitude hitting you and then going through it, you'll see after you're through it, some things that you could have done better -

MS. NEWBURY:

Q. Okay.

DR. WILLIAMS:

A. - or some suggestions that could be made and I presume, hopefully, that some of the things that'll come out of this -

MS. NEWBURY:

Q. And I guess what I'm looking for, what your

Page 288

suggestions might be. Would you think that putting all relevant information there as well as the source of that would have helped?

DR. WILLIAMS:

A. Well, I think in retrospect, getting the information first of all and making contact, thought about making contact, and we actually didn't. The important thing, I think, in retrospect, was the initial contact with media before any of this broke.

MS. NEWBURY:

Q. Right, okay, but in terms of -

DR. WILLIAMS:

A. But build, I guess, build on it from there.

MS. NEWBURY:

Q. Yes. But in terms of just--not just the communication with the media, but overall, the handling, sort of, the timing of the response by Eastern Health to the problem. Could you have benefitted by having a comprehensive report, not just to communicate with other people, but to make decisions about, will we test positive people or not or, you know, have we contacted all the regional health authorities and have we sent out protocols to

Page 289

other regional health authorities about fixation? Just to keep track of where you've been and where you're planning to go in your response.

DR. WILLIAMS:

A. And I think that's one of the things I've already said, when I look back at this, is having a dedicated task force with no other role, senior leadership just to deal with this issue because this in itself was a full time role.

MS. NEWBURY:

Q. I appreciate that. And in the absence of having such a task force in place, who would be responsible for doing the types of things that would be entailed in that job?

DR. WILLIAMS:

A. I would have responsibility myself, among other people, people who were working with me, yes.

MS. NEWBURY:

Q. Regarding the decision in around July and August, 2005, not to notify the patients until the retest results were back, as I understand your evidence and correct me if I'm wrong, was

Page 290

this decision primarily arising from the concern of oncologists about the anxiety of patients who would have to await the results of the retest.

MS. NEWBURY:

Q. I guess that was the biggest factor, yes, as far as I can recollect and my notes say.

MS. NEWBURY:

Q. And you were fairly certain as an organization or you personally as VP of medical services that certain patients, ER status would, in fact, convert upon retesting.

DR. WILLIAMS:

A. We'd already had some conversions at the time, yes. We would expect some more.

MS. NEWBURY:

Q. Yeah. So, it wasn't like a minimal, you know, fewer than one percent are expected to convert. It was a really significant percentage.

DR. WILLIAMS:

A. Yeah, we, I guess, looked--by that time we looked at our data and looked at what was happened in the literature, looked at the rates and, you know, knew that we'd have

Page 291

conversions. That's what we said at the time.

MS. NEWBURY:

Q. Sure. So, would you agree, looking back at it, that there were competing interests here in play between basically those patients who would, ultimately, convert and could benefit from, perhaps early knowledge about what's happening versus those patients who would ultimately not convert and might have worried needlessly in that interim period.

DR. WILLIAMS:

A. There was that issue and the oncologists were very concerned that if we went out, as we said earlier, we would create a major panic in all people and if--you know, to have a heavy workload, they'd get a lot of calls, they wouldn't know how to deal with it and it maybe impact their ability to carry on with the care, this type of thing. So, all these considerations were considered.

MS. NEWBURY:

Q. Was there any specific focus on attempting to weigh the risk to the two different groups of patients; those that might ultimately convert and those who might have worried needlessly?

Page 292

DR. WILLIAMS:

A. I don't think there was in the sense, we'll weigh the risks there. It was just a feeling and a lot of concern by the people who are closest to the patients that this was an issue.

MS. NEWBURY:

Q. Was there any effort to, at least, identify those patients who might be expected, because of their make up, the factors involving their diagnosis of breast cancer, was there any effort to identify those patients who were more likely to convert from ER negative to ER positive?

DR. WILLIAMS:

A. That wasn't the thought that came forward from anybody.

MS. NEWBURY:

Q. Okay.

DR. WILLIAMS:

A. The whole focus was let's get, I guess, retesting done as soon as we can and get the results done. The sooner we get things up--and there's a lot of work involved in doing that--the sooner we'll have the reports.

Page 293

MS. NEWBURY:
Q. So, there's no thought about sending perhaps a memo to all of the oncologists to say, listen, you might have patients who fall into this category and based on their make up, statistically speaking, they might be expected to convert and perhaps you can disclose the information, at least, to those patients.
DR. WILLIAMS:
A. There was some discussion, I think, with Dr. Carter and Dr. Laing somewhere that, if there was any urgent cases that they were concerned about, they would contact Dr. Carter. I think there's a note there.
MS. NEWBURY:
Q. And was that distributed to all oncologists in the province?
DR. WILLIAMS:
A. Well, I think, I believe that Dr. Laing and Dr. McCarthy were there at all the meetings. Dr. Ganguly was involved. Dr. Zulfiqar was involved from time to time. So, I presume that Dr. Laing--they were a small group of people that they were conversant with all those issues.

Page 294

MS. NEWBURY:
Q. And in terms of the decision, the ultimate decision to not notify the patients until the retest results were back, who ultimately made that decision?
DR. WILLIAMS:
A. I think it was a consensus decision about, well, with the people that were involved.
MS. NEWBURY:
Q. Okay. And what meeting was that?
DR. WILLIAMS:
A. I'd have to look at my notes to see.
MS. NEWBURY:
Q. Yes, sure, if you could, please.
DR. WILLIAMS:
A. It looks like it was first raised at August 15 meeting.
MS. NEWBURY:
Q. And you think that the consensus was made at that particular meeting?
DR. WILLIAMS:
A. No, I think that concern was raised and then it was--I think there was a subsequent meeting with the minister. I'd have to look at the notes to see -

Page 295

THE COMMISSIONER:
Q. I'm sorry, subsequent meeting with?
DR. WILLIAMS:
A. The minister.
THE COMMISSIONER:
Q. Minister.
MS. NEWBURY:
Q. And that would be Minister Ottenheimer?
DR. WILLIAMS:
A. No, maybe that's--I don't--let me see
THE COMMISSIONER:
Q. Would it be helpful if I took the afternoon break at this stage. So, that would give Dr. Williams a chance to look at the documents without the timing pressure.
MS. NEWBURY:
Q. Sure.
THE COMMISSIONER:
Q. Why don't we do that?
MS. NEWBURY:
Q. Thank you.
(RECESS)
THE COMMISSIONER:
Q. Please be seated. Ms. Newbury.

Page 296

MS. NEWBURY:
Q. Thank you. Dr. Williams were you able to locate the document you were looking for?
DR. WILLIAMS:
A. Well, all I can, my notes of August 10 there's a fairly lengthy section there on Dr. Laing talking about the issue of disclosure and the need to wait, this type of thing. Now, whether there was some other discussions before that because lots of times we had discussions on the phone, I may not have taken notes of everything that happened.
MS. NEWBURY:
Q. Sure, okay.
DR. WILLIAMS:
A. But that's the first time--I didn't get a chance to look back at all the notes, but -
MS. NEWBURY:
Q. Okay, no, that's fine.
DR. WILLIAMS:
A. There's a lengthy discussion at that meeting on August 10 and then there's a lengthy discussion with the Minister on August 15.
MS. NEWBURY:
Q. Okay.

Page 297

DR. WILLIAMS:
A. They're the two detailed references I have.
MS. NEWBURY:
Q. The August 10 meeting, do you have a note number at the top of your -
DR. WILLIAMS:
A. Note number 17.
MS. NEWBURY:
Q. Note number 17. And who was at that meeting?
DR. WILLIAMS:
A. Dr. Laing, Mr. Tilley, Ms. Pilgrim, Dr. Cook and myself.
MS. NEWBURY:
Q. Okay. And the August 15 meeting--did you say it was an August 15 meeting?
DR. WILLIAMS:
A. August 15 meeting, Note number 19 with the minister, the minister was there, Dr. Fleming from the department, Ms. Hennessey, Mr. Tilley, Dr. Cook, Dr. Laing and myself.
MS. NEWBURY:
Q. And those are the two meetings that the decision was made not to -
DR. WILLIAMS:
A. Well, there was discussion and -

Page 298

MS. NEWBURY:
Q. - notify patients until retest -
DR. WILLIAMS:
A. - a consensus was reached -
MS. NEWBURY:
Q. Okay.
DR. WILLIAMS:
A. - and that's my recollection. There may be other minutes, meetings, sorry and there may be other phone conversations that I wouldn't have captured.
MS. NEWBURY:
Q. Okay. Would any of them been after the August 15 meeting?
DR. WILLIAMS:
A. I would not know. I guess I didn't take notes in preparation for a detailed--I just take notes to try to capture the essence of what meetings we had and what decisions we might have made and where we were going. It was just so I could look back and if I had a note a week earlier and just try to update myself on what was going on.
MS. NEWBURY:
Q. In terms of problems that Eastern Health has had from time to time with shortage of pathologists, how would a shortage in that area, that speciality compare with other specialities?
DR. WILLIAMS:
A. It depends on the speciality. Over--in my days with the Health Care Corporation of St. John's, from time to time we've had shortages of specialists in certain disciplines. I alluded to the fact that we had a problem with hematological oncologists. Over time the cancer foundation would have had trouble with oncologists. Now, they were associated with us, but it would have affected the inpatient side of our organization, but not the ongoing care of most patients because most patients were seen in the cancer clinic. Over time we've had, you know, problems in pediatric surgery where you got two pediatric general surgeons and something happens and you're down to one. Early on, I had a problem like that and that can be a severe problem because you only got two and you lose one, you lose 50 percent of the people. But the issue with pathologists was not unlike some other issues

Page 299

Page 300

that we've had from time to time, but it causes some problems and it culminated in us having to send out specimens to Gama DynaCare, late 2005, early 2006, that timeframe. And I still think they're sending out, but I'm not sure about that.
MS. NEWBURY:
Q. And does this ability to out source some of the pathologist work, does that help Eastern Health deal with a problem -
DR. WILLIAMS:
A. Well, that's the first time we've ever done it.
MS. NEWBURY:
Q. Oh really, okay.
DR. WILLIAMS:
A. Before we would send out consultations to other labs, like the Canadian Cancer Reference Centre in Ottawa from time to time to get a second opinion or down to the Mayo clinic or some other place to get a second opinion, but most of that was related to, not our ability to process and examine, but our need to get a second opinion.
MS. NEWBURY:

Page 301

Q. You might have a complex case -
DR. WILLIAMS:
A. An expert opinion because if our pathologists coming together weren't sure and you got a big grey area, they'd ask some outside consultation. That's the first time, to my knowledge, that we sent out any large number of specimens because we just couldn't continue to cope with it. Now, we've had ups and downs in pathologists before, and a lot of people retire and one person died, people going and coming, I really have to trace the numbers by month and by year to see if we've had that problem, but certainly in the fall of 2005 and into 2006, we had enough of a problem that we weren't able to produce a timely result for patients. So, we had to refer cases out.
MS. NEWBURY:
Q. Is it easier, I guess, to deal with the shortage of pathologists in the sense that it's the samples that you would have to send out versus the patients having to go to another centre.
DR. WILLIAMS:
A. Yes. If we had a shortage of hematologist

Page 302

oncologists for instance, we'd have to send the patient out and all that entails with the family and then patients are very, very sick. They're in a strange city and all that stuff. So, that's worse. At least with the pathology, you can send out the specimens and it doesn't affect the individuals, as long as you can get a good place to do the work and get a decent turnaround time, but you got to be very careful when you send out a large number of specimens. If any of them go missing or displaced or disorganized or something, and you lose specimens, you have not diagnostic tool then to make a diagnosis. You might have removed a mole -
MS. NEWBURY:
Q. Sure.
DR. WILLIAMS:
A. - mole is gone, you don't know if it's a melanoma or if it's a normal mole. And you can't get a specimen to replace it. So, you got a problem. So, it's very important to spend a lot of time on the up side of that, dealing with it.
MS. NEWBURY:

Page 303

Q. And how quickly can arrangements be made if there's a sudden departure of a couple of pathologists?
DR. WILLIAMS:
A. I took us a while to get Gama DynaCare. We tried some other hospitals who couldn't do the work. I understand now, given issues that we predicted back probably about three years ago, other centres--because now they're having to send out the ER and PR because the people involved in it are moving on. We're not able to keep that subspecialty service together. They're having quite a bit of difficulty getting other centres to take up the work load because of the problems they're having themselves keeping up with the workload.
MS. NEWBURY:
Q. Okay.
MR. WILLIAMS:
A. And if they can't do their own workload on a timely basis, they're not going to take on somebody else's workload.
MS. NEWBURY:
Q. Sure.
MR. WILLIAMS:

Page 304

A. They'll have the surgeons and the other people at their own centre, you know, saying "look, you can't be taking on this. You can't give us a timely turn around of our own work." So that's going to be--my prediction, that'll be tougher and tougher.
MS. NEWBURY:
Q. But so far you haven't had difficulties with this one particular lab that you -
MR. WILLIAMS:
A. Just this because Gamma Dynacare at the time was available and we were able to do that. But I'm not sure, in this milieu now, which apparently it's gotten worse, whether they'll have that ability in the future.
MS. NEWBURY:
Q. And do you now have standing arrangements with this particular lab to do testing in the future, if and when you need it?
MR. WILLIAMS:
A. I'm not sure if they got that with Gamma Dynacare. I'm not sure. This is a group in Ottawa. This is a group of pathologists who set up their own business, so to speak.
MS. NEWBURY:

Page 305

Q. Okay.
MR. WILLIAMS:
A. Who do that in after hours and on weekends. They don't do it on the--these are a group from the Ottawa General or Ottawa Civic Hospital. So I don't know if we have a standing--we had a relationship with them then.
MS. NEWBURY:
Q. At the time.
MR. WILLIAMS:
A. To do what we needed to do. Whether--because I'm not in the organization any more. We're continuing to send out, but I understand in some conversations I've had that our ability in the future to do those kind of things is going to be much more limited, so we got a problem.
MS. NEWBURY:
Q. And can you comment on whether there are any advantages or disadvantages to sending out difficult tests or more complicated tests, such as IHC, out to a central specialized lab in some other jurisdiction?
MR. WILLIAMS:

Page 306

A. First of all, you got to get another lab to take on the responsibility for you, in terms of their own workload, and we've seen with Mount Sinai, I doubt if they, you know, would want to take on much more workload. They had quite a bit of difficulty doing our work for us. So that would--that could be a problem. It could be more of a problem now again because things seem to have deteriorated in the last two or three years and workloads are going up, but the pathologists are not going up commensurate with the workload, so I think there's more of a relative shortage of pathologists. So what worries me is that if we can't do the work here, are we going to be able to get somebody else to do the work? I guess we could always try the U.S. situation, but we tried, obviously with the ER/PR. We tried the Mayo Clinic, which we've used before, but they weren't comfortable with the results they were getting, so we didn't use them.
MS. NEWBURY:
Q. Would there be any economies of scale, for example, if rather than a lot of labs across

Page 307

the country or across the Atlantic region trying to do--struggle to get their own done, recognizing that there might be some shortage of pathologists, could a group of pathologists do the work more quickly, do you think?
MR. WILLIAMS:
A. Well, that's an issue that would have to be explored, for some subspecialized work like immunohistochemistry. The other thing that would have to be done if we decided, you know, we meaning Eastern Health, that's not we any more, but Eastern Health decided that they weren't going to do any immunohistochemistry or were going to send out these tests permanently, then there'd have to be some discussions with the medical school because we train pathologists here. We have a residency training program for pathologists and we would probably need to send the residents out of the province to get that training or get that exposure. That came up before when we had a problem with the number of MRI machines here. The residency program in diagnostic imaging said that if we didn't get more MRI machines so the residents could get exposure to MRI, we

Page 308

might have to send the residents out of the province to fulfil their resident training program. So that might be an issue. It's not an overriding issue, but it's an issue that would have to be explored.
MS. NEWBURY:
Q. So it's not insurmountable, but it -
MR. WILLIAMS:
A. No, it's not insurmountable. The insurmountable part might be that if the system can handle that type of an approach, yes.
MS. NEWBURY:
Q. I wonder if I could have Exhibit P-0493, please. This is a letter that Dr. Cook wrote to you and you were referred to that earlier. I just want to refer you to paragraph two, and it states "on the surface, a negative rate of 50 percent, though not the greatest, is not too bad when you compare a 60 percent positive and 40 percent negative rate according to figures provided by Dr. Joy McCarthy. We also need to correlate these figures more with our population. There may very well be a large number of women who have high grade lesions

Page 309

who would normally be negative for estrogen and progesterone receptors."

Dr. Williams, do you know if this correlation exercise was ever carried out?

MR. WILLIAMS:

A. No, to my knowledge, it wasn't carried out because we got--we made a decision to retest everybody and a lot of work was involved in that. Really the focus was on getting things together and getting the testing done as quick as we could, and we thought we were going to have that done in a couple of months. So the time to do that, we thought it would probably be better invested in, you know, getting everything together and getting the tests back for patients as soon as we could, to be honest with you. That's something one could now, just to see -

MS. NEWBURY:

Q. Sure, for extra reflection.

MR. WILLIAMS:

A. But at the time, it would have involved people's time who were in short supply and given the situation we were in, we thought--now I don't think we sat down and said "now,

Page 310

we won't do this because of this." I think just things overtook us and we had to get on with it.

MS. NEWBURY:

Q. Okay. Do you know if this type of exercise, outside of dealing with a problem such as ER/PR, do you know if this type of an exercise is carried out in any part of Eastern Health as an organization, monitoring trends in the population to see if, for example, there are a large number of women who have high grade lesions?

MR. WILLIAMS:

A. No, the only trend, the only thing that would be done in terms of cancer trends would be through the Cancer registry.

MS. NEWBURY:

Q. Okay.

MR. WILLIAMS:

A. And they now should have good data because our lab, back in 2002-2003, and I hope other labs agree that we would go online with them so all our cancer pathology reports would go directly to their registry. There's a linkage, and I'm pretty sure--I doubt if other labs would not

Page 311

do that. I know we did and we had to sign an agreement with them.

MS. NEWBURY:

Q. So you signed an agreement, that's Eastern Health?

MR. WILLIAMS:

A. Well, it would be the Health Care Corporation, I'm pretty sure.

MS. NEWBURY:

Q. It was the Health Care Corporation?

MR. WILLIAMS:

A. I'm pretty sure it was when Bertha Paulse was there as CEO, and I'm thinking it was 2002-2003, but I may be wrong on that, but there was a request that we provide, and other labs provide, this data online so that the registry could be accurate, and I know we did sign up and linked to them online. I'd be very surprised if that didn't--I'm pretty sure we signed up on that and supported them in doing that. So they're monitoring, I guess, cancer trends in our province. There's a national--cancer trends are published yearly, incidence rates and mortality rates are published and I think our province is part of those, part of

Page 312

that database.

MS. NEWBURY:

Q. And were you ever made aware of any problems with the cancer statistics from this province, due to lack of information being provided about mortality rates?

MR. WILLIAMS:

A. I think that's why Bertha Paulse wanted to link with our lab, to get the incidence rates, but I don't know about mortality rates, how they get their information, whether they link with Vital Statistics or not, I'm not sure. You'd have to ask them that.

MS. NEWBURY:

Q. So the types of information that you understood would be relayed to the Cancer Registry as a result of this agreement, you've mentioned incident rates and you're not sure about mortality?

MR. WILLIAMS:

A. I would think they would get the pathology reports.

MS. NEWBURY:

Q. Okay.

MR. WILLIAMS:

Page 313

A. From our lab directly. We wouldn't have mortality rates in our lab.
MS. NEWBURY:
Q. Okay.
MR. WILLIAMS:
A. Our lab would only be giving them the reports of the cancer pathology that they did.
MS. NEWBURY:
Q. So they deal with the pathologist as opposed to the oncologists?
MR. WILLIAMS:
A. Yes, they deal with--that gives them information from our lab directly, not the pathologists, but just the information. There's some kind of an online arrangement we signed that when reports on cancer were sent--were signed out, that they would get a copy of that.
MS. NEWBURY:
Q. Okay.
MR. WILLIAMS:
A. So they would know.
MS. NEWBURY:
Q. So there's no comparable agreement that would require that oncologists -

Page 314

MR. WILLIAMS:
A. No.
MS. NEWBURY:
Q. - provide any information at all?
MR. WILLIAMS:
A. No.
MS. NEWBURY:
Q. It's solely the lab?
MR. WILLIAMS:
A. All mortality data would be housed in the Registry of Vital Statistics. Now is there a link with the Registry to the Cancer Registry linking with the Registry of Vital Statistics, you'd have to ask them that. That would be a linkage with the Department of Health and Community Services. I don't know why--I don't see why they wouldn't, if they wanted an up to date registry, because their registry needs to have information on incidence rates and mortality rates.
MS. NEWBURY:
Q. So aside from this arrangement with the Cancer Registry, are you aware of any other additional formal or informal procedures in place in Eastern Health for monitoring any

Page 315

trends, you know, proliferation of breast cancer or looking at any, you know, possible environmental causes or looking for that type of information?
MR. WILLIAMS:
A. No, I think that would be a function of the Cancer Registry. Now the Cancer Registry is now under Eastern Health, because everything else seems to be under Eastern Health, it's so big, so that's something that you would have to ask those responsible for the Cancer Care program within Eastern Health. But I'm pretty sure that that information exists there.
MS. NEWBURY:
Q. Could I have Exhibit P-0785 please? This is an e-mail that you're neither the sender or the recipient, but I just wanted to show this--actually, sorry, you are a recipient of it, down below. This is August the 8th, 2005. It's an e-mail from Heather Predham to Dr. Williams, Dr. Cook, Terry Gulliver and Patricia Pilgrim. The heading, first heading there is database, and Ms. Predham says "I've got the lab database and the NCRTF database combined." Would that be the Cancer Registry?

Page 316

MR. WILLIAMS:
A. Yes.
MS. NEWBURY:
Q. Okay. "But I still have issues to clarify. There are data quality issues such as people with the same name and address and different MCP numbers and people with different names and addresses but with the same MCP numbers. Also, there are a lot of individuals with incomplete MCP numbers. I'll work on that today. There are a couple of issues that came to light though during this process," and the third bullet, "rough numbers from the combined database show 4,510 people overall. The Cancer registry does not identify almost 2100 of individuals who had ER/PR testing. Current status, living or deceased is only identified in 1,245 of those people. It's going to be difficult to determine this for the rest of the individuals."
And the next bullet, "ER/PR status is indicated in 1,230 people with an overall positivity rate of 55 percent" and then she goes on to say the overall positivity rate by year.

Page 317

So were you focused, upon receipt of this e-mail, were you focused upon the deficiencies in the Cancer registry that appear to be -

MR. WILLIAMS:

A. Yes, I think Mr. Coffey showed me this e-mail in his questioning earlier, and knowing what I know about the registry and the issues they had of getting adequate information from the labs and asking for an online transfer of information, I felt that that--they might have a deficiency of information there from all health boards, in terms of this issue.

MS. NEWBURY:

Q. And you had indicated that Eastern Health Board, when you were answering Mr. Coffey's question, that Eastern Health Board had signed up, but you weren't sure if other health boards had signed up?

MR. WILLIAMS:

A. Yes, and even if they did sign up, it probably wasn't anything retroactive to go back for previous years. I think it was on a go-forward basis. That's my recollection, and you really have to go back and find out what year that was, but it was when Mrs. Paulse was

Page 318

the Executive Director, and she left in 2004.

MS. NEWBURY:

Q. In 2004, Ms. Paulse left?

MR. WILLIAMS:

A. Yes, she left in December 2004, so it was sometime before that that they asked for that, and there was a formal contract, I think, or agreement we had to sign with respect to the information and how it would be used and that. So I don't know what year that was. So the fact that they may not have had as many individuals there made me think that perhaps, you know, that's why she asked for that to be put in place.

MS. NEWBURY:

Q. So some of that might have been prior to this formal contract coming into play?

MR. WILLIAMS:

A. Yes.

MS. NEWBURY:

Q. And do you know if Eastern Health, while you were still VP of Medical Services, followed through on its contract?

MR. WILLIAMS:

A. Oh yes, I'm pretty--we had a contract signed

Page 319

when I was with the Health Care Corporation of St. John's and if we didn't follow through with what we signed, I'm pretty sure Mrs. Paulse would have brought it up.

MS. NEWBURY:

Q. So there weren't any health boards that you're aware of that were unwilling to participate in this?

MR. WILLIAMS:

A. I can't answer that question. She would have dealt with them individually, rather than she would have dealt with us, but we had no problem with doing that. We felt it was something valuable that should be done. So I don't think there was any hesitation on our part. That's all I recollected.

MS. NEWBURY:

Q. Okay. Were there any issues with, you know, the database transferring the information from the pathologist to the cancer registry?

MR. WILLIAMS:

A. I don't recall--I think probably her people, Ms. Paulse's people in the cancer registry may have worked with our people to get those things clarified. I never heard there was an

Page 320

issue with it. She never came back to me and said you haven't been cooperating or haven't been giving us the information. So I just presume, on that basis, that we did do what we said we would do.

MS. NEWBURY:

Q. And the agreement, I take it, didn't provide for retroactive reporting of results?

MR. WILLIAMS:

A. No, I think it was on a go-forward basis, but again, that's my recollection, but I have to--there is a signed agreement that should be available if somebody wants to -

MS. NEWBURY:

Q. And were you the signature on that agreement?

MR. WILLIAMS:

A. I may have been a signature on it. I may not have been, but I may have been. I would have been aware of it because of the lab role.

MS. NEWBURY:

Q. And you weren't made aware of any resource issues regarding this contract on either the cancer registry side or the pathologists?

MR. WILLIAMS:

A. I'm pretty sure we signed off on it and did

Page 321

what we were supposed to do. I think it was just linking our computer systems to theirs. Now that's not simple to do, but I'm sure people know how to do that.

MS. NEWBURY:

Q. Sure.

MR. WILLIAMS:

A. And get the information. I'd have to go back and check really, if you wanted to pursue that, but I'm pretty sure that we--our intent was to cooperate, put it that way.

MS. NEWBURY:

Q. Okay, thanks, and I think other witnesses might be along who can elaborate on that. One of the recommendations of Dr. Banerjee was for pathologists to attend educational and scientific conferences.

MR. WILLIAMS:

A. Yeah.

MS. NEWBURY:

Q. And this was noted to be ongoing in the recommendations spreadsheet.

MR. WILLIAMS:

A. Yes.

MS. NEWBURY:

Page 322

Q. Are these educational and scientific conferences mandatory for pathologists?

MR. WILLIAMS:

A. Pathologists in our organization have to participate in MOCOMP. That's the maintenance of competence program run by the Royal College of Physicians and Surgeons. It requires them to undertake so much CME activity in any given time frame, and if they don't, they could lose their certification by the Royal College. So all our pathologists are supposed to participate in that and do participate. That's my understanding from Dr. Cook.

Number two is we've always had money available for our salaried physicians to attend conferences. Now it may not be enough. It's never enough, in a sense, and we tried to get more, but every pathologist every year was entitled to $2,000 a year to assist in attending a conference of his or her choosing, because the conferences would be outside the province. We didn't run any CME in the province. It would be usually at a larger centre, so probably Toronto, Montreal, maybe sometimes in Chicago or some places in the

Page 323

U.S. they went. But we supported them within the budget that we had. I don't think I ever denied a pathologist that $2,000. Now I had to fight every year, especially in times of restraint, the first thing that they'd want to cut was CME funding and travel and all that stuff.

MS. NEWBURY:

Q. So since Dr. Banerjee made the recommendation, what changes have there been, in terms of pathologists attending CME programs?

MR. WILLIAMS:

A. Well, I'm not sure if there's anything in a sense, except that we--specifically, we did sent Dr. Elms out to Dr. Allan Gown's lab for a period of time to gain expertise in immunohistochemistry, in particular, and I would think that we would have just continued to fund our pathologists. I did argue one year and got a little bit more money in one year, just to make sure that we wouldn't run short of money. I had over $100,000, I think, or so to assist people, but I had to deal with pathologists, some general practitioners and some psychiatrists. Most of our salaried

Page 324

people were in that category people. The university people, what I did with the university people was in order to protect the money I had for the non-university people, the university people have funding that they get from Memorial University as part of their appointment as a GFT and there's about six or seven of those people that I didn't let them access our funding, because they could access the university funding. So I could protect the funding for our own people. They're all our people, but -

MS. NEWBURY:

Q. Sure.

MR. WILLIAMS:

A. Yes, but they had another source of funding.

MS. NEWBURY:

Q. Yes, you want to get as much money as possible, sure.

MR. WILLIAMS:

A. Yes.

MS. NEWBURY:

Q. So then in terms of the education and scientific conferences that are attended by pathologists, is there any--do they attend

Page 325

them more frequently or are they more comprehensive in the types of conferences that they attend since Dr. Banerjee made his recommendations?

MR. WILLIAMS:

A. I'm not sure. You'd have to go back and look at--I used to keep a record in a black binder every year of how we spent that money, so I would know who went off to a conference and how much. We usually gave the maximum contribution because the cost was always more than 2,000, and the clinical chief got 2500.

MS. NEWBURY:

Q. Okay, and you indicated that the pathologists are required to participate in MOCOMP?

MR. WILLIAMS:

A. Yes.

MS. NEWBURY:

Q. And how long have they been engaged in that?

MR. WILLIAMS:

A. I would think that's been probably under way now for four or five, maybe six years. The Royal College brought that in. That can be done by online conferencing. They can participate in some of the things these days

Page 326

are done online, so they can participate in a conference that's probably online, and that counts or meetings or maybe tumour board rounds and clinical rounds also count.

MS. NEWBURY:

Q. Okay.

MR. WILLIAMS:

A. So things that they can do internally, in terms of maintaining competence also count, not just conferences. That's just one form.

MS. NEWBURY:

Q. Dr. Williams, you've discussed several times about the change in cut-off points and you indicated that initially the cut off for recommending Tamoxifen was 30 percent and then it was reduced to ten percent -

MR. WILLIAMS:

A. Yes.

MS. NEWBURY:

Q. - and later down to one percent.

MR. WILLIAMS:

A. No, I don't -

MS. NEWBURY:

Q. Oh, it hasn't been?

MR. WILLIAMS:

Page 327

A. Not so sure it's down to one percent. You'd have to ask our oncologists about that. It depends--the one percent rule or the one percent feature, whatever you want to call it, may depend on where you are. I'm not too sure, unless it's just happened recently that there's a total consensus around the one percent right across Canada. That was one of the issues that Dr. McCarthy alluded to in one of the documents, and maybe that's part of the National Cancer Strategy that there should be some--I mean, every--I don't--I guess I don't understand why there's a cut off here in this area and over here, we deal with it in this way.

MS. NEWBURY:

Q. Right.

MR. WILLIAMS:

A. It seems to me that if there's a scientific-- if there's scientific knowledge, there should be scientific knowledge and that's what people treat. Now in medicine, unfortunately there's no absolutes, but my understanding is some oncologists in some areas would treat on the basis of one percent. Some would treat on the

Page 328

basis of ten percent. Up until 2000, the end of 2000, it was 30 percent here. And I suspect some oncologists would give a trial of therapy even if there was no standing in some areas, depending on the situation. So that's an area that needs resolution, I guess.

MS. NEWBURY:

Q. Sure, okay, I appreciate that. Focusing now on the, I guess, the point in time where Eastern Health decides or someone decides that the protocol would change and now rather than recommending Tamoxifen or a comparable drug when a patient's 30 percent positive, that it would now be ten percent positive. Looking at the point in time do you know if an oncologist typically advised patients of this who might have been, say, diagnosed or tested for ER positivity in the six months before?

DR. WILLIAMS:

A. Yes. As far as I gather, that was not done. The cancer clinic, though, was a separate organization from the Health Care Corporation and Eastern Health at that time.

MS. NEWBURY:

Q. Um-hm.

Page 329

DR. WILLIAMS:
A. The oncologists were credentialed in Health Care Corporation for their inpatient work, but the majority of the work was done on an outpatient basis. I was not made aware that anybody had been contacted when that changed, but you would have to ask the oncologists that.
MS. NEWBURY:
Q. Was that ever an issue discussed -
DR. WILLIAMS:
A. Well -
MS. NEWBURY:
Q. - in responding to ER/PR?
DR. WILLIAMS:
A. I guess it was never an issue discussed, because we didn't need to discuss it, we retested all those patients.
MS. NEWBURY:
Q. Right, okay. But just in terms of dealing, you know, looking at the whole situation, would that not be information -
DR. WILLIAMS:
A. It would be something, I think, if we didn't retest and some people would say that, well,

Page 330

you know, why retest, just go back and if they're, you know, have a certain percentage, just advise them that there's new protocols come into place. But I can't tell you if that was done back in 2000.
MS. NEWBURY:
Q. Right.
DR. WILLIAMS:
A. But because we retested everybody, we didn't need to consider that because the test -
MS. NEWBURY:
Q. You were picking them up anyway?
DR. WILLIAMS:
A. Yes, we were going to pick them up anyway, that's right.
MS. NEWBURY:
Q. Right. But you don't know now to this day whether typically the patients who were tested for ER/PR six months before the change in protocol from 30 to 10 percent, you don't know if the oncologists would advise their patients accordingly -
DR. WILLIAMS:
A. My understanding -
MS. NEWBURY:

Page 331

Q. - and perhaps offer treatment to them?
DR. WILLIAMS:
A. - that hadn't changed, but I stand to be corrected on that. That was my understanding. But again, we didn't need to get into it because we were retesting everybody anyway.
MS. NEWBURY:
Q. Right. Are you aware of any protocols in place for handling that sort of general situation where there's a new best practice -
DR. WILLIAMS:
A. No.
MS. NEWBURY:
Q. - out there?
DR. WILLIAMS:
A. No.
MS. NEWBURY:
Q. Nothing?
DR. WILLIAMS:
A. Not here or in other centres, as far as I know.
MS. NEWBURY:
Q. So it's left to individual physicians to make that decision?
DR. WILLIAMS:

Page 332

A. I think so, I think that may be correct. Again, you'd have to ask others, but that's my understanding.
MS. NEWBURY:
Q. Dr. Williams, you were talking on a couple of occasions about meta-analysis?
DR. WILLIAMS:
A. Yes.
MS. NEWBURY:
Q. And you had requested Dr. Parfrey to see if he could locate any meta-analysis on the benefit of Tamoxifen?
DR. WILLIAMS:
A. Yes.
MS. NEWBURY:
Q. In the ER/PR receptor positive patients with breast cancer. And you had defined, as I understood it, meta-analysis to be a review of all of the literature that's been done on an issue and put together in one document and draws conclusions on all of the studies done. Do you know if meta-analysis has, I guess, a more detailed quantitative calculation of all of these various studies?
DR. WILLIAMS:

Page 333

A. Well, yes, it would, because if you look at any one study or two studies or three studies, you will get a result based on those studies. You might find some studies say one thing. In epidemiology you might find that an association in one study doesn't really exist, and in another study it does exist on the same thing. So this tends to put together, instead of ten studies or of one study, you get the impression of one study, you put together all the studies that have ever been done in this-- good studies that have been done in this area and it gives you a full picture of, in fact, what the issues and what the outcomes are.

MS. NEWBURY:

Q. So it's the aggregate of studies. But do you know if it's done from a statistical perspective -

DR. WILLIAMS:

A. Yeah, it's expected to be better than analysis of any one study, because you might find that 100 studies are done showing in 15 percent that this is the result and then in the other 80 percent or 85 percent that it's this result. You put them all together and you get

Page 334

a--you might reach one conclusion on one set of studies, but when you put everything together, you might reach a different set of conclusions. So scientifically it's supposed to be an advance over what was in place before.

MS. NEWBURY:

Q. Okay.

DR. WILLIAMS:

A. So that's why we asked Dr. Parfrey if he could do it.

MS. NEWBURY:

Q. Sure. Now, I understand the concept of getting together the different studies, but my focus is in on how you pull all of those studies together. Are you aware of whether or not as a statistical or quantitative analysis--and I'll give you an example. If you've got a study that lasted for five years and involved 100,000 patients versus a six-month study of two patients, would you give more weight to one -

DR. WILLIAMS:

A. Yes, you'd give more weight to the study that did 1000 patients. It's quantitative in that

Page 335

sense, yes.

MS. NEWBURY:

Q. Okay.

DR. WILLIAMS:

A. The person really to, person that's most knowledgable in this area would be Dr. Parfrey and he's--he didn't do it when I asked him, but he subsequently has done it.

MS. NEWBURY:

Q. Oh, has he done it in relation to this -

DR. WILLIAMS:

A. Yes. And he's--yes, he's done some work on this whole area and the last time I saw her wrote an article in the paper.

MS. NEWBURY:

Q. Okay. But did he -

DR. WILLIAMS:

A. Some months ago.

MS. NEWBURY:

Q. And it was considered a meta-analysis? Why was it -

DR. WILLIAMS:

A. I expect that's how he did it. You'd have to really ask him to come here and question him on it, how he did it. I asked him to do it

Page 336

because, again, I wanted to see, have an overview of what this all meant.

MS. NEWBURY:

Q. Okay.

DR. WILLIAMS:

A. For what we were doing and how it might affect people overall. I was just trying to get a feel for it.

MS. NEWBURY:

Q. Sure.

DR. WILLIAMS:

A. It didn't affect us going and retesting because we were going to retest and we were going to provide that information to the physician and the physician's patient and then have that best input go into that. But I wanted to see the whole picture.

MS. NEWBURY:

Q. Sure.

DR. WILLIAMS:

A. And so I think he didn't, he couldn't do it at the time because he was busy, and it wasn't germane to--we were going to retest anyway, but I would have liked to see the whole picture. And I think subsequently I think

Page 337

he's done that and so he'd probably be in a good position to provide you with that information.

MS. NEWBURY:

Q. Did you actually ask Dr. Parfrey to do a meta-analysis or were you asking him to see if there was one that already existed.

DR. WILLIAMS:

A. Well, I asked him to see what was out there, basically.

MS. NEWBURY:

Q. Okay.

DR. WILLIAMS:

A. I don't have the -

MS. NEWBURY:

Q. That's what I understood. I can pull up the exhibit if you want to see it, because that was what I understood.

DR. WILLIAMS:

A. Yeah, I sort of asked him if he could help us there, is there a meta-analysis or do you know of something that can help us there and pull this all together. And I don't know if that's been done for that, so the best thing would be to ask Dr. Parfrey.

Page 338

MS. NEWBURY:

Q. Sure, okay. And in terms of looking at the literature out there, is there something, I guess, less sophisticated or less quantitative than a meta-analysis, just a general review of the literature without putting it together in a -

DR. WILLIAMS:

A. I think if we wanted to do something there, there's a meta-analysis done or if he could do a meta-analysis, I mean, he has people that he's training at the master's level in epidemiology.

MS. NEWBURY:

Q. Sure.

DR. WILLIAMS:

A. I've asked him to do things before for me when I was at the Health Care Corporation of St. John's on different issues that had come up. And he used to be able to find a master's level student who always wanted a few extra dollars to try to get through their master's so he'd put them onto the project. So I think he's probably have somebody over there who's doing a master's level in epidemiology who he could assign to that and get that information brought together. And then obviously he'd review it to make sure it was done properly, but.

Page 339

MS. NEWBURY:

Q. But I guess I'm wondering if there's something perhaps less complicated than a meta-analysis -

DR. WILLIAMS:

A. There may be -

MS. NEWBURY:

Q. - just a systematic review of literature without doing weighted studies and -

DR. WILLIAMS:

A. Yeah. There may be, but I'm not aware of it.

MS. NEWBURY:

Q. You're not aware?

DR. WILLIAMS:

A. That's why I asked him.

MS. NEWBURY:

Q. Sure, okay. And are you aware of the term "evidence-based decision making"?

DR. WILLIAMS:

A. Yeah, I'm aware of that.

MS. NEWBURY:

Page 340

Q. Okay. What, can you describe what that means?

DR. WILLIAMS:

A. Well, you're supposed to make a decision for patient care based upon the best evidence that's available. So that's evidence-based decision making. Let me give you an example that everybody can probably understand. And evidence would indicate that most sore throats are caused by viruses, so people don't need an antibiotic, okay. There's some things you can do if you suspect they have strep throat because that's the only kind of a--that's the only person who should get an antibiotic for a sore throat is somebody who had a strep throat. Now, there's a simple test you can do that's called, it's--and you can get the results in 24 hours, so. Evidence-based decision making would indicate that if you think it's a strep throat, you order this test, have the result back in 24 hours and then you treat the patient.

MS. NEWBURY:

Q. Okay.

DR. WILLIAMS:

A. If you don't feel it's a bacteria because

Page 341

there's no exudate on their throat and their tonsils are not swollen, you don't have a fever and headache and all that stuff you get with a sore throat--with a strep throat, then you just treat them on the basis that it's a viral sore throat and you don't treat them at all. But evidence-based decision making is not always in place in our systems and sometimes we find that a lot of people with a sore throat get an antibiotic.

MS. NEWBURY:

Q. Okay.

DR. WILLIAMS:

A. When the majority won't need it. That's what I mean by evidence-based decision.

MS. NEWBURY:

Q. Okay.

DR. WILLIAMS:

A. In its simplest explanation.

MS. NEWBURY:

Q. And would a meta-analysis be a tool used in evidence-based decision making?

DR. WILLIAMS:

A. Yes.

MS. NEWBURY:

Page 342

Q. Okay. And are there any other examples of tools that might be used?

DR. WILLIAMS:

A. Well, studies like that. Study, you might have a study that -

MS. NEWBURY:

Q. Okay.

DR. WILLIAMS:

A. - in itself is so good and the epidemiology is so good and somebody's reviewed it.

MS. NEWBURY:

Q. Sure.

DR. WILLIAMS:

A. So just because it gets published in the literature doesn't mean it's any good, okay. That's what we want to make sure.

MS. NEWBURY:

Q. Okay. And -

DR. WILLIAMS:

A. The good, good journals like the New England Journal have junk published in them sometimes.

MS. NEWBURY:

Q. Okay. Does Eastern Health incorporate evidence-based decision making in its decisions?

Page 343

DR. WILLIAMS:

A. We've had some clinical practice guidelines developed over time and some of the clinical chiefs try to do that. Like, you know, x-rays for people who have sinusitis, Dr. Collingwood did some work there. Some work on the use of x-rays in neck problems and things like that. I'd have to go back and look, but there are examples that our clinical chiefs introduced to our organization that we try to propagate throughout the organization, but you have to work at it. And there's books written on evidence-based decision making and how to impact clinical decision making based on evidence. There's books written on it.

MS. NEWBURY:

Q. Sure.

DR. WILLIAMS:

A. And it's very difficult to change old habits.

MS. NEWBURY:

Q. Right.

DR. WILLIAMS:

A. And that's why I think you really have to work at some of these people when they're in medical school.

Page 344

MS. NEWBURY:

Q. Okay. And aside from in a clinical setting are there other types of areas that Eastern Health would incorporate evidence, or evidence-based decision making, for example, policy decisions on resource allocation?

DR. WILLIAMS:

A. There was some work done on that, yes.

MS. NEWBURY:

Q. Okay.

DR. WILLIAMS:

A. Sometime over the past number of years we had some work done on that and it went to the ethics committee, I think, in the last year or two when I was there, and Dr. Pullman was involved in that. There should be a document on that somewhere, if you want to see it. I don't know where it is. But it is in there. It proved quite difficult to try to get a handle on it.

MS. NEWBURY:

Q. Um-hm.

DR. WILLIAMS:

A. But there was a document. I remember going to a meeting or so or a series of meetings. And

Page 345

you'd have to ask Ms. Jones or something to produce that document, but there was something done on, you know, how do you allocate resources among competing demands in a health care system. So you might have a demand over here with good strong, you know, support and a demand over here with good strong report. This requires 50,000, this requires 50,000, you only have 50,000, what do you do, that kind of stuff.

MS. NEWBURY:

Q. And would efficacy of whatever it is you're looking at also be an issue?

DR. WILLIAMS:

A. Yes, that would be all factors. Somebody would have to make the case. So that was done for just in the end of the Health Care Corporation or early Eastern Health. Louise Jones would have probably been involved in that. I remember we went to a couple of meetings to--with the ethicists there to try to get a handle on what factors should we consider.

MS. NEWBURY:

Q. Are you aware if evidence-based decision

Page 346

making was ever applied in the context of the laboratory medicine program?

DR. WILLIAMS:

A. No, I can't remember in terms--what happens in the laboratory medicine program is they happen to be there, they're a service provider and everybody out there, the GPs and physicians in our organization request tests. They might be a cholesterol test or this type of thing. But it's hard for people in the lab to know if that test is justified on that patient. You'd have to get the patient's history and go into it and this type of--the lab is really just in a situation where they're responding to things, requests from people who are licensed to ask for those things to be done.

MS. NEWBURY:

Q. So more the oncologists, perhaps, that would have to make those decisions?

DR. WILLIAMS:

A. No, I think all physicians make decisions and the laboratory just is a responder, they provide a service. Just like the diagnostic imaging is a provider. X-rays are ordered by physicians and it's probably in some of the

Page 347

things if they're a little bit outrageous, based upon the history they get on the requisition for an x-ray, maybe occasionally a radiologist might ask some questions before they do the procedure.

MS. NEWBURY:

Q. Um-hm.

DR. WILLIAMS:

A. But we get thousands and thousands and thousands per day of individual tests and individual patients. It's very difficult. We tried it one time to get a utilization officer into the laboratory to see if we impact on that, but we didn't have the resources. It would mean laying off somebody on the front lines. The lab is, requests are going up in the lab about six percent a year because new tests are coming on and this type of thing, and that's, they're a provider that they just can't respond.

MS. NEWBURY:

Q. And how about the oncologists, would there be any role for evidence-based decision making in that group?

DR. WILLIAMS:

Page 348

A. Yes, there would be. There would be a lot of articles on oncology in the literature -

MS. NEWBURY:

Q. And is it done collectively or individually by physicians?

DR. WILLIAMS:

A. I think the physicians would look at the latest literature, would read the latest literature. And sometimes documents are published that they would look at, published literature. And maybe a meta-analysis is every now and then published about a major event, too, but I think most of the oncologists would look at what's propagated in the literature. Some of the oncologists, not all our physicians, some of our physicians have training in clinical epidemiology at a master's level that we provide in the organization, so some of them would be able to read the literature with a jaundiced eye, which is what it needs to be read with. But a lot of our physicians would not.

MS. NEWBURY:

Q. So would the oncologists, aside from having evidence-based decision making taken into

Page 349

account for clinical decisions, how about the policy, broader policy decisions?

DR. WILLIAMS:

A. In what sense?

MS. NEWBURY:

Q. Are they involved in that at all, you know, resource allocation or -

DR. WILLIAMS:

A. Oh, sure, they--one of the issues I had to deal with when Ms. Paulse left and before Eastern Health came--well, when Eastern Health came together, but before they really came together, Mr. Tilley asked me to take over as CEO of the Cancer Foundation, so one of--Cancer Foundation. So one of the things we were--they were dealing with there is issues relating to resources for colon cancer.

MS. NEWBURY:

Q. Um-hm.

DR. WILLIAMS:

A. And some new evidence had come out that certain drugs offered an advantage over the previous drugs, and then we had do battle to get some resources in the budget to enable us to implement those new regimes. So that's the

Page 350

kind of things they'd be dealing with on a day-to-day basis. So that affects--that's a clinical issue that affects policy.

MS. NEWBURY:

Q. And in terms of your request to Dr. Parfrey, you were looking to see if there are any existing studies, meta-analysis of the benefit of Tamoxifen. Is that something that Eastern Health or its predecessor, the Health Care Corporation would have looked at before introducing that drug?

DR. WILLIAMS:

A. No. No, I don't think that -

MS. NEWBURY:

Q. You don't expect that that -

DR. WILLIAMS:

A. - that level of detail, no. I'm pretty sure every time a drug comes on, they don't do that.

MS. NEWBURY:

Q. Okay.

DR. WILLIAMS:

A. They'd be doing a lot of it if they did, but they rely on, I guess, published articles and what the consensus is and the generally

Page 351

accepted approach to it is.

MS. NEWBURY:

Q. Right.

DR. WILLIAMS:

A. That's my understanding.

MS. NEWBURY:

Q. So not as detailed or intricate as a meta-analysis but -

DR. WILLIAMS:

A. No. Correct.

MS. NEWBURY:

Q. - you would think that they would do some sort of literature review?

DR. WILLIAMS:

A. Yes, the physicians would review the literature and be current. They might go to a conference and there might be a guest speaker come and speak at that conference on some new developments in there, so they would get it from reviewing the literature or going off to conferences and bringing back that information back to the organization.

MS. NEWBURY:

Q. So those are all, I guess, clinical decisions made on evidence that's available, the best

Page 352

evidence that's available.

DR. WILLIAMS:

A. Yes.

MS. NEWBURY:

Q. But there's no sort of separate, well, we'll look at the policy of it for the organization, in terms of resource allocation, as an example, and I'm not sure what the implications are. I know it was an issue for Herceptin, but I don't know if it was as much of an issue with regard to Tamoxifen, in terms of the cost -

DR. WILLIAMS:

A. No, then Tamoxifen came in, I think that--I can't remember because again, the cancer clinic was separate from the Health Care Corporation of St. John's and those patients would be getting that on an out-patient basis, so it wouldn't be a relative issue that we would have dealt with in the Health Care Corporation at the time.

MS. NEWBURY:

Q. Okay, and in terms of responding to a crisis or a major adverse event or a series of adverse events, do you think there would be a

Page 353

role for evidence based decision-making in so responding?

DR. WILLIAMS:

A. Yes, if you got the time to go and search it out. We already made the decision to retest, I just wanted to see when I asked Dr. Parfrey after we made the decision, what's the evidence here and -

MS. NEWBURY:

Q. Sure.

DR. WILLIAMS:

A. - what the implications are.

MS. NEWBURY:

Q. What about other types of decisions that you're making, for example communication with patients, disclosure with patients? Would there be a role for looking out there to see what's the literature on best available practices, what's the best evidence on that?

DR. WILLIAMS:

A. You know, I think now we'll see a lot more literature on that.

MS. NEWBURY:

Q. Okay, how about a decision whether or not to retest ER positive patients? Would you think

Page 354

there's a role for evidence based decision-making on that, going out to find if there is literature, best practices -

DR. WILLIAMS:

A. As far as I know, positives, there's very little in the literature. There's a lot of literature about negatives and problems there. I haven't seen any in the literature about positives and the problem with the positives, that's what--I haven't seen, it's not been brought to my attention.

MS. NEWBURY:

Q. Well I guess the question is did anyone look for that? Was anyone looking for the best available evidence on the issue of ER positive issues?

DR. WILLIAMS:

A. Well yes, we had a lot of information on the ER and PR testing and the only thing that was in that literature which was, I suspect balance literature, was the problem with negatives being missed.

MS. NEWBURY:

Q. Okay.

DR. WILLIAMS:

Page 355

A. I don't remember anything in the literature that related to positives being a problem.

MS. NEWBURY:

Q. So you understand that your search or the search that was conducted by people at Eastern Health was broad enough to have picked up any issues about ER positive patients?

DR. WILLIAMS:

A. I think if you're talking about ER and PR testing, they would have picked up that there was a problem with the positives and a problem with negatives, most of the problem--all of them were talking about the negatives.

MS. NEWBURY:

Q. I'd like to refer to exhibit P-0503 please? These are meeting notes.

DR. WILLIAMS:

A. Yes.

MS. NEWBURY:

Q. You were one of the individuals in attendance along with Ms. Predham, Dr. Cook and Mr. Gulliver and item No. 4, one of the issues discussed was to assess current testing standards, cross referencing with another laboratory, it only speaks of one laboratory

Page 356

there, is that your recollection of what would have been discussed at that meeting?

DR. WILLIAMS:

A. No, I think what was subsequently done, Dr. Cook did some cross referencing with the Montreal Jewish Hospital and I guess retesting, all the retesting we did with Mount Sinai, you could consider that too, probably some cross referencing, but he did have some discussions with the Montreal Jewish and he did have some discussions with Dr. O'Brien in New Brunswick, Dr. Dogan down in the Mayo Clinic at some stage along the way.

MS. NEWBURY:

Q. Was there a more comprehensive analysis, a review of testing standards, for example, all across Canada?

DR. WILLIAMS:

A. Yes, there was a survey carried out, quality carried it out and that should be in your package. It didn't give us a lot of, what I call information that was, you know, we could really use.

MS. NEWBURY:

Q. Did that relate to rates of positivity, as

Page 357

opposed to actual standards for testing?
DR. WILLIAMS:
A. Yeah, if they had any problems and what's your rate of positivity and do you track that thing, this kind of thing, these are the kind of questions and they're all there. The referencing would have been Dr. Cook talking to Montreal Jewish and our ongoing efforts, I guess, with the Mount Sinai people.
MS. NEWBURY:
Q. But there was no analysis of labs throughout the country as to how they do their testing, what their testing standards are to identify, for example, whether other labs use internal controls or not?
DR. WILLIAMS:
A. Not to that level of detail, I don't know what's in--I'd have to refresh my memory about what was in that document, but it would have told us what kind of systems they used at the time, I'm pretty sure.
MS. NEWBURY:
Q. Whether it was DAKO or Ventana -
DR. WILLIAMS:
A. Yes.

Page 358

MS. NEWBURY:
Q. But not the testing, not all the detail that Dr. Banerjee and Ms. Wegrynowski detailed in their various reports.
DR. WILLIAMS:
A. No. And, of course, Dr. Cook did follow up with those organizations at the time and then Dr. Banerjee when he came in and debriefed us, he would have talked about his knowledge of what was going on. And then we had Dr. Gown come in, of course, who would be recognized as an expert.
MS. NEWBURY:
Q. But in addition to having these external reviewers come in, do you think it would have been helpful for Eastern Health to look for the best available evidence across the country as to the current testing standards so that they could make decisions about quality of care and also communication with patients and the public?
DR. WILLIAMS:
A. I don't think that was, communication with the patient and public wouldn't have been an issue and Dr. Cook had some discussions, we were

Page 359

dealing with Mount Sinai, which was the gold standard as we understood it, and Dr. Banerjee, so I think we would have known, you know, we didn't know that certain things were possible with a lot of detail going into the testing and analysis.
MS. NEWBURY:
Q. It was Mr. Tilley's evidence, as I understand it, that part of the reluctance or reservations that he had about identifying a cause of the ER/PR problems was distinguishing between what's inherent in Eastern Health itself verses what are problems inherent in ER/PR testing generally and whether or not everyone or a lot of other labs across Canada are experiencing the same types of problems. And I'm just wondering in terms of communication with patients, shouldn't Eastern Health have taken steps to identify that so they can relay the best information available to their patients?
DR. WILLIAMS:
A. Well, I think this issue--you mean the other labs, we should tell the other people across the other -

Page 360

MS. NEWBURY:
Q. No, no, whether you should do an analysis or survey to find out what are the testing standards across the country to find out whether this is a problem inherent in Eastern Health or whether it's part of a larger national problem or some combination, so that patients can then be informed.
DR. WILLIAMS:
A. Well we know from what work has been done in Great Britain and some conversations that we had with Dr. Banerjee that--and literature coming out of the U.S., although there is not much literature in Canada, that there are problems with this testing and that other countries have seen fit to introduce some external quality and proficiency into their country so that labs doing this test had to meet certain standards. That issue was called for in the U.S. in some of the literature, but had not--there's nothing put in place as far as I know yet, so we knew that these were issues that had been in other countries, had been in the U.S., nothing had been published in Canada. There was no central quality

Page 361

assurance for this, so we would have assumed that there's a potential there, we would have--by phoning around we wanted to find out if other people had experienced some issues, and Dr. O'Brien said that they had some issues in New Brunswick. The other ones that reported back said they weren't monitoring, but they didn't know of any issues at the time.

MS. NEWBURY:

Q. But not so much to find out if other people are having problems because some people might be having it and haven't identified it, but to find out what are your testing standards? How do you do these tests or how have you been doing these tests the past number of years? Would that be information that could be of some benefit to Eastern Health to perhaps find out why did another lab, using the DAKO system, why were they able to do this successfully and maybe that could be informative for Eastern Health in a broader sense about IHC testing in general.

DR. WILLIAMS:

A. Well, I think you'd look at Mount Sinai as sort of a reference lab like you had in Great

Page 362

Britain and they were the gold standard and they had expertise and they were, I guess, dealing with this in a detailed manner and had things in place. But I don't recollect, you know, other labs saying that--getting into that level of detail. We knew we had a problem at this time and what we wanted to do was get somebody in and identify the problem and fix it for us--or help us fix it.

MS. NEWBURY:

Q. Sure.

DR. WILLIAMS:

A. That's what our focus was at the time.

MS. NEWBURY:

Q. I can appreciate that was a priority, but I'm wondering -

DR. WILLIAMS:

A. And then the other focus was getting everything together as quickly as we could and get the retesting.

MS. NEWBURY:

Q. I appreciate that, but I'm just wondering on looking back whether it might have been useful for Eastern Health to delve into it a little bit further and perhaps that would be

Page 363

information useful to Eastern Health to ascertain why it took a major event such as this to put the proper procedures in place and whether other labs were able to put the proper procedures in place without needing a large adverse event?

DR. WILLIAMS:

A. Uh-hm. I guess when we contacted them, we didn't get any information to that effect. We put out something, went out nationally that there was a problem here and I guess that would give them a chance to go back and see if they had a problem themselves, but we didn't get any feedback from--I think there was one call came from one lab asking a little bit about it.

MS. NEWBURY:

Q. Thank you, those are all the questions I have.

THE COMMISSIONER:

Q. Thank you. Ms. Taylor?

DR. ROBERT WILLIAMS, EXAMINATION BY MS. PAMELA TAYLOR

MS. TAYLOR:

Q. Commissioner, I don't think that I would finish this afternoon, however Ms. Newbury has covered a lot of the territory that I would

Page 364

want to cover. Perhaps if I could continue with Dr. Williams to about 4:45 break, I will review my questions and then finish off in the morning?

THE COMMISSIONER:

Q. All right.

MS. TAYLOR:

Q. Good afternoon, Dr. Williams.

DR. WILLIAMS:

A. Good afternoon.

MS. TAYLOR:

Q. My name is Pam Taylor; I'm here on behalf of the breast cancer testing class action group. I'm going to ask you a couple of preliminary questions on the disclosure aspect of things. Now, you've answered a number of questions on that and I just want to be clear on a couple of points. Your view on disclosure when this issue first arose, what I took from your evidence was that you were in favour of public disclosure, that personal contact with patients would be the way to go. I think that there was some issue between personal contact in the form of a phone call verses a letter, those sorts of things, but then we have

Page 365

discussions with the oncologist where that influenced the thinking on disclosure. And I understand that with the oncologists and particularly Dr. Laing putting forth the position on behalf of some other oncologists, that to contact patients when the results weren't back and not having something to tell them might unnecessarily panic them. The other issue on disclosure was there was some information that was provided in terms of public disclosure that legal counsel and risk management were advising against disclosure at some point early on, particularly before the impacted patients have had the opportunity to hear about this from us, "us" being Eastern Health. So those were some of the dynamics entering into the issue of disclosure verses do we disclose now or do we wait, is that correct?

DR. WILLIAMS:

A. Uh-hm.

MS. TAYLOR:

Q. Now, around that time, going back to the August meeting with the oncologists, you would have known at that time that some people had

Page 366

been informed.

DR. WILLIAMS:

A. Yes.

MS. TAYLOR:

Q. And I think that I saw a reference to approximately ten people having been informed -

DR. WILLIAMS:

A. Yes.

MS. TAYLOR:

Q. At the time of that meeting with the oncologists in August.

DR. WILLIAMS:

A. Uh-hm.

MS. TAYLOR:

Q. So they already knew that there had been a problem with the testing and that they had test results which had changed. They had been informed of that.

DR. WILLIAMS:

A. Uh-hm.

MS. TAYLOR:

Q. At the time in terms of trying to think about well what's going to happen, there's information already out there to at least a

Page 367

certain group of individuals that, you know, they're aware that there has been a problem in Eastern Health, they're aware of difficulties, what was the sense in terms of--what was your thoughts on if we wait, what if this gets out there publicly before we have a chance to tell patients, wouldn't they be negatively impacted or stressed by that?

DR. WILLIAMS:

A. I think that's probably and I can't remember some of the issues we discussed because I just didn't have any notes on them and I can't remember what I might have said at some of the meetings, but I understand I was, from some people, laying out some of the pros and cons of this, so whether that was an issue we discussed, I'm not sure.

MS. TAYLOR:

Q. Right.

DR. WILLIAMS:

A. But obviously we knew and the results came back, we're not going to not tell people because we had an obligation to tell people and their physicians as soon as possible to get on with whatever, anything else that

Page 368

needed to be done. So I'm sure maybe that was something we discussed, but I can't remember in detail the thoughts around that, but basically my feeling initially was the only way we could get to individuals was by something public because we didn't know who those individuals were. It's not that we go public for the sake of going public, it's the sense of going public because we need to try to inform individuals, we're not going to know who they are at the time.

MS. TAYLOR:

Q. And in terms of when it did go public, the October 2005 news article, Mr. Coffey was asking you some questions about whether or not there had been any actual concrete planning done as to how disclosure was going to be handled when the first wave of results came back and there's a meeting in early October where you sit down with other individuals to talk about that.

DR. WILLIAMS:

A. Uh-hm.

MS. TAYLOR:

Q. You had indicated that although there were a

Page 369

lot of draft things that had been done, there wasn't really--that that meeting was about sitting down at that time looking at, okay, when we get the test results back, see what they are, then we do a strategy about going public. So at that point there wasn't a plan in place?

DR. WILLIAMS:

A. I think we felt that when the reports were coming back, we would have a little bit of time, we'd see what they were, it takes awhile to get them into--and you'd have a few days or maybe a week to develop a strategy. I think that's what happened, but my notes don't--I'm not clear on that.

MS. TAYLOR:

Q. Right. But at the same time the clock is ticking -

DR. WILLIAMS:

A. Yes, I understand.

MS. TAYLOR:

Q. That people know and that information could get out there, so there was no separate group that was working on having a hard and fast strategy in place in terms of disclosure and

Page 370

how we deal with this issue and exactly what we're going to say if things come out -

DR. WILLIAMS:

A. There were documents developed and things like that, but we needed to then sit down and say now, which way are we going to go? I think that's what the thinking was.

MS. TAYLOR:

Q. Right. And I think in terms of a spokesperson while Dr. Laing, I think, was put forth for an interview around that time, and there had been some discussions about whom might be a spokesperson, that it doesn't seem like that had been completely decided, that in fact she would be the spokesperson, that this has already been identified because you had to find her, actually, in another province?

DR. WILLIAMS:

A. Yes, when this happened, she was in another province, when this story broke, so we had to respond immediately. She was contactable by phone on a regular basis, so we reached her and talked about it, early on we thought we'd have somebody speak from the clinical perspective, rather than from the laboratory

Page 371

perspective, the laboratory perspective would come later.

MS. TAYLOR:

Q. Right, but from the point of time when people are first notified, when that smaller group of people become aware that there's a problem with their test results, at that point there is some information that's out there to some members of the public -

DR. WILLIAMS:

A. Uh-hm.

MS. TAYLOR:

Q. So wouldn't, from that point until October when the story actually comes out, each day it could have come out.

DR. WILLIAMS:

A. Yes.

MS. TAYLOR:

Q. So time is of the essence in making sure that you have your plan in place as to how you would respond to queries from people, concerns, the media, patients, so that wasn't being worked on at that point?

DR. WILLIAMS:

A. I think it was being worked on but we needed

Page 372

to come together then and see what we had done and spend some time, depending on what was coming back, how we would deal with it.

MS. TAYLOR:

Q. Would you say that the approach at that time, looking back on it now, that it was maybe more of a reactionary approach, rather than proactive?

DR. WILLIAMS:

A. When we look back on things, obviously we learn from what you've done and what the outcomes are, so you hopefully learn something and the next time around you might do it differently, this type of thing. So that's--sometimes you do something and new information becomes available, what you've done, I guess you try to learn from that and you would take a different approach the next time.

MS. TAYLOR:

Q. And in terms of the contact that was when it was finally decided that contact would be made by phone with patients, wasn't one of the factors that weighed heavily in that, wasn't it the fact that a person had come forward, you dealt with an individual, I believe it

Page 373

came forward through an e-mail from Ross Reid, I believe. You met with the individual along with Pat Pilgrim -

DR. WILLIAMS:

A. Uh-hm, yes.

MS. TAYLOR:

Q. And you had provided evidence that, you know, she made a number of good points about why people should know -

DR. WILLIAMS:

A. Yes, sure.

MS. TAYLOR:

Q. And that you thought that probably factored heavily into making sure we got the information out to people and we decided to do it by phone. So again, at that point someone has come forward, then it's decided we'll contact everybody by phone, but wasn't it being thought of--it wasn't being thought of before then that we need to do this?

DR. WILLIAMS:

A. Yes, it was being thought of before then that we need to do that, the comments that that person made would have some impact on the ultimate decision. I know I favoured

Page 374

personally the individual contact by phone.

MS. TAYLOR:

Q. Right.

DR. WILLIAMS:

A. That was my own personal view and some other people, obviously, would have supported that.

MS. TAYLOR:

Q. And when you were talking about your own personal view on that, the individual contact, that you had said that that was your own thoughts and you didn't have any expertise in communications in terms of mass communications, was there anybody on staff who would have had any sort of expertise from a disclosure point of view on mass communications?

DR. WILLIAMS:

A. I guess our communications people would have.

MS. TAYLOR:

Q. And mass communications in the sense of disclosure of an adverse event of this size?

DR. WILLIAMS:

A. I'm not sure if anybody, to the extent that we had, would have had a lot of experience with that.

Page 375

MS. TAYLOR:

Q. Right. Was any inquiry made in that regard, do you know?

DR. WILLIAMS:

A. No, I don't know.

MS. TAYLOR:

Q. It wasn't a thought that had come to your mind in terms of do we have somebody who may have dealt with an issue like this before?

DR. WILLIAMS:

A. No, we have communications people there, we'd seen what happened in Labrador when they dealt with it and some of the issues that were there, but -

MS. TAYLOR:

Q. Was there any other--well Labrador was looked at, was there any other organizations or any other advice sought from outside sources on how something of a similar nature may have been dealt with previously, in terms of disclosure?

DR. WILLIAMS:

A. Not to my knowledge, I hadn't seen any and I don't know if our communications people might have contacted somebody in their line of work,

Page 376

but I don't--I'm not aware of it.

MS. TAYLOR:

Q. And it wasn't something that you considered at that time or thought that maybe this would be something that might be helpful?

DR. WILLIAMS:

A. Well again, there's so much going on and with this, it's a lot of things that I, you know, it just didn't come out.

MS. TAYLOR:

Q. Now if we could turn to P-0067? Now, Dr. Williams, this is the memo from Dr. Cook to you, dated May 24th, '05.

DR. WILLIAMS:

A. Uh-hm.

MS. TAYLOR:

Q. We've talked about this a bit already. Now you answered previously that in your previous background you would have had very little knowledge, certainly from a clinical perspective of ER/PR testing prior to becoming aware of this issue in 2005, is that correct?

DR. WILLIAMS:

A. Yes.

MS. TAYLOR:

Page 377

Q. Okay, and I think that you had also testified that you didn't know about the lab closure that had occurred prior to seeing it in this letter, when Dr. Ejeckam had shut down the lab testing on this issue back in 2003?
MR. WILLIAMS:
A. There was some reference in 2003 correspondence, but I don't remember having focused in or been alerted to that in my own mind. I wasn't told at the time.
MS. TAYLOR:
Q. This was the first time that you would have been focused in on it?
MR. WILLIAMS:
A. Yes.
MS. TAYLOR:
Q. Is that correct?
MR. WILLIAMS:
A. Yes.
MS. TAYLOR:
Q. Okay. Now, Dr. Cook provides a brief explanation as to how the receptor status may influence treatment. I'm just going to find that, the top paragraph there on page two, and according to this, "those patients that are

Page 378

ER/PR negative will be given chemotherapy with its side effects much earlier in the course of treatment. It's possible that the patient who is ER and PR positive and responds favourably to hormone manipulation may not require the full chemotherapeutic regime." And the first sentence, that "receptor status influences at what stage chemotherapy will be given to a patient." Now at this point, at least, you would have been aware that if there's problems with the test and therefore some of the test results there could be cancer patients that may have either missed out on treatment, i.e. the hormone manipulation and/or received incorrect or possibly unnecessary treatment. Is that correct?
MR. WILLIAMS:
A. Yes, we would have.
MS. TAYLOR:
Q. Okay. Now in the third paragraph on that page, when he's talking about one system, the DAKO system, being replaced by the new Ventana system, in the last paragraph he's saying "it is my understanding that all previously reported ER negative patients under the old

Page 379

manual technique had positive controls."
MR. WILLIAMS:
A. Yes.
MS. TAYLOR:
Q. Okay, but then in the next paragraph, towards the end of the paragraph, he--first of all, he's talking a bit about immunoperoxidase staining and gives a bit more of an explanation of it, but then he says that "there are potential pitfalls to immunoperoxidase stains. Many of these pitfalls can be avoided by scrupulous quality control, periodic checking of antibody activity and proper use of negative and positive controls."
Now when you read that, did that--did your mind twig to any difference there that "wait now, it's saying under the old method -
MR. WILLIAMS:
A. No, it didn't twig to anything different there. I saw controls as controls and didn't twig. You know, we're talking -
MS. TAYLOR:
Q. A difference between use of positive and negative versus the positive.

Page 380

MR. WILLIAMS:
A. Yeah, you know, we're talking about it now in retrospect obviously, but it didn't twig anything in my mind at the time.
MS. TAYLOR:
Q. So it wasn't a difference that you questioned or you would have asked Dr. Cook about at that time?
MR. WILLIAMS:
A. No.
MS. TAYLOR:
Q. Okay. Now in terms of the recommendations themselves there on the last page, the first recommendation, the immediate establishment of external proficiency testing and monitoring program for immunoperoxidase testing, you had said that you thought that this was already in place, in terms of proficiency testing. You would have thought -
MR. WILLIAMS:
A. I thought we had proficiency testing throughout our organization, yes.
MS. TAYLOR:
Q. Right, and in the lab and in this portion of the lab, you would have thought that there

Page 381

would have been proficiency testing?
MR. WILLIAMS:
A. I understood that we had proficiency testing throughout our organization in the lab.
MS. TAYLOR:
Q. Is that an assumption that you are making or had somebody told you that previously?
MR. WILLIAMS:
A. Oh, I'd been told that before, not with respect to immunohistochemistry, but just in a general sense.
MS. TAYLOR:
Q. A general sense?
MR. WILLIAMS:
A. Yes.
MS. TAYLOR:
Q. So whether or not it was specific to that -
MR. WILLIAMS:
A. No, it wouldn't -
MS. TAYLOR:
Q. - that certainly was your understanding?
MR. WILLIAMS:
A. That wouldn't have come up, in terms of the specific issue.
MS. TAYLOR:

Page 382

Q. Now you said when you asked Dr. Cook about it, that he described it as an island in the sea?
MR. WILLIAMS:
A. Yes.
MS. TAYLOR:
Q. Can you explain that reference for me?
MR. WILLIAMS:
A. That all around we had proficiency testing and this area, there was not any.
MS. TAYLOR:
Q. And in terms of with Dr. Ejeckam and the--I understand that you asked Dr. Cook to look into the issue of why there was a stoppage in the lab.
MR. WILLIAMS:
A. Yes.
MS. TAYLOR:
Q. Did you ask for any sort of written report?
MR. WILLIAMS:
A. No, I asked him to look at it. He didn't give me a written report, and that's one report he's given me, and other correspondence, but no, I didn't ask for a written report at the time.
MS. TAYLOR:

Page 383

Q. What would be your normal practice in terms of when you're asking somebody to look into a particular issue?
MR. WILLIAMS:
A. I would ask him to look into it and brief me on what his findings were.
MS. TAYLOR:
Q. And you would take an oral briefing over a written report?
MR. WILLIAMS:
A. I would take a--I took an oral briefing in this case, yes.
MS. TAYLOR:
Q. Okay. Madame Commissioner, I'm going to get into comparing some of this to another document, so perhaps that would be a good place to break at this time.
THE COMMISSIONER:
Q. All right. 9:30 in the morning. Thank you.

Page 384

CERTIFICATE

I, Judy Moss, hereby certify that the foregoing is a true and correct transcript in the matter of the Commission of Inquiry on Hormone Receptor Testing, heard on the 20th day of May, A.D., 2008 before the Honourable Justice Margaret A. Cameron, Commissioner, at the Commission of Inquiry, St. John's, Newfoundland and Labrador and was transcribed by me to the best of my ability by means of a sound apparatus.
Dated at St. John's, Newfoundland and Labrador this 20th day of May, A.D., 2008
Judy Moss

-Q-

-T-