COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

September 29, 2008

Appearances:

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

Rolf Pritchard/Jackie Brazil . . . . Her Majesty in Right of NL

Peter Browne/Jane Hennebury . . . . . Doctors Kara Laing et al

Daniel Simmons . . . . . Eastern Regional Integrated
. . . . . Health Authority

Laura Brocklehurst. . . . . Members of the Breast Cancer
. . . . . Testing Class Action

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

LIST OF EXHIBITS

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THE COMMISSIONER:
Q. Mr. Coffey.
COFFEY, Q.C.:
Q. Thank you, Commissioner. The next witness is Dr. Alan Kwan.
DR. ALAN KWAN (SWORN) EXAMINATION BY BERNARD COFFEY, Q.C.
REGISTRAR:
Q. Would you please spell your full name, state and spell your first name?
DR. KWAN:
A. Alan Kwan, A-L-A-N, K-W-A-N.
COFFEY, Q.C.:
Q. Dr. Kwan, could you please--actually, while I'm at it, Commissioner, ask that an exhibit be entered, a couple of exhibits be entered first. They're Exhibits P-3085 and C-0266, that's C-0266 and C-0267.
THE COMMISSIONER:
Q. Entered.
EXHIBIT ENTERED AND MARKED P-3085.
EXHIBIT ENTERED AND MARKED C-0266.
EXHIBIT ENTERED AND MARKED C-0267.
COFFEY, Q.C.:
Q. Thank you, Commissioner. Dr. Kwan, could you please provide an overview of your educational

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background and professional background to the Commissioner?

DR. KWAN:

A. Professionally I'm a surgeon. And I guess I graduated from McGill Medical School. I did my surgical residency -

COFFEY, Q.C.:

Q. When would that have been, Doctor?

DR. KWAN:

A. That would have been 1968 when I graduated.

THE COMMISSIONER:

Q. It was a good year.

COFFEY, Q.C.:

Q. Somebody else obviously graduated the same year.

DR. KWAN:

A. And I did my surgical training from 1968 to 1973 at the Montreal General Hospital at McGill system. Having finished in '73 I did a surgical oncology fellowship at the Sloan-Kettering Memorial Hospital in New York City, I completed in 1975. And ever since 1975 to today I've be here in this Province of Newfoundland.

COFFEY, Q.C.:

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Q. And, Doctor, in Newfoundland where have you worked?

DR. KWAN:

A. I started work with the old General Hospital back on Forest Road and we moved up to the Health Science Complex as it now stands and been here ever since. And since 1972 I also work out of St. Clare's Hospital.

COFFEY, Q.C.:

Q. I'm sorry, since?

DR. KWAN:

A. Since 1972, '73. I'm sorry, '92.

COFFEY, Q.C.:

Q. '92 or '93?

DR. KWAN:

A. '92, yes.

COFFEY, Q.C.:

Q. So you were at the General from about--well, you've been at the General from '75 to this day?

DR. KWAN:

A. Correct.

COFFEY, Q.C.:

Q. And beginning in 1992, '93 you started to also do surgery at St. Clare's?

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DR. KWAN:

A. Correct.

COFFEY, Q.C.:

Q. Doctor, I appreciate you're a surgeon. Do you also hold any position at Memorial University's medical school?

DR. KWAN:

A. I was appointed assistant professor and over the years now I'm a full professor of surgery at Memorial University.

COFFEY, Q.C.:

Q. And, Doctor, within the, well it would have been at one point the General Hospital as a stand alone institution, did you hold any administrative positions within surgery?

DR. KWAN:

A. I was the divisional chief in general surgery. I can't remember exactly when I started, it was probably '95 or it was '93, until recently, two years ago.

COFFEY, Q.C.:

Q. Okay, so that would be '93 would be the old General Hospital, '95, around that time, '95, '96 with the Health Care Corporation of St. John's. And up until then 2006 -

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DR. KWAN:

A. Yes, I was -

COFFEY, Q.C.:

Q. - because it became Eastern Health, I'm sorry, you were what, you were?

DR. KWAN:

A. I was the divisional chief of general surgery at the Health Science, not at St. Clare's. Those days it's still two divisions.

COFFEY, Q.C.:

Q. And what does that mean in practice, Doctor?

DR. KWAN:

A. That means I just have the responsible for the operation of the division of general surgery.

COFFEY, Q.C.:

Q. Now, Doctor, you've told the Commissioner that having completed your residency in Montreal you went to Sloan Kettering for a period of time doing surgical?

DR. KWAN:

A. Oncology.

COFFEY, Q.C.:

Q. Oncology?

DR. KWAN:

A. Yes.

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COFFEY, Q.C.:
Q. Could you tell the Commissioner, please, what that involved?
DR. KWAN:
A. That was a subspecialty in surgery related to cancer surgery that I was trained in differ aspects of cancer surgeries related to-- surgery related to cancer. It was within the confines of general surgery. That means I don't do neurosurgery or urology or of that nature.
COFFEY, Q.C.:
Q. And when you came to Newfoundland in the mid 1970s, you've been here for over 30 years now, what types--are there any particular type of surgery that your practice is focused on?
DR. KWAN:
A. I do most--I do oncology.
COFFEY, Q.C.:
Q. Oncology.
DR. KWAN:
A. And at the same time I have to do general surgery because there isn't--you know, that's part and part of my training. I do call for trauma surgeries.

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COFFEY, Q.C.:
Q. But in the main it is surgery related to oncology or cancer?
DR. KWAN:
A. That's correct.
COFFEY, Q.C.:
Q. Doctor, you'd be aware, of course, that this Inquiry is focused on breast cancer, in particular, ER and PR. Doctor, when you first started as a surgeon in Newfoundland in the mid '70s, could you tell the Commissioner then, kind of take us up through time as to what, if any, involvement as a surgeon you would have had in the ER/PR and how was that reported to you at the time, was it reported to you, first of all, in the mid '70s, into the '80s, how was it reported and what, if anything, did it have to do with your treatment of the patients?
DR. KWAN:
A. Well, I think you have to go back to the '70s when -
COFFEY, Q.C.:
Q. '70s, that's what I'm -
DR. KWAN:

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A. When estrogen and progesterone receptors was really basically research tools and a lot of clinical trials, I used them basically on that. And when I first came up here from Sloan-Kettering, within the first two years I started recognizing that is progressively important and I started doing estrogen receptor in my own research lab. And those days that is a pure research tool. I had graduate students who we send down to Toronto for training, do the techniques and we do those as a research tools. After several years of doing this as a research tools I passed this responsibility to, at that time, the General Hospital to continue to do that either in the research lab or in the biochemical lab. I think there is a small gap in between. They were done in one of the research labs and then it was filed along to the chemistry lab, I think.
COFFEY, Q.C.:
Q. Yes. And then as a surgeon then, as time went on?
DR. KWAN:
A. After that that will be my few responsibility

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as that because you remember those days we do not have the number of medical oncologists that we have today. All the cancer treatments are primarily treated by the radiation oncologists at the, those days, I guess, the Cancer Clinic, which is a branch of the General Hospital. We have--in those days that come in, we have to make our own interpretations and treat it.
COFFEY, Q.C.:
Q. And when you say make your own interpretations and treat it, your own interpretations of what?
DR. KWAN:
A. Oh, everything, I think. I'm not particularly restricted to estrogen receptors at that time.
COFFEY, Q.C.:
Q. Okay. And so you would be deciding--as the surgeon you would do the surgery?
DR. KWAN:
A. Well, yes.
COFFEY, Q.C.:
Q. For cancer. How about after the surgery, like, I'm thinking back in the 1980s, how was -

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DR. KWAN:
A. In the ’80s, in the early ’80s we will be looking t the pathology reports and determining on the need for adjuvant treatment.
COFFEY, Q.C.:
Q. Yes.
DR. KWAN:
A. Which, and then those days, I think, we started before, I think that was even before, early ’80s would be before Tamoxifen. I can’t be sure of the date of that. We had to use hormone receptor--hormone treatments even before the day of hormone receptors being widespread use.
COFFEY, Q.C.:
Q. And then as certainly as the 1980s went on, Tamoxifen became available or was certainly used?
DR. KWAN:
A. Yes.
COFFEY, Q.C.:
Q. So who would be prescribing Tamoxifen at that point, what sorts--would you be involved in prescribing it?

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DR. KWAN:
A. Let me think now. Yes, I would be in certain situations because we only had one medical oncologist at that time for the entire province, so we don’t have the resources. We used to discuss it and we may well have to prescribe it.
COFFEY, Q.C.:
Q. And in making a decision as to whether or not to prescribe it, you would be using the results from whom?
DR. KWAN:
A. I’m not remember that we do have that many estrogen receptor available for every patients that we have. We do have some when the estrogen receptor data comes in, we certainly based on the estrogen receptors. If not, you have to base it on your clinical situations where we were--there are certain clinical situations patients are likely to respond to hormone, there are clinical situations that patients are unlikely be response to hormone, so we base it on those other clinical informations.
COFFEY, Q.C.:

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Q. And if the--some test result for ER/PR was available, you would utilize that, as well?
DR. KWAN:
A. It would base--yes, correct.
COFFEY, Q.C.:
Q. Doctor, in the first, then, test results that you used as a treating physician, would they be biochemical results?
DR. KWAN:
A. Those days would be biochemical, yes.
COFFEY, Q.C.:
Q. And the biochemical tests, do you recall where that was done, was that done here in St. John’s?
DR. KWAN:
A. They were done, yes. I think they were done at the General Hospital laboratory. Those reports that I did in my laboratories are purely research tools at that time.
COFFEY, Q.C.:
Q. I appreciate you weren’t doing it for treatment purposes, it was a research tool?
DR. KWAN:
A. Well, research tool and reference back to the patient’s -

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COFFEY, Q.C.:
Q. Yes.
DR. KWAN:
A. - we need those informations.
COFFEY, Q.C.:
Q. But then as time went on the biochemistry department somehow connected with the General Hospital was doing the ER/PR test and providing you with results?
DR. KWAN:
A. Yes.
COFFEY, Q.C.:
Q. Yourself and whomever else was -
DR. KWAN:
A. That’s what I can remember.
COFFEY, Q.C.:
Q. - was treating patients. Doctor, the Commissioner had heard and Dr. Khalifa testified here. Did you know Dr. Khalifa?
DR. KWAN:
A. I knew him very well.
COFFEY, Q.C.:
Q. And he has told the Commissioner that, you know, after he arrived in the mid 1990s, around 1997 or so he started to look into

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utilizing immunohistochemistry, in particular, using paraffin embedded tissue to conduct ER/PR tests. Do you recall that coming on line, as it were, here in St. John's?

DR. KWAN:

A. I'm sure that Khalifa and I had discussions. To say exact date when it come on, I don't know, I can't remember that because certainly he save a lot of preparation of tissues in the operating room and lot of procedures in us to get the tissue for a biochemical determination and is coming on stream and in the national and coming on stream as technologies.

COFFEY, Q.C.:

Q. And, Doctor, during the days when biochemical assay was being utilized here in St. John's, could you tell the Commissioner then as a surgeon how you would provide or what was expected of you in terms of providing tissue for the biochemical assay?

DR. KWAN:

A. Well, from the biochemical assays we would have to take this tumour specimen out in the operating room, get approximately what you estimate a gram of tissue which is purely

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cancer tissue rather than a fat and all the other stuff, fix it and freeze it in the operating was just within minutes that it come off the patients in the liquid nitrogens as provided.

COFFEY, Q.C.:

Q. So you say fix it, I take it that that -

DR. KWAN:

A. No, freeze it.

COFFEY, Q.C.:

Q. Freeze it, yeah.

DR. KWAN:

A. Freeze it in the liquid nitrogens and then transport to the lab to be frozen in minus 70 degree refrigerators. And then they'll be determined by the laboratory at the time.

COFFEY, Q.C.:

Q. And the biochemical test, when that was being utilized here, you understood as a surgeon this is what's expected of me?

DR. KWAN:

A. Well, that's the procedure.

COFFEY, Q.C.:

Q. Procedure, yes.

DR. KWAN:

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A. We were told to do all this procedure that I had been influence in establishing at that time because that was part of the research thing that we did.

COFFEY, Q.C.:

Q. Doctor, during the days that biochemical assay testing for ER/PR was done here in St. John's, it would have been, I gather, for--because it didn't end until the beginning of 1998, so it went on for a period of time, quite a number of years. Doctor, do you ever recall encountering or being told about any test, any questions about the validity of the results? I'm not suggesting there were, I'm just -

DR. KWAN:

A. No, sir, I have not heard any test problems.

COFFEY, Q.C.:

Q. And then Dr. Khalifa introduced the IHC based test. As a surgeon in terms of providing material for that test, what if anything changed?

DR. KWAN:

A. We don't have to put in liquid nitrogen any more.

COFFEY, Q.C.:

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Q. Okay, so what -

DR. KWAN:

A. Because you send the specimen to the laboratory as per usual and was done on fixed tissues.

COFFEY, Q.C.:

Q. Doctor, as a surgeon, I take it, when you first did your residency and then continued in your career, from the time you first started as a surgeon in the OR what, if anything, was your understanding of what was expected of you as a surgeon in terms of preserving tissue, like tumour tissue? Leaving aside the liquid nitrogen.

DR. KWAN:

A. We'll take it out. I mean, there's procedure established in the operating room. We take the specimen out, we hand in to the nurse. The nurse will pass on, will then ask us whether we would like to fix it in formalin or we want to send it for or at that time commonly called frozen section, quick sections or then is part of it want quick sections on or have the pathologist look at it, one or the other. If we say no, we just want it to be

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fixed, it goes directly to formalin.

COFFEY, Q.C.:

Q. And what does that involve? It may be second nature to you, but a nurse asks you and you say, no, I want it fixed?

DR. KWAN:

A. I say, no, I want it--no, the assay fine, I don't need a frozen sections and then they would put it into a formalin. Then I don't hear anything about it, I carry on my operation, which is, as you're probably aware, at that time is by no means complete.

COFFEY, Q.C.:

Q. Yes, I appreciate that. So you would excise with a scalpel the tissue, be asked by the nurses as to what do I do with this, Doctor?

DR. KWAN:

A. Well, we just hand it to the nurses, went back to then, and then when there is a free moment, sometimes we have to do a few things.

COFFEY, Q.C.:

Q. Sure.

DR. KWAN:

A. Write the specimen out and then you--at the free moment ask you can I fix the specimen or

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do you want anything done and you will say, no, yes, or whatever instruction you give them.

COFFEY, Q.C.:

Q. Yes.

DR. KWAN:

A. And she will take the specimen out to the circulating nurse who will put it in the formalin.

COFFEY, Q.C.:

Q. And would this occur actually in the operating room itself?

DR. KWAN:

A. Correct.

COFFEY, Q.C.:

Q. Okay. So the last--from your perspective the last you would see of the tissue would be somebody would be walking away with it?

DR. KWAN:

A. I would, last time I see it is when I hand over to the nurse or if I want, specifically say I want to take a look at the specimen after I complete the operations then, yes, I would then keep it on the operating table, I mean, around the operating table and then I

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look at it when I finished.

COFFEY, Q.C.:

Q. Now, Doctor, within the operating room structure there, your understanding then, I take it, as the surgeon at the time would be that the nurse would take it over and have it placed in formalin? Okay, again, I'm correct in that, am I?

DR. KWAN:

A. Well, the nurse, when I say I don't need it any more, they will take it in there and put it in the--have a bucket which I used to see them around and pour formalin in it.

COFFEY, Q.C.:

Q. Did you have any understanding of then what happened with the tissue samples?

DR. KWAN:

A. That would go down to the laboratory, if I understood, you know.

COFFEY, Q.C.:

Q. Did you have any understanding as to when it would go down to the lab?

DR. KWAN:

A. It usually go outside after the case with the patients outside when the patients are

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wheeling out the operating room, they put it outside, put it into an area out, just on the outside of the operating room where they will be, I understand now, I never seen it, that will be the procedure that they would be signed into the book, with the specimens out and name, patient, identifying informations on the book and the type of specimens there and this will be then taken down to the--at the end of the day or somewhere during the daytime to the laboratory and they will be signed to be received.

COFFEY, Q.C.:

Q. And if you tell the Commissioner in terms of yourself, you wouldn't be actually outside supervising that?

DR. KWAN:

A. No.

COFFEY, Q.C.:

Q. You understood this was going on?

DR. KWAN:

A. That is what I understood that's happening. I really don't see them afterwards.

COFFEY, Q.C.:

Q. Doctor, who was responsible for overseeing

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that aspect of the matter?
DR. KWAN:
A. I would say the nursing department or the manager of the operating room.
COFFEY, Q.C.:
Q. And that would be, in this context, is that the perioperative?
DR. KWAN:
A. That would be the perioperative program, correct.
COFFEY, Q.C.:
Q. Perioperative program, whoever is in charge of the perioperative program?
DR. KWAN:
A. Well -
COFFEY, Q.C.:
Q. In particular, whoever is in charge of it that day at that place?
DR. KWAN:
A. It would be the nurse in charge of the operating room for that suite who would be responsible or the nurse in charge of that particular case who will be responsible for taking the specimen out, filling in the form. And the procedure will then be carried on and

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the procedure book, whether that would be, procedure would be established by the responsible of the operating room or the nurse in charge -
COFFEY, Q.C.:
Q. The nurse.
DR. KWAN:
A. - or manager in charge of the operating room.
COFFEY, Q.C.:
Q. Of the perioperative program and in particular that room?
DR. KWAN:
A. Correct.
COFFEY, Q.C.:
Q. The actual procedure, whatever it was?
DR. KWAN:
A. The actual procedure, yes, I would think.
COFFEY, Q.C.:
Q. Doctor, did you have any understanding as to how often tissue samples were supposed to be brought down to the lab, how often per day?
DR. KWAN:
A. I don't know.
COFFEY, Q.C.:
Q. Okay. Doctor, you've spoken to the

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Commissioner about or mentioned frozen sections or quick sections?
DR. KWAN:
A. Uh-hm.
COFFEY, Q.C.:
Q. They're called.
DR. KWAN:
A. Uh-hm.
COFFEY, Q.C.:
Q. What do they involve?
DR. KWAN:
A. Well, if I need some information to direct what type of procedure I want to do or how the operation could be carried on, or what margins are clear or not, I take a sample of the area that I'm concerned about or I need information on it and ask the pathologist come and examine the specimen, freeze it in some sort of gel and freeze they have and cut it into slice, and have a look at the examination under microscope right then and there, and within, say, usually 15/20 minutes, let me know what the answers are.
COFFEY, Q.C.:
Q. And that was because you need the answer from

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the pathologist right then and there in order to proceed with the operation?
DR. KWAN:
A. Yes, I have to--sometimes, you know, you're doing some form of surgery like (unintelligible) surgery where I have (unintelligible) or not.
COFFEY, Q.C.:
Q. Yes. Doctor, in relation to that, I take it sometimes the samples, the tissue sample that you have taken from the patient, would be utilized fully for the quick section, sometimes it would be broken down, some quick section and some of it will go out into the formalin?
DR. KWAN:
A. That's correct.
COFFEY, Q.C.:
Q. You were referring to the idea that the nurse would ask can I fix all of it or -
DR. KWAN:
A. Well, I take the specimen out and should I have to--it's fixed or it goes fresh.
COFFEY, Q.C.:
Q. And the material that didn't go to the fresh

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or frozen section, you would expect to be fixed and the rest -

DR. KWAN:

A. It would be handled by the pathologist then.

COFFEY, Q.C.:

Q. Yes.

DR. KWAN:

A. The pathologist would already have the specimen.

COFFEY, Q.C.:

Q. The -

DR. KWAN:

A. The quick section.

COFFEY, Q.C.:

Q. The quick section.

DR. KWAN:

A. Yes.

COFFEY, Q.C.:

Q. But the material that was not going to be -

DR. KWAN:

A. That's correct.

COFFEY, Q.C.:

Q. Quick sectioned, would end up in the formalin route?

DR. KWAN:

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A. Correct.

COFFEY, Q.C.:

Q. Doctor, did you--I take it you would have understood or understand that the purpose of putting tissue into formalin is to preserve it?

DR. KWAN:

A. That's correct.

COFFEY, Q.C.:

Q. Did you ever have any complaints or concerns expressed to you over the years about tissue specimens that were not properly fixed?

DR. KWAN:

A. No concern.

COFFEY, Q.C.:

Q. In terms of downstairs, the pathologist or the pathology lab saying -

DR. KWAN:

A. Not directly to me.

COFFEY, Q.C.:

Q. How about indirectly?

DR. KWAN:

A. I mean, the thing is as these things came up, I mean, you heard about through the grapevines but nothing was said to me. I have not heard

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anything about it.

COFFEY, Q.C.:

Q. And in terms of when you say through the grapevine, are you talking about the ER/PR matter?

DR. KWAN:

A. Yes.

COFFEY, Q.C.:

Q. Okay, you're talking about this.

DR. KWAN:

A. Yes.

COFFEY, Q.C.:

Q. I'm talking--leaving aside the ER/PR, we'll get to that in a moment, over the years through the 80s, the 90s, up until 2005, were there ever any complaints came to your attention directly or indirectly about tissue not being properly fixed?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. If there were concerns about that within the pathology lab, who would you have expected, what sorts of individuals would you have expected -

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DR. KWAN:

A. Well, the only person that would know there is a problem are the pathologists and the laboratory people that would know that there is a problem. I wouldn't know that.

COFFEY, Q.C.:

Q. Yes.

DR. KWAN:

A. And they would have to communicate back to us, yes, there is a problem, fix it, but we don't --have never heard of it in my days I was there.

COFFEY, Q.C.:

Q. Doctor, and you're the--for many years the site--well, from the mid 90s until really the mid 2000's, the site chief for surgery at the General?

DR. KWAN:

A. 1999 to 2006.

COFFEY, Q.C.:

Q. Sorry, '99 to 2006.

DR. KWAN:

A. Correct.

COFFEY, Q.C.:

Q. And then--I take it then if there were

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concerns in the lab, and I'll deal with the 2005 in a moment.

DR. KWAN:

A. Right.

COFFEY, Q.C.:

Q. Before 2005, if there were concerns in the lab between '99 and 2005 about the OR not handling tissue properly, if there were--I'm not saying there were. If there were, you would have expected them to be expressed to you as the chief of surgery, to be brought to your attention, anyway?

DR. KWAN:

A. Yes, I would think they would brought to my attention or brought to somebody within the operating room.

COFFEY, Q.C.:

Q. The peri-operative program?

DR. KWAN:

A. The peri-operative program, yes, not necessarily myself, but the peri-operative program.

COFFEY, Q.C.:

Q. And if it was brought to the per-operative program, would you expect that the manager

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would bring it to your attention?

DR. KWAN:

A. I would--you know, I would think so, but I don't necessarily get all information from there.

COFFEY, Q.C.:

Q. Yes. Doctor, you've told the Commissioner that as a surgeon, you certainly earlier in your career were involving in treating people based upon their ER/PR status after surgery. At times you were called upon to do that. What were you taught about that in terms of your approach to hormonal therapy or anti-hormonal therapy?

DR. KWAN:

A. I think we had to do what you need to do for the patient care. I don't have a medical oncologist--I have one medical oncologist, if I can remember, over many, many years. Extensive recruitment has been done and we don't have any medical oncologists, and a significant number of people around who needed treatment. So the radiation oncologist, which is--who are there at that time, and ourselves, have to make some decisions in treatment. Now

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having said that, you know, they've been treating with hormone in breast cancer well before Tamoxifen had become available.

COFFEY, Q.C.:

Q. And when Tamoxifen became available then, Doctor, what was the approach?

DR. KWAN:

A. The approach would be--before Tamoxifen available, we are treating with estrogen, we are treating with male hormones, steroids, that kind approach, but when Tamoxifen, that becomes a drug of choice and that seems to be the one that we'll be using with the patient that we thought was suitable for hormone treatments.

COFFEY, Q.C.:

Q. Doctor, could you tell the Commissioner, please, because I take it that you do do and have over the years done a significant amount of breast surgery, breast cancer surgery?

DR. KWAN:

A. That's correct.

COFFEY, Q.C.:

Q. Within St. John's, and, Doctor, for example, beginning from the time you first started at

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St. Clare's in the early 90s -

DR. KWAN:

A. Yeah, I was at St. Clare's in early 90s, correct.

COFFEY, Q.C.:

Q. Early '90s. Doctor, at that point in time in terms of the breast surgery that was done in St. John's, approximately how much would you do a year?

DR. KWAN:

A. Probably do about 50, somewhere around there.

COFFEY, Q.C.:

Q. And I take it then--do you recall how many breast cancer patients would be operated on in St. John's that time of year?

DR. KWAN:

A. The tumour registry would probably say somewhere between 250--200 to 300, 250, 300, I don't know the exact number. That is the province.

COFFEY, Q.C.:

Q. And who else do you recall in terms of the surgeons was doing breast cancer surgery throughout the 90s? It was yourself and--in the main, the other doctors.

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DR. KWAN:
A. Dr. Felix.
COFFEY, Q.C.:
Q. Dr. Felix.
DR. KWAN:
A. Dr. Thavanathan, Dr. Wells, and a number of others who do the lesser numbers. These are the ones I know that do the major number.
COFFEY, Q.C.:
Q. Yeah, and we've seen their names on some of the material.
DR. KWAN:
A. Sure.
COFFEY, Q.C.:
Q. The surgeons you referred to, and within St. John's itself over the years, proportionately, because you worked at both the General and St. Clare's, where was most of the breast surgery done?
DR. KWAN:
A. I do most of the breast surgery in St. Clare's.
COFFEY, Q.C.:
Q. Was there any particular reason for that?
DR. KWAN:

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A. A couple of reasons. One is the mammogram is at St. Clare's. When you need a localization technique, in other word if I can't feel the tumour, I need to put a wire on the mammographic guidance and ultrasound guidance, the expertise are in St. Clare's. They put a wire so I can sample. And secondly--secondly is breast cancer surgery from a surgical procedure standpoint is the simplest surgery than all the other major abdominal surgery that I do. It's little more convenient to do smaller surgery in the area that I don't attend 24 hours a day, whereas I do a bigger operation at the Health Science where I there 24 hours a day, or something of that nature.
COFFEY, Q.C.:
Q. Doctor, I'm going to ask you then to outline for the Commissioner because it hasn't--she hasn't heard this yet, okay. Now from a surgeon's perspective, your approach as a surgeon if there is such a thing to a typical breast cancer case in terms of when a person would first come to you in your capacity as a surgeon, and how you approach up to and including the point where you're taking the

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tumour?
DR. KWAN:
A. Usually the patient comes to us in the first visit are referred in by their family physician, if that's what you mean.
COFFEY, Q.C.:
Q. Yes.
DR. KWAN:
A. It's usually either they have a lump, they have pain, they have discomfort, they have some concern about their breast, and the first issue is diagnosis. Do we have a malignancy or do we have a benign disease? So then our radiological colleagues and our clinical examination come to play. If we establish that this particular situation is of concern, either mammographically or clinically, then we try to establish the tissue diagnosis.
COFFEY, Q.C.:
Q. Uh-hm.
DR. KWAN:
A. Meaning tissue diagnosis can be established a number of ways. It can be done by a core biopsy, which means putting a needle in there and getting a sample core, or by radiology

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getting a core biopsy because sometimes you can't feel the lump. They will be a core (unintelligible) and x-ray guidance. If it's a lump that's palpable and core biopsy is not suitable, there are situations it is not, then we have to do an open biopsy which means we take the patient to the operating room and take a piece out of it, sometimes under general anesthetics, other times local anesthetics. Once we establish the diagnosis of breast cancer, then we discuss with the patient the treatment. The first and foremost treatment of breast cancer is surgery. Surgery is the first one to do. So what we do is that we will complete the surgical procedure, the are a number of surgical options that are available. One is what we call, if the patients are suitable, is a partial removal of the breast; in other words, a generous removal of the breast, depending on the pathology report, and do the axilla determination whether the axilla is involved or not. And it's a basically staged procedure properly, and after we have done the surgical aspect or completed, satisfactory completed

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the surgical aspect of it, then we--when all the pathology is back, refer the patient in general to the Cancer Clinic or to the medical oncologist or to the radiation oncologist to consider what we call either adjuvant radiation therapy or adjuvant chemotherapy. The treatment of the axillary portion of it now has become another field that has been developing, so called sensitive note (phonetic) and other stuff like that, which is another thing that surgeons now have to be participating in and determining that.

COFFEY, Q.C.:

Q. Doctor, the processes you've just described, and I have asked you about the actual surgery in the OR per se, for example, when you might be taking--removing a patient's entire breast or a portion of it, and you've described how the tissue would be fresh sectioned or preserved in formalin. I want to ask you about the core biopsies and the open biopsy process because you referred to both of them. How is the tissue that is extracted there preserved?

DR. KWAN:

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A. It is the same thing. We take it out, give it to the nurse, put it in formalin. Often on the core biopsies, directly into the formalin.

COFFEY, Q.C.:

Q. And then it would be handled then by the nursing staff in the way you've described it?

DR. KWAN:

A. Correct.

COFFEY, Q.C.:

Q. They would go on with it and do whatever they had to get it down to the lab?

DR. KWAN:

A. To pathology, yes.

COFFEY, Q.C.:

Q. Doctor, in terms of the structure of the-- I'll come back to the actual administrative structure within operating room in a moment, but in the early days you've indicated that there was, at best, one medical oncologist in the province, and at times there were a certain number of radiation oncologists who would be involved in post-operative treatment and surgeons, people like yourself?

DR. KWAN:

A. Right.

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COFFEY, Q.C.:

Q. Doctor, how has that changed over the years? I mean, compared to the mid 90s to now, how has that changed?

DR. KWAN:

A. At the mid 90s, we started changing.

COFFEY, Q.C.:

Q. Okay, perhaps you could tell us.

DR. KWAN:

A. And mid 90s, I think we were able to get a few more medical oncologists and a few more radiation oncologists. Some them come and go, so there have been significant changes over the time. I don't know what exact number we have now. I think if I remember right, we have seven medical oncologists, and five to six radiation oncologists, I don't know the exact number, but compared to what's then.

COFFEY, Q.C.:

Q. And how, if anything, has that changed your practice in terms of having to follow patients after?

DR. KWAN:

A. I don't any more. I send all my patients to the medical oncologists if they wish to go.

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You know, there are patients who say I don't want to enter the door of the Cancer Clinic, but that's a very rare unusual situation.

COFFEY, Q.C.:

Q. And for those who don't want to go to the Cancer Clinic, I take it you would continue treatment?

DR. KWAN:

A. I will--I have a clinic in the Cancer Clinic myself. I follow--do some follow-up in the Cancer Clinic. I don't do any active treatment there any more. So I don't do chemotherapies, or anything of that nature now any more.

COFFEY, Q.C.:

Q. Doctor, you were the site chief at the General Hospital for general surgery beginning in 1999, do I understand that?

DR. KWAN:

A. Correct, yes.

COFFEY, Q.C.:

Q. How about before that?

DR. KWAN:

A. Before that, I think in mid 90s, I was the--I begin to be the chief of surgery, General

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Surgery Division at the Health Science, and 1985 to 1992, I was Director of the Cancer Clinic.

COFFEY, Q.C.:

Q. So '85 to '92, you were Director of the Cancer Clinic, which I take it was then a separate -

DR. KWAN:

A. Under the Newfoundland Cancer Treatment Research Foundation.

COFFEY, Q.C.:

Q. And so from '92 then--if you just take the Commissioner then your administrative positions from '92 up to now?

DR. KWAN:

A. '02 up to now, I was--I was divisional chief from '95 onwards to couple of years ago, a year ago maybe, and I was the site chief of surgery from 1999 to 2006.

COFFEY, Q.C.:

Q. What's the difference between a divisional chief and a site chief?

DR. KWAN:

A. Divisional chief is that I just look after - I have the responsibility of the general surgeons at the Health Science. Co-clinical

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Chief of the Peri-operative Program, I have the responsibility of dealing with the day to day operations of the - related to the surgeons only at the - and the surgical floor at the Health Science.

COFFEY, Q.C.:

Q. So what - if I could ask you then, you're, I'm sorry, Clinical Chief of Peri-operative Program?

DR. KWAN:

A. Co-clinical Chief.

COFFEY, Q.C.:

Q. Co-clinical Chief of the Peri-operative Program?

DR. KWAN:

A. That's correct.

COFFEY, Q.C.:

Q. For the Health Care Corporation or for the General Hospital?

DR. KWAN:

A. Since '99. I don't remember who -

COFFEY, Q.C.:

Q. Okay, '99, it would be - the Health Care Corporation existed the beginning of '95/'96, okay, that's -

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DR. KWAN:

A. I don't know. I can't remember when it changed to Eastern Health.

COFFEY, Q.C.:

Q. And so beginning in 1999, I'm sorry, you were the clinical chief - sorry, co-clinical chief for the peri-operative program?

DR. KWAN:

A. Correct.

COFFEY, Q.C.:

Q. Who was the other clinical chief?

DR. KWAN:

A. That is Dr. Frank King, who is anesthesiologist because operating room is primarily two group of physicians; anesthesia and surgeons.

COFFEY, Q.C.:

Q. Yes.

DR. KWAN:

A. And so we have one group - one individual who would deal with the issues arising from anesthesia and surgeons who would deal with issues arising from surgeries.

COFFEY, Q.C.:

Q. And I take it then in terms of the peri-

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operative program, you as co-chief, co-clinical chief, are responsible for the surgeons?

DR. KWAN:

A. Uh-hm.

COFFEY, Q.C.:

Q. And your colleague was responsible for the anesthetists. Were there any other managers of the peri-operative program?

DR. KWAN:

A. Yes.

COFFEY, Q.C.:

Q. What sorts of individual - who are they, and what -

DR. KWAN:

A. They had a program director who actually have the responsibility overseeing the program.

COFFEY, Q.C.:

Q. Yes.

DR. KWAN:

A. And individual operating room, they have the managers, and then the head nurse in each operating room.

COFFEY, Q.C.:

Q. Yes. In terms of the program direction who

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was that?
DR. KWAN:
A. Maria Tracey.
COFFEY, Q.C.:
Q. Maria Tracey, going back to 1999, Ms. Tracey was -
DR. KWAN:
A. So far as I remember that she was there when I started.
COFFEY, Q.C.:
Q. And what was her role, like, in comparison to yours, what was she responsible for? You were responsible for the surgeons, keeping them in line, dealing with them.
DR. KWAN:
A. She was responsible for all the facets of the operating room, like, the nurses, the cleaners, all the other procedures in the operating rooms, I would assume.
COFFEY, Q.C.:
Q. So she would be responsible for the activities of everyone except the doctors?
DR. KWAN:
A. That too, because we report to Maria Tracey.
COFFEY, Q.C.:

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Q. Okay, and in relation to that now, I want to ask you about that, what sorts of things would you feel that doctors would have to report to Ms. Tracey for?
DR. KWAN:
A. They would go through me, I would hope, but -
COFFEY, Q.C.:
Q. I appreciate that, but in terms of yourself, what sorts of things would you -
DR. KWAN:
A. Well, we discuss, for example, like, simple things like surgeon doesn't show up on time in the morning.
COFFEY, Q.C.:
Q. Yes.
DR. KWAN:
A. Is late, delaying the operating room. If, I'm saying "if" -
COFFEY, Q.C.:
Q. As an example, yeah.
DR. KWAN:
A. Yeah, example, or constantly overbook the case and late, creating significant financial issues or problems and manpower issues, etc those, you know, would have to be dealt with

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collectively. Individual who may be have to be dealt with individually, I mean, by me, and function between physician and nurses -
COFFEY, Q.C.:
Q. If there were any problems -
DR. KWAN:
A. Any problems.
COFFEY, Q.C.:
Q. Okay, and you would deal with Ms. Tracey in that regard?
DR. KWAN:
A. I would deal with it. She would come to me, because I don't get those. Usually the surgeons don't complain. It's somebody that does, and I don't--you know, they--I mean, no complaints, but they complain a different way, but they don't--those things come through their administrative role, in terms of the union rules and all the stuff like that, which I haven't got a clue.
COFFEY, Q.C.:
Q. Now Doctor, in relation to written policies and procedures, were--in the sphere of responsibility that you had as co-clinical chief, the perioperative program, were there

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any written policies or procedures that related to the doctors, that you were aware of? Did the perioperative -
DR. KWAN:
A. How do you dress and gown in the operating room? I'm sure they are all written there somewhere, but it's just been around for so long that I just accept it. I don't think I ever seen one.
COFFEY, Q.C.:
Q. And any written policies and procedures that might apply to staff other than physicians?
DR. KWAN:
A. Oh, I'm sure there are.
COFFEY, Q.C.:
Q. Who was--your understanding, who was responsible for those?
DR. KWAN:
A. I would say the program is.
COFFEY, Q.C.:
Q. The program director?
DR. KWAN:
A. And the nursing department.
COFFEY, Q.C.:
Q. So if there were to be any written standards

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or policies or procedures relating to the preservation of tissue samples, okay, whether they were written or not written, okay, who was responsible for formulating them?

DR. KWAN:

A. That would be, I would say, the nursing department, administrative department.

COFFEY, Q.C.:

Q. And you would have expected them to deal with what other agency in the hospital? The lab, I take it?

DR. KWAN:

A. Laboratory would be the one. Laboratory, the one who have identified any issues and communicate with them and they would have to make issues--to make procedure to correct if there was any problems.

COFFEY, Q.C.:

Q. Doctor, I want to ask, please, Registrar, to look at Exhibit C-0225, C-0225?

DR. KWAN:

A. What do I do with this?

COFFEY, Q.C.:

Q. No, just it'll come up on the screen there, Doctor.

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DR. KWAN:

A. Okay.

COFFEY, Q.C.:

Q. There you go, see. Now Doctor, this is a pathology report. Portions of it have been redacted, blacked out, and here, Doctor, on the second page of the exhibit, there's an addendum one and addendum two.

DR. KWAN:

A. Um-hm.

COFFEY, Q.C.:

Q. And these happen to be reports by Dr. Elms, and there's nothing unique about this particular case. It's just a certain aspect of it, I'm going to refer you to and then ask you a question. Look at addendum number one. You'll notice it says "immunochemical staining is negative for progesterone receptors. The immunohistochemical staining for estrogen receptors has been technically unsatisfactory on two occasions. A repeat attempt will be made and an addendum issued one this investigation has been performed." Signed Ford Elms. This is dated, entered on September 25th, 2001 and signed off by him the next day.

DR. KWAN:

A. Um-hm.

COFFEY, Q.C.:

Q. And then if you look above, you'll see addendum number two, entered October 10th, 2001, signed off the same day, and it reads "immunohistochemical stains for estrogen and progesterone receptors are negative." Now Doctor, back in--this is circa September and October 2001. The idea that Dr. Elms apparently, as a pathologist, was having problems with the--being satisfied with the staining for estrogen receptors and repeat attempt having been required to be made, because there's two attempts here, first of all. He's going to make a third one. Back in 2001 and into 2002, was there any concern that you ever became aware of at all, officially or unofficially -

DR. KWAN:

A. No.

COFFEY, Q.C.:

Q. - about estrogen staining, progesterone staining, back at that time?

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DR. KWAN:

A. No.

COFFEY, Q.C.:

Q. Would you, as a surgeon, when you would get a report, pathologist's report, because that's--like a pathologist report like the one we're looking at there. I'm not suggesting at all you ever saw that one, but when you would get reports like that, I take it that's the format they would be in? Over the years, this is the sort of format they would take?

DR. KWAN:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, did you ever have occasion to notice that--in any report that you saw, that the pathologists apparently were--was reporting that he or she had to repeat the test?

DR. KWAN:

A. I mean, if he's not certain, I have no idea why is he not certain that--the first original study, there could be a number of reasons that can happen. If you roll this pathology report a little higher -

COFFEY, Q.C.:

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Q. I'm sorry, Doctor, higher is the first page?
DR. KWAN:
A. No, no, where the histology report part of it.
COFFEY, Q.C.:
Q. Okay, that's -
DR. KWAN:
A. Oh, you just passed it.
COFFEY, Q.C.:
Q. Okay, right here, yes.
DR. KWAN:
A. And you -
COFFEY, Q.C.:
Q. Pathological interpretation.
DR. KWAN:
A. Right, you will notice that it's poorly differentiated tumour.
COFFEY, Q.C.:
Q. Yes.
DR. KWAN:
A. And poorly differentiated tumours, oftentimes give difficulties. So I mean, I would read it. I mean, I don't know the details of it, but you've seen enough and you look at that they have difficulty, I would not be able to tell what kind of difficulties he may have.

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Partial may be the tissue, tumour itself, and maybe significant other issues, and I would leave it up to resolve those issues himself.
COFFEY, Q.C.:
Q. Now I wanted to ask you about that, as a surgeon, as a treating physician, in your capacity as a surgeon utilizing a pathology report. If you saw a report like this, okay, and I'm not suggesting at all, I repeat, that you saw this one. If you saw a report like this where you noticed, well, okay, poorly differentiated. You would understand that that might be--present some difficulty for the pathologist in the interpretation process. Am I correct on that?
DR. KWAN:
A. I mean -
COFFEY, Q.C.:
Q. It could?
DR. KWAN:
A. - if I was to understand, that could be a possibility.
COFFEY, Q.C.:
Q. And then if there was a note in an addendum or somewhere in the report that technically or

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otherwise there was something unsatisfactory from his perspective or her perspective and then you saw that the pathologist did then though make an actual report, you'll see this one here, this is an assertion that the stains for estrogen and progesterone receptors are negative, would you ever, as a surgeon go behind that? In the sense of, okay, if you saw this sort of one, addendum number one, there was a problem, technical problem of some sort. And now a month--actually not a month, two weeks later, there's a report that they're negative, both of them are negative, would you ever challenge that or go behind it, Doctor?
DR. KWAN:
A. It matches a poorly differentiated tumour.
COFFEY, Q.C.:
Q. Sure.
DR. KWAN:
A. Poorly original--estrogen receptor negatives. I mean, if you get those--if it changed around to something else, I may question it, but if it matches the histological findings that you expect from the situation, I see no reason to question them.

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COFFEY, Q.C.:
Q. Okay, and what about if it--a situation in any particular patients, and I appreciate you've seen quite a number of patients' pathology reports over the years.
DR. KWAN:
A. Um-hm.
COFFEY, Q.C.:
Q. If the information the pathologist was giving you, from your perspective, didn't match or wasn't consistent with the histological report, what was your approach then, Doctor?
DR. KWAN:
A. That's beyond--that's going--when beyond estrogen receptors. Anything that comes through that doesn't match, doesn't seem to be appropriate what I see of things, then I pick up the phone and I talk to them.
COFFEY, Q.C.:
Q. Okay.
DR. KWAN:
A. You know, and I say--I will usually go down with the report, find the pathologist and say "hey, what's happening here?"
COFFEY, Q.C.:

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Q. And he or she would give you an explanation?
DR. KWAN:
A. We would discuss an explanation and he/she may need some clinical history from me in maybe a difficult situation, that we need to share some information between me and the pathologist and maybe after listen to me, he may relook at it or we may decide that whatever needs to be done, do more testing, do more sectioning.
COFFEY, Q.C.:
Q. Now Doctor, do you ever recall doing that in relation to the ER/PR results you received?
DR. KWAN:
A. No, sir.
COFFEY, Q.C.:
Q. Do you ever recall hearing other surgeons talk about them having to follow up on ER/PR results?
DR. KWAN:
A. No, sir.
COFFEY, Q.C.:
Q. Look, please, at Exhibit P-1572? Doctor, when I just referred--that particular one was a 2001 pathology report. There are a number of

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other ones I could show you from 2002.
DR. KWAN:
A. Sure.
COFFEY, Q.C.:
Q. And in fact, even into 2003, that do indicate that, for whatever reason, the ER/PR was rerun and sometimes, in fact, there were changed results and you don't ever remember anybody talking about that or saying, you know, "guess what? I had a patient last week that was ER/PR negative and now they're telling me--now the pathology is telling me they're positive."
DR. KWAN:
A. Most of this, at that time, were probably seen by a medical oncologist, patient have gone down, referred to the Cancer Clinic, the addendum comes back, would have been gone, would be referred.
COFFEY, Q.C.:
Q. I take it then, amongst the--talk amongst the surgeons by the early 2000s, you wouldn't be as involved in the follow-up treatment, adjuvant treatment?
DR. KWAN:
A. Correct, I wouldn't be doing very many of

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those patients or of the patient that comes back to see me with a cancer diagnosis would be automatically referred unless there's some particular reasons.
COFFEY, Q.C.:
Q. If we could look, please, Doctor, this is the minutes of a meeting of April 15th, 2003, Surgical Pathology Review Committee meeting. Present are a number of individuals. Dr. Ejeckam is the chairman. Dr. Battcock, I think, was a surgeon?
DR. KWAN:
A. No.
COFFEY, Q.C.:
Q. I'm sorry.
DR. KWAN:
A. That's Steve Battcock.
COFFEY, Q.C.:
Q. Steve is?
DR. KWAN:
A. Radiologist.
COFFEY, Q.C.:
Q. Radiologist, I'm sorry. Dr. Dawson?
DR. KWAN:
A. Gynecology oncologist.

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COFFEY, Q.C.:
Q. Parai would be a pathologist?
DR. KWAN:
A. Pathologist.
COFFEY, Q.C.:
Q. Siddiqui, a medical oncologist.
DR. KWAN:
A. That's correct.
COFFEY, Q.C.:
Q. Thavanathan?
DR. KWAN:
A. That's a surgeon.
COFFEY, Q.C.:
Q. And yourself, and in fact, yourself and Dr. Thavanathan didn't make the meeting apparently.
DR. KWAN:
A. Correct.
COFFEY, Q.C.:
Q. There are terms of reference set out here. A. 2.1A is standardized reporting of pathology specimens, and Doctor, I'm going to ask you about this, I'm not going to take you through it at length, but the Commissioner has seen this before, and she's heard other evidence on

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this, that there was a significant concern about inadequacies in the completion of requisition forms coming to pathology from surgeons. Do you recall -

DR. KWAN:

A. That's correct.

COFFEY, Q.C.:

Q. And here, "Dr. Ejeckam asked the members for input for standardized reporting of pathology specimens." I want to ask you about that. As a surgeon, reading pathology reports, did you ever have any concerns about the formatting of them? Because we've looked at a number of them and the information could be anywhere in it, all over the place.

DR. KWAN:

A. The new format that's now being used since, I guess, mid 90s has been much improved, compared to before in the past. From a surgeon's perspective, what we want to know, number one, the diagnosis correct. Number two, our margins are clear. Number three, are lymph nodes--in breast cancer I'm talking about, are there lymph nodes involved or not. That would be our primary concern, and

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oftentimes ER and PR receptor comes much later, before--after even--that's why it's addendum one, addendum two, you got those come much later before most time we don't even see that by the time the patient has been referred. So we are concerned about if our margins are not clear, if you're dealing with a breast conservation surgery, if a margin is not clear, then it is necessary to do further surgery before we send the patients off, so that number one, it will be our interest in finding from the pathologist whether our margins are free. And secondly, if the patient have a lymph node involvement that they come as stage two, then that will be advise the patient used to come to talk to us, "do I get chemotherapy, do I not?" We can at least give them some inkling as to what's happening, what may happen to them.

COFFEY, Q.C.:

Q. The lymph node involvement had implications for treatment?

DR. KWAN:

A. Correct.

COFFEY, Q.C.:

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Q. As did ER/PR status?

DR. KWAN:

A. That's correct too.

COFFEY, Q.C.:

Q. Doctor, here, looking at this memo, it says "after much discussion, it was agreed that ER and PR receptors be done automatically on breast surgery cases." See that?

DR. KWAN:

A. That should be done automatically.

COFFEY, Q.C.:

Q. Yes. This suggests that at the time, in the middle of April 2003, it wasn't always being done. Now you're shrugging and -

DR. KWAN:

A. I don't know. I can't answer that.

COFFEY, Q.C.:

Q. At that time, in early 2003, as a surgeon, would you be ordering ER/PR?

DR. KWAN:

A. Since the time when it was done immunohistochemistry.

COFFEY, Q.C.:

Q. In the late 90s that would be.

DR. KWAN:

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A. Late 90s, they were done. We don't have to order that any more.

COFFEY, Q.C.:

Q. Your recollection is, your understanding -

DR. KWAN:

A. That's right.

COFFEY, Q.C.:

Q. - was that some--who was ordering it at that time, in the late 90s?

DR. KWAN:

A. Well, it come up, specimen immunohistochemistry will be done auto--I don't know why it's not done automatically. I really don't under--don't know.

COFFEY, Q.C.:

Q. Okay. There's a reference to -

DR. KWAN:

A. I would assume that it's done automatically.

COFFEY, Q.C.:

Q. And I take it, if you got a pathology report and you were being called upon to follow the breast cancer patient yourself, if it turned out you were, if there was no ER/PR status there -

DR. KWAN:

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A. I'll ask for it.
COFFEY, Q.C.:
Q. - you'd ask for it. Then there's a reference to this clinical information. He has circulate a form listing ten requirements a properly collected specimen requisition form should include. Now Doctor, we will come to this shortly, but could you tell the Commissioner, please, within a year of this, about a year later, you're still having to write a memo to surgeons to tell them to comply with this. Why is that? Explain that to the Commissioner, why.
DR. KWAN:
A. I don't know how people behave. I mean, because oftentimes that you don't sign the pathology report until you're finished the case. When you finish the case, you left, I would say, and now, I mean, and to the point that we have, say, the specimen ain't going out of the operating room until you fill out that form, and partially too, I remember I have some discussion with the pathologist that the form that was previously used, previous at that time, had only a small little bracket

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about this much room for you to write anything, you know. So I advised them to redesign the form and now we had a little broader piece of space to write things. At that time, it was just tiny little corner.
COFFEY, Q.C.:
Q. And I take it you're telling the Commissioner, for whatever reason, some surgeons, it was difficult to get them to comply?
DR. KWAN:
A. I don't know what to tell you.
COFFEY, Q.C.:
Q. To the point where--and we'll see this there, at one point it developed where there was going to be the approach that the specimen would stay in the OR.
DR. KWAN:
A. It would just now.
COFFEY, Q.C.:
Q. Yes.
DR. KWAN:
A. Which is current policy.
COFFEY, Q.C.:
Q. Which is current policy, yes.
DR. KWAN:

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A. They don't leave the operating rooms suite until that pathology report is filled out.
COFFEY, Q.C.:
Q. The requisition form filled out?
DR. KWAN:
A. Correct, the requisition form is filled out.
COFFEY, Q.C.:
Q. And that requires, at least, a satisfactory clinical history to be provided?
DR. KWAN:
A. Sometimes if very simple.
COFFEY, Q.C.:
Q. Sure.
DR. KWAN:
A. If you do a gallbladder, just gallbladder with gallstones, you know. Other times it's more complicated.
COFFEY, Q.C.:
Q. Here, Doctor, under new business, 3.1, ER and PR receptors. It says "Dr. Ejeckam stated that 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

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send one or two technologists to Halifax or Toronto for training." Now Doctor, do you recall--what, if anything, do you recall about this?
DR. KWAN:
A. I wasn't at the meeting, and I must say, I don't know that actually happened.
COFFEY, Q.C.:
Q. Well, the idea that they were not being performed for a period of time, were you aware in 2003?
DR. KWAN:
A. No, sir.
COFFEY, Q.C.:
Q. You were not at the time?
DR. KWAN:
A. No, sir.
COFFEY, Q.C.:
Q. Now these minutes, look down through this, they're signed by Dr. Ejeckam. If we look back up, here, they're actually stamped as having been received by the Vice-President Medical Services, that would be Dr. Williams' office, as of August 11th 2003, suggesting that it was some period of time between April

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15th and August before they were produced. Do you ever recall seeing these minutes yourself?

DR. KWAN:

A. No, sir, and you look at the date and the time, the time of the meeting is 2:10 p.m. in the afternoon on a Tuesday.

COFFEY, Q.C.:

Q. Yes.

DR. KWAN:

A. And Tuesday, at that time, and I remember, is my operating day or my meeting with the clinical chiefs. So it was every Tuesday at that time, I'm occupied and I think I remember telling them that I would not be able to make that meeting at any time, if you don't change it.

COFFEY, Q.C.:

Q. In fact, Dr. Thavanathan is not there either. He's a surgeon. So you're not surprised to find that the minutes note that you and he are not there at that time of day. If we could look, please, at Exhibit P-0113? Doctor, these are what I'll refer to as the Ejeckam 2003 memos. The first page of this is dated April 4th, 2003. It's to all pathologists,

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Health Sciences Centre, St. Clare's and out of town of hospitals from him. This is a memo. Subject is immunohistochemical stains. It reads "please note that the immunohistochemical stains for the following antibodies" and he lists eight of them, ER/PR are the last two, "have remained unreliable, erratic and therefore unhelpful for diagnostic purposes. Consequent on the above, staining with these antibodies will stop forthwith until we can solve the reliability, sensitivity and specificity problems. Efforts are under way and hopefully a solution will be found within the next four to six weeks." Doctor, did you see this memo back in 2003?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. Did you hear anybody speak of the subject matter of it?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. Doctor, if you look then, please, at page two, which is Dr. Ejeckam's May 2nd, 2003 memo, and

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again it's to pathologists and the Health Sciences Centre, St. Clare's and out of town hospitals from Dr. Ejeckam. The subject is ER/PR immunohistochemical stains, and he writes "I am glad to inform you we have rectified the difficulties related to the immunostain of ER/PR. Therefore, we can now resume regular requests for these antibody stains. I will however, like to bring the following information to your attention." Doctor, he then goes on, in paragraph one, "results of the immunostains may be affected by delayed fixation, over fixation, under fixation, uneven fixation, inadequate tissue dehydration and tissue reprocessing." I appreciate E and F would occur in the lab, and perhaps A to D might occur or be related to the lab. But A to D, particularly A, delayed fixation here, might relate to the operating room or the perioperative program. In 2003, did you ever hear any concerns expressed about what was going on in the OR?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

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Q. Or the OR's practices in terms of not getting the tissue down to the pathology?

DR. KWAN:

A. I have never been informed or aware of this.

COFFEY, Q.C.:

Q. And this particular document, Doctor, and I appreciate it's not directed at yourself. It's directed at pathologists and it goes on at some length. Dr. Ejeckam goes on at some length about ER/PR aspects of dealing with breast cancer, and it's copied to the site chief at the Health Sciences Centre in St. Clare's and Mr. Dyer and all technical staff on immunohistochemistry. Doctor, the April 4th and May 2nd, 2003 memos, as the co-clinical chief of the perioperative program at the time, in '03, would you have thought or expected at least you'd be told something about this?

DR. KWAN:

A. I interpret this as the laboratory problems themselves and that they should be--if there is a fixation issue, then the operating--at least the perioperative program or the chief would be saying that we think this is part of

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your area, we should be informed. Yes, I would think they at least--I would think the perioperative program somehow would be informed. If you think there's a fixation or inadequate fixation, whatever issues they think is related to the operating room.

COFFEY, Q.C.:

Q. Particularly in terms at the beginning of the tissue being preserved, if there's a problem, there might be problems down the road, further down in the process, but there could be a problem extending all the way back to the OR?

DR. KWAN:

A. If there is--I mean, it would need to be examined to find out where the process problems are, but you know, but if there's any concern about it, I would think they should bring it to our attention.

COFFEY, Q.C.:

Q. Doctor, how about being told that at least, as he's written here, look back at page one, Dr. Ejeckam, at that time, asserted in writing, April 4th, 2003, that those eight stains, two of them are ER/PR and at times, you would be relying upon ER/PR results for yourself, you

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know, in following your own patients, as well whether you were treating the patient, you know, following the patient or not, they are your patient. You've done the surgery on them, even if a medical oncologist is going to follow them, would you have been interested--you know, at the time, do you think you should have been told that a pathologist had concluded, in writing, that they have remained unreliable, erratic and therefore unhelpful for diagnostic purposes?

DR. KWAN:

A. I would think a notification to department of surgery will be, you know, will be reasonable and expected, I guess, I mean, so we know about it. Whether we can do anything about it, it's a different issue.

COFFEY, Q.C.:

Q. And if it involved a change in some practice in the OR, I take it then you would have--at the time, you'd listen and do what you could to make the change.

DR. KWAN:

A. Well, that would come up with our operating room discussions and find out what needs to be

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done and what has to be done and dialogue between the pathology department and ourselves and find out what the issues are.

COFFEY, Q.C.:

Q. Look, please, I want to look at page five of this document, Doctor. This is the June 19th, 2003, Dr. Ejeckam memo to Terry Gulliver, but at page seven of the exhibit, you'll notice he has copied this to Dr. Desmond Robb, Dr. Cook, Dr. Parai, and Mr. Dyer. At the time, you certainly would have known Mr. Dyer and Mr. Gulliver. Would you have known them? Certainly, Mr. Gulliver?

DR. KWAN:

A. I know to see who he is.

COFFEY, Q.C.:

Q. Okay.

DR. KWAN:

A. But that's about it.

COFFEY, Q.C.:

Q. How about Dr. Robb?

DR. KWAN:

A. I know Desmond very well.

COFFEY, Q.C.:

Q. And Dr. Cook and Dr. Parai?

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DR. KWAN:

A. I know Dr. Cook and I know Dr. Parai.

COFFEY, Q.C.:

Q. And Dr. Ejeckam as well?

DR. KWAN:

A. Yes, I do.

COFFEY, Q.C.:

Q. So looking at this memo, back to it, he opens by saying "following persistent erratic results of immunostains in our laboratory, I accepted to work closely with technical staff in order to rectify this problem. Despite the fact that the problem seems to have been arrested, the state of immunostaining at the General Hospital, Department of Laboratory Medicine pathology is still unsatisfactory" and then he goes on at some length, okay, about the physical location and so on and so forth. But he concludes, Doctor, in paragraph six, the last page, by saying "finally, it is pertinent to mention the results of immunostains are extremely important in histopathologic diagnosis, especially where classification of lymphomas and determination of benign or malignancy of certain lesions,

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for example in the prostate biopsies, depend on crisp, reliable and reproducible staining results. Diagnosis based on inappropriate immunostain will surely jeopardize patient care and may even expose the Health Care Corporation of St. John's to litigation. Therefore, it will be ill-advised to operate an unreliable and erratic immunohistochemical procedures in our laboratory." Now Doctor, were you aware of that sentiment in 2003?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. Doctor, should it have been brought to your attention?

DR. KWAN:

A. I think it should be brought to the whole hospital's attention. I mean, administrative attention, you know, I mean, more than me as a surgeon, because you're looking at diagnosing lymphoma where you don't treat and you look at a number of other diagnosis that have broad spectrum. If that's a situation, what he said, is correct there, then I think the Department of Pathologists will have, you

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know, look at it in a lot more detail. I mean, that's the only thing I can say. I don't know how to interpret what he said here, in terms of the details information that he come to that conclusion.

COFFEY, Q.C.:

Q. But if it was a genuinely held view at the time, by him, as a pathologist -

DR. KWAN:

A. At that time, and if that is confirmed by his colleagues, then yes, I think we need to -

COFFEY, Q.C.:

Q. Address it.

DR. KWAN:

A. - address it, yes.

COFFEY, Q.C.:

Q. If we could, Doctor, just looking at this exhibit, page eight of this exhibit, P-0113, Surgical Pathology Review Committee, this is dated minutes of a meeting September 23rd, 2003, and here, Doctor, of course those present are listed here and the apologies from others. Your name is not on this.

DR. KWAN:

A. I presume when I told him I can never attend

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those meetings at the time, either change it or drop me out of it.

COFFEY, Q.C.:

Q. And the time here of this meeting is 2:05 p.m. on September 23rd. That would be problematic for some one, a surgeon such as yourself attending it. Doctor, in your capacity as a surgeon on the staff of the Health Care Corporation, would you take part in Medical Advisory Committee meetings, MAC meetings?

DR. KWAN:

A. Not as a medical staff, as a clinical chief, co-clinical chief perioperative room, yes.

COFFEY, Q.C.:

Q. Okay, in that context. If we could look, please, at Exhibit P-1916? Doctor, this is an MAC meeting of June 9th, 2004. You're there, top right-hand side. See that? Your name is listed there. It begins by saying, "Ms. Patricia Pilgrim is welcome as a member of the Medical Advisory Committee in her new role of Vice-President Quality and Clinical Services," and then one, "presentation, quality and systems improvement," see that there? And then Ms. Predham and Ms.--"Heather Predham and

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Pam King Jesso were in attendance to speak on patient safety, piecing it together. The following are some of the highlights of their presentation." The first bullet is "Health Care Corporation of St. John's has identified the development of comprehensive patient safety program as a major goal, strategic plan" and there's a formation of the patient safety advisory committee, and shared some educational initiatives and measurement evaluation and finally the adoption of non-punitive reporting structure.

Now, Doctor, up until this point, June of 2004, in terms of patient safety, quality control, quality initiatives in the lab, clinical laboratory, would you have had any knowledge of those at all?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. In your own sphere, would you have had any knowledge of those in surgery?

DR. KWAN:

A. In our own surgery department, our own division of surgery, that usually falls in the

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role of the divisional chief. We have weekly meetings and go through all the patients that we have in-house and those patients that have significant complications and mortalities are reviewed and discussed by the entire staff, resident staff and nursing staff. Partially, as a day-to-day working and partially as to review trend and understanding. We have several ongoing projects, in terms of antibiotic cares (phonetic) in perioperative situations, anti-coagulations in terms of prevention DVTs. We have several projects like this ongoing as quality assurance issues within our department.

COFFEY, Q.C.:

Q. Has there ever been a point, before 2005, okay, where surgeons and pathologists routinely met?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. Okay. In St. John's, in your experience, it just didn't happen?

DR. KWAN:

A. No, sir.

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COFFEY, Q.C.:

Q. And I just use the phrase routinely met, and you've indicated that at times, you would deal with a pathologist one on one.

DR. KWAN:

A. Yeah.

COFFEY, Q.C.:

Q. But in terms of other meetings, like kind of non-routine, large scale meetings -

DR. KWAN:

A. The only time we ever meet--I ever meet with a pathologist on a formal structure is as a clinical chief and Dr. Cook, who was the clinical chief at that time, present at the clinical chief meetings and bring forth his issues to the clinical chief and explain to us, either for information or for support. That's the only formal route that I can ever remember having a formal meeting with pathologists. Now I mean, there may be other sporadic ones, but nothing scheduled.

COFFEY, Q.C.:

Q. Did any concerns about fixation or in particular ER/PR ever come up?

DR. KWAN:

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A. Not that I remember.

COFFEY, Q.C.:

Q. Exhibit P-1582? Doctor, this is a memo of June 17th, 2004 that you wrote to all surgeons at the Health Sciences site. It's about dealing with this issue of specimen without clinical history, and you say "enclosed is a memo from Dr. Ejeckam regarding pathology without adequate clinical history. This has been going on for some time with no improvement with friendly persuasions," and you tell your fellow surgeons, "the history is to be completed on the pathology requisition form before the specimen goes out of the operating room. I have also advised the OR nurses to remind all physicians to do this or the specimen will not leave the operating room unless the clinical history has been completed. Thank you for your attention." And you've attached to that, the second page of this exhibit is the memorandum that Dr. Ejeckam had written to you on June 9th, 2004, about, from his perspective, non-compliance by many physicians with regards to completing the surgical pathology request forms.

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So Doctor, having sent that memo in June of 2004 and adopted the practice that's referred to there, was that practice adopted at the time?

DR. KWAN:

A. Well, ever since then, I think that's the current practice right now.

COFFEY, Q.C.:

Q. Okay. Have you heard any complaints about it since?

DR. KWAN:

A. No. The nurses are very good in getting them doing it.

COFFEY, Q.C.:

Q. And here, Doctor, just looking at Dr.-- actually, both your--I apologize, just go back up a bit. Both your memo of June 17th is sent to Dr. Felix, copied to Dr. Felix, Dorothy Budgell, the manager of OR Health Sciences Centre, and Ms. Shirley Taylor, the manager of the OR at St. Clare's Hospital. It's a direction, I take it, from you to them. Would I be correct in that?

DR. KWAN:

A. Correct.

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COFFEY, Q.C.:
Q. And here though, Dr. Ejeckam, in his memo to yourself of June 9th had copied that to Dr. Williams, Dr. Cook and Dr. Felix, your counterpart. So Doctor, in relation then to June 2004, the idea of sending around a memo or somebody such as Dr. Ejeckam sending a memo, not only to yourself but copying it to the VP Medical, to the clinical chief, Dr. Cook, and to your counterpart, Dr. Felix, that sort of practice certainly existed by '04 and -
DR. KWAN:
A. If there was any important issue like this, there will--I mean, issues, they send us a note or talk to us.
COFFEY, Q.C.:
Q. If we could look, please, at Exhibit P-0021, page 15, when it comes up? Doctor, these are the MAC minutes of a meeting of March 16th, 2005. You'll see that you're there, right there.
DR. KWAN:
A. Um-hm.
COFFEY, Q.C.:

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Q. Want to go to page 21 of the exhibit, and additions to the agenda, policy on disclosure.
DR. KWAN:
A. Um-hm.
COFFEY, Q.C.:
Q. And it says "the draft policy on disclosure was distributed and discussed at a clinical chief's meeting on September 28th, 2004. Detailed discussion was held with Dr. Claude Martin, who's in charge of risk management at CMPA, and Mr. Peter Browne, during a presentation to clinical chiefs. We are currently waiting for the Newfoundland Medical Board's draft policy to ensure that the two policies are consistent. Once we have completed the policy for the Health Sciences Centre, then it will be forwarded to members of the medical staff. Clinical chiefs will be charged with ensuring that all physicians in their programs are made aware of the implications."
So Doctor, I take it then that as of March 2005, going back into 2004, there was discussion at the MAC level about adopting a disclosure policy concerning adverse events,

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and it would involve physicians?
DR. KWAN:
A. It was a document, yeah.
COFFEY, Q.C.:
Q. And that had been talked about for some period of time before March -
DR. KWAN:
A. Well, this is--yeah, this applies to the entire hospital for all the events that can happen.
COFFEY, Q.C.:
Q. If you'd look--just go ahead, Doctor, to page 23 of the same exhibit, P-0021, the minutes of the next meeting, April--or a meeting of April 13th, 2005. Again, you're there, right there, where the cursor is. Business arising, patient disclosure policy, and again, there's a fairly detailed discussion, I take it, or at least a summary of what was discussed here at the time, about how they were moving ahead with this, and it concludes, Doctor, by saying "it was felt that the principles are the same in both policies," because they talked about two different policies, the Health Sciences versus the Medical--the Health Care

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Corporation's versus the Newfoundland Medical Board's, which is specific to physicians. "It was felt that the principles are the same in both policies and that both policies support the right of the patients to have information supplied on a timely basis." So as of April 13th, 2005, Doctor, at the MAC level, was it generally accepted that that was so, what's stated here in that last sentence? Do you think so?
DR. KWAN:
A. I can't recall any reason why it shouldn't be. I mean, you know, at the time, it's something that came up in discussions and I don't know.
COFFEY, Q.C.:
Q. Now Doctor, I'm going to ask you then, when you first heard of the ER/PR problem that's brought us here today, when did you first hear of this?
DR. KWAN:
A. July 2005, I think.
COFFEY, Q.C.:
Q. And who from and in what context, Doctor?
DR. KWAN:
A. Dr. Williams kind of informally talked to me

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and said that we have, you know, this and he was going to call a meeting, would I mind coming.

COFFEY, Q.C.:

Q. What did he tell you?

DR. KWAN:

A. I mean, I didn't know much until when I got to the meeting and they tell us that there were a sentinel case and there has been a number of--that they have the ER and PR has been altered or changed, as been repeated elsewhere and changed. I can't remember exactly what the details were, and at that time, only a small group of patients has been--numbers have been returned, so there has been an issue and how big the issue was, none of us know at that time.

COFFEY, Q.C.:

Q. Exhibit P-0925?

DR. KWAN:

A. P-0925.

COFFEY, Q.C.:

Q. Yes, it'll come up in a second, Doctor.

DR. KWAN:

A. Oh, I'm sorry.

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COFFEY, Q.C.:

Q. No, no, that's fine, Doctor. I'm just asking the Registrar.

DR. KWAN:

A. Okay.

COFFEY, Q.C.:

Q. Page three, please. Doctor, this is typed version of handwritten notes of Dr. Williams. He kept notes and he was kind enough to have them transcribed into typing for us. July 14th, 2005 at five p.m. There's a number of attendees at this meeting, Doctors McCarthy, Laing, Felix, Cook, Gardiner, yourself, Ms. Predham, Ms. Bonnell, Ms. Thomas and Dr. Williams, and there's a general background given by Dr. Williams. Specific overview by Dr. Cook. Issue of results specifically in 2002, change in '97 to immunoperoxidase testing, semi-automated, switched to Ventana late March, early April, 2004. Started January 2004 training, etcetera. And then there are a number of remarks attributed to Dr. Laing here, whether she made them or not, I can't say, but here they attribute to Dr. Laing, "new information, lobular carcinomas

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should all be ER/PR positive. At Sloan-Kettering went from"--well, this says 75 to 100 percent positive. There's some debate about whether it should have been 95 to 100 percent, but it went from something to 100. Everybody has agreed on that. "Dr. Laing requested retesting and a strongly positive result. As a result, asked to retest some patients. Followed up on a lot of patients from 2002. 16 out of 25 on retesting are positive. Doing another 38 patients in a process, farm out testing outside the province. Dr. Cook to get info on who to follow up."

Doctor, is that the meeting you're talking about, the first meeting?

DR. KWAN:

A. That's the--I can't say for sure, but that sounds the right time.

COFFEY, Q.C.:

Q. Doctor, there's reference to "lobular carcinomas should all be ER/PR positive."

DR. KWAN:

A. That's new information at that time, because prior to that, we were not aware. Literature

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had not really covered that in that extent, but literature came out that suggested these all should be positive.

COFFEY, Q.C.:

Q. Doctor, ask you to kind of cast your mind back, if you can, to the meeting, okay. For you, at the time, any such assertion would have been new? The assertion that lobular carcinomas should all be ER/PR positive, in your experience, that would have been new?

DR. KWAN:

A. That would have been new to me at that time, yes.

COFFEY, Q.C.:

Q. Do you recall who said that at the time?

DR. KWAN:

A. No, I can't really. It just came out at that time, that kind of actually new information and I don't know whether this was, at that time, whether because there was a change of percentage that called it positive and lobular fall into the categories become now positive or for some unknown reason, lobular cancer have changed over the years. I don't really have a good grasp on that.

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COFFEY, Q.C.:
Q. There is a reference here to Sloan-Kettering.
DR. KWAN:
A. Yeah.
COFFEY, Q.C.:
Q. And of course, you had trained decades before at Sloan-Kettering.
DR. KWAN:
A. Um-hm.
COFFEY, Q.C.:
Q. Do you recall Sloan-Kettering being mentioned at the meeting?
DR. KWAN:
A. I'm sorry?
COFFEY, Q.C.:
Q. Do you recall during that meeting Sloan-Kettering -
DR. KWAN:
A. Yes, I remember Sloan-Kettering because I think, if I remember right, the sentinel case went to Sloan-Kettering.
COFFEY, Q.C.:
Q. That was your understanding?
DR. KWAN:
A. That's my understanding at that time.

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COFFEY, Q.C.:
Q. Do you recall what your understanding was about--what do you mean by the case went to Sloan-Kettering?
DR. KWAN:
A. I think a second opinion.
COFFEY, Q.C.:
Q. Okay, somebody had asked Sloan-Kettering for an opinion?
DR. KWAN:
A. Asked for a second opinion somewhere. I don't know the details of it. A second opinion was requested from Sloan-Kettering.
COFFEY, Q.C.:
Q. Do you recall anything else being talked about at Sloan-Kettering or about Sloan-Kettering?
DR. KWAN:
A. The only thing I can vaguely remember is that the 75 or 70 percent had been bat around because after number of percentage of positivity and tried to look at our own laboratory, whether the percentage of our positive, ER/PR positive, is at any sort of gauge of how accurate we are. You know, if other laboratories are in the same ballpark as

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we are, maybe we're not too far.
COFFEY, Q.C.:
Q. That would be positivity rates overall?
DR. KWAN:
A. Yeah, right. If you take 100 people and their determinations, if everybody gets 70 percent and we get 70 percent, well, okay, well maybe we're not too far off. But on the other hand, we don't know that. That was just some of the very vague things that we're looking at.
COFFEY, Q.C.:
Q. Doctor, do you know Dr. Bev Carter?
DR. KWAN:
A. Yes, I do.
COFFEY, Q.C.:
Q. We have seen a memo that she wrote to Dr. Cook. It's dated July 14th, 2005, okay, and it proposes a large, very large scale review, okay, and I'll just tell you that, okay, of all breast cancers, ER and PR results, positive and negatives, going back to 1997, up until 2004. I mean, that's what she lays out as a suggestion or an approach that she wants to adopt. Do you ever recall that coming up?
DR. KWAN:

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A. No, sir.
COFFEY, Q.C.:
Q. Until I just told you now?
DR. KWAN:
A. Correct, the first time I heard of it.
COFFEY, Q.C.:
Q. Okay. So Doctor, in terms of what you learned about what the laboratory was doing concerning to investigate this, you learned through these meetings?
DR. KWAN:
A. Correct.
COFFEY, Q.C.:
Q. That would be the way you would be kept apprised of it?
DR. KWAN:
A. Correct.
COFFEY, Q.C.:
Q. Here, there's a reference to--and we're just looking at it there. It say 16 of 25 on retesting are positive. It's said in the context that they've looked at a lot of follow up and a lot of patients from 2002.
DR. KWAN:
A. I would interpret that 25 specimens was sent.

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They were all ER negative and 16 converted to positive. That's how I would interpret it.

COFFEY, Q.C.:

Q. Sure, and that's in fact how everyone here has said what it meant.

DR. KWAN:

A. Okay.

COFFEY, Q.C.:

Q. And they were doing another 38 at the time.

DR. KWAN:

A. Correct.

COFFEY, Q.C.:

Q. Doctor, as a surgeon who'd been treating patients over the years, in fact, going--you would have treated patients in 2002, what was your reaction to that?

DR. KWAN:

A. Concerned.

COFFEY, Q.C.:

Q. And for what reason?

DR. KWAN:

A. Well, I mean, they are--any laboratory, any results wrong, whether some patients should have been treated or should not have been treated. Not all patients that are positive

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will require treatment, but on the other hand, one's will be concerned those patients should have got treatment and didn't.

COFFEY, Q.C.:

Q. Doctor, at the time then, leaving the meeting that day--well, first of all, did you contribute anything to the meeting yourself?

DR. KWAN:

A. Not really. I was there for information and try to absorb to myself what the problem is and how magnitude the problem.

COFFEY, Q.C.:

Q. And leaving the meeting, you understood whose responsibility was it to address the problem, investigate it further?

DR. KWAN:

A. I really can't remember, but on the other hand, we thought that the laboratory would be responsible sending more specimens out to try to delineate how long a period of time that we have and what is the scope of the problems that we are facing, and try to find out, at that very early stage of the game, what is the--where can we find out quickly what the problems are. That could be a number of

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facet, number of issues that could be account for it.

COFFEY, Q.C.:

Q. And your understanding, did--at the time, were you given any understanding, at that time, as to what might be the cause or causes?

DR. KWAN:

A. Well, I think, we were--I think in a subsequent meeting more likely to be is bounding around--I thought about whether this is a test itself, whether it is the technologists? Is it switching of the machines? All these things have to be looked at as a preliminary before we come up to anything more details.

COFFEY, Q.C.:

Q. Doctor, the 25 that had been retested, you understood, as of July 14th, they were retested where? What was your understanding when you first -

DR. KWAN:

A. I can't remember. I think it was Mount--I don't know, Mount Sinai or not. We had to look for other places to retest those patients--if I remember, on the second

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meeting, I think it come up where we have to look for a place to do it.

COFFEY, Q.C.:

Q. And that comes up in a meeting I'm going to refer you to now, but initially when you first showed up, did you have any understanding where the tests -

DR. KWAN:

A. No, I can't - it was sent away is all I can remember.

COFFEY, Q.C.:

Q. Exhibit - same exhibit, Doctor, page eight, 925, page eight. Again these are Dr. Williams' typed notes. Your name is there. It's a meeting of July 24th, 2005. This time Mr. Tilley is there, Dr. Gardiner, Dr. Laing, Cook, Gulliver, Ms. Bonnell, yourself, Ms. Predham, Ms. Thomas, Dan Boone, and Dr. Williams. Now, Doctor, you would have understood Mr. Boone is who?

DR. KWAN:

A. I don't know at that time. I would assume later he was a solicitor of some sort, legal professions.

COFFEY, Q.C.:

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Q. And he first posed an update on the current status and what we know from other centres, and then testing for patients for 2002, 16 of 24, 25 of 32, 22 or 23 to come, which would be the conversions at the time, 16 out of 24, 25 out of 32.

DR. KWAN:

A. Uh-hm.

COFFEY, Q.C.:

Q. "There may be a problem with methodology or with the lab" and it goes on, "Dr. Laing not worried about the weakly positives. Dr. Laing wants to be sure the new system is accurate and not overly sensitive. Working with Mount Sinai and quality control. Should we test the repeats against the Ventana System. Dr. Laing is databased to capture various types of breast cancers with ER/PR results. Need to wait until we know that our results are valid. Controls are run every day on ER/PR. Pathologist reporting is an issue. Dr. Kwan will need more info. He feels happier at this meeting that a large percentage due to technological change duplicate positive conversions before we report. Get database of

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patients retested. Need to check new Ventana System out. Take some of our conversions and send to Montreal General to confirm our results, and need more information, systematic information". The comment attributed to you is right here. What do you recall then, Doctor, about this, about the meeting over all and what's attributed to you?

DR. KWAN:

A. Well, I mean, I can vaguely remember, such a long time ago now, that we are thinking that we have a problem, and I thought that somebody in the meeting said, well, this is probably due to technology changes we have at that time, and if you happy with technology changing, correct that, but if it's something more complex, it will be more difficult to correct, and that's probably what I'm referring to. At least I was at that time given the impression that it may be technological change that we have within the laboratory, but I may be wrong. That was the impression at that time. I don't know what duplicate positive conversion means from Dr. Williams' writing. So I really don't know

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what that--and we need database for all the patients that we have retested.

COFFEY, Q.C.:

Q. So, Doctor, I take it then that the impression you had apparently voiced at the time, or at least Dr. Williams indicates you voiced at the time was - well, first of all, you wanted more information?

DR. KWAN:

A. Yes.

COFFEY, Q.C.:

Q. What sorts of other information would you have wanted?

DR. KWAN:

A. It's hard for me to recall so long ago information. I just wanted to know how good Ventana Systems are compared to Ventana System to other institution that similar size, similar testing, what are the negative and positive results from the other places, and are the other places using the same system to have the same problems. That would be gist of it, if I can vaguely remember.

COFFEY, Q.C.:

Q. Doctor, the idea that "you would feel happier

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at this meeting that a large percentage due to technological change", does that relate to the idea that, well, look, sometimes newer equipment is just better at doing it?

DR. KWAN:

A. Well, it may be, and I think that change in technology - you have new equipment doing things different, and now you get better results than we had before. Maybe Mount Sinai have much better equipment than we have, those I don't know. I mean, and it seems to me that was some sort of topic of that, and if that's so, that is easy to correct.

COFFEY, Q.C.:

Q. Doctor, in the scenario, did anyone tell you that Mount Sinai was using a DAKO machine like the General Hospital used to use back between '97 and '02?

DR. KWAN:

A. That had been mentioned somewhere along the line. That's why we were somewhat concerned about whether Ventana - obvious technical, which I know very little about, but get people's - you know, try to lead me through that. That would be the reason why I thought,

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okay, if it is a technological change and not issue related to how we do business, maybe it is easy to correct.

COFFEY, Q.C.:

Q. Doctor, the next page of the exhibit is page nine. This is a conference call, July 27th, 2005, 5 p.m. and a number of attendees, a longer list, I believe, this time. You're there as a participant, and then there's an "overview of our data, average 73 percent. Dr. Cook gave results of discussion with Dr. Walters in Montreal. They will stain, but send back here for interpretation. Halifax, no info on tested ER/PR. Sloan-Kettering, no information. Mayo Clinic don't know their rates, no gold standard, worried re: this issue, and then a decision to share new information as soon as possible when it becomes available, meet on a regular basis". Doctor, do you recall this meeting?

DR. KWAN:

A. This is a telephone call. It's even worse to remember a telephone call than you remember meetings. The only thing I can tell you is that it goes back to what I say, you're

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looking at a percentage of 73 percent positive rate. We estimated at that time our rate was around 70 percent. Then they gave us this number of 73 percent of tests were positive. Dr. Cook is try to get other hospitals percentage of positive, and get some relative information as to compare us to, and I think that is what he's reporting, we don't have any information on those areas.

COFFEY, Q.C.:

Q. If we could look, please, at Exhibit P-548. Doctor, page two of this--these are George Tilley's handwritten notes, and they're dated August 1, 2005, for a meeting of Donald Cook, Terry Gulliver, Barry Dyer, Bev Carter, Kara Laing, Bob Williams, Susan Bonnell, George Tilley, Pat Pilgrim, Heather Predham, Joy McCarthy and Alan Kwan. Do you recall attending a meeting on August 1st, 2005?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. This would be a meeting where the Commissioner has heard evidence, okay, of--in fact, Dr. Carter has told the Commissioner that there

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was a verbal exchange between her, a very sharp verbal exchange between her and Mr. Gulliver, and if you were there -

DR. KWAN:

A. If I was there, I would remember that, but I don't remember having a meeting - I don't even know what it - the only meeting that I've been in to are usually the administration at the Health Science and I don't think I've been to any other meetings.

COFFEY, Q.C.:

Q. So listing your name here doesn't necessarily, of course, mean that you were there, but you don't recall the -

DR. KWAN:

A. I really seriously don't remember that I was at a meeting where there is sharp exchanges between Bev Carter - I don't even remember being present at a meeting between Bev Carter and administrative meetings. I remember having meeting with at the panel, but not there.

COFFEY, Q.C.:

Q. Doctor, I'm going to ask you then, Doctor, up to this point - up to that point which is the

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meeting that we had just looked at - go back to - I'm going to go back in a moment to P-925, but in the meantime, if I could look, please, at Exhibit P-3085. Doctor, this is a letter from Dr. Cook to yourself, July 18th, 2005, The patient's name and information is redacted, but he writes, "This patient has been previously reported as estrogen receptor and progesterone receptor negative. Repeat testing on the Ventana Benchmark System indicates positive results for both estrogen and progesterone receptors", okay. Doctor, do you recall receiving this?

DR. KWAN:

A. I probably did, but without a name, it's not possible for me to verify that. I mean, it's addressed to me, and I probably did.

COFFEY, Q.C.:

Q. And, Doctor, this is July 18th - if we could then bring up 925 again, please. 925, please I apologize. Thank you. Go back to page three of it, it's July 14th, the first meeting, and you're listed as an attendee.

DR. KWAN:

A. Right.

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COFFEY, Q.C.:
Q. So four days later, it's a letter at least dated four days later.
DR. KWAN:
A. Uh-hm.
COFFEY, Q.C.:
Q. Referring to a patient whose ER/PR results went from negative to positive, and then on the--look at page eight of the exhibit, by July 24th, again you're at a meeting, a larger meeting with a number of individuals. I took you through that. I apologize, on July 27th, this conference call.
DR. KWAN:
A. Uh-hm.
COFFEY, Q.C.:
Q. Which you are indicated to have participated in. Would this then, looking at 3085, would that be the first patient you would have been asked to deal with, 3085, because it's just because of the time frame?
DR. KWAN:
A. I would assume this was--in this letter he said repeating test on Ventana Benchmark System. Does that mean they would send it out

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or was it did ourself?
COFFEY, Q.C.:
Q. Ventana was being done locally.
DR. KWAN:
A. Locally. So, I mean, I just assumed that there was a change they did locally - I was looking at this and there was a change. Now, I may have heard back then, as you know, there are problems, so it didn't came as a surprise to me when it come that.
COFFEY, Q.C.:
Q. As a surgeon at the time in the middle of July, 2005, what, if anything - you had understood, I take it, that this was being sent to you by Dr. Cook because he expected you to do something?
DR. KWAN:
A. I would suspect he notify me and I would have to take actions if I think it is appropriate. I wouldn't--you know, getting something like that, I would first take out the patient's chart and find out what's happening and what's exactly going on with that particular patient.
COFFEY, Q.C.:
Q. Doctor, then - up then to the end of July,

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2005, you had attended a number of meetings?
DR. KWAN:
A. Yes.
COFFEY, Q.C.:
Q. We looked at them.
DR. KWAN:
A. Right.
COFFEY, Q.C.:
Q. There were three of them, attended two, and may have been on the phone with one.
DR. KWAN:
A. That's true.
COFFEY, Q.C.:
Q. What was your understanding of why you were there at all?
DR. KWAN:
A. I presume it's my involvement in breast cancer management over the years, my interest in the progesterone and estrogen receptors back in the 70s, good friend of Bob Williams, and have spoken to him in cancer care deliveries in system, being the previous director at the Cancer Clinic, and Dr. Carter was there as the Director of the Cancer Clinic at that time. I don't really know, you'll have to ask Dr.

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Williams that, but presumably that's -
COFFEY, Q.C.:
Q. I appreciate why from his perspective why he asked you. I mean, we can ask him that, but I'm asking about - you were asked to attend, you did attend, and I'm just asking you to, as best you can, tell the Commissioner what your understanding was at the time of the role that you were expected to play, what you were bringing?
DR. KWAN:
A. My experience as a surgeon and experience in previous treatment of breast cancer, in general. It may not be specifically estrogen receptor or chemotherapy, but certainly in general.
COFFEY, Q.C.:
Q. Now, Doctor, looking at this Exhibit 3085 that's on the screen there, on July 18th, or whatever day after that you would have received this, you've indicated that - well, the first thing you'd do is get out the patient's chart and see what the status of the patient is at that point in time, okay. As the recipient of that letter, would you have

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understood that you were expected to notify the patient about the change in result?

DR. KWAN:

A. I would look at the situation and who's on the care of the patient at that time. I may not have seen this patient for God knows how long. What I would do is find that out, and who is looking after the patient, and transfer the information to the individual who is looking after that patient, or if the patient have received appropriate treatment, this thing has not become an issue, then would just notify them they have no treatment change, or at least in my opinion there is no treatment change, or - but whatever the local condition and situation of the patient and take it from there, you know. It's hard to really second guess or predict or make plans without not knowing more details.

COFFEY, Q.C.:

Q. Sure, and I appreciate--what I'm getting at, Doctor, is this, as the recipient of this, did you understand that you, or someone on your behalf, was supposed to let the patient know about the change?

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DR. KWAN:

A. Right.

COFFEY, Q.C.:

Q. So it was -

DR. KWAN:

A. I would find out the situation and talk to them.

COFFEY, Q.C.:

Q. So the notion of not telling the patient at that point -

DR. KWAN:

A. No.

COFFEY, Q.C.:

Q. Would that have crossed your mind at all?

DR. KWAN:

A. No, I would--I mean, sometimes these patients I haven't seen for a number of times, so I would get whoever to do that.

COFFEY, Q.C.:

Q. And I appreciate there might be a problem tracking the patient down and getting in contact with them and so on. I understand that, and the Commissioner would certainly understand that too, but from your own perspective, receiving such a letter about a

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change in status from the clinical chief of laboratory medicine -

DR. KWAN:

A. Well, the first important thing is to find out if the patients need any treatment altered.

COFFEY, Q.C.:

Q. Yes, and whether they need it altered or not, would you still tell the patient about the change?

DR. KWAN:

A. Tell the patients the changes, yes.

COFFEY, Q.C.:

Q. Okay.

THE COMMISSIONER:

Q. Excuse me, Mr. Coffey, but once again it's one of those while it's in my head, Dr. Kwan, you seem to have become part of a group of individuals who met on a greater or lesser regular basis. Did you look at yourself as being part of a group who were performing a role, or how did you view these meetings?

DR. KWAN:

A. I personally look at it as a resource person at that time.

THE COMMISSIONER:

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Q. Uh-hm.

DR. KWAN:

A. You know, I don't look at myself as a significant expert in estrogen receptor determination, not after 30 years when I haven't done it myself, and immunohistochemistry straining which I'm no longer - I have never been an expert. So I look at myself as a resource person in terms of breast cancer as cancer management. That would be what my assumed role was when I look at it then.

THE COMMISSIONER:

Q. And did you see yourself as being part of a group with perhaps other people with other things to contribute or - I just -

DR. KWAN:

A. Yeah, everybody -

THE COMMISSIONER:

Q. Somebody was calling meetings from time to time and there seemed to be people who were turning up at just about every meeting, so after a while, did you figure that you were part of the group that were dealing with the ER/PR?

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DR. KWAN:
A. I personally need information. That would be my personal - I need variable source that I can get information for myself, what's happening.
THE COMMISSIONER:
Q. Uh-hm.
DR. KWAN:
A. And often - and what I think the overall, and like any practising physician, like, Dr. Felix was there, and Dr. Gardiner, so other people offering their resources as the resource person.
THE COMMISSIONER:
Q. So this was a two way thing from your perspective. Am I reading it right?
DR. KWAN:
A. Correct.
THE COMMISSIONER:
Q. You might be a resource person to Dr. Williams and others who might be seeking your perspective based on your experience, but by the same token, you wanted information?
DR. KWAN:
A. Correct, I wanted information as what is

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happening.
THE COMMISSIONER:
Q. What was happening and to figure out the impact presumably on your own patients?
DR. KWAN:
A. Correct.
THE COMMISSIONER:
Q. Okay. Mr. Coffey, it's getting about break time, in any event, so wherever you can find a place to break.
COFFEY, Q.C.:
Q. While I'm on the point of your role, Doctor, if we could bring up Exhibit P-0544. Doctor, this is an e-mail from Sharon Hopkins, August 3rd, 2005, to Dr. Cook and Ms. Predham. The subject is notes, meeting with Kwan/Williams, and she writes, "Dr. Williams asked that I forward these notes for your info", and then on page two of the exhibit is a typed account of a meeting between yourself and Dr. Williams, August 2nd, 2005, and there are 11 topics here listed. It says, "Send out critical test a.s.a.p. when identified. Do everything to get our Ventana System up to par so we can do the test here reliably; get

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standard samples up and running so that we can have tests certified as accurate; three, extrapolate change over all the patients; four, monitor our results continuously with an outside lab; five, how do other centres report for pathology, do they report on controls; six, need to have outside review of the ER/PR reception testing - need to look at whole immunohistochemistry system; seven, need to consult with all the pathologists in the organization, Dr. Cook has already done; eight, Dr. Kwan feels we should send out information to patients whose test results change; nine, schedule extra clinics for oncologists to see patients; ten, meet with oncologists; eleven, breast tumours are multi-clonal". Doctor, do you recall this meeting?
DR. KWAN:
A. Yes, vaguely. This is a meeting that actually come up after I went to see Dr. Williams for another different issue, and at the end of the meeting which I see him the issue was very short, and he sat me down and said, look, you know, let's talk about something else, and that's what happened, and I didn't realize

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take notes.
COFFEY, Q.C.:
Q. And here you are today.
DR. KWAN:
A. Uh-hm..
COFFEY, Q.C.:
Q. Doctor, can you tell the Commissioner, please, then looking at this, "Send out critical test a.s.a.p. when identified", I take it that's the notion of tests that readily apparent, that it could have an acute effect on the patient?
DR. KWAN:
A. Well, that's critical test, I would presume it is remember, apply to patients on treatment, you know, ongoing treatments, and probably should have it tested quickly so that if they need to be changed, we--you know, so we can have those information back.
COFFEY, Q.C.:
Q. And "do everything to get our Ventana test up".
DR. KWAN:
A. We still had faith at that time.
COFFEY, Q.C.:

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Q. In fact, because - did you understand, Doctor, that in the meantime, that Ventana machine was being used for all other IHC except ER/PR?
DR. KWAN:
A. No.
COFFEY, Q.C.:
Q. Did you have any understanding on that?
DR. KWAN:
A. No, I didn't.
COFFEY, Q.C.:
Q. What did you understand then about the Ventana machine?
DR. KWAN:
A. I know nothing about it except it's a commercial available machine to do all the stuff for us.
COFFEY, Q.C.:
Q. And "Extrapolate change over all the patients", do you know what that's about, Doctor?
DR. KWAN:
A. I don't know.
COFFEY, Q.C.:
Q. "Monitor results continuously with an outside lab. How do other centres report for

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pathology, do they report on controls?" Did that come up?
DR. KWAN:
A. I think that's because some discussions in one of the meetings that whether you can--you probably picked it up in one of the pathology or some say they are controls are positive, other didn't mention any controls at all.
COFFEY, Q.C.:
Q. Yes.
DR. KWAN:
A. So that was picked up at the time and I think that we should report controls and see what other laboratories does report controls or not.
COFFEY, Q.C.:
Q. So you thought that they should -
DR. KWAN:
A. You know, I thought the controls should be reported, but then we don't know whether other laboratories do that, because I'm not a pathologist, I'm not, you know, reporting those things, so I needed--I suggested, well, we check other laboratories, whether they are reporting that or not.

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COFFEY, Q.C.:
Q. Before this arose in July of 2005 had you ever noticed that sometimes some pathology reports would refer to controls and sometimes they wouldn't?
DR. KWAN:
A. I didn't pay attention to that.
COFFEY, Q.C.:
Q. Pay attention. When it came up in July of 2005 you decided it should be -
DR. KWAN:
A. The subsequently you start paying attention to those things, yes.
COFFEY, Q.C.:
Q. And "Need to have outside review of ER/PR reception testing. Need to look at whole immunohistochemistry system." The idea of looking at the whole system, was that your -
DR. KWAN:
A. No, I think it's Dr. Williams, but he probably know more about the immuno system than I do at that time or know more of the inside of it than I do.
COFFEY, Q.C.:
Q. And "Dr. Kwan feels we should send out

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information to patients whose test results change." So did you express that to him at the time?
DR. KWAN:
A. I mean, he said it that way, presumably I have.
COFFEY, Q.C.:
Q. What was your feeling at the time on that, Doctor? This is August 2nd, 2005.
DR. KWAN:
A. My feeling, an overall feeling of the situation is, yes, they should be informed like everybody who had--I also have the feelings that to tell the patient that your test change and not to be able to tell them what can be done about those test changes is another issue that we had to grapple with and to have to understand. If I tell somebody that "Your test changed" now and you ask me, of course the next question they will ask me as a physician is that "How does that affect me?" And now answer is "I don't know," which is little bit difficult. And "How long do I know?" I say, "I don't know" again. "How long does it take you to find out?" I say, "I

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don't know" again. That would be a little difficult in, to the patients. I'm not saying they should be sent--the information be told, but on the other hand we should make preparation to find out whether we could or could not be able to--what can be changed or can be done from the physician's standpoint, from medical treatment standpoints.

COFFEY, Q.C.:

Q. "Schedule extra clinics for oncologists to see the patients."

DR. KWAN:

A. That's comes after because I figure that with that we don't have any regular route of explaining to patients, patient will need to--will want to see somebody very quickly.

COFFEY, Q.C.:

Q. Yes.

DR. KWAN:

A. That would be that's what follows on that. Because at that time we have not make any decision of how to address the issue. It's just a question that I felt that these patients need to be at least to be advised at what medical treatment can remedy the change

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or is there--how that going to impact or affect them.

COFFEY, Q.C.:

Q. So at that point in time it was thought or the approach would be that the patients would see individual oncologists to be dealt -

DR. KWAN:

A. That was, well, we just thought that, you know, we thought that if that happen, it will--they will need more time and we--that they are all tied up doing all kinds of treatment at the moment and that was the thought.

COFFEY, Q.C.:

Q. The idea of scheduling extra clinics for oncologists?

DR. KWAN:

A. To see those patients, if necessary. We still have to do that.

COFFEY, Q.C.:

Q. Now, Doctor, at that point, August 2nd, 2005, did you have any understanding at the time that there would probably be a lot of patients that would have to be re-seen?

DR. KWAN:

A. From what we know of the 40 conversion rate,

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what it is, you can sort of mentally figure out that should be a significant number.

COFFEY, Q.C.:

Q. And now the 40 percent, of course, hadn't been arrived at by then, but you had seen 16 to 25?

DR. KWAN:

A. We seen two batches.

COFFEY, Q.C.:

Q. And 25 out of 32 are, roughly?

DR. KWAN:

A. Two batches.

COFFEY, Q.C.:

Q. So if that was consistent into the future, there were going to be an awful lot of patients?

DR. KWAN:

A. Correct. That was the concern.

COFFEY, Q.C.:

Q. And then the reference to "Meet with oncologists"?

DR. KWAN:

A. That's Dr. Williams.

COFFEY, Q.C.:

Q. Dr. Williams. And the "breast tumours are multiclone" is that your -

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DR. KWAN:

A. I think it's trying to explain to Dr. Williams why somebody is negative and why somebody is positive, why the percentages like, it's more, you know, try to explain to how to interpret them.

COFFEY, Q.C.:

Q. In fact, you had some familiarity with that because you had been involved research going all the way back to the '70s?

DR. KWAN:

A. That's a long time ago.

COFFEY, Q.C.:

Q. Yes. But you did have some basic understanding of it more so than perhaps many surgeons would?

DR. KWAN:

A. Probably.

COFFEY, Q.C.:

Q. Yeah. Commissioner, thank you.

THE COMMISSIONER:

Q. We'll take 15 minutes.

(RECESS)

THE COMMISSIONER:

Q. Mr. Coffey?

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COFFEY, Q.C.:
Q. Thank you, Commissioner. Registrar, could you bring up, please, Exhibit P-1287? Doctor, just looking at the second page of this, it's a memo of Dr. Khalifa to all Newfoundland pathologists, February 16th, 1998. The reference is "Reporting of estrogen and progesterone receptor immunohistochemical results." And this is a memo where Dr. Khalifa advises pathologists throughout Newfoundland about kind of the history of his introduction of IHC, ER/PR, the process that he's followed. And he refers to "We will be now ready to move into the next two and final phases. Phase 2 will be each pathologist will be asked to report results of his or her own case as indicated by the brown staining of nuclei of the invasive neoplastic cells and that will start March 1, '98." And he then--attached, he continues on with saying, "Attached please find a proposal for uniform reporting of ER/PR immunohistochemical staining. This proposal was discussed with many of my colleagues, who mostly agreed with its content and accepted it as a policy. As I

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encourage you to adopt the attached proposal in your reporting to maintain uniformity, it should be clearly stated that this is only a proposal." He talks about there are a lot of publications available to be consulted. And then in the fourth page of the exhibit, third page of his memo, "Proposal for uniformed reporting of ER/PR immunohistochemical assessment. February, 1998." He talks about "The report of a hormone receptor status will have three components. The first component, a statement of whether the stain is positive or negative. Positivity is defined by nuclear staining detected in any number of malignant cells. The second component is a rough estimate of the percentage of the immuno reactive cells in the section examined. This estimate could be a form of a range or a fixed number, as listed in parenthesis. And a third component is a comment regarding only ER and not PR immuno reactivity and is only to be included if, in the report of a small percentage of neoplastic cells from one to thirty percent is positive." And he's got the comment there and he's got two different

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examples. Now, Doctor, would you have seen that memo back in 1998?
DR. KWAN:
A. No, sir.
COFFEY, Q.C.:
Q. You wouldn't. This is the point where he's moving from, the whole system is moving from the biochemical reporting. And you would have been familiar with the way the biochemistry reported?
DR. KWAN:
A. Correct.
COFFEY, Q.C.:
Q. Their testing, to IHC testing for ER/PR. As a surgeon in St. John's at the time, this being early in, well, '97 into 1998, because Dr. Khalifa had been in the meantime reporting cases himself individually, how did you know or how did you approach how you would then interpret these new sorts of reports compared to the biochemical, which is a different--uses a different numbering system entirely?
DR. KWAN:
A. This will be things that I interpret from him is that they will be interpreting with these

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positive, negatives, and report it to us as positive or negative. It's not--because I don't look at the slides so I would not be able to make any judgment as to positive, negativities and they will be reporting this as positive or negative to us and we will take their interpretations.
COFFEY, Q.C.:
Q. And the percentage, what if any significance did that have at that time?
DR. KWAN:
A. Well, I would think that I would leave it that, as I say, they would be either positive, they interpret the literature at that time, what the pathological--what the pathology literature would suggest which is positive or negative and they will have to, they would interpret that for us. You know, they could, at most times it would be 30 percent or ten percent or whatever the literature changes and depending on the techniques or the staining they do. And as I say, I think that they will be interpreted that.
COFFEY, Q.C.:
Q. Did the percentage have any significance to

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you?
DR. KWAN:
A. Means very little. If the report is a positive, I will take the, you know, their interpretation for it because they have the better expertise in that than I do.
THE COMMISSIONER:
Q. Dr. Kwan, I just want to make sure I understood the point you were making. And I take you to be saying that in respect of ER/PR testing, you rely on the pathologist to consult the literature and determine what percentage is positive or negative, given the literature of the moment?
DR. KWAN:
A. Correct.
THE COMMISSIONER:
Q. And that as the treating physician during the period of time when you would have been the treating physician, I recognize that now this information probably goes on to a medical oncologist rather than to you?
DR. KWAN:
A. Probably 1970--1998, at that time I probably won't be treating most of the patients by

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then.
THE COMMISSIONER:
Q. Okay. This transfer of patients into the oncologists would have started prior to -
DR. KWAN:
A. It started prior to that. As the number of medical oncologists increases, as I--if I remember right, since I leave--since I ceased being the director at the cancer clinic at that time, I don't go back to treat chemotherapy very much more and as number of medical oncology increases and I transfer most of those responsibilities to them.
THE COMMISSIONER:
Q. Okay. And that the ceasing to be the director of the cancer clinic was again when?
DR. KWAN:
A. It was 1992.
THE COMMISSIONER:
Q. '92.
DR. KWAN:
A. I mean, it's not immediately I ceased to do so, but as it progresses over the next several years.
THE COMMISSIONER:

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Q. Thank you.
COFFEY, Q.C.:
Q. Now, Doctor, we have seen, we've seen many pathology reports here, redacted versions, but we've seen many of them. Some of them did have or did adopt the approach that Dr. Khalifa advocated, which is to give a number for ER, percentage number or a range for percentages for ER and for PR and include this comment that's right there. Now, at the time if, say in 1998 or 1999, if you got a report saying 20 percent, for example, here, or use example two, "Estrogen receptors positive, one to five percent of cells. Please see comment. Progesterone receptors, negative, zero percent of cells." and saw that comment, how did you, at the time interpret this as to the status?
DR. KWAN:
A. If this one I would consider as negative.
COFFEY, Q.C.:
Q. And why is that?
DR. KWAN:
A. Because if they state it's 30 percent cells in there, saying that it would be positive only up to 30 percent, any less than 30 percent, if

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I interpret it, it would be considered negative at that time. So is the patient's estrogen receptor status at one to five percent, it will fall into the negative category. Now, they basically say the same thing except I have to interpret. If they don't say the 30 percent on the bottom line, I'd say a lot of people wouldn't know how to interpret it.
COFFEY, Q.C.:
Q. And that's what I wanted to ask you about. If they didn't--if they had the same thing there, it was identical but there was no comment?
DR. KWAN:
A. I don't know anybody--not too many people would know how to interpret it. I may know but on the other hand, you know, a lot of people may not know how to interpret it.
COFFEY, Q.C.:
Q. Now, why might you know?
DR. KWAN:
A. Just because I have communication with the oncologists very often.
COFFEY, Q.C.:
Q. And in terms of, for example, that, in 1998,

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if there was no comment here and a person fell into this category, one to five percent and zero percent, they would have been treated for hormonal therapy as being what?

DR. KWAN:

A. They wouldn't be treated, we got negative.

COFFEY, Q.C.:

Q. Negative. They would have been classified as negative?

DR. KWAN:

A. They were classified negative. If they treated that, they will be on the outlying-- I'm not saying they shouldn't be treated, but it's outlying.

COFFEY, Q.C.:

Q. Doctor, we've heard references to 30 percent for ER, anything under 30 being considered negative up until the end of 2000, into 2001, even continuing maybe into 2002. What's your recollection of how that worked? I mean, you worked here in St. John's. I appreciate by that point you wouldn't have been being the primary follow-up physician for very many people, but what was your understanding at the time?

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DR. KWAN:

A. I probably won't be following the literature that closely at that time because I won't be doing very many of them. And I interpret it is that the literate is changing in terms of whether the percentage of cell positive is considered positive. That may be due to a number of reasons, and probably due to technological changes, that cells are being recognized or that we are now accepting a lower percentage of response rate as being positive. Like, if you think that 30 percent give you 90 percent chance of responding to hormone receptors, maybe now the literature is accepting 70 percent as being a positive response. So I really don't have a clear answer to that, but on the other hand it is universally accepted as a change.

COFFEY, Q.C.:

Q. Now, did that come up in any of these discussions, group discussions that you participated in in 2005?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

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Q. Okay.

DR. KWAN:

A. Oh, yes and no. I mean, they did mention there is a change, but I don't think anybody talked about why there is a change.

COFFEY, Q.C.:

Q. Did anyone in the summer of 2005 or the early fall of 2005 ever ask you for your views as to what the cutoff should be?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. To determine--you know what I'm talking about here in 2008 -

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. - but at the time no one ever -

DR. KWAN:

A. The literature would accept that. That's not up to any one of us to determine.

COFFEY, Q.C.:

Q. Well, Dr. Cook and others did decide as to what cutoffs were or -

DR. KWAN:

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A. Presumably they base it on what -

COFFEY, Q.C.:

Q. Yeah. But I'm asking you is, is were you ever asked for your input -

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. - amongst the discussion about like we'll use January 1, 2001 or January 1, 2002 or things like that?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. Okay. Did you overhear any discussion about what the cutoff should be?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. And then if we could just go back then to P-3085? Doctor, this is that letter of July 18, 2005. So here Dr. Cook is in the middle of July has written to you saying that "This patient previously reported as ER/PR negative. Repeat testing indicates positive for both." For your purposes, I take it, that sufficed in

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terms of making--if there was going to be treatment -

DR. KWAN:

A. That has a change. I mean, this is telling me that whatever mechanism he interpreted, the estrogen receptor status now has changed.

COFFEY, Q.C.:

Q. Okay.

DR. KWAN:

A. That's all I can interpret from those two sentences.

COFFEY, Q.C.:

Q. And but how positive is positive here, like, the percentages?

DR. KWAN:

A. He would have look at those numbers, concluded that these are positive changes and tell me it's a positive change.

COFFEY, Q.C.:

Q. And for your purposes in approaching the patient, the difference between if, for example, I'll just use a figure, 20 percent was considered positive, anything greater than 10 was positive, so if it was 20 or 90, from your perspective as -

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DR. KWAN:

A. If it's positive, from my perspective as a clinician is that this patient warrants treatment.

COFFEY, Q.C.:

Q. Consideration for, yes.

DR. KWAN:

A. Consideration for treatment. If they are positive, they should, negative, it may not be. So that's only basis I use, I can determine on.

COFFEY, Q.C.:

Q. Exhibit P-0729, please? Doctor, this takes us to the end of September, 2005. In the summer then of 2005 you understood then by the end of the summer what was going on with ER/PR? We'll get--this deals with a letter from Dr. Cook, I'll get to this in a moment. But I'm just asking you then by Labour Day, Doctor, what did you understand was going on?

DR. KWAN:

A. 2005 is I vaguely remember we got a problem.

COFFEY, Q.C.:

Q. Okay, and who was addressing it?

DR. KWAN:

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A. I would hope--I have nobody told me who addressed it, but I assume administration would be addressing it.

COFFEY, Q.C.:

Q. Were you ever asked, Doctor, for any--your own views or input into or on the issue of whether patients should be told they were being retested?

DR. KWAN:

A. After the meeting Dr. Williams and I had, nobody asked me specifically.

COFFEY, Q.C.:

Q. And whether they asked you at all, specifically?

DR. KWAN:

A. Nobody asked me at all, no.

COFFEY, Q.C.:

Q. Were you aware of any decisions that had been made in that regard?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. So, Doctor, after that meeting of August 2nd with Dr. Williams, the one where he sat you down in his office, kind of lured you in and

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sat you down and spoke to you, your next involvement, did you have any further involvement with this group that you recall?

DR. KWAN:

A. Well, after leaving the office, I guess this must be August the 2nd or something of that nature, after leaving the office and summertime maybe I'm on holidays, and I thought about the problems. My concern is still at that time what should we tell, how should be--what is the medical issues in terms of how to correct the problems that has been resulted from the estrogen, progesterone results change, is there any information out there we can base on, what can we offer these patients. I spent a lot of time thinking about it and I don't come up with a good answers as to what we can--should these patients get treatment, should these patients stop treatment? There's so many complex issues related to history of the individual that I cannot--none of us could make a blanket statement. So I thought about it and I think--I can't remember exactly when, probably into September, I went to talk to Dr. Kara Laing

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about this.
COFFEY, Q.C.:
Q. Go ahead and tell the Commissioner about that?
DR. KWAN:
A. And thought that I am--what does she think about any particular they offer to them and she quoted some--one of these article I think we came across and I said, "How do we go about", you know, I think the best thing we came up with at that time, I said, "What do you think about having a panel review all these patients?" And so none of us will--I mean, none of us ever had the full understanding of because no precedent to help us as to what to decide what to do, and so I made that proposal.
COFFEY, Q.C.:
Q. And who did you make that to?
DR. KWAN:
A. Dr. Williams.
COFFEY, Q.C.:
Q. And the purpose of the panel, you explained to him, would be what?
DR. KWAN:
A. Would be to review the history of the

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patients, the medical history of the patients there is and the breast cancer and current (phonetic) and comorbidity of the patients as involved and versus the breast cancer issue that was there and see whether there is any treatment can be offered or not offered or not necessary at that time with the--and make a recommendation as to whether the group has to, anything to offer.
COFFEY, Q.C.:
Q. And recommendations would be made to whom?
DR. KWAN:
A. The recommendation will made to--regard to the patient and then we at that time have not decided upon how we want to put those informations to anybody. I think that has not been--it's just I think off my head that we may need to--whether we should explore that.
COFFEY, Q.C.:
Q. Doctor, when you made this, you brought up this idea of a panel with Dr. Williams, do you recall when that was?
DR. KWAN:
A. Not exact date, sir.
COFFEY, Q.C.:

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Q. How close was it to the first meeting involving the panel?
DR. KWAN:
A. Oh, it must be--oh, I would say two weeks before, two, three weeks before.
COFFEY, Q.C.:
Q. Had the matter then--by the time you brought up the panel idea with Dr. Williams, was this already publicly known?
DR. KWAN:
A. No, sir.
COFFEY, Q.C.:
Q. Okay, it was still--it still hadn't -
DR. KWAN:
A. As far as I know.
COFFEY, Q.C.:
Q. Yes.
DR. KWAN:
A. As far as I can aware, I don't think. If I can remember, I don't think it was -
COFFEY, Q.C.:
Q. It was before it broke in the news publicly in a big way? It started October 2nd, we know that.
DR. KWAN:

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A. Yeah. It's around that time, but I can't remember. I think it's before that, but I can't exactly pinpoint a time.
COFFEY, Q.C.:
Q. Then the composition of the panel and what their formal role should be, who was that left to?
DR. KWAN:
A. Dr. Williams.
COFFEY, Q.C.:
Q. Did he ask you anything more about that?
DR. KWAN:
A. Well he asked me who I think may be in there, and I said certainly the medical oncologists. And beyond that I don't think I said anything more.
COFFEY, Q.C.:
Q. So, Doctor, in terms of this panel, your initial idea was is, look, this is, in effect, was sometimes two heads or three heads are better than one, that in the sense of people could examine problematic cases and make a recommendation?
DR. KWAN:
A. Something of that nature, yes.

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COFFEY, Q.C.:
Q. Did the panel have any investigatory role?
DR. KWAN:
A. No, sir.
COFFEY, Q.C.:
Q. At the time?
DR. KWAN:
A. Yes and no. We need to find out what the patient's histories are.
COFFEY, Q.C.:
Q. Yeah, I appreciate in terms of individual patients. But like a larger investigative role?
DR. KWAN:
A. No, sir.
COFFEY, Q.C.:
Q. At the time. Doctor, just looking at this, this is an e-mail of September 29, 2005 from Denise Dunn to Ms. Jones, Ms. Tracey and Dianne Clements to see "Louise, Maria, can the surgery and perioperative program leaders review, please," and sending Dr. Felix's and Kwan's copies by fax. And what's being sent here is this letter of September 26th, 2005, it's to Dr. Williams from Dr. Cook, ER and PR

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review. And it says, "Following the exit interviews of both the medical and technical consultants one of the issues identified, the immunohistochemical staining of ER/PR concerns adequate fixation of the specimen. It appears in some cases that mastectomy specimens and other breast biopsies could very well be left lying overnight or over the weekend in the OR without adequate formalin fixation. I would strongly recommend that all mastectomies, needle localizations and lumpectomies with axillary node dissection should be booked first thing in the morning in the OR from Monday to Friday. Ideally this procedure should not performed on Friday afternoons. Every effort should be made to ensure these cases are forwarded to the lab in a timely fashion. I would appreciate if this information could be forwarded to those individuals responsible for OR bookings." Now, apparently this was sent and then was distributed to a number of people, including yourself and Dr. Felix. In fact, you'll note, you'll see here, and it's difficult to read, but it's Dr. Williams indicated it should be

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distributed to, amongst others, yourself?
DR. KWAN:
A. Yeah.
COFFEY, Q.C.:
Q. First of all, did you receive a copy of this, Doctor?
DR. KWAN:
A. I probably, I'm sure I did.
COFFEY, Q.C.:
Q. And what, if anything, did you do about it?
DR. KWAN:
A. I think they went to the OR, operating room committee and with the--and to be advised with the policy and procedure to be adjusted accordingly.
COFFEY, Q.C.:
Q. And who was responsible for making such adjustments?
DR. KWAN:
A. I would say Maria Tracey.
COFFEY, Q.C.:
Q. And, Doctor, there's a reference here to this exist interviews of medical and technical consultants. Did you know that there were medical and technical consultants that come in

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and looked -
DR. KWAN:
A. No, sir.
COFFEY, Q.C.:
Q. So this would be the first time you were advised about it?
DR. KWAN:
A. Well, we talked about it later.
COFFEY, Q.C.:
Q. Yes. But this here would be the first time that you were aware that that's so. They've identified an issue concerning adequate fixation of the specimen, the idea that certain tissue could be left over, lying over--left overnight from, perhaps from a Wednesday to a Thursday or even over a weekend without adequate, according to this, formalin fixation. Had you had ever had any inkling before this -
DR. KWAN:
A. No, sir.
COFFEY, Q.C.:
Q. - that that could be so?
DR. KWAN:
A. I didn't have any idea that this being an

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issue.
COFFEY, Q.C.:
Q. And did you make any inquiries as to whether or not it had happened?
DR. KWAN:
A. On the Friday afternoons, no, I didn't make any inquiries on that.
COFFEY, Q.C.:
Q. Well how about the fact it could be left overnight?
DR. KWAN:
A. I can't remember whether I asked of them or not. We generally do not leave specimens overnight in the operating room area.
COFFEY, Q.C.:
Q. But I take it, Doctor, when this was discussed in late September, when this came up, this is something that had to be addressed, there would have been inquiries made about, look, well, Cook is saying this could happen, Dr. Cook is saying this and there would have been discussions amongst the group in the perioperative program about, look, has this happened?
DR. KWAN:

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A. Well, it's usually if I am--I can't remember the details what the discussion. I would--and I say that we're sure that we don't leave specimens in the operating room overnight. They all go down to the laboratory at 4:00 or whatever it times interesting. The only time they overnight is a specimen that came up late, the case isn't operated on, say, until middle of the night and then they go down the next morning.
COFFEY, Q.C.:
Q. Sure. But, so, Doctor, at the time then when this was discussed at the end of September, 2005, no one acknowledged that this could have happened?
DR. KWAN:
A. I am not aware of it, at least these overnight things. Whether is other issues than that, I don't know, but that's certainly I was--I'm not aware that specimens are left overnight in the operating room area, routinely. Now, presumably they are sometimes forgotten or left there, but routinely that's not that I'm aware of.
COFFEY, Q.C.:

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Q. And in terms of addressing then Dr. Cook's expression of concern, that would be the director of the perioperative program?
DR. KWAN:
A. Correct.
COFFEY, Q.C.:
Q. And in terms of surgery scheduling?
DR. KWAN:
A. That would be the perioperative program, as well. That would be discussion with the surgeons. Now, I don't operate Friday afternoons, so there was no breast being done at the Health Science Friday afternoons.
COFFEY, Q.C.:
Q. How about in the mornings?
DR. KWAN:
A. Friday mornings?
COFFEY, Q.C.:
Q. No, no, the idea of operating first thing in the morning Monday or Friday?
DR. KWAN:
A. They are not always feasible.
COFFEY, Q.C.:
Q. I take then that was discussed?
DR. KWAN:

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A. I don't think that's--I don't remember they ever discussed this, but I don't think that's really feasible to have first thing Monday morning for everybody for breast tumours, for all breast tumours, the numbers are too big.
COFFEY, Q.C.:
Q. He says first thing every morning Monday to Thursdays is what Dr. Cook is looking for. But that, from your perspective that's not--it wasn't feasible?
DR. KWAN:
A. It's just not technically feasible because there are other patients that requires to be operated first in the morning, a number of them, people with diabetes and people who has a latex allergies, all these things require 8:00 morning operating time.
COFFEY, Q.C.:
Q. Doctor, the policy that we looked at dating back to 2004 that specimens would stay in the OR unless the requisition form was properly filled out?
DR. KWAN:
A. Yeah.
COFFEY, Q.C.:

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Q. Then we looked at that earlier.
DR. KWAN:
A. Right.
COFFEY, Q.C.:
Q. Was that policy enforced?
DR. KWAN:
A. After what we were--the date -
COFFEY, Q.C.:
Q. In 2004, June -
DR. KWAN:
A. No, I think the letter we wrote was when, I can't remember what time I signed the letter out.
COFFEY, Q.C.:
Q. June 17, 2004.
DR. KWAN:
A. Okay, shortly after that, that's pretty well the nurses instruct not to leave the specimens upon (phonetic - coughing) leaving the OR even until the surgeon or his assistants have completed the form.
COFFEY, Q.C.:
Q. So the surgeon or if someone didn't complete the form -
DR. KWAN:

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A. They were called back to fill it out for the patient's specimen. If the specimen doesn't leave the OR suite, the next case can't come on.
COFFEY, Q.C.:
Q. But if they were the last specimen for the day?
DR. KWAN:
A. Then the residents come back and sign it. The nurses can't go home, either, I would think.
COFFEY, Q.C.:
Q. And, Doctor, look at Exhibit P-0634? Page--doctors--well, the first page is a fax cover sheet, it's to Dr. Carter from Dr. Williams. It refers to Dr. Cook having informed Dr. Williams that Dr. Carter agreed to sit on this panel. And she will be an expert in the area of breast pathology and would help with the deliberations of the panel. And then there's attached to this exhibit is a memo of October 12th, 2005, it's from Dr. Williams to Doctors Laing, yourself, Felix, McCarthy, Zulfiqar and Ganguly, Cook and Ms. Predham. Doctor, you would have received a copy of this at the time?

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DR. KWAN:
A. Yes, I would.
COFFEY, Q.C.:
Q. Did you take any issue with Dr. Williams or have any concerns about Dr. Williams' formulation of what the panel was going to be about?
DR. KWAN:
A. No. They are very competent individuals.
COFFEY, Q.C.:
Q. Here, Doctor, is a reference to, in the second paragraph, "So that a plan can be recommended to the physician who is following up on each of these patients." The idea is is that get together a panel of physicians to redo all patients in this category, which would be the category would be those who were retested at Mount Sinai. And they talk about the best time for the meeting. Dr. Laing agreed to chair the panel and secretarial support is described, then what Dr. Cook's role would be. Of course, Dr. Carter ended up being added to it. Doctor, was it your understanding that every patient who had retest results would be dealt with by the panel?

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DR. KWAN:
A. I understand the only thing they have changed.
COFFEY, Q.C.:
Q. The ones whose results have changed?
DR. KWAN:
A. Correct.
COFFEY, Q.C.:
Q. And change in this context meant what?
DR. KWAN:
A. Change in context means, as I interpret it, from ER negative, or actually, I can't remember how we do. I think there's change, not necessary all ERs are negative to positive, just changed, significantly changed would be reviewed.
COFFEY, Q.C.:
Q. So if there's--I'm sorry, what kind of a change?
DR. KWAN:
A. Significant change.
COFFEY, Q.C.:
Q. Significant change. And what -
DR. KWAN:
A. I think that, a lot of the people there are some 50 percent, there's 90 percent for

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example, that would be--we would consider as a (unintelligible) change. I think some of them have looked at them that way.

COFFEY, Q.C.:

Q. How about going, for example, from a negative to five percent or negative to two percent?

DR. KWAN:

A. They remain negative, then we won't--that won't be -

COFFEY, Q.C.:

Q. No, I'm sorry, going from what was originally described as negative.

DR. KWAN:

A. Yes.

COFFEY, Q.C.:

Q. Just negative, period, no percentages.

DR. KWAN:

A. Right.

COFFEY, Q.C.:

Q. To now, say, I'll just pick a figure, two percent?

DR. KWAN:

A. That would still remain negative and we probably won't review those.

COFFEY, Q.C.:

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Q. And who -

DR. KWAN:

A. As a change.

COFFEY, Q.C.:

Q. Yeah. Who made that determination?

DR. KWAN:

A. I don't know, I really can't tell you the determination. Now, whether we--that--if there are patients like that we have looked at.

COFFEY, Q.C.:

Q. Yes.

DR. KWAN:

A. You know, which is zero to two, we just looked at, yeah, it was zero to two is not changed and that's it, you know, next case.

COFFEY, Q.C.:

Q. So who, Doctor -

DR. KWAN:

A. I think, actually, all the patients were presented, have been retested were presented and then were just as a real -

COFFEY, Q.C.:

Q. So if, for example -

DR. KWAN:

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A. Can't remember exactly.

COFFEY, Q.C.:

Q. - it was negative and if Mount Sinai reported zeros?

DR. KWAN:

A. Yes.

COFFEY, Q.C.:

Q. Well, then, there'd just be a long list of patients with zeros and you wouldn't be dealing with them?

DR. KWAN:

A. Right.

COFFEY, Q.C.:

Q. That would be -

DR. KWAN:

A. And I think this was all the test results come back was real (phonetic) through. We have the flow that goes through and then those who doesn't have to be discussed, we just passed them.

COFFEY, Q.C.:

Q. You passed on because you could look, it was Mount Sinai ER zero or Mount Sinai -

DR. KWAN:

A. No change to -

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COFFEY, Q.C.:

Q. - less than one percent, you just pass right on?

DR. KWAN:

A. We just pass on it.

COFFEY, Q.C.:

Q. How about between, like, a patient that fell between one and ten, how were they dealt with, were they actually looked at?

DR. KWAN:

A. I can't remember, but I'm sure there would be discussion as in should we look at this one. We may look at the history of the patient very quickly and see whether we need any recommendation or the patient been on treatment before, then we don't--I can't remember exactly how we dealt with those, but I think -

COFFEY, Q.C.:

Q. Doctor, who--what was your understanding of who was deciding, like, which patients ended up before the panel at all?

DR. KWAN:

A. I think a list came out and we all--the numbers are presented and we all say, yes,

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should we discuss this one and the answer say no, agree, then that, then we just moved on.

COFFEY, Q.C.:

Q. Who provided the list?

DR. KWAN:

A. Administration.

COFFEY, Q.C.:

Q. Who is the -

DR. KWAN:

A. I think Heather is there with the list -

COFFEY, Q.C.:

Q. Okay, Ms. Predham is there. So that's what I'm trying to get some sense for the Commissioner in terms of you're a physician, the end of a long day, 5:00, you're showing up and it would all be kind of ready for you, I take it, in the sense of the lists and -

DR. KWAN:

A. Well, she got the list ready and actually in beginning we had the list beforehand to see any of these are our patients that belongs to me to bring information.

COFFEY, Q.C.:

Q. Yes.

DR. KWAN:

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A. If this list of my--have any information from my own file to bring them.

COFFEY, Q.C.:

Q. Because they would be presumably the current?

DR. KWAN:

A. Correct.

COFFEY, Q.C.:

Q. Yes. Doctor, but in terms of what criteria, for example, if Ms. Predham was making the determination as to who was to be seen in the sense by the panel?

DR. KWAN:

A. Well, just the list that was coming back. I don't think you'd make any decisions.

COFFEY, Q.C.:

Q. Oh, no, I appreciate that. What I'm asking is is this, were you ever asked yourself for any input into who should end up in front of a panel at all?

DR. KWAN:

A. No.

COFFEY, Q.C.:

Q. Okay.

THE COMMISSIONER:

Q. In the answer to an earlier question I got the

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impression that you were getting a list of the results that were coming back in a summarized form?

DR. KWAN:

A. I don't get the list.

THE COMMISSIONER:

Q. And that--you don't get the list?

DR. KWAN:

A. No. I get the list of the patients that are coming up for discussions.

THE COMMISSIONER:

Q. Okay.

DR. KWAN:

A. The day before or the day--in the beginning. Later on we didn't, the beginning is to see whether there was any patients of mine that I bring in any information that I have.

THE COMMISSIONER:

Q. Okay.

DR. KWAN:

A. To the panel.

THE COMMISSIONER:

Q. And that list that contained the names of those who were coming up before the panel would imply, since the panel didn't seem to

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deal with every patient, that some person had -

DR. KWAN:

A. Well, the list is there. I think we go through all of them, if I remember -

THE COMMISSIONER:

Q. Yes, that was my point. I was getting the impression from you that, in fact, you got the results from everybody?

DR. KWAN:

A. No. I think the list is presented, those changed had presented, so the one that Mr. Coffey presented, those number change are--all the retesting are there and then when we looked at the number change, this one needs to be looked at, this one doesn't need to be looked at. As I remember -

THE COMMISSIONER:

Q. So does that mean there were sort of two decision making processes that before the list came to you somebody had decided there were a group of patients who need not even go on a list?

DR. KWAN:

A. No, no, no. That's the list that came up is

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the list of patients that will come up at the time.
THE COMMISSIONER:
Q. Yeah.
DR. KWAN:
A. The only reason the list came to me is to ask for whether any of those are my patients that I bring in informations.
THE COMMISSIONER:
Q. Yes.
DR. KWAN:
A. So that's the only, as I interpret, that is the only reason for that list.
THE COMMISSIONER:
Q. All right.
DR. KWAN:
A. And then when we go to the meeting, Heather will be have all these things together and we go through these are the patients we're going through.
THE COMMISSIONER:
Q. Um-hm.
DR. KWAN:
A. And the chart will be there.
THE COMMISSIONER:

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Q. Yes.
DR. KWAN:
A. And then the collective decision should we review the entire case. That's the understanding, that is my recollection of what's happening.
THE COMMISSIONER:
Q. Okay. Now, but if, for example, Mount Sinai had sent back the results on 30 patients, assuming for the moment that 15 of those had negative results which we know they would have had negative results before they went to Mount Sinai, assuming for the moment that Mount Sinai sent back zero, zero on all 15 of them, you would never see those names, would you?
DR. KWAN:
A. No. that would be if it's identical results, there would be not looked, that would just pass, say, yeah, zero, zero, and it's gone. We don't look at the chart at all.
THE COMMISSIONER:
Q. All right. Now, if there is a change which is very small, would that get to you definitely -
DR. KWAN:
A. That would -

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THE COMMISSIONER:
Q. - or would someone make a decision before it got to you?
DR. KWAN:
A. We make a look, decision at the time and say zero, zero, zero, one.
THE COMMISSIONER:
Q. Um-hm.
DR. KWAN:
A. So no, we don't look at those at all either.
COFFEY, Q.C.:
Q. So what criteria were you utilizing to make that determination?
DR. KWAN:
A. I think it was anything we considered changed.
COFFEY, Q.C.:
Q. Okay, so what number did Brendan Mullen have to report before it became changed and causing you to look at it?
DR. KWAN:
A. If previously we consider a negative, for example, now, say--that's why I'm hesitating because as you know back in 1997 we had 30 percent positive, now in 2005 is ten percent positive.

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COFFEY, Q.C.:
Q. So what I'm -
DR. KWAN:
A. So those are the issues that we have to consider now today as being positive and we have to look at.
COFFEY, Q.C.:
Q. So if it was 10 percent--and the 10 percent was retroactively all the way back to 1997 by the panel?
DR. KWAN:
A. That was the way we did it.
COFFEY, Q.C.:
Q. So it was discussed, the idea of what kind of approach we should take with the '97, '98, and '99?
DR. KWAN:
A. That's the way I remember it, that we discussed it at the time. I don't know what Kara Laing said at the time, but that's what I remember.
COFFEY, Q.C.:
Q. And so the panel's approach was going to be 10 percent is positive, 10 percent or more would be positive?

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DR. KWAN:
A. Yeah.
COFFEY, Q.C.:
Q. If Brendan Mullen reported 10 percent or more, we'll consider it positive?
DR. KWAN:
A. They would consider a change, although change may not be related to the laboratory, a change in therapy.
COFFEY, Q.C.:
Q. Yes, you would consider the--the person then would be considered for a possible change in treatment?
DR. KWAN:
A. Correct.
COFFEY, Q.C.:
Q. If Mount Sinai reported the ER and PR as less than 10.
DR. KWAN:
A. Yeah.
COFFEY, Q.C.:
Q. Then they wouldn't be considered for change?
DR. KWAN:
A. They wouldn't be considered, yeah.
COFFEY, Q.C.:

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Q. They were just simply--fell into another category, and we won't review them. So they would not be reviewed?
DR. KWAN:
A. That would be my understanding. If I remember, that's what we did.
COFFEY, Q.C.:
Q. And if we could, just to address something the Commissioner was just asking about, Exhibit P-2554, 2554. Doctor, this is a redacted version of a document entitled "Charts for Panel Review". This one happens to be Thursday, October 27th, 2005. You can see the patient's names and, of course, the MCP numbers are redacted. There are 25 of them originally listed. The physician's names are listed there.
DR. KWAN:
A. Uh-hm.
COFFEY, Q.C.:
Q. And the OPIS number, we've redacted those, but there's - the word "hold" is written on a number of them. As well when we look down through it, yours is here, right there I'm pointing to, and then as we go down the page

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there are actually quite a number of yours; here, here, here, here, here, here. See those?
DR. KWAN:
A. Yes, I presume it has my name as the operating surgeon, or the one who is sending the specimen.
COFFEY, Q.C.:
Q. Yes. So because your name is here doesn't necessarily mean that you were the follow -
DR. KWAN:
A. No.
COFFEY, Q.C.:
Q. Follow-up physician.
DR. KWAN:
A. No.
COFFEY, Q.C.:
Q. The person actually treating at that point.
DR. KWAN:
A. No.
COFFEY, Q.C.:
Q. Although some of these when we look here, Ganguly, for example, would not be a surgeon, McCarthy would not be a surgeon, or Laing.
DR. KWAN:

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A. Presumably - I can only assume now. I mean, memory is that these patients are being followed by them or being treated by them.
COFFEY, Q.C.:
Q. Doctor, is this the sort of sheet you were talking about before to identify patients, your own patients?
DR. KWAN:
A. No, these are other people's patients.
COFFEY, Q.C.:
Q. Okay, so you would sometimes get a sheet -
DR. KWAN:
A. That's beginning. Later I don't get them any more.
COFFEY, Q.C.:
Q. So in the beginning you would get a sheet, and what would be on the sheet?
DR. KWAN:
A. Just these are patients who have been reviewed and we will be discussing in the panel, do you have any information related to these patients, bring it.
COFFEY, Q.C.:
Q. And that sheet would come from whom?
DR. KWAN:

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A. I would say Heather Predham. That's the beginning of the first few meetings that we had.

COFFEY, Q.C.:

Q. Exhibit P-0635, please. Doctor, this is a fax sheet of October 12th, 2005. It's from Dr. Williams to yourself and other individuals, people on the panel really. It says, "Please see attached letter. Supper will be provided", and then it notes here, location, and then dates beginning October 20th, 2005, 27th, November 3rd, November 10th, November 17th, December 1st, and December 15th, and the activity is listed there, room number, and the location. Doctor, was this a listing of what was planned to be then panel meetings, do you know?

DR. KWAN:

A. I don't know. I never saw the list. It's a list that we sat at meetings. We certainly meet often enough, but I don't know whether these are schedules for our meetings, no.

COFFEY, Q.C.:

Q. Doctor, from time to time then, how would you know - I take it you got that first memo

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saying show up at a particular place.

DR. KWAN:

A. Each meeting - how I got that, either Heather Predham will say we don't have the results coming back, and they would tell us when the next meeting be when these arrive for us to sit down and talk about.

COFFEY, Q.C.:

Q. So Ms. Predham would organize it, and at the end of a meeting if there was one planned for the next day or the next week, she'd tell you?

DR. KWAN:

A. That's right.

COFFEY, Q.C.:

Q. And if you could make it, you would be expected to show up?

DR. KWAN:

A. Correct.

COFFEY, Q.C.:

Q. Exhibit P-1309. Doctor, these are the minutes - this particular version is revised, October 20th, 2005, for it's for the physician panel meeting, October 13th, 2005. You're there and others, and the second sentence notes that Dr. Williams thanked yourself and Dr. Laing for

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suggesting the idea of a panel. Here, Doctor, the mandate of the panel is spelled out here. There's a note here that Dr. Laing also stated the discussion of the group will be officially minuted and will stay as a record. All in attendance agreed. Doctor, did you ever see any minutes afterward?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. As time went on, do you know whether there were even any minutes kept?

DR. KWAN:

A. I never saw any minutes from this meeting, sir.

COFFEY, Q.C.:

Q. The second paragraph says, "Discussion ensued as to who would be notified whose responsibility it would be to carry out the follow-up of each patient. All agreed the referring physician should be notified, the primary cancer treating physician would be responsible for follow-up. Other recommendations from the panel; notification would be in writing, mechanism put in place to

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confirm follow-up physician has received notification. Also include a paragraph to the effect the primary care physician if that physician is not comfortable carrying out the change in treatment, they have the option of referring the patient to an oncologist at the Cancer Clinic", and then they go on and talk about, the memo does, about the research from the French National Cancer Centres dealing with a study, TAM, T-A-M 02, "and this article was circulated to the panel and Dr. Laing advised that the recommendations for treatment would be based on the findings in this article. It was agreed that Heather Predham ask an epidemiologist to review this research". Now, Doctor, this is research - there's a quote here referring to a randomized controlled trial from September, 1986, to October, 1998.

DR. KWAN:

A. '89.

COFFEY, Q.C.:

Q. 1989, I apologize, '86 to '89, found in an article entitled "Delayed adjuvant Tamoxifen, ten year results of a collaborative randomized

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controlled trial in early breast cancer". Doctor, I wanted to ask you, from your perspective sitting there, October 13th, 2005, did you have any real information before you got this about whether it was useful or not?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. To engage in -

DR. KWAN:

A. I have no - until Dr. Laing brought this article, I have no reference articles that deal with this issue of delayed Tamoxifen.

COFFEY, Q.C.:

Q. Doctor, did you make any further inquiries in that regard?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. A reference here to asking - agree that Ms. Predham ask an epidemiologist to review this research, which would be presumably that paper?

DR. KWAN:

A. I presume so, yes.

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COFFEY, Q.C.:

Q. Did you ever hear anything afterward about any such -

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. Epidemiologist comment.

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. Did it ever come up afterward?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. So once this was embarked upon, the panel's approach was, as asserted here by Dr. Laing, the recommendations for treatment would be based on -

DR. KWAN:

A. I believe Dr. Laing talked about a number of times another informations. There is a vague - there is another somewhere. I can't - I don't know if I saw that one, dealing with the same issue and that's the best information that we have.

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COFFEY, Q.C.:

Q. So the panel then, once they set out on this course, they continued on?

DR. KWAN:

A. That's the best information that we got in terms of how to deal with this. At least there's some scientific basis for how we can treat these patients.

COFFEY, Q.C.:

Q. And there's a reference to what form would be used to record certain information, and, Doctor, here on the second page of this exhibit, there's an action plan styled and there's patient information that's redacted, the original reported ER/PR, the Mount Sinai report on ER/PR, and then recommendations/follow-up, and then the follow-up physician is identified. I take it this would be the physician to whom the letter is being addressed?

DR. KWAN:

A. Correct.

COFFEY, Q.C.:

Q. And there are a number of different recommendations. The recommendations, doctor,

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were there ever any disagreements?

DR. KWAN:

A. Sometimes.

COFFEY, Q.C.:

Q. And how were they resolved?

DR. KWAN:

A. Consensus.

COFFEY, Q.C.:

Q. And, in essence, what does consensus in this context mean? I take it, somebody would change their mind.

DR. KWAN:

A. Somebody would have presented enough to convince the other people that this is what would be reasonable.

COFFEY, Q.C.:

Q. Did it ever have to be decided on the basis of kind of a majority vote?

DR. KWAN:

A. No, sir, not that I can remember.

COFFEY, Q.C.:

Q. And who would actually participate in this in the sense of -

DR. KWAN:

A. Mostly it's the medical oncologists, and we

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participated at times that we have anything to contribute, and the pathologists will interpret the pathology reports, and perhaps sometimes the estrogen receptor results.

COFFEY, Q.C.:

Q. If we could, I'm just going to look at the third page. Here, this patient at the top of the page here, negative/negative originally, and now 80/0 from Mount Sinai. Recommendation, Dr [redacted] advised the panel that this was her patient and the patient has been notified and started on Tamoxifen, and follow-up physician would be presumably the same doctor. How was this handled?

DR. KWAN:

A. Patient notified, has agreed upon, and been started, and we agreed that Tamoxifen is appropriate thing to do, and already been started - I'm presuming that patient is same letter you showed me from Don Cook, who send a letter way out before these things happened, and individual probably got a letter from that and has dealt with the issue.

COFFEY, Q.C.:

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Q. And, for example -

DR. KWAN:

A. And came down to the panel discussion and we agreed and that that was it.

COFFEY, Q.C.:

Q. Here in the second patient on this page, Recommendation, "As patient has already received Tamoxifen, she will be informed of the change in ER/PR status, originally negative/negative and then Mount Sinai 20 and 50". In terms of that, there's no way of telling from this when the patient received Tamoxifen, is there?

DR. KWAN:

A. There's no way of telling why it was started, no way of telling why who have a - who got a crystal ball to tell it could be changed, I mean, without information like that. I'm just going to say back is that there are situations that occasionally we do treat them. As you know, sometimes negative estrogen receptor of patient, no other thing to offer, to offer you a 6 to 10 percent chance of response, and occasionally we do start them on them in situation where you have nothing to offer.

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COFFEY, Q.C.:

Q. Despite the fact that their hormonal status is reported to be negative?

DR. KWAN:

A. D e s p i t e - - b e c a u s e t h e y s u g g e s t negative/negative, occasionally they do respond.

COFFEY, Q.C.:

Q. Doctor, in fact, the third patient falls in the same category. The patient has already received Tamoxifen.

DR. KWAN:

A. It may be again - this may be that people get - don't forget, this is the first group of patients came in here, and the physician may have already gotten the letter at that time and then started treatment.

COFFEY, Q.C.:

Q. Doctor, I'm going to ask you about this, at times would you be receiving the pathology reports? We understand that Mount Sinai was reporting these generally in spreadsheet results, Excel Spreadsheet, and Dr. Cook was entering them in the Meditech, individual patients.

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DR. KWAN:

A. Okay.

COFFEY, Q.C.:

Q. Would you get a copy then of - if you were the patients' surgeon, would you get a copy of the pathology report?

DR. KWAN:

A. I would get a copy of the pathology report. If I remember, I do get - I can't remember if I get every one of them, but I certainly do remember receiving some of the addendum reports in 2005 of something back in 1996. I mean, I just have to look. I said what am I supposed to do with this.

COFFEY, Q.C.:

Q. Doctor, with respect to that, at times were some of those pathology reports ending up in your mail slot, as in pathology reports relating to the retest results before people were being panelled?

DR. KWAN:

A. No, I don't think so.

COFFEY, Q.C.:

Q. Okay, and now - here, and this is just the second page of the exhibit, there's an entry

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here, fourth entry, less than 30 percent, less than 30 percent is the original results, and now 60 and 70 from Mount Sinai. Recommendation, this patient should be offered Tamoxifen.

DR. KWAN:

A. Uh-hm.

COFFEY, Q.C.:

Q. I take it, this is somebody the panel would have considered, looked at the -

DR. KWAN:

A. That's a recommendation for the panel, and this patient would have got - physician would have got a letter and advised the patient to start.

COFFEY, Q.C.:

Q. Doctor, the third page - because we just looked at the three of them at the top of the page there, "Advised this particular patient has been notified and started on Tamoxifen", would the patient actually review that patient?

DR. KWAN:

A. Would just make sure that they did, is getting Tamoxifen - some of these patients are Cancer

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Clinic patients. We do have the full chart on these patients. So look at it and say, yes, has been started and be happy with it.

COFFEY, Q.C.:

Q. And some of these, I'm going to suggest to you, in fact would only have been started because of the retest that had occurred -

DR. KWAN:

A. Probably, yes.

COFFEY, Q.C.:

Q. - during the past month or so, but would the panel - what I'm asking you is this, if someone present in the room, a pathologist said, look - an oncologist said that's my patient, I have started him or her on hormone therapy.

DR. KWAN:

A. Uh-hm.

COFFEY, Q.C.:

Q. I got the results recently and I've started him or her. Would the panel then actually review that patient?

DR. KWAN:

A. Probably not as detailed as we reviewed the others. We would look at it, and we probably

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won't go through, sort of, the fine tooth--as to--particularly the medical oncologists would make their recommendations who have taken the role in treating that patient, and she has, or he or she become the treating physician since we are not in our role to - we may give advice, but we won't be going against them very quickly.

COFFEY, Q.C.:

Q. Do you ever recall any instance where the panel was told or learned that a patient had been - because of change results, had had their treatment changed, and the panel had misgivings about it? I'm not suggesting it happened.

DR. KWAN:

A. No.

COFFEY, Q.C.:

Q. I'm just asking you.

DR. KWAN:

A. No, not that I can remember. No, nothing i can -

COFFEY, Q.C.:

Q. Sure. Doctor, here in the end of these minutes on page four, [redacted] was the last

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patient reviewed at this meeting. The panel agreed to proceed through Dr [blank] patients at the next meeting, and Dr. Cook requested that certain patients be added for discussion at the next meeting. Doctor, the meeting was adjourned at 6:35. First of all, I'm going to ask you the idea that particular doctor's patients be looked at at the next meeting, do you recall that happening?

DR. KWAN:

A. I presume he must have an issue that he wants panel discussed, that he wants our opinion as to what to do with that particular situation. I really can't comment.

COFFEY, Q.C.:

Q. This seems to be through--all of that doctor's patients? It looked like the doctor was going to have whatever patients of his had retest results looked at. Do you recall that coming up?

DR. KWAN:

A. "Agree to proceed through" -

COFFEY, Q.C.:

Q. Not "a" patient, it's "through that doctor's patients at the next meeting". The idea of

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somebody's patients who are jumping the queue.
DR. KWAN:
A. I don't remember selecting anybody as jumping the queue for whatever reason, but again maybe occasionally - I mean, I don't even remember. I'm just guessing here where it is convenient that you will be here next meeting, bring all his charts in, you know, that kind of stuff like that.
COFFEY, Q.C.:
Q. Sure.
DR. KWAN:
A. May occur, but I don't think I ever recall saying so and so got to go above so and so.
COFFEY, Q.C.:
Q. Doctor, here this meeting was scheduled again at 5 o'clock. Look here at - it adjourned at 6:35, which is an hour and a half. Now, Doctor, how long then would be spent per patient?
DR. KWAN:
A. That all depends. You know, like any chart review you do, and how well the charts are organized for you, and how much information that is easily accessible, and if those

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informations are within the computer system or not. If it's in the computer system, it's much easier, a lot faster. Mostly it's information gathering at the same time so that we are not missing something in the individual. Comorbidity is one of the serious issues that we have to know. Making a recommendation of patient to take Tamoxifen who have an extensive DVT will be a bad thing.
COFFEY, Q.C.:
Q. So, Doctor, I mean, just doing the arithmetic, there were twelve patients looked at that day.
DR. KWAN:
A. Ten minutes.
COFFEY, Q.C.:
Q. Ten minutes.
DR. KWAN:
A. Fifteen minutes, yeah.
COFFEY, Q.C.:
Q. Ten minutes or less.
DR. KWAN:
A. I would think that would be -
COFFEY, Q.C.:
Q. Well, it would be less than ten for each.
DR. KWAN:

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A. It say it starts at five o'clock, but often time we were there 4:30, you know, it can be started at such and such a time. You know, I mean, I can't remember exactly we started five o'clock or early when clinics are finished.
COFFEY, Q.C.:
Q. Doctor, let me ask you this. I appreciate if patient "A"'s name comes up and the medical oncologist there says, well, she's my patient, I got the results two weeks ago, a week ago, or back in the summer -
DR. KWAN:
A. Uh-hm.
COFFEY, Q.C.:
Q. And I put her on Tamoxifen for the following reason -
DR. KWAN:
A. Uh-hm.
COFFEY, Q.C.:
Q. The panel then might take 45 seconds actually, if they accept -
DR. KWAN:
A. Probably document the fact that we looked at it and say yes, this is good enough, and off we go.

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COFFEY, Q.C.:
Q. And then other cases where they were more problematic, you'd spend more time at it?
DR. KWAN:
A. Yes, you would look at when the patient--for example, a patient who had lymphoma, in that chart over there, that patient probably got a lot more discussions as to whether we should or should not treat it. We didn't come to any conclusion at the end of that day.
COFFEY, Q.C.:
Q. Yes, that patient, in fact you're looking, Doctor, the second one, second last one, in fact.
DR. KWAN:
A. I just came through when you came up there -
COFFEY, Q.C.:
Q. The second last patient, "this patient should be brought back to the clinic to check the status of her low grade lymphoma."
DR. KWAN:
A. I mean, obviously that patient would have gone through--consume a lot more time in looking at what this is, what kind of lymphoma it is, what type it is and whether--how extensive,

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you know, what is the status is like. I mean, those are the situation that would have been taken a lot more time.

COFFEY, Q.C.:

Q. Doctor, here, looking at the third last patient, the original result was the DAKO ER/PR is negative, negative, and then Mount Sinai's is 90 and 20. The recommendation, under follow up, is "as this patient died shortly after diagnosis, the change in ER/PR status had no impact on care and therefore, no action is required." Now Doctor, what is that about?

DR. KWAN:

A. Well, as the patient died very shortly after, she could have been died--whatever reason she died of, I don't know, okay. She maybe died of something else totally unrelated, you know, so at this time, the patient had deceased, so no opportunity even for hormone receptor to work and hormone treatment is not a rapidly changing thing. Rather hormones effects on breast cancer is over a period of--lengthy period of time before it produces effect. It's not something that change within a week,

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like you give penicillin for an infection.

COFFEY, Q.C.:

Q. And Doctor, that is the treatment effect of -

DR. KWAN:

A. The treatment effect of hormones, it takes time to become effective.

COFFEY, Q.C.:

Q. Now Doctor, here, why would it be noted or why was it seen fit to note that the change in ER/PR status had no impact on care?

DR. KWAN:

A. Well, I don't know the details when the patient died, what time the patient--you know, she may--she died post-operatively as a surgical complication, anasthetic complication, therefore there's no opportunity. I don't know that.

COFFEY, Q.C.:

Q. I appreciate that. What I'm asking is this, why was the panel recording whether or not the change in status had any impact on that patient's care? Why would that be?

DR. KWAN:

A. I can't really--without the details, really can't comment on it.

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COFFEY, Q.C.:

Q. The validity of the assertion, I'm not asking you about, and I appreciate you can't answer without--why would it be the panel address its mind to it at all?

DR. KWAN:

A. Well, always the same that there is--because if the patient had been deceased immediately post-op, what the ER and PR percentage of the patient have no impact on care.

COFFEY, Q.C.:

Q. So the panel then, at least initially, was keeping track of, for the deceased -

DR. KWAN:

A. We saw the results.

COFFEY, Q.C.:

Q. Yes. So the panel was keeping track of, initially, if the patient was dead. They were told the patient was dead, and was making an assertion as to whether or not -

DR. KWAN:

A. It probably came up with the chart.

COFFEY, Q.C.:

Q. - whether or not the ER/PR change had an impact on care. That's what I'm getting at

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here.

DR. KWAN:

A. I realize that. I think that the only information and how we got at this patient had been deceased, probably came up when we reviewed the chart.

COFFEY, Q.C.:

Q. Sure.

DR. KWAN:

A. And it came up and if the patient happened, and happened to decease very shortly after the operation or shortly after the diagnosis, then the level of the ER and PR really had no impact on the patient's death. It may impact for the tumour, but no patient impact on the patient's survival.

COFFEY, Q.C.:

Q. P-1384, please? Doctor, this is the minutes of a physician panel meeting. It's styled number three, October 27th, 2005. I just note you were there, listed as being there. So Doctor, I take it then--I'm not going to take you through each of them in detail--that you tried to make the panel meetings. You made an effort to actually -

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DR. KWAN:
A. I did try, yes.
COFFEY, Q.C.:
Q. And you're recorded as--were there some that you were not able to make?
DR. KWAN:
A. That's correct.
COFFEY, Q.C.:
Q. If we could, please, I'm just going to ask that perhaps Exhibit 2554. It's page--I'm just going to flip through to page seven. Doctor, this is a physician panel review, ER/PR results sheet. The date patient reviewed is here. Of course, the name, MCP and OPUS numbers are redacted. The date of pathology, the specimen number, this is a 2000 case, 00, original report locally was NN, negative, negative, and Mount Sinai zero, zero, and patient did not convert. You're listed as the follow-up physician, Kwan.
DR. KWAN:
A. That's me, yeah.
COFFEY, Q.C.:
Q. Yes, and the follow-up physician in this context would be the person who was going to

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do what?
DR. KWAN:
A. If need to be informed, the patients, that I will get the letter and I will tell the patient anything that need to be done. I would contact the patients.
COFFEY, Q.C.:
Q. And here, to do what?
DR. KWAN:
A. Original report is negative, negative. Mount Sinai is zero and zero. There's nothing to be done.
COFFEY, Q.C.:
Q. So would you have told the patient?
DR. KWAN:
A. No.
COFFEY, Q.C.:
Q. You wouldn't have told -
DR. KWAN:
A. Have no change, no, I wouldn't have contacted the patient, no.
COFFEY, Q.C.:
Q. About the fact that they had been retested and were zero, zero?
DR. KWAN:

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A. I mean, the only concern of retesting is when they have a change. With a change in diagnosis, I would tell the patient. When nothing is changed, I didn't tell the patient.
COFFEY, Q.C.:
Q. If there was a change, but it didn't result in a change in treatment, would you tell the patient?
DR. KWAN:
A. That may well be with laboratory changes and errors, I won't tell the patients either. I mean, you're talking about zero to one, one to two, that could well be treated within laboratory errors.
COFFEY, Q.C.:
Q. So your practice was, when you would receive these panel letters, if they fell under that category, you would -
DR. KWAN:
A. There's a much more formal letters than that.
COFFEY, Q.C.:
Q. Sure. But when you were -
DR. KWAN:
A. This is not what I'll get.
COFFEY, Q.C.:

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Q. Yes, but when you would receive the letter, for example, for this patient, you wouldn't pass that on to the patient?
DR. KWAN:
A. I wouldn't pass it on, no.
COFFEY, Q.C.:
Q. And if there was a small change from like zero or negative to two -
DR. KWAN:
A. If it's affecting the treatment, yes, I will.
COFFEY, Q.C.:
Q. How about a situation, Doctor--and there are a number of patients who whom it was true, that--let me see if I can find one here easily. Here, if we could look at 1384? Thank you. Page one, which we're on. This is the same panel meeting, Doctor, October 27th, and we'll look here at the second patient. The date of pathology is July--I'm sorry, January 26th, 2001. The original report ER/PR was five to ten percent ER, 30 to 40 percent PR. Now Mount Sinai was reporting it as 40, 20, okay? And patient previously treated with Tamoxifen and no follow-up treatment required.
DR. KWAN:

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A. Um-hm.
COFFEY, Q.C.:
Q. Would you, when you got this panel letter, would you inform the patient of that?
DR. KWAN:
A. The panel letter which says that there's no change in treatment, I wouldn't tell them. I mean, I wouldn't make--wouldn't go looking for them. I would say that form letter that we sent outside (unintelligible) language that this disease had numbers and no change of treatments, already get adequate treatment, I would not. I mean, I wouldn't have to call the patients that time.
COFFEY, Q.C.:
Q. And here, Doctor, the top of the second page, original report ER/PR, it was negative for ER, positive for PR, this particular patient, this is a 2001 situation, June 13th, 2001. Mount Sinai report, 70 ER 80 PR. The recommendation: patient previously treated with Tamoxifen and no follow-up treatment required. You wouldn't have told--if this happened to be your patient, you wouldn't have told the patient, even to this day?

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DR. KWAN:
A. Has had adequate treatment, yes, I don't--you know, the purpose of my interest is to look at the patients where the treatments are changed. I mean, if the treatments are changed, yes, I think these patients need to be informed, you know, that in fact treatments have changed. That's why we do ER and PRs. Either one of them is positive, we don't--we do the treatments. Just we didn't do the single receptors.
COFFEY, Q.C.:
Q. Now, so Doctor, if the panel letter, a panel letter said "look, there's no treatment--the result has changed -
DR. KWAN:
A. I'm sorry?
COFFEY, Q.C.:
Q. If the panel letter pointed out negative, positive, and now 80, 90, which is two positives, but no treatment change required because the patient is already on Tamoxifen, if the panel letter went on to say that you--asked you to inform the patient about the changed results -

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DR. KWAN:
A. I would do that.
COFFEY, Q.C.:
Q. Would you?
DR. KWAN:
A. If it was asked--that's what the panels are there for. If they think that I should inform them, then, yes, I would, you know. Personally, whether it would change, it may not change treatments at all, but they would be told.
COFFEY, Q.C.:
Q. Exhibit P-0684, please? Doctor, this is an e-mail of Heather Predham, November 24th, 2005. It's to Dr. Williams, copied to a number of individuals, Dr. Cook, Ms. Elliott and Ms. Pilgrim, not yourself, update on ER/PR. She writes "as you requested, here is an update on ER/PR. There hasn't been much activity other than getting two more converter results back. Dr. Kwan made a suggestion at the last panel that I should track those we may have potentially harmed. We had agreed to classify patients as being converted with or without recommendations, but Dr. Kwan, and rightly so,

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felt it didn't accurately reflect those who have been impacted. For example, if a person was initially diagnosed with breast cancer in the left breast and was ER/PR negative and then had metastases to the right breast which was ER/PR positive, the patient would be then treated with Tamoxifen. So when we panelled the person after their first results converted, the panel would have no recommendations, but there has been a potential impact. At the last panel meeting, out of the 17 panelled, there were seven patients that were potentially negatively impacted. I will have to review all the patients panelled, but I'll try to have this complete information for you next week. As always, if you have any questions, please call" and the briefing note is right there, is attached here as pages two and three, and goes on at some length, and it breaks down the numbers in a very detailed way.
Now Doctor, I want to ask you about the e-mail. Did you bring up the topic that Ms. Predham here says you did?
DR. KWAN:

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A. I'm sure I brought up something, but whether it's accurately represented or not is that I don't know. Somewhere that I couldn't--I looked at this before. As I said, I can't recall and interpret as to what she really meant what I said. I did at always time be looking at the possibility of gaining informations and research informations and information from these people that has been treated or started on Tamoxifen late as to what's happened in order to gain some long-term information from the situation and I always tell them that we should probably keep track with all these patients that has either converted or have partially converted and see what these patients are like in the long term, and that would help us to get some insight information as to what we're doing. I'm not so sure what he's mentioned about right breast and left breast because it would be a terribly unusual situation from a right breast tumour (unintelligible) an opposite breast.

MR. COFFEY:

Q. She's just using that as an example here because she does say, in the third sentence,

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the second paragraph, for example. Doctor, did you ever ask, at the panel meetings, or suggest at the panel meetings that we should--we, as a group, should be keeping track of who is potentially harmed or negatively impacted here?

DR. KWAN:

A. I think we should keep track on these people that we have changed there and follow it up as to see what the long term results of this situation is, you know. I think that we had invaluable bit of information that we can get from it.

COFFEY, Q.C.:

Q. Doctor, did you--Ms. Predham here has said--now she's not saying this to you, because although she attributes the subject matter as having arisen because you raised it in the group at the panel, did you ever see any such information? She says here "I will have to review all the patients panelled. I'll try to have this complete information for you next week."

DR. KWAN:

A. No, sir.

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COFFEY, Q.C.:

Q. You never did?

DR. KWAN:

A. Not that I can recall.

COFFEY, Q.C.:

Q. Have you ever heard any discussion about it?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. Have you ever made any inquiries since about it?

DR. KWAN:

A. No.

COFFEY, Q.C.:

Q. Doctor, if we could just bring up, please, Exhibit P-0046? Doctor, this is Dr. Banerjee's--well, it's a covering letter, Dr. Banerjee's report of October 17th, 2005 concerning his visit to St. John's in September 2005. Were you ever--well, before the Commission of Inquiry got going, were you ever made aware of what Dr. Banerjee's observations had been?

DR. KWAN:

A. No, sir.

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COFFEY, Q.C.:

Q. Did you ever make any inquiries about what he had found?

DR. KWAN:

A. I didn't even know he was here.

COFFEY, Q.C.:

Q. How about Ms. Wegrynowski, she's the lady from -

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. - from Mount Sinai. No?

DR. KWAN:

A. No. That may have come from the discussion I had with Dr. Williams back on August the 2nd.

COFFEY, Q.C.:

Q. And have you read the report since?

DR. KWAN:

A. No, sir.

COFFEY, Q.C.:

Q. Either of them?

DR. KWAN:

A. I'm sorry?

COFFEY, Q.C.:

Q. Either of them, you haven't read either of

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them?
DR. KWAN:
A. No, sir.
COFFEY, Q.C.:
Q. Have you discussed them with anybody?
DR. KWAN:
A. No, sir.
COFFEY, Q.C.:
Q. Is there any reason why you haven't, Doctor?
DR. KWAN:
A. Because I don't know even where to get a copy.
COFFEY, Q.C.:
Q. Pardon me?
DR. KWAN:
A. I don't know where to get a copy.
COFFEY, Q.C.:
Q. Well, there are -
DR. KWAN:
A. I'm sure they are available. I'm sure it's available, but -
COFFEY, Q.C.:
Q. So Doctor, in terms of yourself, I mean, from your own curiosity perspective, I mean, you've worked here in this city for--in the province for over 30 years, and this has involved your

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patients, you've never decided to go and find out what it was -
DR. KWAN:
A. I just wait for this Commission to--you know, probably had a better insight, the whole overall problems than the one external report.
COFFEY, Q.C.:
Q. Doctor, we've heard evidence that in the fall of 2005, there was a certain amount of--well, the great bulk of results didn't come back here until January of 2006. Did you ever discuss that, the kind of wait time with people?
DR. KWAN:
A. With the administration?
COFFEY, Q.C.:
Q. Yes.
DR. KWAN:
A. No, because we all get so busy.
COFFEY, Q.C.:
Q. Doctor, in terms of your own patients, because you would have discussed this at times with your own patients, I'm not going to ask you about any individual patient, but you would have discussed this whole matter at times?

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DR. KWAN:
A. Most of my patients, as I said, at that time is probably gone to the Cancer Clinic. I only have a few patients that I followed.
COFFEY, Q.C.:
Q. Have you discussed it with any of them?
DR. KWAN:
A. If they had change, yes.
COFFEY, Q.C.:
Q. And have you ever been asked or were you ever asked about why did this happen or how did it happen?
DR. KWAN:
A. I'm sure they have, I just cannot offer them a clear answer.
COFFEY, Q.C.:
Q. What would you tell them or what did you tell them?
DR. KWAN:
A. I just tell them the change, something happened in the laboratory. At this time, we have been finding out the causes.
COFFEY, Q.C.:
Q. Now Doctor, when we looked at those minutes back in July, one of them attributes to you,

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you're comforted or happy to note, or comforted to note or at least relieved to note that perhaps it was just a change in technology, just in the sense of it's a better machine. That's the sense of it there. Did you, at any time, ever come to any different views on that?
DR. KWAN:
A. Well, subsequently, they'd obviously proven probably not going to be true. As you remember, that's a very early meeting at the time, and we are still grappling with the problem and tried to find out what is the problems and I was happier if it's an easier problem that I can--that the laboratory can correct.
COFFEY, Q.C.:
Q. Doctor, when did you first come to the realization that it wasn't simply it's a better machine?
DR. KWAN:
A. Subsequently, I think, not too soon after that, I would assume.
COFFEY, Q.C.:
Q. So by the -

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DR. KWAN:
A. I can't remember a particular time, but I would say after the first--maybe another meeting or another--I don't know, perhaps even after my meeting with Dr. Williams, discussion with Dr. Williams. I can't remember exactly when.
COFFEY, Q.C.:
Q. That it was a more complicated problem, a more complex problem than simply it's a better machine, move on?
DR. KWAN:
A. Um-hm.
THE COMMISSIONER:
Q. Mr. Coffey, it's getting near the luncheon break.
COFFEY, Q.C.:
Q. Yes. If we could, please, Exhibit P-0423? Doctor, this is an e-mail of November 6th, 2006. It's notifying people about Dr. Denic giving a presentation to a large group, November 20th, this would be 2006. It's to include a number of people, including surgeons who do breast surgery, and you'd fall into that category. Do you recall, did you go or

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attend this presentation in November of 2006?
DR. KWAN:
A. No, sir.
COFFEY, Q.C.:
Q. Did you receive any information concerning it afterward about -
DR. KWAN:
A. No, sir.
COFFEY, Q.C.:
Q. Like a copy of the slide deck or the slide presentation or anything like that? The answer is no?
DR. KWAN:
A. No, sir.
COFFEY, Q.C.:
Q. When we look at the second page, "surgeons that do breast surgery," you're listed, yourself and Dr. Felix are at the top there. So Doctor, after getting involved in the October and into November 2005 with this review panel, okay, other than your involvement with the review panel, did you have any other involvement with the ER/PR matter?
DR. KWAN:

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A. No, sir.
COFFEY, Q.C.:
Q. And perhaps then if we could come back then after lunch, Commissioner, and I'll finish up.
THE COMMISSIONER:
Q. All right then. We'll take the luncheon break. We'll meet again at 2:15.
COFFEY, Q.C.:
Q. Thank you.
(LUNCH BREAK)
THE COMMISSIONER:
Q. Please be seated. Mr. Coffey.
COFFEY, Q.C.:
Q. Yes, Doctor, we've heard evidence concerning a breast disease site group which there's been some evidence, first, well it was contemplated and then formed in 2006. Were you involved in that at all?
DR. KWAN:
A. Not really. I think, if I understand correctly, that is within the Cancer Clinic.
COFFEY, Q.C.:
Q. Okay, and so it didn't involve yourself. Doctor, you've indicated to the Commissioner, you know, in terms of the idea of setting up a

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panel, a review panel, remember that, that you would have medical oncologists, radiation oncologists, surgeons, some--a pathologist or two and as it turns out, Dr. Carter was there, she's a breast pathologist, and some administrative support. That was the -
DR. KWAN:
A. I think that's Dr. Williams' structure.
COFFEY, Q.C.:
Q. Dr. Williams, the way it finally came?
DR. KWAN:
A. That we looked at it, yes.
COFFEY, Q.C.:
Q. But yourself, your view of it was that we're in uncharted territory here because of the delayed treatment, which -
DR. KWAN:
A. Correct.
COFFEY, Q.C.:
Q. - would happen potentially, and it might be that you could only have a certain amount of expertise around the table to provide advice to people such as yourself, for example, who are not in a day to day sense involved in following cancer patients after surgery any

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more.
DR. KWAN:
A. Not at the moment, yes.
COFFEY, Q.C.:
Q. Yes, and at the time, I mean, by 2005 certainly, you weren't involved in that, as you pointed out to the Commissioner. Those patients were few and far between for you by that point?
DR. KWAN:
A. That's correct.
COFFEY, Q.C.:
Q. And I take it, Doctor, that you would have thought, at the time, "well, look, there'll be myself, there'll be Dr. Felix and perhaps other surgeons in the same position." Did you understand, at the time, because this had gone all the way back to '97, '98, '99, went back for years, that some patients would no longer be patients of the Cancer Treatment Centre?
DR. KWAN:
A. That's correct.
COFFEY, Q.C.:
Q. They would be followed for about five years.
DR. KWAN:

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A. Yeah, I mean, it all depends what the follow up, how some--some patients would have been discharged from the Cancer Clinic. That is correct, no longer followed.
COFFEY, Q.C.:
Q. And so some of them, there'd be a group of patients who would have been discharged, having been followed by the Cancer Treatment Centre for a period of time, or some, perhaps, who had never been followed by the--for whatever reason, not followed by the Cancer Treatment Centre, and but their particular physicians, their--in many cases, their surgeon or their general practitioner would need to be told -
DR. KWAN:
A. Correct.
COFFEY, Q.C.:
Q. - if there was a change, the fact that they changed had occurred, as well might require some advice as to--from people who would presumably be in the best position to know, expert advice, as to what is appropriate. That was your--at the time, your approach?
DR. KWAN:

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A. Correct.
COFFEY, Q.C.:
Q. Doctor, was there ever any discussion about the fact that for many of these patients, they would already be patients of the Cancer Treatment Centre, current patients?
DR. KWAN:
A. Yes, we do go through--if they found it with the Cancer Treatment follow up program care, we would identify the oncologist who's looking after it and send him a letter.
COFFEY, Q.C.:
Q. Send him or her?
DR. KWAN:
A. Him or her, yeah.
COFFEY, Q.C.:
Q. In the main, Doctor, if the treating oncologist, currently treating oncologist, was a medical oncologist, for example, Dr. Siddiqui, Dr. McCarthy, Dr. Laing, and there'll be others, was there actually any need to have the panel look at those patients? Because the medical oncologist who's sitting next to you on the panel, Dr. Laing or Dr. McCarthy, would actually be making the

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decision anyway.
DR. KWAN:
A. Probably not, you know, in that sense, but we don't isolate and identify patients on that, and I think this is generally the panel is making as a recommendation. For anybody who has expertise in that matter, they can either accept our recommendation or not accept our recommendation.
COFFEY, Q.C.:
Q. Sure. Doctor, by the time the panel first sat, which is around October 13th, 14th, the first meeting, and then October 20th, 27th, and there are meetings thereafter at times, by the time the panel first sat, you would have understood that there were, I don't know, 700-800 patients or more that were going to be retested? Would you have understood that at the time?
DR. KWAN:
A. No, I didn't.
COFFEY, Q.C.:
Q. Okay, just -
DR. KWAN:
A. We didn't know how many numbers was there.

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COFFEY, Q.C.:
Q. Okay, and I just want to kind of canvas some of that with you. When did you realize, like what turned out to be the actual numbers, not the precise number, but the kind of sheer magnitude?
DR. KWAN:
A. As it goes along, it seems to be never ends. Then we start getting the feeling that there's a lot more number than, than at least I anticipated. I don't know about the others, at least I anticipated it.
COFFEY, Q.C.:
Q. Doctor, if you had known two things, if you had known the sheer number involved, okay, of patients that were going to be retested, and for the sake of argument here, we'll assume for the moment that, say 40 percent had a change in result, if you had known that, and I'll just pick a figure, 500 patients being retested, 40 percent of that, 200 patients that would have to go through your panel, and in fact, on 1,000 patients, it would be 400 patients would have to go through your panel, if you'd known the sheer size of the numbers

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and realized how many of those patients were already patients, current patients of the Cancer Centre, already had a medical oncologist, would you have given any consideration to only having the panel look at the non-cancer -
DR. KWAN:
A. Certainly if we know that it would take a horrendous amount of effort to go through the sheer magnitude of the number, it may well be a reasonable approach to screen those out and say, yes, if they got a problem, then have those patients referred back to the tumour board, which is totally different entity, to discuss their management of that group. That will be certainly a consideration, but that wasn't -
COFFEY, Q.C.:
Q. It just didn't happen, it didn't come up?
DR. KWAN:
A. It just didn't happen, no.
COFFEY, Q.C.:
Q. It was never--once the panel itself, in the middle of October, kind of embarked on the process, there was no actual kind of--that you

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can recall at any time at which there was a reevaluation of the position we're in here?
DR. KWAN:
A. No. I think we were trying to do as much as we can as the report comes back, to try to deal with it as quick and as soon as we can. So we may have occasionally lost track of the sheer numbers that has to come through eventually.
COFFEY, Q.C.:
Q. And if we could, please, Doctor, if we could please, Registrar, Exhibit P-1420? Doctor, this is a letter of September 19th, 2007. It's addressed to Marian Crowley, the quality and risk information coordinator at Eastern Health. It's about a letter sent to patients and families of August 17th, 2007 regarding ER and PR retesting. It's "respectfully yours," that would be your signature, I believe, right there?
DR. KWAN:
A. Yeah.
COFFEY, Q.C.:
Q. And it's copied to a number of people within Eastern Health, including people on the

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executive, and Doctor, how is it that you came to sign this letter?
DR. KWAN:
A. Well, it was brought to my attention, by both the medical oncologists and the radiation oncologists, some inaccuracy in that letter. I think it's the letter applied screening, which really wasn't a test that we were concerned about screening. So we thought that we should mention it to them and they asked, mentioned to us, to them that this letter, this process, there's some error in their letter, and it added further confusions to already confused situation. We thought that they should know and we thought that collectively we should put our signatures on it.
COFFEY, Q.C.:
Q. Do you recall who drafted the letter?
DR. KWAN:
A. No, I don't. The letter was brought to me through McCarthy and Laing and Ganguly and, I think that's what the -
COFFEY, Q.C.:
Q. And you read it and then signed it?

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DR. KWAN:
A. And I read it and then signed it, yes.
COFFEY, Q.C.:
Q. Doctor, at the time, do you know or did you inquire about or make any inquiries or be told about how it was that the letter had come to be sent at all?
DR. KWAN:
A. I don't know. I saw the original letter that was sent out, a copy of a letter that actually, if I remember correctly, now I have not--because I don't receive a copy of that letter, it's brought to the attention to one of the medical oncologists through his patients, his or her patient, I don't even know who it was, and I read it and it was, in fact, using breast screening tests was what's the word used, and we thought that that was an incorrect description was the problems were. We thought that they needed to be made aware of that.
COFFEY, Q.C.:
Q. Did you make any inquiries about whether or not anybody ran this past us, as a group, before it was sent out?

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DR. KWAN:
A. Yes. We talked about--we talked within ourselves has anybody seen this letter before it goes out, the answer is no, none of us have seen this letter before it went out.
COFFEY, Q.C.:
Q. Have you made any inquiries since?
DR. KWAN:
A. No, sir.
COFFEY, Q.C.:
Q. If we could, Exhibit P-0731? 0731, please. Doctor, this is a letter of October 11th, 2007. It's addressed to a number of individuals. Here's a third name there. It's from Ms. Crowley. It's copied to the people that were copied on that letter that we just looked at, and it's re: a court order, a letter sent to patients and families, August 17th, 2007, regarding estrogen and progesterone retesting, and she acknowledges receipt of your letter, yours and others, and she says "in an effort to clarify our involvement, I will highlight key points related to the circumstances around the letter for those of you who may not be familiar."

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And the second bullet says "professionals involved in this matter were sent a copy of the court order, but were unable to provide a list of the patients involved," and then talks about the days spent trying to identify patients who met the criteria stated in the court order, and in the third bullet, it says "staff of the Quality and Risk Management department coordinated the logistics of getting the letter out, including consulting with physicians and others to confirm which patients should be included and getting MCP numbers, addresses and labels. We eventually determined that the patients who were panelled by the ER/PR physician review panelling group met the legal definition of patients who converted from clinically negative to clinically positive."
And then "on August 16th, 2007, Eastern Health received a copy of a cover letter to accompany the class action notice from the lawyers and the registered letters had to be in the mail by August 17th." She says "we understood from our lawyers we could not change the wording which included the

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inaccurate reference to screening."
So Doctor, I'm going to ask you here, in terms of this third bullet, were you ever, because you had been involved in the physician review panelling group, ever approached concerning who should get the letter?
DR. KWAN:
A. No, sir, not me personally.
COFFEY, Q.C.:
Q. Doctor, was there ever any concern amongst the panel members about the amount of time it was taking to get through them?
DR. KWAN:
A. Sometimes we had to wait for the list of patients to come through, you know. I don't know--I guess we just meet and meet and sometimes we just lost track of how long we took.
COFFEY, Q.C.:
Q. Did you ever encounter yourself any difficulty in contacting patients to let them know about the review letters?
DR. KWAN:
A. Sometimes it takes a few phone calls, yes, to track the patients down, and, you know.

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COFFEY, Q.C.:
Q. Were there any patients of your own that you were not able to contact?
DR. KWAN:
A. No, sir.
COFFEY, Q.C.:
Q. And did anyone from Eastern Health ever follow up with you to question or to ask of you whether you had contacted all your patients?
DR. KWAN:
A. I think somebody did. They did call and say have you contacted; yes. I don't know who, though, but I remember somebody called the office.
COFFEY, Q.C.:
Q. Doctor, you'll recall earlier this morning I referred you to minutes, in particular, MAC minutes referring to adverse events, policies, that sort of thing. Doctor, in relation to your involvement then in ER/PR, did anyone, to your knowledge, within your earshot, or involving you, yourself, ever discuss with anybody the idea of following that policy or policies in dealing with your patients concerning ER/PR, actually getting out that

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policy -
DR. KWAN:
A. I'm thinking now whether anybody talked to me about ER/PR. No, I don't believe so.
COFFEY, Q.C.:
Q. The idea of - okay, we're into this, we do have a policy concerning adverse events, because you had been looking at it in the MAC just before this all happened.
DR. KWAN:
A. I don't - I don't think everybody took that and applied the ER/PR right away. Now may have done it -
COFFEY, Q.C.:
Q. Afterwards.
DR. KWAN:
A. After, but that moment, I don't think anybody spoken to me and said we need to do it. They may have done, but I don't know.
COFFEY, Q.C.:
Q. And if they have, you have never been told?
DR. KWAN:
A. No.
COFFEY, Q.C.:
Q. Commissioner, that's all the questions I have.

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Thank you. Thank you, Doctor.
THE COMMISSIONER:
Q. Ms. Brazil.
MS. BRAZIL:
Q. No questions of this witness, Commissioner.
THE COMMISSIONER:
Q. Mr. Simmons.
DR. ALAN KWAN - EXAMINATION BY MR. DAN SIMMONS
MR. SIMMONS:
Q. Good afternoon, Dr. Kwan. Dan Simmons, I'm the lawyer here for Eastern Health. I just had one thing I wanted to ask you about concerning the contact that you would make with your patients after receiving a panel letter after they'd been panelled, and the letter went out. I'm going to show you just some samples of some of the letters first and that's at C-229, please. This was a selection of letters that we looked at with a witness earlier. I'm just going to show you the first couple because they are examples of the form that a lot of the letter take. In this particular one which comes from October 20th, 2005, the second paragraph there says, "The patient as discussed at the physician review

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panel, October 13th, 2005, and a review of the patient's chart revealed that she had been notified of the change in results and started on Tamoxifen", and it says the panel had no further recommendations at this time, and the next page is an example of another form of letter that appears frequently, and the second paragraph there is similar, but it starts in a similar way, "This patient was discussed at the physician review panel on October 20th, 2005. The recommendation of the panel is that there be no change in treatment as the patient has been previously treated with Tamoxifen", and it continues, "We would ask that you communicate the change in results to your patient as soon as possible". Do you recognize the format of these letters as being the format that would have been used for those panel letters that you received?
DR. KWAN:
A. Yes.
MR. SIMMONS:
Q. When you received a letter like this one on page two which asks that you communicate the change in results to your patient, even though

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there's no recommended change of treatment, what would you have done upon receiving a letter like that?

DR. KWAN:

A. Followed the instructions.

MR. SIMMONS:

Q. And -

DR. KWAN:

A. At least make an attempt to. Now having said that, all total I probably received maybe half a dozen of letters from the panel that I'm still remained the contact physician, although most of my patients have either been transferred or discharged.

MR. SIMMONS:

Q. Right.

DR. KWAN:

A. And no longer the contact physician.

MR. SIMMONS:

Q. So in any cases where if you received any letters like this which asked you to ensure that the communication took place, do you know if you followed up on that, or if there was -

DR. KWAN:

A. If I remember, I've contacted every one of

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them that I was - in that category that I can remember.

MR. SIMMONS:

Q. Good. Fine, thank you, Dr. Kwan.

THE COMMISSIONER:

Q. Mr. Pritchett.

MR. PRITCHETT:

Q. No questions, Commissioner. Thank you, Dr. Kwan.

THE COMMISSIONER:

Q. Ms. Newbury.

DR. ALAN KWAN - EXAMINATION BY MS. JENNIFER NEWBURY

MS. NEWBURY:

Q. Good afternoon, Dr. Kwan. My name is Jennifer Newbury, and I represent the Canadian Cancer Society. I want to ask you a couple of questions about the physician review panel as well. When you were initially suggested the physician review panel as an idea back in probably the summer of 2005, somewhere around that time, did you expect that the patient's current medical history would be made known to the panel?

DR. KWAN:

A. We would have to update the history if we

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found it necessary to do so. We have situations where - particularly in patients, for example, in central Newfoundland and things of that nature, we need to ask permission to get those history before we can make any decisions, and sometimes have to be delayed the next panel visit discussion before we can form any answers, yes, we did.

MS. NEWBURY:

Q. And so the mechanism in place for patients outside of the St. John's area was different from those within -

DR. KWAN:

A. No, no, applied to every - I'm just using that as an example. It's exactly the same anywhere.

MS. NEWBURY:

Q. Okay, and in your view, as the panel meetings proceeded, the ones that you attended, I guess you can speak to specifically, was it your understanding that current medical history was available before the panel made recommendations to the attending physician?

DR. KWAN:

A. Certainly as close as we can get.

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MS. NEWBURY:

Q. Okay.

DR. KWAN:

A. You know, I mean, sometimes you get patient's last visit. That's all the information that we have, particularly related to tumours, and there's no particular indications up to that point that we can - felt that we can make the recommendation, we would.

MS. NEWBURY:

Q. And you're not aware of any consideration of allowing the attending physicians to participate, either by telephone, or perhaps attending the meeting or providing any other sort of written recommendations to the panel before it met?

DR. KWAN:

A. Oh, I don't think we ever considered that, no. The issue will be a significant hurdle. We did offer, as you know, if they have any questions, please refer the patient back to us. That was included in the letter going out to them.

MS. NEWBURY:

Q. Okay. So as far as you know, you did have, I

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guess, best possible up to date information for the patients before the panel made recommendations?

DR. KWAN:

A. As much as we can make a decision on.

MS. NEWBURY:

Q. Okay.

DR. KWAN:

A. I mean, we don't go farther into details and details of which that we don't think is necessary for our information.

MS. NEWBURY:

Q. And do you know whether the panel ever left it to the attending physician to meet with the patient to update the medical history after the panel had met and made its recommendations?

DR. KWAN:

A. All these things is a recommendation. The panels can only make recommendations. The panel cannot make absolute decisions or treatment. If the individual physicians take this recommendation and say that, look, there's something wrong in the history, I can't cope - I can't apply this

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recommendation, then we're available for them to refer the patient back, discuss the issue, and maybe we were - the information is missing. I think that's why the decision is not sent to the patients, but the physicians.

MS. NEWBURY:

Q. Okay, and in terms of communication then with the physician who ultimately will meet with the patient and make the decision, how would those physicians know the information that was available to the panel when it made its recommendation, if there as no other direct communication with the treating physicians?

DR. KWAN:

A. When they think there's a contraindication for treatment, for example, if the patient, we recommend Tamoxifen, and within the last month they develop huge deep vein thrombosis and a stroke, for example -

DR. KWAN:

A. Sure.

MS. NEWBURY:

Q. Then he would then recognize there is a contraindication here now, which happened within last month or two, whatever, and may

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think that there's a contraindication to treatment.

MS. NEWBURY:

Q. Uh-hm.

DR. KWAN:

A. Then he or she contact back to the oncologist and refer the patient back for discussion.

MS. NEWBURY:

Q. And if the treating physician, the primary recipient of the panel letter, haven't met with his or her patient within, say, the last eighteen months or two years, was there an expectation by the panel that the physician meet with the patient, get an update of the medical history, and then verify the panel's recommendation?

DR. KWAN:

A. I think the - I think there would be expectation of the physicians to discuss the patient's treatment, the change and that, and treatment recommendation that had been altered with the patients, and explain to him or her what the issues are so they can understand the issue and then if things are not clear enough, then refer back, and if the physician have any

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question about that, to refer the patient back. That is the expectation.

MS. NEWBURY:

Q. And would there be any concerns that perhaps the treating physician might make assumptions about the availability or access to information that the panel had? Perhaps the physician who receives a panel letter might assume that the panel had more up to date information if - you know, if maybe the patient was seen at the cancer clinic more recently, that that decision -

DR. KWAN:

A. If at the Cancer Clinic more recently, we will have that information in our computers to tell us that the patients have been there and those who were there.

MS. NEWBURY:

Q. But the recipient of the letter, though, may not necessarily know what information the panel did or did not have?

DR. KWAN:

A. They may not know, but the communication has to occur. I mean, it's difficult for us to cover every aspect of it.

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MS. NEWBURY:
Q. Sure, and you're not aware of any sort of general direction to the recipients of these letters in terms of how to proceed upon receipt of the panel letters, how to incorporate them in terms of their own treatment of the patient?
DR. KWAN:
A. No. I mean, we didn't have any communication to tell them what exactly to do, but always hope that they are physicians and they should be able to handle some of those issues.
MS. NEWBURY:
Q. Sure. Now these circumstances, though, are perhaps a little different than what a physician might normally refer for a consultation, more contemporaneously with treating a particular patient?
DR. KWAN:
A. Sure. They would be available for consultations and they refer backwards.
MS. NEWBURY:
Q. And you had indicated that the current medical history is certainly a significant issue -
DR. KWAN:

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A. Yes, some -
MS. NEWBURY:
Q. Comorbidity would be -
DR. KWAN:
A. Most definitely.
THE COMMISSIONER:
Q. Dr. Kwan, just in answer to that last question, were you assuming that the letter from the panel was the only information that a general practitioner who might have been the recipient would have received in the sense of official communication from -
DR. KWAN:
A. I wouldn't know if they have received anything else from anybody else at Eastern Health directly. I don't know that.
THE COMMISSIONER:
Q. So you don't know whether or not they might have received other information -
DR. KWAN:
A. Correct.
THE COMMISSIONER:
Q. Of a general nature about the issue.
DR. KWAN:
A. Correct.

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MS. NEWBURY:
Q. Dr. Kwan, you mentioned at some of the panel meetings where a patient of your own was listed to be panelled, you would bring along information to the panel meeting?
DR. KWAN:
A. Yeah, just in event it was not covered. I mean, I had my own office chart which is basically - my office charts are duplication from the computer of the hospitals. In the event sometimes the computer glitch, you then have the information, you save time from digging it out and have it in my file.
MS. NEWBURY:
Q. Okay. So then you would your own chart, but you expect it should be a duplicate of the -
DR. KWAN:
A. Yes, my chart is all duplicate from what's in the computer.
MS. NEWBURY:
Q. And you'd mentioned that when you arrived at the meeting, the charts would be there. So even our own patient chart would still be there at the meeting.
DR. KWAN:

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A. All the Cancer Clinic charts would be there.
MS. NEWBURY:
Q. Okay.
DR. KWAN:
A. Don't usually have the hospital chart, but hospitals are in computer, Meditech.
MS. NEWBURY:
Q. Okay.
DR. KWAN:
A. But Cancer Clinic chart which is in a different system, and we oftentimes don't have access to it.
MS. NEWBURY:
Q. Okay. Dr. Kwan, you were shown a letter that was forwarded to you from Dr. Cook, July 18th, 2005. That was early on in the retesting.
DR. KWAN:
A. Uh-hm.
MS. NEWBURY:
Q. And did you receive any other similar letters early on?
DR. KWAN:
A. I think there's one more, if I remember, I mean, just because I went through it. I wouldn't remember it, but there was - I was

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brought to attention there's one more.
MS. NEWBURY:
Q. Okay, and were you able to handle those two letters without the benefit of a review panel, and if so, how did you make a decision about what to -
DR. KWAN:
A. I think they both reviewed.
MS. NEWBURY:
Q. Okay, they were both -
DR. KWAN:
A. They were - if I remember, they were all subsequently reviewed, but those patients were contacted as soon as I got the letter.
MS. NEWBURY:
Q. Okay, and were any recommendations made to the patients in the interim, or did you suggest awaiting the outcome of the review panel?
DR. KWAN:
A. No, both of them did not require any -
MS. NEWBURY:
Q. So it was just an information -
DR. KWAN:
A. Just happened to not require any change in treatment.

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MS. NEWBURY:
Q. Okay, and if, for example, and this is a hypothetical, of course, if there had been a change recommended, would you have been able, as a surgeon, to have made recommendations without the benefit of a panel?
DR. KWAN:
A. I would be on very thin grounds.
MS. NEWBURY:
Q. Yes.
DR. KWAN:
A. Let's put it this way. I certainly would like to tell the patient then and wait until these things have been given answer. We are panelling patients that are well, you know, not--and they are panelling patients that their treatments at that time, 2005, maybe even they're panelling 2002 patients, so there really don't have that immediate treatment in a week or two that we have to get an answer from. If the situation does arrive, we would suggest then to go to the tumour board and refer it back to the medical oncologist.
MS. NEWBURY:
Q. And if either you didn't have the benefit of

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the review panel that was in place at this time or if you wanted to make a more urgent decision before the panel was put in place, what other options would have been available to you to help make a decision as to -
DR. KWAN:
A. That's what I was just mentioning, that we will refer the patient to the medical oncologist directly.
MS. NEWBURY:
Q. Okay.
DR. KWAN:
A. Or bring the--I have the advantage of of bringing the patient to the tumour board, which is totally different than the panel.
MS. NEWBURY:
Q. Right.
DR. KWAN:
A. And have them to send it in that situation and get some answers.
MS. NEWBURY:
Q. Okay. Dr. Kwan, you mentioned that you only received about a half dozen letters from the physician review panel?
DR. KWAN:

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A. About that. I don't know, I don't remember the exact number, but it's not a huge amount.
MS. NEWBURY:
Q. Just certainly not a huge amount?
DR. KWAN:
A. No.
MS. NEWBURY:
Q. And those were letters that you were the primary recipient as opposed to being copied on the letter?
DR. KWAN:
A. Correct.
MS. NEWBURY:
Q. And how quickly were you able to make your calls to those patients to advise of the results?
DR. KWAN:
A. Most of those patients, those patients were patients because I'd been primary physician they are followed, I have regular clinic visit from them.
MS. NEWBURY:
Q. Okay.
DR. KWAN:
A. They come visit. So it wasn't that difficult

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for me to pick up the phone and say I'll see you next week or in two weeks down the road, whatever the conveniences are and deal with it.

MS. NEWBURY:

Q. Okay. In either of those cases would you have just simply put the letter in the file and await the next regularly scheduled appointment, you know, several months down the road or would you -

DR. KWAN:

A. No, no, those are patients I'd call them.

MS. NEWBURY:

Q. Okay.

DR. KWAN:

A. Or bring them in clinic earlier.

MS. NEWBURY:

Q. And were you given any, aside from what might have been stated in the letter itself, were you given any direction in terms of the timing of communication with patients, the fact that they may or may not be awaiting results and that the only person who might communicate this, the results of the retesting was you?

DR. KWAN:

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A. The two group of paper, letters I get now.

MS. NEWBURY:

Q. Sure.

DR. KWAN:

A. The first group is coming from Don Cook's group, which is have no recommendation or treatment.

MS. NEWBURY:

Q. Um-hm.

DR. KWAN:

A. And that were the patients that unfortunately in that particular situation both my patients does not require any change or any treatments. The second group of letters I get were those where the panel with recommendations about what to do, those are the patients which I have brought back to my clinic a lot earlier and informed them of that issues and change. And, in fact, many of them, I would say with the exception of one patient, have all been referred back to the medical oncologist for their opinion and discussion.

MS. NEWBURY:

Q. Okay. So you communicated with them but -

DR. KWAN:

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A. Correct.

MS. NEWBURY:

Q. - referred them on for -

DR. KWAN:

A. Yes, I told them that what the changes and referred them to what the options of treatments and referred them back to a medical oncologist to get their opinion as to say, so that they get opportunity to discuss it with the medical oncologist.

MS. NEWBURY:

Q. Okay. And was it your understanding that if you had not communicated those results to the patients, that there would be no one else communicating those results to the patients, necessarily?

DR. KWAN:

A. With the letter addressed to me to ask me to do the job, I thought that since I'm on a panel, there's no way I can get away with not doing it -

MS. NEWBURY:

Q. Sure, okay.

DR. KWAN:

A. - I will do it.

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MS. NEWBURY:

Q. So you didn't think that there was some other parallel process going on -

DR. KWAN:

A. Let's put it this way, I didn't expect anybody to be able to do that for me.

MS. NEWBURY:

Q. Okay. Dr. Kwan, during the various panel meetings that you attended and we do have some minutes for some meetings but not for all, as I understand it, I'm wondering if you ever dealt with a situation where patients were initially PR positive and ER negative, but upon retesting were both ER and PR negative?

DR. KWAN:

A. That is difficult to remember any of that because with ER and PR positive you would be treated with Tamoxifen.

MS. NEWBURY:

Q. Okay. So in your view, as a surgeon, you would have treated -

DR. KWAN:

A. Yeah, I would assume we would be treating either ER, both ER or PR positive, even one of them will be treated.

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MS. NEWBURY:
Q. Okay.
DR. KWAN:
A. Given Tamoxifen as considered positive for treatment if the situation fits, the required Tamoxifen would have been prescribed, so that would be very few of them. And if compared to be negative, I don't think I ever come across one that become negative.
MS. NEWBURY:
Q. Okay.
DR. KWAN:
A. In the situation to suggest--I can see where you're asking because it would be on negative you may go to retesting and you come back both negative, I can see where you're asking, asking the question, but I don't believe we ever come across one of those situations.
MS. NEWBURY:
Q. Okay.
DR. KWAN:
A. And if they do come out, they will be admin Tamoxifen, unfortunately they will be treated by Tamoxifen unnecessary or because becoming PR positive.

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MS. NEWBURY:
Q. Right. So based on the fact that they are PR positive, they would -
DR. KWAN:
A. They would have been started on Tamoxifen -
MS. NEWBURY:
Q. - obviously -
DR. KWAN:
A. - and they become negative, I'm don't--I'm not so sure -
MS. NEWBURY:
Q. So that doesn't ring a bell to you?
DR. KWAN:
A. No, it doesn't ring a bell anybody came across like that would be an issue, but didn't came across it.
MS. NEWBURY:
Q. Just for your information, the only minutes that I saw that you attended where there's anything close to that was P-2632. And I'll just bring that up for the record. And this is the panel, just a fairly recent one, January 28th, 2008, and you're listed there. And on the second page this is actually ER and PR, five to ten, and then it converted to

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zero, zero. So that's the closest thing I could see to that situation and that case it wasn't dealt with because the patient was deceased.
DR. KWAN:
A. Deceased, yes.
MS. NEWBURY:
Q. Looks like from that. During this meeting can you recall any other discussion about retroconversions, either retroconversions from ER and PR positive to ER/PR negative or the PR positive alone to ER, just sort of any general discussions about that type of situation?
DR. KWAN:
A. I don't recall any particular discussion in that situation. If the situation arrives, then all we--we will be reviewing and discussing whether it is appropriate to stop therapy or whether it's appropriate to continue therapy. I think that will be one of the issues that will have to be discussed.
MS. NEWBURY:
Q. Okay. And you'd mentioned, I think, earlier this morning that on some occasions lists were available to the panels, you thought all

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patients were presented to the panels, even though their charts may not be available to the review panel. Am I correct in that?
DR. KWAN:
A. Yeah, well they may not be available. There were--I think the list is made up as the reports comes back.
MS. NEWBURY:
Q. Um-hm.
DR. KWAN:
A. And we don't--like, I'm pretty sure that all the reports come back and the chart, patient were assumed to be a cancer clinic patient, so the chart would be available. By the time it comes in there, they weren't the cancer clinic patients and the chart wasn't available and have to be sorted somewhere else or the chart will have went over to, say, central Newfoundland on a peripheral clinic, the chart went out there and has not come back and those have been delayed and but retrieved.
MS. NEWBURY:
Q. But were there some patients for whom the results were there and available on a list but because there wasn't considered to be a

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change, their chart wasn't reviewed?
DR. KWAN:
A. I don't recall that. I don't think we make any decisions, if I remember right, make a decisions without the charts. I don't think so.
MS. NEWBURY:
Q. I guess these would be cases where it was felt that a decision wasn't necessary, you're deciding who should or should not be panelled?
DR. KWAN:
A. You mean those patients that are ER and--I'm trying to think of scenario. But patients who are ER and PR positive then that was on treatment, they usually don't get retested in the first place.
MS. NEWBURY:
Q. Okay.
DR. KWAN:
A. And those patients who are negative and retest is positive, that need to be reviewed.
DR. KWAN:
A. Or ER negative and PR positive and then converted to -
DR. KWAN:

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A. That will be reviewed. I mean, if you are on treatment, that would still be looked at.
MS. NEWBURY:
Q. Okay.
DR. KWAN:
A. But I don't remember -
MS. NEWBURY:
Q. So if they were ER negative and PR positive and converted to negative ER -
DR. KWAN:
A. Negative, negative.
MS. NEWBURY:
Q. - and negative PR?
DR. KWAN:
A. Yes.
MS. NEWBURY:
Q. You believe that they would have been reviewed?
DR. KWAN:
A. I believe those would have been changed. Anything altered significantly, that would be looked at.
DR. KWAN:
A. Okay. But you had no recollection -
DR. KWAN:

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A. I can't recall because that must be very few and far between and I can't remember anyone that we really hassle a lot through that.
MS. NEWBURY:
Q. And in your view it would be appropriate to panel those cases because a change of treatment might be required?
DR. KWAN:
A. I'm sorry?
MS. NEWBURY:
Q. And in your view it would be appropriate for the panel to have reviewed those cases -
DR. KWAN:
A. Yes, they would have -
MS. NEWBURY:
Q. - because the change of treatment -
DR. KWAN:
A. - change of treatment may be required.
MS. NEWBURY:
Q. - might be required? Thank you. Dr. Kwan, you'd mentioned earlier this morning that it was your suggestion that patients be tracked long term, the group of patients that were involved in the retesting here. Can you recall when you first suggested that?

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DR. KWAN:
A. I think I talked about it July meetings, I think. I can't remember about the dates -
MS. NEWBURY:
Q. July of 2005?
DR. KWAN:
A. Yeah, I think that was somewhat--because I, being academic -
MS. NEWBURY:
Q. Right.
DR. KWAN:
A. And it came out as an opportunity to look at this as to what we do with this group of patients that we did late treating with Tamoxifen, do these patients all uniformally have no recurrence of tumours, say, ten years down the road or we have a higher than average recurrence of the tumours. I think those are very valuable information which, as I said to you, there is very little guidance in literature.
MS. NEWBURY:
Q. Sure.
DR. KWAN:
A. And we have an opportunity to do, make some

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contributions.
MS. NEWBURY:
Q. Okay. And do you think that there would be value in doing so even for the very group of patients involved?
DR. KWAN:
A. I'm sorry?
MS. NEWBURY:
Q. Would there be value not just for general research purposes, but for the particular patients involved?
DR. KWAN:
A. Probably, yes. I think, you know, as I say, my suggestion in mentioning that is that we need to look at this and follow it.
MS. NEWBURY:
Q. And what categories of patients would you have included in this long-term tracking?
DR. KWAN:
A. Anybody that has a changed.
MS. NEWBURY:
Q. Okay. And do you know, are you aware whether or not any efforts have been started to follow your suggestion?
DR. KWAN:

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A. I'm not aware of any organized way of doing it. I'm sure the cancer clinic as to see the patients and to treating the patients, that will be followed.
MS. NEWBURY:
Q. Um-hm.
DR. KWAN:
A. But I'm not aware of any organized ways. I think this would probably, this what I really meant is these patients should be flagged and in the long run, say, five years down the road we should then take this group of patients who have--and looked at again how they do.
MS. NEWBURY:
Q. And do an analysis based on -
DR. KWAN:
A. An analysis based on the status that's available to us.
MS. NEWBURY:
Q. Okay. And how long would you suggest following those?
DR. KWAN:
A. I would say five, ten years, as breast cancers are long-term results before we know anything.
MS. NEWBURY:

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Q. Okay.
DR. KWAN:
A. Difference.
MS. NEWBURY:
Q. Thank you, Dr. Kwan, those are all the questions. Thank you.
THE COMMISSIONER:
Q. Ms. Brocklehurst?
MS. BROCKLEHURST:
Q. No questions, Commissioner, thank you.
THE COMMISSIONER:
Q. Mr. Pike?
MR. PIKE:
Q. No questions.
THE COMMISSIONER:
Q. Mr. Browne?
MR. BROWNE:
Q. No questions, Commissioner, but I do believe Dr. Kwan has a statement he wishes to read out.
THE COMMISSIONER:
Q. Please do.
DR. KWAN:
Q. I just want to read this out to people, maybe personally I wouldn't add any more than that--

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I just say that over the last several years many of us here have been trying to understand and trying to elucidate the reason for the errors of the estrogen receptors and progesterone receptor determinations. I do believe and I believe that this problem is not unique to our laboratories. I would like to credit those who brought those issues to our attentions and encourage us all here and those who are not here to find out the cause and recommend a solution. And I express my regret to those who are adversely impacted. I continue to believe that we have an excellent group of individuals who these includes surgeons, medical oncologists, radiation oncologists, pathologists, laboratory technicians, nurses and managers who are dedicated to produce a high standard of health care system in our province. I also have utmost faith in pathologist colleagues who have over the last 35 years have provided me with excellent service and I trust will continue to provide an accurate diagnosis for all my patients in the future. Estrogen and progesterone receptors is only a part of the

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much important information needed for the diagnosis and management of breast cancer. It should be clear that the error of estrogen receptor and progesterone receptor determination do not in any way affect the histological diagnosis of breast cancer. We in health care are painfully aware of the consequence of errors and are constantly vigilant of the possibility. Unfortunately, error do occurs, particularly in a complex health care system. I feel we need to improve our dialogue and communication with our colleagues, understand our mutual problems and provide mutual support to our endeavour to achieve excellence in health care. Finally, I do believe that given the appropriate resources our immunohistochemistry laboratory will recover and once again become the laboratory that we will be worthy of our trust. Thank you.

THE COMMISSIONER:

Q. Mr. Coffey, is there anything arising?

COFFEY, Q.C.:

Q. No, Commissioner, thank you.

THE COMMISSIONER:

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Q. All right. Thank you, very much, Dr. Kwan, for coming and providing us with your insights.

DR. KWAN:

A. Thank you.

THE COMMISSIONER:

Q. I do appreciate it. Mr. Coffey, do you want to take the afternoon break before we continue with the next witness or -

COFFEY, Q.C.:

Q. Yes, Commissioner.

THE COMMISSIONER:

Q. All right, we'll do that.

(BREAK)

THE COMMISSIONER:

Q. Please be seated. Mr. Coffey?

COFFEY, Q.C.:

Q. Commissioner, the next witness is Maria Tracey.

MS. MARIA TRACEY (SWORN) EXAMINATION-IN-CHIEF BY BERNARD COFFEY, Q.C.

REGISTRAR:

Q. Would you please state and spell your full name for the record?

MS. TRACEY:

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A. My name is Maria Tracey, M-A-R-I-A, T-R-A-C-E-Y.

COFFEY, Q.C.:

Q. Ms. Tracey, would you please outline for the Commissioner your educational and professional background?

MS. TRACEY:

A. I'm the perioperative program director. I graduated with a diploma in nursing in 1997 (sic.) from the Mater Misericordiae Hospital in Dublin, Ireland. I did a post-grad course in midwifery, which I graduated from in 1979.

COFFEY, Q.C.:

Q. Okay, I'm sorry, the first one was in 19 -

MS. TRACEY:

A. '77.

COFFEY, Q.C.:

Q. '77, okay. I thought you said '97, I thought -

MS. TRACEY:

A. I could have.

COFFEY, Q.C.:

Q. You wish. That's '77, I'm sorry, go ahead.

MS. TRACEY:

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A. '77.

COFFEY, Q.C.:

Q. Go ahead.

MS. TRACEY:

A. I moved to live in Newfoundland in 1979 and I obtained a job of staff nurse on an orthopedic unit, 6 West, at St. Clare's Hospital. And in 1984 I became the nursing supervisor of that unit, actually, and I remained in that position for ten years. And then in 1994 I moved to a temporary position as the administrative supervisor of the operating room at St. Clare's and I remained in that position until 1996. In 1996 I became the program, perioperative program director and I'm in that position today. That was for the health care corporation when the hospitals became aligned -

COFFEY, Q.C.:

Q. Amalgamated.

MS. TRACEY:

A. - in the city, yeah.

COFFEY, Q.C.:

Q. By administration. And with the formation of the Health Care Corporation you became -

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MS. TRACEY:
A. That's right.
COFFEY, Q.C.:
Q. - the director of the perioperative program for the Health Care Corporation of St. John's?
MS. TRACEY:
A. Yes, which was the two adult sites.
COFFEY, Q.C.:
Q. Initially, well, initially it would have been the General Hospital?
MS. TRACEY:
A. It would have been the General, St. Clare's and the Grace.
COFFEY, Q.C.:
Q. And the Grace.
MS. TRACEY:
A. Until 2000.
COFFEY, Q.C.:
Q. And the Grace then closed in 2000 and so you would have continued on?
MS. TRACEY:
A. The services at the Grace were divided between St. Clare's and the General site.
COFFEY, Q.C.:
Q. Yes.

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MS. TRACEY:
A. In 2000.
COFFEY, Q.C.:
Q. And what about the Janeway?
MS. TRACEY:
A. I don't have any responsibility for the Janeway.
COFFEY, Q.C.:
Q. Even to this day?
MS. TRACEY:
A. Even to this day. That's under the Women's Health Program.
COFFEY, Q.C.:
Q. Now, Eastern Health was formed in April of 2005. Do you have a position with Eastern Health?
MS. TRACEY:
A. Yes, I do.
COFFEY, Q.C.:
Q. And what's your position?
MS. TRACEY:
A. My title remains the same and my responsibilities remain the same. My reporting structure, the executive realigned so I actually still reported when the Health

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Care Corporation was in place, I reported to the position was the vice-president of patient care services who was Louise Jones. When Eastern Health came into place, I reported still to Louise Jones but her title changed to chief operating officer for adult acute care.
COFFEY, Q.C.:
Q. Okay, and the institutions then that you're responsible for even today are the General Hospital here in St. John's and St. Clare's?
MS. TRACEY:
A. Correct.
COFFEY, Q.C.:
Q. Here in St. John's.
MS. TRACEY:
A. The operating rooms.
COFFEY, Q.C.:
Q. Operating rooms, yes. When I say the institutions, I meant the perioperative programs in them.
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. The other hospitals, for example, within Eastern Health, I'll just name Carbonear,

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Clarenville and any other facility, do you have any responsibility for perioperative and anything else?
MS. TRACEY:
A. No.
COFFEY, Q.C.:
Q. Who does that fall under, the other locations?
MS. TRACEY:
A. Actually, they all fall under different chief operating officers in the regions.
COFFEY, Q.C.:
Q. Okay, and the director of perioperative programs in the different hospitals would -
MS. TRACEY:
A. I don't believe they're structured the same as--because the hospitals--the operating rooms are a smaller number.
COFFEY, Q.C.:
Q. Yes.
MS. TRACEY:
A. So I would--I'm not quite sure about the structure, it wouldn't be the same.
COFFEY, Q.C.:
Q. So, for example, and I'll be asking you in a moment about what a director of perioperative

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program does.
MS. TRACEY:
A. Um-hm.
COFFEY, Q.C.:
Q. But if I was to ask you, for example, what that person or the equivalent did or does in Carbonear, say, as an example, you would have to find out the title of the person who actually does it and refer me or the Commissioner to that person?
MS. TRACEY:
A. That's correct.
COFFEY, Q.C.:
Q. And the same thing would be true in Clarenville?
MS. TRACEY:
A. That's correct.
COFFEY, Q.C.:
Q. In terms of breast surgery, which is really in the main what we're here about, other than Clarenville and Carbonear, the only other two places in which breast surgery occurs are the Grace and--I'm sorry, St. Clare's and the General? St. Clare's and the General. Do you know if breast surgery occurs anywhere other

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than Carbonear?
MS. TRACEY:
A. I couldn't say.
COFFEY, Q.C.:
Q. You don't know?
MS. TRACEY:
A. No.
COFFEY, Q.C.:
Q. Okay. Now then, what--so beginning in 1995, '96, if it's changed over the years, you could let the Commissioner know. Beginning in '95, '96 when you took over as the director of the perioperative program for the Health Care Corporation what were your responsibilities? You reported to Ms. Jones?
MS. TRACEY:
A. Correct. I -
COFFEY, Q.C.:
Q. Who reported to you and what were your responsibilities?
MS. TRACEY:
A. I had, at that time there were four managers reporting to me, because the Grace was still open. Today there's three managers who report to me. My position involved strategic

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planning for the perioperative program to make sure that our programs and goals were in alignment with what would have been the Health Care Corporation at that time. I am responsible for the financial management, human resource management and quality assurance within the program.
COFFEY, Q.C.:
Q. And you said there were initially four managers reported to you?
MS. TRACEY:
A. That's correct.
COFFEY, Q.C.:
Q. They were located where?
MS. TRACEY:
A. The Grace operating room and that person had responsibility for the recovery room, OR and the surgical daycare in that department. The St. Clare's operating room, and that person had responsibility for recovery room and surgical daycare at the Grace--at St. Clare's, sorry.
COFFEY, Q.C.:
Q. How about outpatients?
MS. TRACEY:

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A. The outpatients does not come under my program.
COFFEY, Q.C.:
Q. Okay. Wait now, I'm sorry, outpatients. Day surgery, I'm sorry, because you referred to the--you listed in the Grace, you listed three different ones.
MS. TRACEY:
A. Okay.
COFFEY, Q.C.:
Q. You said OR, recovery and, at the Grace?
MS. TRACEY:
A. Surgical daycare.
COFFEY, Q.C.:
Q. Surgical daycare.
MS. TRACEY:
A. And the same at St. Clare's.
COFFEY, Q.C.:
Q. Oh, St. Clare's is the same thing?
MS. TRACEY:
A. Yeah, surgical daycare.
COFFEY, Q.C.:
Q. The manager over there took care of those three things at St. Clare's?
MS. TRACEY:

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A. That's correct.
COFFEY, Q.C.:
Q. I'm sorry.
MS. TRACEY:
A. Then at the Health Science site the manager is in charge of the operating room and the recovery room. There's a different manager for the surgical daycare department, it's a much bigger division at that site, and that person also is in charge of the pre-admission clinics at St. Clare's and the General.
COFFEY, Q.C.:
Q. And that person reported to you?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. And still does?
MS. TRACEY:
A. Yes. Originally the pre-admission clinics were not part of the perioperative program, they were part of the ambulatory care program but they were realigned within perioperative because they were a better fit there.
COFFEY, Q.C.:
Q. Do you recall when that occurred?

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MS. TRACEY:
A. Late 1990s, I'm not exactly sure when. It was probably '98, '99.
COFFEY, Q.C.:
Q. Now, could you tell the Commissioner, because we've heard the word "perioperative" a number of times here, what is, what does perioperative mean in the context of these institutions?
MS. TRACEY:
A. It involves the pre, intra and postoperative care, the immediate pre, intra and postoperative care of patients. So we prepare the patients in the pre-admission clinic for their surgery. In surgical daycare the morning of surgery they are actually given the final preparation and they are brought to the OR for their surgical experience, recovered in recovery room and either admitted or discharged from--they're either admitted to the hospital, which is the inpatients units, from recovery or else recovery room discharges the patients to the surgical daycare department because those patients are going home the same day.

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COFFEY, Q.C.:
Q. And so in terms of the perioperative, as the director of perioperative care, of the perioperative division, you're responsible for, I gather, the pre-operation stage?
MS. TRACEY:
A. The education of patients -
COFFEY, Q.C.:
Q. Inter, inter--and this would be during the operation itself, what's going on in the OR?
MS. TRACEY:
A. Uh-hm.
COFFEY, Q.C.:
Q. And then in the recovery room.
MS. TRACEY:
A. Phase 1 and 2 of recovery, yes.
COFFEY, Q.C.:
Q. The immediate aftermath of that.
MS. TRACEY:
A. That's correct.
THE COMMISSIONER:
Q. Should I ask what the difference is between a Phase 1 and a Phase 2?
MS. TRACEY:
A. It's immediate post-operative phase and bring

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a patient - it has - they scored where it's appropriate to be discharged from recovery room. They are discharged either to in-patient units or to surgical day care, which is Phase 2, which means they are recovering from their anesthetic in an appropriate manner, and they're ready for discharge. So it's the staging of the discharge after an anesthetic.
THE COMMISSIONER:
Q. Okay. You were just saying you won't take them directly from the recovery room to out the door. There's a -
MS. TRACEY:
A. There's an interim stage, yes.
COFFEY, Q.C.:
Q. Or they end up on the ward being in the hospital.
MS. TRACEY:
A. Correct.
COFFEY, Q.C.:
Q. At which point whomever is up on the ward, it's their responsibility to care for the patient?
MS. TRACEY:

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A. That's correct.
COFFEY, Q.C.:
Q. They pass from you.
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. Commissioner, there are a number of exhibits. If I could please have them entered.
THE COMMISSIONER:
Q. Yes.
COFFEY, Q.C.:
Q. They are the following; P-2729, 2730, and then there's 2827, 2828, 2829, 2830, and then, Commissioner, P-2884, P-3082, P-3083, 3084, 3087, 3088, and 3089, as well as C-268, 269, 270, 271 and 272.
THE COMMISSIONER:
Q. Entered.
EXHIBIT P-2729 AND 2730 MARKED AND ENTERED
EXHIBIT P-2827 THROUGH P-2830 MARKED AND ENTERED
EXHIBIT P-2884 MARKED AND ENTERED
EXHIBIT P-3082 THROUGH P-3084 MARKED AND ENTERED
EXHIBIT P-3087 THROUGH P-3089 MARKED AND ENTERED
EXHIBIT C-268 THROUGH C-272 MARKED AND ENTERED
COFFEY, Q.C.:

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Q. Thank you. Now as Director then, Ms. Tracey, of Peri-Operative Program, what is the division of responsibility between you and the physicians, for example, Dr. Kwan's role?
MS. TRACEY:
A. There are two co-clinical chiefs in a leadership team with me, and what Dr. Kwan was from 1999 onwards, the co-clinical chief for surgery for surgery until 2006, there is a co-clinical chief for anesthesia, Dr. Frank King.
COFFEY, Q.C.:
Q. And -
MS. TRACEY:
A. So the physicians look after the physicians within the program.
COFFEY, Q.C.:
Q. And you looked after everyone who was not an MD, in effect?
MS. TRACEY:
A. Essentially, yes, and some - it was, I guess - we worked as a team, so physician issues would come to my attention perhaps, but I would defer to Dr. Kwan or Dr. King as appropriate, or currently--there's one clinical chief because Dr. Rockwood, who replaced Dr. Kwan,

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has resigned.
COFFEY, Q.C.:
Q. And so right now there is co-clinical chief of anesthesia?
MS. TRACEY:
A. Anesthesia.
COFFEY, Q.C.:
Q. And the surgery position is vacant?
MS. TRACEY:
A. Is vacant.
COFFEY, Q.C.:
Q. How long has that been vacant?
MS. TRACEY:
A. July 1st, I believe it was around then, July 1st or 2nd.
COFFEY, Q.C.:
Q. Of this year?
MS. TRACEY:
A. Uh-hm.
COFFEY, Q.C.:
Q. Dr. Rockwood had replaced Dr. Kwan, and he resigned effective sometime in July?
MS. TRACEY:
A. Uh-hm.
COFFEY, Q.C.:

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Q. Dr. Kwan was just here and he told the Commissioner, for example, that Ms. Tracey might come to me if a surgeon is supposed to start at 7 o'clock and doesn't arrive, doesn't show up -
MS. TRACEY:
A. That's correct.
COFFEY, Q.C.:
Q. She might bring it to my attention.
MS. TRACEY:
A. Uh-hm.
COFFEY, Q.C.:
Q. He just used that as one example of sort of an administrative thing.
MS. TRACEY:
A. Sure, that would be true, yes. If there is a complaint about an issue or an occurrence within the OR, I would defer to Dr. Kwan. We would probably discuss it and he would discuss it with the physician and follow up appropriately.
COFFEY, Q.C.:
Q. Now you report in that position to Louise Jones until Ms. Jones, I take it, became the interim CEO?

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MS. TRACEY:
A. That's correct.
COFFEY, Q.C.:
Q. And she was replaced -
MS. TRACEY:
A. Norma Baker.
COFFEY, Q.C.:
Q. Norma Baker, and you report to her currently?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. Who do Dr. Kwan or Dr. Rockwood, the co-clinical chiefs -
MS. TRACEY:
A. They report to Dr. Oscar Howell.
COFFEY, Q.C.:
Q. Okay, so they go off in the medical route.
COFFEY, Q.C.:
Q. As the director of perioperative program, it's one thing to say you're responsible for a particular thing. What, in practice, other than budgets and administrative things would you be involved in?
MS. TRACEY:
A. The majority of the day to day issues would be

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looked after by the managers.
COFFEY, Q.C.:
Q. Those four managers you referred to?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. Go ahead.
MS. TRACEY:
A. If there was complex issues or serious incidents occurs, they would be immediately brought to my attention by the managers. I'm also responsible for policy development, standards of care within the program, and oversees the audit process and accreditation, those kind of things.
COFFEY, Q.C.:
Q. And your office is located where?
MS. TRACEY:
A. At the General site in administration.
COFFEY, Q.C.:
Q. That's been so since you became the director?
MS. TRACEY:
A. That's right.
COFFEY, Q.C.:
Q. Perioperative program. How about things like

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policies and procedures?
MS. TRACEY:
A. I sign off on the policies and procedures for the program.
COFFEY, Q.C.:
Q. And that goes back - dates back to the time you became director?
MS. TRACEY:
A. That's correct.
COFFEY, Q.C.:
Q. And you're responsible then for ensuring, for example, that policies and procedures even exist?
MS. TRACEY:
A. That's correct.
COFFEY, Q.C.:
Q. And if so, having them changed for time to time and so on?
MS. TRACEY:
A. I might not initiate the change, but I will sign off on the final policy.
COFFEY, Q.C.:
Q. Who might initiate any change?
MS. TRACEY:
A. Change in practice usually is what initiates

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the change, or change in current literature that our practice was no longer appropriate, those kind of things usually initiate a change in policy, and the standards we follow closely, the Operating Room Nurses Association of Canada Standards, and changes in those standards would cause us to review our polices and change our appropriately. Now the frontline policy development takes place through an OR Practice Committee which is chaired by the clinical educators within my program, and it consists of frontline staff, nurses.
COFFEY, Q.C.:
Q. What, if any--when you first started in 1995, 1996 -
MS. TRACEY:
A. 1996.
COFFEY, Q.C.:
Q. When you first started in 1996 as the director, what if any interaction would you have with the clinical laboratory or people from the clinical laboratory?
MS. TRACEY:
A. Not a lot of direct interaction. The

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specimens were retrieved in the operating room and in surgical day care departments and they were to be sent to the laboratory. I would guess if there was major issues, it would be brought to my attention, but I would not have had a lot of interaction with the laboratory.

COFFEY, Q.C.:

Q. Now if there was a concern from the perspective of - from the clinical laboratory's perspective, concerning, for example, mislabelling a specimen, would that be brought to your attention?

MS. TRACEY:

A. One specimen, no, it would not. It would be - actually, as soon as the specimen is brought to the laboratory and there's an issue, the manager of the OR is contacted immediately by the person in the lab. So that person would follow up with it. I would expect if there was a lot of issues, then it would be brought to my attention.

COFFEY, Q.C.:

Q. So a pattern of problems you would expect to be brought to your attention by whom?

MS. TRACEY:

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A. By either a manager or director within the laboratory program, or one of the physicians, and the laboratory has always had a close association frontline with the operating rooms in that the pathologists do the frozen sections actually in the pathology lab within each OR.

COFFEY, Q.C.:

Q. They actually come up?

MS. TRACEY:

A. They could come up to the operating room, yes.

COFFEY, Q.C.:

Q. And do the frozen section work right there?

MS. TRACEY:

A. Yes, right there in the operating room, so that the operating managers know them well and the operating staff.

COFFEY, Q.C.:

Q. I just want you, if you could, just explain that a bit to the Commissioner in terms of the OR is a room and there's a series of side -

MS. TRACEY:

A. There's a lot of rooms, yes.

COFFEY, Q.C.:

Q. There's a lot of rooms, exactly, the operating room theatre overall, so an operating room, for example, where breast surgery was being done, where would the pathologist come to do a frozen section if he or she was asked to?

MS. TRACEY:

A. There's a pathology lab at the back of the operating room at the General site, so the pathologist would come in the back door to the OR. At St. Clare's, they would come in the front door because the pathology lab was in the front.

COFFEY, Q.C.:

Q. Whether they came in front or back, I take it it wouldn't at all be unusual to have a pathologist -

MS. TRACEY:

A. No, it's a frequent occurrence, daily occurrence.

COFFEY, Q.C.:

Q. And whether for breast surgery or for some other type of surgery, to do a frozen section is quite a common thing?

MS. TRACEY:

A. Yes.

COFFEY, Q.C.:

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Q. And so - and these would be actual pathologists, Dr. whomever, would show up to do the frozen section?

MS. TRACEY:

A. Yes.

COFFEY, Q.C.:

Q. This was not an assistant, this would be the -

MS. TRACEY:

A. No, this is the actual pathologist and an assistant would often come with him.

COFFEY, Q.C.:

Q. Sure.

MS. TRACEY:

A. Yes.

COFFEY, Q.C.:

Q. And so that would involve a certain amount of interaction then between the OR staff, the nurses, for example, who would provide the specimen -

MS. TRACEY:

A. Uh-hm.

COFFEY, Q.C.:

Q. In its raw state to the pathologist, and from your perspective then, there would be a fair amount of contact?

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MS. TRACEY:
A. Yes, frontline.
COFFEY, Q.C.:
Q. Frontline contact?
MS. TRACEY:
A. Yes, it would.
COFFEY, Q.C.:
Q. So if there - in terms of, for example, a problem involving preservation of tissue, fixation, for example, fixation in formalin, is not the only way, I gather, to preserve tissue, but it's one of them -
MS. TRACEY:
A. Uh-hm.
COFFEY, Q.C.:
Q. If there was a concern in the clinical laboratory, either at the Grace, say, at one time did have their own clinical lab -
MS. TRACEY:
A. That's correct, they had a lab in their OR too as well.
COFFEY, Q.C.:
Q. Or a concern in the clinical laboratory at St. Clare's or the General Hospital about fixation, at one or more of those sites, who

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would you have expected to bring that to whose attention? An example of one specimen that was poorly fixed, what would you have anticipated would happen?
MS. TRACEY:
A. I would expect that the pathology manager or the pathologist would call the OR manager.
COFFEY, Q.C.:
Q. And -
MS. TRACEY:
A. And discuss it with them, and then she would follow up with the staff who were actually the scrub and circulating nurses for that case.
COFFEY, Q.C.:
Q. And to discuss how -
MS. TRACEY:
A. That's right.
COFFEY, Q.C.:
Q. If there was a problem, how it happened.
MS. TRACEY:
A. That's right.
COFFEY, Q.C.:
Q. And how we address it?
MS. TRACEY:
A. Yes, and monitor any pattern of occurrences

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similar to that.
COFFEY, Q.C.:
Q. Now that's the next question I had. That's a single one. If there was a pattern, say in a period of time -
MS. TRACEY:
A. I would expect that we would review--that the OR manager would actually use--there's in-service time every Tuesday morning for all the operating room staff at every site between eight and nine, so the managers take those opportunities to remind staff of policies and to review policies with them and to bring occurrences that are repetitive to their attention, or even one occurrence that's significant to the attention of the staff.
COFFEY, Q.C.:
Q. Now until 2005, prior to August of 2005, or perhaps I'll ask, prior to July 2005 first -
MS. TRACEY:
A. Okay.
COFFEY, Q.C.:
Q. - do you recall it ever coming to your attention that there was ever any expression of concern by any of the clinical labs about

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poor fixation?
MS. TRACEY:
A. I do not recall a pattern of concern being brought to my attention, no. I would expect a single situation that needed to be addressed would have been brought to the managers, but the managers weren't giving me feedback either that they were getting recurrent issues with specimens.
COFFEY, Q.C.:
Q. And so, looking back on it, you certainly have no record that you were ever so advised?
MS. TRACEY:
A. No.
COFFEY, Q.C.:
Q. And no memory of being so advised?
MS. TRACEY:
A. No.
COFFEY, Q.C.:
Q. The managers at that time, like in the time period '97, '98, '99, 2000 at the Grace, same period of time but continuing up until 2005 at St. Clare's and the General, have those managers remained the same?
MS. TRACEY:

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A. Yes.
COFFEY, Q.C.:
Q. They have, over the years. Have you discussed with them, to this day, whether there were fixation problems back then, back in '96, '97, '98, '99? Have you ever had that discussion with them?
MS. TRACEY:
A. There was not a--they were not aware of a pattern of issues with fixation.
COFFEY, Q.C.:
Q. And you've discussed that with them?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. More recently, you've discussed that with them?
MS. TRACEY:
A. In the last few years.
COFFEY, Q.C.:
Q. Yes, that's what I'm saying, since this all became -
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:

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Q. - certainly within Eastern Health, a problem, a recognized problem, you've discussed with them, canvassed with them, "look, did you ever know anything about--or hear anything about this?"
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. And you've been told?
MS. TRACEY:
A. There was no pattern.
COFFEY, Q.C.:
Q. Any individual problems that you've been told of? Not the particular patient's name, but things that when you would discuss this more recently, somebody would say "well, actually, there was no pattern, but once in a while, a -
MS. TRACEY:
A. Once in a while, things were brought to their attention, occasionally, but that could--it could be any number of reasons why there was issues with a specimen. It could be labelling. It could be, you know, wrong site marked, something like that. So there's numerous issues why--you know, there are

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ongoing issues with specimens. We would treat thousands of specimens in a year.
COFFEY, Q.C.:
Q. Oh yes. How about problems with fixation? Like poorly -
MS. TRACEY:
A. I don't recall them, you know, identifying a lot of issues with fixation, no.
COFFEY, Q.C.:
Q. How about any?
MS. TRACEY:
A. I would--I don't feel comfortable in saying there was never any, but it was a very limited amount.
COFFEY, Q.C.:
Q. And did any of--do you know, like looking back on it, did any of them relate to perhaps a specimen having been left in the OR in formalin overnight or left in the OR over the weekend?
MS. TRACEY:
A. I'm sorry, I'm not sure?
COFFEY, Q.C.:
Q. Did any of these--do you ever recall, until--prior to 2005, because we'll get to that in a

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moment, prior to 2005, was there ever any concern raised, to your knowledge, about look, somebody left a specimen, a tissue specimen, in formalin in the OR over the weekend?
MS. TRACEY:
A. I'm not aware of issues with it, of complaints about it. It was a practice at that time.
COFFEY, Q.C.:
Q. I'm sorry, it was?
MS. TRACEY:
A. I'm not aware of -
COFFEY, Q.C.:
Q. Of complaints?
MS. TRACEY:
A. - complaints about it.
COFFEY, Q.C.:
Q. But it was?
MS. TRACEY:
A. At times, specimens could have been left.
COFFEY, Q.C.:
Q. So I'm going to ask you then about that. Could you tell then, the Commissioner, prior to 2005, and we'll get to then what, if anything, has changed since, prior to July, August, September 2005, what the practice was

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in terms of--in the OR, in terms of handling of specimens, tissue specimens that were going into formalin? How would it work?

MS. TRACEY:

A. Tissue specimen, how it was handed off by the surgeon?

COFFEY, Q.C.:

Q. Yes.

MS. TRACEY:

A. The surgeon hands the specimen to the scrub nurse. The scrub nurse then gets permission from the surgeon to hand it off the set up. She passes the specimen to the circulating nurse. She places it in a container. The circulating nurse and the scrub nurse check the labelling of the specimen that the correct site and the correct name, correct patient, are all indicated correctly on the specimen. Then the specimen is kept in the operating room and was always--our practice is the specimens are kept in the operating room unless they're for frozen section. If they're for frozen section, they immediately go to the pathology lab to the pathologist. When the patient -

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COFFEY, Q.C.:

Q. Which is right at the back of the current lab?

MS. TRACEY:

A. That's right, yes.

COFFEY, Q.C.:

Q. Okay. But if it's not going for a frozen section or the portion is not going for a frozen section, what was done with that?

MS. TRACEY:

A. Once it was placed in formalin, the specimen remained in the operating room with the patient, until the patient exited the operating room and then the specimens were brought out.

COFFEY, Q.C.:

Q. And then what would happen?

MS. TRACEY:

A. Then the specimens were collected by a porter and brought to the laboratory a few times during the day.

COFFEY, Q.C.:

Q. And was there any particular times of the day?

MS. TRACEY:

A. I wouldn't feel comfortable in telling you accurately what time of the day they were

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collected back then. Now they're collected in the morning and the afternoon.

COFFEY, Q.C.:

Q. So prior to the summer of 2005, because we'll get to what's happened since, your understanding was that they were to be collected by porters -

MS. TRACEY:

A. Um-hm.

COFFEY, Q.C.:

Q. - at some point in the day and brought down to the clinical laboratory?

MS. TRACEY:

A. Yes.

COFFEY, Q.C.:

Q. I take it then, there was no set pattern as to like you're supposed to do it at 10 and 12 and 2?

MS. TRACEY:

A. I couldn't--I don't recall what the times were for the specimen collection. There would have been pattern--there would have been actually designated times for it.

COFFEY, Q.C.:

Q. Who was responsible for designating the times?

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MS. TRACEY:

A. The laboratory would have coordinated that with the portering pool. The porters were not OR porters.

COFFEY, Q.C.:

Q. Okay. Whose porters were they?

MS. TRACEY:

A. They actually report to diagnostic imaging. It's just the relationship within the program.

COFFEY, Q.C.:

Q. Okay.

MS. TRACEY:

A. There's a manager who they report to.

COFFEY, Q.C.:

Q. And that manager worked in diagnostic imaging?

MS. TRACEY:

A. Yes. Part of the responsibility designated to porters would have been collection of specimens from the operating room and bringing them to the pathology lab or whatever lab.

COFFEY, Q.C.:

Q. And how often that happened a day you can't say?

MS. TRACEY:

A. I can't say, no.

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COFFEY, Q.C.:
Q. Or what times of the day?
MS. TRACEY:
A. No.
COFFEY, Q.C.:
Q. What about in terms of how late in the day would it happen?
MS. TRACEY:
A. 3:00 in the afternoon is--it happens now and I'm presuming the last collection would have been around that time too.
COFFEY, Q.C.:
Q. Back in '98, '99, 2000?
MS. TRACEY:
A. I'm not comfortable in commenting ten years back because I don't recall.
COFFEY, Q.C.:
Q. Well, how about 2002, 2003?
MS. TRACEY:
A. I would expect to be in the afternoon sometime.
COFFEY, Q.C.:
Q. Sometime mid afternoon?
MS. TRACEY:
A. Yes.

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COFFEY, Q.C.:
Q. What then would happen with a specimen that didn't make it out of the operating room proper until after the last pick up? How was that handled? Like if the patient, along with the specimen, didn't leave the OR until 4:30?
MS. TRACEY:
A. The specimen--if the surgeon didn't request the specimen to be sent immediately to the pathology lab, the specimen would have remained overnight in the operating room.
COFFEY, Q.C.:
Q. And when you say in the operating room, you mean in the whole -
MS. TRACEY:
A. There's a designated holding area for specimens.
COFFEY, Q.C.:
Q. Okay, and so it would have been--the specimen would be sitting in a container in formalin overnight?
MS. TRACEY:
A. Correct.
COFFEY, Q.C.:
Q. And would be taken with the first porter run

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in the morning, presumably?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. In the meantime then, I take it then the specimen would be in formalin just as the specimen was excised?
MS. TRACEY:
A. Correct.
COFFEY, Q.C.:
Q. And then if there was a large specimen, a relatively large piece of tissue, it wouldn't have been bread loafed or scored in any way?
MS. TRACEY:
A. No.
COFFEY, Q.C.:
Q. So it would just be there overnight?
MS. TRACEY:
A. It would have remained in the container it was placed in in the operating room until it was retrieved.
COFFEY, Q.C.:
Q. Was any concern about that kind of a practice ever brought to your attention?
MS. TRACEY:

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A. No.
COFFEY, Q.C.:
Q. Did you have any knowledge of, for example, ideas like formalin penetration rates?
MS. TRACEY:
A. Not specific knowledge, no.
COFFEY, Q.C.:
Q. About like how long it would actually take formalin to seep into a tissue or anything like that?
MS. TRACEY:
A. No. That would have come under the purview of the laboratory. It wouldn't be my expertise.
COFFEY, Q.C.:
Q. And when I say, referring to tissue specimens here, I mean, that could include breast tissue. It could include kidney, any type of tissue, I take it. There's nothing -
MS. TRACEY:
A. Correct.
COFFEY, Q.C.:
Q. Would all follow this pattern, that frozen section, that portion of it, the pathologist would get right away when he or she came. Other than that, it would go into formalin in

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the OR in the manner in which it was taken -
MS. TRACEY:
A. The surgeon decided if the specimen--today, which is still the practice, the surgeon decides if the specimen is to go downstairs fresh and immediately it would be transported.
COFFEY, Q.C.:
Q. Okay.
MS. TRACEY:
A. Or if it went site in formalin, it would stay in the operating room.
COFFEY, Q.C.:
Q. And it would stay there until the patient went out. It would accompany the patient out to the holding area for tissue?
MS. TRACEY:
A. That's correct.
COFFEY, Q.C.:
Q. And remain there in a container in formalin -
MS. TRACEY:
A. It remained in the pathology--actually, the specimens were--there's a designated area in each OR where the specimens were collected.
COFFEY, Q.C.:
Q. And it would remain there in the form it came

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off or out of that person's body -
MS. TRACEY:
A. In the container it was put in in the operating room.
COFFEY, Q.C.:
Q. Until the porter picked it up, whether it was late--an hour, whether it was five minutes later or the next morning?
MS. TRACEY:
A. That's correct.
THE COMMISSIONER:
Q. Excuse me. Ms. Tracey, it's just that fresh has been used in different ways. When you say the surgeon decides if it goes to the lab fresh, do you mean just in timing or are you -
MS. TRACEY:
A. I mean that it's not fixed in any formalin.
THE COMMISSIONER:
Q. Not fixed at all?
MS. TRACEY:
A. No.
THE COMMISSIONER:
Q. Yes, okay, thank you.
COFFEY, Q.C.:
Q. Now and that practice that you've described,

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work flow pattern, was that true at the Grace, St. Clare's and the General for breast surgery?
MS. TRACEY:
A. I don't remember what our practice was at the Grace, to be quite honest with you.
COFFEY, Q.C.:
Q. In terms of the--and I'm talking about like within the OR.
MS. TRACEY:
A. Whether the specimens were actually brought by the OR porter or whether they were actually collected by central portering, I'm not sure if there was a central portering process in the Grace. I don't think there was, so I would think it would be the OR porter which would have brought those to the lab, but I am not positive about that.
COFFEY, Q.C.:
Q. And now this portering system, did they have any written policies or procedures that you are aware of?
MS. TRACEY:
A. I'm not aware of that. I'm not familiar with whether they do or they don't.

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COFFEY, Q.C.:
Q. What about even today?
MS. TRACEY:
A. I'm not sure what their policies and procedures are.
COFFEY, Q.C.:
Q. Even as we sit--we're here now.
MS. TRACEY:
A. Correct.
COFFEY, Q.C.:
Q. For example, at the General Hospital, is the portering still done by central portering?
MS. TRACEY:
A. Yes, it is.
COFFEY, Q.C.:
Q. And it's run out of diagnostic imaging?
MS. TRACEY:
A. That's correct.
COFFEY, Q.C.:
Q. And whatever policies and procedures they might have -
MS. TRACEY:
A. Would be under the diagnostic imaging department.
COFFEY, Q.C.:

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Q. - you don't know whether they're written or -
MS. TRACEY:
A. No.
COFFEY, Q.C.:
Q. - just understood, and what time -
MS. TRACEY:
A. I would imagine there must be something written because obviously people have designated jobs.
COFFEY, Q.C.:
Q. But I'm thinking about, for example, particular times.
MS. TRACEY:
A. That's correct.
COFFEY, Q.C.:
Q. For the day, you don't know -
MS. TRACEY:
A. I don't know what the -
COFFEY, Q.C.:
Q. Who would you ask, if I was to ask you to find out overnight who that is, who would you have to ask?
MS. TRACEY:
A. I would ask, I guess, program director, Sean Thomas.

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COFFEY, Q.C.:
Q. In diagnostic imaging?
MS. TRACEY:
A. Diagnostic imaging.
COFFEY, Q.C.:
Q. How about at St. Clare's, what's the situation there?
MS. TRACEY:
A. They would be--they are still under the diagnostic imaging department.
COFFEY, Q.C.:
Q. And it's the same individual?
MS. TRACEY:
A. That's correct.
COFFEY, Q.C.:
Q. Now, if we could look please at exhibit P-2828? Now this is, well it's entitled "St. Clare's Site Perioperative Committee Minutes, Wednesday, February 18th, 1988." And Ms. Taylor, Shirley Taylor is the chair.
MS. TRACEY:
A. She's the manager at that site.
COFFEY, Q.C.:
Q. Yes, she's chairing the committee and she is the manager of that site.

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MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. And it's noted in passing that you're in attendance, as are a number of others. These would be, well there's Dr. Felix, Dr. Peddle and Dr. Williams, they would be -
MS. TRACEY:
A. Dr. Felix was the clinical chief for surgery at that time. He was the divisional chief for general surgery. Dr. Peddle was the chief for orthopedics; John Williams was the chief of anesthesia at St. Clare's site. Diane Sullivan was the manager of pre-admission clinic. Margie Burke was the patient care co-ordinator in the recovery room. Sylvia Carter was an operating room technician in the operating room. Linda Ezekiel is the patient care co-ordinator in the operating room. Glenda Tapp is the clinical educator in the operating room. Val Tilley is an OR nurse at St. Clare's site and Cheryl Abbott is my secretary and she recorded the minutes.
COFFEY, Q.C.:
Q. So a representative, pretty well, from all of

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the interested groups.
MS. TRACEY:
A. Uh-hm. There are actually more physician members, but sometimes they can't make the meetings.
COFFEY, Q.C.:
Q. Here under paragraph 3.01 and there's a reference to handling of specimens. There's a record book for all specimens being sent to the lab was introduced on February 2nd, 1998 and this method of tracking seems to be working well. The new lab is now required to tick off and sign for the specimens they have taken, as well needle localization specimens are being signed for in the pathology lab when they are delivered. So I take it this was related to keeping track of them.
MS. TRACEY:
A. The Grace had a process of tracking specimens an St. Clare's did not have a similar log, so a record book was introduced to St. Clare's.
COFFEY, Q.C.:
Q. And this is the record of the introduction?
MS. TRACEY:
A. That's correct.

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COFFEY, Q.C.:
Q. If I could, please, could you bring up, please, exhibit P-3089? Which is a record that was received from yourself, and here, these are entitled "The General Hospital Health Sciences Centre, Departmental Procedure" and you will notice here, Ms. Tracey, that's page one of four and it goes on, two of four, three of four and four of four. And they're all for--the department is the operating room, issued by the director of nursing and critical care -
MS. TRACEY:
A. Which was Norma Baker at the time.
COFFEY, Q.C.:
Q. Norma Baker at the time. And then the numbering system is roman numeral IIV-5, there's a date, 1986-01, would be January, 1986 revised, September 1991 and, revised again, I take it, RV?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. August, 1994 and the section is called "Specimens", there's a procedure, sub-section

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which involves, I take it, the page numbers and the pathology specimens, care and handling. And now when you took over then as the director of the perioperative program, what was the situation in terms of the Health Care Corporation in terms of these sorts of policies and procedures?
MS. TRACEY:
A. Our practice was that the operating rooms followed the existing policies until the policies were realigned. When we took over within--when we took over and became the Health Care Corporation, it was a time of a lot of turmoil, it was a time of a lot of anxiety and there were three new managers within--at least four new managers at that time within my program. All of them had responsibilities that were new to them and three of them were at different sites than they had previously managed.
COFFEY, Q.C.:
Q. I'm sorry, three of them?
MS. TRACEY:
A. Were at different sites.
COFFEY, Q.C.:

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Q. Okay.
MS. TRACEY:
A. So we put in place a committee, I guess, of frontline staff to begin the process of standardizing policies and at first it was a very onerous task. Staff from the three operating rooms did not know each other and the other part of it was, the Grace was going to close, so that was also a lot of anxiety attached to that. And staff did not always get to choose where they were going to have a new position, even were they going to have a position, so it was a lot of turmoil within the whole system at that time.
COFFEY, Q.C.:
Q. And that would be beginning with the Health Care Corporation being -
MS. TRACEY:
A. That's correct.
COFFEY, Q.C.:
Q. - up and running. Go ahead, I'm sorry.
MS. TRACEY:
A. We began by standardizing policies that were very simple to try and get the process in place on how this was going to work. And

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policies, the first policies were developed in 1998 and we simply did the scrubbing technique and we did the dress code for the operating rooms. Also have to remember the staff were using different records. The papers they were writing on were different.
COFFEY, Q.C.:
Q. Different forms?
MS. TRACEY:
A. Different forms and they all had to be standardized, absolutely everything in the practice had to be standardized. So we tried to start very simple and it was a long and difficult process at first, but it became easier and better as the time evolved.
COFFEY, Q.C.:
Q. Now here, in the meantime I take it at any one site, what continued to -
MS. TRACEY:
A. The policies in place governed the practice at that site.
COFFEY, Q.C.:
Q. So historically whatever was written, the policy and procedure as it existed at the time the Health Care Corporation came into being,

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in particular, for example, this is the General Hospital -

MS. TRACEY:

A. That's correct.

COFFEY, Q.C.:

Q. This would have continued to apply then in '95, '96, '97 and '98 at the General?

MS. TRACEY:

A. Yes.

COFFEY, Q.C.:

Q. And do you know if each site had its own policies and procedures?

MS. TRACEY:

A. St. Clare's site did. I'm not familiar with the policies that were at the Grace, exactly what they were.

COFFEY, Q.C.:

Q. And the General, obviously, at least had this one that we're looking at here.

MS. TRACEY:

A. Uh-hm.

COFFEY, Q.C.:

Q. Just to look at this particular one, it says "Pathology/histology specimens care in handling, procedure obtain separate specimen

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container for each specimen" and points of emphasis, "use larger enough container to allow fixative of one to ten"--which would be a volume of ten to one, I take it, ten times the amount of volume of fixative to the size of the specimen.

MS. TRACEY:

A. Specimen.

COFFEY, Q.C.:

Q. And here, this actually then in a fairly systematic fashion talks about labelling, what's supposed to go in the labelling, "tear the backing off the label and affix to the specimen container before accepting the specimen, label the container and not the lid. Hold the empty label container with a gloved hand for scrub nurse to place specimen inside. A filled container may splash, use gloves. Check the label with scrub nurse." And I can take you on down through it, this is fairly detailed, almost a step by step literally -

MS. TRACEY:

A. Uh-hm.

COFFEY, Q.C.:

Q. As to how this is supposed to be done. And

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here, the second last one, "Ask surgeon if he wants the specimen put in formalin"--which you've just referred to, the nurse actually asks -

MS. TRACEY:

A. That's the practice to this day, yes.

COFFEY, Q.C.:

Q. This day. And the note is, the point of emphasis is the surgeon may want to examine it fresh after the operation, but before it goes into the formalin.

MS. TRACEY:

A. At times the surgeon asks for the specimen to be left on the set up.

COFFEY, Q.C.:

Q. And Dr. Kwan was just in here telling us about that, at times he would want to see it, when he could get back to it.

MS. TRACEY:

A. That's right. So the nurse isolates it on her set up and marks what the specimen is, so that there can be no mistake with that.

COFFEY, Q.C.:

Q. And I take it after he or his fellow surgeon had done whatever examination -

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MS. TRACEY:

A. If the surgeon is asking for it, he wants to see it himself.

COFFEY, Q.C.:

Q. Sure, and then they might then say, well now you can put it in the formalin after I've-- he's finished with it.

MS. TRACEY:

A. Yes.

COFFEY, Q.C.:

Q. Here it goes on to say, "Upon request, open up bowel, uterus or other hollow organs, except bladder. (Tie off openings with silk, except one, fill with formalin, tie off)."

MS. TRACEY:

A. That's no longer a practice.

COFFEY, Q.C.:

Q. Yeah, I appreciate that, but here on the other side it says, in terms of points of emphasis related to that, is "to allow the formalin to penetrate the specimen or to contact all surfaces."

MS. TRACEY:

A. Uh-hm.

COFFEY, Q.C.:

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Q. So at the time your understanding in the late 1990's was what, in terms of what was required to fix a specimen?
MS. TRACEY:
A. That the specimen would be saturated in formalin. The specimen actually or as graphs describe it, it would float in formalin, so that all surfaces were surrounded, well surrounded with formalin.
COFFEY, Q.C.:
Q. Float, meaning, I take it, float to the surface?
MS. TRACEY:
A. Well that it's absolutely, totally covered in formalin.
COFFEY, Q.C.:
Q. So much sufficient that if it would float, the type of tissue -
MS. TRACEY:
A. The formalin would penetrate the specimen is the object.
COFFEY, Q.C.:
Q. Now that's what I wanted to ask you about. Did you--because it says "to penetrate the specimen or to contact all surfaces." What

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was your understanding of that in terms of, was your understanding, look, if it's in formalin and it's completely emersed, then that's sufficient?
MS. TRACEY:
A. Sufficient for what?
COFFEY, Q.C.:
Q. To preserve the tissue.
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. That was your understanding at the time.
MS. TRACEY:
A. Yes. I would not have had knowledge about the -
COFFEY, Q.C.:
Q. Yeah, and that's what I'm asking, in terms of that too and for the Commissioner to have some sense of what you would have understood at the time.
MS. TRACEY:
A. And that's what the OR staff would have believed that if the specimen was in formalin, there wasn't really--I was not aware there was a length of time that it was optimum for the

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specimen to be in formalin, yes.
COFFEY, Q.C.:
Q. Or the idea, for example, that the specimen should be cut relatively thinly to allow and would -
MS. TRACEY:
A. I would not have had that knowledge, no.
COFFEY, Q.C.:
Q. From your perspective, the specimen, no matter how large it was or small, or large it was, as long as it was completely emersed in formalin -
MS. TRACEY:
A. That was adequate.
COFFEY, Q.C.:
Q. That would preserve it, adequate fixation.
MS. TRACEY:
A. That's right.
COFFEY, Q.C.:
Q. Have you ever learned any different?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. Since all this has arisen, okay. And here at 3 of the exhibit, page 2 of the actual

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departmental procedure, it says under procedure "Pour formalin as soon as possible in the container. Add ten times the amount of formalin compared to tissue, then put a lid on the container." And points of emphasis, "Tissue has to be completely covered. Formalin may splash when being poured on the specimen." I take it that was to warn you that you should be careful of -
MS. TRACEY:
A. Formalin is toxic.
COFFEY, Q.C.:
Q. Is toxic, yes. And it says here, "After the operation, place the specimen and requisition on the bottom shelf of the patient stretcher, bring it to the main desk and place it in the specimen carrier." Which is what you--the particular place in the OR where they were stored?
MS. TRACEY:
A. That's correct.
COFFEY, Q.C.:
Q. Here on page 4 of the departmental procedure, it says, "Biopsy of breast for estrogen receptor", do you see that? And this is a

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revised version as of August, 1994. It says, this is 1994 now, "Have a container of liquid nitrogen available." And I take it this is back in the days of biochemical assays, so this is--if there was a biopsy that required liquid nitrogen to be used, this is the procedure to be followed?

MS. TRACEY:

A. I don't actually remember when we used to do that, my staff didn't remember it either, but apparently--a long time ago, many years ago, yes.

COFFEY, Q.C.:

Q. And here it notes here, "Take the specimen container to the main desk for porter to bring to the chemistry lab immediately." Do you see that?

MS. TRACEY:

A. Uh-hm.

COFFEY, Q.C.:

Q. So that would be on down to biochemistry. And what I'm looking at is that that, in terms of the usage of liquid nitrogen to preserve, cold, bring it down immediately, while the policy we just look at before, the formalin

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one -

MS. TRACEY:

A. There's no indication of a time -

COFFEY, Q.C.:

Q. The timeframe.

MS. TRACEY:

A. Uh-hm.

COFFEY, Q.C.:

Q. So I take it and I'm going to ask you about this, was there any sense at the time, from your perspective, of urgency in getting formalin, you know, preserved tissue down stairs?

MS. TRACEY:

A. No.

COFFEY, Q.C.:

Q. I say downstairs generally in the hospital, it's not always the case it's downstairs. Here, page six of the exhibit, there's actually a--there's a procedure for frozen sections, care and handling. And here it's noted that the pathologist comes to the theatre to pick up the specimen and the requisition and enables the pathologist to converse with the surgeon concerning the

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specimen, so there was a different procedure or process set out here for frozen sections than for formalin fixed. You've indicated, Ms. Tracey, that with the formation of the Health Care Corporation initially and people reapplying for positions and the prospect of the Grace closing there was a certain amount of tension and turmoil.

MS. TRACEY:

A. Yes, it was.

COFFEY, Q.C.:

Q. You've indicated, I believe, that you kind of started simply with developing a uniform policy, procedure process and it evolved from there. Can you tell the Commissioner about that, like when did it really get going and how did it evolve?

MS. TRACEY:

A. The process gradually developed as we became more comfortable--as the staff became more comfortable working with each other. The practices were subtly different at each site and everybody believed their practice was the best. The outcomes to the patients were different, but the practices within the

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departments were different and it took a lot of education and time for people to realize that one practice had to be adopted and that meant that two different hospitals had to change their practice. So it did take time. We were guided by current literature, by the (Unintelligible) Standards and by Best Practice Guidelines, and by practices within other national hospitals.

COFFEY, Q.C.:

Q. Do you know who, in the late 1990's then, was responsible for this? I mean, ultimately I take it it would be you, but in a day to day -

MS. TRACEY:

A. In the actual initial drafting of the policies?

COFFEY, Q.C.:

Q. Yes.

MS. TRACEY:

A. The clinical educators at the St. Clare's site and at the General site; the Grace site did not have a clinical educator.

COFFEY, Q.C.:

Q. So the clinical educators were supposed to get together -

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MS. TRACEY:
A. They chaired a committee of frontline staff, which was the nurses from each site. And they would have done the research and probably drafted something because, otherwise, it's very hard to get the discussion going on what's actually going to be the outcome, so they would have come with a draft policy and then they would iron out what was appropriate and get input from the departments, like pathology, if that was appropriate.
COFFEY, Q.C.:
Q. Now we just looked at the General Hospital departmental procedure--it's still there on the screen, one of them, from their revised version, August 1994. Have you been able to locate any for St. Clare's dating back to that timeframe?
MS. TRACEY:
A. No, I haven't.
COFFEY, Q.C.:
Q. You've looked and -
MS. TRACEY:
A. I've looked. They were destroyed.
COFFEY, Q.C.:

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Q. And they did exist at one time.
MS. TRACEY:
A. They did, yes.
COFFEY, Q.C.:
Q. And whatever the written policy or procedure at St. Clare's or the Grace, for that matter, said at the time, I take it formalin fixed tissues, there was no indication that they were supposed to get to the lab right away.
MS. TRACEY:
A. No.
COFFEY, Q.C.:
Q. Exhibit P-2830. This is records of an OR practice meeting in November 29th, 2001, certain individuals present. Here there's "business arising, draft policies circulated for review, a) orientation development and ongoing education policy, minor changes were made as policy is currently under review by the perioperative management team." So I take it that this is a time period in which policies and procedures were being developed.
MS. TRACEY:
A. They were being developed right from, probably 1997 onwards, it's an ongoing process, the

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frontline or practice committee develops the policy. When they feel that they have the policy finished, they forward it on. Once a month my managers and I meet with the clinical educators, we review the policies and if they're acceptable, make minor changes if necessary. If they're acceptable, I sign off on them.
COFFEY, Q.C.:
Q. Now if we can look, please, at exhibit P-2729? Thank you. This is an OR practice meeting minutes of January 29th, 2003.
MS. TRACEY:
A. Uh-hm.
COFFEY, Q.C.:
Q. There are a number of individuals present, you're not listed as one of then, but I take it this is kind of a sub-group?
MS. TRACEY:
A. I'm not a member of this team.
COFFEY, Q.C.:
Q. No, you wouldn't be.
MS. TRACEY:
A. They are the frontline staff.
COFFEY, Q.C.:

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Q. Frontline staff. And here, after welcoming a particular individual, they say "Business arising, one, the new OR manuals having delivered to the OR's, only a Table of Contents is included to date. We have not received any signed policies." I take it that as of January--the end of January, 2003, that was the situation?
MS. TRACEY:
A. Actually there were some policies in place since 1998. The first thing we developed was the Table of Contents and then obviously the policy development followed on from that. My secretary would have sent out the new manuals and I guess what they meant was, because once we developed new policies, they replaced the existing policies in the existing manuals, this was a perioperative manual which was going to replace all the site manuals.
COFFEY, Q.C.:
Q. And they were just noting the manual is here, the Table of Contents is here and the policies, as soon as we get them, will follow?
MS. TRACEY:
A. Policies will follow, yes.

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COFFEY, Q.C.:
Q. Number two here, it says, "During the physician job action this past fall, both sites"--and that would be the General and St. Clare's, in this context, I take it both sites, "spent time drafting/reviewing policies. These policies were submitted. Some of these policies need to be typed. The policies drafted will be compiled by Wendy and Glenda prior to the next meeting." So I take it there was a physician job action the fall of 2002?
MS. TRACEY:
A. Uh-hm.
COFFEY, Q.C.:
Q. And the staff didn't waste any time, they went on drafting policies.
MS. TRACEY:
A. Yeah, they were formed into teams, if I remember correctly, to review policies.
COFFEY, Q.C.:
Q. To review them and then redraft them as necessary.
MS. TRACEY:
A. That's correct.

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COFFEY, Q.C.:
Q. Now on that point, this is what I want to ask you about because by that point it would have been four or five years since this process had started back in '97. I take it that if the-- when there was a physician job action going on, there was no operating going on -
MS. TRACEY:
A. It was emergency surgery only.
COFFEY, Q.C.:
Q. Emergency, but generally there was no -
MS. TRACEY:
A. That would be one team of nurses that would-- the remaining staff would not be working in the operating room.
COFFEY, Q.C.:
Q. So was this, looking back on it, was this the first real opportunity the staff had to actually sit and go through and do what they did at this point in time in terms of reviewing policies?
MS. TRACEY:
A. It was the first--if I remember correctly, the clinical educators co-ordinated this whole big--used it as an opportunity to actually

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involve all of the staff, as opposed to a representative group which had been to that date, and they were given copies of the policies from sites to look at redrafting them.
COFFEY, Q.C.:
Q. As a practical matter prior to this, if it wasn't going to be left to just one or two people to review and draft the policies, to revise them -
MS. TRACEY:
A. It's actually the committee named here where the -
COFFEY, Q.C.:
Q. I appreciate that, but how much time did people actually have available to them in their workday to do that?
MS. TRACEY:
A. They met regularly, it was scheduled meetings, but it was once a month as opposed to, you know. Actually, the clinical educators would usually meet and draft a policy that they would bring to this group to look at.
COFFEY, Q.C.:
Q. And number three here, is policy review and it

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says, "The three specimen policies have been redrafted based on feedback from committee members, head nurses, pathology department and quality initiatives, QI. QI also contacted the RNC for input in the legal specimen policy" and the RNC is?
MS. TRACEY:
A. Royal Newfoundland Constabulary.
COFFEY, Q.C.:
Q. "And the following policies were again reviewed, legal specimens, specimen care, guidelines for the management of specimens. Revisions were made, the committee agreed to have these policies with revisions be sent to the managers for review/signing." I take it that -
MS. TRACEY:
A. The policies were in final draft, so then they would come to the management group to be reviewed. And for discussion, the clinical educators were the people who actually drafted the policies would be there to discuss it with us.
COFFEY, Q.C.:
Q. Exhibit P-2730? These are the minutes of the

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perioperative program, clinical educators' meeting of January 30th, 2003. In attendance are yourself and four others, Ms. Taylor--and who is the one from the general -

MS. TRACEY:

A. Wendy Walsh is the clinical educator from the General; Glenda Tapp is the clinical educator from St. Clare's; Dianne Sullivan was the manager--she's since retired, she was the manager of surgical daycare at the General site; and Shirley is the manager of St. Clare's O.R.

COFFEY, Q.C.:

Q. And here under "Business arising, policies, O.R. Practice Group. It's noted 12 policies were drafted during the physician job action and are to be reviewed. The specimen policy was reviewed yesterday and will be ready shortly for review by managers. Some issues still require clarification. Example, responsibility for writing specimens in log book, practice for checking specimens is different at both sites and needs to be reviewed. What role the scrub nurse plays in confirming the identity of the patient also

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needs to be looked at. Time for a meeting of the O.R. practice group is difficult to co-ordinate as both O.R.'s are short of staff. There are numerous policies to be drafted."

MS. TRACEY:

A. Uh-hm.

COFFEY, Q.C.:

Q. Does that fairly describe the situation at the time?

MS. TRACEY:

A. Yes, it does. If the O.R. was short staff that day, the staff went to the O.R., as opposed to drafting policies.

COFFEY, Q.C.:

Q. Now here, if we could look, please, at Exhibit P-3087? This is a nine-page document, it's a Health Care Corporation of St. John's Perioperative Program Operating Room Policy Manual. And the number is IX J11, it's May, 2003. I take it this would be one of those guidelines?

MS. TRACEY:

A. Yes.

COFFEY, Q.C.:

Q. And guidelines for the management of specimens

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and specimens for pathology. And here it notes, one, "Routine pathology specimens are brought to a) the designated area in day surgery, b) the front desk part of the general main O.R., c) the frozen section room at St. Clare's O.R. where they are transported to the pathology department throughout the day." And there's no note here as to when throughout the day or--so it was entirely conceivable and at times would happen, it would remain overnight. If it missed the last -

MS. TRACEY:

A. Yes.

COFFEY, Q.C.:

Q. Kind of round -

MS. TRACEY:

A. Last run from the porters.

COFFEY, Q.C.:

Q. Last round of porters, it would stay overnight and the porter would be expected to pick it up the next morning.

MS. TRACEY:

A. Yes.

COFFEY, Q.C.:

Q. And the same thing would happen on a Friday.

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MS. TRACEY:

A. Yes.

COFFEY, Q.C.:

Q. It would be over the weekend.

MS. TRACEY:

A. Yes.

COFFEY, Q.C.:

Q. There's a reference to frozen sections as to how they are to be handled and the recording of pathology specimens in the log book, which is taking track of them, I take it. Here under specimens for--I'm just going to show you, cytology, bacteriology, chemistry, hematology, etcetera, it says, "These specimens are brought to the O.R. front desk with a requisition and delivered to the appropriate department by the PCA or porter as soon as possible. After hours or weekends, these specimens are transported to the lab department by porter, PCA or nursing staff as soon as possible, exception is the General site, bacteriology specimens other than an aerobic are placed in a refrigerator and the PWA to be transported the following morning." So, what sorts of specimens were these

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compared to, the specimens for pathology above?
MS. TRACEY:
A. They would have been retrieved in the same way, but for, following surgeon's direction, they would have wanted the specimens to go to these designated areas within the lab.
COFFEY, Q.C.:
Q. See here, under this heading, "Specimens for Cytology, Bacteriology, Chemistry, Hematology" et cetera, and I take it that's in contradistinction to specimens for pathology?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. So these other ones down here, cytology, et cetera, they are to be brought as soon as possible, it's actually noted and number two, "after hours or on weekends, go as soon as possible, with one exception." So there was a sense, I take it, of urgency where cytology, bacteriology, chemistry, hematology -
MS. TRACEY:
A. Yes, these were time sensitive.
COFFEY, Q.C.:

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Q. And they were understood generally to be time sensitive?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. In the way that at the time it was not understood the pathology -
MS. TRACEY:
A. The pathology specimens were.
COFFEY, Q.C.:
Q. As long as they were in formalin, sufficient formalin -
MS. TRACEY:
A. They were felt to be fixed adequately. And that would be from, that would not be the O.R.'s direction, that would be input from pathology.
COFFEY, Q.C.:
Q. Well on that, because this is the one, I take it, the guideline for the management of specimens that remained in place, we're going to look at another one because it was revised briefly--not briefly, moderately in -
MS. TRACEY:
A. 2005.

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COFFEY, Q.C.:
Q. Actually it was revised initially in March of '04, but in drafting these guidelines for the management of specimens in '02, '03 and '04, was the clinical laboratory consulted, do you know?
MS. TRACEY:
A. Yes, it is, and I think there's some minutes to reflect that, that input was obtained from Dr. Ford Elms.
COFFEY, Q.C.:
Q. Okay, and your recollection is that they were asked about it and there certainly is--I don't--yes, bring up, please, Exhibit P-2830? Here, this is this OR practice meeting of November 29th, 2001 I showed you earlier, which is under A there. We've looked at that already. When we go down, policy development issues, middle of the page under B, it says "Glenda requested site forms for specimen policy." So I take it Glenda was kind of gathering up all the different forms that existed for procedures here from different sites.
MS. TRACEY:

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A. Um-hm.
COFFEY, Q.C.:
Q. And "Ford Elms, pathologist at St. Clare's, is currently reviewing the lab manual to verify if the content is still accurate. Glenda will follow up with Dr. Elms." And then there's Catherine Parnell.
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. Phone number, ongoing.
MS. TRACEY:
A. Yes, she's the staff--she was a staff member of the lab. Glenda was--that's Glenda's writing, I pretty well feel sure.
COFFEY, Q.C.:
Q. That's Glenda's here, yes.
MS. TRACEY:
A. Yes, that's her writing.
COFFEY, Q.C.:
Q. So your understanding at the time was what was going on with this then? This is back in '01 and I take it -
MS. TRACEY:
A. I am understanding that Glenda gave the policy

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in draft format to Dr. Elms to ask him if it was relevant and current and accurate.

THE COMMISSIONER:

Q. What does a site form mean?

MS. TRACEY:

A. Each hospital would have had it's own forms, each site.

COFFEY, Q.C.:

Q. It's own specimen policy, I take it?

MS. TRACEY:

A. Yeah.

COFFEY, Q.C.:

Q. So site forms mean -

MS. TRACEY:

A. And the forms used for pathology.

COFFEY, Q.C.:

Q. The actual forms themselves?

MS. TRACEY:

A. Yes. They were eventually consolidated, but they weren't initially. There would have been different forms the physicians would have filled out to request analysis of the specimen.

COFFEY, Q.C.:

Q. So was Dr. Elms reviewing the site forms, the

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site requisition forms?

MS. TRACEY:

A. No, Dr. Elms is actually reviewing the lab manual to verify the content is still accurate. So he was reviewing -

THE COMMISSIONER:

Q. The content of what?

MS. TRACEY:

A. The content of the policy they were developing.

THE COMMISSIONER:

Q. Which is the site form for specimen -

MS. TRACEY:

A. No, the site form was--that's separate.

THE COMMISSIONER:

Q. Okay. So you read this as saying that Dr. Elms was looking at the whole of this policy?

MS. TRACEY:

A. The policy we were drafting, for input.

COFFEY, Q.C.:

Q. And it's your understanding that by the time it got issued in May of 2003, that's the one we just saw, by that point in time, the clinical laboratory, in the person of Dr. Elms, was satisfied with it? That's your--and

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we just looked at, for some sorts of specimens, it's specified "as soon as possible" and pathology, there's no reference to "as soon as possible."

MS. TRACEY:

A. No.

COFFEY, Q.C.:

Q. And your understanding is that Dr. Elms had reviewed it?

MS. TRACEY:

A. Yes, and I discussed that with Glenda and that's her recollection of it.

COFFEY, Q.C.:

Q. You've discussed it with her since?

MS. TRACEY:

A. Yes.

COFFEY, Q.C.:

Q. Since 2005, and I take it if there were some concern expressed by the clinical lab that they wanted it down as soon as possible -

MS. TRACEY:

A. We would have incorporated it into the policy.

COFFEY, Q.C.:

Q. Like you did the other one?

MS. TRACEY:

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A. Yes.

COFFEY, Q.C.:

Q. Like you did the specimen for cytology, for example.

MS. TRACEY:

A. Our object is to get the specimen in the best quality to the pathology lab or whatever lab it is going to.

COFFEY, Q.C.:

Q. If we could look at--go back to Exhibit P-3087, please? Here, on page two, because the actual--you'll see that basic specimen care, and then tissue for routine pathology and it refers to particular body parts, but then it says "fixative ten percent formalin." So I take it that was what was to be used?

MS. TRACEY:

A. Um-hm.

COFFEY, Q.C.:

Q. And then "place in specimen container with 20 to one formalin to specimen. Identify specimens on pathology requisition. Physician will complete and sign the requisition." That will be the surgeon, I take it?

MS. TRACEY:

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A. Yes.
COFFEY, Q.C.:
Q. Now this idea of using 20 to one, the older one from the ’90s we looked at was ten to one.
MS. TRACEY:
A. Um-hm.
COFFEY, Q.C.:
Q. Do you recall where the 20 to one came from?
MS. TRACEY:
A. I actually discussed it with Glenda. She does not exactly recall. It was some documents or at least some literature she reviewed she feels she had obtained that from. She did discuss it with Dr. Elms and he supported this.
COFFEY, Q.C.:
Q. Now 20 to one as a volume -
MS. TRACEY:
A. Is very large.
COFFEY, Q.C.:
Q. - is very large, isn’t it? If you have a specimen of any size at all -
MS. TRACEY:
A. That’s right.
COFFEY, Q.C.:

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Q. - the container would have to be -
MS. TRACEY:
A. Well, our specimen containers range from a tiny test tube to beef bucket size.
COFFEY, Q.C.:
Q. And five gallon?
MS. TRACEY:
A. Big, yes.
COFFEY, Q.C.:
Q. Okay. But to get it 20 to one -
MS. TRACEY:
A. It’s very large.
COFFEY, Q.C.:
Q. - volume, you would have to have a very large container, if the specimen is of any size at all.
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. Now in practice, from your perspective, again looking back at it, what sort of ratios were actually being utilized?
MS. TRACEY:
A. I would think, in practice, that the specimen was very well saturated, as I described. The

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nurses felt that the specimen should be well floating in the formalin.
COFFEY, Q.C.:
Q. So enough formalin to float the specimen off the bottom of the container?
MS. TRACEY:
A. Really well, and surround it.
COFFEY, Q.C.:
Q. Surround it.
MS. TRACEY:
A. Um-hm.
COFFEY, Q.C.:
Q. But if--and whether that took four to one or 15 to one?
MS. TRACEY:
A. I guess there’s no accurate measurement. It’s a perception of the person fixing the specimen.
COFFEY, Q.C.:
Q. In fact, to this day, there’s no real accurate way of doing that, is there?
MS. TRACEY:
A. No. There’s a lot more education around it has occurred.
COFFEY, Q.C.:

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Q. Yes. Here, we go to the next page, it’s for general surgery specifics, and when we look down through it, needle localization, breast biopsy, St. Clare’s OR, fixative nil, and it says "special care. Place the specimen in a blue grid container. Avoid excessive compression. Label porter transports, specimen mammogram to mammography, then specimen and film to radiologist and finally specimen to pathology with requisition." And I take it this would be -
MS. TRACEY:
A. This is procedure carried out at St. Clare’s site only.
COFFEY, Q.C.:
Q. Yes, and this would be in relation to what was perceived to be or potentially breast cancer?
MS. TRACEY:
A. Yes, usually a lump that was very small would be difficult for the surgeon to locate, probably couldn’t palpate it, it was that small. So prior to the patient coming to the OR, they would have a needle placed in it.
COFFEY, Q.C.:
Q. And here, there’s no fixative utilized here

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for this.
MS. TRACEY:
A. No.
COFFEY, Q.C.:
Q. And how long--did you ever make any inquiry or have you made any inquiries about how long it might take the specimen to finally get down to pathology?
MS. TRACEY:
A. No.
COFFEY, Q.C.:
Q. What's a blue grid container?
MS. TRACEY:
A. It's a special container that was--well, it literally had a grid in it for this purpose. So it was to map--it was, you know, was the specimen retrieved correctly.
COFFEY, Q.C.:
Q. Was there any sense of urgency associated with this particular procedure, in terms of this part of it?
MS. TRACEY:
A. Not at that time.
COFFEY, Q.C.:
Q. Not then. How about now?

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MS. TRACEY:
A. There is a different sense of urgency about all breast specimens now.
COFFEY, Q.C.:
Q. If we could look, please, at--there are a number of others. I'm not going to take the Commissioner through them, really germane. Look at 2827, please? This is that same guidelines for management of specimens, except here you'll see it's revised.
MS. TRACEY:
A. Um-hm.
COFFEY, Q.C.:
Q. March of '04. The formatting here in specimens for pathology has changed slightly in the way it's written, but again, it refers to the specimens being brought to particular locations and then transported throughout the day, there's no sense of urgency specified here, and the second page, the tissue for routine pathology, and ten percent of formalin. This would cover ordinary breast tissue?
MS. TRACEY:
A. Yes.

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COFFEY, Q.C.:
Q. So that's the same as it was before, and here, under the needle localization, breast biopsy at St. Clare's OR, again that appears to be, does it not, the same?
MS. TRACEY:
A. Yes, it is.
COFFEY, Q.C.:
Q. As the one we just looked at. Now here, as well, noticed on these, see here issuing authority here is yourself, your signature?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. So by this point certainly, in this particular copy anyway, we have--you were seen as and perceived to be the issuing authority?
MS. TRACEY:
A. Um-hm.
COFFEY, Q.C.:
Q. These would be circulated where, these sorts of policies?
MS. TRACEY:
A. Circulation in each OR and in surgical day care at the General site, because procedures

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are done there, not at St. Clare's.
COFFEY, Q.C.:
Q. Do you know if pathology was consulted about the revisions in 2004?
MS. TRACEY:
A. I'm presuming that the revisions took place because of some feedback.
COFFEY, Q.C.:
Q. Okay. Would there be any record of whether they were consulted?
MS. TRACEY:
A. I haven't got a record of that and I looked for it. The change in 2004 was pretty small. Oftentimes, the changes occur out of changes in practice as well.
COFFEY, Q.C.:
Q. Now Ms. Tracey, are there any other policies and procedures, written ones, that, you know, again relating to breast operations that you're aware of that we haven't looked at, before we get to '05, because we'll get there now?
MS. TRACEY:
A. Before this, no, these are the policies that we had in place.

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COFFEY, Q.C.:
Q. Yes, this is it. If we could look, please, at Exhibit P-1939? And this is a memorandum from Dr. Cook of August 23rd, 2005 to yourself involving mastectomy specimens. Before I look through this though, Ms. Tracey, can you tell me when you first heard of this ER/PR as kind of a topic?
MS. TRACEY:
A. I'm not exactly sure when. It was the summer of 2005. I can't pinpoint exactly when.
COFFEY, Q.C.:
Q. And the context?
MS. TRACEY:
A. I'm not totally sure. It was pretty well from, I think, one of my peers I heard it and then I did speak to Dr. Kwan about it, to gain a better understanding of what was happening at that time.
COFFEY, Q.C.:
Q. So one of your colleagues, nursing colleagues -
MS. TRACEY:
A. One of my program director colleagues.
COFFEY, Q.C.:

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Q. Program directors, had said something to you about there's something going on with -
MS. TRACEY:
A. That's right.
COFFEY, Q.C.:
Q. - ER/PR breast tissue specimens?
MS. TRACEY:
A. Um-hm, so it was late summer 2005, I believe.
COFFEY, Q.C.:
Q. You spoke to Dr. Kwan to make inquiries of him.
MS. TRACEY:
A. To ask him a little bit more about it.
COFFEY, Q.C.:
Q. What did he tell you at the time, do you recall?
MS. TRACEY:
A. Well, issues with the specimens, yes. Not an in-depth conversation, just a brief "there are issues."
COFFEY, Q.C.:
Q. Did he tell you the nature of what the issues were?
MS. TRACEY:
A. Not that I recall. I actually did not know very much about ER/PR, I have to say, until that. It was the first time I became aware of it.
COFFEY, Q.C.:
Q. And in terms of the--when he spoke of the issues or potential issues, was it in the context of fixation being a potential problem?
MS. TRACEY:
A. I don't recall. It was very brief. I really did not understand the, I guess, significance of all that was going on at that time. It was just starting to become knowledge of--all our knowledge, you know, was increasing about the issue at that time.
COFFEY, Q.C.:
Q. Did it occur to you at that time that this might involve my program and require changes of our program at that point?
MS. TRACEY:
A. I guess the first time I heard of it, probably not, but quickly it became -
COFFEY, Q.C.:
Q. Okay, we'll get to that now. Would this be the first real sign to you?
MS. TRACEY:

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A. I believe it was, yes.
COFFEY, Q.C.:
Q. That -
MS. TRACEY:
A. It's the first time I actually recall, it was the first time I received something in writing about it.
COFFEY, Q.C.:
Q. And here, this is from Dr. Cook. It's dated July 23rd, 2005. He signed it. Here it says "September -
MS. TRACEY:
A. 12th.
COFFEY, Q.C.:
Q. - 12th, '05, copy Dianne, Dorothy and Shirley.
MS. TRACEY:
A. They're my three managers.
COFFEY, Q.C.:
Q. And this is your handwriting?
MS. TRACEY:
A. Yes, it is.
COFFEY, Q.C.:
Q. So you would have sent--after you got this from Dr. Cook -
MS. TRACEY:

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A. I was, I believe, on holidays at that time. So by the time I came back from holidays, I sent it out.
COFFEY, Q.C.:
Q. And it says--it's addressed to yourself as the program director and to Dr. Dan Fontaine, the site chief at the General, and Dr. Cook was already the clinical chief and at St. Clare's presumably he was aware of what he was sending.
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. So he's letting you, as the program director for surgical, the surgical perioperative program -
MS. TRACEY:
A. Yes, which I'm not the surgical program director.
COFFEY, Q.C.:
Q. Yes, I appreciate that. It should have been -
MS. TRACEY:
A. Perioperative.
COFFEY, Q.C.:
Q. - perioperative program.

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MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. Dan Fontaine, the site chief at the General, know the following. He says "I am requesting that all mastectomy specimens be placed in a large container and completed immersed in ten percent formalin. Specimens should be immediately forwarded to the pathology lab where the breast tumour is appropriately sectioned to allow for even penetration and fixation by formalin." Okay, I'm going to stop there, okay, for a moment. The first sentence, "all mastectomy specimens be placed in a large container and completely immersed in ten percent formalin." Well, you would have understood that back certainly in the mid 1990s and probably before.
MS. TRACEY:
A. That's correct.
COFFEY, Q.C.:
Q. So that really didn't change.
MS. TRACEY:
A. No.
COFFEY, Q.C.:

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Q. Then he says "immediately forward to the pathology lab." That would be a change?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. "Where the breast tumour is appropriately sectioned to allow for even penetration and fixation by formalin." Was that news to you?
MS. TRACEY:
A. Yes, that was a change for us.
COFFEY, Q.C.:
Q. Now I take it, it wouldn't actually--other than sending it down immediately, you wouldn't--your people wouldn't be involved in the sectioning?
MS. TRACEY:
A. No.
COFFEY, Q.C.:
Q. But the fact that it--did this suggest to you though that breast -
MS. TRACEY:
A. It suggested that cases were not to be-- specimens were not to be left lying around.
COFFEY, Q.C.:
Q. And they should be sectioned and immersed--

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immersed in formalin, sectioned and presumably put back into formalin.
MS. TRACEY:
A. I would have seen our role in that as getting the specimen faster to the lab.
COFFEY, Q.C.:
Q. He does say then "cases should not be left overnight or over the weekend unsectioned as this may interfere with proper fixation of tissue." So up to that point in time, there had been--as you pointed out to the Commissioner, no attempt to avoid this, to avoid things being left overnight or the weekend?
MS. TRACEY:
A. No, that's correct.
COFFEY, Q.C.:
Q. And then "for cases that occur after normal working hours, the pathologist on call should be notified." Now that would be new, wouldn't it?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. Was that then done?

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MS. TRACEY:
A. Yes. I sent it to the managers and my expectation would be that anything like this, it would be implemented.
COFFEY, Q.C.:
Q. Did you receive any feedback from them saying that they couldn't do it?
MS. TRACEY:
A. No.
COFFEY, Q.C.:
Q. And he also -
MS. TRACEY:
A. We were already sending some specimens immediately to the lab.
COFFEY, Q.C.:
Q. Such as?
MS. TRACEY:
A. The bacteriology, cytology specimens.
COFFEY, Q.C.:
Q. Yes, okay, all those other ones that we looked at.
MS. TRACEY:
A. So this was just a change in practice for one type of specimen.
COFFEY, Q.C.:

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Q. Which is all the pathology ones.
MS. TRACEY:
A. Yeah.
COFFEY, Q.C.:
Q. Yes. "Please make every attempt to ensure -
MS. TRACEY:
A. No, it's only mastectomy specimens.
COFFEY, Q.C.:
Q. Mastectomy, I appreciate. This is mastectomy and I'm going to ask you about that in a moment, okay. "Please make every attempt to ensure these cases are done early in the day and submitted to the lab before four p.m." Now was that a practical suggestion, from your perspective?
MS. TRACEY:
A. No, it wasn't.
COFFEY, Q.C.:
Q. And why is that?
MS. TRACEY:
A. Later, I did discuss that with Dr. Cook. The operating room does the more complex cases first thing in the morning. The sicker patients that need the most resources, that need surgeons and anasteseologists and nursing

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staff fresh, longer cases and the more complex cases. Mastectomy patients are usually well, but they do have cancer, but the procedure is a short procedure. It's not resource intensive.
COFFEY, Q.C.:
Q. From an OR -
MS. TRACEY:
A. From the OR perspective, yes. So these cases are often fitted around the bigger cases because it helps the flow of the operating room. A big case goes first, maybe a smaller case next, and then maybe another big case. So practically, that was not a solution for the operating room. As well as that, it depended on the surgeon's operating time. Some surgeons only have afternoon slots on certain days of the week. So ultimately, doing cases earlier in the day was not always a solution.
COFFEY, Q.C.:
Q. And you discussed that with Dr. Cook?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:

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Q. And so what was the result of that, your discussion?
MS. TRACEY:
A. My discussion was that pathology would have to be more available to us.
COFFEY, Q.C.:
Q. And his response?
MS. TRACEY:
A. He took it under advisement and actually did improve the service, the availability of pathology to us. The other part of it is, mastectomy and breast biopsy specimen, or at least surgeries are elective surgeries. So they are usually completed by about 4:00 in the day. The elective surgery slots are usually eight to four. So I wouldn't be expecting that there'd be a lot of after hours cases or any actually. Very rarely would there be any breast specimens after hours.
COFFEY, Q.C.:
Q. Now the idea that they would be--should be immediately forwarded to the pathology lab, in the beginning, right here, and certainly if it could be done before four, but whatever time it got done, immediately go down to the lab,

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what arrangements were made in that way?
MS. TRACEY:
A. Our porters bring the specimens down to the lab.
COFFEY, Q.C.:
Q. I appreciate that, but they'd always--did you always have OR porters?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. Okay. So they're different than the central portering service?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. And there have always--in your time, there have always been OR porters?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. So prior to this, late August 2005, the OR porters had existed, they just hadn't been utilized to bring down the -
MS. TRACEY:
A. They weren't bringing the mastectomy

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specimens. They were bringing -
COFFEY, Q.C.:
Q. Other specimens?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. We've seen a list of some of them.
MS. TRACEY:
A. Yes, and all the urgent specimens, we run--our porters take them immediately. We don't wait for somebody.
COFFEY, Q.C.:
Q. And then Ms. Tracey, then in relation to -
MS. TRACEY:
A. At times, central portering can also be called to do these.
COFFEY, Q.C.:
Q. Yes, I appreciate that. So for example, for some reason you didn't have a porter immediately available in your own service, you would get central portering?
MS. TRACEY:
A. Yes, but there can be a delay, so this wouldn't be really appropriate.
THE COMMISSIONER:

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Q. When you say "our porters bring the mastectomy specimens down to the lab," would that be all of them or the ones that come up after the 3:00 run?
MS. TRACEY:
A. The ones that--no, all of them now, yes, because those specimens are not left at all.
THE COMMISSIONER:
Q. Okay.
COFFEY, Q.C.:
Q. And that started in August, September 2005, that time period, kind of, okay, mastectomy, we'll get it down there -
THE COMMISSIONER:
Q. We're just talking about mastectomy specimens?
COFFEY, Q.C.:
Q. Yes.
MS. TRACEY:
A. Yes. Mastectomy and breast specimens, I guess, would be more specific.
COFFEY, Q.C.:
Q. Ms. Tracey, the--and that was so and even if it was after four, if for some reason a breast operation went until 5:00?
MS. TRACEY:

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A. Yes.
COFFEY, Q.C.:
Q. Still there'd be somebody -
MS. TRACEY:
A. And if the--I'm sure we will be looking at other memos that state if the pathologist isn't available, that he must be called.
COFFEY, Q.C.:
Q. Called. Page him and get him in here?
MS. TRACEY:
A. Um-hm.
COFFEY, Q.C.:
Q. Other specimens, any non, like, non-breast specimens, did any of that, the way they were handled in terms of being taken down to the OR pathology, non-breast specimens, did that change in August of '05?
MS. TRACEY:
A. No.
COFFEY, Q.C.:
Q. So whatever the practice you described earlier had been, existed for years, continued on, some specimens, non-breast specimens, pathology specimens could remain in formalin -
MS. TRACEY:

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A. Overnight.
COFFEY, Q.C.:
Q. - overnight?
MS. TRACEY:
A. Um-hm.
COFFEY, Q.C.:
Q. Or over the weekend?
MS. TRACEY:
A. Um-hm.
COFFEY, Q.C.:
Q. In the OR?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. Is that still true?
MS. TRACEY:
A. The time line now is 48 hours, 48 hours for specimens fixed in formalin. Ideally they should be brought to the OR within 24, but they can be left in the OR up to 48 hours.
COFFEY, Q.C.:
Q. Okay. That's for non-breast?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:

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Q. If we could look, please, at Exhibit, while I'm at it, P-3082? This is another one of those documents. And before I pass on completely to 2005 and '06, Ms. Tracey, this is a Health Care Corporation of St. John's perioperative program, operating room policy manual, the issuing authority is yourself. This would be May, 2003, specimen care. And here under, well, it says, "Specimens in the OR may include soft tissue and other types of tissues." Policy, amongst other things, number five, "specimens for routine pathology are placed in a container of 20 to one formalin with specimen." And then there's a description of the procedure which I take it is the procedure in terms of these specimens that occurs within the OR?
MS. TRACEY:
A. That's correct.
COFFEY, Q.C.:
Q. And -
MS. TRACEY:
A. Everything within the OR while the surgery is in progress is very rigid. There's policies and practices for all of it.

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COFFEY, Q.C.:
Q. Okay. And, in fact, if we looking under "scrub nurse" here there's five steps. In fact, it tells here exactly what to do.
MS. TRACEY:
A. That's correct.
COFFEY, Q.C.:
Q. And the circulating nurse, the same thing, in effect. But then number three was "follow the specimen chart in the guidelines for the management of specimens." Which is the one we, the larger one -
MS. TRACEY:
A. We just looked at.
COFFEY, Q.C.:
Q. - we looked at?
MS. TRACEY:
A. Yes. Because that's the specific fixation for the specimen.
COFFEY, Q.C.:
Q. And so this, as you point out, in specimen care, particularly in the OR, very rigid and very detailed rules. Then you got a bit more general when you looked at--and perhaps not as rigid in the sense of as detailed when you got

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out to the guidelines?
MS. TRACEY:
A. Well, there's two parts to the policy.
COFFEY, Q.C.:
Q. Yes.
MS. TRACEY:
A. You have to follow both of it. The first part is how the specimen is actually handed off.
COFFEY, Q.C.:
Q. Yes.
MS. TRACEY:
A. And the second part just the fixation.
COFFEY, Q.C.:
Q. Fixation?
MS. TRACEY:
A. Um-hm. And the treatment of or the care of the specimen.
COFFEY, Q.C.:
Q. Here under "Circulating nurse," number two, it says, "Receive specimen in appropriate container based on size/destination following confine and contain principles and then follow the specimen chart," which is the ones we looked at earlier?
MS. TRACEY:

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A. Yes.
COFFEY, Q.C.:
Q. Look, please, at Exhibit P-3083? These are, it's an e-mail, it's a letter, first of all, September 26th, 2005 from Dr. Cook to Dr. Williams, "ER and PR review." And then back to an e-mail from Denise Dunn to, amongst other people, on September 29th, amongst other people, yourself, Maria, "Louise and Maria, can the surgery and perioperative programs leaders review, please." And the first page of this is also a fax from Dr. Williams' office to yourself sending along that letter, yourself and others, including Ms. Jones, Dr. Felix and Dr. Kwan. She says the same thing except it's Bob Williams saying it there. Now, what I wanted to ask you about is is this, when yourself and Dr. Cook spoke--I should ask about his letter of August 23rd. You distributed--you came back from vacation in September, distributed it. You would have spoken to Dr. Cook?
MS. TRACEY:
A. Dr. Cook popped his head in around my door, actually, that he was going to meet with Dr.

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Williams, wanted to talk to me about this.
COFFEY, Q.C.:
Q. So is it this letter or the one before, the August 23rd?
MS. TRACEY:
A. I'm not--I can't exactly recall the date because it was in this time frame.
COFFEY, Q.C.:
Q. Okay.
MS. TRACEY:
A. And it wasn't something I have a record of. I have a recollection of it, but I don't have a record of it.
COFFEY, Q.C.:
Q. Okay, go ahead and tell us then what you recall about it?
MS. TRACEY:
A. Dr. Cook asked about the scheduling of breast surgical patients.
COFFEY, Q.C.:
Q. Um-hm.
MS. TRACEY:
A. Could they--he was asking if we could avoid doing mastectomies and breast surgery on Friday afternoons. And I explained to him

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that the OR couldn't function in that way, that really it was not practical to even consider this, and for the reasons I've already explained to you.
COFFEY, Q.C.:
Q. Um-hm.
MS. TRACEY:
A. And that what we needed was pathology to be more available to us so that the limitations were not put on the OR because we couldn't survive with those kind of limitations.
COFFEY, Q.C.:
Q. Yes. And his response?
MS. TRACEY:
A. And his response was that he would go speak to his colleagues, which he did. And we were occasionally having issues with the, you know, with locating pathologists, so there was another letter subsequently outlining how to actually contact pathologists. And Dr. Cook realized that, you know, the OR couldn't change its practice how these surgeries were scheduled, that indeed, you know, they were not large surgeries for the OR and that pathology actually had to change its practice

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and he agreed. So the pathologists--and there was a letter too later on outlining how to actually contact pathology if there was any issues.
COFFEY, Q.C.:
Q. Actually working out the nitty, setting out the nitty gritty of -
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. - how to deal with -
MS. TRACEY:
A. Because at times the OR was waiting to get-- for extended periods before pathologists answered pages and things, so I brought that to Dr. Cook's attention. And one on one these situations would have been brought to the attention of Dr. Cook by the OR managers if their staff had difficulty contacting pathologists.
COFFEY, Q.C.:
Q. Why were you having difficulty contacting pathologists, do you know?
MS. TRACEY:
A. I can't actually say. It was just at times

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they were--they'd be slow responding to the operating room.

COFFEY, Q.C.:

Q. Did that change?

MS. TRACEY:

A. Yes, it did.

COFFEY, Q.C.:

Q. After, around this time, the fall of 2005 it changed?

MS. TRACEY:

A. Yes, it did, yes.

COFFEY, Q.C.:

Q. Had it been going on, had that been a problem for some period of time before that?

MS. TRACEY:

A. It was a problem at St. Clare's more than at the General site, I recall. Not a huge problem, just occasionally frustration.

COFFEY, Q.C.:

Q. But in any case, beginning in the fall of 2005 it became less of a problem?

MS. TRACEY:

A. Corrected, yes. The problem is addressed in one of the later memos.

COFFEY, Q.C.:

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Q. Here, looking at this, he makes the assertion in the second sentence, third line, "Appears in some cases the mastectomy specimens and other breast biopsies could very well be left lying overnight or over the weekend in the OR without adequate formalin fixation."

MS. TRACEY:

A. Um-hm.

COFFEY, Q.C.:

Q. Which is the same assertion as in the August 23rd letter?

MS. TRACEY:

A. That's correct, um-hm.

COFFEY, Q.C.:

Q. He then goes on to talk about strongly recommending that these types of surgical procedures be booked first thing in the morning, Monday to Friday, and not, in any case, not be done Friday afternoon.

MS. TRACEY:

A. Afternoon. And I explained to Dr. Cook the OR is working Friday afternoon same as any other day of the week, so that wasn't a choice. And also, surgeons' times, there are surgeons who have time at St. Clare's only on Friday

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afternoons, so he understood that and he appreciated that.

COFFEY, Q.C.:

Q. Here -

MS. TRACEY:

A. I guess when you're on the outside it's hard to understand the functioning of an operating room, but he was open to the discussion.

COFFEY, Q.C.:

Q. Here it says, "Every effort should be made to ensure that these cases are forwarded to the lab in a timely fashion." Here, I'll bring you back to 1938, please, P-1939? That August 23rd memo, the second sentence says, "Specimens should be immediately forwarded to the pathology lab where the breast tumour is appropriately sectioned to allow for even permeation and fixation by formalin." So back in August 23rd in the memo you circulated to your managers on September 12th said immediate, immediately, I'm sorry, forwarded. If we could go back then to P-3083, at September 26th, 2005 letter it says, it's framed instead in the context of "Every effort should be made to ensure that these cases are

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forwarded to the lab in a timely fashion." which is not necessarily the same thing as "immediately." Did you, at the time, what was your understanding by the time you'd received this?

MS. TRACEY:

A. I would presume that the letter of August -

COFFEY, Q.C.:

Q. 23rd.

MS. TRACEY:

A. - the third was the one that actually designated what the practice should be.

COFFEY, Q.C.:

Q. Yes. There's a reference here to "Following the exit interviews of both the medical and technical consultants, one of the issues identified in immunohistochemical staining of estrogen and progesterone receptors concerns adequate fixation of the specimen." Was this the first that you'd heard of this? First of all, did you know about these external consultants?

MS. TRACEY:

A. No.

COFFEY, Q.C.:

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Q. So it would be the first you heard of them?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. This being them having identified--one of the issues being identified in IHC staining of ER/PR was adequate fixation of the specimen. Is that the first time that was brought to your attention?
MS. TRACEY:
A. Yes. Well, the August letter was the first time.
COFFEY, Q.C.:
Q. In terms of what should get done?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. But I'm thinking of it in terms of external consultants.
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. Relating it to fixation. This is the first time you would have heard of that?
MS. TRACEY:

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A. Yes.
COFFEY, Q.C.:
Q. Did you ever have any discussion with anybody about that, the fact that these people had come in from outside and had noted that there was potentially a problem with our practice in terms of fixation?
MS. TRACEY:
A. I was aware around this time that there was issues and concerns about the ER/PR testing and that I guess my knowledge of what was actually happening and--was evolving as the situation became more into focus, I guess.
COFFEY, Q.C.:
Q. Exhibit P-3084? 3084. Now, this is a document, "OR information session, October 4th, 2005."
MS. TRACEY:
A. Okay. This is Tuesday in-service -
COFFEY, Q.C.:
Q. Yes.
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. And I was going to ask you about that.

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MS. TRACEY:
A. Yes, this would be--yes.
COFFEY, Q.C.:
Q. Is this sort of minutes of the in-service meeting?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. I won't say minutes, but it's -
MS. TRACEY:
A. Yeah.
COFFEY, Q.C.:
Q. - it's a summary?
MS. TRACEY:
A. It's a summary. In-service time is often, you know, designated to demonstrate new techniques or new instruments or new practices, but there is also some time set aside to discuss changes in practice or anything new the staff need to know in the operating room.
COFFEY, Q.C.:
Q. Here on the second page of this is a heading "Specimens." "Have to be covered completely with formalin. Make sure we use lots of formalin to cover specimens. Place specimens

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in larger containers. Mastectomies, large container. Cover completely with lots of formalin and send directly to"--I'm sorry, "Send direct to pathology. Breast reduction specimens are treated the same. Small specimen container is used for very small specimens only." So I take it that this -
MS. TRACEY:
A. This is staff being educated.
COFFEY, Q.C.:
Q. About this?
MS. TRACEY:
A. Um-hm.
COFFEY, Q.C.:
Q. About the two memos?
MS. TRACEY:
A. Um-hm.
COFFEY, Q.C.:
Q. Particularly the first memo?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. And the change in practice here is make sure the container is large enough, it's got enough formalin in it and -

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MS. TRACEY:
A. It's a reminder of actually what the policy is already saying, but - you know, and outlining that there were issues.
COFFEY, Q.C.:
Q. And it was a change for the staff in that this idea of sending it direct and now?
MS. TRACEY:
A. Yes, that's a change of practice.
COFFEY, Q.C.:
Q. That was a practice. Were the staff able to accomplish that?
MS. TRACEY:
A. Yes, they were already doing that for the other specimens.
COFFEY, Q.C.:
Q. A whole list of non-pathology specimens. If we could look, please, at Exhibit P-2884. Now here this is again a staff meeting of November 22nd, 2005. It's from Shirley Taylor. Remind us again she is -
MS. TRACEY:
A. Manager St. Clare's OR.
COFFEY, Q.C.:
Q. St. Clare's.

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MS. TRACEY:
A. The majority of the specimens are done there.
COFFEY, Q.C.:
Q. The majority of the breast specimens are nowadays and in '05 from St. Clare's?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. So this would be sent to all the staff, I take it?
MS. TRACEY:
A. Yeah. The staff were present during this period.
COFFEY, Q.C.:
Q. Oh, yes.
MS. TRACEY:
A. This is a record afterwards of what was discussed.
COFFEY, Q.C.:
Q. And here -
MS. TRACEY:
A. So the staff who weren't present could read it.
COFFEY, Q.C.:
Q. There are a number of different entries here,

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but number nine is, "Any mastectomy specimens coming out for the OR after hours needs to be written in the path book and taken up to the lab. If there is no one there to receive it, we need to page the pathologists and let them know it is there". I take it this was the -
MS. TRACEY:
A. Yes, that's the practice.
COFFEY, Q.C.:
Q. November 22nd.
MS. TRACEY:
A. Uh-hm.
COFFEY, Q.C.:
Q. It had changed, the overall practice?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. Now we understand that certainly there are a number of written policies and procedures now in place and the Commissioner has seen one in particular involving the clinical laboratory that's more than 300 pages long, okay. In terms of the ER/PR matter as time went on then, and we've looked at what happened in September of 2005, Dr. Cook spoke to you and

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then you dealt with - yourself and Ms. Jones would have talked about his letter about scheduling.
MS. TRACEY:
A. Uh-hm.
COFFEY, Q.C.:
Q. What then happened in terms of your own involvement with ER/PR? Did you have any involvement at all?
MS. TRACEY:
A. Not really, no. No, just to follow through on the policies and change our practice to meet the policies needed for the laboratory.
COFFEY, Q.C.:
Q. Now there is one - I apologize, Commissioner, there is one - look at, please, 3088. This is a specimen care policy for the perioperative program. The issuing authority is yourself. The original one is May of 2003, the revised in March of 2007.
MS. TRACEY:
A. Uh-hm.
COFFEY, Q.C.:
Q. And do you know if there was a similar revision around that time relating to the

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guidelines for the management of specimens?
MS. TRACEY:
A. I'm not sure.
COFFEY, Q.C.:
Q. Now you were telling the Commissioner that generally there have been - you've been involved in changing policies and procedures and we just took you through some of the practical end of that.
MS. TRACEY:
A. Uh-hm.
COFFEY, Q.C.:
Q. How about more formal written policies and procedures involving fixation and the OR?
MS. TRACEY:
A. The formal policies from the lab? Are you talking about those?
COFFEY, Q.C.:
Q. That would affect the OR's practices. I mean, what is, for example, the current policy?
MS. TRACEY:
A. The policy now that we - we implemented the laboratory policies. They superseded the policies that we have in place, and so we're following those, but even since then, there

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has been a change in practice because we were placing specimens in formalin in the refrigerator up until two weeks ago, and now we are no longer doing that because the cold atmosphere in the fridge was affecting the formalin's ability to penetrate the specimens.
COFFEY, Q.C.:
Q. That changed -
MS. TRACEY:
A. That changed two weeks ago after Dr. Dabb was here.
COFFEY, Q.C.:
Q. And that had begun when - that had begun back when?
MS. TRACEY:
A. When did we start placing the formalin -
COFFEY, Q.C.:
Q. Yes.
MS. TRACEY:
A. The summer, this summer.
COFFEY, Q.C.:
Q. Summer of '08?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:

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Q. So it's relatively recent?
MS. TRACEY:
A. Yes.
COFFEY, Q.C.:
Q. And after -
MS. TRACEY:
A. Oftentimes our practice changes and the policies come behind it.
COFFEY, Q.C.:
Q. And -
MS. TRACEY:
A. Because if there's something that's affecting the specimen, we're anxious to get it sorted out immediately. Policies are a slow process.
COFFEY, Q.C.:
Q. Now -
MS. TRACEY:
A. So actually Bev Rowe called us, called my clinical educators about that to inform us.
COFFEY, Q.C.:
Q. Just looking at this particular one, 3088, page one, for specimen care, is this one still in place?
MS. TRACEY:
A. Yes, but - actually that's in the process of

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being revised now to - that one is the general specimen policy.
COFFEY, Q.C.:
Q. Yes.
MS. TRACEY:
A. Actually the one that has the - we're going to change this to align it to actually designate that you follow the lab policies.
COFFEY, Q.C.:
Q. Okay, in relation to specimen care.
MS. TRACEY:
A. Yes, and I suppose down at the bottom it says that you follow the other policy.
COFFEY, Q.C.:
Q. That guideline -
MS. TRACEY:
A. That one, guidelines for the management of specimens, it will now say follow the lab policy, and the lab policy is actually immediately following that in our manual.
COFFEY, Q.C.:
Q. So what would happen is that, well, within the OR, we'll have our own, you've got it spelled out here -
MS. TRACEY:

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A. Yes, because this is -
COFFEY, Q.C.:
Q. Or however you might change it.
MS. TRACEY:
A. Our practice in that won't change.
COFFEY, Q.C.:
Q. And the hand off one down here?
MS. TRACEY:
A. That will change.
COFFEY, Q.C.:
Q. That will change and follow the -
MS. TRACEY:
A. But that is - that policies from the lab cover pathology specimens. We don't have specific specimens for cytology, bacteriology, so we have got to conform - revise our policy to reflect that. In the meantime, I understand there will be policies coming from them shortly as well.
COFFEY, Q.C.:
Q. For the cytology, bacteriology and so on?
MS. TRACEY:
A. Bacteriology, but in the meantime, we have to have something in place so our staff will know what to do. So my educators are actually

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working on that now.
THE COMMISSIONER:
Q. Mr. Coffey, it is -
COFFEY, Q.C.:
Q. What I'm going to ask then, Commissioner, because it is late, it's 5 o'clock, I anticipate I may - I'd just like to think about it overnight. I'm probably done, but if I could come back in the morning.
THE COMMISSIONER:
Q. 9:30.
Upon conclusion.

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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 29th day of September, 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 29th day of September, A.D., 2008
Judy Moss

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