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Product Summary:

DOCTOR CONCERNED OVER LAB TESTS: More details have surfaced about the kind of concerns a doctor had about laboratory medical tests carried out by Eastern Health
Wednesday, June 13, 2007 08:22AM Item # 14
CBC Radio St. John's

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JEFF GILHOOLY: More details have surfaced about the kind of concerns a doctor had about a laboratory medical tests carried out by Eastern Health. As you know the provincial government has launched its own judicial inquiry into inaccurate breast cancer tests and the class action suit has also been filed. In the beginning Eastern Health said it knew about problems as early as 2005. But about three weeks ago now the news came out that Dr. Gershon Egecham was criticizing aspects of lab work as early as 2003. He left Nfld about a year ago and he's now back in his native Nigeria. He's not doing radio interviews. But CBC's National Reporter Vic Adophia had a brief chat with him on a crackly phone line. Vic joins me now in our studio. Good morning.

VIC ADOPHIA: Hi, Jeff.

JEFF GILHOOLY: Look lets just go back over who this doctor was, tell me about Dr. Egecham.

VIC ADOPHIA: Yeah he's Dr. Gershon Egecham and he came to St. John's from Doha, Qatar in August 2002. Qatar is a gulf state in the Middle East and that's where he worked as a chief pathologist and within a few months of arriving in St. John's he was assigned to quality control for amino histo-chemical testing at the pathology lab. Now that amino histo-chemical that's the long word that describes this sophisticated testing that includes the hormone receptor tests that determines if a patient's breast cancer is being spread by hormones.

JEFF GILHOOLY: I remember when we first covered it. It seemed very serious

this letter that he wrote. Can we just go back over what his concerns really were.

VIC ADOPHIA: Sure it began in April 2003 so this shortly maybe half a year after he arrived. He wrote a memo to all the hospitals in the province that he was suspending all amino histo-chemical tests for four to six weeks. And he says the testing process was, in his words were unreliable, erratic and unhelpful. So he suspended these tests and this is two years before Eastern Health acknowledged publically that there were problems in the lab.

JEFF GILHOOLY: Alright how did the conditions here then compare with what he was used to in other parts of the world?

VIC ADOPHIA: Well it is surprising that, he said compared to his last job as a pathologist in Doha St. John's was just not up to par and mostly because here they didn't at the time have the staff dedicated solely to this complex amino histocal-chemical testing which requires a bit of experience and expertise. And at the time he came they did not dedicate to this one type of testing. So he said that had to change and he, he urshered in that change.

JEFF GILHOOLY: Okay alright I know that Eastern Health took it fairly seriously it seemed. I talked with George Tilley, the CEO of Eastern Health and said that action was taken. What did they do?

VIC ADOPHIA: Well Dr. Egecham did have the authority to suspend all of those tests and he did do that and after a couple of weeks Dr. Egecham says with the problems with the hormone receptor tests, that's related to the breast cancer testing were resolved, but, you know, in a later memo his tone had an air of alarm. And as I mention the ER, PR testing to do with breast cancer was taken care of but there were still other testing problems with prostate biopsies and there was that alarm. And he said test results could jeopardize patient care, it could open up health officials to litigation. So he really didn't feel like enough was being done. What he said to me was that when he found, he sent this initial memo he received no response from the department, the administration and he said he didn't get a response for what he calls quite a while. And he's a bit critical here. He says the program director for the Pathology Department isn't a physician and he felt that might have affected how the problem was dealt with because he felt maybe, you know, if there was a doctor in charge of the department, perhaps there would have been action sooner and they would have appreciated the gravity of the situation here.

JEFF GILHOOLY: Oh okay. Because in that interview, I'm just, go back to it on the Morning Show with George Tilley, again he said that he was quite confident that all the problems by Dr. Egecham had been looked after. It caused me to wonder well if that was, especially with the breast cancer testing if that was fixed somewhere around 2003 what happened between then and 2005 when we start to

get the misreadings.

VIC ADOPHIA: Exactly that, that is the question. What did happen bet3ween two those years. As you said 2005 was when they announced publically okay we have a problem here but Dr. Egecham said there was a problem two years earlier. So that information has to be released because there is no year by year breakdown just yet of the numbers of false test results. So we don't know if Dr. Egecham, when he said okay I fixed everything in the lab, if false test results continued prior to his, or after his intervention. We don't know that just yet. But we do know that the percentage of patients rejected for the anti-hormone therapy was closer to what was considered normal after he made these changes.

JEFF GILHOOLY: Okay.

VIC ADOPHIA: Prior to him intervening we got a high rate of people rejected for this treatment to do with breast cancer. And this is what Ches Crosbie, the lawyer is saying, that you know, the red flag should have gone up sooner, in 2002 even, in 2001, that you know, a lot of people are being rejected for this treatment that should not have been rejected just by, based on percentage not even their test results. Just, they're out of whack. So we do know that after he did make these changes the levels are, the percentage of people who are getting the treatment was up to normal.

JEFF GILHOOLY: Vic, has Dr. Egecham been following this story here now?

VIC ADOPHIA: Well when, when I did contact him and he's now back in Nigeria where he is the chief of a Pathology Department and is trying to start up a med school there, he knew all about the class action lawsuit and you, as you can imagine was a little reluctant to speak to me at first. I mean in the end he said he was not at all surprised at the high percentage of women rejected for this therapy given the problems in the lab and given the way they were doing things. But he said, you know, they're not completely out of whack with maybe some other labs across North America. Of course we don't have the benefit of comparing us to anyone else because really who out there would do a mass retesting.

JEFF GILHOOLY: Right.

VIC ADOPHIA: [inaudible]

JEFF GILHOOLY: Alright, we appreciate this. Thanks, Vic.

VIC ADOPHIA: You're welcome, Jeff.

JEFF GILHOOLY: That's Vic Adophia, he's CBC Radio's National Reporter

based here in St. John's.

Eastern Health

FAX TRANSMISSION

TO: Tansy Muridon FROM: Joyce Penney

FAX: 729-0121 PAGES:

SUBJECT: DATE: 5/31/2007

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply

COMMENTS:

Forwarded on behalf of George Tiley

Thanks

Joyce

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729-0121

TO: PATHOLOGISTS, HSC, ST. CLARE'S AND OUT OF TOWN HOSPITALS

FROM: DR. G. EJECKAM, PATHOLOGIST, HSC

SUBJECT: IMMUNOHISTOCHEMICAL STAINS

DATE: APRIL 4, 2003

Kindly note that immunohistochemical stains with the following antibodies: CKHMW-34BE12, CD3, CD5, CD20, CD79a, CEA, ER and PR, have remained unreliable, erratic and, therefore, unhelpful for diagnostic purposes.

Consequent on the above, staining with these antibodies shall stop forthwith until we can solve the reliability, sensitivity and specifity problems.

Efforts are underway and hopefully a solution will be found within the next four to six weeks.

You will be duly informed when such stains can resume.

Thank You

Dr. G. Ejeckam

cc: Barry Dyer
All technical staff on Immunohistochemistry

SURGICAL PATHOLOGY REVIEW COMMITTEE (SPRC)
HEALTH SCIENCE CENTRE, HCCSJ
MINUTES OF MEETING, APRIL 15, 2003

PRESENT: Dr. G. Ejeckam, Chairman
Dr. S. Battcock
Dr. L. Dawson
Dr. M. Parai
Dr. J. Siddiqui
Theresa Curtis, Secretary

APOLOGIES: Dr. M. Thavanthan
Dr. A. Kwan

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1. CALL TO ORDER

The first meeting of the Surgical Pathology Review Committee was called to order by Dr. G. Ejeckam, Chairman at 2:10 p.m. on April 15, 2003 in Room 2864, HSC.

3. NEW BUSINESS

3.1 ER and PR Receptors

Dr. G. 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 send one or two technologists to Halifax or Toronto for training.

DR. Ejeckam

HealthCare
Corporation of St. John's

TO: PATHOLOGISTS, HSC, ST. CLARE'S AND OUT OF TOWN HOSPITALS

FROM: DR. G. EJECKAM, PATHOLOGIST, HSC

SUBJECT: ER/PR IMMUNOHISTOCHEMICAL STAINS

DATE: May 2, 2003.

I am glad to inform you that we have rectified the difficulties related to the immunostain of ER/PR, therefore, we can now resume regular request for these antibody stains. I will, however, like to bring the following information to your attention:

1. Results of the immunostains may be affected by:

   (a) Delayed fixation.

   (b) Over fixation.

   (c) Under fixation.

   (d) Uneven fixation.

   (e) Inadequate tissue dehydration.

   (f) Tissue reprocessing.

   The optimal fixation time for immunostains is 18 - 24 hours, in 10% neutral buffered formalin. If you use a different fixative, please specify that when you send your request.

   It is advisable to maintain a regular check on the PH of the buffered formalin even if it is procured commercially. Regular check and change of grades of alcohol in the Tissue Processor will eliminate inadequate tissue dehydration.

2. ER/PR false negative results increase in core biopsies, therefore, where possible restrict request to excision biopsies.

3. Check normal breast acini in your sections as internal controls. This is a second level control. Nuclear staining in normal breast tissue is heterogeneous and varies with menstrual cycle.

4. In carcinoma of the breast, most PR+ tumors are also ER+, however, 10% of PR+ tumors are ER-.

   Patients with PR+ tumors have significantly longer disease free survival than patients who are PR-.

5. Reporting of ER/PR:

   Several formulae are in the literature.

   FOR POSITIVE RESULTS:

   ER+ greater or equal to 5% nuclear staining.

   ER+ 10% of tumor staining.

   ER+ 1% - shown to benefit from endocrine treatment.

   Consensus Statement on Adjuvant Therapy of Breast Cancer, November 1-3, 2000, National Institute of Health. "Any positive nuclear ER immunostaining is considered to be a positive result and should be a definitive reason for instituting antiestrogen therapy for a patient." The medical oncologist may require percentage of tumor positivity.

6. Higher staining intensity does not reflect better results. This is a function of staining procedure and may alter. All cytoplasmic staining in ER and PR immunostain are to be considered as negative.

7. ER+ve tumors:

   - Tubular.
   - Mucinous.
   - Papillary.
   - Ductal (low nuclear grade).

8. Low nuclear grade tumors are usually positive for ER/PR and negative for Her2Neu while high grade tumors tend to be positive for Her2Neu and negative for ER/PR.

We are working on the remaining antibodies and hopefully all normal immunostains will resume soon.

Thank You,

Dr. G. Ejeckam

cc: Site Chief, HSC and St. Clare's
Barry Dyer
All Technical Staff on Immunohistochemistry

HealthCare
Corporation of St. John's

TO: TERRY GULLIVER

FROM: Dr. G. EJECKAM

SUBJECT: IMMUNOHISTOCHEMICAL STAINS AT HEALTH SCIENCE CENTRE

DATE: JUNE 19, 2003

Following persistent erratic results of immunostains in our laboratory, I accepted to work closely with the technical staff in order to rectify this problem. Despite the fact that the problem seems to have been arrested, the state of immuno stain at the General Hospital Department of Laboratory Medicine and Pathology is still unsatisfactory.

1. The physical location of this facility is unsatisfactory. Immunohistochemical stains need to be housed in a separate room with proper humidity control. This is lacking in the corner of an open laboratory where the procedures are carried out at the moment.

2. Immunohistochemical stain is not just another special stain. It is affected by far more numerous factors than may apply in other special stains. It is an extremely sensitive procedure, therefore, a haphazard and lassie affair approach to it is not the way to go.

3. The staff arrangement as it stands now is grossly inadequate and unacceptable for problem free or minimal problem operations. There has to be a dedicated staff to take over this special procedure. The staff is expected to read wide on the subject and to understand the theory and practical aspects of the immunohistochemistry. The staff

should be a problem shooter and that can only materialize through thorough understanding of the subject. Besides the designated staff there should be a need for a stand-by staff in case of holidays or illness of the designated staff. The dedicated staff should cut and stain all cases while the assistant/standby staff does that twice a week. The designated staff uses this valuable time for house keeping jobs in immuno. This will include dealing with ordering and titrating new antibodies. This ensures that the stand-by staff is in tune with the procedure and can produce acceptable results when the need arises.

To do less will simply become a gamble where you may win or lose. This obviously will spell disaster.

4. The volume of immunohistochemical procedures continues to increase. Every day more diagnostic antibodies are added to the armamentarium of immunohistochemistry. Each new antibody poses its own special problem that needs to be mastered and solved before reliable, reproducible and consistent results can be obtained. Since this is the only centre in the province that performs this test there is enough case to be made for identifying this activity as special and unique, therefore, requires financing and staffing.

5. The present staff performing this procedure are doing the best they can but with myriads of other duties that take them away from the immuno stain fairly regularly it is virtually impossible for them to devote the time required to master the intricacies of this procedure.

The fairly good stain we have now is a credit to them but they do not have

enough time to spare.

It is my understanding too, that some of them have less that two or three years in the establishment and their exit will create a vacuum and another period of uncertainty for immunohistochemistry.

6. Finally it is pertinent to mention that results of immuno stains are extremely important in histopathologic diagnosis, especially where classification of lymphomas and determination of benign or malignancy of certain lesions, for example, in the prostate biopsies depend on crisp, reliable and reproducible staining results.

Diagnosis based on inappropriate immuno stain will surely jeopardize patient care and may even expose the HCCSJ to litigation.

Therefore, it will be ill advised to operate an unreliable and erratic immunohistochemical procedures in our laboratory.

I, therefore, advise that you kindly take a hard look at the above and then commit the necessary resources, human and financial to this special, all important and only service in the Province of Newfoundland.

Thank You,

Dr. G. Ejeckam

GE/jp

cc: Dr. Desmond Robb, Agl. Chairman, Discipline of Laboratory Medicine
Dr. D. Cook, Clinical Chief and Site Chief, St. Clare's
Dr. S. Parai, Site Chief, HSC
Barry Dyer, Manager, Histopathology

SURGICAL PATHOLOGY REVIEW COMMITTEE (SPRC)
HEALTH SCIENCE CENTRE, HCCSJ
MINUTES OF MEETING, SEPTEMBER 23, 2003

PRESENT: Dr. G. Ejeckam, Chairman
Dr. J. Siddiqui
Dr. M. Parai
Dr. D. Tennent
Mary Connors, Secretary

APOLOGIES: Dr. L. Dawson
Dr. S. Battcock

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1. CALL TO ORDER

Dr. G. Ejeckam, Chairman called the meeting to order at 2:05 p.m. on September 23, 2003 in Room 2864. HSC. Dr. Ejeckam asked if there was anything that needed to be changed in the previous minutes. Dr. Siddiqui moved to accept the minutes, second by Dr. M. Parai.

2. BUSINESS ARISING

2.1 Estrogen and Progesterone Status

Dr. Ejeckam stated that the technical problem with staining for ER and PR stains has been solved.

St. John's lab problems flagged in 2003, memo shows

Patient care could be jeopardized by problems, pathologist warned

Last Updated: Friday, June 1, 2007 | 7:46 AM NT

CBC News

Warnings were issued about the largest pathology laboratory in Newfoundland and Labrador in 2003, two years before problems with hormone receptor tests were disclosed, internal memos show.

A judicial inquiry is pending on flawed hormone receptor tests — which determined what course of treatment breast cancer patients should received — carried out at the Eastern Health lab between 1997 and 2005.

A class action lawsuit involving about 100 breast cancer patients was certified Monday at Newfoundland Supreme Court.

Concerns were raised in 2003 about staffing levels and physical conditions at the St. John's laboratory now managed by Eastern Health. (CBC)

Eastern Health has maintained it was not aware of problems at the lab until 2005, when samples were sent to Mount Sinai Hospital in Toronto for retesting.

However, a June 2003 memo written by former pathologist Gershon Ejeckam lays out a litany of problems with the lab, from "grossly inadequate" staffing to "persistent [and] erratic results of immunostains."

Ejeckam, who retired last year, wrote that the lab was doing tests in a location without proper humidity controls, which might affect results.

He also warned about an ever-increasing workload, inadequate relief staffing and concerns about obtaining "reliable, reproducible and consistent results" with samples.

Ejeckam, whose memo identified lab problems that extended beyond hormone receptor tests, clearly flagged the risks of not dealing seriously with quality issues.

"Diagnosis based on inappropriate immunostain will surely jeopardize patient care and may even expose the [authority] to litigation," he wrote.

The memo was sent to an administrator with the former St. John's Health Care Corp., one of the authorities merged into Eastern Health.

The memo was obtained this week by CBC News.

In response, Eastern Health released other memos on Thursday that suggest Ejeckam's concerns were dealt with, and that he was satisfied.

Chief executive officer George Tilley maintains the concerns were a part of a routine quality control

program within the system.

"So what we shared with you today is a snapshot of a piece of quality control work that's been going on in the laboratory and in fact really shows some of the complexity of the organization," he said.

The memos that Eastern Health released included an April 15, 2003, minute that shows that hormone receptor testing was suspended for six weeks because of a technical problem.

Tilley said that the problems identified in 2003 did not affect the diagnosis or treatment of patients.

"Within months of that letter coming out, the person who oversaw that particular area signed off on the resolution to it," Tilley said.

In 2005, Eastern Health became aware of inaccurate results of hormone receptor tests.

In late 2006, the authority said that retests showed an error rate ranging between 10 and 15 per cent.

However, documents filed with the Newfoundland Supreme Court show that the error rate involving hundreds of retested samples is 42 per cent.

Of 763 breast cancer patients who had tested negative, 317 had been given wrong results, according to an affidavit signed by Heather Predham, assistant director of quality and risk management with Eastern Health.

Of those, 104 patients required a change in treatment, with 96 eventually being prescribed Tamoxifen, an anti-hormonal drug that has been clinically shown to improve a patient's chances of survival.

A subsequent document filed with the court showed that 36 women who have since died had received inaccurate hormone receptor tests.

The hormone receptor issue has been at the forefront of political debate for weeks, since CBC News reported the error rate outlined in the court affidavit.

On Thursday, the Liberal Opposition called on Premier Danny Williams to replace Tilley as Eastern Health's CEO. Williams earlier in the week appointed Robert Thompson, the province's chief civil servant, to prepare a pending judicial inquiry and to serve as deputy minister of health.

From: Robert Thompson
To: Moira Hennessey; Tansy Mundon; Wiseman, Ross
Date: 6/14/2007 8:59:40 AM
Subject: Feedback on Lab testing

Blair Fleming talked to Oscar Howell about our questions. These questions focused on what did EH do after the June 2003 letter about the remaining problems at the EH labs.

Dr. Howell essentially repeated what he told Moira earlier in the day: 1) stopped rotating staff and focused on 2-3 people to improve their technical skills; 2) switched to the semi-automated Ventana system, and 3) concentrated the tesing in one area of the facility to reduce risks. Dr. Howell said in response to Dr. Fleming's questions that these improvements were done mainly to address the ER/PR situation. Therefore, the changes were not focused on the other antibodies that were the subject of tests addressed in the letter, or the other types of cancer mentioned in the letter (e.g., prostate). He said that the focus was on ER/PR because there was an index case that converted from negative to positive, which started the ball rolling on everything else, but there was no such index case for other types of tests. However, he notes that the improvements directed toward ER/PR testing would generally cause improvements in other related tests in immunohistochemistry.

These answers give rise to other questions. As the letter pointed out, lab weaknesses related to 5 or 6 tests other than ER/PR, and given the lack of focus on these tests in particular, is it possible that there were unacceptable errors in these other tests that should have been investigated retrospectively? If they had been investigated and an error rate established, then there would be a benchmark for assessing improvements due to the new lab procedures. The significance of this question, and the implication that other cancer patients may not have received appropriate treatment if error rates were high, is dependent on a better understanding of how these tests are used and whether they play as criticial a role in treatment decisions as does ER/PR. Dr. Fleming will give us more perspective on this question.

In regard to the other question on whether only breast cancer patients were re-tested for ER/PR, and the possibility that other ER/PR tests for non-breast cancer patients were not retested, Dr. Howell says that ER/PR is not used for other cancers than breast cancer. (When I received that answer I gave Dr. Fleming more deatails about how we discovered that ER/PR might be used for other than breast cancer, and he will do another follow-up on this question.)

Robert

Robert Thompson
Deputy Minister
Department of Health and Community Services
Government of Newfoundland and Labrador
709-729-3125