PET ISSUES RAISED TO THE PET STEERING COMMITTEE ON BEHALF OF ONTARIO'S BREAST CANCER PATIENTS:

PET PREDICT TRIAL ON EARLY STAGE BREAST CANCER PATIENTS:

NOTE:

As outlined in the introductory letter to this series of letters:

- ***I will be using Dr. Hoskins' demands for evidence to justify imaging tests performed on patients, and with a particular emphasis on the total radiation exposure to patients from their diagnostic imaging tests, where appropriate.***
- ***Unless someone is able to finally provide evidence with sufficient power and widespread international based agreement to support the use of HTA in keeping with the 'extreme position' the Ontario Liberal Government has taken on PET:***
    - ***NO HTA EVIDENCE WILL BE ALLOWED TO JUSTIFY POSITIONS OF THE PET STEERING COMMITTEE WITH RESPECT TO PET.***

PREAMBLE OF GENERAL ISSUES:

What has been established to date is as follows but please feel to challenge and offer appropriate documentation and literature challenge anything someone feels is inaccurate so that adjustments can be made if necessary.

A: Based on a conversation with Dr. Julian Dobranowski and various letters the following is true:

1. Cancer Care Ontario is aware that there is no scientific basis or justification sufficient to assess PET or any other diagnostic imaging device with HTA,
2. However, Cancer Care Ontario will continue to use HTA to assess PET for use in Ontario.
3. That the Ethics Review Committees and Patients entering trials were not informed that there was no basis to use HTA to design the PET trials in Ontario, nor to evaluate the results of these experiments.
4. That the actual purpose of the PET Trials was NOT to evaluate PET, but ***to use PET to try and validate HTA.***

QUESTIONS PART A:

1. Please explain in detail why the various CCO committees knowingly used the HTA to evaluate PET given it's utter lack of established evidence to support its use, particularly in light of the end result for Ontario's patients.

2. Why have CCO Committee's and physicians, with but one exception, refused to defend the use of HTA to evaluate PET?
3. Do the Committee members agree with the statement of Dr Laupacis the original President and CEO of ICES, that all that was required to justify the use of HTA was his FAITH in the process?

Given that I have previously these type of question to the PET Steering Committee and they have refused to answer:

- ***The ongoing refusal to answer these relevant and critical questions will be noted and sent to the appropriate persons and groups involved with demanding CCO defend its actions on PET in Ontario.***

- ***I will include a separate set of statements and questions to be addressed.***

B: **STATEMENT:**

The PET Steering Committee [PSC] took the public position that the PET Trials and their design would be open and transparent and that experts were invited to participate.

REALITY:

The trials were written in secret and repeated attempts by the Ontario Association of Nuclear Medicine [OANM] and others who were actual PET experts to be part of the trial designs were rejected by the PSC. In fact in the JCO paper by Evans et al, and statements made in the press were clear that this was one of the best examples of cooperation amongst physicians in Ontario to introduce PET.

> *"First, oncologists and nuclear medicine physicians, who, in Canada, have rarely collaborated on research have worked together to design and execute clinical trials."*
>
> *'..standardizing how PET scans were performed and reported**, and gaining acceptance by health professionals for the evaluative program.'***

The only way that the OANM physicians were able to see what was happening in the trial design was that someone from the PSC, and clearly not Dr. Tracey, leaked copies to the executive.

- The one true PET expert, Dr. Kevin Tracey was removed from the PET Steering Committee in part because of his insistence that scientifically valid and acceptable methods to evaluate PET must be used or at least the HTA shown to be fully established as a valid scientific methodology for the task at hand.

- Repeated attempts by the OANM to have Dr. Tracey's position on the committee replaced by a qualified PET Nuclear Physician were rejected by the PSC.
- At the time of writing the trials it had been established that to be considered an adequately trained and qualified PET physician, that they:
    - ***Be a certified Nuclear Medicine physician and should have at least three months training at a recognized PET center of excellence.***
    - ***That this training MUST take place outside Ontario, since no PET centre in Ontario did sufficient PET work to allow a Nuclear Medicine Physician to get adequate training.***
- To the best of my knowledge, no one involved in designing the PET trials, and in particular the PET PREDICT Trial had the minimal recommended qualifications.
- Dr. Karen Gulenchyn who was involved with the trial design, and although reading PET at a McMaster Hospital, ***did not have the minimal requirements to be considered a 'PET expert to supervise and read PET little alone write major trials that would impact tens of thousands of Ontario cancer patients.***
- ***Dr. Gulenchyn was a member of the OANM executive at this time. It is worth noting that the OANM Executive were so disturbed by the actions of Dr. Gulenchyn that it was unanimously agreed that she could no longer be part of any OANM Executive discussions related to PET.***
- In articles written about the use of HTA, the point has been made that HTA uses try if at all possible to avoid the involvement of actual experts in the particular field that HTA is being applied to:
    - ***This because they would be biased and thus best to have those using HTA to have little or no expertise in the studies, in this case involving PET.***

QUESTIONS PART B:

1. Why were the PSC Trials written in secret and the repeated effort of the OANM to have fully qualified PET experts involved rejected?
2. Please account for the discrepancy between the claims in the media and the JCO paper by Evans et all about the great cooperation amongst physician groups when it came to working on PET, when in reality there has never been a more divisive issue amongst Canadian Nuclear Medicine community and the work of the CCO committees, as well as the profoundly severe and unprecedented accusations of "unethical and bordering on immoral" experiments on cancer patients,

C:POSTER PRESENTATION STOPS THE INTRODUCTION OF PET IN ONTARIO:

In the late 1990's a Multidisciplinary Team of experts in Diagnostic Imaging and Oncology looked at the literature on PET for five possible indications for PET. Amongst their recommendations was that anywhere from 24 to 40,000 patients would benefit from PET scans

as part of their imaging management of their diseases. They went to their final meeting expecting to that PET would finally be available to Ontario patients much like it already was in places like Chile.

- ***A Ministry of Health representative presented a 35 mm slide of a 'poster presentation' on a couple of pieces of bristol board at an Australian Medical meeting claiming that PET did not change lung cancer management.***
- ***On the strength of this single 'poster' the government announced that given the controversy the MOH would have to do it's own PET studies to determine what if any roles there would be for PET.***
- ***The first report from ICES concluded that ZERO patients would benefit from PET because of the 'poor quality of papers'.***
    - ***We have already established that this assessment was made using a tool that had ABSOLUTELY NO BASIS OR JUSTIFICATION FOR DETERMINING THE QUALITY OF THESE PAPERS.***
- ***Dr. Driedger bypassed the Chairman of the PET Steering Committee and wrote to the Minister of Health, Mr. George Smitherman. Dr. Driedger made the accusation that the government members of the PSC were downplaying evidence that favoured PET. Mr. Smitherman refused to respond to this letter on more than one occasion.***
    - ***Drs. Ware and Hicks published an article in the Journal of Nuclear Medicine showing Dr. Driedger was correct.***
    - ***They confirmed not only that the 'mere poster' had stopped PET, but:***
        - ***THIS POSTER WAS ELEVATED TO A LEVEL A QUALITY EVIDENCE PAPER.***
        - ***PAPERS THAT WERE LEVEL A AND B ACCORDING TO ICES CRITERIA, BUT FAVOURED PET WERE 'DOWNGRADED' TO UNACCEPTABLE PAPERS.***

<u>QUESTIONS PART C:</u>

1. Do committee members support the use of the 'poster presentation' to overturn the conclusions of the Multidisciplinary Committee.
2. Do committee members support that this poster was sufficient to justify the need for Ontario to perform it's own PET Trials through various Cancer Care Ontario committees which would be set up to do so?
3. Do committee members support the 'promotion of a poster presentation' to a Level A paper that did not favour PET, and the 'downgrading to unacceptable' papers which favoured PET and thus supported the accusations Dr Driedger made to Mr. Smitherman.
    a. ***If anyone chooses to disagree with Dr. Driedger or challenge the paper written by Drs Ware and Hicks, I would be happy to send your rebuttals to them.***

2016 STATEMENT BY PROFESSOR RODNEY HICKS TO ME IN AN EMAIL REGARDING PET ISSUES:

"Ontario has the most egregious and politically motivated agenda against PET in the world."

D: THE PET PREDICT TRIAL VERSION ONE:

One of the mandates of the PET STEERING COMMITTEE amongst others, was to set up experiments to determine what would be the most appropriate roles if any for particular cancers.

When it came to the issue of possible roles for breast cancer, I think everyone will at least agree on the fact that ***the Ontario Ministry of Health and Cancer Care Ontario Committees made 'very special efforts' to in the end, and still present to this day, block women with locally advanced breast cancer from access to PET/CT exams on a routine basis.***

TIMELINE:

- The OANM executive were aware they were finalizing the PET Breast Trial.
- A copy was leaked to us. We were shocked when we read it. Instead of proposing an experiment that would determine a role for PET in women with breast cancer:
    - ***They deliberately designed the experiment to fail!***
    - ***This is blatantly "unethical" and against an document on guidelines for experimenting on humans.***
    - ***They chose women with early stage breast cancer where they would be expected to have small lesions and by definition most likely did not have any spread of cancer to the lymph nodes in their axilla.***
        - ***Even microscopic spread of cancer to these nodes significantly affects patients prognosis and thus how aggressive the proposed treatments will be.***
        - ***It was well established at this time, that based on the imaging characteristics of the standard PET camera's of the time that they were often missing breast cancers, within the breast as much as two centimeters in size.***
        - ***The resolution would be expected to be worse in the axilla and clearly no PET scanner or any imaging device would be able to pic up microscopic metastasis.***
- **IN SHORT:**
        - ***The PET camera was incapable of seeing the very cancers they would tell women considering entering the trial, they would be looking for.***

The OANM Executive declared this an “unconscionable’ action, and considering that the radiation dose to these patients would be equivalent to approximately 300-400 plain chest x-rays, that this was an assault on these women!

- Without explanation the trial was pulled. It would be some two years before a new version would be put forward. I had numerous email exchanges with Dr. Bill Evans, the Chairman of the PSC and one of the authors on the paper.
- Dr. Evans assured me that they were all working very hard on getting the new version out.
    - The delay of course fit nicely into the ‘tools’ used to ‘delay’ the introduction of PET.
- The new version was again leaked to the OANM Executive.
- After reading it over the conference call, there was stunned silence!
    - ***The ‘new and improved version’ was IDENTICAL to the first version with such a trivial addition to it that it was laughable, something that could be given to a FIrst Year Nuclear Medicine Resident as a project.***
    - ***In short THE BLATANTLY UNETHICAL DESIGN CONCERNS WERE LEFT UNTOUCHED!***
- This lead to a press conference at Queen’s Park with the new President of the OANM speaking, Dr. Christopher O’Brien and taking questions.
- There was no outcry from politicians or the media.
- Behind the scenes there was much discussion I was involved with since I had just finished my PET training at UCLA. It was in preparation for the upcoming meeting of the Canadian Association of Nuclear Medicine to be held in Vancouver, and how to handle ***this egregious issue blatantly using these women terrified with their new diagnosis of breast cancer as mere pawns in their game to block PET.***
- Several motions were passed by the CANM at the 2005 meeting. In short:
    - 1. The CCO PET trials in Ontario were declared “unethical”.
    - 2. The Trials must be stopped immediately.
    - 3.***That a panel of acknowledged Canadian experts in Medical Ethics and Health Policy be put in place to determine how this could have happened in Ontario.***
- The motions were rejected and ignored by the Minister of Health Mr. George Smitherman, the PSC and the various CCO groups.

<u>QUESTIONS RELATED TO SECTION D:</u>

1. In light of the fact that there were limited funds to complete the PET trials, indeed the trials were deliberately underfunded so they could not be completed:
    a. The five hospitals doing the PET scans were only funded to perform 32 scans per year, and it would take approximately 1,500 patients to complete the PSC trials.

Why does the …..support the design of an experiment on a group of breast cancer where it had to fail?

Even knowing what that the very strong objections raised by PET experts and the motions of the CANM, your group continued to support a trial that by design would have to fail, and did fail to show any usefulness in this group of breast cancer patients you supported this trial, **WHY?**

- Given that all documents on Ethical Human Experimentation are clear that you cannot deliberately design a trial to fail:
    1. ***Why did the PET STEERING COMMITTEE deliberately violate this principle of Ethical Human Experimental Design, and continue to support this trial to this day as a reason to block women with breast cancer, AND the appropriate indications to have a PET, TO NOT BE ALLOWED TO HAVE A ROUTINE PET/CT SCAN?***
    2. ***Surely the women with breast cancer in this province deserve to know why this experiment was allowed to be written, re-written and performed in spite of unprecedented opposition and condemnation.***
        i. ***Is the PET Steering Committee prepared to release a statement to the women who took part in this trial and the women in this province in general explaining your support of this trial?***
- If the PET STEERING COMMITTEE disagrees with the claims of the “unethical nature” of these trials then surely the ultimate litmus test would be to have a full and complete Ethical Review which had unfettered access to all the material they needed to ‘support your claims’ of ethical experiments.
    1. ***Are the members of the PET Steering Committee willing to demand this Ethics Review take place immediately to clarify the issue and make clear why the PSC is so proud of their efforts on PET?***
    2. ***If not, then why not?***

PET PREDICT VERSION 2 E:

The PET PREDICT TRIAL was carried out and finally completed and published demonstrating what it set out to do:

- ***That PET scanning was not indicated in early stage breast cancer.***

QUESTIONS REGARDING SECTION E:

Since a compulsory component of Ethical Experimental design is to make sure that all those considering entering the trial are given as much information as possible, and in particular any controversial issues that might be related to the experiment:

1. **Why were neither the Ethics Review Committee nor the women considering entering this trial TOLD THAT THERE WAS ABSOLUTELY NO BASIS FOR USING HTA TO DESIGN OR ANALYZE THE TRIAL THEY WERE BEING ASKED TO PARTICIPATE IN?**

To the best of my knowledge the women considering entering the trial were ***NOT TOLD THAT THE PET CAMERA WITH SOME 300-400 CHEST X-RAYS OF RADIATION EXPOSURE WAS INCAPABLE OF DETECTING THE VAST MAJORITY OF THE CANCERS THE WOMEN WERE TOLD THE 'EXPERIMENTERS' WERE LOOKING FOR:***

- If the women were not informed of this, ***and keeping in mind Dr. Hoskin's very valid concerns about radiation exposure from diagnostic imaging tests:***

    2. ***WHY WERE THE PARTICIPANTS NOT TOLD THAT THE PET CAMERA WAS VERY UNLIKELY TO DETECT THEIR CANCERS AND THUS THE EXPERIMENT WOULD BE A NEGATIVE RESULT?***

It is unquestionable that these women and their families would have been under an enormous amount of emotional stress, no doubt convinced they were going to die of their cancer in many cases. Having to wait for diagnostic imaging appointments; wait in the waiting rooms; go through the imaging procedure; and then the agonizing wait to get the results of the test from their physicians. Above all these women would be looking to the physicians treating them and those asking them to be part of this experiment with this 'new imaging device' ***would be desperately looking for reassurance and trusting of these people***:

3. ***Why did the PET Steering Committee deliberately put these women through what was clearly unnecessary EXTRA STRESS knowing already the results of the trial and that the trial would fail?***
4. ***Is the PET Steering Committee prepared to release a statement to these women making clear why this was necessary and thus this trial is a source of PRIDE for the PET Steering Committee and Ms. Wynne and Dr. Hoskins?***
5. ***If not, THEN WHY NOT?***

<u>THE ETHICAL PRINCIPLE OF EQUIPOISE PART F:</u>

Principles of Ethical Experimental design are clear:

A: If it becomes clear during the trial that the principle in question is clear the correct answer, for example a drug for hypertension, then the trial must be stopped and everyone gets the drug.

B: Equally true ***is that if it clear the experiment will fail THEN IT MUST BE STOPPED IMMEDIATELY.***

- During the experiment Dr. Karen Gulenchyn, one of the authors of the study gave an update at a meeting of the OANM meeting in Toronto. Dr. Gulenchyn stated words to the effect that:
    - ***"We are seeing a lot of histologically positive lymph nodes for cancer that are negative on the FDG PET scan."***
- By this point I had known Dr. Gulenchyn for many years. It was and remains my distinct impression that she seemed 'genuinely surprised' by this finding.
- Indeed my response was to effectively snicker and make the statement that the rest of the world was doing PET, and we in Ontario ***"are being forced to keep playing in a sandbox!"***
- Dr. Christopher O'Brien, the meeting monitor, ended discussion at this point.

However regardless of the manner in which it was expressed raises several critical questions:

1. Did Dr. Gulenchyn truly not know that the PET cameras used in the experiment ***were not capable of detecting these small cancers in the lymph nodes?***

Given the history of the objections to the first 'identical version' rejected for this very reason by actual PET experts:

2. Why would Dr. Gulenchyn try and 'pull the wool over her own colleagues eyes' knowing full well there were actual PET experts, myself included, in the audience?

The principle of Equipoise was not discussed, and even though the PSC could have known after less than 20 patients the experiment would fail, as it was designed to do:

- ***More than 300 women, terrified with their new diagnosis; deliberately exposed to useless and therefore harmful radiation in the vast majority of cases from the PET scan; were put through the PET PREDICT TRIAL.***

The issue raises two absolutely critical further questions:

FIrstly, during any human experiment it is the job of the Ethics Review Committees to monitor the progress of the trials.

3. In light of the CANM motions, and fundamental and critical job of Ethics Review Boards to make sure the claims of those proposing the experiment, ***HOW IS IT THAT THE MCMASTER ETHICS REVIEW BOARDS WERE UNAWARE OF THE FACT THAT:***
    a. ***That there was NO validation to support the use of HTA?***

   b. ***<u>THAT THE PET CAMERAS WERE NOT PHYSICALLY CAPABLE OF DETECTING THE LESIONS THE PATIENTS WERE TOLD THEY WERE LOOKING FOR?</u>***
   c. ***<u>That the women not told any of these facts as part of being fully informed before they decided to join the trial?</u>***
4. ***SINCE IT WAS OBVIOUS IMMEDIATELY THE TRIAL, AND BY DESIGN WOULD FAIL, WHY WASN'T THE PET PREDICT TRIAL HALTED AS DEMANDED BY THE ETHICAL PRINCIPLE OF EQUIPOISE?***

The PET Steering Committee members have in the past and continue to stand behind this trial and support it's ongoing use to block women with the proper indications for PET, from access to a routine PET/CT as part of their initial workup. Repeated attempts to get CCO members and Committees to respond to the 'ethics' of this trial' ***which in light of the unnecessary radiation exposure to these women, and especially the 'cruel' addition of the extra stress of this useless test have been ignored.***

- ***In light of Dr. Driedger's' claims of a process "bordering on immoral" and the other equally serious accusations it is a fair statement that these women:***
   - ***We're used as 'hapless pawns' by CCO to carry out its mandate of discrediting and blocking PET as discussed in meetings with Mr Michael McCarthy who was the OANM hired lobbyist, and was present when CCO was given its 'marching orders' on PET.***
   - ***That even worse, THESE WOMEN WERE, and the like patient I am currently dealing with, could reasonably considered VICTIMS OF AN ASSAULT .***

Therefore:

5. ***Is the PET Steering Committee prepared to release a statement defending their support for and "pride" in the PET PREDICT TRIAL?***
6. ***If not, then why not?***

<u>WHY WERE WOMEN THAT WOULD HAVE BENEFITTED FROM A PET EXCLUDED? G:</u>

If in fact the stated goal of the PET STEERING Committee opporating with a crippling shortage of funds, was to come up with possible use for PET:

7. ***WHY WERE THE VERY PATIENTS, SUCH AS MY PATIENT WITH LOCALLY ADVANCED BREAST CANCER, DELIBERATELY EXCLUDED FROM THE TRIAL EVEN THOUGH BEYOND THE 'HALLWAYS OF THE ONTARIO MOH AND CCO' IT WAS CLEAR THAT THIS WAS THE GROUP OF WOMEN MOST LIKELY TO GET POTENTIALLY CRITICAL BENEFIT FROM A PET/CT.***
   a. ***For example like my patient with locally advanced and palpable disease in her right axilla. Had she not have paid for her own PET scan, her***

physicians would not have known about the retrosternal metastasis she had, and this would have been excluded from her radiation fields, with obvious consequences.

b. ***Consequences, that people with cancer are subjected to on a daily basis across this province because of the 'proud actions' of CCO medical experts who refuse to defend their methodology in assessing PET.***

ONE FINAL POINT:

Over the years I have repeatedly made the statements to colleagues, patients, and during lectures that:

- ***The Ontario Liberal Ministry of Health and Cancer Care Ontario works by threats and intimidation.***

In January of this year I was consulted by some oncologists of the appropriate imaging management of their patients in light of my expertise and knowledge regarding PET. Then there of course there is the issue is that if they attend International Medical Meetings, it is painfully obvious they are being forced to practice not just substandard but incompetent medicine.

Therefore if I felt a PET/CT would be useful and not routinely covered by OHIP, I made the application to PET ACCESS. However I informed PET ACCESS that:

- Ontario patients are fully entitled to have all their questions and concerns regarding any proposed investigation or treatment answered, that:
    - ***The time had come for those who would 'play god' as to whether they got a PET firstly explain:***
        - ***Given there was no evidence to support HTA to make the decision, ON WHAT BASIS WOULD PET ACCESS DECIDE WHETHER THE PATIENT WOULD GET A PET/CT?***
        - ***Then, in keeping with the demands of Dr. Eric Hoskins, to provide the appropriate documentation supporting the compulsory need for CT scans to even qualify for a PET/CT and ESPECIALLY make very clear the benefits of the radiation exposure they were getting from their CT exams.***

The patients were given all the backing documentation and 'standard medical literature' that withstand a legal challenge in court rather than FAITH based and "agenda driven" decisions so they could make up their own minds about how they were being managed based on CCO Compulsory' algorithms.

- As the patient's expected, that although PET ACCESS granted their PET/CT exams, and in both cases seriously too late, ***THE PET ACCESS PANEL DISMISSED THEIR***

QUESTIONS AND CONCERNS REFUSING TO ACKNOWLEDGE OR ANSWER THEM.

RESPONSE OF CCO TO MY ACTING AS AN IMAGING CONSULTANT FOR TWO PATIENTS:

1. Although there was no discussion about me not being able to order PET scans for my patients when I applied to PET ACCESS for the forms:
    a. ***After a few weeks, I received an email stating that I was NOT ALLOWED to apply for PET scan through PET ACCESS.***
    b. ***I demanded on several occasions that they provide me with the documentation to back their statements.***
        i. ***To this date and in spite of several communications with Senior CCO executives, NO SUCH DOCUMENTATION HAS BEEN SUPPLIED.***
        ii. ***THEIR POSITION ON MY BEING ABLE TO ORDER THESE PET SCANS HOWEVER REMAINS UNCHANGED.***

Then when this did not stop my efforts to act in the best interest of my patients:

- This would be the second time that I would be informed, not by my Department Chief, or someone from the Senior Administration at the hospital in question, ***but my colleague, that administration and CCO was not happy with my actions.***

Approximately a month ago, someone from Senior Administration at CCO called the Senior Administration at the hospital in question and they were told:

- ***To shut me down or else.***

It was clear from conversations with the referring oncologists and their patients, that these physicians ***had been told to end this kind of information process to patients about PET.***

A couple of weeks later a physician from this hospital, who is CCO representative in administration asked to meet with me. What was made clear was:

1. I was to no longer provide such ‘consulting services’ for oncologists for patients connected to this hospital.
2. It then became clear that this also meant that I could not even use case examples from the hospital, even when there was absolutely no way of identifying the patients or where the cases originated from.
3. However, CCO ***“encouraged me to continue to advocate for patients about PET/CT”!***

I wrote a letter the physician who spoke to me asking him to elaborate, and in particular what would I be allowed to so called ‘advocate for patients’.

- ***In keeping with 'standard CCO policy' the physician refused to answer a single question.***

BOTTOM LINE:

- ***If I continue to speak to physicians and patients, or even use case material from this hospital:***
  - ***I WILL NO LONGER BE ABLE TO WORK AT THIS PARTICULAR HOSPITAL!***

So much for the websites from CCO declaring:

- Openness, transparency and accountability!.

FINAL QUESTION TO THE PET STEERING COMMITTEE:

1. Does the PET Steering Committee support the use of threats and intimidation to my ability to work as a physician in this hospital if I do not follow their 'recommendations'?

Respectfully submitted

Dr. Dave Webster.