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PET ACCESS PROGRAM
Cancer Care Ontario
620 University Avenue
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RE:PET ACCESS PROGRAM FOR ONTARIO PATIENTS.

To Whom It May Concern:

This will be the first in a series of letters I will be submitting to PET ACCESS on behalf of patients you have dealt with in the past, and current patients who will be making applications for PET scans. Except in this case, they won't be filling out your various forms for application, and you will be replying directly to the patients and their physicians who will have ordered the PET. They will be applying for PET scans that would have been routinely available in most medically advanced jurisdictions in the world. Sadly, these patients have the misfortune of living in the province of a so-called evidence-based approach to PET. This in spite of the fact that pretty much everyone, including CCO officials acknowledge the methodology has absolutely no scientific basis or justification to assess any diagnostic imaging device PET or otherwise.

These patients will have been made aware that how Cancer Care Ontario has assessed PET has been subject to unprecedented and severe condemnation from Canadian and International PET experts since at least 2005. They will be given access to all the supporting documents backing these accusations. In return, PET ACCESS will be supplying all the appropriate backing documents to the patient and their physicians to defend it's position on PET.

My colleagues and I have tried without success for some 15 years to get Ministry of Health representatives and various Cancer Care Ontario physicians to respond to concerns and questions about how PET was evaluated in Ontario. This is about to change. That is unless those making the decisions on PET are going to 'stonewall' patients too.

In this first letter I will be asking two questions and I do expect answers and appropriate documentation. The PET ACCESS COMMITTEE is a publically funded program run by Cancer Care Ontario where it's public servants are expected to behave in a supposedly open, transparent and accountable manner. I would respectfully suggest that to continue the pattern of 'stonewalling' would not be effective or acceptable. I will use and any and all legal means available to me to persist, until a PET ACCESS representative responds with detailed answers and appropriate backing documentation with respect to questions and issues submitted.

PREAMBLE:

I have taken the following position:

1. With respect to PET in Ontario, physicians are being forced to practice not just substandard medicine, but medicine, which could be considered incompetence or worse beyond our provincial border.
    a. The majority of OHIP funded PET scans are related to lung masses, and the exact opposite of the entire world expert body of opinion. Dr. Rodney Hicks published a study showing how the data was 'manipulated' to come up with the indications, and confirmed the suspicions of Dr. Al Driedger when he bypassed the Chair of the PET Steering Committee in 2004 and wrote directly to the Minister of Health, Mr. Smitherman. Mr. Smitherman would, on more than one occasion refuse to acknowledge the receipt of Dr. Driedger's letter, in spite of being required do so by law.
2. Patients are entitled to full and detailed explanation of any tests and procedures being proposed to them. (Unlike the patients entering the CCO PET trials, which were officially declared "unethical", and "bordering on immoral" by Dr. Al Driedger, when he resigned in disgust from the PET Steering Committee.)
3. The time has come for those who 'make the rules' to give the full and detailed explanation, including all risks and benefits, radiation exposure, alternative possibilities, and all of course backed by the relevant literature DIRECTLY TO THE PATIENTS and their physicians.
4. In addition, I have received a letter from Dr. Eric Hoskins, our Minister of Health who has outlined what he expects from any diagnostic test funded by OHIP. Your responses, will need to fit his criteria, and again with the appropriate medical literature as necessary. I will send a copy of Dr. Hoskins letter for your records, and reference for the 'standards' your response will need to meet.

The mantra for some 15 years has been Ontario uses an 'evidence-based approach' to the evaluation which has shown there is little or no 'quality evidence' to support the routine use of PET. When asked to defend this statement: "Repeat above statement." This will not be acceptable to me, and certainly not to the patients.

ANATOMICAL AND FUNCTIOAL IMAGING 101

One further point, is that all patients and physicians you will be dealing with will be fully educated as to the differences between 'anatomical imaging methods such as CT', and 'functional imaging technology' such as PET. The fundamental concept in summary is best represented by the following analogy.

When looking for osteoblastic metastatic bone disease pre-functional imaging, Total Skeletal Surveys were routinely ordered. This involved dozens of x-rays of all the bones in the skeleton. They found almost nothing. Then along came a 'functional imaging test' called a 'bone scan'. A bone scan could detect osteoblastic metastatic disease as much as 18 months before it would be detected on a skeletal survey.

Thus the current standard of investigation for osteoblastic disease evolve is to perform the bone scan first. Given the non-specificity of these scans, one might consider ordering an anatomical test such as x-rays of the site of concern to try and make the best and informed decisions for patient management.

- ***To suggest that to look for osteoblastic metastasis in the 'Era of Functional Imaging' would be to order the Skeletal Survey to decide whether or not the patient should have, or could have a bone scan would at a very minimum suggest a poorly trained and perhaps even an incompetent physician.***
- *As you well know, ORDERING A SKELETAL SURVEY REMAINS THE STANDARD WHEN LOOKING FOR LYTIC OR MARROW SPACED DISEASE whereas in Paraguay physicians would be aware of and accept the use of PET as the 'standard' of imaging investigation and management of patients.*
- *You will have ample opportunity to defend the Skeletal Survey approach for lytic and marrow spaced disease for Ontario's patients.*

Yet of course using 'anatomical tests' to determine whether the patients would benefit from a 'functional imaging PET scan ***is exactly how PET is being introduced into Ontario!***

In order to determine whether the patient can get access to a PET scan, the 'cornerstone of functional imaging in the era of personalized medicine, and the accepted world standard of imaging management in places such as Chile for in some case more than 15 years:

- ***THE PATIENTS MUST HAVE A CT SCAN, A HIGH RADIATION ANATOMICAL TEST, OFTEN WITH THE RISK OF CONTRAST REACTION TO DETERMINE WHETHER THEY CAN HAVE THE FUNCTIONAL PET SCAN.***
- **Recognized Diagnostic Imaging experts have called a CT scan "the view from 10,000 feet in the era of PET scanning."**

    - ***Indeed you will have lots of opportunities to explain directly to patients, some who have had 15 to 20 CT scan, why this was Cancer Care Ontario's Standard of Care, and indeed meeting Dr. Hoskins criteria for diagnostic imaging tests for patients!***

FIRST TWO QUESTIONS SUBMITTED TO PET ACCESS ONTARIO

ROLE OF HEALTH TECHNOLOGY ASSESSMENT [HTA] AND THE CANM MOTIONS FROM 2005

1. Justification for the use of HTA for evaluating PET in Ontario.

Although in keeping with the 'stonewalling' of questions regarding the use of PET it is clear that pretty much everyone involved with PET around the world acknowledges:

- ***There is no scientific validity or justification to use HTA to evaluate PET or any other diagnostic imaging technology.***

Dr. Les Levin confirmed this when I met with him in 2004.

- ***In fact he ridiculed it, saying it was something that would be found in the back pages of the less reputable medical journals!***

Then in conversation in 2009 with Dr. Julian Dobranowski, who as you know was Provincial Health of Imaging for Cancer Care Ontario, confirmed the following:

1. ***There is no evidence to support or validate the use of HTA to assess PET or any other diagnostic imaging device, but that CCO would continue to use HTA to do just that.***
2. ***That the Ethics Review Boards assessing PET Steering Committee PET Trials and the patients entering the trials were not told there was no evidence to support HTA design or evaluation of the experiments.***
3. ***That CCO was not evaluating PET, but in reality using PET to try and validate HTA, and that no one was told this either.***

You may also be aware of the Editorial in the Journal of Nuclear Medicine by Dr. Sandy McEwen that commented on:

- ***The arbitrary and capricious use of a scientifically baseless process (HTA) to block access to PET in Ontario.***

I will be happy to send you a copy in case you haven't read this damning editorial in one of the most prestigious medical journals in functional imaging in the world

So unless someone from PET ACCESS is prepared to refute these statements and positions, with all the supporting documentation ***we will all assume that there simply is no scientific basis to justify the use of HTA to evaluate PET***.

However, if the process of assessing PET was not based on science it is reasonable to assume that it was ***agenda based.*** Dr. Rodney Hicks an Australian PET expert who published an article in the Journal of Nuclear Medicine outlining how the evidence related to PET in lung cancer was 'manipulated'. In particular he will show in detail how a mere 'poster presentation' claiming PET was not useful was 'promoted' ***to a Level A paper***. Indeed as Dr. Driedger has pointed out:

- ***A 35 mm slide of this poster presentation was THE reason used to justify stopping PET in Ontario and as an excuse to perform the Ministry of Health PET trials.***
- ***Members of PET ACCESS, like authors on a medial paper will of course be expected to defend this 'evidence-based' approach, along with any consequences or liabilities.***

In a recent email, Professor Hicks wrote:

- *"David, medical jurisdictions are still trying to block PET, sadly even Australia.* ***However Ontario has the most egregious and politically motivated agenda against PET (ie our patients) in the world."***

Dr. Driedger would resign in disgust from the PET Steering Committee and state publically that:

- ***"What those who are blocking PET in Ontario are doing borders on immoral."***

No doubt those from PET ACCESS will want to make a strong objection to these statements, and this will be the opportunity to do so.

You will no doubt support the statement that Dr. Les Levin's made to me at the end of our 2004 meeting regarding the controversy surrounding the evaluation of PET.

- ***"Dave, this has nothing to do with money, this is about doing just what is best for Ontario's cancer patients."***

This should be the perfect opportunity for PET ACCESS members to finally put all their critics in their place and prove to the world, that Ontario government physicians alone were able to figure out how new imaging technology should be evaluated, even if it's methods are not based on science.

- ***I will be happy to send any rebuttals to Dr. Driedger, Dr. Hicks, and the other physicians who have published editorials or otherwise made statements condemning CCO committees, so they can respond to the PET ACCESS COMMITTEE'S defence of its actions and decisions.***

PREAMBLE FOR QUESTIONS:

1. Given the unprecedented accusations and condemnation of Cancer Care Ontario's process of evaluating PET, ICES, and PET ACCESS using 'evidence-based' methods, any explanations to justify this position must be very powerful, convincing and well documented to be able to stand up to the withering criticisms.

2. In 2005 the Canadian Association of Nuclear Medicine [CANM] passed motions declaring the PSC PET Trials as "unethical" ***and demanded an independent panel of Canadian experts in Medical Ethics and Health Policy investigate the 'ethics' of the Liberal Government's approach to cancer patients.***

QUESTIONS:

1. Therefore I would respectfully request that the PET ACCESS Committee provide the 'powerful and compelling arguments along with appropriate documentation' to defend the use of Health Technology Assessment and any other 'evidence-based medicine' approaches to evaluate PET and use this as a basis to decide the appropriateness of submissions put to PET ACCESS for consideration.

In the response, you will have access to what Dr. Eric Hoskins expects from diagnostic imaging tests funded in Ontario and therefore your responses will clearly need to meet his criteria. The criteria he has laid out is something I'm sure we could all agree would be ***'just what is best for our patients".*** You will also note his special and very justified concern about unnecessary radiation exposure from diagnostic tests. You will have ample opportunity to justify to patients who have had 23 CT scans and counting, with but a single PET scan, that this is CCO sanctioned 'standard of care'.

2. The ultimate 'litmus test' of the use of 'evidence-based' methods used by PET ACCESS in evaluating PET would be to assess the 'ethics' of it's methodology since it is this aspect that has lead to the most disturbing accusations.

    a. ***Therefore, will the PET ACCESS COMMITTEE vote to support demands to finally carry out the CANM motion to have a full independent and unfettered review of the 'ethics' of how PET was assessed by the Ontario Ministry of Health?***

To do so would surely give full credibility to Dr. Les Levin's claim:

- ***"It is just about doing what is best for Ontario's cancer patients."***

If PET ACCESS does not want it's work to undergo this ultimate scrutiny this would surely suggest that they have something rather disturbing to be hidden from the public, and give credence to Dr. Driedger's statement about actions ***"bordering on immoral."***

- Therefore if PET ACCESS will not support this motion for the ethical review of it's work ***please send a detailed response outlining the reasons for this position so the public and physicians can judge for themselves whether this position is reasonable and defensible or not.***

Your responses to these two questions, along with subsequent questions about the methodology used by PET ACCESS will be made widely available, and certainly to any patient you will be dealing with.

I would ask that someone from PET ACCESS respond as soon as possible. Timing is of the essence since I will be immediately submitting the first patient's case so members of PET ACCESS can answer all his questions and give him a full and detailed account of the decision of the committee with documentation.

In this particular case I will also ask that you send your response also to the patient and his physicians who will be asking you to deal directly with them with their request for a PET scan for this man with ureteral cancer. I will include the appropriate contact information when I submit the application for funding his PET. A copy of this letter has been forwarded to the patient in question.

Respectfully Submitted

Dr. Dave Webster

This letter will also be sent by Registered Mail shortly