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Dear  Senior Executives of CCO, Chairman of the CCO Board, and CCO Committee Chairs:

The following document is in part from a letter I sent to Dr. Julian Dobranowski in April 2017.

## INTRODUCTORY LETTER TO THE VARIOUS CCO AND AFFILIATED GROUPS EVALUATING PET FOR THE ONTARIO GOVERNMENT

The following information package with relevant backing documents will be given to physicians, patients or anyone else who has an interest in what kind of province they actually live in. It will help them understand the facts behind the condemnation of the efforts of CCO groups from Canadian and International PET experts and why patients have the most restricted, and inappropriate access to PET last place in OECD countries.

In addition, if it is of interest or relevant to any actions patients might decide to take in light of the answers they receive, or lack of information from the CCOIG, I will make available to them all the relevant documents that I have accumulated over the past 15 years of the 'fruitless efforts' of my colleagues and me to get the Liberal Government and their medical experts to respond to questions submitted by various medical groups, physicians and by me.

## INFORMATION PACKAGE

A key document all will receive will be a copy a letter I received from Dr. Eric Hoskins from August 2016. In this letter he outlines what his expectations are of diagnostic imaging tests. A copy of this letter will be appended to this document. All the responses to the patients and physicians questions and concerns addressed to the CCOIG:

- *Will need to be fully compliant with the demands Dr. Hoskins has made regarding the basis for funding for diagnostic imaging tests, AND CRITICAL ISSUES OF RADIATION EXPOSURE to our patients.*

## KEY STATEMENTS FROM DR. HOSKINS LETTER:

1. "In Ontario appropriateness is built into the front end of decisions about when PET diagnostic scans will be used as a tool for patients with specific medical indications based on evidence. PET is an imaging test where patient management is part of the criteria. In Ontario, PET diagnostic services must be:

- *Effective (sensitive, specific, accurate)*
- *Have the potential to impact patient management*
- *Have benefits over other tests/imaging"*

**ASIDE:**

*Experts agree that the chief utility of Health Technology Assessment is that it allows those using it, in this instance, Cancer Care Ontario 'medical experts', to come up with the answers ( "appropriateness" )that the government has already decided on.*

2. "You, as a clinician, would understand that the benefits of exposure to radiation from a diagnostic intervention such as PET scans must be considered along with risks and limitations of the result of the scan. It is essential that the ministry also strives to achieve the correct balance.

He is of course implying that PET is "unproven technology."

- *The patients and their physicians are very concerned about radiation risks given the very real possibility of patients surviving their cancers only to develop a second cancer related to their exposure to mostly CT but also other medical imaging sources of radiation. All the relevant material to understand the impact of their current 'Cancer Care Ontario seal of approval' levels of radiation exposure from investigations will be made available.*

- *THEREFORE THE EXPECTATION OF THE PATIENTS IS THAT SPECIAL ATTENTION AND BACKING DOCUMENTATION BE GIVEN TO 'DEMONSTRATE THE BENEFITS OF' THE MEDICAL IMAGING DIAGNOSTIC RADIATION THEY HAVE BEEN EXPOSED TO SO FAR IN THEIR DISEASE MANAGEMENT.*

**DISEASE SPECIFIC INFORMATION WITH RESPECT TO ROLES FOR PET/CT**

All will be given a package containing all the relevant information and supporting documentation so that they fully understand the role of PET beyond Ontario's borders with reference to their particular situation.

- *I will make sure that the patients are given sufficient educational material to understand fully the basis of the questions that will be put to the CCOIG on their behalf as well as my discussion around the appropriate imaging based management of their diseases.*
- *The questions asked by each patient will be very relevant to their case, and most importantly will help them understand how they have been exposed to what could be considered an 'obscene amount' of radiation from almost useless CT scans.*

**ESTABLISHED FACTS AT THIS POINT IN TIME INCLUDED IN INFORMATION PACKAGE:**

As already established in my earlier letter to the imaging group:

1. The CCOIG, as all other CCO groups involved with assessing PET agree that there is *no scientific basis or validity to using Health Technology Assessment [HTA] to assess roles for PET, yet nevertheless the CCOIG will continue to use HTA to assess PET.*
2. Even though decisions regarding the use of PET in Ontario by the CCOIG are not based on the usual validated methods of science, the CCOIG refuses to offer up an explanation or basis of how decisions are made:
3. Given that how PET is evaluated by the CCOIG is not based on science, a reasonable position to take is in keeping with the statement of Professor Rodney Hicks of Australia:
    a. *The PET Steering Committee bases the assessment of PET on an 'agenda driven process'. It is also reasonable to assume and to quote Dr. Hicks that this agenda "is the most egregious and politically motivated agenda against PET (ie. Ontario's patients) in the world."*
4. The CCOIG chose not to acknowledge the unprecedented criticisms leveled at it by Canadian and International PET experts. In particular there was no mention in the Committee's response of the extraordinary motions passed by the Canadian Association of Nuclear Medicine in 2005 condemning the work of the CCO groups as unethical and demanding an independent review of the 'ethical actions of the Committee's assessment of PET', but most importantly didn't challenge the statements. Thus:

    a. *The CCOIG is not prepared to voluntarily offer the process by which they have evaluated PET up for formal ethical review.*

**IMPORTANT EDITORIALS AND STATEMENTS BY KEY PET EXPERTS:**

They will be given a copy of the 2005 motions by the Canadian Association of Nuclear Medicine [CANM] declaring the Ontario PET Trials as "unethical" and demanding an independent review by Canadian experts in ethics and health policy.

They will be given other statements such as from an Editorial in the Journal of Nuclear Medicine, Dr. Sandy McEwen, when he commented on:

> *"The capricious use of a scientifically baseless process [HTA]" to block Ontario patients from access to PET.*

The statements by Professor Rodney Hicks declaring Ontario *"as having the most egregious and politically motivated agenda against PET in the world.* They will also have access to what he has published about how CCO groups manipulated medical evidence and data to come up with indications for PET.

They will be given examples, such as the PET PREDICT Trial on women with breast cancer, deliberately designed to fail, and the details related to the controversy surrounding this trial, which was what precipitated the CANM motions in 2005.

**BACKGROUND INFORMATION TO PATIENTS REGARDING RADIATION EXPOSURE FROM DIAGNOSTIC IMAGING TESTS:**

I will also assume that panel members would recognize that if one were to insist that a patient being investigated for possible metastatic bone disease *had to have a skeletal survey to determine whether they would be allowed to have a "bone scan" which is a 'functional imaging" test, that this would at a minimum indicate a 'fundamental ignorance of basic anatomical and functional imaging technology'. It will be made clear how this is exactly how PET is being approached in Ontario:*

- *In order to have the 'cornerstone of functional imaging management in the Era of Personalized Medicine, a PET/CT, THEY MUST HAVE THE ANATOMICAL TEST, THE CT TO DECIDE IF THEY QUALIFY FOR PET SCAN.*
- *One key difference with the 'skeletal survey' analogy, is that the CT scans will involve much higher doses of radiation and the possibility in many cases of reaction to CT contrast material.*

The current CCOIG 'seal of approval' standards for cancer investigation beg the obvious question as reflected in a key question from the PET ACCESS Application:

- *"What will a PET scan demonstrate that cannot be proven by other means?"*

Just why does the CCOIG think the physician is requesting a PET/CT?

- If the CT and MR exams had of been able to answer the critical questions the physician and patients needs:
    - *THERE WOULD HAVE BEEN NO NEED TO ASK FOR THE PET/CT!!*

But of course the CCO approach has typically already lead to serious doses of CT with in many cases at least 6-8 CT exams, and indeed in one case a patient has had 23 and counting CT exams.

Any questions regarding the 'benefits' of the CCO approach to their cancer investigation will above all else *address Dr. Hoskins justified concerns about risks of radiation exposure.*

**ANATOMICAL VERSUS FUSED ANATOMICAL/FUNCTIONAL IMAGING:**

- All will be made aware that a PET scan is performed in conjunction with a low dose format CT without IV contrast agent unless a high resolution CT of for example of the chest is required when the expected metastasis would be below the PET/CT scanner.
- That a CT scan has almost no ability to determine if a detected mass is cancer, or for example, scar tissue post successful therapy for their cancer.

- The critical advantage of the PET portion, and thus the basis why it has been the accepted world standard of imaging management of most cancers, and in particular for lung nodules and cancer for almost 20 years is because:

    i. *By direct imaging the 'glucose metabolism' or other functional tracer content of the mass, the patient and their physicians have the best chance of making a decision on how to next proceed in their care and management.*
    ii. *Thus in post therapy situations with persistence of a mass on CT, the PET can better assist the physician to differentiate between scar tissue, and persistent active cancer.*
    iii. *THIS WOULD BE ACHIEVED AT A FRACTION OF RADIATION EXPOSURE CCO INSISTS THE PATIENT HAVE.*
- It is not uncommon for lymph nodes that that meet 'normal criteria' based on CT and MR reports *demonstrates active FDG uptake and therefore are potential sites of metastasis.*
- Further that it is not uncommon for positive findings on a CT or MR are missed because of the massive amount of imaging information on the scans. However it is a daily situation in any Nuclear Medicine department that an abnormality is identified on a functional image such as a bone scan, because of the fact that the abnormalities *stand out against the background activity, thus drawing appropriate areas to focus the interpreter's attention.*
- *On average a PET/CT will upstage 30% of patients because of findings missed on the anatomical exams. However PET/CT can downstage people appropriately as well.*
    *i. Thus most appropriately Staging and guiding patient management as pointed out by Worsley et al, with PET helping them make more informed decisions in almost 85% of cases compared to the CCO 'gold standard' of serial CT exams.*
- That the radiation dose to patients from a PET/CT is similar in range to that from a diagnostic quality CT exam.

**DIRECT BIOPSIES AND STAGING:**

A clear advantage of PET is in directing physicians to appropriate areas to biopsy such as a location that would give the patient the highest staging category which often is a much safer place to biopsy for the patient.

In addition, it is not uncommon for a CT guided biopsy of a mass to be negative for cancer since it has no way of differentiating which parts of the mass are active cancer versus scar tissue from infarcted tumour.

- *Yet the PET appropriately points out the most appropriate place to place the biopsy needle to minimize the chances of non-diagnostic biopsies.*
- *By imaging directly the 'glucose metabolism' of the constituents of the mass it*

*dramatically increases the probability that the lung mass is cancer versus non cancer and thus whether a biopsy is required immediately, or the mass can be followed more conservatively.*

- *Where there has been more distant metastasis, it points to what is often a much safer place to biopsy; points to the most likely site to get the right tissue for pathologist; and at the same time CORRECTLY ESTABLISHES THE STAGE OF THE PATIENTS CANCER compared to the 'Anatomical based Standard of imaging management' demanded by CCO experts.*

**SUMMARY:**

The patients in Ontario who would otherwise be candidates for a PET scan in almost any civilized medical jurisdiction offering PET on the planet, will be asking you very specific and evidence and fact based questions. They are entitled to answers to their questions and concerns, ***especially when it comes to the radiation exposures*** they have had during their cancer management. It is the duty of the CCO committee members to address each and every question and provide the specific documentation backing the Panel's opinion.

All communications and documents both to and from the Cancer Care Ontario Imaging Group will be shared with all involved with this process of trying to get CCO experts to defend how they have assessed PET in Ontario.

And finally if I have any questions or issues specifically with respect to how CCOIG responds to the questions, I will send them to Dr. Rodney Hicks of Australia or other appropriate experts for their comments.

Respectfully Submitted.

Dave Webster MD FRCP