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RE:PET PREDICT TRIAL DEFENDED

Dear Members of OCOG:

LETTER ONE REGARDING PET PREDICT TRIAL
ON WOMEN WITH EARLY STAGE BREAST CANCER

PART 1:

It is acknowledged that OCOG sponsored the trial by the PET Steering Committee to investigate potential roles for PET in women with breast cancer.

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.

> Evidence-Based Approach to the Introduction of Positron Emission Tomography in Ontario, Canada
> *William K. Evans, Andreas Laupacis, Karen Y. Gulenchyn, Les Levin, and Mark Levine*
>
> *J Clin Oncol 27:5607-5613. © 2009 by American Society of Clinical Oncology*

STATEMENT FROM EVANS ET AL. PAPER

> *"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."

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 order to see the PET PREDICT Trial proposal, someone from the PSC 'leaked it" it to the Executive of the OANM.

Secondly, the trials lead to unprecedented and to this day ongoing condemnation of what CCO experts are prepared to do to Ontario cancer patients to block and delay PET/CT for patients.

In a 2009 Editorial in the Journal of Nuclear Medicine by the President of the Society of Nuclear Medicine, Dr. Sandy McEwan about how PET was being assessed in Ontario :

- Dr. McEwan spoke of the "capricious use" of a scientifically baseless process [HTA] to block Ontario cancer patients from PET scanning.

There were two versions of PET PREDICT. When the OANM Executive read the first version our response was that this was *"unconscionable"* that the committee would deliberately design the trial to fail. The result was that, without explanation by the PSC, the trial was withdrawn and a considerable time of more than a year elapsed as the PSC presumably worked on a new version. In email communications with Dr. Bill Evans, Chair of the PSC, that they were working on it very hard.

When version two was about to be released, again a copy was 'leaked' to the Executive of the OANM. We were dumbfounded, since it was identical to the first version with a trivial addition. Most importantly the "unethical deliberate design of trial to fail" was unchanged.

NOTE:

To the public reading this letter it must be kept in mind that besides discrediting evidence supporting PET, another method to block PET by CCO was to delay the issues. By taking the time to come up with version two, they had accomplished a significant delay before they would even deal with the issue of PET in women with breast cancer.

POINT OF CLARIFICATION ONE:

- *Please explain and defend the clear incongruence between the public statements of the 'openness and co-operation of the PSC and other CCO committees and the 'Canadian Nuclear Medicine Imaging community' when it came to writing the PET PREDICT Trial.*
- *Please explain the discrepancy between the statement: "and gaining acceptance by health professionals for the evaluative program" and the unprecedented condemnation of these PET Trials by Canadian and International "health professionals'.*

DESIGN OF PET PREDICT TRIAL:

The Helsinki Accord outlining ethical human research and experimentation is very clear that:

- ***It is unethical to deliberately design an experiment on humans to fail.***

The outrage precipitated by the PET PREDICT Trial was related to the deliberate decision to only include women with early stage breast cancer, Stage I and II. To this day there is not an imaging device, beyond a microscope, that could visualize the potential metastasis to the axillary lymph nodes in this group of breast cancer patients. In short:

- ***The PET PREDICT Trial was deliberately designed to fail.***

QUESTION 1:

Although some members of the PET Steering Committee, including the Chair, were not involved with the design and implementation of the PET PREDICT Trial, the key people of the CCO Imaging Committee and PSC are fully aware of this trial and the claims by credible medical professionals of an "unethical and bordering on immoral" experiment on these women. In spite of being given a chance to defend this trial or distance themselves from this PET Trial, there has not been a single response to my letters asking committee members to defend the PET Trials and the HTA.

- **Therefore, why did OCOG defend the PET STEERING Committee design, and continue to support, an experiment on cancer patients that was STRUCTURED TO FAIL?**

QUESTION 2:

As mentioned in my introductory letter, Dr. Hoskins expressed to me his concerns about unnecessary radiation exposure to patients. I am sure that as physicians we would all fully

support his concern. The women entering these trials would receive a ‘non-trivial’ amount of radiation exposure for their PET scans:

- Please justify the radiation exposure to these women in light of Dr. Hoskins statements, and in addition given that this radiation could serve no useful purpose for these women since the trial was designed to fail.
- Is OCOG prepared to make a statement to the women who took part in the PET PREDICT Trial?

Respectfully submitted

Dr. Dave Webster