



Office of the Premier
The Right Honourable Ed Stelmach
Room 307, Legislature Office
Legislature Building
10800 - 97 Avenue
Edmonton, AB
T5K 2B6

Re:

- The inaccuracies found in the FOIP-released documents for basing the rejection of Enterra™ Therapy (aka: gastric electrical stimulation or GES). There needs to be a re-evaluation of this process in order to restore public confidence.
- The FOIP documents, taken together, show a cautious endorsement for gastric electrical stimulation; therefore we encourage the Minister's office to approve immediate coverage for gastric electrical stimulation and initially restrict this approval for the treatment of severe gastroparesis related to **Type I diabetes**. There is strong support by the majority of GI specialists for this recommendation.
- That the Minister's office needs to be directed to request a medical ethics report in order to gain an additional dimension for reconsidering the approval of GES.

Dear Mr. Stelmach:

In February 2005, our non-profit association requested a full review for inclusion under the Alberta Health Care Insurance Plan of gastric electrical stimulation (Enterra™ Therapy) — the treatment device used for controlling intractable nausea and/or vomiting caused by gastroparesis. Gastroparesis is a severe neuro-muscular disorder, commonly found as one of the complications from long-standing Type I diabetes. Gastric electrical stimulation (GES) is reserved for those gastroparetic patients who are unable to gain good symptom management from their anti-nauseant and anti-vomiting drug cocktails. Severe gastroparesis represents stomach organ failure for which there are precious and limited treatment options.

The previous Minister of Health, after a yearlong review process, denied Albertans access to the vital treatment device of GES.

As it stands, gastric electrical stimulation is the only approved therapy for the treatment of severe gastroparesis. It is a technically easy surgery requiring no

specialized surgical equipment and is reversible. The device used, the Itriel III, is a generic neuro-stimulating device used in applications such as spinal cord stimulation (SCS), and further is approved for marketing by the Federal government of Canada for both the applications – SCS and for gastric electrical stimulation (GES).

The Itriel III is fully covered under the Alberta Health Insurance Plan for the use of SCS and patients with intractable pain have full, unfettered access; but our gastroparetic patients remain unintentionally discriminated against for access to the Itriel III for control of their intractable nausea and vomiting.

Implantable neuro-stimulating devices have been clinically used for nearly 35 years. The safety of the Itriel III neuro-stimulating device is well documented and medical benefits far outweigh risks.

For all applications of neuro-stimulation, processes are in place for good candidate selection.

With regards to complications, such as an infection, GES is found to be at an acceptable level, matching rates of infection found in spinal cord stimulation.

This and other complications are manageable and no mortalities have ever been documented over the 15 years of implanting gastric electrical stimulators. This safety record is not matched with regards to some of the therapies currently used in our patients who are suffering intractable vomiting.

Finally, the cost savings from reduced emergency room visits and hospitalizations related to better symptom management of nausea and vomiting pays back immediately in dividends to tax payers and to the patients themselves.

Our association has recently had the opportunity to review the background documents (through the FOIP process) by which the previous Minister of Health based her decision to deny coverage for gastric electrical stimulation. The documents do show a theme of cautiously endorsing gastric electrical stimulation on a humanitarian basis. Yet, inadequacies and inaccuracies have been found in these documents, sufficient enough — and documented in our new submission — as to bring into question the whole review process by which our government based its decision.

The government's conclusion, and main basis for denying coverage for GES, was to state that it is “**experimental**”. This statement flies in the face of common sense as well as evidence provided by patients who are fortunate to benefit from access to GES.

You have met one of our patients and had a chance to hear first hand how effective Enterra therapy has been for her. Each of the 4 patients in Southern Alberta who paid out-of-pocket for their own GES all have similar stories of reduced disability — something unachieved over the accumulated years of suffering before receiving their Enterra therapy.

Furthermore, the FOIP documents received does not show any direct submissions and written opinions by those experts in the field who have a wealth of clinical experience with both research and usage of GES. Yet, **direct submissions** were sought from specialists in our province who lack clinical experience with GES. Though, experts were invited to submit information and review the AHFMR (Alberta Heritage Foundation for Medical Research) report (which was generated last year as part of the Ministers consideration for GES approval), we do not gain any insight as to the level of agreement between the experts and AHFMR. AHFMR controls the process and has the final say to veto any information which is not in parallel with their perspective.

At the end of the day, medicine is as much an art as it is a science. That is why clinical expertise should be valued in the decision making process.

We urge a new handling of the process, one that is more open with clearly stated measures and objectives and seeks direct submission from experts in the field.

Our patients suffer with inescapable and constant nausea and vomiting as well as compromised nutrition, and their families toil under the unrelenting burden of caring for their loved ones without available, effective treatment options. We need leadership from the top to help restore confidence and to **make GES accessible now for our Type I diabetic patients who suffer from gastroparesis.**

This is the compassionate and right choice for Albertans.

Please see our new submission to the office of the Minister of Health. I respectfully request your direct involvement in the reappraisal of GES.

We will contact your office in two weeks to follow up with our request.

Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Keith-Ferris', written in a cursive style.

Jeanne Keith-Ferris, RN, BScN

cc:

Honourable Dave Hancock

Honourable Harry Chase

Honourable Laurie Blakeman