

PE1493/UUU

24th February 2016

Sigrid Robinson
Assistant Clerk to the Public Petitions Committee
T3.40
Scottish Parliament
Edinburgh
EH99 1SP

Dear Ms Robinson,

**Submission to the Scottish Parliament - Petition PE1463
Re: Public Petitions Committee Meeting held 9th February 2016**

I am writing in respect of the above meeting and would ask that this letter is submitted on behalf of Thyroid UK.

Having watched the meeting via the Scottish Parliament website I would like to register Thyroid UK's concern at not only the poor quality evidence given by the Scottish Minister for Public Health (Maureen Watt) and Professor Graham Leese but by the lack of understanding of the subject matter by Minister Watt and her apparent lack of preparation for the meeting.

I am very concerned that it was intimated that Thyroid UK did not fulfil the remit in respect of the Hypothyroid Patient Experiences Survey. In fact, the remit was that we should run a survey covering the *whole of the UK* which would be *part of* a listening exercise run by the Scottish Government, not *the actual* listening exercise.

Minister Watt stated that, "It should be recognized that progress in clinical science has been and should continue to be based on properly conducted, scientifically based trials that strive to eliminate any error or unrecognized confounding issues." Unfortunately, in research, the correct question is not always asked and studies are not always done in the correct way and therefore the outcome of the research will not be clear.

In respect of the T3 studies, patients were not differentiated into those that did convert their T4 to T3, those that did not and those with the DIO2 gene. It's not surprising that some patients felt adverse effects or did not improve when given liothyronine (T3).

I am also concerned that the Minister stated, "The people who responded [to our survey] are very involved in the issue and the figures quoted are likely to be an overestimation of the situation." The survey was meant to find out exactly what is happening to hypothyroid patients in respect of diagnosis and treatment. The survey was sent not only to people "involved" with Thyroid UK but it was also sent by direct messages to all the Clinical Commissioning Groups and Health Boards in the UK as well as to other health related organisations including doctors, practitioners and other non-thyroid health charities.

The British Thyroid Foundation were asked if they would place a link to the survey on their website and in their magazine. This was refused due to (a) the choice of an online survey was not the most robust approach for answering some of the questions, and (b) that this was a very complex and perhaps over-ambitious venture and also that, "...the greatest concern in the survey is the biases that creep up as a result of selection of the sample."

Throughout the meeting there seemed to be some confusion in regard to guidance, best practice, statements and guidelines. Let me make it clear for the committee which is which:

- UK **Guidelines** for the Use of Thyroid Function Tests – **July 2006** (which have not been updated and there is no intention to do so)
- The Royal College of Physicians **Statement** on The Diagnosis and Management of Primary Hypothyroidism - Endorsed by the Royal College of General Practitioners – **19th November 2008**
- 2012 **ETA (European Thyroid Association) Guidelines**: The Use of L-T4 + L-T3 in the Treatment of Hypothyroidism – **2012**
- Guidelines for the Treatment of Hypothyroidism - Prepared by the **American Thyroid Association Task Force on Thyroid Hormone Replacement – 2014**
- Management of Primary Hypothyroidism - **Statement** by the **British Thyroid Association Executive Committee** - Endorsed by the Association for Clinical Biochemistry and Laboratory Medicine, British Thyroid Foundation, Royal College of Physicians and the Society for Endocrinology – **Updated May 2015** (which is a review of the current Guidelines of The American Thyroid Association (ATA) and the European Thyroid Association (ETA) and recommendations made based on the current literature and **in line with best principles of good medical practice.**)
- **There are no NICE or SIGN guidelines on the diagnosis and treatment of hypothyroidism**

Minister Watt and Professor Leese mentioned the British Thyroid Foundation for reasons which were not entirely clear. They mention that they have written Frequently Asked Questions for patients and GP's in regard to the BTA statement. I would like to point out that the BTF trustees consist of two lay people and the rest are clinicians of various endocrine areas of medicine. Some of the trustees also have had or currently have links with the BTA. The BTF do not write any of their content without it being edited and approved by their trustees.

Professor Leese mentioned that blood tests are not the whole picture and that treatment is a balance between treating symptoms and treating the blood tests. Unfortunately, many clinicians only treat the symptoms up to the point that patients' TSH tests become normal again. After that, any symptoms are regarded as being due to some other health problem they may have. Patients are sent to various specialists and given various drugs which do not help. Such a waste of NHS funds.

Professor Leese talks of a wide range for TSH. This is not correct. The average range for TSH is at most only 0.4 – 4.5. The average range for an FT4 test which is very often not done, is 10 – 22. The average range for a vitamin B12 test is 250 – 900. In our experience the majority of doctors will not even allow their patients' TSH to go down to the bottom of the range to see if this alleviates their symptoms.

FT3 is very rarely tested on the NHS. To get tested and then possibly treated with liothyronine (T3) the patient often needs a referral to an endocrinologist.

We hear all the time that either the GP refuses to refer because the TSH is normal or that the GP sends an email to the endocrinologist with the patient's TSH levels and the referral is refused due to normal test results. How can the endocrinologist know whether the patient needs liothyronine (T3) without an FT3 test being done? It is now well known that if a patient has the DIO2 gene causing low conversion of T4 to T3, it does not show up in a thyroid function test. The NHS do not undertake DIO2 testing. It's a vicious circle.

The BTA statement states, “If a decision is made to embark on a trial of L-T4/L-T3 combination therapy in patients who have unambiguously not benefited from L-T4 then this should be reached following an open and balanced discussion of the uncertain benefits, likely risks of over-replacement and lack of long-term safety data. Such patients should be supervised by accredited endocrinologists with documentation of agreement after fully informed and understood discussion of the risks and potential adverse consequences. Many clinicians may not agree that a trial of LT4/ L-T3 combination therapy is warranted in these circumstances and their clinical judgement must be recognised as being valid given the current understanding of the science and evidence of the treatments (2/+00).”

In other words, if the endocrinologist does not want to prescribe liothyronine (T3), they don't have to, whether the patient would like a trial or not and whether the patient would sign an agreement or not. When patients have an operation, they must sign a consent form. Why could we not have a consent form for a trial of liothyronine (T3)? This is why so many patients are purchasing their own medications from the internet.

Another barrier to being prescribed T3 is the huge cost to the NHS due to there being only one company that manufactures this drug in the UK. The cost of liothyronine (T3) in Europe is a tenth of the cost in the UK and in some countries it is available over the counter.

Minister Watt stated that there were “significant theoretical concerns” about the long term safety of liothyronine (T3). Would that be from an evidenced-based clinical study or is that anecdotal? Furthermore, exactly what are these theoretical concerns, and are they supported by reliable evidence? It is not acceptable to raise such matters without quoting the sources from which they come and the conclusions drawn.

Although the Scottish results of our survey cannot be extrapolated, statistically, 8.3% of the UK population reside in Scotland and therefore, this figure could be used as an approximation of the number of respondents to the survey residing in Scotland.

Interestingly, the vast majority of the studies in relation to liothyronine were not carried out in the UK and yet this information is considered acceptable evidence for UK patients (statistically). It is also interesting to note that the combined number of participants in these studies amounts to 1,473, which is a significantly lower participation rate than the Thyroid UK Hypothyroid Patient Experiences survey.

Patients on these trials did not have low FT3 levels or symptoms and in some of them, the conclusions in the abstracts are not detailed enough, missing important statements in the full text about preference and improvements. The last clinical trial on combination therapy was 2010. There have been recent trials about the reasons why patients do not do well on levothyroxine. Why were none of these mentioned in evidence? Dr John Midgley, one of the authors of these trials, should be invited to give evidence so that the committee, and perhaps thyroid experts have a clearer understanding of these trials.

Interestingly, Professor Leese did not bring up the fact that he is author to a paper entitled, “Safety review of liothyronine use: a 20 year observational follow up study.” This study found that there was no increased risk of death, fractures, atrial fibrillation or cardiovascular disease.

Thyroid UK does plan to take the report to the UK Parliament but since the Scottish Parliament is more forward thinking than the UK Parliament and have taken this subject seriously, we were waiting to see what the outcome was from this petition.

Professor Leese mentions that thyroid disease could be included in GP training. Perhaps he could instigate discussions regarding this with the Royal College of Physicians?

Thyroid UK would be very willing to run another survey, this time to all GP's and endocrinologists in the UK, including data of the location of the clinicians to ascertain their views on diagnosis and treatment of patients with hypothyroidism.

Kind regards,

Lyn Mynott
Chair/Chief Executive
Thyroid UK