Thyroid UK

Research – How hard can it be?

By

Lyn Mynott

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Lyn Mynott - My case study

- Ill for 15 years
- Symptoms – muscle pain; vertigo; hair loss; Carpel Tunnel Syndrome; constipation
- Had many tests – thyroid (several times)
- NHS treatment
- Complementary treatment

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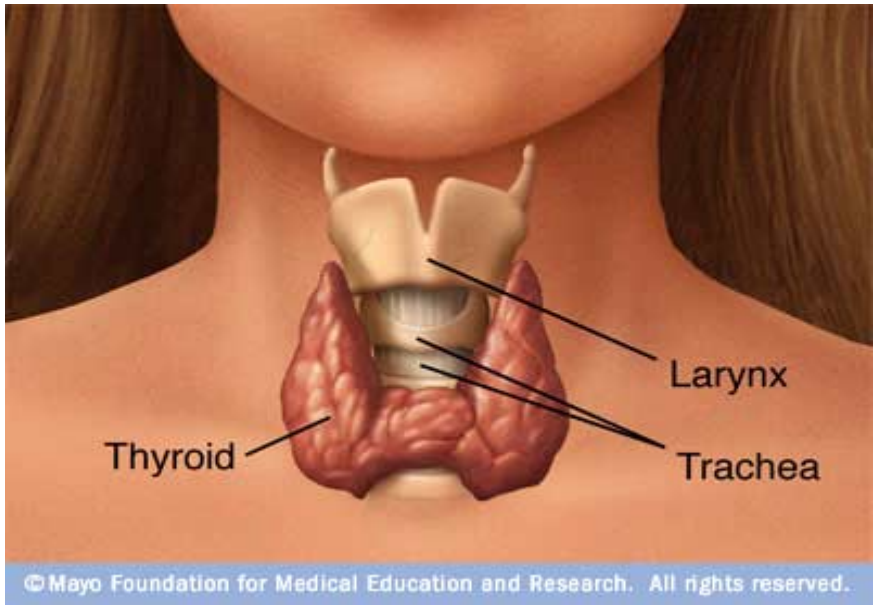
Journey to Recovery

- Lump in thyroid
- Scan
- Fine Needle Aspiration
- Thyroidectomy
- Treatment
- Health improvement



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Thyroid UK's Beginnings

- 1998 - Started campaigning - Thyroid Action Group
- 1999 - BBC Watchdog - Healthcheck
- 2000 - Set up a Committee
- 2001 - Changed name to Thyroid UK

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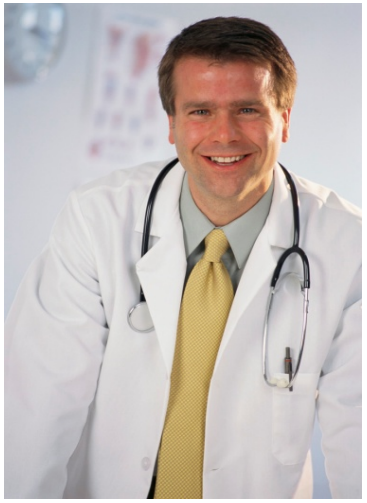
About Thyroid UK



- Over 14,000 contactees
- Website
- Telephone Helpline
- Medical Advisory Panel
- Quarterly Newsletter
- Members of:
  - The James Lind Alliance
  - National Voices
  - Patients Information Forum
- On Working Group for Health Accreditation Scheme
- Worked with Goldshield Pharmaceuticals on a survey about thyroid medications

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Incidence of Thyroid Disease

"In the United Kingdom alone, an estimated 4.5 million people have a thyroid problem out of a population of 60.4 million. ..... a further two million people are believed to have over or underactive thyroid glands that remain unrecognised, although these cases are often mild.

Alan L. Rubin, MD and Dr Sarah Brewer

"About 1 in 50 women, and about 1 in 1000 men develop hypothyroidism at some time in their life. It most commonly develops in adult women, and becomes more common with increasing age. However, it can occur at any age and can affect anyone."

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Signs and Symptoms of Hypothyroidism

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Signs

Dry coarse skin, hair loss and cold peripheries.
Puffy face, hands and feet.
Bradycardia.
Delayed tendon reflex relaxation.
Carpal tunnel syndrome.
Serous cavity effusions e.g. pericarditis or pleural effusions.

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Symptoms

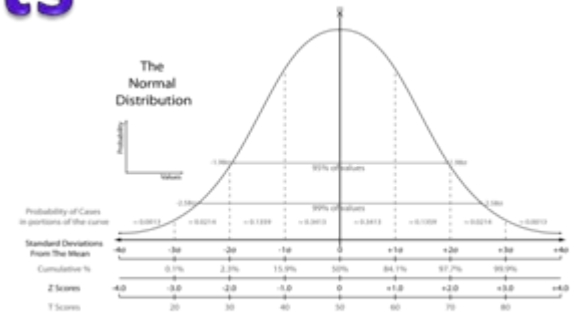
Tiredness, lethargy, intolerance to cold.
Dry skin and hair loss.
Slowing of intellectual activity e.g. poor memory and difficulty concentrating.
Constipation.
Decreased appetite with weight gain.
Deep hoarse voice.
Period problems.
Impaired hearing due to fluid in middle ear.
Reduced libido

Patient UK

The affected person may be lethargic, easily fatigued, slowed in body and mind and in many cases suffer from muscle aches, loss of menstruation, deafness, angina pectoris, heart failure, anaemia and constipation.

NHS Direct

Thyroid Function Tests



TSH (Thyroid Stimulating Hormone)
Free T4 (thyroxine)
Free T3
Thyroid antibodies

- The reference range is based on a normal bell-shaped graph, with serum levels of TSH and FT4 outside the 95% reference interval described as pathological. The normal range for TSH is 0.5 – 5.0.
- Recent guidelines state that patients need not be treated until they reach 10 in the reference range.
- "…. large numbers of thyroid function tests are carried out because patients describe vague non-specific symptoms. Doctors are frequently faced with decisions on the management of patients who have little or no clinical signs of thyroid dysfunction, but have abnormal tests."

The Pharmaceutical Journal Vol. 265 No 7109 p240-244

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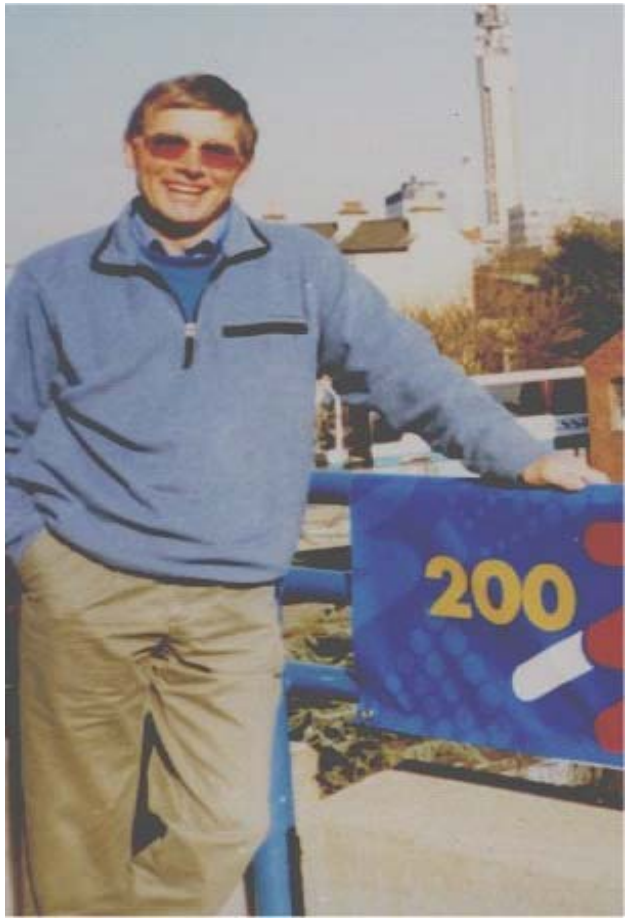
How the study came about

- Andrew Bull died on 1st April 2004 from a heart condition.
- Donations came in from his friends and family
- It was decided to use this money for a study



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How did we start?

- Report in Autumn 04 Newsletter
- Jane Evans, Clinical Research Co-ordinator
- Set up Study Working Group

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Research using Urine Tests

1. Thyroid Insufficiency. Is TSH Measurement the Only Diagnostic Tool? W. V. Baisier MD; J Hertoghe MD and W Eeckhaut MD - Journal of Nutritional & Environmental Medicine (2000) 10, 105-113

2. 24-h urine hormone measurements : the better tests to screen for milder degrees of hormone deficiency? Hertoghe TM, Nguyen D, Namer P, Baiser W, Gadomsky A, Poutet B, Hertoghe TA, Everard B, Duboë B, Gouita J, François M. - Belgian Society of Anti-Aging Medicine

Question: Could the urine tests be a better predictor of thyroid disease?

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First Study Working Group Meeting - February 2005

- Which tests to study
- How many patients and controls
- Decided on which signs and symptoms to use and the grading
- Who would write the first draft of the protocol and who would contact the Ethics Committee
- Discussed how much money we needed to raise

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What happened next?

- Report in November 04 Newsletter and on our website asking for donations
- Caroline Bull went to the US and had a meeting with one of our Medical Advisers, Dr John Lowe, Director of Research for the Fibromyalgia Research Foundation who agreed to help us with the protocol and statistics
- We contacted testing laboratories
- Jane Evans contacted local Ethics Committee for an initial meeting

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Second Working Group Meeting - June 2005

- Agreed amendments to the draft Protocol
- Which laboratories to use for the tests
- Where tests would be carried out
- Further equipment costs

Other Work Covered by phone, letter and email

- Indemnity Insurance
- Several drafts of the Protocol!
- Change of title – Comparison of Urine, Saliva and Blood Tests for Thyroid Function and Their Correlations with Presenting Symptoms
- Ethics Approval Application

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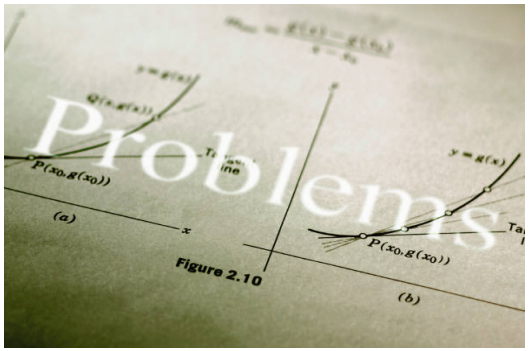
Outcome of Ethics Committee Review – 12.6.06.

- The Ethics Committee's statistician had some concerns
- We disagreed with the statistician's comments
- Sent the statisticians report to Dr John Lowe
- Sent a response to the Committee on 23.10.06. explaining why we wanted to keep the statistics as they were



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Ethics Sub Committee Meeting - 25.10.06.

The Ethics sub Committee members wanted us to change:

- patient grouping for testing
- symptom profile

This would have meant a fundamental change to the protocol and would affect the results of the research.

We decided to regroup!

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Response to Ethics Committee – 8.5.07.

After lots of discussions it was agreed that we would inform the Ethics Committee :

- too costly due to having to pay for more tests
- it would show bias to the TSH test
- no previous questionnaires used were validated
- all the symptoms on our list were on well accepted symptom lists

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Ethics Approval Received on 10th May 2007

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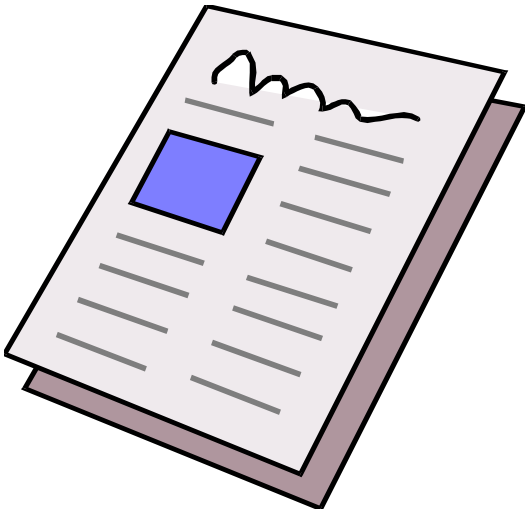
Next Step

- Report in our newsletter
- Report on our website
- We asked for volunteers to be participants in the study
- We told them we would be fundraising to pay for the study



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How did we raise funds?

Funds came in from our subscribers and people who use our website:

- Donations
- Raffles
- Christmas Cards
- Friends of Andrew did the Three Peaks Challenge
- My PA's fiancé dyed his hair purple!
- We held a Masquerade Ball
- Large donation

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Major problem!

- Laboratory saliva test machine broke down!
- Change to protocol needed.
- Re-submission to Ethics Committee

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Ethics Approval - Again!

Where are we now?

- 19 patients have been tested
- 2 patients booked in for assessment
- Controls are being recruited now

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Writing Up of the Study

This will be done by Caroline Bull but with input from the whole Working Group , with Dr Lowe proofreading it for us!

Publishing Results

- BMJ and The Lancet?
- Journal of Nutritional and Enviromental Medicine and the on-line journal, Thyroid Science

Dissemination

- Newsletter
- Website
- Press Release

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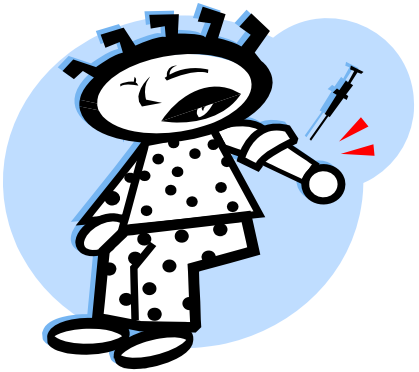
What Do We Hope to Achieve?

- Change in Practice?
- Urine testing is non-invasive and easy to do
- Patient will be more involved in their diagnosis and treatment
- Better quality of life
- Find out why so many people are ill with the "non-specific" symptoms of hypothyroidism and yet have normal blood test results.



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How hard can it be?

Not very, actually!

You do need:

- To talk to and listen to your members
- A good idea that is relevant to your members
- A good Committee
- Commitment
- Funds
- Patience!

Would we do it again?

Most Certainly!

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