

The Quality Assessment Life-Years (QALY) Argument for Continuing a T3 Therapy

By Eric Pritchard

There are people, mostly women, who have unrecognised mimics of hypothyroidism. These mimics are so unrecognised they do not appear in the training for endocrinologists. The medical practice guidelines for hypothyroidism do not address these mimics, they do not prescribe, or they proscribe, the potential diagnostics. And they proscribe the proper therapies.

I would like to discuss two cases, Patient S and Patient K. But first, QALY requires description. It is Quality Assessed Life-Years. For each year that the patient is expected to live, a value is estimated for their quality of life. Death is indicated by zero. Good health is indicated by one. Then all of the annual QALY's are added up for a total QALY. When this is used to evaluate a medical intervention, the pre-intervention QALY estimate is subtracted from the post-intervention QALY estimate. Obviously, if this value is negative, the intervention should not be performed because the patient would be worse with it than without it.

Patient S has been prescribed Armour for some years. She was prescribed Armour because all of the other therapies relevant to the symptoms of hypothyroidism did not manage her chronic symptoms. But Armour did. Now, with the advent of the Royal College of Physicians guideline "The Diagnosis and Management of Primary Hypothyroidism," physicians are not willing to renew prescriptions for thyroid-related hormone replacements that are not levothyroxine sodium, i.e., any hormone replacement that contains triiodothyronine (T3), in this case Armour. Nominally, her case as already demonstrated that she does not have primary hypothyroidism, yet statements in the conclusion drive physicians to deny new prescriptions for Armour. By her own history, we know that her QALY figure for denying Armour is negative -- her life will become horrible, since Armour is the one therapy that works -- that gave her life back.

Patient K was examined for thyroid deficiencies more than 40 years ago. She was told that she did not have a thyroid problem -- it was just a little low. One day she passed out and broke her leg in two places. Upon examining her, the emergency room physician claimed that he would fix her leg immediately and her "thyroid" the next day. In fact, pictures of Patient K from that time demonstrate the classic appearance of someone quite lacking in thyroid-related hormones. The physician went on to claim that she was quite lucky that she did break her leg because if she had not, her condition would not have been recognised and she would have died in a myxoedema coma. Indeed, Patient K was planning her own funeral. Her pretreatment QALY index was less than one. The physician prescribed liothyronine sodium (one of the currently banned/boycotted hormone replacements). In retrospect her post treatment QALY index was greater than 40 as she is still quite alive and in good health. So if the present guideline were followed, it would have killed her. By doing proscribed diagnostic (observation only) and prescribing one of the proscribed hormone replacements, her QALY index went up more than 40 points. (Something is wrong with the hypothyroidism guidelines.)

But 25 years later, her physician retired. Patient K was now forced to find another. The physician applied the philosophy of the present guideline, and prescribed levothyroxine sodium. Soon she began to circle life's drain. But with the knowledge of her prior experience, she searched for a physician who would prescribe liothyronine sodium. Her well being rapidly. It was returned with that prescription. Once again the proper application of the guideline reduced her QALY index and disobeying it raised her QALY index. Thus, in two series of applications of the spirit of the subject guideline, it actually lowered the QALY index of the patient -- the first time could have, absent an accident, brought death. (Something is wrong with the hypothyroidism guidelines.)

My analysis of "The Diagnosis and Management of Primary Hypothyroidism" is that it is substantially correct for Primary Hypothyroidism. It errors in the conclusion statements that embrace the unrecognised

post thyroid physiology. To be more specific, post thyroid physiology is not recognised by medical practice, but well known to medical science. Refetoff in the early 60's found some patients were resistant to thyroxine therapies, the very therapies that are prescribed by the present guideline and all other guidelines for hypothyroidism. Later that decade Refetoff and others discovered that our cells have hormone receptors to receive the hormones circulating in our blood and that these were a source of thyroxine resistance. In 1970, Braverman and others discovered that the bulk of the active hormone, triiodothyronine (T3) was metabolised at sites on various organs. While the thyroid produces only 20% of the requirements, the liver produces 60%. Other organs, like the brain, produce the remainder. So, since 1970, medical science knows. But since 1970 medical practice insists upon ignoring or dismissing.

There are two forcing issues, differential diagnostics and the *Bolitho* case. In differential diagnostics, all the potential causes for symptoms are first stipulated, and via scientific investigation, eliminated until there is only one left. Since medical practice does not acknowledge the existence of these potential causes, they are not stipulated and not considered. So when all fails, as it did in the above examples, but without a knowledgeable and brave physician, the patient is routinely diagnosed by something like "functional somatoform disorders." I.e., the patient's suffering is created, imagined by the patient. That follows the old pattern, if you cannot treat the patient properly, blame the patient.

The *Bolitho* case found that standards of care that cannot be justified scientifically cannot be a defense against malpractice. This guideline, "The Diagnosis and Management of Primary Hypothyroidism" is an instrument of mass malpractice. It ignores the medical science of post thyroid physiology of the peripheral metabolism of the primary thyroid gland secretion, the relatively inactive hormone thyroxine (T4) to the active hormone, triiodothyronine (T3) and the peripheral cellular hormone reception of T3 for use by the cells' nuclei. (Braverman, Refetoff, et al.) The expert physician should know this.

About 13% of all those treated for hypothyroidism are not happy with their therapies. (Saravanan, et al.) With the prevalence in the UK for hypothyroidism at 3% and most of them being women, we can assume that about 3/4% of all women in the UK have this problem to some degree. Since there are about 30 million women in the UK, that 13% becomes about 22,000 potential cases. All these cases demonstrate a poor QALY with the potential, with the appropriate use of medical science, of having their QALY index raised.

In conclusion there are these facts.

1. There are patients whose QALY index is lowered by the application of "The Diagnosis and Management of Primary Hypothyroidism" because its language improperly embraces physiology which medical practice does not recognise and which is not taught in endocrinology curriculums.
2. These patients need not suffer by empirical proof: "Thyroid Insufficiency. Is Thyroxine the Only Valuable Drug?" by WV Baisier, J Hertoghe, and W. Eeckhaut.
3. These patients need not suffer by theoretical proof: "The Linguistic Etiologies of Thyroxine-Resistant Hypothyroidism," by Eric K. Pritchard, which cites works by post thyroid function pioneers, Refetoff, Braverman, et al.
4. These patients, and numerous other members of thyroid forums are anecdotal proof – some of success, but most of failure by the endocrinology establishment
5. If the guidelines for the authorship of guidelines were followed, the present guideline would not be an instrument of mass misery and malpractice. These guidelines are *Concise Guidance to Good Practice*, Clinical Effectiveness & Evaluation Unit, Royal College of Physicians, 2003, and Mechanic JI, Berman DA, Braithwaite SS, Palumbo PJ, *American Association of Clinical Endocrinologists Protocol for Standardized Production of Clinical Practice Guidelines*, *Endocr Pract*, 2004, 10(4), Table 4. Furthermore, the stipulation of definitions is a legal standard of practice.

6. Certainly, there is no proper reason, as demonstrated by their QALY evaluation, for anyone with failed levothyroxine therapy and successful T3-containing therapy to be put back on levothyroxine sodium. The patient's own medical history would substantiate a favorable *Bolitho* ruling.