

**Controversy concerning  
the diagnosis and treatment of hypothyroidism:  
Stakeholders' views and recommendations**

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**C A Phillips**

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## **Abstract**

A literature review was undertaken to determine the nature of any controversy within and between stakeholder groups such as medical professionals, researchers and producers of guidelines in relation to the diagnosis and treatment of hypothyroidism. Further analysis was undertaken to determine the recommendations of the above stakeholders for resolution of any controversy in relation to the diagnosis and treatment of hypothyroidism.

Interviews were carried out and questionnaires were distributed in order to find out the views of a sample of individuals involved in providing information and/ or support to members of the public with hypothyroidism (via charities/ voluntary organisations/ patient support groups) regarding the nature of any controversy in relation to the diagnosis and treatment of hypothyroidism. The recommendations of the aforementioned respondents for resolution of any controversy in relation to the diagnosis and treatment of hypothyroidism were determined.

On the basis of the information gained via carrying out interviews and distributing questionnaires, recommendations were made regarding the need for research and dialogue.

There appears to be large areas of agreement between members of the scientific/ medical community and those involved in providing information and/ or support to the hypothyroid patient community over research that needs to be carried out. However, in light of feedback from respondents, it is recommended that future research should include an evaluation of patients' perspectives and preferences on a consistent basis.

The findings from the interviews and questionnaires demonstrate that dialogue is desired by many involved in running/ working for thyroid charities/ voluntary organisations and patient support groups.

With regards to an additional/ alternative strategy, it was suggested that members of the hypothyroid patient community should have more input into the education and ongoing training of medical professionals.

(284 words)

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## Preface

A scientific background coupled with personal experience of hypothyroidism led me to co-author the book *Hypothyroidism in Childhood and Adulthood* (Phillips and Roach, 2006) in order to present both scientific information about hypothyroidism and the patient's perspective with the belief that both standpoints can enrich one another.

My current project has been undertaken for the MSc project module (S810) and builds upon the knowledge gained during the MSc Science and the public module (S802) and complements the knowledge gained whilst carrying out my S802 MSc mini-project (Phillips, 2010a) which was on a related topic within the same subject area namely hypothyroidism (Please see Appendix A for a copy of the title and abstract). Although, my current project is not based upon the MSc Issues in brain and behaviour module (SD805) also undertaken as part of this MSc in Science course, a few of the references cited within the literature review are research studies investigating the link between thyroid hormone treatment and mood and cognition.

My own experience of hypothyroidism and of the difficulties and delays that can be encountered in being diagnosed and monitored correctly and in being prescribed a treatment that enables health to be restored, and my background reading (Please see Bibliography) has led me to believe that there are many areas of controversy with regards to the way that hypothyroidism is diagnosed and treated and therefore, I feel compelled to explore these issues further.

# 1 Introduction

In this section, background information about the thyroid gland and a description of hypothyroidism and its impact will be provided.

## 1.1 The biology of hypothyroidism

### 1.1.1 *The thyroid gland and the thyroid hormones*

The neck is where the thyroid gland is found (Pluta et al., 2010, p.1402). Formed within the thyroid gland are the thyroid hormones thyroxine (3,5,3',5'-tetra-iodothyronine) (T4) and tri-iodothyronine (3,5,3'-tri-iodothyronine) (T3) to be secreted subsequently into the circulatory system (Durrant-Peatfield, 2006, p.11-13). The thyroid hormones promote metabolic activities (Gaby, 2004, p.157) and the author of this report has experience of their necessity for growth and development (Phillips and Roach, 2006). The thyroid also secretes the hormone calcitonin which reduces bone breakdown (Stamato et al. 2000, p.177&179).

### 1.1.2 *The feedback mechanism to regulate thyroid hormones*

If the thyroid hormones in the blood serum become insufficient, a feedback mechanism forces the hypothalamus to issue thyrotrophin release hormone (TRH) thus prompting the pituitary to produce thyroid stimulating hormone (TSH) to trigger the thyroid gland to turn up thyroid hormone release, whilst sufficient thyroid hormones in the serum have the reverse result (Durrant-Peatfield, 2006, p.9-10).

### 1.1.3 *Types of hypothyroidism*

Hypothyroidism can be induced by failure of the thyroid or problems with the pituitary or harm to the hypothalamus which would result in primary, secondary and tertiary hypothyroidism respectively (Kostoglou-Athanassiou and Ntalles, 2010, p.82&84). Damage to the thyroid can be as a result of autoimmune attack by autoantibodies (Kostoglou-Athanassiou and Ntalles, 2010, p.83). According to Tjørve et al. (2007, p.913), manifestations of hypothyroidism can result from inadequate thyroid hormone secretion and from diminished thyroid hormone activity at the tissue level. Tjørve et al. (2007, p.914) cite Dumitrescu and Refetoff who highlighted that the effect of thyroid hormone will be reduced if various processes such as entry of thyroid hormone into the cell, the nucleus of the cell and cellular receptor binding sites and the biochemical transformation of T4 into T3 are not taking place efficiently.

### **1.1.4 Causes of hypothyroidism**

According to Laurberg et al. (2010, p.14), the ideal level of consumption of iodine within a population should remain within a narrow range to prevent the thyroid problems that can result from too low or too high an intake.

The National Health Service Clinical Knowledge Summaries (NHSCKS) (National Institute for Health and Clinical Excellence [NICE], accessed 2011, May 18) explain that iodine is required for thyroid hormone production and cite Weetman (2003) who stated that lack of iodine can result in hypothyroidism but that this is a negligible causal issue within the United Kingdom (UK). However, in a study by Vanderpump et al. (2011, p.2007), on the basis of the urinary iodine levels of teenage females within the UK, it was inferred that just over two thirds were consuming an inadequate intake of iodine.

Paradoxically, on a population level, Pedersen et al. (2002, p.4462) found that an increase in iodine consumption due to supplementation to correct an inadequate intake was correlated positively with a rise in the number of cases of hypothyroidism.

However, according to Weetman (2008, p.36), hypothyroidism is often the result of an autoimmune attack or treatment for an overactive thyroid.

Kajantie et al. (2006, p.4955) cite Hansen et al. (2006) who found that genetic factors can play a role in predisposing an individual to hypothyroidism. However, environmental factors can also be involved e.g. Pearce and Braverman (2009) have reviewed some substances in the environment that are thought to be damaging to the thyroid. In a cross-sectional study, Ostroumova et al. (2009, p.745) found a link between exposure to iodine-131 prior to the age of 18 due to the incident at Chernobyl and subsequent development of hypothyroidism.

### **1.2 The health and social impacts of hypothyroidism**

Symptoms of hypothyroidism included in a scoring system by Zulewski et al. (1997, p.773) include reduced perspiration, dryness of the skin, weight gain, slowed bowel movements, numbness of the hands and feet and decrements in hearing ability. Jaeschke et al. (1994, p.323-324) consulted published articles, medical professionals and hypothyroid individuals to determine the range of symptoms and difficulties experienced by hypothyroid individuals and questioned hypothyroid individuals to elucidate the relevance of each issue.

The list provided by Jaeschke et al. (1994, p.325) encompasses problems such as breathlessness, reduced energy, unjustified fatigue, increased sleep requirements, depressed mood, impaired concentration and memory, and loss of libido.

It can be implied that the aforementioned problems would have an impact upon the ability of hypothyroid patients who have not been diagnosed and/ or treated adequately to fulfil their roles within society.

A review by Watt et al. (2006, p.503) found that thyroid dysfunction such as under and overactivity of the thyroid was detrimental to quality of life prior to treatment and, in numerous patients, continued to have a detrimental impact despite treatment.

### **1.3 Comments on a controversy**

Diana Holmes (2002) writing from a patient's perspective has highlighted the difficulties in being diagnosed or receiving an adequate level of treatment that many hypothyroid individuals have experienced as a result of the dependence on the use of blood tests known as thyroid function tests (TFTs). Skinner (2003) writing from a doctor's perspective has raised concern about the non-diagnosis, misdiagnosis and under treatment of hypothyroidism that is taking place.

According to Weetman (2006, p.231), endocrinologists are encountering dissatisfaction and, *'the field appears to be in some turmoil'*. Therefore, the nature of this controversy will be investigated further and a sample of stakeholders with an interest in hypothyroidism will be questioned to determine what they suggest could be done to help to resolve any controversy. My objectives are outlined in the following section.

## Aim and objectives

### Aim

To determine the nature of any controversy within and between the stakeholder groups outlined below over the way that hypothyroidism is diagnosed and treated and to find out what a sample of stakeholders with an interest in hypothyroidism would suggest could be done to resolve any controversy.

### Objectives

- To carry out a literature review to determine the nature of any controversy in relation to the diagnosis and treatment of hypothyroidism within and between stakeholder groups such as medical professionals, researchers in this field and producers of guidelines in this area.
- To analyse the literature further to determine the recommendations of the above stakeholders for resolution of any controversy in relation to the diagnosis and treatment of hypothyroidism.
- To carry out interviews and distribute questionnaires in order to find out the views of a sample of individuals involved in providing information and/ or support to members of the public with hypothyroidism (via charities/ voluntary organisations/ patient support groups) regarding the nature of any controversy in relation to the diagnosis and treatment of hypothyroidism.
- To determine the recommendations of the aforementioned respondents for resolution of any controversy in relation to the diagnosis and treatment of hypothyroidism.
- To make recommendations regarding the need for research and dialogue to resolve any controversy over the way that hypothyroidism is diagnosed and treated (if applicable) on the basis of the suggestions put forward by respondents.

## 2 Methods

This project has been undertaken via a literature review and interviews/ questionnaires.

### 2.1 Methodology for carrying out the literature review

The Open University (OU) library was used to initiate the search for relevant articles within the literature on 19<sup>th</sup> February 2011. Various OU library search facilities and a wide variety of search terms were used (Please see Appendix H). It was not practicable to undertake a comprehensive analysis. Furthermore, information about the nature of the views held was sought but information about the proportion of individuals within each stakeholder group holding a particular view was not evaluated.

### 2.2 Methodology for designing the questionnaires/ interview plan and distributing the questionnaires and carrying out interviews

A search within the OU library and internet was carried out in order to identify charities/ voluntary organisations and hypothyroid patient support groups based in the UK providing information and/ or support to members of the public with hypothyroidism. As a result of information from the organisations found in this way, a few further organisations/ groups were identified. The contact details of key contacts in a position to pass on correspondence to the other individuals involved in each organisation/ group were sought.

Prior to designing the draft questionnaire/ interview plan, an article regarding personal data usage (The Open University, S802, 2003) was consulted which contained advice on the Data Protection Act 1998 in order to ensure that the covering letter/ covering information was appropriate. The design of the questionnaire was inspired by some of the research that has been cited within the literature review.

In the opinion of Taylor-Powell (1998, p.14), a piloting stage prior to finalisation of the questionnaire layout is imperative. As a result of a piloting stage and discussions with my tutor, changes were made to the draft covering letter/ information and draft questionnaire/ interview plan. This process was more time consuming than anticipated.

Key contacts at the organisations identified were contacted by email and/ or telephone to confirm that they were happy for others within their organisation to be contacted/ to forward information to others within their organisation and that no further permissions were required. The information that was provided to them is shown in Appendix B.

Contact was made or attempted with ten representatives in total, five of whom agreed to forward an email/ pass a message on to others involved in running their organisation/ group. The email that was forwarded on is shown in Appendix C.

According to Boynton and Greenhalgh (2004), if all questionnaires are presented in the same way, presentation is standardised and hence the questionnaire is more reliable, however, during the piloting stage, one volunteer completed the questionnaire by interview then self-completion and another followed the reverse sequence and the type of responses were similar despite the methods of presentation and it was decided that providing choice would increase the number of respondents available without impacting upon questionnaire reliability.

If potential respondents requested an interview/ telephone interview, the covering information and questionnaire adapted for this purpose in Appendix D was used. Likewise, the same covering information and questionnaire underwent adaptation for both posting and emailing as shown in Appendix E and F respectively as the availability of the latter option seemed to be expected. When conducting interviews, responses were noted manually but only 5 interviewees agreed to have their replies read back to them.

There were 27 respondents in total, the majority of whom had elected to be interviewed and a great deal of qualitative information was obtained. As mentioned by Taylor-Powell (1998, p.6), open-ended questions can produce a wide range of responses which can be difficult to evaluate. A paper by Braun and Clarke (2006) was consulted which provides advice on carrying out a thematic analysis and therefore, the information provided within the completed questionnaires was broken down into separate pieces of information which were tabulated, arranged in a more logical order and codified both in the margin of the questionnaires and within the tables so that the original information could be located more easily. For brevity, this process was repeated and certain categories of information were merged and recoded. Subsequently, on the basis of guidance provided by Braun and Clarke (2006), the separate pieces of coded information throughout the completed questionnaires were drawn together to create a series of themes. Statistical analysis would have been inappropriate. The tables of results and a log of activities undertaken can be found in Appendix G and H respectively.

### **3 Literature review: Dispute between researchers/ medical professionals and guideline producers over the way that hypothyroidism is diagnosed and treated**

A literature review has been carried out to determine the nature of any controversy in relation to the diagnosis and treatment of hypothyroidism within and between stakeholder groups such as medical professionals, researchers and guideline producers in this area. In this section, the information found will be reviewed thus fulfilling one of my objectives.

The National Institute for Health and Clinical Excellence (NICE) has not produced guidance regarding the diagnosis and management of hypothyroidism (Personal emails from the Department of Health, 2011 and the National Institute for Health and Clinical Excellence, 2011). The NHSCKS (NICE, accessed 2011, May 18) provide advice on dealing with hypothyroidism for use by NHS medical practitioners based in England only. Guidelines for the UK have been produced jointly by the Association for Clinical Biochemistry (ACB), the British Thyroid Association (BTA) and the British Thyroid Foundation (BTF) (Beastall et al., 2006) and a statement has been issued by the Royal College of Physicians (RCP) et al. (2008). However, some of the contents of the guidelines by the ACB et al. (Beastall et al., 2006) and the statement by the RCP et al. (2008) have been challenged within the guidelines produced by the Thyroid Special Interest Group of the British Society for Ecological Medicine (BSEM) (2010) thus throughout the literature review, examples of such challenges have been cited.

The aforementioned documents will be discussed within this section but it was beyond the scope of this project to discuss all the advice, position statements and commentaries available on this topic and all the guidelines available in countries other than the UK, although certain ones will be mentioned for purposes of comparison only. Furthermore, when citing references, it was not practicable to specify the position of the author each time e.g. whether the author was a researcher and/ or a medical professional.

### **3.1 Controversy regarding the definition of subclinical and clinical/ overt hypothyroidism**

McDermott and Ridgway (2001, p.4585) describe subclinical hypothyroidism (SH) as a condition in which the free T4 level (FT4) and free T3 level (FT3) within the serum of the blood remain within the reference range (RR) despite a rise in the TSH.

In their consensus statement, Vanderpump et al. (1996) describe SH as a T4 level within and a TSH level above the RR and absence of symptoms. The term SH seems to suggest that signs and symptoms are absent but McDermott and Ridgway (2001, p.4585) cite research by Canaris et al. (2000) and Zulewski et al. (1997) indicating that just under a third of individuals with SH could be symptomatic. In the opinion of Mohanty et al. (2008, p.281), the presence of elevated anti-thyroid peroxidase antibody levels despite a TSH level within the RR is an indication that SH is present.

As can be seen in the following sections, debates over the various methods of diagnosing clinical/ overt hypothyroidism have an impact on how the condition is defined.

### **3.2 Controversy over the need for screening for hypothyroidism in adulthood**

It is beyond the scope of this project to discuss controversy over the need to screen various adult groups including pregnant women. Instead the review will be restricted to controversy over the need for routine screening for hypothyroidism within the general population in adulthood.

Some are in favour of such screening e.g. Abu-Helalah et al. (2010, p.164-165) carried out a double-blind crossover study of the effect of synthetic thyroxine treatment (T4) versus placebo in adults from a group found to have a raised TSH level after having a TSH test as part of a British United Provident Association (BUPA) screening because they belonged to one of three groups i.e. a group aged 35-49, 50-79 and 65-79 (containing female participants who had relatives with thyroid disorders, female participants and male participants respectively). As a result of the response to T4, Abu-Helalah et al. (2010, p.164) recommend routine screening for adult hypothyroidism on the basis that about 1 in a 100 would benefit.

However, others are in opposition to such screening e.g. Vaidya and Pearce (2008, p.288) cite a 2004 recommendation statement in which it was concluded that routine screening schemes for thyroid dysfunction in adulthood could not be justified on the basis of research findings.

Some guideline producers are in favour of such screening e.g. the American Thyroid Association guidelines by Ladenson et al. (2000, p.1573) advocate TSH testing of the general adult population from 35 years of age onwards at half decade intervals.

In contrast, other guideline producers oppose such screening e.g. in their consensus statement, Vanderpump et al. (1996) conclude that routine population screening for hypothyroidism in adulthood is not warranted. The guidelines by the ACB et al. (Beastall et al., 2006, p.18) do not advocate schemes to screen for hypothyroidism within the general population in adulthood; and the NHSCKS (NICE, accessed 2011, May 18) do not advocate such screening.

Therefore, both researchers and guideline producers appear to be divided on the issue but such screening is not recommended by the ACB et al. (Beastall et al., 2006, p.18) and the NHSCKS (NICE, accessed 2011, May 18).

### **3.3 Controversy regarding the way that hypothyroidism is diagnosed and confirmed**

According to the charity Thyroid Patient Advocacy (TPA) (2010a, p.4), a Public Enquiry into the inadequate diagnosis and treatment of hypothyroid patients within the population is required. The reliability of the TSH test on its own to diagnose hypothyroidism has been questioned e.g. Wheatland (2010, p.458&460) claims that if there are clinical indications of hypothyroidism, treatment with thyroid hormone should be instituted and asserts that a positive response indicates the presence of hypothyroidism more reliably than the TSH test and cites research by Wikiland et al. (2001) and Faglia et al. (1979) to demonstrate that the TSH test does not detect all cases of primary hypothyroidism and fails to detect secondary/tertiary hypothyroidism respectively.

In correspondence to the *BMJ*, Price and Weetman (2001, p.798) comment that secondary/tertiary hypothyroidism would be indicated by a reduced FT4 level despite a TSH level within the RR but that this same pattern would be prevalent due to other illnesses; this comment demonstrates that the TSH test needs to be used in conjunction with the FT4 level for secondary/ central hypothyroidism to be detected and that on its own the TSH can give rise to false negatives but even in conjunction with the FT4 test can give rise to false positives.

The examples outlined below show that various factors can have an impact upon TSH levels. Surks et al. (2005, p.5492) cite a range of studies demonstrating that factors such as timing, prior food consumption and sleep patterns can alter the TSH.

De Groot (1999, p.151) describes how illness can lead to a decrease in T4 and T3 levels as a result of non-thyroidal illness syndrome. In addition, De Groot (1999, p.157) cites research by Bianco et al. (1987) in animals demonstrating that high glucocorticoid levels as a result of a stressor can reduce TSH and thyroid hormone levels.

Furthermore, according to other research cited by De Groot (1999, p.158), a certain cytokine (i.e. a substance within the body that can trigger inflammation) can lower TSH and T3 levels but raise the thyroid hormone metabolite reverse T3 (3,3',5',-tri-iodothyronine) (rT3). This is of concern since Forestier et al. (2009, p.207) carried out a study on a sample of the population who were 65 years of age and above and who were living within the community and found that there was an inverse correlation between levels of rT3 and survival time within the duration of the study.

In light of the aforementioned factors that can impact upon TSH levels, it is unsurprising that in a study by Khromova and Gray (2008, p.36), it was found that 30% of trainee doctors desired more training in the use of the TSH test.

Even the guidelines by the ACB et al. (Beastall et al., 2006, p.17) cite research by de los Santos et al. (1989) demonstrating that the TSH test does not have a sensitivity/ specificity of 100%; this indicates that both false positives and negatives can occur. The existence of false positives is acknowledged in the NHSCKS (NICE, accessed 2011, May 18) by the statement that if hospital inpatients have a raised TSH level, it could be due to non-thyroidal illness.

Guideline producers have backed the use of the TSH in conjunction with the FT4 test e.g. the guidelines by the ACB et al. (Beastall et al., 2006, p.24) state that both the FT4 and the TSH test are needed in order to diagnose primary hypothyroidism.

Likewise, the RCP et al. (2008) state that such a diagnosis requires the tests for FT4 and TSH, and if the FT4 is not out of its RR, T4 is recommended in certain circumstances such as when the TSH level exceeds 10 mU/L and they comment that saliva, urine and temperature tests to identify the presence of hypothyroidism aren't backed by scientific findings.

However, Baisier et al. (2000, p.105&111) found an inverse relationship between the level of the FT3 in urine over a 24 hour period and the number of symptoms of hypothyroidism experienced. Furthermore, the charity Thyroid UK (Accessed 2011, August 1) reported in May 2010 that their study investigating the relative efficacy of blood and urine tests for detecting thyroid problems/ gauging clinically apparent symptomology was nearing completion. Trustees for Thyroid UK provided information on the way in which their study was planned and carried out for an interview with the organisation INVOLVE who were interested in the fact that the study had been planned and managed by hypothyroid patients (Thyroid UK, 2010, p.6).

TFTs which would include the blood tests for TSH, FT4 and FT3 have been criticised for their lack of correlation with symptoms e.g. Fraser et al. (1986, p.808) found that in individuals taking T4, there was no reliable correlation between TFTs and symptoms of hypothyroidism except in severe cases. In addition, according to Chopra (1997, p.331), non-thyroidal illness syndrome can cause changes in TFTs that can give rise to false positives or negatives for thyroid dysfunction.

However, the use of clinical methods for the diagnosis of hypothyroidism has been investigated by Zulewski et al. (1997, p.773&776) who developed a means of scoring the clinical picture of hypothyroidism but concluded that it was not adequate for diagnostic uses. Likewise, the possibility of the existence of clinical hypothyroidism in the absence of biochemical hypothyroidism is opposed e.g. according to Weetman (2002), an individual does not have hypothyroidism, if their TSH and FT4 are within the RR even if they are symptomatic. The RCP et al. (2008) state that the presence of primary hypothyroidism cannot be pronounced unless confirmed by the FT4 and TSH tests and according to the NICE (NICE, accessed 2011, May 18), TSH and FT4 levels within the RR rule out hypothyroidism.

Individuals who consider themselves to be clinically hypothyroid but biochemically euthyroid have been criticised e.g. Toft and Beckett (2003, p.295) describe such patients as a '*vociferous minority*' whose symptoms could have a '*psychosocial*' cause. Weetman (2006, p. 232) asserts that most individuals experiencing the apparent symptoms of hypothyroidism in the absence of the confirmatory blood tests who wish to be treated with thyroid hormone are suffering from '*somatoform disorders*' but the evidence upon which this assertion is based is not specified.

In addition, Todd (2009, p.656) describes the assertion that many individuals have clinical hypothyroidism in the presence of biochemical euthyroidism as belonging to a '*vociferous school of thought*' and suggests that other reasons for any symptoms need elucidation.

However, others believe clinical hypothyroidism in the absence of biochemical hypothyroidism could be explained by thyroid hormone levels that are within the RR in the blood but inadequate within the tissues e.g. on the basis of various references, Schäffler (2010, p.829) explains that there can be differences in the gene coding for the deiodinase enzyme responsible for catalysing the biochemical transformation of the precursor thyroid hormone T4 into the potent thyroid hormone T3 and speculates that if individuals had a less efficient version of the enzyme within their tissues, it could result in insufficient levels of T3 being produced.

Tjørve et al. (2007) have reviewed a range of references to present a few factors that would lead to a reduction in thyroid hormone activity at the tissue level that would not necessarily be detected by TFTs and hypothesise that the resulting acquired thyroid hormone resistance could have a higher prevalence than the rare congenital version of the condition.

The physician consensus of the International Hormone Society (IHS) (Accessed 2011b, May 17) backs the possibility that some individuals may have overt hypothyroidism in the absence of biochemical confirmation on the basis that the TFT RRs are too wide.

As exemplified by the following two citations, researchers are divided over whether clinical hypothyroidism in the presence of biochemical euthyroidism warrants treatment.

Skinner et al. (2000) conducted an intervention study which demonstrated that some individuals have clinical hypothyroidism in the presence of biochemical euthyroidism and T4 can be of benefit. At the start of the study, the participants in the study had an average of approximately 13 symptoms/ signs of hypothyroidism and had been suffering with symptoms of hypothyroidism for three quarters of the preceding decade on average. However, T4 was administered and by the end of the study period the participants had an average of three symptoms/ signs only. The study's design did not permit any influence of the placebo effect to be ruled out but it was pointed out by the authors that some non-subjective parameters were evaluated and that many of the participants had previously tried an assortment of remedies to no avail.

Conversely, Pollock et al. (2001, p.891) conducted a double-blind crossover study in which individuals who were biochemically euthyroid but had some symptoms of hypothyroidism were allocated to receive T4 at the start of the study then placebo at the end of the study or vice versa and the authors concluded that any improvements were due to the placebo effect.

It should be noted that the minimum threshold for inclusion in the study by Pollock et al. (2001, p.891) was to have been experiencing only three of the seven symptoms of hypothyroidism listed by the researchers for a period of half a year i.e. ten symptoms less than the average number of symptoms being experienced by the participants at the start of the study by Skinner et al (2000, p.118).

Commentary within the literature has also demonstrated that there is an unwillingness to treat individuals who have symptoms of hypothyroidism but are biochemically euthyroid as shown by the following examples. In correspondence to the *BMJ*, Shepherd (1997, p.814) suggests that providing T4 to individuals with symptoms of hypothyroidism who have TFTs within the RR is acceptable in a clinical trial but unacceptable in clinical practice and could lead to detrimental consequences and legal action against the doctor concerned.

Owen and Lazarus (2003, p.259) state that providing T4 to individuals who appear to be hypothyroid on the basis of symptoms but not on the basis of their biochemistry involves widely acknowledged risks but they advocate trialling T4 in certain circumstances in individuals found to have SH. However, whether an individual would be classified as being clinically hypothyroid but biochemically euthyroid or would be described as having SH depends on where the upper limit of the TSH RR lies and as can be seen from the citations within Section 3.4, there is dispute over where this boundary should be positioned.

Those who advocate treatment of individuals who are clinically hypothyroid but biochemically euthyroid evoke criticism e.g. Allahabadia et al. (2009) allege that there has been a rise in the number of patients being provided with a diagnosis of hypothyroidism despite having TFTs within the RR but they do not cite evidence for this claim.

Kendall-Taylor (2001/ 2002, p.7) warned of the existence of websites which are in agreement with the provision of treatment to individuals who are clinically hypothyroid despite TFTs within the RR and suggested that such websites should be observed so that countermeasures could be initiated if this became necessary.

<sup>1</sup>Burne (2008, January 8) recounts the situation faced by Dr Skinner who was called before the General Medical Council (GMC) for treating individuals who were clinically hypothyroid but biochemically euthyroid, and despite being found to be impaired by the GMC, the GMC permitted Dr Skinner to carry on treating such individuals, hundreds of whom had written letters in his defence and many of whom had provided verbal testimonies in praise of his treatment protocols. Thus by their decision, the GMC confirmed that it was permissible to provide T4 to individuals who are clinically hypothyroid but biochemically euthyroid and set a precedence to this effect. Furthermore, others are in favour of providing treatment to such patients as demonstrated by Skinner (2007, p.12-13) who sent a questionnaire to medical practitioners working in the field of endocrinology and reported that 12% of respondents admitted that they had given treatment for hypothyroidism to one or more patients whose FT4 and TSH levels were within the RR.

The guidelines by the BSEM (2010, p.2) permit the commencement of thyroid hormone treatment when the individual is suffering from the symptoms of hypothyroidism even if their TFTs are just within the RR.

### **3.4 Controversy regarding the TSH range**

As demonstrated by the citations within this section, an issue of controversy is whether the upper limit of the TSH range should be narrowed which would mean that some individuals who have a TSH level within the TSH RR at present would then have a TSH level situated above the RR. Wartofsky and Dickey (2005, p.5483) refer to research demonstrating that the mean TSH level of a sample of a population with adequate iodine intake was 1.5 mU/litre (mU/L) and assert that studies demonstrating higher means and correspondingly higher upper boundaries for the RR are based on population samples that contained subjects with thyroid problems. In addition, Wartofsky and Dickey (2005, p.5486-5487) cite studies in support of their stance in favour of narrowing the TSH RR and suggest an upper limit of 2.5 so that individuals likely to develop clinical hypothyroidism can be identified and retested and treated promptly if necessary.

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<sup>1</sup> Footnote: Since the submission of this project, with reference to Dr Skinner, a General Medical Council Fitness to Practise Panel (2011) concluded, "However the Panel cannot fail to take notice of the fact that your approach to treatment, whereby both clinical and biochemical parameters are assessed, falls within the guidelines of *Good Medical Practice*." and "This Panel has therefore determined that your fitness to practise is no longer impaired by reason of your misconduct or deficient professional performance." Reference: General Medical Council, Fitness to Practise Panel, 2011, 17 November, Day Four, pp. 9-10.

According to Spencer et al. (2007, p.4238), the RR for TSH can demonstrate a higher upper reference interval than it should if it is determined on the basis of a population sample encompassing subjects with thyroid disorders that are not apparent on the basis of the levels of the antibodies associated with thyroid dysfunction.

Furthermore, Hamilton et al. (2008, p.1224-1225), on the basis of their study in a sample of subjects without thyroid dysfunction (as demonstrated by medical history, the absence of the antibodies associated with thyroid dysfunction and no detectable abnormalities of their thyroid during external evaluation and an examination via ultrasound) conclude that the upper boundary of the TSH RR should be reduced to 4.

However, the sample of subjects studied had been exposed to iodine-131 as a result of being based in Hanford although the authors cite their previous studies which indicated that this exposure had not impacted upon thyroid health (Hamilton et al. 2008, p.1226-1227). However, there could have been effects that were not evaluated in this study or had preferentially impacted upon individuals who had declined to participate.

Surks et al. (2004, p.231) cite the National Academy of Clinical Biochemistry's guidelines in 2002 in which the potential need to set the upper reference interval of the TSH RR at 2.5 mIU/L is raised.

However, Surks et al. (2005, p.5489-5490) argue against reducing the upper reference interval of the TSH RR on the basis that the number of false positives would increase and that the advantages and disadvantages of treating this group have not been fully elucidated.

Subsequently, Surks and Boucai (2010, p.496) have reviewed various studies and concluded that different ethnic groups and generational groups should have their own TSH RR.

However, the ACB et al. (Beastall et al., 2006, p.56) do not recommend a reduction in the upper reference interval of the TSH range.

### **3.5 Controversy over whether subclinical hypothyroidism warrants treatment**

In addition to controversy over the TSH range, there is debate over whether SH is harmful and whether treatment is required on a routine basis as exemplified by the citations within this section.

McDermott and Ridgway (2001, p.4585-4587) assert that SH usually warrants thyroid hormone treatment and cite various pieces of research indicating that individuals with SH are at increased risk of cardiovascular complications.

In a randomised, double-blind study, Monzani et al. (2004, p.2099) found that a group of individuals with SH had greater thickening within the wall of their carotid artery compared to controls of the same gender and age but when the former group was provided with T4 or placebo for six months, the thickening within the carotid artery wall decreased significantly in the group on T4.

Iqbal et al. (2006, p.53) found that an increase in TSH concentrations correlates with an increase in cholesterol levels and when they undertook a double-blind study in individuals with SH, T4 resulted in a lowering of cholesterol in comparison to a placebo.

Adrees et al. (2009, p.298&302) found that providing T4 to a group of women with SH for a year and a half improved certain markers of cardiovascular health and kidney function so that they became similar to the values found within the control group of females without health problems but as the authors noted, there was no placebo-treated group.

Bono et al. (2004, p.59) found that when a group of women with SH were treated with T4 for half a year, TSH levels decreased and a beneficial effect upon mood was found, and the authors of the study recommended that SH should be treated even if there are no symptoms present, however, the study's design did not encompass a placebo-treated group.

In a double-blind study by Samuels et al. (2007, p. 2545) with a crossover design, a group of female participants with hypothyroidism were randomly allocated to have their thyroid medication kept the same or reduced so that they developed SH to see if this impacted upon their symptoms, mood and cognition. Samuels et al. (2007, p.2546-2547) state that on the morning of their preliminary visit, participants didn't have their T4 prior to having blood tests and completing various tests including an evaluation of cognition but do not specify whether participants had T4 and/ or food prior to the latter test during this or subsequent visits.

Despite this, Samuels et al. (2007, p.2549) found that participants had poorer health, mood and working memory when on the phase of the trial during which SH was induced; a result which does raise ethical concerns.

Conversely, examples of research which demonstrate that SH doesn't necessarily require treatment also exist e.g. Jorde et al. (2006, p.145-146) carried out a double-blind trial in which participants with SH were randomly allocated to receive T4 or placebo for 12 months and according to the authors of the study, T4 was not found to have impacted upon cognitive abilities or symptoms of hypothyroidism, however, according to the study's authors, subjects were classified as having SH on the basis of their TFT results and the absence of clear symptoms of hypothyroidism and it can be inferred that this definition of SH would have reduced the possibility that any changes in symptoms would be significant.

Looking at a cross section of the population in Osaka, Takashima et al. (2007, p.191&194) were unable to demonstrate that there was a significant link between SH and lipid levels within the blood and recommended against treating SH.

There are also differences in the conclusions of reviews and meta-studies as shown in the following examples.

As mentioned previously, McDermott and Ridgway (2001, p.4585) have written a review article in which they recommend treatment for SH for the majority of patients. In addition, a meta-study by Rodondi et al. (2010, p.1365) merged the findings of 11 cohort studies and in the subjects with SH, a link was found between raised TSH values and the likelihood of a fatality resulting from coronary heart disease.

In contrast, Col et al. (2004) consider that not treating SH (in those with a TSH level that does not exceed 10 mIU/L is probably not detrimental to the individual concerned and state that if symptoms of hypothyroidism are not apparent, there is a lack of proof that provision of treatment is beneficial to the individual concerned but subsequently cite studies indicating that not treating SH in a pregnant woman could be harmful to her offspring.

As part of the Cochrane Database of Systematic Reviews, Villar et al. (2007, p.1-2) carried out a review of 12 randomised controlled trials (RCTs) investigating the impact of providing T4 to individuals with SH and concluded that it did not have a significant impact on symptoms and quality of life but conceded that certain findings suggested that treatment was beneficial to the cardiovascular system.

In their review of double-blind studies evaluating the efficacy of T4 treatment in individuals with SH, Biondi and Cooper (2008, p.93) comment that although the findings were contradictory, there were variations in the inclusion criteria, methodology and the TSH levels reached at completion of the studies.

In addition, as the remaining citations within this section demonstrate, guideline producers disagree on whether SH is problematic and usually requires treatment.

Gharib et al. (2005, p.581-582) on behalf of three organisations in the field of endocrinology or thyroid disorders appraised the findings of a consensus conference commissioned by the same three organisations and differed with the consensus conference's view that SH should not be treated on a regular basis if the TSH concentration has not exceeded 10 mIU/L.

The guidelines by the ACB et al. (Beastall et al., 2006, p.19&27) do not advocate treatment of SH if the TSH level is between the upper limit of the TSH RR and 10 mU/L unless the patient is pregnant or the medical practitioner deems a trial of T4 to be appropriate in the patient concerned.

Likewise, the NHSCKS (NICE, accessed 2011, May 18) do not advocate treatment of an individual with SH whose TSH level is below 10 mU/L but include caveats such as the recommendation for treatment if pregnancy is being contemplated or has been confirmed and the suggestion that T4 could be trialled if the clinical picture is indicative of hypothyroidism.

Thus from the aforementioned citations, it can be seen that there is controversy between researchers and between guideline producers over whether SH usually warrants treatment.

### **3.6 Controversy regarding the recommended treatment options**

The citations within this section illustrate that some researchers have questioned the efficacy of T4.

In a study using rats, Escobar-Morreale et al. (1995, p.2828&2832) found that provision of T4 on its own at a dose that permitted the thyroid hormones in the blood to enter their RR did not result in euthyroidism in the majority of the tissues of rats whose thyroids had been removed.

Fadeyev et al. (2005, p.101) undertook research in which they found that when a group of female participants whose hypothyroidism was being treated with T4 were evaluated, at a dose that kept their TSH level within the RR, they had attained significantly higher FT4 and lower FT3 concentrations in their blood serum than in the serum of a control group.

Saravanan et al. (2002, p.577) carried out research which suggested that wellbeing amongst a proportion of individuals whose hypothyroidism was being treated with T4 and whose TSH levels were within the RR was reduced in comparison to age and gender matched controls.

Wekking et al. (2005, p.747-749) found that in individuals with primary hypothyroidism being provided with T4 whose TSH levels were within the RR, various evaluations indicated that cognitive function and wellbeing were diminished in comparison to population based standards for these parameters.

In research on a section of the population, Panicker et al. (2009a, p.575-576) found that the percentage who were anxious and the percentage who were depressed was greater amongst women being treated with T4 than amongst women who did not require T4 and the differences were statistically significant and were not impacted by corrections to compensate for factors that varied such as TSH levels.

In a study by van der Deure (2008, p.804), it was found that in study participants with primary hypothyroidism, there was a link between possession of certain versions of the gene for the biological structure involved in transferring T4 from the blood to the brain and indications of tiredness and depressed mood.

Nygaard (Accessed 2011, March 30) describes T4 as potentially helpful in treating individuals with a diagnosis of primary hypothyroidism but of unconfirmed efficacy for SH but concedes that its use in treating clinical hypothyroidism is based on agreement between medical practitioners rather than the findings of RCTs and comments that the use of a placebo-treated group of clinically hypothyroid participants would be precluded due to ethical constraints.

In addition, Blakesley (2005, p.E42-E45) has reviewed a study by Blakesley et al. (2004) that casts doubt on the reliability of tests approved by the Food and Drug Administration in the United States of America (USA) to confirm the bioequivalence of different brands of T4.

### ***3.6.1 Controversy over the use of thyroxine/ tri-iodothyronine combination treatment***

An alternative to T4 only is synthetic thyroxine and synthetic tri-iodothyronine combination treatment (T4/T3), however, the citations within this section demonstrate dispute between researchers over whether T4/T3 is superior to T4.

Walsh and Stuckey (2004, p.1487) suggest that hypothyroid individuals who believe that T4/T3 provides greater benefit than T4 may be experiencing the placebo effect.

However, Escobar-Morreale et al. (1995, p.2836) cite the earlier research finding by Escobar-Morreale et al. (1994) that T4/T3 in a physiological ratio resulted in euthyroidism throughout the tissues of rats whose thyroids had been removed; in this case the placebo effect would not be applicable.

Bunevičius et al. (1999, p.424-427) carried out a small crossover study assessing the impact of T4/T3 versus T4, but do not clarify whether participants had breakfast prior to evaluation of their mood and cognition, nevertheless, when study subjects were switched to T4/T3, certain test results demonstrated enhancements to mood and cognition.

Subsequently, Bunevicius and Prange (2000, p.167-171) re-evaluated the data in the aforementioned study excluding the findings relating to the subjects who were male or clinically depressed or who had a TSH level above the RR and found that T4/T3 was more beneficial to mood and cognitive function than T4 in the subjects who had been treated for thyroid cancer and were taking doses that were high enough to suppress their TSH levels.

In a double-blind crossover study by Escobar-Morreale et al. (2005a) comparing T4/T3 in a physiological ratio with T4 in female subjects all of whom were receiving the same T4 dose for primary hypothyroidism, the authors specify that participants had thyroid treatment when they awoke then blood tests two hours later then breakfast prior to various evaluations including tests of cognitive function and although they found that certain aspects of cognition were enhanced to a small extent, the full panel of test results did not demonstrate any benefits of T4/T3 on cognition but T4/T3 was preferred by the majority of participants.

In a double-blind crossover study by Nygaard et al. (2009, p.895-896) evaluating the relative efficacy of T4/T3 in comparison to T4 in which ongoing dose alterations were made to keep TSH levels steady and within the RR, T4/T3 resulted in beneficial enhancements to mood and quality of life in comparison to T4.

In contrast, Walsh et al. (2003) carried out a double-blind crossover study and found that hypothyroid patients who had their treatment adjusted by replacing 50µg T4 with 10µg synthetic tri-iodothyronine treatment (T3) did not experience benefits to their cognition and quality of life, but the authors of the study do not clarify whether participants had been given the opportunity to take thyroid treatment or eat before undertaking cognitive tests, furthermore, as the authors commented, the rise in the mean TSH level of participants when T4 was replaced with T4/T3 indicated that 10µg T3 is equivalent to less than 50µg T4.

Around three quarters of a decade after the aforementioned study, using the TSH results as an end point, Celi et al. (2010, p.709) found T3 to be equivalent to T4 when given at a third of the amount.

Perhaps for the study to demonstrate reliably that T4/T3 has a significantly more beneficial effect on cognition than T4, the researchers need to ensure that participants are provided with the opportunity to have had their thyroid hormone treatment then breakfast prior to tests of cognition and that the mean TSH levels are equivalent after the T4/T3 phase and the T4 phase of a crossover study.

Even in the study by Bunevičius et al. (1999, p.425-426), the authors specify that participants had their thyroid treatment but do not specify whether they had breakfast before tests of cognition but comment that average TSH levels in each group of participants were comparable after either treatment regime.

Whilst, in the study by Escobar-Morreale et al. (2005a), participants had thyroid hormone treatment and later had breakfast prior to having their cognitive performance evaluated but the study included two different T4/T3 phases using a different T4/T3 dose and ratio for each phase and in one phase the mean TSH level fell and in the other phase the mean TSH level rose in comparison with the T4 phase indicating that neither dose was comparable with the dose in the T4 phase.

Siegmund et al. (2004, p.750-751) carried out a double-blind crossover trial to compare T4 with T4/T3 and the latter treatment was not found to have a more beneficial effect upon mood and cognitive function than T4, however, participants were healthy and the study was small.

In a double-blind study by Appelhof et al. (2005a, p.2666&2673), over half of participants given T4/T3 in a 5 to 1 ratio considered it to be superior to T4 but this was not backed by objective findings other than weight loss but on the basis of TSH test results, the authors suggested that some participants had been provided with excess T4/T3.

Fadeyev et al. (2010) carried out research into the effect of treating hypothyroid female participants with either T4/T3 or T4 for six months upon a range of biological and clinical endpoints and found that after the former treatment, total cholesterol had fallen significantly but an indicator of bone breakdown had risen significantly.

Escobar-Morreale et al. (2005b, p.4946&4950) carried out a review of nine studies investigating the relative efficacy of T4/T3 and T4, and T4/T3 seemed to be superior in a solitary study but participants preferred T4/T3 in three of the five studies that had evaluated this parameter. This indicates that on an objective basis, T4/T3 is not deemed to be superior to T4, but on a subjective basis, T4/T3 is favoured.

Joffe et al. (2007, p.379) carried out a meta-study of nine research studies comparing the relative efficacy of T4 and T4/T3 on psychiatric parameters and concluded that the criteria considered had not permitted researchers to demonstrate the superiority of either treatment.

Many of the same studies were included in a meta-study by Grozinsky-Glasberg et al. (2006, p.2592) who looked at various parameters related to both mental and physical health and concluded that T4/ T3 was not superior to T4.

Wiersinga (2009, p.955) suggests that the quality of studies evaluating the effect of including T3 with T4 might be enhanced if they were designed to keep the FT4 and FT3 levels within the blood similar to the levels in individuals with a functioning thyroid and if slowly absorbed forms of T3 were used.

Appelhof et al. (2005b, p.6296) did not find a correlation between possession of one of two different versions of the gene for type 2 deiodinase (an enzyme that converts T4 into T3) being considered and cognitive performance on T4 or satisfaction with T4/T3.

Peeters et al. (2006, p.658-659) have reviewed research into different versions of the genes for deiodinase 1, 2 and 3 involved in metabolising T4 by converting it to T3 and/ or rT3 (depending on which deiodinase is being considered) and the impact that different versions of these genes can have on thyroid hormone levels in the serum. In a study by Panicker et al. (2009b, p.1623), a particular version of the gene for deiodinase 2 possessed by 16% of participants was linked with the poorest mental wellbeing on T4 and the most enhancements to this parameter on T4/T3 but did not influence serum thyroid hormone concentrations.

Many guidelines do not advocate T4/T3 e.g. the ACB et al. (Beastall et al., 2006, p.26) provide advice on monitoring T3 but cite a range of studies to back up the contention that it cannot be stated conclusively that T4/T3 is superior to T4 and the RCP et al. (2008) advise against providing T3 to hypothyroid patients with the caveat that endocrinologists should be permitted to treat with T3 in certain cases. The NHSCKS (NICE, accessed 2011, May 18) do not advocate T3/T4 and refer to a review by Chao et al. (2009) in which cognitive function was enhanced on T4/T3 in comparison to T4 and the difference was statistically significant but was declared to be clinically insignificant.

However, some guidelines do advocate T4/T3 e.g. in guidelines by the BSEM (2010, p.3), it is recognised that T3 can facilitate the recovery of certain hypothyroid individuals. Furthermore, the physician consensus of the IHS (Accessed 2011a, May 17) advocates the use of T4/T3.

Again, the above citations reveal ambiguity and dispute over the relative efficacy of T4 and T4/T3 both between researchers and between guideline producers.

### ***3.6.2 Controversy over the use of natural desiccated thyroid treatment***

Similarly, there is debate over whether natural desiccated thyroid treatment (NDT) (a treatment derived from dried porcine thyroid glands) is superior to T4 as shown by the citations discussed within this section.

Baisier et al. (2001, p.159&163) found NDT to be superior to T4 in hypothyroid subjects who had not recovered on T4 and although the study was not double-blind, the authors believed that such a trial would be unethical and considered the magnitude of improvement to be greater than what would be achievable via the placebo effect alone.

Das et al. (2007) describe three cases in which hypothyroid patients were unable to recover on T4 but were responsive to NDT and suggest that the latter treatment may be of use to certain patients. In a study by Lewis et al. (2008), it was found that patients who had failed to recover on synthetic thyroid hormones had benefitted from taking NDT.

Di-iodothyronine (T2) and mono-iodothyronine (T1) are also present in NDT (BSEM, 2010, p.4) and in a study in rats by Lombardi et al. (2009, p.E497), T2 appeared to promote oxidation of fatty acids within the mitochondria.

In addition, TPA is collecting questionnaire responses from hypothyroid patients who were unable to recover on T4 but able to recover when T3 and/ or NDT were provided within their treatment protocol (Thyroid Patient Advocacy, 2010b, p.1).

Nevertheless, opponents exist e.g. in correspondence to the *BMJ*, Williams (1997, p.814) speculates that doctors who prescribe NDT rather than synthetic thyroid hormones are doing so to provide ‘*mystique*’. Weetman (2006, p.233) suggests that T4 should be used for the treatment for hypothyroidism on a routine basis in preference to NDT.

This dispute is reflected in the conflicting advice given within guidelines e.g. the use of NDT is not endorsed by the RCP et al. (2008) but in the guidelines by the BSEM (2010, p.2&4), it is recognised that numerous individuals with hypothyroidism have found NDT to be of benefit and advice about prescribing this treatment is provided. The physician consensus of the IHS (Accessed 2011a, May 17) advocates the use of NDT.

However, according to Vaidya and Pearce (2008, p.288), research has not been undertaken to compare T4 and NDT in which participants are randomly allocated to receive one or the other; therefore, although the superiority of NDT has not been confirmed in this way neither has the superiority of T4 over NDT. Hence, controversy over the relative efficacy of T4 and NDT remains unresolved.

### **3.7 Controversy regarding the monitoring and adjustment of treatment**

In a study of data held on the patients of general practitioners at clinics in an area of Wales, Okosieme et al. (2010) found that on the basis of TSH results, nearly a fifth of hypothyroid sufferers were classified as receiving too much thyroid hormone and nearly a fifth of hypothyroid sufferers weren't receiving sufficient thyroid hormone.

However, even for those hypothyroid patients who are classified as receiving the correct dose of thyroid hormone treatment on the basis of TFTs within the RR, some question whether adjusting the dose of thyroid hormone until TFTs are within the RR is adequate for all hypothyroid patients as shown by the following citations.

A consensus statement by Vanderpump et al. (1996) stated that in order to render patients clinically euthyroid, some require adjustments in their T4 dosage until their T4 and TSH levels are elevated and below the RR respectively.

With regards to FT4, Bayliss (1996, p.1488) commented in a letter to the *BMJ* that for many individuals with hypothyroidism, their serum FT4 levels need to be approaching or just exceeding the top of the RR for optimal wellness to be achieved.

With regards to T3, Alevizaki et al. (2005, p.637) found that when average TSH concentrations in a group of hypothyroid subjects and a group of euthyroid controls were of similar values, in the former group the average FT4 and T4 concentrations were greater and the average T3 concentrations were less than in the latter group and the differences were statistically significant.

Questions have been raised regarding the appropriateness of adjusting thyroid hormone treatment on the basis of the TSH levels rather than clinical symptoms e.g. O'Reilly (2010) cites research by Cotton et al. (1971) in which the TSH test was first used to monitor T4 therapy and it was concluded that by adjusting dosages on the basis of TSH levels rather than on the basis of symptoms, T4 doses could be reduced by around 50% but an evaluation of the symptoms being experienced by the patients concerned following this reduction was not provided; this implies that the correlation between TSH levels and the clinical picture was not evaluated at the outset.

O'Reilly (2010) recommends that the T4 dose is adjusted on the basis of the clinical picture and T3 levels rather than on the basis of the TSH level.

In contrast, Weetman (2008, p.40) suggests that individuals with hypothyroidism should not be permitted to have treatment at a dose that is high enough to keep their TSH level beneath the RR other than in certain circumstances such as when counteracting thyroid cancer.

In the NHSCKS (NICE, accessed 2011, May 18), it states that some hypothyroid individuals remain symptomatic despite treatment with T4 and TFTs within the RR but it also states that if T4 restores biochemical euthyroidism but symptoms remain, causes other than hypothyroidism must be elucidated.

Likewise, the RCP et al. (2008), state that if someone with primary hypothyroidism is on T4, once the dose has been adjusted so that their TSH concentration has stabilised at an appropriate position within the RR, the reason behind any ongoing symptoms needs to be identified so that treatment can be provided; implying that non-thyroid causes are suspected.

In the guidelines by the ACB et al. (Beastall et al., 2006, p.26-27), it is recommended that TFTs and symptoms should be considered when the T4 dose required is being elucidated, however, despite citing a reference by Carr et al. (1988) that indicates that some hypothyroid patients feel better when their TSH is suppressed, the guideline authors still recommend that in these circumstances the T4 dose is decreased gradually so that the TSH level rises and remains between the upper and lower interval of the TSH RR.

Concerns have been raised about excess T4 e.g. Crilly (2003, p.1086) in correspondence to the *BMJ* cites various studies to back his claim that providing T4 at a dose that lowers the TSH level too much could be a risk factor for thinning bones and irregular heartbeat.

Stamato et al. (2000, p.177) have cited a reference by Furlanetto et al. (1991) indicating that hypothyroidism has a negative impact on calcitonin availability and have carried out a study comparing the total bone calcium of women with primary hypothyroidism before and after provision of T4 or both T4 and nasal calcitonin for the period of a year and have found that total bone calcium was reduced significantly in the group on T4 for a year but was preserved in the group of participants being provided with calcitonin in addition to T4. This raises the question whether any purported link between T4 and bone thinning is due to an excess of T4 and/ or a deficiency of calcitonin.

In a retrospective study, Turner et al. (2011) found that subjects of 70 years of age and above were less likely to be experiencing a bone breakage if their T4 dose had been raised in the preceding 12 months and more likely if their dose had been reduced and the authors of the study hypothesised that the prior iatrogenic under treatment that had prompted the aforementioned upward adjustment in dose was responsible for the lower risk to the bones, and the prior iatrogenic over treatment that had prompted the aforementioned downward adjustment in dose was responsible for the higher risk to the bones. However, their hypothesis demonstrates an unwillingness to consider the possibility that increasing the treatment resulted in benefits to the bones that were not investigated.

Yet, according to the findings of a cohort study by Flynn et al. (2010, p.186), individuals being treated with T4 who have a TSH level that is suppressed or above the upper interval of the RR are more likely to break their bones or develop cardiovascular disorders.

Various factors can impact upon TFT results e.g. according to a study by Bach-Huynh et al. (2009, p.3905-3906), ingesting T4 one hour prior to the first meal of the day rather than just afterwards was linked with a significantly decreased TSH level, and Arafah (2001, p.1743) found that in postmenopausal females being provided with T4 for hypothyroidism, oestrogen treatment led to a reduction in their FT4 levels but in postmenopausal females who did not require treatment for hypothyroidism, oestrogen treatment did not impact upon FT4 levels.

Saravanan et al. (2006, p.3389) found that in hypothyroid individuals being treated with T4, there was a link between FT4 and TSH levels and indicators of mental wellbeing. However, according to the findings of a study by Müller et al. (1995, p.966), female smokers with clinical hypothyroidism were more symptomatic than non-smokers with clinical hypothyroidism even though the TSH levels of both groups were comparable.

## **4 Literature review: The views of researchers/ medical professionals and guideline producers on ways of resolving issues of dispute over the way that hypothyroidism is diagnosed and treated**

In this section, the literature has been analysed further to determine the recommendations of a sample of stakeholders for resolution of any controversy in relation to the diagnosis and treatment of hypothyroidism thereby fulfilling another one of my objectives.

### **4.1 The views of researchers/ medical professionals regarding the need for research**

Pollock et al. (2001, p.895) identified the need for a further trial to investigate the effect of providing T4 to individuals who are clinically hypothyroid but biochemically euthyroid with the proviso that it had to be on a bigger scale than their study.

McDermott and Ridgway (2001, p. 4589) called for large randomised trials to evaluate both the impact of SH and of treatment. Owen and Lazarus (2003, p.260) made the recommendation that more subjects should be included in further RCTs to evaluate the impact of treating SH with T4.

Walsh (2002, p.720) stated that there was insufficient evidence to confirm that certain hypothyroid individuals were correct in their claim that T4 was inadequate.

Bunevicius et al. (2002, p.132) recommended that further trials comparing the efficacy of T4/T3 with T4 should be on a larger scale and should include hypothyroid individuals who have been unable to recover fully on T4. Appelhof et al. (2005a, p.2673) suggested that trials comparing T4/T3 with T4 should be designed so that the participants remain euthyroid for the duration of the study.

In addition, Joffe et al. (2007, p.383) suggested that uncovering the reason why some hypothyroid individuals would rather be treated with T4/T3 than T4, even though objective parameters indicate that T4/T3 and T4 are equivalent, may need additional investigation.

Wiersinga (2009, p.956) cites a selection of studies comparing T4/T3 to T4 which included participants with spontaneous or iatrogenic hypothyroidism and comments that those with iatrogenic hypothyroidism should have been excluded.

#### **4.2 The views of guideline producers regarding the need for research**

Further research recommended in the guidelines by the ACB et al. (Beastall et al., 2006, p.68) include investigations to evaluate the TSH and FT4 ranges during pregnancy; to determine whether TFTs are suitable for the purpose of routine screening in adulthood or for diagnostic purposes in individuals who have been hospitalised; to evaluate the utility of TFTs when making dose adjustments; and to examine their efficacy in comparison to objective indicators of thyroid hormone activity at the tissue level. In addition, the guidelines by the ACB et al. (Beastall et al., 2006, p.68) recommend that further research should be carried out to compare the prognosis of individuals whose T4 dose has been adjusted so that their TSH level is between the reference intervals in comparison to individuals whose TSH level is under the lower reference interval. On the basis of the genetic study by Panicker et al. (2009b), the NHSCKS (NICE, accessed 2011, May 18) concede that T4/T3 may be superior to T4 in some individuals but suggest that more research is needed. The RCP et al. (2008) state that T4/T3 and NDT need to be the subject of additional scientific studies of a sufficient standard before they can be recommended for widespread use.

#### **4.3 The views of researchers/ medical professionals regarding the need for dialogue**

Indications that certain medical professionals weren't perceived to be promoting dialogue were found as illustrated by the following example. On the About.Com Thyroid Disease website (Shomon, M., accessed 2011, July 3) it can be seen that in 2005, Diana Holmes collected signatures from the hypothyroid community for a petition which was to be presented to the GMC to complain about the many medical professionals who were dependent on the use of blood tests for diagnosis and dismissed the clinical picture in hypothyroid individuals; failed to show consideration for the hypothyroid individuals who were not receiving treatment at all or not receiving the appropriate treatment; refused to use T3 on its own or with T4, or NDT; and were unwilling to promote clinical studies and dialogue. Nearly 3000 individuals signed the aforementioned petition (Holmes, accessed 2011, August 11).

Thyroid UK (2009, p.28) reports on the World Thyroid Register of individuals who would be willing to contribute to the cost of legal proceedings to improve the plight of the hypothyroid patient community.

Martin (2004, p.720) refers to a range of references that provide examples of the ways in which those who challenge mainstream medicine from within can be marginalised such as by being denied medical positions, funding, opportunities for publication, and ongoing registration as a medical professional. One can question whether such behaviours have been or are being used to quash dissenting views and stifle dialogue with regards to how hypothyroidism should be diagnosed and treated.

Weetman (2006, p.232) asserts that with regard to research to determine whether the TSH RR should be altered and to evaluate whether individuals with SH should be treated, meeting the costs involved is likely to be challenging. Grozinsky-Glasberg et al. (2006, p.2597) speculate that additional studies investigating the efficacy of T4/T3 are not required on the basis that if any findings are pooled with the current overall findings that have failed to demonstrate the superiority of T4/T3, the conclusions that have already been drawn are unlikely to be overturned. The former comment indicates that there are obstacles related to finance and the latter comment shows that preconceptions exist.

With regard to prevention of publication, difficulties have been documented previously e.g. Zalewski (1997, p.5) refers to various sources to give an account of a pharmaceutical company's attempt to prevent publication of research demonstrating that a brand version of T4 was not superior to generic versions. In addition, Zalewski (1997, p.2) reports on an article in which an editor based in the USA related their struggle to locate thyroid specialists without monetary links to the major pharmaceutical company involved in producing thyroid hormone treatment.

Furthermore, with reference to the threat to the registered status of medical professionals, Gaby (2004, p.168) describes how some doctors have been brought before medical boards for making a diagnosis of hypothyroidism on the basis of symptoms or for using NDT. Thyroid UK (2006, p.17) reports on the difficulties being experienced by certain doctors as a result of GMC actions.

#### **4.4 The views of guideline producers regarding the need for dialogue**

Certain guideline producers have provided some opportunities for public input whilst formulating guidelines e.g. it is noted within the guidelines by the ACB et al. (Beastall et al., 2006, p.5) that patient representatives were involved in their creation and patients participated in their review, and the draft version of the guidelines was displayed on the internet so that members of the public were permitted to make suggestions about them which led to alterations before publication of the guidelines. In addition, in the guidelines by the ACB et al. (Beastall et al., 2006, p.6), it states that after their publication, suggestions from members of the public were permitted for 12 months and a review was scheduled after 36 months but the guidelines had not been updated to confirm whether this took place.

However, within the guidelines by the BSEM (2010, p.1), it is suggested that the guidelines by the ACB et al. (Beastall et al., 2006) and statement by the RCP et al. (2008) have led to great discontentment amongst hypothyroid individuals.

#### **4.5 The views of researchers/ medical professionals regarding the need for an additional/ alternative strategy**

Villar et al. (2007, p.10) recommend additional randomised trials on a bigger scale to assess whether those with SH benefit from T4. However, Villar et al. (2007, p.10) suggest that in the interim period, the opinion of both the medical practitioner and their patient need to be taken into account. Das et al. (2007) suggest the possibility of trialling NDT in hypothyroid individuals who are unable to recover on T4.

#### **4.6 The views of guideline producers regarding the need for an additional/ alternative strategy**

The guidelines by the ACB et al. (Beastall et al., 2006, p.5) provide advice with the proviso that the medical practitioner must deal with each patient on a case by case basis and the RCP et al. (2008) state that specialists could be consulted if individuals experience ongoing symptoms despite biochemical euthyroidism even if treatment for hypothyroidism has been provided so that a reason unrelated to hypothyroidism can be found. The latter comment demonstrates the preconception that clinical hypothyroidism is ruled out by biochemical euthyroidism.

## 5 Results

All tables of results can be found in Appendix G, however, in this section a brief overview of the contents of each table has been provided.

### 5.1 Response and characteristics of respondents

#### *Table 1 (Please see Appendix G)*

This table demonstrates that there were 27 respondents in total, and two thirds were interviewed over the telephone, 3 were interviewed in person and 6 elected to self-complete the questionnaire and return it by email or post.

#### *Table 2 (Please see Appendix G)*

In this table, it can be seen that nearly two thirds of respondents were involved in running/ working for a charity/ voluntary organisation providing information and/ or support to members of the public with hypothyroidism.

#### *Table 3 (Please see Appendix G)*

In this table, it can be seen that nearly a third of respondents ran, helped to run or had previously run a hypothyroid patient support group. Not all respondents provided support via face to face meetings, some provided support via the telephone and/ or an internet forum and/ or email but included themselves in the 'yes' category. However, of 11 respondents (i.e. nearly a third of respondents) who included themselves in the 'no' category or 'no response' category, 10 were providing support via one of the methods listed above and one had provided telephone support previously.

Since some respondents filled more than one role, the sum of the respondents involved in a charity/ voluntary organisation and a patient support group came to more than 27 i.e. more than the total number of respondents.

#### *Table 4 (Please see Appendix G)*

This table provides a breakdown of the types of roles played by respondents, 12 roles within the infrastructure of thyroid charities/ voluntary organisations were filled by respondents, 39 roles involving communication with hypothyroid individuals were filled by respondents and 13 roles that involved finding/ providing and checking information were filled by respondents.

For each of the three categories of roles, some respondents filled more than one role within each category and hence the total number of roles filled came to more than the total number of respondents.

## 5.2 Responses to the questions presented

### ***Table 5 (Please see Appendix G)***

This table demonstrates that with regards to the issues listed within question 4a, which are based upon the various controversies discussed in the literature review, all or the majority of respondents considered each issue to be controversial. This demonstrates a high awareness of controversial issues among respondents.

### ***Table 6 (Please see Appendix G)***

This table demonstrates that with regard to issues of debate regarding the diagnosis, treatment and monitoring of hypothyroidism, nearly two thirds of respondents believed that the situation would be helped by an additional/ alternative strategy; two thirds believed that research would help and the majority of respondents thought that more dialogue would help to resolve the situation.

### ***Table 6(i) (Please see Appendix G)***

This table demonstrates that reservations about research were expressed by some respondents such as concerns that the type of research being carried out would not be helpful to patients, that funders and researchers were biased and that the design of the trial could skew the findings.

There was concern that research of help to patients was being ignored and that how the patient was actually feeling was dismissed.

One respondent was concerned that there was insufficient dialogue between patients and researchers and two respondents expressed concern that if dialogue did occur, the patients would be given less opportunity for input than other participants.

***Table 6(ii) (Please see Appendix G)***

In this table, reservations expressed about dialogue are outlined. Reservations included concerns about: financial and practical restraints; difficulties due to the polarised nature of the debate; unwillingness by the medical community to consider the patient's perspective; the medical community's attitude and unwillingness to have their viewpoint questioned by others. Other concerns raised related to the fact that patients weren't being given a voice, that previous attempts to engage the medical community in dialogue had brought about negative consequences for the patient and if dialogue did occur it wouldn't necessarily be of help to patients. Disagreement between campaigners was also a concern.

***Table 6(iii) (Please see Appendix G)***

Additional strategies suggested were varied and are documented in this table and include the proposition that doctors should start listening to patients and recognise the importance of clinical assessment and acknowledge that some hypothyroid patients require T4/T3 and/ or NDT and the proposition that medical practitioners need more knowledge about the condition.

***Table 7 (Please see Appendix G)***

This table provides a list of stakeholder groups and the number of respondents who thought that each stakeholder group should be involved in deciding research priorities. The majority of respondents thought that patient groups and thyroid charities should be involved. Additional stakeholder groups suggested included the Department of Health, Members of Parliament and doctors with success in diagnosing and treating hypothyroidism.

***Table 8 (Please see Appendix G)***

The most urgent research studies that respondents thought should be carried out are listed within this table. Suggestions include research into: the causes of hypothyroidism; childhood hypothyroidism; the usefulness of screening; the reliability of TFTs; the existence of clinical hypothyroidism in the presence of biochemical euthyroidism and the provision of treatment to such individuals; the bioequivalence of different brands of T4; reasons for the inadequacy of T4; the need for and use of T3, T4/T3 and NDT; the impact of hypothyroidism upon weight; and the patient's viewpoint.

***Table 9 (Please see Appendix G)***

This table provides a list of stakeholder groups and the number of respondents who thought that each stakeholder group should be involved in dialogue.

All respondents thought that general practitioner groups should be involved and the majority of respondents thought that patient groups, thyroid charities, endocrinologists and researchers should be involved. Additional stakeholder groups suggested by respondents included patients, pharmacists, the Department of Health, Members of Parliament, the media, a minute taker, doctors with success in the diagnosis and treatment of hypothyroidism, and an independent neutral body to hold the dialogue.

***Table 10 (Please see Appendix G)***

With regards to the methods by which dialogue should be carried out, the full list of suggestions made by respondents is provided in this table and dialogue via some form of group meeting was the most popular suggestion.

***Table 11 (Please see Appendix G)***

This table provides the comments made by respondents regarding what they would consider to be the ideal outcome of such dialogue. Popular suggestions included were that the ideal outcome would be: that patients are given a voice; modification of guidelines on the basis of input from patient groups so that each patient's individual needs are met; improvements in diagnosis and treatment with a more tailored approach; diagnosis that is no longer based on TFTs only/ TSH only/ RR only but also upon consideration of symptoms; recognition that T4 only treatment does not meet the needs of all individuals with hypothyroidism and a willingness to prescribe T4/T3 and/ or NDT when needed.

***Table 12 (Please see Appendix G)***

Examples of the types of comments provided by respondents are listed within this table. Comments were made regarding research, financial considerations, screening, dialogue, individual variation, the value of information provided by patients, NDT, diagnosis and treatment, guidelines, and education of medical practitioners.

### 5.3 Concerns and thematic analysis

#### ***Table 13 (Please see Appendix G)***

Concerns expressed by respondents are provided in this table and include concerns that: there are regional/ global differences in diagnosis/ monitoring/ treatment of hypothyroidism; blood tests are not reliable when diagnosing hypothyroidism; many individuals are misdiagnosed; many hypothyroid individuals cannot recover on T4 and require T3 or NDT but find it impossible or difficult to obtain this treatment via the NHS.

There was concern that doctors who use their clinical judgement in accordance with the needs of each individual patient so that their patients are returned to health are brought before the GMC if they contravened professional guidelines in order to restore health and this is deterring doctors from treating patients in accordance with their individual needs.

#### ***Table 14 (Please see Appendix G)***

This table provides a thematic analysis. Eleven themes were identified and these themes will be discussed within the next section.

## 6 Discussion

From the citations throughout the literature review, it can be seen that there are many areas of controversy relating to the diagnosis, treatment and monitoring of hypothyroidism both between researchers/ medical practitioners and between guideline producers. Therefore, it was of interest to elucidate whether individuals involved in providing information and/ or support to members of the public with hypothyroidism would have an awareness of such controversies.

As described previously, interviews were conducted and questionnaires were distributed. This was in fulfilment of my objective to find out the views of a sample of individuals involved in providing information and/ or support to members of the public with hypothyroidism (via charities/ voluntary organisations/ patient support groups) regarding the nature of any controversy in relation to the diagnosis and treatment of hypothyroidism and my objective to determine the recommendations of the aforementioned respondents for resolution of any controversy. In this section, the information gained will be reviewed.

Five out of ten key contacts agreed to forward an email/ pass a message to others involved in running their organisation/ group so that potential respondents who wished to be interviewed/ be sent the questionnaire could make contact. It is possible that individuals with strong feelings and a desire for change were more likely to agree to forward a message on to others/ be interviewed/ complete a questionnaire than individuals who were satisfied with the current situation with regards to the diagnosis and treatment of hypothyroidism.

There were 27 respondents in total. However, the individuals who were interviewed or completed the questionnaire weren't necessarily representative of voluntary workers within the organisations who did not pass on my email to others or other voluntary workers within their own organisation who didn't respond. Nevertheless, they represented a specific sector of the public who are knowledgeable about hypothyroidism and/ or who are in a position to be aware of feedback from members of the public suffering from hypothyroidism and therefore, their views should be sought and taken into consideration. Some but not all of the respondents were known to the author of this report but this did not appear to impact upon the types of responses provided and the strength of feeling displayed.

## **6.1 Respondents' views regarding the nature of any controversy over the way that hypothyroidism should be diagnosed, treated and monitored**

Respondents demonstrated a high level of awareness of any controversy over the way that hypothyroidism is diagnosed and treated (Table 5, Appendix G).

Some respondents expressed concern that the way that hypothyroidism is being diagnosed within the NHS is inadequate with undue reliance on the T4 test and TSH test and that many tests are not carried out at all and clinical evaluation is not carried out/ given full consideration and that as a result, many individuals with hypothyroidism remain undiagnosed or are misdiagnosed with conditions such as depression, stress, myalgic encephalomyelitis (ME), chronic fatigue syndrome (CFS) or it is attributed to the menopause or ageing (Table 14, Appendix G).

In addition, some were concerned that T4 is not adequate for the recovery of some individuals with hypothyroidism but that treatments such as T4/T3 and/ or NDT which are required for the full recovery of certain individuals are not being made available via the NHS and as a result many are mistreated (Table 14, Appendix G).

Concerns were also raised about the way that hypothyroidism is being monitored within the NHS. There is concern that monitoring is inadequate with undue reliance on the T4 test and TSH test, that many tests are not carried out at all and that clinical evaluation is not carried out/ given full consideration and that as a result many individuals with hypothyroidism are undertreated (Table 14, Appendix G).

There was concern that the guidelines do not cater to the needs of the individual and hence diagnosis and treatment is inadequate (Table 14, Appendix G).

Not diagnosing and misdiagnosing hypothyroidism and not treating and undertreating hypothyroidism were estimated to be having a negative financial impact upon the NHS as a result of the cost of treating the numerous symptoms resulting from the untreated or undertreated hypothyroidism separately, and upon the patient as a result of lost earnings and the cost of private consultations, tests and treatments (Table 14, Appendix G).

There was concern that private doctors who treat each patient as an individual and diagnose and treat their hypothyroidism and restore their health even if this means going outside of the guidelines are being threatened with action by the GMC and/ or brought before the GMC and that this is deterring many doctors within/ outside of the NHS from even considering diagnosing and treating such patients (Table 14, Appendix G).

## **6.2 Respondents' views on whether any controversy could be resolved via research**

Two thirds of respondents thought that more research would help to resolve issues that are the subject of debate (Table 6, Appendix G). However, some respondents expressed concern that research that could demonstrate that the guidelines with regard to the diagnosis, treatment and monitoring of hypothyroidism do not help all individuals with this condition is either not funded, not undertaken, designed so that such individuals are in the minority and statistical significance isn't reached or if statistical significance is reached, the research is ignored (Table 14, Appendix G).

The involvement of patient groups and thyroid charities in deciding research priorities was considered important to the majority of respondents (Table 7, Appendix G). Respondents provided a rich variety of suggestions regarding research that should be carried out (Table 8, Appendix G). Areas of research considered to be important included the reasons for the inadequacy of T4 and the need for and use of T3, T4/T3 and NDT, and research into the reliability of the TFTs and each RR. (Table 8, Appendix G).

In relation to the Netherlands, Caron-Flinterman et al. (2007) found that members of the patient community have little opportunity to help to determine research priorities but can have an impact on such decisions by becoming involved in the campaign work of patient organisations, providing their views to intermediaries for presentation to the scientific establishment or becoming a member of a panel established to recommend or commission research.

In the UK, the National Institute for Health Research has financed the organisation INVOLVE which encourages members of the public to become involved in the activities of the health related research community on the understanding that the resulting research would be more applicable (INVOLVE, accessed 2011, August 22).

In addition, the National Institute for Health Research provides finance towards the James Lind Alliance which encourages health professionals and individuals with experience of various medical conditions to collaborate to work out the most important issues to be investigated in relation to the impact of treatment for those conditions (The James Lind Alliance, accessed 2011, August 22).

‘Involving People’ (Accessed 2011, August 23) provides information about ways in which those with experience of various medical conditions can become involved in health related research being carried out in Wales as team members throughout the process. ‘People in Research’ (Accessed 2011, August 23) informs those who wish to become involved in a research study on ways of achieving this objective. ‘ThinkWell’ (Accessed 2011, August 23) also promotes public participation in research.

According to Rabeharisoa and Callon (2002, p.63-64), with regard to identifying which research should take priority, patient led organisations bring demands not met by government funded research or profit led research. However, according to Thompson et al. (2009, p.209), there is a disparity between the UK DOH’s campaign for researchers to involve members of the public in their research activities and the number of opportunities for involvement being offered.

Thompson et al. (2009, p.209&217) found that with regard to involving members of the public in research related to health, some researchers feared that their expertise would be questioned. Boote et al. (2010, p.18-19) draw upon a range of citations to illustrate that there are obstacles to public participation in deciding how research should be carried out which include discord between participants, inadequate comprehension of the terminology and methodology used during clinical studies and resource limitations.

However, in the opinion of Staniszewska (2009, p.297), when members of the patient community are involved in the activities of the research community, the input of all stakeholders needs appreciation. Though, Savory (2010, p.194) does point out that the perspective of patients, patient organisations and the public would differ in their breadth. Abma and Broerse (2010, p.160) have designed a series of stages to facilitate dialogue in which patients have the opportunity to raise issues related to health that they consider to be in need of investigation via research.

Rabeharisoa and Callon (2002, p.60-62) partition patient organisations into three different categories i.e. those that let the experts decide which studies to commission/ develop the expertise needed to be involved in such decisions; those that collate the experiences of patients; and those that campaign against interference from the mainstream scientific community.

### **6.3 Respondents' views on whether any controversy could be resolved via dialogue**

Nearly all respondents thought that dialogue would help to resolve issues of controversy related to the diagnosis and treatment of hypothyroidism (Table 6, Appendix G).

All respondents thought that general practitioner groups should be involved and the majority of respondents thought that patient groups, thyroid charities, endocrinologists and researchers should be involved. (Table 9, Appendix G).

The method of dialogue suggested by many of the participants was some form of face to face meeting (Table 10, Appendix G).

If dialogue should take place, the desired outcomes included an improvement in the quality, quantity and relevancy of research, an improvement in guidelines based on input from patient groups so that each individual's needs are met, understanding and respect for patients, improvements in diagnosis so that it was no longer based upon blood tests only and a recognition that some patients need T4/T3 and/ or NDT (Table 11, Appendix G).

A certain amount of debate has taken place in the media e.g. Barbour (2011, July 3) wrote an article in the *Mail on Sunday* highlighting the plight of a woman who had experienced great difficulty in being diagnosed with hypothyroidism and then had been provided with T4 for almost a decade but had failed to recover until provided with T3. In the article, TPA commented that due to the guidelines, hypothyroidism is being diagnosed incorrectly or treated inadequately, the endocrinologist Dr Vanderpump defended not using T3 on the basis of evidence-based medicine, and Sheila Turner of TPA defended its use on the basis of the large quantity of '*anecdotal evidence*' available (Barbour, 2011, July 3).

Moore and Stilgoe (2009, p.654) have analysed the way in which the presentation of ‘*anecdotal evidence*’ can either encourage or discourage dialogue. To illustrate, Moore and Stilgoe (2009) have reviewed references and carried out interviews in order to demonstrate the acceptance of ‘*anecdotal evidence*’ from the public and their call for research into the risks from mobile phones and the rejection of ‘*anecdotal evidence*’ and research requests in relation to concerns regarding the MMR vaccine.

Some respondents expressed concern that the attitudes of the medical profession and guideline producers would make dialogue unlikely to take place or that if it did take place, patients would be inadequately represented and/ or their views dismissed (Table 14, Appendix G). There was concern about the difficulties that would arise due to the polarised nature of the debate (Table 6(ii), Appendix G). Similarly, Phillips (2011, p.82) cites Foucault (1977) who contended that dialogue in which there is no imbalance of power is unattainable. Therefore, if dialogue does take place in the future, efforts should be made to ensure that all stakeholders with an interest in the diagnosis and treatment of hypothyroidism including thyroid charities and patient groups ought to have the opportunity to contribute and to have their contributions taken into consideration.

However, even if dialogue that includes a wide range of stakeholders does not take place in the near future, the issues arising from the thematic analysis (Table 14, Appendix G) deserve serious and urgent consideration so that individuals or groups who share the concerns that have been raised are not disenfranchised.

#### **6.4 Respondents’ views on whether any controversy could be resolved via an additional/ alternative strategy**

A theme that predominates is that of disempowerment: hypothyroidism could be considered disempowering due to its impact upon the mind and energy levels; certain guidelines could be considered disempowering if they do not take individual needs into account; the attitudes of some members of medical profession within the NHS could be described as disempowering if as some respondents reported, some patients aren’t being heard, taken seriously and respected; furthermore, the actions of the GMC could be considered disempowering if as some respondents reported, doctors who feel that the guidelines do not cater to all patients and diagnose/ treat in accordance with individual needs are under threat from the GMC (Table 14. Appendix G).

Another theme that was interwoven throughout the responses of respondents was the theme of despair: it is feared that the situation is serious and that it is deteriorating (Table 14, Appendix G).

It is possible that such a sense of disempowerment and despair made some respondents feel that research and dialogue alone would be inadequate and an additional strategy was needed. Indeed, nearly two thirds of respondents thought that an additional/ alternative strategy would help to resolve issues regarding the diagnosis and treatment of hypothyroidism that are in dispute (Table 6, Appendix G).

Popular additional/ alternative strategies suggested centred around the need for medical professionals to better themselves as a result of improvements to their education regarding hypothyroidism, a recognition of the importance of clinical assessment and a recognition of the need to listen to the patient (Table 6(iii), Appendix G).

In the absence of dialogue, the internet provides an opportunity for various stakeholders to present their views. A final theme that has become apparent is the emergence of a challenge to the status of scientific/ medical information: as a result of the internet, patients can now access, discuss and question such information and provide information of their own (Table 14, Appendix G). As exemplified below, the flow of information via the internet engenders differing responses. Weetman (2006, p.232) cites two research articles with contrasting views on whether SH requires treatment and contends that the availability of these articles via the internet could cause hypothyroid patients to become concerned. In contrast, the charity DIPEX has produced a website, as a learning resource for both the patient and medical community, on which patients' experiences of various conditions have been described by the patients themselves (DIPEX, accessed 2011a, August 24). However, hypothyroidism is not one of the conditions included on the DIPEX website (DIPEX, accessed 2011b, August 24).

Themes covered within the MSc Science and the public module (S802) that have been examined within this project within the context of controversy over the way that hypothyroidism is diagnosed and treated include '*situated knowledge*' (Irwin, 1998) in terms of the knowledge amassed by respondents and '*dialogue*' (Day et al. 2006) in relation to the necessity for dialogue that has emerged.

## **7 Conclusions and recommendations**

In this section, conclusions have been drawn and in fulfilment of my final objective, on the basis of the suggestions put forward by respondents, recommendations have been made regarding the need for research and dialogue to resolve any controversy over the way that hypothyroidism is diagnosed and treated.

### **7.1 Conclusions and recommendations regarding the need for research**

In the opinion of the authors of some of the articles cited within the literature review, particular issues that warrant further research include the effect of treating individuals who are biochemically euthyroid but clinically hypothyroid (Pollock et al. 2001, p.895), the effect of treating individuals with SH (McDermott and Ridgway, 2001, p.4589; Owen and Lazarus, 2003, p.260), the reasons for the subjective benefits of T4/T3 (Joffe et al. 2007, p.383) and the effect of T4/T3 in comparison to T4 in hypothyroid patients who have not recovered fully on T4 (Bunevicius et al. 2002, p.132). Areas of research considered to be important by respondents include the reliability of TFTs and each RR, the reasons for the inadequacy of T4 in certain individuals, and the need for and use of T3, T4/T3 and NDT (Table 8, Appendix G).

Therefore, from the citations within the literature review and the responses of respondents referred to above, there appear to be areas of agreement between members of the scientific/medical community and those involved in providing information and/ or support to the hypothyroid patient community over research that needs to be carried out. However, in light of feedback from one of the respondents in particular and many of the respondents in general, it is recommended that future research should include an evaluation of patients' perspectives and preferences on a consistent basis (Table 8 and 14, Appendix G).

### **7.2 Conclusions and recommendations regarding the need for dialogue**

Searches undertaken failed to uncover indications that researchers and medical practitioner groups were actively seeking dialogue with patients and/ or the public with regard to research into the diagnosis and treatment of hypothyroidism, although this does not rule out the existence of such activities.

The need for public involvement has been implicitly acknowledged within the guidelines by the ACB et al. (Beastall et al., 2006, p.5-6) but not to the satisfaction of all stakeholders (BSEM, 2010, p.1).

However, the findings from the interviews and questionnaires demonstrate that dialogue is desired by many involved in running/ working for thyroid charities and patient support groups (Table 6, Appendix G). However, this desire is tempered by the concerns of some respondents regarding the difficulties that would arise due to the viewpoints and attitudes held by certain members of the medical community and the concern that patients would have their views dismissed (Table 6(ii), Appendix G).

Therefore, if dialogue should take place, it would be important that some of the suggestions that have been made by respondents are utilised i.e. that any dialogue is widely advertised (Table 10, Appendix G), that a range of stakeholder groups are invited (Table 9, Appendix G) and that a neutral body plays a moderating role (Table 9, Appendix G). It would be imperative that patients and their representatives are given the opportunity to give their views and that these are taken into account.

Concerns expressed by respondents included: concern over regional variability in dealing with hypothyroidism; concern over the reliability of blood tests; concern that many hypothyroid individuals cannot recover on T4 and require T3 or NDT but find it impossible or difficult to obtain this treatment via the NHS; and concern that the guidelines and the GMC are deterring doctors from treating patients in accordance with their individual needs (Table 13, Appendix G). In light of these concerns, any dialogue that takes place in the future should permit these issues to be raised by hypothyroid patients, and representatives from a range of thyroid charities/ voluntary organisations and hypothyroid patient support groups. Additional points of discussion to be included within any future dialogue could include suggestions regarding research that could be undertaken and ways in which certain guidelines could be improved, and hypothyroid patients and representatives from a range of thyroid charities/ voluntary organisations and hypothyroid patient support groups ought to be given the opportunity to describe the impact of various guidelines upon the hypothyroid patient community.

In the absence of face to face dialogue, this report presents a range of issues of concern that have been raised by respondents (Table 14, Appendix G).

### **7.3 Conclusions and recommendations regarding the need for an alternative strategy**

With regard to an additional/ alternative strategy, a popular suggestion centred on the need for medical professionals to learn more about hypothyroidism, recognise the importance of clinical assessment and recognise the need to listen to the patient (Table 6(iii), Appendix G).

It was suggested that hypothyroid patients could be given the opportunity to contribute to the education of medical students and the ongoing education of general practitioners (Table 12, Appendix G).

In light of this suggestion, it is recommended that hypothyroid patients and representatives of a range of thyroid charities/ voluntary organisations and hypothyroid patient support groups should have more input into the education and ongoing training of medical professionals.

Perhaps curriculum developers and organisations that provide resources for the training of medical professionals could consider the need for hypothyroid patients and representatives from a wide range of thyroid charities/ voluntary organisations and patient support groups to be involved in the education of medical professionals e.g. by presenting the patient's perspective via educational resources such as a booklet or taped interview/ lecture.

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## Appendices

### Appendix A - Copy of the title and abstract of the mini-project for the S802 module

**Dialogue between those conducting research into hypothyroidism and members of the public with hypothyroidism**

**by**

**C A Phillips**

#### **Abstract**

The research question investigated was whether there is a direct and/or indirect dialogue between those researching into hypothyroidism and members of the public with hypothyroidism, however, the same question was also applied to dialogue between those drawing up guidelines regarding hypothyroidism and members of the public with hypothyroidism.

Individuals who were providing information and/ or support to others with hypothyroidism or who had hypothyroidism were questioned and they indicated that dialogue between researchers and hypothyroid individuals and dialogue between those drawing up guidelines regarding hypothyroidism and hypothyroid individuals was perceived or assumed to be inadequate. Improved dialogue appears necessary.

**(100 words)**

## **Appendix B - Covering information provided to a key contact at each charity/ voluntary organisation/ patient support group [via a telephone call and/ or email]**

My name is C Phillips and I am carrying out a project for my Master of Science degree with the Open University. As part of my project, I will be looking into the views held by various stakeholders regarding the diagnosis and treatment of hypothyroidism.

I have carried out a library and internet search in order to identify charities/ voluntary organisations involved in providing information and support to members of the public with hypothyroidism and to identify hypothyroid patient support groups.

As you are involved in running/ working for such a charity/ voluntary organisation or patient support group, I am contacting you to find out whether you would be willing to complete a questionnaire over the telephone as I am interested in finding out the views of individuals such as yourself. All contributions would be of great value and I would be happy to provide your group/ organisation with a summary of my findings/ recommendations if requested. Replies are anonymous. Furthermore, the completed reply sheets will be kept confidential and will not be shared with any third parties and will be utilised only for the purposes of research.

All questions are of a general nature and no personal questions regarding specific individuals have been included.

If you are willing to be interviewed, I would be very grateful and shall arrange a time and date when it would be convenient for me to telephone you in order to interview you over the telephone and make a note of your replies which can then be read back to you to check that there is nothing extra that you want to add to your replies.

If you would prefer to be posted the questionnaire and to send your reply back to me, this option can also be made available.

In addition, as you are involved in running a charity/ voluntary organisation/ hypothyroid patient support group, would you be willing for me to contact those involved in running your support groups/ working for your charity to see whether they would be willing to be complete a questionnaire over the telephone (although a covering letter and questionnaire could be sent through the post if this method is preferred) as I am interested in finding out the view of such individuals?

Please could you confirm that you are happy for me to proceed with contacting the aforementioned individuals with covering information and that no other permissions are required?

Thank you for your help in this matter.

Kind regards,

C Phillips

## **Appendix C - Email distributed to potential respondents**

My name is C Phillips and I am carrying out a project for my Master of Science degree with the Open University. As part of my project, I will be looking into the views held by various stakeholders regarding the diagnosis and treatment of hypothyroidism.

I have carried out a library and internet search in order to identify charities/ voluntary organisations involved in providing information and support to members of the public with hypothyroidism and to identify hypothyroid patient support groups.

As you are involved in running/ working for such a charity/ voluntary organisation or patient support group, I am contacting you to find out whether you would be willing to complete a questionnaire over the telephone as I am interested in finding out the views of individuals such as yourself. All contributions would be of great value and I would be happy to provide your group/ organisation with a summary of my findings/ recommendations if requested. Replies are anonymous. Furthermore, the completed reply sheets will be kept confidential and will not be shared with any third parties and will be utilised only for the purposes of research.

All questions are of a general nature and no personal questions regarding specific individuals have been included.

If you are willing to be interviewed, please could you send me an email? My email address is [email address] and I would be very grateful and would arrange a time and date when it would be convenient for me to telephone you in order to interview you over the telephone and make a note of your replies which could then be read back to you to check that there is nothing extra that you want to add to your replies. Thank you for your help in this matter.

If you would prefer to be posted the questionnaire and to send your reply back to me, this option can also be made available.

Kind regards,

C Phillips

## **Appendix D - Covering information provided to potential interviewees and questionnaire used for interviews/ telephone interviews**

My name is C Phillips and I am carrying out a project for my Master of Science degree with the Open University. As part of my project, I will be looking into the views held by various stakeholders regarding the diagnosis and treatment of hypothyroidism.

I have carried out a library and internet search in order to identify charities/ voluntary organisations involved in providing information and support to members of the public with hypothyroidism and to identify hypothyroid patient support groups.

As you are involved in running/ working for such a charity/ voluntary organisation or patient support group, I am contacting you to find out whether you would be willing to complete a questionnaire over the telephone as I am interested in finding out the views of individuals such as yourself. All contributions would be of great value and I would be happy to provide your group/ organisation with a summary of my findings/ recommendations if requested. Replies are anonymous. Furthermore, the completed reply sheets will be kept confidential and will not be shared with any third parties and will be utilised only for the purposes of this research.

All questions are of a general nature and no personal questions regarding specific individuals have been included.

If you are willing to be interviewed, I would be very grateful and shall arrange a time and date when it would be convenient for me to telephone you in order to interview you over the telephone and make a note of your replies which can then be read back to you to check that there is nothing extra that you want to add to your replies. Thank you for your help in this matter.

If you would prefer to be posted the questionnaire and to send your reply back to me, this option can also be made available.

Questionnaire to be used for interviews/ telephone interviews	For office use only
<p><b>1. Do you run/ work for a charity/ voluntary organisation involved in providing information and support to members of the public with hypothyroidism?</b> <i>[Please place a tick in the brackets next to one of the options below]</i></p> <p>Yes [ ]</p> <p>No [ ]</p>	
<p><b>2. Do you run a hypothyroid patient support group?</b> <i>[Please place a tick in the brackets next to one of the options below]</i></p> <p>Yes [ ]</p> <p>No [ ]</p>	
<p><b>3. What is your role within a thyroid charity/ voluntary organisation / hypothyroid patient support group? I'll read a range of options to you.</b> <i>[Please place a tick in the brackets next to the applicable option(s) in the list below]</i></p> <p>Administrator [ ]</p> <p>Manager [ ]</p> <p>Trustee [ ]</p> <p>Patron [ ]</p> <p>General Advisor to hypothyroid patients [ ]</p> <p>Supporter of hypothyroid patients via face to face meetings [ ]</p> <p>Supporter of hypothyroid patients via the telephone [ ]</p> <p>Supporter of hypothyroid patients via an online forum [ ]</p> <p>Scientific/ Medical Expert [ ]</p> <p>Author of position statements/ guidelines regarding the diagnosis/ treatment of hypothyroidism [ ]</p> <p>Author of articles for a newsletter/ website [ ]</p> <p>Fundraiser [ ]</p> <p>Other [ ] <b>Please specify</b> _____</p>	

<p><b>4. With regard to the diagnosis, treatment and monitoring of hypothyroidism:</b></p> <p><b>a) In your opinion, which (if any) of the issues from the list that I'll read to you in a moment are the subject of debate or dispute between stakeholder groups with an interest in hypothyroidism? [Please place a tick in the brackets next to the applicable option(s) in the list below]</b></p> <p>The way that subclinical hypothyroidism is defined [ ]</p> <p>The way that hypothyroidism is defined [ ]</p> <p>The prevalence of hypothyroidism [ ]</p> <p>The necessity of screening various adult groups for hypothyroidism [ ]</p> <p>The evaluations that are necessary to diagnose hypothyroidism [ ]</p> <p>The evaluations that are necessary to confirm hypothyroidism [ ]</p> <p>The TSH level at which treatment should be provided [ ]</p> <p>The recommended treatment options [ ]</p> <p>The benefit of treatment with tri-iodothyronine [ ]</p> <p>The benefit of Natural Desiccated Thyroid treatment [ ]</p> <p>The evaluations necessary to monitor the efficacy of treatment [ ]</p> <p>Whether treatment for hypothyroidism should be increased due to symptoms no matter where in the reference range the TSH is situated [ ]</p> <p>Other [ ]</p> <p><b>Please specify</b></p> <p>None of the above [ ]</p>	
<p><b>b) If any of the issues listed in the previous question are the subject of debate or dispute now or become the subject of debate in the future, what could be done to help to resolve this situation? I'll read a range of options to you. [Please answer by placing a tick in the brackets next to all the applicable option(s) in the list below]</b></p> <p>More research would help to resolve this situation [ ]</p> <p>More dialogue would help to resolve this situation [ ]</p> <p>An additional/ alternative strategy would help to resolve this situation [ ]</p> <p><b>Please specify</b></p>	





## Appendix E - Covering letter and questionnaire used for postal distribution

[My address]

[My telephone number]

[Name of potential respondent]

[Address]

[Date]

Dear [Name of potential respondent],

My name is C Phillips and I am carrying out a project for my Master of Science degree with the Open University. As part of my project, I will be looking into the views held by various stakeholders regarding the diagnosis and treatment of hypothyroidism.

I have carried out a library and internet search in order to identify charities and voluntary organisations involved in providing information and support to members of the public with hypothyroidism and to identify hypothyroid patient support groups.

As you are involved in running/ working for such a charity/ voluntary organisation or patient support group, I am writing to find out whether you would be willing to complete the enclosed questionnaire as I am interested in finding out the views of individuals such as yourself. Your contribution would be of great value and I would be happy to provide your group/ organisation with a summary of my findings/ recommendations if requested. Replies are anonymous. Furthermore, the completed questionnaires will be kept confidential and will not be shared with any third parties and will be utilised only for the purposes of this research.

All questions are of a general nature and no personal questions regarding specific individuals have been included.

If you are willing to complete the questionnaire, I would be very grateful and look forward to receiving your reply by [date] in the self-addressed envelope provided. Thank you for your help in this matter.

Yours sincerely,

C Phillips B.Sc. (Hons)

Questionnaire to be used for postal distribution	For office use only
<p><b>1. Do you run/ work for a charity/ voluntary organisation involved in providing information and support to members of the public with hypothyroidism?</b> <i>[Please answer by placing a tick in the brackets next to one of the options below]</i></p> <p>Yes [ ]</p> <p>No [ ]</p>	
<p><b>2. Do you run a hypothyroid patient support group?</b> <i>[Please answer by placing a tick in the brackets next to one of the options below]</i></p> <p>Yes [ ]</p> <p>No [ ]</p>	
<p><b>3. What is your role within a thyroid charity/ voluntary organisation / hypothyroid patient support group?</b> <i>[Please answer by placing a tick in the brackets next to the applicable option(s) in the list below]</i></p> <p>Administrator [ ]</p> <p>Manager [ ]</p> <p>Trustee [ ]</p> <p>Patron [ ]</p> <p>General Advisor to hypothyroid patients [ ]</p> <p>Supporter of hypothyroid patients via face to face meetings [ ]</p> <p>Supporter of hypothyroid patients via the telephone [ ]</p> <p>Supporter of hypothyroid patients via an online forum [ ]</p> <p>Scientific/ Medical Expert [ ]</p> <p>Author of position statements/ guidelines regarding the diagnosis/ treatment of hypothyroidism [ ]</p> <p>Author of articles for a newsletter/ website [ ]</p> <p>Fundraiser [ ]</p> <p>Other [ ] <i>[Please specify]</i> _____</p>	

<p><b>4. With regard to the diagnosis, treatment and monitoring of hypothyroidism:</b></p> <p><b>a) In your opinion, which (if any) of the issues listed below are the subject of debate or dispute between stakeholder groups with an interest in hypothyroidism?</b> <i>[Please answer by placing a tick in the brackets next to the applicable option(s) in the list below]</i></p> <p>The way that subclinical hypothyroidism is defined [ ]</p> <p>The way that hypothyroidism is defined [ ]</p> <p>The prevalence of hypothyroidism [ ]</p> <p>The necessity of screening various adult groups for hypothyroidism [ ]</p> <p>The evaluations that are necessary to diagnose hypothyroidism [ ]</p> <p>The evaluations that are necessary to confirm hypothyroidism [ ]</p> <p>The TSH level at which treatment should be provided [ ]</p> <p>The recommended treatment options [ ]</p> <p>The benefit of treatment with tri-iodothyronine [ ]</p> <p>The benefit of Natural Desiccated Thyroid treatment [ ]</p> <p>The evaluations necessary to monitor the efficacy of treatment [ ]</p> <p>Whether treatment for hypothyroidism should be increased due to symptoms no matter where in the reference range the TSH is situated [ ]</p> <p>Other [ ] <i>[Please specify]</i></p> <p>None of the above [ ]</p>	
<p><b>b) If any of the issues listed above are the subject of debate or dispute now or become the subject of debate in the future, what could be done to help to resolve this situation?</b> <i>[Please answer by placing a tick in the brackets next to all the applicable option(s) in the list below]</i></p> <p>More research would help to resolve this situation [ ]</p> <p>More dialogue would help to resolve this situation [ ]</p> <p>An additional/ alternative strategy would help to resolve this situation [ ] <i>[Please specify]</i></p>	

**5. With regard to research regarding the diagnosis, treatment and monitoring of hypothyroidism:**

**a) Which of the stakeholder groups listed below do you think should be involved in deciding research priorities?** [*Please answer by placing a tick in the brackets next to the applicable option(s) in the list below*]

- |                  |                          |                                |                          |
|------------------|--------------------------|--------------------------------|--------------------------|
| Researchers      | <input type="checkbox"/> | Guideline producers            | <input type="checkbox"/> |
| Medical students | <input type="checkbox"/> | Educators                      | <input type="checkbox"/> |
| Endocrinologists | <input type="checkbox"/> | General practitioner groups    | <input type="checkbox"/> |
| Patient groups   | <input type="checkbox"/> | Thyroid charities              | <input type="checkbox"/> |
| Regulators       | <input type="checkbox"/> | Pharmaceutical Companies       | <input type="checkbox"/> |
| Other            | <input type="checkbox"/> | [ <i>Please specify</i> ]_____ |                          |

**b) What is the most urgent research study (if any) that you think should be carried out?**



## **Appendix F - Covering email and questionnaire attachment used for email distribution**

My name is C Phillips and I am carrying out a project for my Master of Science degree with the Open University. As part of my project, I will be looking into the views held by various stakeholders regarding the diagnosis and treatment of hypothyroidism.

I have carried out a library and internet search in order to identify charities and voluntary organisations involved in providing information and support to members of the public with hypothyroidism and to identify hypothyroid patient support groups.

As you are involved in running/ working for such a charity/ voluntary organisation or patient support group, I am writing to find out whether you would be willing to complete the enclosed questionnaire as I am interested in finding out the views of individuals such as yourself. Your contribution would be of great value and I would be happy to provide your group/ organisation with a summary of my findings/ recommendations if requested. Replies are anonymous. Furthermore, the completed questionnaires will be kept confidential and will not be shared with any third parties and will be utilised only for the purposes of this research.

All questions are of a general nature and no personal questions regarding specific individuals have been included.

If you are willing to complete the questionnaire, I would be very grateful and look forward to receiving your reply during May 2011. Thank you for your help in this matter.

Kind regards,

C Phillips B.Sc. (Hons)

Questionnaire to be used for email distribution	For office use only
<p><b>1. Do you run/ work for a charity/ voluntary organisation involved in providing information and support to members of the public with hypothyroidism?</b> <i>[Please answer by placing a tick in the brackets next to one of the options below]</i></p> <p>Yes [ ]</p> <p>No [ ]</p>	
<p><b>2. Do you run a hypothyroid patient support group?</b> <i>[Please answer by placing a tick in the brackets next to one of the options below]</i></p> <p>Yes [ ]</p> <p>No [ ]</p>	
<p><b>3. What is your role within a thyroid charity/ voluntary organisation / hypothyroid patient support group?</b> <i>[Please answer by placing a tick in the brackets next to the applicable option(s) in the list below]</i></p> <p>Administrator [ ]</p> <p>Manager [ ]</p> <p>Trustee [ ]</p> <p>Patron [ ]</p> <p>General Advisor to hypothyroid patients [ ]</p> <p>Supporter of hypothyroid patients via face to face meetings [ ]</p> <p>Supporter of hypothyroid patients via the telephone [ ]</p> <p>Supporter of hypothyroid patients via an online forum [ ]</p> <p>Scientific/ Medical Expert [ ]</p> <p>Author of position statements/ guidelines regarding the diagnosis/ treatment of hypothyroidism [ ]</p> <p>Author of articles for a newsletter/ website [ ]</p> <p>Fundraiser [ ]</p> <p>Other [ ] <i>[Please specify]</i> _____</p>	

<p><b>4. With regard to the diagnosis, treatment and monitoring of hypothyroidism:</b></p> <p><b>a) In your opinion, which (if any) of the issues listed below are the subject of debate or dispute between stakeholder groups with an interest in hypothyroidism?</b> <i>[Please answer by placing a tick in the brackets next to the applicable option(s) in the list below]</i></p> <p>The way that subclinical hypothyroidism is defined <span style="float: right;">[ ]</span></p> <p>The way that hypothyroidism is defined <span style="float: right;">[ ]</span></p> <p>The prevalence of hypothyroidism <span style="float: right;">[ ]</span></p> <p>The necessity of screening various adult groups for hypothyroidism <span style="float: right;">[ ]</span></p> <p>The evaluations that are necessary to diagnose hypothyroidism <span style="float: right;">[ ]</span></p> <p>The evaluations that are necessary to confirm hypothyroidism <span style="float: right;">[ ]</span></p> <p>The TSH level at which treatment should be provided <span style="float: right;">[ ]</span></p> <p>The recommended treatment options <span style="float: right;">[ ]</span></p> <p>The benefit of treatment with tri-iodothyronine <span style="float: right;">[ ]</span></p> <p>The benefit of Natural Desiccated Thyroid treatment <span style="float: right;">[ ]</span></p> <p>The evaluations necessary to monitor the efficacy of treatment <span style="float: right;">[ ]</span></p> <p>Whether treatment for hypothyroidism should be increased due to symptoms no matter where in the reference range the TSH is situated <span style="float: right;">[ ]</span></p> <p>Other <span style="float: right;">[ ]</span> <i>[Please specify]</i></p> <p>None of the above <span style="float: right;">[ ]</span></p>	
<p><b>b) If any of the issues listed above are the subject of debate or dispute now or become the subject of debate in the future, what could be done to help to resolve this situation?</b> <i>[Please answer by placing a tick in the brackets next to all the applicable option(s) in the list below]</i></p> <p>More research would help to resolve this situation <span style="float: right;">[ ]</span></p> <p>More dialogue would help to resolve this situation <span style="float: right;">[ ]</span></p> <p>An additional/ alternative strategy would help to resolve this situation <span style="float: right;">[ ]</span> <i>[Please specify]</i></p>	





## Appendix G - Results in tabular form

**Table 1: Method by which questionnaire was completed/ provided/ not completed/ not provided**

<b>Method</b>	<b>Number of respondents</b>	<b>Percentage of respondents</b>
Self-completed and returned via email/ post	6	22
Completed by interviewer [i.e. myself] during telephone interview	18	67
Completed by interviewer [i.e. myself] during a face to face interview	3	11
Sent via email/ post but not returned	6	22
Interview booked but cancelled/ not carried out	2	7
<b>Total number of respondents</b>	<b>27</b>	<b>100</b>

Throughout this section, ‘/’ is an abbreviation for ‘and/ or’ and all percentages have been rounded up or down to the nearest whole per cent. Furthermore, the total number of replies in relation to each topic does not necessarily equal the number of respondents, because all respondents didn’t necessarily reply to all questions or sometimes certain respondents gave more than one response to a particular question. However, on the whole, every respondent has provided a relatively similar quantity of information.

**Table 2: Results for question 1: Do you run/ work for a charity/ voluntary organisation involved in providing information and support to members of the public with hypothyroidism?**

<b>Response &amp; [Code for each response]</b>	<b>Number of respondents</b>	<b>Percentage of respondents</b>
Yes [1A]	17	63
No [1B]	10	37
<b>Total number of respondents</b>	<b>27</b>	<b>100</b>

N.B. Two respondents within the 'no' category did provide assistance to a charity/ voluntary organisation on a voluntary basis but perhaps they ticked 'no' because the role was unpaid and/ or ad hoc.

**Table 3: Results for question 2: Do you run a hypothyroid patient support group?**

<b>Response &amp; [Code for each response]</b>	<b>Number of respondents</b>	<b>Percentage of respondents</b>
Yes [2A]	12* **	44
No [2B]	14	52
No response [2C]	1	4
<b>Total number of respondents</b>	<b>27</b>	<b>100</b>

\*One respondent ran a hypothyroid patient support group previously and no longer ran the group but their response has been included in the 'yes' category as it is still of value.

\*\* Two respondents didn't run a hypothyroid patient support group themselves but were involved in helping to run a support group and therefore their responses have been included in the 'yes' category as they are still of value

N.B. Not all respondents provided support via face to face meetings, some provided support via the telephone and/ or an internet forum and/ or email but included themselves in the 'yes' category. However, of 11 respondents who included themselves in the 'no' category or 'no response' category, 10 were providing support via face to face meetings and/ or the telephone and/ or an internet forum and/ or email and 1 had provided telephone support previously.

**Table 4: Results for question 3: What is your role within a thyroid charity/ voluntary organisation / hypothyroid patient support group?**

<b>Response &amp; [Code for each response]</b>	<b>Number of roles filled</b>
<b>Roles within the infrastructure of the organisation</b> e.g. Administrator/ Assistant/ Manager/ Trustee/ Patron/ Fundraiser/ Charity supporter [3A]	12
<b>Roles that involves communication with hypothyroid individuals</b> e.g. General Advisor to patients/ Supporter of hypothyroid patients via face to face meetings/ Supporter of hypothyroid patients via the telephone/ Supporter of hypothyroid patients via an online forum/ Supporter of hypothyroid patients via email* [3B]	39
<b>Roles that involves finding/ providing/ checking information</b> e.g. Researcher/ Scientific/ Medical Expert/ Author of position statements/ guidelines regarding the diagnosis/ treatment of hypothyroidism/ Author of articles for a newsletter/ website/ Evaluator/ Checker of documents/ proofreader [3C]	13

\* This category wasn't in my original questionnaire but four respondents provided this information during interview and one respondent provided this information when self-completing the questionnaire, however, it is not known whether other respondents would have responded to this category if it had been included.

N. B. Some respondents filled more than one role and hence the total number of roles filled comes to more than the total number of respondents.

**Table 5: Results for question 4a: With regard to the diagnosis, treatment and monitoring of hypothyroidism: In your opinion, which (if any) of the issues listed below are the subject of debate or dispute between stakeholder groups with an interest in hypothyroidism?**

<b>Response &amp; [Code for each response]</b>	<b>Number of respondents</b>	<b>Percentage of respondents</b>
The way that subclinical hypothyroidism is defined [4aA]	26	96
The way that hypothyroidism is defined [4aB]	25	93
The prevalence of hypothyroidism [4aC]	21	78
The necessity of screening various adult groups for hypothyroidism [4aD]	19	70
The evaluations that are necessary to diagnose hypothyroidism [4aE]	27	100
The evaluations that are necessary to confirm hypothyroidism [4aF]	27	100
The TSH level at which treatment should be provided [4aG]	25	93
The recommended treatment options [4aH]	26	96
The benefit of treatment with tri-iodothyronine [4aI]	27	100
The benefit of Natural Desiccated Thyroid treatment [4aJ]	26	96
The evaluations necessary to monitor the efficacy of treatment [4aK]	27	100
Whether treatment for hypothyroidism should be increased due to symptoms no matter where in the reference range the TSH is situated [4aL]	25	93
Other: *The causes of hypothyroidism [4aM]  *This issue was not included but was suggested by a respondent and therefore, it is not known if other respondents would have responded to this category had it been included. Many other issues were mentioned but they all fell within the categories of issues already listed and therefore were not counted again as separate issues but for completeness, the comments have been listed elsewhere in the Results section.	1	4
None of the above [4aN]	0	0

**Table 6: Results for question 4b: With regard to the diagnosis, treatment and monitoring of hypothyroidism: If any of the issues listed above are the subject of debate or dispute now or become the subject of debate in the future, what could be done to help to resolve this situation?**

<b>Response &amp; [Code for each response]</b>	<b>Number of respondents</b>	<b>Percentage of respondents</b>
More research would help to resolve this situation [4bA]	18	67
More dialogue would help to resolve this situation [4bB]	24	89
An additional/ alternative strategy would help to resolve this situation [4bC]	16	59

**Table 6(i): Results for question 4b(i) - Reservations expressed about research**

Types of response & [Code for each type of response]	Number of times each type response was given
<b>Concern was expressed that the type of research being carried out would not be helpful to the patients e.g. in relation to the question of whether research would be helpful, comments included, ‘Depends on what the research is.’ and ‘No, because they don’t do the right research.’</b> [4b(i)A]	2
<b>Concern was expressed that funders and researchers were biased e.g. ‘Yes, in theory but the problem is that the purse strings are held by those who are predominantly the same people who currently restrict debate.’ and ‘Independent sources of funding should be available so that research is carried out that is not under the influence of biased funders.’ and ‘The conflicts of interest held by researchers need to be taken into account so that researchers with conflicts of interest aren’t conducting research that would be detrimental to patients.’</b> [4b(i)B]	3
<b>Concern was expressed that the design of the trial could skew the findings e.g. ‘If there are only one or two T4 resistant patients in a large trial [comparing T4 with T4/T3], the impact is diluted down and isn’t statistically significant in a double-blind trial.’</b> [4b(i)C]	1
<b>Concern was expressed that research/ knowledge of benefit to patients was already available but was being ignored but needed to be relearnt</b> [4b(i)D]	3
<b>Concern was expressed that how the patient actually felt was dismissed e.g. ‘Around 10% and perhaps up to 17% do better on combination therapy – the last research I looked at said there was no difference but certain patients felt better but this is being ignored.’</b> [4b(i)E]	1
<b>Concern was expressed that there was insufficient dialogue between patients and researchers e.g. ‘There need to be more open channels of communication between patients and researchers.’</b> [4b(i)F]	1
<b>Concern was expressed that if dialogue did occur, the patients would be given less opportunity for input than the other participants e.g. ‘A lot depends on the balance...scientists’, endocrinologists’ and GPs’ input is less important.’</b> [4b(i)G]	2

**Table 6(ii): Results for question 4b(ii) - Reservations expressed about dialogue**

Types of response & [Code for each type of response]	Number of times each type of response was given
<b>Concern was expressed about financial restraints e.g.</b> <i>‘There are the financial costs and the current climate isn’t conducive to seeing improvements.’</i> [4b(ii)A]	1
<b>Concern was expressed about practical restraints e.g.</b> <i>‘People don’t come together as a group so it would be difficult to get them together as a group.’</i> [4b(ii)B]	1
<b>Concern was expressed about the difficulties that would arise due to the polarised nature of the debate and there was concern that some members of the medical community would be unwilling to consider the patient’s perspective e.g.</b> <i>‘Currently the views are so diametrically opposed, the established organisations appear to want to keep the status quo and the campaign groups want change – hopefully with debate some sort of compromise could be reached - but it’s difficult to see how this could happen.’</i> and <i>‘I appreciate that it would be potentially very difficult and confrontational as I feel that the endocrinologists and GPs would not see the necessity of having such discussions, considering that there is not currently any issue with their diagnosis and treatment methods.’</i> and <i>‘All the endos are blinkered about the fact that they are not treating thyroid patients properly.’</i> and <i>‘They aren’t paying attention, we need to be listened to and attention paid to what patients are saying, it’s all out there but the endos [endocrinologists] who set the guidelines aren’t listening.’</i> [4b(ii)C]	5
<b>Concern was expressed about the difficulties that would arise as a result of the attitudes held by certain members of the medical community such as medical professionals and endocrinologists e.g.</b> <i>‘negativity’</i> and <i>‘ego’.</i> [4b(ii)D]	2
<b>Concern was expressed about the difficulties that would arise due to the medical community’s unwillingness to let their viewpoint be questioned by non-medical groups such as patient organisations e.g.</b> <i>‘The establishment has had control of information for a long time and doesn’t want to give it up, they are making out that everything is black and white.’</i> and <i>‘There are elements of professional organisations that don’t want to be influenced by outside organisations.’</i> [4b(ii)E]	2

<p><b>Concern was expressed that previous attempts to engage the medical community in dialogue had brought about negative consequences for the patient community e.g.</b> <i>‘Most conventional avenues have already been tried, doctors with different ideas have attempted to publish and raise debate, patient groups have campaigned for changes and the outcome has been reactionary from the establishment to publish stronger and more restrictive guidelines to further restrict treatment options for individuals with hypothyroidism including to alter reference ranges for diagnosis i.e. widening of the TSH reference range in the UK when virtually every other country is lowering the upper limit of the TSH reference range.’</i> [4b(ii)F]</p>	1
<p><b>Concern was expressed that patients weren’t being given a voice e.g.</b> <i>‘Patients should be listened to more.’</i> [4b(ii)G]</p>	1
<p><b>Concern was expressed that there was disagreement between campaigners e.g.</b> <i>‘But it’s difficult to see how that [dialogue] would work due to the acrimonious relationships between some of the groups involved and even between campaign groups which tends to dilute their message. It’s sad that all the groups can’t work more effectively together.’</i> and <i>‘There is dispute between charities.’</i> [4b(ii)H]</p>	2
<p><b>Concern was expressed that if dialogue did occur, it would not be necessarily be of help to patients e.g.</b> <i>‘As things stand dialogue is unlikely or if it does occur patient groups would be ignored.’</i> [4b(ii)I]</p>	3

**Table 6(iii): Results for question 4b(iii) - Additional/ alternative strategies suggested**

Strategy & [Code for each type of response]	Number of times each type of response was given
<b>It was suggested that an alternative strategy would help but no suggestion was made</b> [4b(iii)A]	1
<b>It was suggested that an alternative strategy would help but no suggestion could be conceived</b> [4b(iii)B]	2
<b>It was suggested that the range of diagnostic tests carried out should be widened e.g.</b> <i>‘More testing...so that all the thyroid function tests are done including antibodies.’</i> and <i>‘Include a range of techniques e.g. urine testing, saliva testing, pulse and temperature measurements’</i> [4b(iii)C]	2
<b>It was suggested that the importance of clinical assessment needed to be recognised</b> [4b(iii)D]	4
<b>It was suggested that doctors needed to start listening to patients</b> [4b(iii)E]	5
<b>Routine screening of adults was suggested</b> [4b(iii)F]	1
<b>It was suggested that patients should have access to a nurse who was knowledgeable about the condition</b> [4b(iii)G]	1
<b>It was suggested that medical professionals required more knowledge about the condition e.g.</b> <i>‘Further education of health professionals concerning hypothyroidism.’</i> and <i>‘I think GPs have to be more aware of the symptoms of hypothyroidism.’</i> and <i>‘The endocrinologists need more training.’</i> [4b(iii)H]	3
<b>It was suggested that doctors with success in treating hypothyroid patients should be provided with the opportunity to educate other doctors e.g.</b> <i>‘Doctors who are treating successfully should be listened to.’</i> [4b(iii)I]	1
<b>It was suggested that doctors acknowledge that some hypothyroid patients need T4/T3 and/ or NDT treatment e.g.</b> <i>‘Doctors should ...realise that some people need NDT.’</i> [4b(iii)J]	2
<b>It was suggested that legal action may be necessary e.g.</b> <i>‘Litigation may be required if all else fails.’</i> [4b(iii)K]	1

**Table 7: Results for question 5a: With regard to research regarding the diagnosis, treatment and monitoring of hypothyroidism: Which of the stakeholder groups listed below do you think should be involved in deciding research priorities?**

<b>Response &amp; [Code for each response]</b>	<b>Number of respondents</b>	<b>Percentage of respondents</b>
Researchers [5aA]	18	67
Guideline producers [5aB]	12	44
Medical students [5aC]	6	22
Educators [5aD]	14	52
Endocrinologists [5aE]	20	74
General practitioner groups [5aF]	19	70
Patient groups [5aG]	25	93
Thyroid charities [5aH]	22	81
Regulators [5aI]	8	30
Pharmaceutical Companies [5aJ]	8	30
Other: Patients [5aK]	5	19
Representatives of patients [5aL]	1	4
Pharmacology researchers [5aM]	1	4
Department of Health [5aN]	1	4
Members of Parliament [5aO]	1	4
Doctors with success in diagnosing and treating hypothyroidism [5aP]	1	4

**Table 8: Results for question 5b: With regard to research regarding the diagnosis, treatment and monitoring of hypothyroidism: What is the most urgent research study (if any) that you think should be carried out?**

Type of response & [Code for each type of response]	Number of times each type of response was given
<p><b>It was suggested that research into the causes of hypothyroidism should be carried out e.g.</b> <i>‘I think that identifying risk factors could be looked at to see if there is any way of reducing them.’</i> and <i>‘Fluoride/ soya effects’</i> and <i>‘Hereditary/ genetic issues should be looked at because it does run in families.’</i> [5bA]</p>	3
<p><b>It was suggested that research into childhood hypothyroidism should be carried out e.g.</b> <i>‘I would like to see research into children, I think that it’s [hypothyroidism] not necessarily being picked up in childhood. Although they take a TSH reading at birth, childhood research is a neglected area.’</i> [5bB]</p>	1
<p><b>It was suggested that research into the values of thyroid function tests prior to the onset of hypothyroidism and the age of onset and the usefulness of screening e.g.</b> <i>‘Research into how early people are afflicted with hypothyroidism should be required – earlier mandatory screening should be looked into – perhaps it should be a yearly test.’</i> and <i>‘When a child is born and then well as child, they should check levels to know normal levels for that child so that this can be compared against in the future because each individual has their own reference range and the standard reference range may not suit them.’</i> [5bC]</p>	2
<p><b>It was suggested that there should be research into the reliability of the TFTs and the reliability of the reference ranges e.g.</b> <i>‘A reassessment of all thyroid function tests’</i> and <i>‘The TSH reference range needs to be looked at – it’s being narrowed in America – but the TSH needs to be high in this country before it’s treated.’</i> and <i>‘Research into the use of TSH as a measure for hypothyroid diagnosis and the reliability of the ‘normal’ reference range for TSH’</i> [5bD]</p>	4
<p><b>It was suggested that there should be research into the existence of clinical hypothyroidism in the presence of biochemical euthyroidism.</b> [5bE]</p>	2

<p><b>It was suggested that there should be research into the effect of providing thyroid hormone treatment for patients who were clinically hypothyroid but biochemically euthyroid e.g.</b> <i>‘They should study small doses of thyroxine on patients with symptoms of hypothyroidism but TFTs within the reference range as sometimes they improve even though their TFTs weren’t out of the reference range.’</i> [5bF]</p>	2
<p><b>It was suggested that there should be research into improving the diagnosis and treatment of hypothyroidism e.g.</b> <i>‘Establishing diagnostic methods that incorporate both clinical and biochemical measures so that people who require it get treatment and just as importantly that those who are sufferers are treated at the correct dosage and the optimal treatment type for their individual need.’</i> [5bG]</p>	2
<p><b>It was suggested that there should be research into the bioequivalence of different brands of T4</b> [5bH]</p>	1
<p><b>It was suggested that there should be research into the reasons for the inadequacy of T4 only treatment, thyroid hormone activity at the tissue level and ways of compensating for the inadequacy of T4 only treatment e.g.</b> <i>‘I think there should be some research into why some people don’t respond to thyroxine and aren’t converting T4 to T3, if reasons were found doctors might be more open minded about NDT.’</i> and <i>‘Into patients who fail to fully improve on synthetic thyroid medication and have other underlying problems such as adrenal fatigue’</i> and <i>‘If research is being carried out, there should be more research into the effect of hypothyroidism on the down regulation of thyroid hormone action at the tissue level.’</i> and <i>‘Research into helping to alleviate the tiredness experienced by hypothyroid patients – thyroxine doesn’t help sufficiently – would other lifestyle changes help e.g. exercise, diet?’</i> and <i>‘Research into why a small percentage of patients do not have all their symptoms relieved by levothyroxine only treatment’</i> [5bI]</p>	5
<p><b>It was suggested that there should be research into the need for and use of T3 only treatment, T4/T3 combination treatment and NDT treatment e.g.</b> <i>‘To research the factors behind the need for T4, T3 etc. to find out why people respond differently to different treatments’</i> [5bJ]</p>	12

<p><b>It was suggested that there should be research into the impact of hypothyroidism upon weight e.g.</b> <i>‘The relationship between weight gain and hypothyroidism should be looked into – the patients need to be made aware of this link and this can be a cause of depression – it is more difficult for thyroid patients to lose weight.’</i> [5bK]</p>	1
<p><b>It was suggested that there should be research into the viewpoint of patients regarding the adequacy of their diagnosis/ treatment e.g.</b> <i>‘Patient satisfaction needs to be looked at.’</i> [5bL]</p>	1
<p><b>No suggestion for research that should be carried out was made e.g.</b> <i>‘[I have] no particular bugbear [regarding research that should be carried out].’</i> [5bM]</p>	1

**Table 9: Results for question 6a: If dialogue between stakeholder groups regarding the diagnosis, treatment and monitoring of hypothyroidism should be required, which of the stakeholder groups listed below do you think should be included in such dialogue?**

<b>Response &amp; [Code for each response]</b>	<b>Number of respondents</b>	<b>Percentage of respondents</b>
Researchers [6aA]	21	78
Guideline producers [6aB]	18	67
Medical students [6aC]	10	37
Educators [6aD]	14	52
Endocrinologists [6aE]	23	85
General practitioner groups [6aF]	27	100
Patient groups [6aG]	26	96
Thyroid charities [6aH]	23	85
Regulators [6aI]	10	37
Pharmaceutical Companies [6aJ]	11	41
Other: Patients [6aK]	4	15
Representatives of patient groups/ charities [6aL]	2	7
Clinicians [6aM]	1	4
Pharmacists [6aN]	1	4
Department of Health [6aO]	1	4
Members of Parliament [6aP]	1	4
The media [6aQ]	1	4
A minute taker [6aR]	1	4
An independent neutral body to hold the dialogue [6aS]	1	4
Doctors with success in diagnosing and treating hypothyroidism [6aT]	1	4

**Table 10: Results for question 6b: By which method(s) should such dialogue be carried out?**

<b>Response &amp; [Code for each type of response]</b>	<b>Number of times each type of response was given</b>
<b>Response not provided/ not known [6bA]</b>	4
<b>It was suggested that there could be dialogue via some form of group meeting e.g. face to face meetings/ a seminar/ a conference/ a consultation/ an open debate [6bB]</b>	17
<b>It was suggested that dialogue could take place at a conference already scheduled to occur e.g. ‘It requires an open and frank debate between the various parties both within the academic press and the public press in a conference setting such as the British Endocrinology Society and groups such as Thyroid UK, BTF and BTA and the [ACB] and TPA and the RCP should be involved.’ [6bC]</b>	1
<b>It was suggested that advertising would be required/ that information could be presented prior to dialogue e.g. ‘There would need to be sufficient advertising, thyroid charities could contact members and there could be leaflets at doctor’s surgeries.’ and ‘There should be a good readable information package and presentation.’ [6bD]</b>	2
<b>It was suggested that opinions could be sought via a range of methods other than or in addition to a group meeting e.g. via an opinion poll and/ or questionnaire and/ or patient survey and/ or circulating letter and/ or interviews and/ or research [6bE]</b>	5
<b>It was suggested that dialogue could also take place via telephone meetings [6bF]</b>	2
<b>It was suggested that dialogue could also take place via an internet forum [6bG]</b>	4
<b>It was suggested that information could be distributed after the dialogue [6bH]</b>	1
<b>It was suggested that dialogue needed to involve participants from different fields e.g. ‘Perhaps a more multi-disciplinary debate around the subject is required.’ [6bI]</b>	1

**Table 11: Results for question 6c: What would be the ideal outcome of such dialogue?**

Type of response & [Code for each type of response]	Number of times each type of response was given
<b>No comment was made</b> [6cA]	1
<b>It was suggested that the ideal outcome would be the identification of research needs/ improvements in the quantity, quality and relevancy of research e.g.</b> <i>‘To identify further research required’</i> and <i>‘More research is carried out – proper research’</i> and <i>‘Basically, I think it would be improved research with an increase in the relevancy of research so that it reflects the needs of patients.’</i> [6cB]	3
<b>It was suggested that the ideal outcome would be that medical practitioners are more aware of research findings e.g.</b> <i>‘Awareness of GPs and endocrinologists about the results of research into treatments for hypothyroidism, the prevalence of this illness and the unreliability of the reference range for TSH’</i> [6cC]	1
<b>It was suggested that the ideal outcome would be that the various parties involved had learnt from one another e.g.</b> <i>‘A multi-way flow of information so that patients are more informed and doctors and researchers are more informed’</i> [6cD]	1
<b>It was suggested that the ideal outcome would be a modification to the guidelines on the basis of research e.g.</b> <i>‘To adjust/ adapt guidelines in accordance with the outcome of such research [i.e. research as a result of the first phase of dialogue] including a full review of research that is already available’</i> [6cE]	1
<b>It was suggested that the ideal outcome would be a modification of the guidelines on the basis of input from patient groups so that each patient’s individual needs are met/ modification of guidelines on the basis of consensus between all stakeholder groups (which would include patient groups) e.g.</b> <i>‘Reappraisal of diagnosis and management of hypothyroidism’</i> and <i>‘To reach a consensus on things they agree on and to decide on how to go forward on things they don’t agree on’</i> and <i>‘A consensus on a way forward towards a more effective and reliable diagnosis and treatment of hypothyroidism’</i> [6cF]	7

<p><b>It was suggested that the ideal outcome would be that the guidelines were changed so that doctors had more autonomy e.g.</b> <i>‘That guidelines are changed to allow doctors the freedom to treat using methods they consider appropriate and in the best interests of the patient without fear of reprisal’</i> [6cG]</p>	1
<p><b>It was suggested that the ideal outcome would be that patients are listened to/ that patients have more input/ that patients are understood/ that patients are respected</b> [6cH]</p>	8
<p><b>It was suggested that the ideal outcome would be improvements in diagnosis and treatment with a more tailored approach e.g.</b> <i>‘That people were given the treatment that they needed for their thyroid condition’</i> and <i>‘For people to be diagnosed much more quickly than at present’</i> and <i>‘Improved diagnosis’</i> and <i>‘The ideal outcome would be a better range of testing and treatments.’</i> and <i>‘That they [patients] would get speedy and effective treatment for their condition [hypothyroidism] easily from their GP and endocrinologist without being treated as if their problems are all in their mind’</i> and <i>‘[That patients are diagnosed correctly] rather than patients being told that they have CFS or depression or fibromyalgia’</i> and <i>‘People would be diagnosed correctly, many people with ME have hypothyroidism that has been misdiagnosed as ME.’</i> and <i>‘A flexible approach to hypothyroidism and the realisation that everyone is different’</i> [6cI]</p>	9
<p><b>It was suggested that the ideal outcome would be improved diagnosis that is no longer based on TFTs only/ TSH only/ reference ranges only but also upon consideration of symptoms e.g.</b> <i>‘People with undiagnosed thyroid conditions being clinically diagnosed rather than undiagnosed due to the inaccurate blood tests’</i> [6cJ]</p>	7
<p><b>It was suggested that the ideal outcome would be a recognition that T4 only treatment does not meet the needs of all individuals with hypothyroidism and a willingness to prescribe T4/T3 combination treatment and/ or NDT treatment when needed e.g.</b> <i>‘To address the issues of the small percentage of patients who don’t respond well to levothyroxine only treatment’</i> and <i>‘That minds are opened and alternative treatment methods are more readily accepted and used’</i> [6cK]</p>	4

<p><b>It was suggested that the ideal outcome would be improved monitoring of hypothyroidism that is no longer based on TFTs only/ TSH only/ reference ranges only but also upon consideration of symptoms e.g. ‘Improved ... monitoring of hypothyroidism’ and ‘That patients are treated until they are up to their optimum not until their blood tests reach a certain number but the patients remain unwell’ [6cL]</b></p>	2
<p><b>It was suggested that the ideal outcome would be that patients have their health restored e.g. ‘That patients would then not have to suffer unnecessarily as at present’ and ‘They make patients well’ [6cM]</b></p>	2
<p><b>It was suggested that the ideal outcome would be that views presented would be backed up by scientific findings e.g. ‘All participants should be able to back up their stance with scientific evidence that has been conducted so far.’ [6cN]</b></p>	1

**Table 12: Results for question 7: Do you have any other comments?**

<b>Response &amp; [Code for each response/ type of response]</b>	<b>Number of times each response/ type of response was given</b>
<b>No comment made [7A]</b>	8
<b>Comments regarding research</b>	
<i>'I think that research into this subject is important.'</i> [7B]	1
<i>'Further research should be carried out into adrenal gland problems which often goes hand in hand with hypothyroidism but is largely ignored or dismissed by many NHS doctors. Adrenal gland issues are often the cause of patients being unable to become well on levothyroxine alone.'</i> [7C]	1
<i>'Perhaps there should be more international collaboration and cooperation between researchers because this would improve knowledge amongst researchers which could be of benefit to patients in due course.'</i> [7D]	1
<b>Comments regarding financial considerations</b>	
<i>'The NHS doesn't have the funds to take this forward but non diagnosis of hypothyroidism is costing the NHS a lot of money.'</i> [7E]	1
Correct diagnosis and treatment of hypothyroidism would save the Government money e.g. <i>'Improvement in diagnosis and treatment would alleviate suffering among many and save funds for the NHS as often patients are treated for other conditions instead of the root cause – hypothyroidism.'</i> and <i>'Hypothyroidism leads to other conditions so if this was treated correctly, it would save the country a lot of money.'</i> [7F]	2
<b>Comments regarding screening for hypothyroidism</b>	
<i>'Thyroid screening should be mandatory for all women at regular intervals throughout their life.'</i> [but until there's a reliable test, there's no point said two respondents unless it is by clinical assessment said one] [7G]	1
<i>'Possibly certain groups should be screened e.g. children with Down syndrome.'</i> [7H]	1
There is debate over screening in pregnancy [7I]	1

<b>Comments regarding dialogue</b>	
<i>‘For the sake of the patients – and it is the patients who count here - dialogue is desperately needed but dialogue alone is not enough, sensible and positive action is needed to help to diagnose and treat hypothyroid patients.’ [7J]</i>	1
<i>‘Achieving even some of the above [a consensus on a way forward towards a more effective and reliable diagnosis and treatment of hypothyroidism] would demonstrate significant progress for all thyroid patients.’ [7K]</i>	1
<i>‘I think that proper dialogue is overdue.’ [7L]</i>	1
<b>Comments regarding individual variation</b>	
<i>Individuality needs consideration e.g. ‘They need to allow for individuality.’ and ‘[There is] the complexity of the disease and the individual manifestation of the conditions and treatment requirements.’ and ‘They should treat the patient as an individual.’ [7M]</i>	3
<i>‘In other areas of medicine, it is being realised that certain types of treatment don’t suit all genetic types and further research in this area might shed light on the hypothyroidism debate.’ [7N]</i>	1
<b>Comment regarding the value of information provided by patients</b>	
<i>‘This is a debate of the 21<sup>st</sup> century – without the access that the patients have to medical articles, academic journals, published patient histories on the internet, self-help communities etc. this debate would be limited between biochemists and doctors and in some ways, the doctors, academics and biochemists are rooted in a pre-21<sup>st</sup> century reactionary stance. It’s only when these organisations begin to embrace the benefits in mining the data within these new sources of information provided by patients (e.g. patient testimonies on the internet) that the debate can move on.’ [7O]</i>	1
<b>Comments regarding NDT treatment</b>	
<i>‘Someone can suddenly need NDT even after years of taking T4 only.’ [7P]</i>	1
<i>‘Sometimes, there’s a supply problem with NDT.’ [7Q]</i>	1
<i>‘It would be better if it was manufactured in the UK’ [7R]</i>	1

<b>Comment regarding diagnosis and treatment</b>	
<i>‘There is a wide diagnostic test and treatment with a narrow therapeutic range.’ [7S]</i>	1
<b>Comment regarding guidelines</b>	
<i>‘Proper guidelines would help.’ [7T]</i>	1
<b>Comments regarding education of medical practitioners</b>	
<i>Education of GPs is needed e.g. ‘GPs aren’t experts in hypothyroidism so they need to be given more education and informed by their consultants that they must listen to what patients say and not just go by the blood tests. Hypothyroid patients must be listened to and GPs must learn to spot the clinical signs.’ and ‘GPs require education.’ [7U]</i>	2
<i>‘There could possibly be a meeting or seminar between hypothyroid patient volunteers and medical students within the curriculum and also GPs as part of ongoing training or as an evening event at a GP surgery.’ [7V]</i>	1

N.B. Certain comments provided answers to questions that had been asked at another point within the questionnaire and therefore, have been situated in the tables appropriate to the question to which they provide an answer. In addition, certain comments would be classified more appropriately as ‘concerns’ and therefore, a table of concerns raised in the comments section and at random points throughout the completed questionnaires is shown overleaf. Likewise, in addition to answering the questions posed within the questionnaire, general comments were sometimes made and they have been included in the table of comments above.

**Table 13: Types of concerns put forward throughout the completed questionnaires not already classified elsewhere**

Types of concerns raised & [Code for each type of response]	Number of times each type of concern was raised
<p><b>Concern that fluoridation is causing hypothyroidism</b> e.g. <i>‘They should stop putting fluoride in the water - years ago fluoride was used to treat hyperthyroidism - it’s causing an epidemic of hypothyroidism.’</i> [A]</p>	1
<p><b>Concern that fluoridation is making diagnosis of hypothyroidism more difficult</b> e.g. <i>‘Fluoride in the water could affect thyroid function tests.’</i> [B]</p>	1
<p><b>Concern that the incidence of hypothyroidism is increasing</b> e.g. <i>‘It is common and seems to be...increasing but diagnosis and treatment is not.’</i> [C]</p>	1
<p><b>Concern that people should be provided with more information</b> e.g. <i>‘Very little information is being provided, people should be made more aware of the warning signs [of hypothyroidism].’</i> [D]</p>	1
<p><b>Concern that hypothyroidism can be frightening</b> e.g. <i>‘It [hypothyroidism] is very frightening for some people because it can affect your state of mind as well.’</i> [E]</p>	1
<p><b>Concern that not enough is known</b> e.g. <i>‘Insufficient information is known about the condition.’</i> [F]</p>	1
<p><b>Concern that the biochemical tests are being used for diagnosis and monitoring on the basis of inadequate evidence</b> e.g. <i>‘When they invented the blood tests they only had a small cross section of people.’</i> [G]</p>	1
<p><b>Concerns that there are regional differences in the way that hypothyroidism is treated and differences in the care that patients receive</b> e.g. <i>‘Care varies throughout the country.’</i> and <i>‘It [treatment] varies from doctor to doctor and area to area.’</i> [H]</p>	2

<b>Concerns that there are regional/ global differences in diagnosis and/ or monitoring. [I]</b>	6
<b>Concerns that the blood tests [TSH and/ or T4] are not reliable when diagnosing hypothyroidism e.g.</b> <i>‘The diagnosis is based on TSH tests, T3 can be off the scale but this isn’t always checked – the blood test doesn’t show the whole picture. They are looking at TSH and T4 but not T3.’</i> and <i>‘One of the worst things is the blood tests, doctors work on the basis of blood tests without considering symptoms and in thousands of people blood tests don’t necessarily correlate with symptoms.’</i> and <i>‘Sometimes people have perfect TFTs but still display the clinical signs and symptoms of hypothyroidism – some people have hypothyroidism but this doesn’t show up in the blood tests.’</i> and <i>‘The reliability of the TFTs especially when there could be so many variables, there is an issue there’</i> and <i>‘My greatest bugbear has been that people have lots of symptoms [of hypothyroidism] but their [blood] tests come back normal.’</i> and <i>‘The TSH test on its own isn’t any good.’ [J]</i>	7
<b>Concern that blood tests results take precedence over the clinical picture e.g.</b> <i>‘Only blood tests are used – TSH and T4 – there is not much regard for the patients themselves.’[K]</i>	1
<b>Concern that many individuals are undiagnosed or take a while to be diagnosed. [L]</b>	3
<b>Concern that many individuals are untreated e.g.</b> <i>‘Refusal of medical profession to supply thyroid replacement to the patients’ [M]</i>	1
<b>Concern that many individuals are misdiagnosed e.g.</b> <i>‘The misdiagnosis by doctors saying that a patient has depression, ME because they are reliant on blood test results and misread symptoms’</i> and <i>‘They sometimes blame patients for the condition e.g. weight gain and depression and give medication for depression rather than treat the thyroid condition.’</i> and <i>‘They treat the symptoms rather than the cause.’</i> and <i>‘Some patients are being diagnosed with chronic fatigue and ME because they have hypothyroidism but their blood tests are within the reference range.’</i> and <i>‘Because a lot of hypothyroid patients are women and are older, the doctors get it mixed up with the menopause.’</i> and <i>‘It being blamed on other factors e.g. age, stress etc., sex i.e. being female.’ [N]</i>	6

<p><b>Concern that the full range of diagnostic tests aren't being carried out e.g.</b> <i>'The full range of tests should be done and taken note of.'</i> and <i>'All tests should be done before decisions are made.'</i> and <i>'If [NHS] doctors ask for T3 [the FT3 blood test], it isn't being done by the [NHS] lab.'</i> and <i>'Antibody tests aren't being carried out [by the NHS].'</i> [O]</p>	4
<p><b>Concern that any adrenal issues aren't being adequately addressed e.g.</b> <i>'Improved adrenal tests are required also'</i> and <i>'Patients with longstanding hypothyroidism nearly always have some degree of adrenal insufficiency but doctors are refusing to even test for this.'</i> [P]</p>	2
<p><b>Concern that patients have to have certain tests done privately e.g.</b> <i>'FT3 levels'</i> and <i>'Some patients are being forced to have these tests [antibody tests] carried out privately.'</i> [Q]</p>	2
<p><b>Concern that many hypothyroid individuals cannot recover on synthetic thyroxine only and require tri-iodothyronine or NDT treatment.</b> [R]</p>	4
<p><b>Concern that many hypothyroid individuals who require tri-iodothyronine or NDT find it impossible or difficult to obtain this treatment via the NHS.</b> [S]</p>	5
<p><b>Concern about the costs resulting from hypothyroidism e.g. Untreated/ undertreated hypothyroidism is of great financial expense to patients in terms of e.g. lost earnings/ private tests/ private treatments.</b> [T]</p>	2
<p><b>Concern that the TSH test/ blood tests are not reliable for monitoring hypothyroidism and patients aren't being monitored clinically e.g.</b> <i>'Lots of women can't have their medication increased because their TSH is normal despite symptoms.'</i> [U]</p>	3
<p><b>Concern that hypothyroid patients aren't trusted to self-monitor e.g.</b> <i>'If you compare hypothyroid patients to diabetics, diabetics are trusted to take their own blood tests and adjust their own insulin but hypothyroid patients aren't trusted at all.'</i> [V]</p>	1

<b>Concern that patients aren't being fully informed e.g.</b> <i>'They are told that if they are over treated they could get heart problems or osteoporosis but not told that without thyroid treatments they could get furred arteries.'</i> [W]	1
<b>Concern about the consequences of under treatment of hypothyroidism e.g.</b> <i>'If undertreated, individuals can't reach their full potential.'</i> [X]	1
<b>Concern that the guidelines are restrictive e.g.</b> <i>'The use of guidelines by thyroidologists' professional bodies as straight-jackets to limit doctors' treatment options and their continued pressure on doctors to adhere completely to what are no more than guidelines.'</i> and <i>'The NHS aren't allowed to do anything.'</i> and <i>'Endocrinologists are restricted.'</i> [Y]	3
<b>Concern that doctors who use their clinical judgement in accordance with the needs of each individual so that their patients are returned to health are brought before the GMC if they contravened professional guidelines in order to restore health and this is deterring doctors from treating patients in accordance with their individual needs.</b> [Z]	5
<b>Concern that the situation is serious and worsening e.g.</b> <i>'The treatment of hypothyroidism is a disgrace.'</i> and <i>'This is a very serious situation damaging countless lives that no one seems to be addressing.'</i> and <i>'The situation [regarding] diagnosis and management of hypothyroidism is worsening by the moment.'</i> [A2]	4
<b>Concern that patients aren't being heard</b> [B2]	2
<b>Concern that the patients are vulnerable e.g.</b> <i>'The patients are in a difficult situation because one of the symptoms is low energy and energy is needed to fight the situation.'</i> [C2]	1
<b>Concern about attitudes within the medical profession e.g.</b> <i>'The attitude of GPs and endocrinologists despite the Government's desire for more patient centred treatment/ decision making.'</i> and <i>'Some doctors are very paternalistic.'</i> [D2]	2
<b>Concern about lack of understanding e.g.</b> <i>'I don't think most endos know what this condition is like.'</i> and <i>'I wish that all of the people dealing with thyroid patients would realise that it is life changing and if undiagnosed could be life threatening.'</i> [E2]	2

**Table 14 – Thematic analysis**

<b>Themes that have become apparent on the basis of responses/ types of responses to questions 4-7 [Tabulated and coded within Tables 6-13 of Appendix G]</b>	<b>Code for the responses/ types of responses [From Tables 6-13 of Appendix G] that provide evidence for each theme's existence</b>
There is concern that the way that hypothyroidism is being diagnosed within the NHS is inadequate with undue reliance on the T4 test and TSH test, whilst many test are not carried out at all and clinical evaluation is not carried out/ given full consideration and that as a result, many individuals with hypothyroidism remain undiagnosed or are misdiagnosed with conditions such as depression, stress, myalgic encephalomyelitis (ME), chronic fatigue syndrome (CFS) or it is attributed to the menopause or ageing	4b(iii)C, 4b(iii)D, 4b(iii)E, 5bD, 5bE, 5bG, 5bL, 6cJ, G, J, K, L, M, N, O, P, Q.
Concerns were also raised about the way that hypothyroidism is being monitored within the NHS, with some fearing that monitoring is inadequate with undue reliance on the T4 test and TSH test, whilst many tests are not carried out at all and clinical evaluation is not carried out/ given full consideration and that as a result many individuals with hypothyroidism are undertreated.	5bD, 5bE, 6cL, G, U, X.
There is concern that T4 is not adequate for the recovery of some individuals with hypothyroidism but that treatments such as T4/T3 and/ or NDT which are required for the full recovery of certain individuals are not being made available via the NHS and as a result many are mistreated.	4b(iii)J, 5bG, 5bI, 5bJ, 5bL, 6cK, R, S, X.
There is concern that the guidelines do not cater to the needs of the individual and hence diagnosis and treatment is inadequate.	6cF, 6cH, 6cI, 6cM, 7M, 7N, 7T.
Not diagnosing and misdiagnosing hypothyroidism and not treating and undertreating hypothyroidism were estimated to be having a negative financial impact upon the NHS as a result of the cost of treating the numerous symptoms resulting from the untreated or undertreated hypothyroidism separately, and upon the patient as a result of lost earnings and the cost of private consultations, tests and treatments.	7E, 7F, T.
There is concern that private doctors who treat each patient as an individual and diagnose and treat their hypothyroidism and restore their health even if this means going outside of the guidelines are being threatened with action by the GMC and/ or brought before the GMC and that this is deterring many doctors within/ outside of the NHS from even considering diagnosing and treating such patients.	6cG, 7T, Y, Z.

<p>Asking about research evoked optimistic and pessimistic responses i.e. the majority of respondents thought that more research would help but some expressed concern that research that could demonstrate that the guidelines with regard to the diagnosis, treatment and monitoring of hypothyroidism do not help all individuals with this condition is either not funded, not undertaken, designed so that such individuals are in the minority and statistical significance isn't reached or if statistical significance is reached, the research is ignored.</p>	<p>4bA, 4b(i)A, 4b(i)B, 4b(i)C, 4b(i)D, 4b(i)E, 4b(i)F, 4b(i)G.</p>
<p>Asking about dialogue evoked optimistic and pessimistic responses i.e. the majority of respondents thought that more dialogue would help but some expressed concern that the attitudes of the medical profession and guideline producers would make it unlikely to take place or that if it did take place, patients would be inadequately represented and/ or their views dismissed.</p>	<p>4bB, 4b(i)G, 4b(ii)C, 4b(ii)B, 4b(ii)D, 4b(ii)E, 4b(ii)F, 4b(ii)G, 4b(ii)H, 4b(ii)I, 7J, 7K, 7L.</p>
<p>A theme that predominates is that of disempowerment: hypothyroidism could be considered disempowering due to its impact upon the mind and energy levels; certain guidelines could be considered disempowering if they do not take individual needs into account; the attitudes of some members of medical profession within the NHS could be described as disempowering if as some respondents reported, some patients aren't being heard, taken seriously and respected; furthermore, the actions of the GMC could be considered disempowering if as some respondents reported, doctors who feel that the guidelines do not cater to all patients and diagnose/ treat in accordance with individual needs are under threat from the GMC.</p>	<p>6cF, 6cH, 6cI, 6cJ, 7M, 7N, 7T, E, B2, C2, D2, E2, Y, Z.</p>
<p>Another theme that is interwoven throughout is the theme of despair: it is feared that the situation is serious and that it is deteriorating.</p>	<p>C, A2.</p>
<p>A final theme that has become apparent is the emergence of a challenge to the status of scientific/ medical information: as a result of the internet, patients can now access, discuss and question such information and provide information of their own.</p>	<p>4b(i)E, 7O, G.</p>

## Appendix H - Log

Week Number	Date that week started	Tasks that have been carried out (in blue)	Comments (in black) & Further actions (in red)
-4 -3 -2 -1 1 2	3/1 10/1 17/1 24/1 31/1 7/2	<p>During January and this week I carried out background reading re: planning &amp; implementation i.e. I read the <i>Introduction</i> to the Project Module (Marshall et al., 2011)*, the <i>Course Guide</i> for the Project Module (The Open University, S810, 2007)*, <i>Handbook of Science Communication</i> (Wilson et al., 1998)*, <i>Preparing Scientific Illustrations</i> (Briscoe, 1996)*, <i>How to Read a Paper: The basics of evidence-based medicine</i> (Greenhalgh, 2010)*, <i>Beyond Reasonable Doubt: A guide to designing experiments in the behavioural sciences</i> (Bearman et al. [eds.], 2006)* and <i>Statistics Without Tears</i> (Rowtree, 2000)*. I carried out background reading within the relevant subject area i.e. I read <i>Evidence-Based Medicine: How to Practice and Teach EBM</i> (Straus et al., 2005)*, <i>How Doctors Think: Clinical Judgment and the Practice of Medicine</i> (Montgomery, 2006)*, <i>Your Thyroid and how to keep it healthy</i> (Durrant-Peatfield, 2006)*, <i>Breast Cancer and Iodine</i> (Derry, 2001)*, <i>Tears Behind Closed Doors</i> (Holmes, 2002)*, <i>Diagnosis and Management of Hypothyroidism</i> (Skinner, 2003)*, <i>Solved: The Riddle of Illness</i> (Langer and Scheer, 2000)*, <i>Your Guide to Metabolic Health</i> (Honeyman-Lowe and Lowe, 2003)*, <i>The Thyroid Solution</i> (Arem, 1999)*, <i>Hypothyroidism: The Unsuspected Illness</i> (Barnes and Galton, 1976)*, <i>Hypothyroidism Type 2: The Epidemic</i> (Starr, 2005)*.</p>	<p>I reread my MSc Project Proposal (Phillips, 2010b)* prior to jotting down ideas on rough paper and formulating an 'Action Plan'. I put labelled folders and files ready for the year both in the real world and on my computer. I sketched and typed a first draft of my Gantt chart and skills audit.</p>
3	14/2	<p>I forwarded an amended MSc Project Proposal (Phillips, 2011a)* and my S802 MSc Mini-Project (Phillips, 2010a)* to my tutor/supervisor (TS). As part of background reading of relevant subjects, I read the chapters by Brent and Larsen (2000)*, Ladenson (2000)*, Refetoff (2000)* and Ross (2000)* in <i>Werner &amp; Ingbar's The Thyroid: A Fundamental and Clinical Text</i>.</p> <p>I started my literature search using the Open University (OU) library. A variety of search terms were used including: 'Hypothyroidism; hypothyroidism AND thyroxine; hypothyroidism AND levothyroxine; hypothyroidism AND T4; hypothyroidism AND tri-iodothyronine; hypothyroidism AND liothyronine; hypothyroidism AND T3; hypothyroidism AND natural desiccated thyroid; hypothyroidism AND NDT; hypothyroidism AND Armour Thyroid; hypothyroidism AND TSH; hypothyroidism AND free T4; hypothyroidism AND free T3; hypothyroidism AND thyroid function tests; hypothyroidism AND guidance; hypothyroidism AND guidelines; hypothyroidism AND management; hypothyroidism AND consensus; hypothyroidism AND conflict; hypothyroidism AND controversy; hypothyroidism AND quality of life; hypothyroidism AND patient perspective; hypothyroidism AND patient satisfaction; hypothyroidism AND dialogue; hypothyroidism AND dissent; hypothyroidism AND stakeholders AND views; hypothyroidism AND stakeholders AND dialogue; hypothyroidism AND qualitative research; hypothyroidism AND diagnosis; hypothyroidism AND treatment'.</p>	<p>I intend to obtain additional resources from local libraries.</p>

4	21/2	<p>I had a brief discussion with my TS on 21<sup>st</sup> February.</p> <p>I registered with Zotero (Zotero, accessed 2011, February 26)*.</p> <p>I continued my literature search using the OU library.</p>	<p>I arranged a further discussion with my TS in week 6.</p>
5	28/2	<p>I carried out background reading re: planning &amp; implementation by reading a portion of <i>SPSS Explained</i> (Hinton et al., 2004, pp. 273-290)* and I read <i>Quantity and Quality in Social Research</i> (Bryman, 1988)*.</p> <p>I continued with my literature search re: stakeholders' views &amp; dialogue.</p> <p>I began making rough notes re: tutor marked assignment (TMA) 01.</p>	
6	7/3	<p>I had a discussion with my TS on 7<sup>th</sup> March and subsequently forwarded a copy of my objectives and my Gantt chart to my TS.</p> <p>On the evening of 7<sup>th</sup> March, I attended the S810 introductory Elluminate meeting (Open University, accessed 2011, March 7)*.</p> <p>As part of my background reading re: planning &amp; implementation, I read <i>Questionnaire Design, Interviewing and Attitude Measurement</i> (Oppenheim, 1992)*.</p> <p>I began designing covering letters, a semi-structured interview plan &amp; questionnaire.</p> <p>I continued with my literature search re: stakeholders' views &amp; dialogue.</p> <p>I continued making rough notes re: TMA 01</p>	<p>I arranged to email my TS and have a further discussion in week 9.</p>
7	14/3	<p>I submitted TMA 00</p> <p>I carried out background reading re: planning &amp; implementation by reading information by Le Voi (1998)* and Wilson and McClean (1994)*.</p> <p>I continued designing my draft covering letters/ covering information, semi-structured interview plan &amp; questionnaire.</p> <p>I continued with my literature search re: stakeholders' views &amp; dialogue</p> <p>I began analysing &amp; critically reviewing literature**.</p> <p>I made rough notes for TMA 01.</p> <p>I wrote up &amp; proofread TMA 01</p>	
8	21/3	<p>I submitted TMA 01 (Phillips, 2011b)* by 23/3.</p> <p>I continued with my literature search re: stakeholders' views &amp; dialogue.</p>	

		<p>In addition, I began analysing &amp; critically reviewing the literature**.</p> <p>In preparation for conducting the interviews and printing/ posting the questionnaires during future weeks, I continued to prepare covering information that could be used when telephoning and/ or emailing a key person at each charity/ hypothyroid patient support group.</p>	
9	28/3	<p>I had a discussion with my TS and have decided to email and/ or phone key contacts at charities/ voluntary organisations/ hypothyroid patient support groups for permission to contact/ have an email forwarded to others involved in running their charity/ voluntary organisation/ support group and I have decided to elucidate the views of guideline producers from the literature.</p> <p>I continued with my literature search re: stakeholders' views &amp; dialogue and I continued to analyse &amp; critically review the literature**.</p>	I arranged to email my TS and have a telephone discussion in week 11.
10	4/4	<p>I emailed my TS.</p> <p>I carried out background reading re: planning &amp; implementation by reading <i>Information skills for researchers</i> (Open University, accessed 2011, April 6)*.</p> <p>I continued with my literature search re: stakeholders' views &amp; dialogue and I continued to analyse &amp; critically review the literature**.</p>	
11	11/4	<p>I carried out background reading re: planning &amp; implementation by reading a paper by Braun and Clarke (2006)*.</p> <p>I continued my literature search re: stakeholders' views &amp; dialogue and I continued to analyse &amp; critically review the literature**.</p> <p>I piloted my interview plan/ questionnaire &amp; amended it in line with feedback.</p> <p>I emailed my TS with an update.</p> <p>I had a discussion with my TS.</p> <p>I emailed my TS with further updates.</p>	
12	18/4	<p>I had a discussion with my TS.</p> <p>I emailed my TS with further updates.</p> <p>I continued with my literature search re: stakeholders' views &amp; dialogue.</p> <p>I continued to analyse &amp; critically review literature**.</p>	
13	25/4	<p>I continued with my literature search re: stakeholders' views &amp; dialogue.</p> <p>I continued to analyse &amp; critically review literature**.</p>	

		<p>I finished preparing covering information to use within an email or during a telephone call to key contacts (i.e. gatekeepers) [Please see Appendix B]. I sent emails to the key contacts with covering information. I awaited permission to interview/ send questionnaires to key contacts and permission to email / have an email forwarded and/ or phone others involved in running their charity/ voluntary organisation/ support group.</p>	
14	2/5	<p>I continued with my literature search re: stakeholders' views &amp; dialogue.</p> <p>I continued to analyse &amp; critically review literature**.</p> <p>I continued to await permission to interview/ send questionnaires to key contacts and their permission to email/ have an email forwarded and/ or phone others involved in running their charity/ voluntary organisation/ support group. To date, three key contacts have agreed for a covering email to be forwarded on so that those interested in being interviewed/ sent the questionnaire could contact me and one individual agreed to pass a message on to the others involved in running their support group.</p> <p>I tried phoning some of the key contacts that I had already emailed plus one who had not provided an email address but most contacts were unavailable by this method. One key contact's telephone number no longer existed and therefore, it is possible that their group had disbanded. Some responses were received as a result of my emails and phone calls and hence, I phoned two potential respondents with whom I had made an appointment and interviewed them/ completed the questionnaire on their behalf.</p> <p>I prepared emails with covering information and questionnaires attached, which I sent to five potential respondents who had requested this option. I awaited return of questionnaires and received one by email.</p>	
15	9/5	<p>I continued with my literature search re: stakeholders' views &amp; dialogue and I continued to analyse &amp; critically review literature**.</p> <p>I continued to await permission to interview/ send questionnaires to most of the key contacts and their permission to email/ have an email forwarded and/ or phone others involved in running their charity/ voluntary organisation/ support group.</p> <p>With respect to the latter permission, one key contact was unable to grant this request and one key contact sent me an email notifying me that permission was denied.</p> <p>I phoned three potential respondents and visited one potential respondent with whom I had made an appointment and interviewed them/ completed the questionnaire on their behalf.</p> <p>I emailed two further questionnaires as requested by two potential respondents. I awaited return of questionnaires and received three by email.</p>	

16	16/5	<p>I carried out background reading re: relevant subjects by reading <i>The Hormone Solution</i> (Hertoghe &amp; Nabet, 2002)*.</p> <p>I continued with my literature search re: stakeholders' views &amp; dialogue and I continued to analyse &amp; critically review literature**.</p> <p>I continued to await permission to interview/ send questionnaires to some of the key contacts and their permission to email/ have an email forwarded and/ or phone others involved in running their charity/ voluntary organisation/ support group.</p> <p>Another key contact agreed for a covering email to be forwarded on so that those interested in being interviewed/ sent the questionnaire could contact me if they wished.</p> <p>I phoned one potential respondent with whom I had made an appointment and interviewed them/ completed the questionnaire on their behalf. I emailed two questionnaires as requested by two potential respondents and awaited return of the questionnaires.</p>	<p>Responses have been coming in more slowly than I had hoped and therefore, next week I intend to email or phone key contacts and contacts (where permission has been granted) who have not responded to emails and/ or who have been unavailable via the telephone.</p>
17	23/5	<p>I continued with literature search re: stakeholders' views &amp; dialogue. I continued to analyse &amp; critically review literature**.</p> <p>I continued to await permission to interview/ send questionnaires to some of the key contacts and/ or their permission to email/ have an email forwarded and/ or phone others involved in running their charity/ voluntary organisation/ support group. With respect to the latter permission, another key contact was unable to grant this request.</p> <p>I began to email/ phone key contacts/ contacts who have not responded to emails/ phone calls.</p> <p>I phoned eight potential respondents and interviewed them/ completed the questionnaire on their behalf.</p> <p>I emailed two questionnaires as requested.</p> <p>I awaited return of questionnaires.</p> <p>On the evening of 25<sup>th</sup> May, I attended the Open University S810 Elluminate meeting (Accessed 2011, May 25)*.</p>	
18	30/5	<p>I continued with my literature search re: stakeholders' views &amp; dialogue.</p> <p>I continued to analyse &amp; critically review literature**.</p> <p>I contacted five potential respondents and interviewed them/ completed the questionnaire on their behalf.</p> <p>I awaited return of questionnaires.</p> <p>I received one questionnaire by email and one by post.</p> <p>I had a discussion with my TS.</p>	

19	6/6	<p>I continued to analyse &amp; critically review literature**.</p> <p>I began to analyse the questionnaires &amp; tabulate results whilst awaiting return of any further questionnaires.</p>	
20	13/6	<p>I continued to analyse &amp; critically review literature**.</p> <p>I continued to analyse questionnaires &amp; tabulate results whilst awaiting return of any further questionnaires.</p> <p>I made rough notes re: TMA 02.</p> <p>I began to type up some sections of TMA 02.</p>	
21	20/6	<p>I phoned a potential respondent and interviewed them/ completed the questionnaire on their behalf.</p> <p>I awaited return of any further questionnaires.</p> <p>I continued to analyse questionnaires &amp; tabulate results.</p> <p>I continued to analyse &amp; critically review literature**.</p> <p>I began to make rough notes re: Introduction and Discussion for the project report.</p> <p>I emailed my TS with an update of my progress.</p> <p>I made rough notes re: TMA 02.</p> <p>I continued to type up some sections of TMA 02.</p>	
22	27/6	<p>I continued to await a reply from one of the key contacts regarding their permission to email/ have an email forwarded and/ or phone others involved in running their charity/ voluntary organisation/ support group but no reply was received.</p> <p>I awaited return of questionnaires.</p> <p>I finished analysing questionnaires and tabulating results received so far.</p> <p>I continued to analyse &amp; critically review literature**.</p> <p>I continued to make rough notes re: Introduction and Discussion for my project report and began to make rough notes ready for the first draft of my project report.</p> <p>I had a discussion with my TS.</p> <p>I finished typing TMA 02 and I proofread TMA 02.</p>	
23	4/7	<p>I submitted TMA 02 (Phillips, 2011c)* by 6/7.</p> <p>I continued to make rough notes re: the first draft of my project report.</p>	

24	11/7	On the evening of 11 <sup>th</sup> July, I attended the Open University S810 Elluminate meeting (Accessed 2011, July 11)*.  I continued to make rough notes re: the first draft of my project report and had a discussion with my TS.	
25	18/7	I continued to make rough notes re: the first draft of my project report.	
26	25/7	I carried out a literature search using the key terms used previously so that any significant papers that have emerged in recent weeks could be identified and included within the literature review if necessary.  I finished making rough notes re: first draft of project report and typed up the notes.	
27	1/8	I began to draw upon and add my typed notes to start writing the first draft of the project report.	
28	8/8	I continued to draw upon and add to my typed notes to continue writing the first draft of the project report.	
29	15/8	I continued to draw upon and add to my typed notes to continue writing the first draft of the project report.  I had a discussion with my TS.	
30	22/8	I continued to draw upon and add to my typed notes to continue writing the first draft of the project report.	
31	29/8	I continued to draw upon and add to my typed notes to continue writing the first draft of the project report.	
32	5/9	I continued to draw upon and add to my typed notes to continue writing the first draft of the project report.  I emailed my TS	
33 34	12/9 19/9	I continued to draw upon and add to my typed notes to finish writing the first draft of the project report.  I emailed my TS  I edited/ checked/ proofread the project report  I submitted my project report by 30/9	
35	26/9	Extra time in case of emergencies	

\*Please see Bibliography for the reading material and resources marked with an asterisk within the Log.

\*\*Please see the section entitled References for the full list of literature marked with two asterisks within the Log.

**Addendum: S802 Mini-project**

**Dialogue between those conducting research  
into hypothyroidism and members of the  
public with hypothyroidism**

**by**

**C A Phillips**

**(5824 words)**

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## Abstract

The research question investigated was whether there is a direct and/or indirect dialogue between those researching into hypothyroidism and members of the public with hypothyroidism, however, the same question was also applied to dialogue between those drawing up guidelines regarding hypothyroidism and members of the public with hypothyroidism.

Individuals who were providing information and/ or support to others with hypothyroidism or who had hypothyroidism were questioned and they indicated that dialogue between researchers and hypothyroid individuals and dialogue between those drawing up guidelines regarding hypothyroidism and hypothyroid individuals was perceived or assumed to be inadequate. Improved dialogue appears necessary.

**(100 words)**

## Introduction

I have chosen to investigate whether there is a problem regarding a lack of dialogue between those carrying out research into hypothyroidism and individuals with hypothyroidism both directly and indirectly via various intermediaries as outlined previously (Phillips, TMA02, 2010).

### Research Questions

My main research question and associated subsidiary research questions as referred to previously (Phillips, TMA02, 2010) are provided below:

Main research question:

Is there a direct and/ or indirect dialogue between those researching into hypothyroidism and members of the public with hypothyroidism?

Subsidiary research questions:

Do the findings of research into hypothyroidism reach members of the public with hypothyroidism directly and/ or indirectly via various intermediaries who disseminate the information?

How?

Is the message biased?

Is the message trusted?

Do researchers and experts seek the views of members of the public with hypothyroidism when designing research and drawing up policy respectively?

Is research and policy enriched by the input of those with hypothyroidism to whom it applies?

Do members of the public with hypothyroidism feel that their views are taken into account by researchers and policy makers?

My research questions raise topics such as 'trust', 'experts', 'situated knowledge', 'policy', 'regulation', 'participation' and 'dialogue' which are subjects included within the study calendar provided in the Introduction and Guide (The Open University, S802, 2010, p.31) and the pertinence of these issues will be included later (Please see Discussion).

My research questions are within an area of interest to me since I have hypothyroidism and I am co-author of a book entitled 'Hypothyroidism in Childhood and Adulthood' (Phillips and Roach, 2006).

I made a timetable (Phillips, TMA02, 2010) to be undertaken in order to complete the mini-project within the time required. I reviewed my timetable at intervals and found that the time I'd allocated for each task originally e.g. carrying out interviews was rather optimistic and it was necessary to spread each task over a longer period of time; my amended timetable is shown in Appendix 1. Although I originally intended to contact researchers, intermediary organisations, individuals whom I would consider to be lay experts and individuals with hypothyroidism, due to the time constraints involved I amended my plan so that I would be contacting individuals from my circle of contacts within the latter two groups only and details of this amendment have been submitted previously (Phillips, TMA03, 2010). In addition, I submitted amendments to my plan to show that I intended to gauge the views of researchers and intermediary organisations via my literature search (Phillips, TMA03, 2010).

## Methods

I have co-authored a book in the subject area of 'hypothyroidism' (Phillips and Roach, 2006) and have previously made contacts who have an interest in hypothyroidism and/ or have hypothyroidism. According to Wilson (1979, p.18), questionnaires are an efficient and economical way of collecting data and this is the research method that I chose to obtain information from the aforementioned contacts. In line with my tutor's feedback on 31<sup>st</sup> May 2010, I opted to offer potential participants the choice of being interviewed or sent the questionnaire by post or email for self-completion and return via post or email to attempt to improve the response.

When recruiting volunteers and providing a covering letter that I either read prior to interview or sent to participants with my questionnaire, I followed the advice provided within Open University documentation (The Open University, S802, 2003) so that I complied with the requirements of the Data Protection Act 1998. The final covering letter is included in Appendix 2.

Boynton and Greenhalgh (2004) stress the importance of attempting to design a questionnaire that demonstrates reliability and validity and I bore this in mind when designing my questionnaire. On 25<sup>th</sup> May 2010, an individual involved in providing information for others with hypothyroidism gave me feedback on a draft of my questionnaire; piloting the questionnaire in this manner was recommended by Taylor-Powell (1998, p.14) and based on the feedback obtained, I subsequently simplified three of the questions. Following a telephone discussion with my tutor on 31<sup>st</sup> May 2010 and further feedback from my tutor on 2<sup>nd</sup> June 2010, I made some further modifications to my questionnaire.

Day (S802 MMR, p.12) cites Shaw and Baker's 2004 description of the 'expert patient programme' designed to empower patients to deal with their long term illnesses optimally in cooperation with their medical practitioners and I asked respondents whether they had participated within an expert patient programme.

Multiple choice questions were kept to a minimum. A diverse range of responses can be generated by inviting spontaneous responses rather than providing a choice of predetermined answers (Taylor-Powell, 1998, p.5). The final questionnaire is included in Appendix 3.

According to Boynton and Greenhalgh (2004), varying the ways in which questionnaires are completed could decrease reliability. However, using the questionnaire to carry out interviews indicated that the questions were relatively straightforward and it was hoped that offering a choice of completion methods would increase the response rate.

When carrying out interviews, I made notes of the replies obtained. According to Martin and Tait (1992, p.39), members of society should not be assumed to form a uniform group, hence, I was aware that the views obtained could not be generalised to all individuals with hypothyroidism or all individuals providing information and/ or support to others with hypothyroidism.

I kept to the timetable in Appendix 1. In addition, I built-up a file of notes and relevant articles that I made or came across respectively so that they were available when required at the appropriate stage in my mini-project timetable.

## Results

I initiated contact with 28 individuals (17 in person or by telephone and 11 by email) to ask if they would be willing to complete my questionnaire. Sometimes, individuals were unavailable and a repeat phone call was needed, hence, I also used email to initiate contact. If individuals contacted were willing to complete the questionnaire, I gave them the choice of either being interviewed in person (if applicable) or by telephone or being posted or emailed the questionnaire so that they could complete it in their own time and post or email it back. The sample size is very small and non-randomly selected and therefore cannot be analysed to produce meaningful statistical information but can nevertheless provide valuable qualitative information and insights. Furthermore, many respondents were involved in providing information about hypothyroidism and/ or support to individuals with hypothyroidism and therefore they were in regular contact with a large number of individuals with hypothyroidism and therefore well informed about the experiences and views of such individuals. All respondents lived in Great Britain. The response obtained is shown in Table 1 below. The response rate was 61%.

**Table 1 - Response**

<b>Response</b>	<b>Number</b>
Interviewed in person or by telephone	9
Completed questionnaire & returned it by mail	7
Completed questionnaire & returned it by email	1
Did not ask to be sent questionnaire or did request questionnaire by email or post but did not return it by either method	11

### Characteristics of Respondents

I approached individuals within my circle of contacts (acquaintances, family and friends) either because they were providing information about hypothyroidism and/or support for individuals with hypothyroidism or because they had hypothyroidism.

Although I did not inform respondents whether I considered them to be 'lay experts in hypothyroidism' or not, originally I had assumed that individuals within the former group would classify themselves as lay experts whilst individuals within the latter group would not. However, it became clear that individuals can be providing information but still not be willing to classify themselves in this way, whilst others not providing information might classify themselves as a 'lay expert' (please see Table 2&4) presumably on the basis of personal experience.

Therefore, for clarity, I divided respondents into two groups:

<b>Group A</b>	<b>Group B</b>
Individuals (some of whom have hypothyroidism) who are providing information about hypothyroidism and/ or support to individuals with hypothyroidism	Individuals with hypothyroidism (who are not providing information about hypothyroidism or support to individuals with hypothyroidism)

Please note that in the remainder of the tables the symbol '/' stands for 'and/ or' but has been used for brevity. Since the answers were open ended, respondents often provided answers within more than one category, hence, the totals within the various tables add up to a number greater than the total number of respondents. Furthermore, for Tables 6-9, sometimes replies were complicated and had to be simplified and the same complex answer fitted within more than one simplified category. Details that would identify sources in Tables 6-9 have been omitted.

**Table 2 - Characteristics of Group A (comprising 11 individuals)**

Number who are hypothyroid	7
Number who have family/ friends with hypothyroidism	11
Number running/ working for a charity/ organisation that provides information for patients with hypothyroidism	4
Number who have authored a book/ books/ newsletter/ magazine/ newspaper articles about hypothyroidism/ website about hypothyroidism/ moderated an internet forum used by hypothyroid patients	14
Number who provide telephone support for individuals with hypothyroidism/ run a support group/ organise meetings for individuals with hypothyroidism	6
Number who have been/ are campaigning for better diagnosis and treatment of individuals with hypothyroidism	10
Number who have attended an expert patient programme	2
Number who have attended events related to hypothyroidism	8
Number who considered themselves to be lay experts	8
Number who weren't sure if they were a lay expert or not	1
Number who didn't consider themselves to be lay experts	2
Number who were currently employed as professional scientists/ medical doctors or endocrinologists	0

**Table 3 - Demographics of Group A**

Male	2
Female	9
30-39 years of age	1
40-49 years of age	2
50-59 years of age	1
60-69 years of age	4
70-79 years of age	3

**Table 4 - Characteristics of Group B (comprising 6 individuals)**

Number who are hypothyroid	6
Number who have family/ friends with hypothyroidism	5
Number running/ working for a charity/ organisation that provides information for patients with hypothyroidism	0
Number who have authored a book/ books/ newsletter/ magazine/ newspaper articles about hypothyroidism/ website about hypothyroidism/ moderated an internet forum used by hypothyroid patients	0
Number who provide telephone support for individuals with hypothyroidism/ run a support group/ organise meetings for individuals with hypothyroidism	0
Number who have been/ are campaigning for better diagnosis and treatment of individuals with hypothyroidism	2
Number who have attended an expert patient programme	0
Number who have attended events related to hypothyroidism	2
Number who considered themselves to be lay experts	3
Number who weren't sure if they were a lay expert or not	0
Number who didn't consider themselves to be lay experts	3
Number who were currently employed as professional scientists/ medical doctors or endocrinologists	0

**Table 5 - Demographics of Group B**

Male	1
Female	5
30-39 years of age	1
40-49 years of age	0
50-59 years of age	2
60-69 years of age	2
70-79 years of age	1

**Sources used to find information about hypothyroidism****Table 6 - Sources used to find information about hypothyroidism by Group A**

Source	Number
Journals/ research papers	7
The library/ books	11
Guidelines	2
Doctors and their advice/ books/ websites	10
Professors	1
Internet websites/ forums	9
Reporters/ newspapers/ magazines	2
Personal experience	0
The experiences of other patients and their testimony/ books/ websites	4
Patient support groups/ charities/ organisations	6

**Table 7 - Sources used to find information about hypothyroidism by Group B**

Source	Number
Journals/ research papers	1
The library / books	5
Guidelines	0
Doctors and their advice/ books/ websites	2
Professors	0
Internet websites/ forums	6
Reporters/ newspapers/ magazines	1
Personal experience	2
The experiences of other patients and their testimony/ books/ websites	2
Patient support groups/ charities/ organisations	1

**Sources of information trusted****Table 8 - Sources of information trusted by Group A**

Source	Number
Scientists/ doctors and their advice/ journal articles/ books/ websites	10
The experiences of other patients and their testimony/ books/ websites	5
Patient support groups/ charities/ organisations	2
The library/ books (without specifying the type of book)	2
Science journalists	1
BBC reporters	1

**Table 9 - Sources of information trusted by Group B**

Source	Number
Scientists/ doctors and their advice/ journal articles/ books/ websites	3
The experiences of other patients and their testimony/ books/ websites	2
The library/ books (without specifying the type of book)	1
The Internet	1

**Views regarding members of the public with hypothyroidism being consulted at the design stage of research proposals and the reasons given**

All respondents in Group A believed that the quality of research into hypothyroidism would be improved if members of the public with hypothyroidism were consulted at the design stage of research proposals and the table below lists their reasons:

**Table 10 – Group A’s reasons why patients should be consulted at the research study design stage**

Reason	Number
So that their views are taken into account	3
To improve current situation	3
To improve understanding	1
To improve diagnosis and treatment	2
So that signs and symptoms aren’t omitted from study	2
So that the right research is done	1
So that the right questions are asked	2
For mutual benefit of patients and researchers	1

All respondents in Group B believed that the quality of research into hypothyroidism would be improved if members of the public with hypothyroidism were consulted at the design stage of research proposals and the table below lists their reasons:

**Table 11 - Group B’s reasons why patients should be consulted at the research study design stage**

Reason	Number
Current research is probably biased/ prejudiced	3
To eliminate ‘guesswork’	1
To improve understanding of how the patient feels	1

**Views regarding members of the public with hypothyroidism being consulted during the drawing-up of guidance/ guidelines regarding the diagnosis and management of hypothyroidism**

All respondents in Group A believed that the quality of guidance/ guidelines regarding the diagnosis and treatment of individuals with hypothyroidism would be improved if the views of members of the public with hypothyroidism were obtained and taken into consideration throughout the process and the table below lists their reasons:

**Table 12 – Group A’s reasons why patients should be consulted during the drawing-up of guidance/ guidelines**

Reason	Number
Guidance is currently unacceptable/ to improve current guidance	4
So that symptoms are taken into account in addition to thyroid function blood tests	1
So that variation between individuals is taken into account	1
So that patients are given a voice	2
So that patients can provide knowledge or ‘insights’	2

One individual expressed concern that uninformed patients would be asked rather than patients who had become ‘lay experts’. Two individual said yes with the caveat that the views of those consulted would be taken into account.

All respondents in Group B believed that the quality of guidance/ guidelines regarding the diagnosis and treatment of individuals with hypothyroidism would be improved if the views of members of the public with hypothyroidism were obtained and taken into consideration throughout the process and the table below lists their reasons:

**Table 13 – Group B’s reasons why patients should be consulted during the drawing-up of guidance/ guidelines**

Reason	Number
Guidance/ guidelines are currently unacceptable/ need improvement	3
So that symptoms are taken into account in addition to thyroid function blood tests	2
So that patients are given a voice	2
So that patients can provide knowledge or ‘insights’	2

**Other comments made****Table 14 - Other comments made by Group A**

<b>Comments</b>	<b>Number</b>
Diagnosis and treatment varies between areas/ countries	2
The UK guidance/ guidelines are 'flawed'	2
Endocrinologists should listen to patients/ treat their signs and symptoms rather than their thyroid function test results	2
Doctors are being prevented from helping patients	1
Inadequate diagnosis and treatment of hypothyroidism is resulting in an unaffordable cost to the country	1
A Public Enquiry is needed	2
The General Medical Council should not be used against doctors with a differing opinion who are helping patients	1
Peer reviewers may be restricting the funding and publication of those with differing views	1
Patients should be given a voice/ more dialogue is needed	3

**Table 15 - Other comments made by Group B**

<b>Comments</b>	<b>Number</b>
It is currently being diagnosed on the basis of thyroid function blood tests rather than symptoms	2
Current methods of diagnosis are inadequate	1
More follow-up consultations with general practitioners/ endocrinologists should be provided	2

## Discussion

I shall consider each subsidiary research question and the main research question referred to previously (Phillips, TMA02, 2010) in turn to see whether they have been addressed by the findings within the Results section.

### **Do the findings of research into hypothyroidism reach members of the public with hypothyroidism directly and/ or indirectly via various intermediaries who disseminate the information and if so, how?**

As can be seen from Table 6 and 7, a large proportion of individuals within both Group A and B made use of resources such as research papers and/ or books about hypothyroidism indicating that many were actively seeking out primary and secondary sources of research findings.

Members of the public can be capable of both assimilation and creation of scientific information (S802 SITUATED KNOWLEDGE, p.5). This is exemplified by the achievements of members of Group A which can be seen in Table 2 and include working for/ running charities/ organisations providing information and/ or support for individuals with hypothyroidism and authoring books, newsletters and websites.

Patient organisations can become a resource for both affected members of the public and medical practitioners (Gregory and Miller, 1998, p.229). However, according to Rabeharisoa and Callon (2002, p.60-62), patient organisations can be classified as 'auxiliary', 'partner' and 'opposing' depending on their relationship with medical experts.

### **Is the message biased?**

As illustrated by Table 6 and 7, a wide range of resources were consulted by individuals in Group A and B but the views of researchers and intermediaries and any potential bias within research and disseminations of research could not be gauged without carrying out an extensive 'content analysis' which is beyond the scope of this mini-project and impossible to include within the permitted word count even though I had hoped originally to have included this information. However, one respondent in each of the groups questioned the unreliable/ controversial nature of some of the information provided on the internet and one respondent in Group B questioned the reliability of information within newspapers and magazines (Appendix 4).

### **Is the message trusted?**

This question raises the issue of 'trust' referred to within the Introduction section. According to research by Martin and Tait (1992, p.34-36), certain sources of scientific findings are trusted more than others.

As can be seen from Table 8 and 9 respectively, the majority of individuals in Group A and half of individuals in Group B expressed trust in various scientists/ doctors and their advice/ journal articles/ books/ websites, however, a proportion of individuals in both groups also mentioned trust in the experiences of fellow patients learned about via direct communication and via books and websites. As mentioned in the Results section, details that would identify the individuals providing the sources of information referred to in Tables 6-9 have been omitted but this information did indicate that trust was often placed in particular scientists/ doctors rather than scientists/ doctors in general.

One respondent in Group A mentioned that they trusted books containing descriptions that reflected the experience of individuals with hypothyroidism that they knew (Appendix 4).

With regard to the issue of 'situated knowledge' referred to in the Introduction section, one insight gained is that as demonstrated in Table 8 and 9, respondents valued information provided by both lay people and scientific experts and the fact that many classed themselves as lay experts even if they weren't providing information and/ or support to others, as demonstrated in Table 4, meant that they valued their own accumulated knowledge. Members of the public are likely to compare scientific pronouncements with their own experience (Irwin, 1995b, p.116). Irwin (1995a, p.84-85&92) cites the example of advice for residents in case an emergency at the nearby industrial site arose and points out that the residents concerned were aware when there appeared to be a discrepancy between official pronouncements and their lay knowledge. In order to demonstrate that members of the public are capable of seeing flaws in scientific advice and compiling their own information, Irwin (1995b, p.111-112) cites the example of agricultural workers discussing the use of a particular pesticide.

### **Do researchers seek the views of members of the public with hypothyroidism when designing research?**

According to Rennie and Stockmayer (2003, p.770), lay expertise is not considered to be useful to scientists. However, the government is promoting public involvement in research related to health with some believing that this will enhance the research findings (Entwistle et al., 1998, p.463-464).

Thompson et al. (2009, p.210) cite various policies in favour of involving lay people (including patients) as partners in research related to health, but cite research conceding that progress has been limited. However, according to a source cited by Smith (S802 ETHICS, p.20), Research Councils are increasingly involving members of the public in decisions regarding funding priorities.

The James Lind Alliance (Accessed 2010, June 7) is an organisation attempting to involve members of the public with various health conditions in determining which research questions need investigation. Abma and Broerse (2010, p.160) have created a 'Dialogue Model' for use when patients are involved in dialogue to determine which research should take priority.

The organisation INVOLVE (Accessed 2010, June 5) is encouraging those carrying out research into health issues to incorporate lay members into their team so that the research is pertinent, dependable and stands a greater chance of being applied. However, as I did not question a sample of researchers carrying out studies related to hypothyroidism, I was not able to find out whether they were involving individuals with hypothyroidism in the design of their research studies.

### **Is research enriched by the input of those with hypothyroidism to whom it applies?**

The information provided next to Table 10 and 11 respectively demonstrates that all respondents in both groups believed that the input of individuals with hypothyroidism at the design stage of research proposals would improve the quality of research into hypothyroidism.

The reasons provided by respondents in Group A in Table 10 are as follows: so that their views are taken into consideration; to improve current situation; to improve understanding; to improve diagnosis and treatment; so that signs and symptoms aren't omitted from study; so that the right research is done; so that the right questions are asked; and for the mutual benefit of patients and researchers.

Likewise, Boote et al. (2010, p.10&17) have reviewed research in which members of the public had input into the structure of the study and found that in two of the studies members of the public suggested additional health related factors to be evaluated at the end of the study and Entwistle et al. (1998, p.464) refer to citations suggesting that involving the public in carrying out research could raise the likelihood that the researcher's revelations will be regarded as relevant.

Thompson et al. (2009, p.212&215-216) interviewed researchers to gauge their views regarding public involvement in their scientific studies and received feedback such as: it was sometimes necessary to meet research proposal criteria; it enhanced quality and pertinence; it made some researchers feel wary. Collaboration between members of the public and researchers can reduce the researchers' level of control (Staniszewska, 2009, p.297).

Boote et al. (2010, p.18-19) refer to a citation describing an incidence of strain in the relationship between the public and researchers when the public wished to introduce non-standardised investigations into the research design and cite an example of randomisation being perceived by the public as unjust to the study subjects assigned to be controls.

Thompson et al. (2009, p.210) cite sources which illustrate that involving the public in research creates a requirement for additional funding and training. However, although the aforementioned citations give an insight into the attitude of health researchers, the attitude of those carrying out research into hypothyroidism was not specified within the studies discussed and it was beyond the scope of the mini-project to question such researchers.

Entwistle et al. (1998, p.465) suggest that sometimes members of the public may be provided with the opportunity to give their opinions regarding research but may not be permitted to influence the choices made subsequently. Savory (2010, p.192) cites the 2006 Cooksey Report's message that the findings of research need to be applied in practice before patients can benefit.

### **Do members of the public with hypothyroidism feel that their views are taken into account by researchers?**

As mentioned in the Results section, all respondents in both groups believed that the quality of research into hypothyroidism would be improved if members of the public with hypothyroidism were consulted at the design stage of research proposals.

The reasons provided by respondents in Group A in Table 10 such as: so that their views are taken into account; to improve current situation; to improve understanding; and to improve diagnosis and treatment indicate that respondents believed that the views of hypothyroid patients weren't currently being taken into account by researchers either at all or to an adequate extent.

### **Do experts seek the views of members of the public with hypothyroidism when drawing up policy?**

This question addresses the issues of 'participation', 'policy' and 'regulation' referred to within the Introduction section.

According to an announcement on the Royal College of Physicians' of London's website (Accessed 2010, August 31), the British Thyroid Foundation's Patient Support Group was involved in the development of the statements regarding hypothyroidism by the Royal College of Physicians et al. (2008).

Likewise, according to the 'UK Guidelines for the Use of Thyroid Function Tests' by the Association for Clinical Biochemistry et al. (Beastall et al., 2006, p.4-6), the team writing the document included two members of the British Thyroid Foundation to represent individuals with thyroid conditions, patients were involved in reviewing the document and members of the public were able to view the draft version online and provide feedback which resulted in some amendments to the draft version prior to production of the final version.

The Clinical Knowledge Summaries (CKS) provide information regarding the diagnosis and treatment of hypothyroidism for use by National Health Service medical practitioners (National Institute for Health and Clinical Excellence, accessed 2010b, August 31). On one of the web pages of the website providing CKS, members of the public are notified that a draft document providing further information about hypothyroidism can be commented upon in November 2010 (National Institute for Health and Clinical Excellence, accessed 2010a, August 31).

### **Is policy enriched by the input of those with hypothyroidism to whom it applies?**

Leadbeater and Miller (2004, p.16) recommend that dilemmas related to health ought to be resolved by considering input from both experts and those with lay knowledge.

As mentioned in the Results section, all the respondents questioned felt that policy would be improved by the input of individuals with hypothyroidism and their reasoning is summarised in Tables 12-13.

### **Do members of the public with hypothyroidism feel that their views are taken into account by policy makers?**

The responses in Table 12 and 13 indicate that many respondents thought that current guidance/guidelines needed improving and that the input of individuals with hypothyroidism would result in improvement implying that many did not feel that the views of individuals with hypothyroidism had been taken into account either at all or to an adequate extent.

Day et al. (S802 DIALOGUE, p.8) differentiate between 'public consultation' and 'public engagement' on the premise that the former seeks out the public's perspective prior to determining policy whilst the latter seeks to permit the public's perspective to have an influence upon the policy.

Furthermore, Wilsdon and Willis (2004, p.38-39) cite the terms 'instrumental', 'substantive' and 'normative' to describe engagement that involves ulterior motives, permits members of the public to participate in policy-making procedures and seeks to fulfil a democratic requirement respectively.

'Mandated science' is drawn upon with the intention of terminating disputes (S802 REGULATION, p.4). According to Peters (S802 EXPERTS, p.9), whilst scientific researchers need to present the limitations of their findings fully, experts need to limit such details.

The statement put forward by the Royal College of Physicians et al. (2008) asserts that the diagnosis of an underactive thyroid must be verified by investigating the blood thyroid stimulating hormone levels and that synthetic levothyroxine is the only treatment that should be used.

A British Medical Journal article by Allahabadia et al. (2009) refers to the statement by the Royal College of Physicians et al. (2008) and re-iterates the main points regarding identification and treatment of hypothyroidism, however according to a declaration at the end of this article, it did not undergo peer review by outside reviewers.

Furthermore, O' Reilly (2010) cites a reference demonstrating that numerous hypothyroid individuals are complaining of insufficient symptom relief and links this to the policy of using blood thyroid stimulating hormone levels to monitor the level of treatment required.

According to O'Reilly (2010), there is no evidence that a blood thyroid stimulating hormone level within the target interval correlates with clinical wellbeing. Therefore, with regard to the subject of 'experts' referred to within the Introduction section, the aforementioned citations demonstrate disagreement amongst experts.

O'Reilly (2010) refers to a patient initiated petition criticising medical practitioners for depending upon blood thyroid function tests rather than clinical evaluation to diagnose hypothyroidism. Likewise, many of the respondents questioned expressed concern at the way diagnosis and treatment of hypothyroidism was being carried out as shown in Tables 12-15.

In addition, as can be seen in Table 14, one respondent in Group A expressed concern that researchers with dissenting views may have difficulty receiving funding and getting published. According to Yearley (S802 TRUST, p.3), bias can sometimes enter the process of peer-review.

As can be seen in Table 14, another respondent in Group A stated that the General Medical Council should not be used against doctors with a differing opinion who are helping patients. Yearley (1994, p.255) cites an article which highlights the role that professional bodies with the power to take punitive action against their members play in preventing certain scientific knowledge from being accepted.

According to Irwin (1995b, p.120&121), policy-makers are loath to allow lay knowledge to have an influence on policy and scientists are discouraged from approaching decision-making bodies on behalf of members of the public. In the case of environmental issues, Irwin (1992, p.571) calls for policy-makers to involve various groups holding differing viewpoints in dialogue, recognise gaps in knowledge and be willing to form policy that can be amended on the basis of ongoing feedback. However, the aforementioned recommendations would also be pertinent to health related issues.

**Main Research Question: 'Is there a direct and/ or indirect dialogue between those researching into hypothyroidism and members of the public with hypothyroidism?'**

This question addresses the issue of 'dialogue' referred to in the Introduction section. Farmelo (1997, p.183) calls for a two-way passage of information between the scientists and society. Table 6 and 7 indicate that many respondents were actively seeking out information about hypothyroidism from research articles and/ or books and presumably some of these would be likely to cite such articles.

However, certain responses within Table 10 and 11 indicate that certain respondents believed that researchers weren't taking the views of individuals with hypothyroidism into account.

Likewise, certain responses within Table 12 and 13 indicate that certain respondents believed that those drawing-up policy regarding the diagnosis and treatment of hypothyroidism weren't taking the views of individuals with hypothyroidism into account.

Some of the responses provided within the tables throughout the Results section indicate that most respondents in Group A and some respondents in Group B appeared knowledgeable about research and/ or guidelines, however, there is also the possibility that some respondents in Group B were not aware of current research and guidelines but still assumed that the input of individuals with hypothyroidism would lead to improvements which indicates the high value placed upon lay knowledge.

## Conclusions

My main research question asked whether there was a direct and/ or indirect dialogue between those researching into hypothyroidism and members of the public with hypothyroidism. As mentioned previously, the findings within Table 6 and 7 indicate that there are many means by which individuals with hypothyroidism are seeking information about research being carried out both directly and indirectly.

However, with regard to the flow of information from individuals with hypothyroidism to researchers, although the previously mentioned citations did investigate the views of health researchers in general, citations have not been provided about the views of those researching hypothyroidism in particular. Furthermore, due to restraints of time and space, it has not been possible to present the views of organisations acting as intermediaries.

However, the findings mentioned previously indicate that one outcome of the mini-project was that some of those questioned indicated that they considered dialogue between researchers and individuals with hypothyroidism to be inadequate and some respondents indicated that they considered dialogue between those drawing up guidelines regarding the diagnosis and treatment of hypothyroidism and individuals with hypothyroidism to be inadequate.

To re-iterate, my mini-project investigated whether there is a problem regarding a lack of dialogue between those carrying out research into hypothyroidism and individuals with hypothyroidism both directly and indirectly via various intermediaries as outlined previously (Phillips, TMA02, 2010).

The responses within Table 14 and 15 demonstrate that a proportion of respondents were calling for more dialogue whilst a proportion of respondents implied that current levels of dialogue were unsatisfactory. The concerns raised by certain respondents within the Results section indicate the need for further investigation and genuine dialogue.

A shortcoming of the mini-project is that those questioned were selected in a non-random way (please see Introduction) and the numbers were too small (please see Results section) for any statistical analysis to be carried out. Furthermore, respondents in Group A would not necessarily be representative of all individuals providing information and/ or support to individuals with hypothyroidism whilst respondents in Group B would not necessarily be representative of all individuals with hypothyroidism.

However, as illustrated by Table 2, many of the individuals in Group A were involved in activities which would bring them into contact with many other individuals with hypothyroidism on a regular basis and therefore, their insights are of great value.

A further shortcoming was that due to time constraints my initial plan was over ambitious and had to be amended to the version shown in Appendix 1, but, this lessened the extent to which the research questions posed could be fully addressed. However, the achievement of this project is that as already outlined it has provided some answers to the research questions posed.

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## Appendix 1

### Amended timetable for mini-project tasks to be undertaken

Month of 2010	Tasks to be undertaken
<b>May</b>	<ul style="list-style-type: none"> <li>◆ Design a draft covering letter and questionnaire.</li>   <li>◆ Obtain feedback on draft questionnaire from an individual providing information about hypothyroidism to others and from tutor.</li>   <li>◆ Carry out a literature search.</li> </ul>
<b>June/ July/ August</b>	<ul style="list-style-type: none"> <li>◆ Complete a draft covering letter and questionnaire.</li>   <li>◆ Contact 28 individuals to ask if they would be willing to complete my questionnaire (and provide them with the information in the covering letter). If they are willing to complete the questionnaire, give them the choice of either being interviewed in person (if applicable) or by telephone or being posted or emailed the questionnaire so that they could complete it in their own time and post or email it back.</li>   <li>◆ Carry out a literature search.</li> </ul>
<b>August</b>	<ul style="list-style-type: none"> <li>◆ Analyse the questionnaires that have been returned.</li>   <li>◆ Work on first draft of mini-project.</li> </ul>
<b>September</b>	<ul style="list-style-type: none"> <li>◆ Work on first draft of mini-project.</li>   <li>◆ Amend and check first draft &amp; complete mini-project.</li> </ul>

## Appendix 2

### Covering Letter to go with Questionnaire

[Address]

[Date]

Dear \_\_\_\_\_

I am studying with the Open University and as a mini-project for my Master of Science degree, I am carrying out research into the dialogue between members of the public with hypothyroidism and researchers studying 'hypothyroidism'. I would be most grateful if you would be willing to complete the anonymous questionnaire attached. Even if you identify yourself within the questionnaire (inadvertently or by choice), any information collected will be used anonymously for the sole objective of research and no transfer of data to third parties will take place and the data will be anonymised within the report. I do not require any personal details relating to the health of individuals.

The questionnaire should take approximately 10 minutes to complete and I have attached a stamped addressed envelope so that the questionnaire can be returned to the above address upon completion by the end of August 2010. Many thanks for your help.

Yours sincerely,

Ms C A Phillips

### Appendix 3

#### QUESTIONNAIRE

1. Please tick the age range to which you belong:

- 18-29 years of age.
- 30-39 years of age.
- 40-49 years of age.
- 50-59 years of age.
- 60-69 years of age.
- 70-79 years of age.
- 80-89 years of age.
- 90+ years of age.

2. What is your gender? \_\_\_\_\_

3. Please tick the box(es) which describe(s) your occupational status:

- I am not working, if so please state usual position \_\_\_\_\_
- I am a student, if so please state subject area \_\_\_\_\_
- I am employed, if so please state position \_\_\_\_\_
- I am doing voluntary work, if so please state position \_\_\_\_\_
- I am retired, if so please state former position \_\_\_\_\_

4. Do you consider yourself to be a lay expert in hypothyroidism? Please tick the applicable box:

- No
- Yes
- I'm not sure





10. Please tick any of the boxes below that describe yourself:

- I have hypothyroidism.
- I have family/ friends with hypothyroidism.
- I have conducted/ I am conducting research into hypothyroidism as a lay expert.
- I am running/ working for a charity/ organisation that provides information for patients with hypothyroidism.
- I am the author of a book/ books about hypothyroidism.
- I am the author of newsletter/ magazine/ newspaper articles about hypothyroidism.
- I am the author of a website about hypothyroidism.
- I am the moderator of an internet forum used by hypothyroid patients.
- I provide telephone support for individuals with hypothyroidism.
- I run a support group/ organise meetings for individuals with hypothyroidism.
- I have been/ am campaigning for better diagnosis and treatment of individuals with hypothyroidism.
- I have attended an expert patient programme.
- I attend events related to hypothyroidism e.g. \_\_\_\_\_

**Thank you for completing this questionnaire.**

## Appendix 4

### Additional quotes of interest by respondents within Group A

*"I'm not saying that the internet isn't good but there's a lot of controversy on the internet."*

*"I trust books but only from trusted sources when the individuals provide information that correlates with my family's experience."*

### Additional quotes of interest by respondents within Group B

*"The internet contains more that you don't agree with – there's more incorrect information on the internet."*

*"Don't know reliability of magazines and newspapers."*