Cynulliad Cenedlaethol Cymru
National Assembly for Wales

Y Pwyllgor Deisebau

Adroddiad Cwblhau

Crynodeb o ystyriaeth y Pwyllgor Deisebau o P-03-137 Hypothyroidedd yng Nghymru

Medi 2009

Cyflwynwyd yr e-ddeiseb
19 Mai 2008

Dyfarnwyd yn dderbyniadwy
1 Hydref 2008 (ar ôl casglu llofnodion)

Ystyriaeth gychwynnol

16 Hydref 2008

Ystyriaeth gychwynnol

Ystyriodd y pwyllgor y ddeiseb am y tro cyntaf, a chytunodd i ysgrifennu ar y Gweinidog dros Iechyd a Gwasanaethau Cymdeithasol

(Gweler Atodiad 1 ar gyfer y darn perthnasol o'r trawsgrifiad o'r cyfarfod a gynhaliwyd ar 16 Hydref 2008, ac Atodiad 2 ar gyfer y llythyr a anfonodd y Cadeirydd at y Gweinidog dros Iechyd a Gwasanaethau Cymdeithasol)

Ystyriaeth bellach

20 Tachwedd 2008

Ystyriodd y Pwyllgor ymateb gan y Gweinidog dros Iechyd a Gwasanaethau Cymdeithasol, a chytunodd i ysgrifennu at y deisebwr i ofyn iddi ddweud wrth y Pwyllgor pa gamau penodol yr hoffai weld y Gweinidog yn eu cymryd i ymdrin â'i phryderon

(Gweler Atodiad 1 ar gyfer y darn perthnasol o'r trawsgrifiad o'r cyfarfod a gynhaliwyd ar 20 Tachwedd 2008, ac Atodiad 2 ar gyfer y llythyr a gafwyd gan y Gweinidog dros Iechyd a Gwasanaethau Cymdeithasol)

10 Chwefror 2009

Ystyriodd y Pwyllgor ymateb gan y prif ddeisebwr, a chytunodd i ysgrifennu at y Gweinidog dros Iechyd a Gwasanaethau Cymdeithasol i ofyn iddi ymateb i'r pwyntiau a godwyd yn ymateb y deisebwr.

(Gweler Atodiad 1 ar gyfer y darn perthnasol o'r trawsgrifiad o'r cyfarfod a gynhaliwyd ar 10 Chwefror 2009, ac Atodiad 2 ar gyfer y llythyr a anfonwyd at y Gweinidog dros Iechyd a Gwasanaethau Cymdeithasol)

5 Mai 2009

Ystyriodd y Pwyllgor ymateb gan y Gweinidog dros Iechyd a Gwasanaethau Cyhoeddus, a chytunodd i ysgrifennu at Goleg Brenhinol y Meddygon a'r Sefydliad Cenedlaethol dros Iechyd a Rhagoriaeth Glinigol i ofyn am eu barn ar y ddeiseb

(Gweler Atodiad 1 ar gyfer y darn perthnasol o'r trawsgrifiad o'r cyfarfod a gynhaliwyd ar 5 Mai 2009, Atodiad 2 ar gyfer yr ymateb a gafwyd gan y Gweinidog dros Iechyd a Gwasanaethau Cymdeithasol, Atodiad 3 ar gyfer y llythyr a anfonwyd i Goleg Brenhinol y Meddygon, ac Atodiad 4 ar gyfer y

llythyr a anfonwyd i'r Sefydliad Cenedlaethol dros Iechyd a Rhagoriaeth Glinigol)

7 Gorffennaf 2009

Ystyriodd y Pwyllgor ymateb gan Goleg Brenhinol y Meddygon, a chytunodd i aros am ymateb gan y Sefydliad Cenedlaethol dros Iechyd a Rhagoriaeth Glinigol.

(Gweler Atodiad 1 ar gyfer y darn perthnasol o'r trawsgrifiad o'r cyfarfod a gynhaliwyd ar 7 Gorffennaf 2009, ac Atodiad 3 ar gyfer yr ymateb a gafwyd gan Goleg Brenhinol y Meddygon)

22 Medi 2009

Ystyriodd y Pwyllgor ymatebion gan y Sefydliad Cenedlaethol dros Iechyd a Rhagoriaeth Glinigol a'r deisebwr, a chytunodd i ddod â'r broses o ystyried y ddeiseb i ben gan nad oedd modd mynd â'r ddeiseb ymhellach.

(Gweler Atodiad 1 ar gyfer y darn perthnasol o'r trawsgrifiad o'r cyfarfod a gynhaliwyd ar 22 Medi 2009, ac Atodiad 4 ar gyfer yr ymateb a gafwyd gan y Sefydliad Cenedlaethol dros Iechyd a Rhagoriaeth Glinigol)

Clerc y Pwyllgor Deisebau
Hydref 2009

Atodiad 1

Trawsgrifiadau o gyfarfodydd y Pwyllgor Deisebau

16 Hydref 2008

Val Lloyd: Our next petition is on hypothyroidism. The petition calls,

'upon the National Assembly for Wales to investigate the non-diagnosis and mismanagement of hypothyroidism in Wales with a view to producing recommendations to rectify this situation'.

This petition was raised by Dr Sarah Myhill, and 1,433 signatures have been collected.

We have also had a thick information pack—that is not from a petitioner, but from a Mrs Cameron. I must confess that I have not had time to read that yet.

Bethan Jenkins: Again, can we write to the Minister for Health and Social Services about that?

Val Lloyd: Yes, in the first instance, I believe that we need to write to the Minister for Health and Social Services.

Michael German: We can then consider our actions in light of that.

20 Tachwedd 2008

Val Lloyd: The next petition, P-03-137, is on hypothyroidism. We first considered this in the last meeting in October. We have also had an additional paper. We have had a letter back from the Minister for Health and Social Services, and we have also had a letter from the petitioner.

Andrew R.T. Davies: The Minister has responded to a point in the letter that we had on 5 November. Perhaps we should dialogue with the petitioner to see what—

Michael German: Sorry, I do not like that use of the English language: 'dialogue' is a noun, not a verb.

Andrew R.T. Davies: I stand corrected. [*Laughter.*]

Val Lloyd: Mike must have had the same grammar teacher as me.

Michael German: I am sorry, it just grates on me.

Andrew R.T. Davies: We need to see where we can go with this. It is important that the petitioner feels that the dialogue has taken place in the light of what the Minister has come back and said to us.

Val Lloyd: Has the petitioner not said that in her letter of 14 November, which she sent to all of us?

Andrew R.T. Davies: I am not sure whether I have had it.

Michael German: It came the day before yesterday, I think.

Ms Webber: That letter was circulated separately, because it came in after the briefing papers were sent out. So, it was sent out with the report on the plastic bags, I think—sorry, it was sent out with Joanest's paper on the Llanbedr legal point.

Val Lloyd: She does not answer the question. It is a comprehensive letter from the petitioner, but I cannot find any specific reference to what she wants done. So perhaps we should write to her first, thanking her for this letter and asking her what steps she would like to see the Minister take to improve the situation regarding diagnosis and management.

Michael German: I presume that the recommendations and guidelines in the last but one paragraph on the second page are some of the things that she would like to see addressed. However, I am guessing.

Val Lloyd: She is referring to the situation in America in 2006, is she not? It is now nearly 2009, so the situation could have changed again. We will write to ask exactly what she would like, and then we can ask the Minister a specific question. Are you happy with that?

Andrew R.T. Davies: Yes.

Val Lloyd: It takes a while to get through that letter.

10 Chwefror 2009

Val Lloyd: The next petition is P-03-137 on hypothyroidism. We received a response from the Minister for Health and Social Services, which we sent to the petitioners, and we now have the petitioners' response to that letter. It is quite a technical response, is it not? I am not sure that we—

Michael German: We need to raise these concerns again with the Minister, because we are now drilling down to a much deeper level. We need a more detailed response from the Minister on the concerns raised in the letter, which amplify what was demanded in the petition.

Val Lloyd: I do not think that any one of us is technically qualified to make a judgment on that evidence. So, it would be a good way forward to send it to the Minister asking for her comments or actions.

Michael German: When we get the response, perhaps we could measure it against the queries raised in the Members' briefing note, so that those of us who have less technical skill in this matter might be able to make a judgment.

Val Lloyd: That sounds like a good way forward. Thank you.

5 Mai 2009

Val Lloyd: The next petition is P-03-137 on hypothyroidism. There was a very clear statement on this in February from the Royal College of Physicians.

Bethan Jenkins: It seems to contradict the petitioners, so perhaps we should write to the Royal College of Physicians to ask for its view on this petition in light of the fact that the petitioners do not seen to concur that it should be the only treatment available to those who suffer from hypothyroidism.

Michael German: We could write to the National Institute for Health and Clinical Excellence as well.

Val Lloyd: Yes—we will write to the RCP and to NICE asking for their views. I think that that is the only way that we can take this forward. Thank you.

7 Gorffennaf 2009

Sandy Mewies: The third petition is P-03-137 on hypothyroidism in Wales, raised by Dr Sarah Miles.

Michael German: I have a technical question on this one.

Sandy Mewies: I will refer you to the department. [*Laughter*.]

Michael German: Yes. It is about the role of the National Institute for Health and Clinical Excellence. Essentially, the petitioners take the Royal College of Physicians to task—I am not in a position to judge that, and I do not think that I would ever want to be. Will NICE be the arbiter in this matter? Is it NICE's role to state how the care and management of different types of conditions should be dealt with? The petitioners are saying that the Royal College of Physicians has got it wrong, but is NICE the arbiter? I do not know the answer to the question.

Sandy Mewies: I think that that is highly unlikely—I would not have thought that it would be within NICE's remit. However, we can find out, because I do not know who the arbiter would be.

Andrew R.T. Davies: We should ask for a Members' research service brief on it and find out who looks into these types of things.

Sandy Mewies: We will inquire into that. I would not have thought the arbiter was NICE, but the next question is: who is it?

Michael German: Should there be one? I do not know.

Sandy Mewies: Possibly. Are you happy if we do that? I see that you are.

22 Medi 2009

Val Lloyd: The next update is on petition P-03-137, Hypothyroidism in Wales. We considered this twice in 2008 and in February, May and July of this year. Since our last meeting, we have had an update from the Royal College of Physicians, and the National Institute for Health and Clinical Excellence has also confirmed that it has decided not to develop guidance on hypothyroidism.

Michael German: I think that we have taken this as far as we can, because NICE has decided not to develop guidance. Unless we were to investigate the three reasons given at the bottom of page 48 of the report on why NICE has taken that decision, I do not see where else we can go with this petition.

Val Lloyd: NICE, in its conduct, has used experts and members of the lay public. I think that it is beyond our scope to discuss it further. I am sure that its decision has been properly arrived at.

Michael German: The route is always open to petitioners if they want to address the NICE issue, because they could send us a petition on that matter.

Val Lloyd: Are you all in agreement that we should formally close the petition? I see that you are. Thank you.

Atodiad 2

Y Pwyllgor Deisebau

Petitions Committee

Bae Caerdydd / Cardiff Bay
Caerdydd / Cardiff CF99 1NA

Edwina Hart AM
Minister for Health and Social Services
Welsh Assembly Government
Cardiff Bay
CF99 1NA

Our ref: PET-03-137

28 October 2008

Dear Edwina

PETITION: HYPOTHYROIDISM IN WALES

At its meeting on 16th October, the Petitions Committee gave initial consideration to a petition urging the National Assembly for Wales to investigate the non-diagnosis and mismanagement of hypothyroidism in Wales. A link to the petition wording is attached below:

http://assemblywales.org/gethome/e-petitions/eform-sign-petition/p-03-137.htm

During the meeting, the Committee agreed to ask you for the Welsh Assembly Government's policy on the treatment of hypothyroidism.

Thank you for your consideration of this matter, and I look forward to hearing from you.

Yours sincerely

Val Lloyd

Val Lloyd
Chair, Petitions Committee

Edwina Hart AM MBE
Y Gweinidog dros Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services

Our ref: EH/05045/08
Your ref: PET-03-137

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Val Lloyd AM
Chair
Petitions Committee
National Assembly for Wales
Cardiff Bay
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31ST October 2008

Dear Val

Thank you for your letter dated 28 October about the Welsh Assembly Government's policy on the treatment of hypothyroidism.

The Welsh Assembly Government does not provide clinical guidelines on individual conditions. Treatment for hypothyroidism, is a matter for individual professional judgement. We would expect that up to date evidence of effective management and treatment to be taken into account by the professionals concerned in dealing with individual cases.

I am aware that a few years ago the National Public Health Service undertook a review into the evidence of the benefit of treating sub-clinical hypothyroidism, and I attach a website address for your information
http://www.attract.wales.nhs.uk/question_answers.cfm?question_id=1719

Y Pwyllgor Deisebau

Petitions Committee

Bae Caerdydd / Cardiff Bay
Caerdydd / Cardiff CF99 1NA

Our ref: PET-03-137

13 February 2009

Edwina Hart AM
Minister for Health and Social Services
Welsh Assembly Government
Cardiff Bay
CF99 1NA

Dear Edwina

PETITION: HYPOTHYROIDISM IN WALES

As you are aware, the Petitions Committee has received a petition calling for:

"the National Assembly for Wales to investigate the non-diagnosis and mismanagement of hypothyroidism in Wales with a view to producing recommendations to rectify this situation."

The petitioners have provided us with more information on how the signs and symptoms of the condition may be going unnoticed because of inappropriate reliance on blood tests to the exclusion of additional clinical assessment. They also raise the issue of how lowering the threshold for prescribing thyroid hormone could lead to more hypothyroid patients being diagnosed and treated. A copy of the petitioners' letters and supporting information is enclosed.

The Committee would welcome your view on whether consideration could be given to a review of the diagnosis and treatment of hypothyroidism in Wales in light of the evidence submitted by the petitioners.

Thank you for your consideration of this matter, and I look forward to your response.

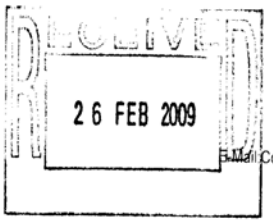
Yours sincerely

Val Lloyd

Val Lloyd
Chair, Petitions Committee

Edwina Hart AM MBE
Y Gweinidog dros Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services

Our ref: EH/00608/09
Your ref: PET-03-137



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Val Lloyd AM
Chair
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Dear Val

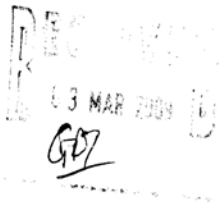
26th February 2009

Thank you for your letter dated 13 February about the development of clinical guidelines for the assessment and management of hypothyroidism in Wales.

Decisions about the most appropriate clinical intervention are a matter for professional judgement based on clinical evidence. The National Institute for Health and Clinical Excellence (NICE) develops clinical guidelines for the NHS in Wales and England on the care and management of a range of conditions. It currently has no plans to develop guidelines for hypothyroidism, but it is open to anyone to suggest a topic for NICE guidance. Further details on how to do this are available on the Institute's website: www.nice.org.uk. There are other sources of clinical evidence available to professionals including the Cochrane Library and the BMJ publication 'Clinical Evidence'. I understand both have described the current state of the evidence on this condition to assist professionals.

The National Public Health Service undertook a review of the evidence around treating sub-clinical hypothyroidism and I attach a website address for your information

http://www.attract.wales.nhs.uk/question_answers.cfm?question_id=1719



Atodiad 3

Y Pwyllgor Deisebau

Petitions Committee

Prof. Ian T Gilmore MD PRCP
President
The Royal College of Physicians
11 St Andrews Place
Regent's Park
London
NW1 4LE

Bae Caerdydd / Cardiff Bay
Caerdydd / Cardiff CF99 1NA

Our ref: PET-03-137

18 May 2009

Dear Prof. Gilmore

PETITION: HYPOTHYROIDISM IN WALES

The Petitions Committee of the National Assembly for Wales has been considering a petition that calls for a review of the treatment and diagnosis of hypothyroidism. I enclose a copy of the petition wording, and some of the supporting information that the lead petitioner has provided.

The Committee is aware of your recent statement on the treatment and diagnosis of hypothyroidism, and it would very much welcome your views on this petition. I have also written to the National Institute of Clinical Excellence to seek its views, and copied this letter to the Clinical Vice President of the Royal College of Physicians, Dr Mike Cheshire for information.

Should you require any further information regarding this petition please contact the clerk to the Committee, Alun Davidson. He can be contacted at alun.davidson@wales.gsi.gov.uk or on 029 2089 8639.

I thank you for your consideration of this matter and look forward to your response.

Yours sincerely

Val Lloyd

Val Lloyd
Chair, Petitions Committee

c.c. Dr Mike Cheshire MBFRCP, Clinical Vice President

Royal College of Physicians
Setting higher medical standards

From the President
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Val Lloyd
Chair
Petitions Committee
National Assembly for Wales
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GDT

10th June 2009

Dear Ms Lloyd,

Petition: Hypothyroidism in Wales

Thank you for your letter reference PET-03-137 dated 18th May 2009 and for sharing with us the petition you have received about hypothyroidism in Wales.

As you say, this College in partnership with the Society for Endocrinology, the British Thyroid Association, the British Thyroid Foundation Patient Support Group, the Association for Clinical Biochemistry the British Society of Paediatric Endocrinology and Diabetes. endorsed by the Royal College of General Practitioners, has recently produced a statement on the diagnosis and treatment of primary hypothyroidism that we believe to be based on the best evidence. We stand by its content, and enclose a copy for your reference. In our opinion, if this is followed in Wales, problems of misdiagnosis and mismanagement will be avoided.

Kind regards,

Yours,

Enc.

The Association for Clinical Biochemistry

Royal College of Physicians
Setting higher medical standards

British Thyroid Association

BRITISH THYROID FOUNDATION

Society for Endocrinology

The Diagnosis and Management of Primary Hypothyroidism

A statement made on behalf of

The Royal College of Physicians
in particular its Patient and Carer Network and the Joint Specialty Committee for Endocrinology & Diabetes

The Association for Clinical Biochemistry

The Society for Endocrinology

The British Thyroid Association

The British Thyroid Foundation Patient Support Group

The British Society of Paediatric Endocrinology and Diabetes

Endorsed by the Royal College of General Practitioners

Hypothyroidism, underactivity of the thyroid gland, is common. It can make people unwell and should be treated with thyroxine (T4) tablets. Symptoms of hypothyroidism, for example tiredness, are not specific for thyroid underactivity and occur in many other situations. It is important to diagnose hypothyroidism with a blood test, because it can be dangerous to take T4 or other thyroid hormones if they are not needed. We are therefore very concerned that some patients with and without thyroid disease are being inappropriately diagnosed and managed, using thyroxine and other thyroid hormones, in ways which compromise patient safety. This is potentially an enormous problem, given that in any one year one in four of the population has their thyroid function checked.

The vast majority of patients with suspected thyroid disease are supported very well in primary care by their General Practitioners and their condition, hypothyroidism or otherwise, is appropriately diagnosed and well managed. However some patients are inappropriately diagnosed as being hypothyroid (often outside the NHS) and are started on thyroxine or other thyroid hormones which will not only cause them possible harm but leaves the true cause of their symptoms undiagnosed and therefore untreated.

This statement refers only to primary hypothyroidism. Secondary hypothyroidism is a different condition and should be managed by accredited endocrinologists in the same way as all other pituitary diseases.

DIAGNOSIS OF PRIMARY HYPOTHYROIDISM

(a) The symptoms of hypothyroidism are very common, both in many other conditions and even in states of normal health. It is therefore essential that thyroid function is tested biochemically alongside a careful clinical assessment of the individual patient. Clinical symptoms and/or signs alone are insufficient to make a diagnosis of hypothyroidism.

(b) The only validated method of testing thyroid function is on blood, which must include serum TSH and a measure of free thyroxine (T4).

(c) There is no evidence to support the use of thyroid hormone testing in urine, saliva, etc or the measurement of basal body temperature in the diagnosis of thyroid dysfunction.

(d) The results of blood tests for thyroid function can be influenced by other factors, for example in some illnesses which do not permanently damage the thyroid gland. In this case the tests will return to normal after the illness and thyroid hormone therapy is not needed (and can be harmful).

(e) We recognise that different test methods can give different results and we support the international initiative for greater harmonisation of reference ranges and of the units used in expressing results.

TREATMENT OF PRIMARY HYPOTHYROIDISM

(a) The aim of the treatment of hypothyroidism is to render the patient back to the normal or 'euthyroid' state.

(b) When a sufficient dose of thyroid treatment is given to lower the TSH to the normal range (reference range) for the test method used, patients usually lose their symptoms of hypothyroidism.

(c) Fine-tuning of TSH levels inside the reference range may be needed for individual patients.

(d) Patients with continuing symptoms after appropriate thyroxine treatment should be further investigated to diagnose and treat the cause.

(e) Overwhelming evidence supports the use of Thyroxine (T4) alone in the treatment of hypothyroidism. Thyroxine is usually prescribed as levothyroxine. We do not recommend the prescribing of additional Tri-iodothyronine (T3) in any presently available formulation, including Armour thyroid, as it is inconsistent with normal physiology, has not been scientifically proven to be of any benefit to patients, and may be harmful.

(f) There are potential risks from T3 therapy, using current preparations, on bone (eg osteoporosis) and the heart (eg arrhythmia). We note that the extract marketed as Armour thyroid contains an excessive amount of T3 in relation to T4. Over-treatment with T4, when given alone, has similar risks.

TREATMENT OF SUB-CLINICAL HYPOTHYROIDISM

(a) Sub-clinical hypothyroidism is defined as being present in a patient when the TSH is above the upper limit of the reference range but Free T4 levels are within the reference range.

(b) Some patients, particularly those whose TSH level is greater than 10mU/l, may benefit from treatment with thyroxine in the same way as for hypothyroidism as above, as indicated in national guidelines (Thyroid function testing, Association of Clinical Biochemists, British Thyroid Association, British Thyroid Foundation, July 2006: http://www.british-thyroid-association.org/TFT_guideline_final_version_July_2006.pdf).

PATIENTS WITH NORMAL THYROID FUNCTION TESTS

(a) We recommend that those patients whose thyroid blood tests are within the reference ranges but who have continuing symptoms, whether on thyroxine or not, should be further investigated for the non-thyroid cause of the symptoms.

(b) A further opinion or help with these patients may be sought from appropriate specialists on specialist registers of the Royal College of Physicians or the Royal College of Paediatrics and Child Health.

CONCLUSION

(a) Patients with suspected primary hypothyroidism should only be diagnosed with blood tests including measurement of TSH.

(b) Patients with primary hypothyroidism should be treated with T4 using levothyroxine tablets (BNF) alone.

(c) There is no indication for the prescription of T4 or any preparation containing thyroid hormones to patients with thyroid blood tests within the reference ranges.

(d) In patients with suspected primary hypothyroidism there is no indication for the prescription of T4 or any preparation containing thyroid hormones to patients with thyroid blood tests initially within the normal range. Thus patients with normal T4 and TSH do not have primary hypothyroidism and even if they have symptoms which might suggest this should not be given thyroid hormone replacement therapy.

(e) The College does not support the use of thyroid extracts or thyroxine and T3 combinations without further validated research published in peer-reviewed journals. Therefore, the inclusion of T3 in the treatment of hypothyroidism should be reserved for use by accredited endocrinologists in individual patients.

(g) Laboratories which measure thyroid function in other bodily fluids besides blood need to provide analytical and clinical validation to demonstrate their efficacy.

(h) The above statements reflect best practice of clinical endocrinologists accredited by the Royal College of Physicians and the Royal College of Paediatrics and Child Health.

19th November 2008

Atodiad 4

Y Pwyllgor Deisebau

Petitions Committee

Enquiry Handling Team
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Clinical Excellence
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Caerdydd / Cardiff CF99 1NA

Our ref: PET-03-137

18 May 2009

Dear Enquiry Handling Team

PETITION: HYPOTHYROIDISM IN WALES

The Petitions Committee of the National Assembly for Wales has been considering a petition that calls for a review of the treatment and diagnosis of hypothyroidism. I enclose a copy of the petition wording, and some of the supporting information that the lead petitioner has provided.

The Committee agreed that it would very much welcome your views on this petition, and on whether any clinical guidelines exist, or are in the process of being produced, for the diagnosis and treatment of hypothyroidism. I have also written to the Royal College of Physicians to seek its views.

Should you require any further information regarding this petition please contact the clerk to the committee, Alun Davidson. He can be contacted at alun.davidson@wales.gsi.gov.uk or on 029 2089 8639.

I thank you for your consideration of this matter and look forward to your response.

Yours sincerely

Val Lloyd

Val Lloyd
Chair, Petitions Committee

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National Institute for Health and Clinical Excellence

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Valerie Lloyd
Chair, Petitions Committee
National Assembly for Wales
Cardiff Bay
CF99 1NA

Dear Ms Lloyd,

Thank you for your letter of 18 May 2009 about a petition calling for a review of the treatment and diagnosis of hypothyroidism.

NICE is responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health, in three areas:

- Health technologies – guidance on the use of new and existing medicines, treatments and procedures, including interventional procedures used in the NHS.
- Clinical practice – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS
- Public health – guidance on the promotion of good health and prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector

The Department of Health commission us to develop clinical guidelines, guidance on public health and technology appraisals. The topics that we consider come from a number of sources such as clinical and public health professions, the Department of Health's national clinical directors and policy teams or the National Horizon Scanning Centre which suggest new and emerging health technologies that might need to be assessed. Topics can also be suggested directly to the institute for consideration.

NICE has responsibility for managing the administration of the early stages of the topic selection process on behalf of the Department of Health. Ministers at the Department of Health have responsibility for the final decision about which topics are referred to NICE.

When considering topics, NICE reviews each of the suggestions received to ensure they are appropriate and to check whether they are already included in its work.

The topics that we develop guidance on are chosen according to the Department of Health's topic selection criteria – the selection criteria takes into account:

- Burden of disease (population affected, morbidity, mortality)
- Resource impact (i.e. the cost impact on the NHS or the public sector)
- Policy importance (i.e. whether the topic falls within a government priority area)
- Whether there is inappropriate variation in practice across the country
- Factors affecting the timeliness or urgency for guidance to be produced

The suggestions are then reviewed by consideration panels composed of experts in the topic area, generalists with a good knowledge of the health service, public health and the public sector, and patient and carer representatives. The panels' recommendations go to the Department of Health and a health Minister makes the final decision on which topics are referred to NICE for guidance to be produced.

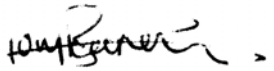
Our topic selection consideration panel meeting on Long Term Conditions (LTC) met on Friday 16th March 2007 to consider developing a guideline on 'the diagnosis and management of hypothyroidism (1794) and 'the diagnosis and management of thyrotoxicosis (968).' These topics were considered together. It was felt that there was insufficient robust evidence available to facilitate the production of a guideline on hypothyroidism (i.e. thyrotoxicosis).

The panel consisted of a number of clinical professionals – including a primary care representative. The primary care representative felt confident in dealing with straightforward cases of hypothyroidism in the absence of guidance, perhaps because the Quality and Outcomes Framework states that this condition should be monitored within the community. GPs are also able to recognise the more difficult cases which require referral to an endocrinologist.

As a consequence, this topic scored 2 out of a potential score of 5 – deeming it a low priority with the final decision not to develop guidance on this topic. Currently, we do not have any specific guidance on the diagnosis and management of hypothyroidism nor, have we been commissioned by the Department of Health to issue guidance on this topic.

I hope that this information is of help.

Yours sincerely



Tony Beaman
Communications Executive (Public Affairs)

Enc. Minutes of Long Term Conditions (LTC) Friday 16th March 2007

NHS
National Institute for
Health and Clinical Excellence

Topic selection consideration panel meeting: Long Term Conditions (LTC)

Minutes: Confirmed

Date and time: Friday 16 March 2007 12.00-4.00pm

Venue: The Royal College of Paediatrics and Child Health
50 Hallam Street
London
W1W 6DE

Attendees

Vice Chair

- Dr Orest Mulka, General Practitioner, Council Member RCGP (Vice Chair)

Voting members

- Professor Max Bachmann, Professor of Health Care Interfaces
- Mr Graham Brack, Pharmaceutical Adviser
- Ms Elizabeth Brain, Lay Vice Chair of Patient Participation Group of the Royal College of General Practitioners
- Professor David Chadwick, Consultant Neurologist
- Professor Usha Chakravarthy, Consultant Ophthalmologist
- Professor Peter Crome, Professor of Geriatric Medicine, Keele University; Consultant Geriatrician, North Staffordshire Combined Healthcare NHS Trust
- Professor Brendan Delaney, Professor of Primary Care
- Dr Stuart Dollow, Vice President and UK Medical Director, GSK, representing ABPI
- Dr Kevin Gormley, Assistant Director of Education, School of Nursing and Midwifery, Queens University, Belfast
- Dr Carol Hawley, Principal Research Fellow
- Ms Amanda Hutchinson, Head of Long Term Conditions and Older People Strategy, Healthcare Commission
- Ms Robin Mackenzie, Director of Medical Law and Ethics
- Ms Elaine Oliver, Head of Health Economics, Medtronic Ltd, representing ABHI
- Ms Lynda Price, Non Exec Chair, East Devon PCT
- Dr Michael Rudolf, Consultant Physician
- Dr Peter Selby, Consultant Physician

Non-voting members

- Dr Bob Coates, Director of Public Health/Visiting Fellow, NCCHTA
- Ms Sarah Evans, Research Associate, NHSC
- Ms Luan Linden, Research Associate, NHSC
- Dr Norma O'Flynn, Clinical Director, National Collaborating Centre for Primary Care
- Dr Cathryn Thomas, Senior Lecturer representing Appraisals Committee

Specialist advisors

- Professor Janusz Jankowski, Consultant in Gastroenterology for topic 823, the diagnosis and management of coeliac disease
- Dr John Lee, Consultant in Pain Medicine, National Hospital for Neurology and Neurosurgery for topic 227, the use of drugs for neuropathic pain

Also in attendance

- Ms Laura Boughen, Implementation Coordinator, NICE
- Ms Caroline Miller, Information Specialist, NICE
- Ms Janet Robertson, Technical Advisor, NICE / Observer
- Ms Nuzhat Sen, Topic Selection Administrator, NICE
- Dr Nicholas Summerton, Consultant Clinical and Public Health Advisor, NICE
- Ms Andrea Sutcliffe, Deputy Chief Executive, NICE
- Ms Lindsey Wilby, Topic Selection Project Manager, NICE

Apologies

- Dr David Colin-Thomé, National Clinical Director for Primary Care (Chair)
- Dr Noemi Eiser, Chest Physician
- Dr Mercia Page, Clinical Practice Centre Director, NICE
- Mr Mark Salmon, Topic Selection Associate Director, NICE

1. Welcome and introductions

The Vice Chair, Dr Orest Mulka, introduced himself and welcomed members – particularly those joining the panel for the first time – to the second meeting of the Long Term Conditions Topic Selection Consideration Panel.

The members of the panel introduced themselves.

2. Apologies for absence

Apologies were received from Dr David Colin-Thomé, Dr Noemi Eiser, Dr Mercia Page, and Mr Mark Salmon.

3. Appointment of a Vice Chair

In the absence of the Chair, Andrea Sutcliffe proposed the appointment of Dr Mulka as Vice Chair for an initial period of one year, after which the post will be opened up to nominations from the panel. Ms Sutcliffe thanked Dr Mulka

for agreeing to chair this meeting at short notice. The panel agreed to the proposal.

4. Evaluation of the first round of panel meetings

It was highlighted that, in response to comments made by panel members following the first meeting in November 2006, NICE had made various adjustments to the meeting arrangements and the documentation presented to the panels.

As it had originally been envisaged that some of the panel meetings would be held in Manchester, the panel was asked to confirm whether they would be able to attend if one of the 2008 meetings was held there. The majority of the panel confirmed that this would be acceptable to them.

Action: Topic Selection Secretariat to arrange one of the 2008 panel meetings in Manchester.

5. Minutes of the previous meeting

Other than a typographical error at section 2.1, the minutes were agreed to be a true and accurate record of the meeting of December 5th 2006.

6. Matters arising not covered elsewhere on the agenda

There were no matters arising.

7. Progress of topics discussed at the first panel meeting

The progress report provided by the secretariat at item 3 in the briefing pack was reviewed, and Andrea Sutcliffe gave an update on the functioning and outcome of the first meetings of both the Consistency Checking Group (CCG) and the Referral Oversight Group (ROG). Andrea Sutcliffe explained that they need to devise a method of ensuring that topics which are valuable, but not immediately successful at progressing through the process, are not "lost", but are available for future referral.

NICE asked the panel for their comments. Panel members expressed a variety of views. In the discussion it was felt to be useful for panels to emphasise and differentiate between their priorities to the ROG where possible.

8. Declarations of interest

In relation to section 9.1, drugs for neuropathic pain (227), the following declaration of interest were made. Ms Oliver declared that her employer, Medtronic, manufactures some of the devices mentioned in the briefing note for this topic. However, as the focus of the briefing note is on the use of drugs,

it was not felt that this interest should prevent her from taking part in the discussion or voting on this topic.

Professor Chadwick declared that a lot of the drugs mentioned in the briefing note are primarily used in the treatment of epilepsy, which is his area of expertise. However, he has no particular experience of using these drugs for the indication highlighted in the briefing note. Dr Dollow declared that his employer, GSK, manufactures an epilepsy drug which is not licensed for use in the management of neuropathic pain, and there are no plans to seek a licence or promote the product. Professor Crome declared that he has a small shareholding in GSK. As product manufactured by GSK is not licensed for the indication under consideration, these were felt to be non-specific interests, and should not preclude either Professor Chadwick, Dr Dollow or Professor Crome from taking part in the discussion or voting on the topic.

Dr Lee declared that he had received hospitality from numerous drugs companies in relation to drugs for neuropathic pain. However, as he was present in order to advise the panel on this topic, and would therefore not be voting on the topic, this was not felt to be problematic.

In relation to section 9.4, coeliac disease (823), Mr Brack declared that he is a professional member of Coeliac UK, and is therefore aware of their views. As he does not suffer from the condition himself and does not receive payment from the charity, it was not felt that this interest should prevent him from taking part in the discussion or voting on the topic.

In relation to section 9.6, zoledronic acid (2062), Dr Dollow declared that his employer manufactures a direct competitor to this product. It was therefore agreed that he would leave for the duration of the discussion about, and the voting on, this topic. Dr Selby declared that he has received speaker fees from Novartis in relation to this drug. It was agreed that he could stay to answer questions from the panel on this product, but would then absent himself for the remainder of the discussion and the voting on this topic.

In relation to sections 9.7 and 9.8, maraviroc (1742) and raltegravir (2061), Dr Dollow declared that his employer manufactures direct competitors to these products. It was agreed that he would absent himself for the duration of the discussion about, and the voting on, these topics.

9. Topics for discussion – A list

Following a brief introduction of each topic by Dr Nick Summerton, the eight A list topics on the agenda were discussed by the Panel in turn.

9.1 The use of drugs for neuropathic pain (227)

Dr Lee was present to advise the panel on this topic. He made several points:

- Guidance on this topic could alleviate a huge burden of disease. Neuropathic pain and back pain between them account for 70-80% of chronic pain, and NICE is already preparing a guideline on back pain.
- With appropriate guidance, effective treatment could be initiated by GPs and pharmacists. This would greatly reduce the volume of referrals to neurologist and pain clinics. There is evidence that effective early treatment can prevent people from developing a chronic pain condition.
- Patients are often prescribed the correct drugs by non-specialist clinicians, but in sub-therapeutic doses.
- Some patients are being prescribed pregabalin, which is very expensive, when amitriptyline, which is not, might be equally effective.
- Although the briefing note is focused on drugs, it would be wrong to exclude consideration of cognitive behavioural therapy (CBT), as there is a huge evidence base for the effectiveness of this treatment.

The panel was strongly in support of this topic, and felt that the remit should be extended to include consideration of CBT and non-drug treatments such as nerve stimulating devices. The ABHI representative highlighted that "spinal cord stimulation for chronic pain" has recently been referred to NICE within the 13th wave, to be appraised via the MTA process. The outcome of this appraisal could be referred to within a broader guideline.

The panel was of the view that the guideline should be focussed at non-specialists, to enable effective early treatment, be that in general practice or a pharmacy setting.

The Vice Chair summarised the features of this topic in relation to the DH selection criteria, as follows:

- This topic is relevant to both the practice-based commissioning agenda and the 18-week referral target.
- There is a large burden of disease, both recognised and unrecognised.
- There is wide variation in practice: GPs lack the knowledge and confidence to prescribe drugs in sufficiently high doses and/or outside of their licensed indication.
- Guidance on this topic would be timely as, to the best of our knowledge, it does not appear that guidance is being planned or prepared by any other body.

Remit: To prepare a clinical guideline on the identification and management (both drug and non-drug) of neuropathic pain in non-specialist care, including indications for onward referral.

Provisional score: 4.5

9.2 The diagnosis and management of thyrotoxicosis (968)
9.3 The diagnosis and management of hypothyroidism (1794)

These topics were considered together. There was little enthusiasm from the panel for either of them. It was felt that there was insufficient robust evidence available to facilitate the production of a guideline on hyperthyroidism (i.e. thyrotoxicosis).

Remit: To prepare a clinical guideline on the diagnosis and management of thyrotoxicosis.

Provisional score: 1.5

The primary care representative amongst the panel felt confident in dealing with straightforward cases of hypothyroidism in the absence of guidance, perhaps because the Quality and Outcomes Framework states that this condition should be monitored within the community. GPs are also able to recognise the more difficult cases which require referral to an endocrinologist.

Remit: To prepare a clinical guideline on the diagnosis and management of hypothyroidism.

Provisional score: 1.5

9.4 The diagnosis and management of coeliac disease (823)

Professor Jankowski was present to advise the panel on this topic. He expressed his views to the panel as follows:

- The appropriate management of coeliac disease relies on shared care between the GP and gastroenterologist, but 95% of the work could be done by GPs (if they had appropriate guidance). For example, the long term monitoring of the condition may include a gastroenterologist seeing a patient once a year to ask "how they are" – this could clearly be done elsewhere.
- 60% of cases go undiagnosed in the early stages. Late diagnosis is associated with additional morbidity (e.g. osteoporosis and, rarely, untreatable cancer in younger individuals), at great cost to the NHS.
- Some ethnic populations in the UK (e.g. South Asian and Irish) are particularly predisposed to coeliac disease. Differing cultural practices for dealing with symptoms can lead to very late diagnosis when the patient presents with a devastating osteoporotic vertebral collapse.
- The production of guidance would be timely. Given that gastroenterologists are now assisted by endoscopists and numerous new technologies, they would be in a position to a take step back to determine where their services can best be employed, and provide advice to colleagues in primary care.

The panel were strongly in favour of this topic, given that coeliac disease is so hugely under-diagnosed. One panel member had carried out a vignette study in which 80% of GPs tested did not even consider coeliac disease as a potential option, in a scenario where the symptoms described would have supported it as a differential diagnosis.

The panel was particularly concerned about the disproportionate prevalence of the condition within certain ethnic sub-groups. The panel felt that this topic was a particular priority in the absence of a National Service Framework for gastrointestinal disorders.

The panel asked Professor Jankowski about the scale of the problem in children. He explained that 30% of cases occur in children, but these are picked up easily because they are usually more severe, and the condition is well managed in paediatric practice. He was more concerned about elderly patients who have gone undiagnosed for 30-40 years, then present with osteoporotic fractures.

The panel was concerned to emphasise that any guideline should not be restricted to primary care, as coeliac disease is frequently missed by clinicians across a number of specialties. The panel also explored the issue of screening: simple blood tests could prevent the need for endoscopic biopsies. It might even make sense for GPs to screen all of their anaemic patients for coeliac disease.

Remit: To prepare a clinical guideline on the diagnosis and management of coeliac disease in adults and elderly people.

- In both primary and secondary care
- To include an assessment of the appropriate role of diagnostic blood testing

Provisional score: 5

9.5 Ethyl-EPA for Huntington's disease (2063)

[Confidential discussion]

Remit: To prepare a technology appraisal on the clinical and cost effectiveness of Ethyl-EPA for Huntington's disease.

Provisional score: 2.5 (8 votes for deferring)

9.6 Zoledronic Acid – once-yearly treatment for post-menopausal osteoporosis (2062)

[Confidential discussion]

Remit: To appraise the clinical and cost effectiveness of zoledronic acid for the treatment of post-menopausal osteoporosis.

Provisional score: 0

Action: NICE to liaise with osteoporosis GDG as necessary to ensure that this topic is included within the guideline.

9.7 Maraviroc for resistant HIV (1742)
9.8 Raltegravir (MK-0518) for infection with HIV (2061)

[Confidential discussion]

Remit: To produce a technology appraisal on the clinical and cost effectiveness of maraviroc for resistant HIV.

Provisional score: 0

[Confidential discussion]

Remit: To produce a technology appraisal on the clinical and cost effectiveness of MK-0518 for infection with HIV.

Provisional score: 4

10. Prioritising topics for recommendation to Referral Oversight Group: confirmation or amendment of provisional scores

After a comprehensive discussion bringing in the views of all members of the Panel, a decision was taken by the Vice Chair on the priority of each A list topic. This decision reflected the panel consensus on the importance of the topic.

Each topic suggestion was assigned a numerical score between 0 and 5, where 0 indicates that the topic suggestion should not be referred to NICE, and where 5 indicates that the topic suggestion is very high priority for referral to NICE. The scores were as follows:

- The use of drugs for neuropathic pain: 5 (amended from 4.5)
- The diagnosis and management of thyrotoxicosis: 1 (amended from 1.5)
- The diagnosis and management of hypothyroidism: 2 (amended from 1.5)
- The diagnosis and management of coeliac disease: **5***
- Ethyl-EPA (Miraxion) for Huntington's disease: defer
- Zoledronic Acid – once-yearly treatment for post-menopausal osteoporosis: 0
- Maraviroc for resistant HIV: 0
- Raltegravir (MK-0518) for infection with HIV: 4

*Both neuropathic pain and coeliac disease scored 5, but the panel voted to decide which topic was a more urgent priority: 11 voted for coeliac disease, 5 for neuropathic pain. The panel was keen to communicate to ROG that they viewed both topics as being equally important, but coeliac disease as being slightly more urgent, if capacity was not available to commence work on both topics immediately.

11. Topics for discussion – B list and C list

The panel had no comments on these topics.

12. Comments on A list topics assigned to other panels

The panel had no comments on these topics.

13. Any other business

There was no other business.

14. Evaluation and expenses

The Vice Chair drew the attention of the panel to these items within their briefing pack, and asked the panel to give some verbal feedback. Their responses were as follows:

- "We learn more each time we meet, especially about technology appraisals".
- "As a lay person it's quite difficult to know how to participate, but it should become easier with time".
- "We need more data to fully consider technology appraisal topics".
- "We've learnt a lot about NICE".
- "We need to be careful how we use terms like primary and secondary care, as they are used differently across the UK".
- "There was greater consensus as to scores today".
- "A mixture of clinical guideline and technology appraisal topics makes the meeting more interesting".
- "It will be interesting to see the outcome of ROG next time"

15. Date of next meeting

The next meeting of the panel will be on Friday, 20th July at 12.00pm, at the NICE offices, MidCity Place, 71 High Holborn, London WC1V 6NA.

Lindsey Wilby, Topic Selection Secretariat, 27th March 2007