The page from the Ombudsman's refusal letter stating that their clinical adviser had found that Eddie's short synacthen test was normal

The reasons behind our decision

You complained that Dr Savage failed to take a full history and that, if he had, he would have realised that your head injury in 1985 was the cause of your symptoms and would have indicated hypopituitarism. The Trust explained that Dr Savage felt the treatment he offered was appropriate and that *'a history of head trauma years ago does not often lead to the symptom complex that you complained of at the time of referral'*. We asked our adviser about this, and he explained that *'a head injury in 1985 would not necessarily be expected to be associated with a diagnosis of hypothyroid disease in 2004-2006'*.

The Trust explained that the tests undertaken by Dr Savage during the time he saw you, between November 2006 and November 2007, *'suggested a primary problem in the thyroid gland'* and so it was not unexpected that pituitary disease had not been considered. We looked at this very closely, and asked our adviser about the Trust's response. Our adviser explained in detail which test results would indicate hypothyroidism or hypopituitarism, and how your results relate to this, which I will share with you now.

Our adviser explained that thyroid-stimulating hormone (TSH) is produced in the pituitary and instructs the thyroid to produce thyroxine, known as T4 and T3. A primary thyroid problem, therefore, would be indicated by low TSH levels, but a feedback system would instruct the pituitary to produce more TSH in an attempt to stimulate the thyroid, even though the thyroid cannot respond. So, hypothyroidism would result in high TSH, but low T4 and T3 levels. Hypopituitarism would, on the other hand, result in low TSH and low T4 and T3. The Trust explain that you had high TSH levels in May 2005 and June 2006. Our adviser says that this result would *'exclude a pituitary cause for hypothyroidism'*.

Furthermore, the Trust provided the results of a short synacthen test performed in December 2006. This test looks at adrenal function and would identify a problem with the pituitary. Our adviser confirmed that the result was normal, in line with the Trust's response, and that *'this test plus the raised TSH levels excludes an underactive pituitary condition'*.

The Trust explained to you that it would be expected that *'an endocrinologist searching for the cause of pituitary hormone deficiency to consider traumatic brain injury as one of the possible underlying causes, it would not be an expectation when primary thyroid disease is being considered'*. Taking our adviser's explanations into account, we consider the response provided to you by the Trust to be reasonable.

Conclusion

It is clear from your correspondence and our conversation that you have had a difficult time with your health in recent years. I appreciate how confusing and frustrating it must have been for you to go for a number of years without a solution.

The Ombudsman's Clinical Adviser's report sent to Eddie in reply to his Freedom of Information request. Towards the end the report says "The short synacthen stimulation test is not entirely normal as indicated by the Trust."

EN-124295
History Item Number 54

Parliamentary
and Health Service

Provision of Clinical Advice at Assessment Stage

Background Information

Case Identifier (name and number)
EN-124295, Barker

Caseworker's Name
Rob Bancroft

Clinical Adviser's Name and Qualifications
Richard McGonigle MD, FRCP

Relevance of qualifications and/or experience to clinical aspects of this case
As a consultant general and renal physician I am appropriately experienced and qualified to report on this complaint. The case concerns the possible failure to diagnose hypopituitarism as the cause of an under active thyroid, as opposed to primary thyroid failure. As a general physician I am fully conversant with the endocrinology investigations required to investigate hypopituitarism, and both adrenal and thyroid disease.

Conflict of Interest (clarification of any links with Body or clinicians complained about)
There is no conflict of interest, and I do not know any of the individuals involved in this complaint.

Clinical Advice

Documentation Reviewed
I have reviewed as much as possible of the correspondence regarding Mr Barker.
I have reviewed the Trust response dated 6/12/2009 and the 'independent' review by Dr Mishri.

Clinical Summary
Mr Barker had been previously diagnosed with hypothyroidism and was receiving thyroid replacement therapy since 2004, and before Dr Savage reviewed him in August 2006.

Mr Barker continued to be reviewed by Dr Savage until 2007.
He failed to attend an appointment in August 2007 with Dr Savage, and was later reviewed by Professor Davis at Manchester Royal Infirmary in November 2007.
Dr Savage was not further involved in Mr Barker's care.

Questions and Responses

The Trust explain that (see tags 1 and 2), given Mr Barker's symptoms, his treatment for hyptothyroidism was appropriate and that an endocrinologist would not be expected to consider traumatic brain injury in such circumstances. Are these responses reasonable?

The responses from the Trust are reasonable in that a head injury in 1985 would not necessarily be expected to be associated with a diagnosis of hypothyroid disease in 2004/2006.
The independent review by Dr Mishri comments that the TSH levels were elevated in May 2005 and June 2006. This would exclude a pituitary cause for hypothyroidism.
My only concern in the Trust responses relates to the short synacthen stimulation test, which indicates low/normal base line cortisol level, which might be indicative of adrenal insufficiency and reduced response to ACTH. This would imply a pituitary disorder, but the results are marginal.

Mr Barker had multiple symptoms and was reported to have chronic fatigue syndrome in addition to other conditions. Hypopopituitarism as a cause of hypothyroid disease is most uncommon in this age group. Primary hypothyroidism is associated with low T4 and raised TSH.
Hypopituitary disorder is associated with low TSH and low T4.
The evidence provided by the Trust indicates that Mr Barker's TSH levels were elevated above normal.
It is to be noted that Mr Barker's thyroid replacement therapy was initiated by the patient's GP in 2004, before Dr Savage reviewed the patient, and the results of those initial investigations are not available.

Furthermore the results of investigations by Professor Davis and Dr Kearney are not available regarding the confirmation that the patient had reduced growth hormone levels and partial reduced ACTH levels consistent with hypopituitarism.

The Trust response is not unreasonable.

ADDENDUM

The pituitary gland produces hormone releasing factors that are transported by blood to the relevant organs to stimulate those organs to produce the corresponding hormone.
For instance ACTH produced in the pituitary then instructs the adrenal glands to produce cortisol (steroid).
Thyroid-stimulating hormones (TSH) is produced in the pituitary and instructs the thyroid gland to produce thyroxine (T4/T3). Thus, primary thyroid failure will be associated with low T4 and T3 levels, but a feedback system will instruct the pituitary to produce more TSH in an attempt to stimulate the thyroid gland to produce more thyroxine, although the thyroid gland cannot respond.
Thus, primary hypothyroid disease will involve low T4 and T3 and high TSH levels.
Whereas hypoptuitarism causing hypothyroidism will involve a low TSH and a low T4/T3.
If the thyroid gland was overactive with high T4, a negative feedback will instruct the pituitary to stop producing TSH, which would then be low.
There are a number of hormone releasing factors produced in the pituitary including growth

hormone producing factor (GHRF), TSH, ACTH and others.

Conclusions
Fracture of the base of the skull is associated with damage to the pituitary.
However, it would appear from the Trust responses that Mr Barker's underactive thyroid condition was associated with high TSH (thyroid stimulating hormone) levels, indicating a primary thyroid problem.
The short synacthen stimulation test is not entirely normal as indicated by the Trust.

Please contact me if you have any concerns or questions regarding my advice.

Name & Signature

Richard McGonigle

Date
10/2/12

The Ombudsman's letter explaining themselves to Eddie

From the Deputy Director of Investigations:
Marko Jovanovic
postreview@ombudsman.org.uk

Our reference: EN-124295/0131

Parliamentary and Health Service Ombudsman

In Confidence
Mr Edward Barker
224 Bradford Road
Miles Platting
Manchester
M40 7BT

4 October 2013

Dear Mr Barker

Your complaint about the Pennine Acute Hospitals NHS Trust (the Trust)

We wrote to your representatives, Irwin Mitchell solicitors, on 1 August 2013 to explain that we would consider your concerns about our decision on your complaint. That work is now finished. As I will explain, I have concluded that we reached a reasonable decision. However, I have also found that we did not provide you with all of the advice our Clinical Adviser (our Adviser) gave on your complaint. Unfortunately, I suspect that this misled you into believing that we had misunderstood or misinterpreted his advice.

When Rob Bancroft wrote to you on 22 February 2012, he said that our Adviser had confirmed that the result of your short synacthen stimulation test was '*normal*'. As you rightly point out, our Adviser's report (dated 12 February 2012) actually says that the result was '*not entirely normal*'. I can fully understand why this apparent inconsistency alarmed you.

However, shortly after receiving that advice, we received further information from the Trust in connection with your complaint. Included within that information was the result of the test that the Trust had carried out on you. At this point, it became clear that our Adviser had looked at the result of a test which you had undergone as part of your private treatment, rather than the test that the Trust itself carried out.

Mr Bancroft asked our Adviser to look at the test result that the Trust had provided to us. In response, our Adviser confirmed that '*the enclosed synacthen test is normal*'. I have enclosed a copy of that advice. This is the advice that Mr Bancroft was referring to in his letter of 22 February 2012. It shows that we did interpret our Adviser's advice correctly.

Millbank Tower
Millbank
London SW1P 4QP

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I am very sorry that we did not give you this second piece of advice from our Adviser when we replied to your request for information. It is clearly a crucial piece of evidence for our decision. However, I hope that we have now been able to reassure you that we did reach the correct decision on your complaint.

I realise that you are unhappy with the outcome of your complaint, but I have not seen any reason to think that our decision was wrong or unfair, and so I do not believe that there is anything more that we can do to help you. For this reason, we will not take any further action on your complaint and we will not reply to anything else you send us about it unless we decide some action is needed. I hope you will accept that I have taken my decision only after a careful review of your case.

I have sent a copy of this letter to Irwin Mitchell solicitors for their information.

Yours sincerely

Marko Jovanovic
Deputy Director of Investigations

Enc: 1

The emails enclosed with their explanation

Harrigan James

From: McGonigle Richard
Sent: 17 February 2012 14:38
To: Bancroft Rob
Subject: RE: 124295

PROTECT - INTERNAL USE ONLY

Rob,
This enclosed synacthen test is normal, with normal base line cortisol levels.
This test plus the raised TSH levels excludes an underactive pituitary condition as part of the North Manchester Hospital investigations.
Kind regards,
Richard

From: Bancroft Rob
Sent: 17 February 2012 14:00
To: McGonigle Richard
Subject: 124295

PROTECT - INTERNAL USE ONLY

Hi Richard,

Many thanks for the clear advice you provided recently on this case. I have subsequently received more information from the Trust. Would you be able to have a quick look please?

You explained that the short synacthen test available in the file showed a borderline low baseline cortisol level. I think the test results in the file were sought privately and the new information from the Trust has one they performed themselves (page 2 in the attached file - the password to the file is "complaints"). Does this indicate the normal level the Trust refer to?

Many thanks,
Rob

Rob Bancroft
Assessor
Parliamentary and Health Service Ombudsman
Direct Line: 0300 061 4563
Email: Rob.Bancroft@ombudsman.org.uk
www.ombudsman.org.uk

The two documents that the Ombudsman eventually claimed were confused by their clinical adviser. Note that Eddie never had a short synacthen test carried out privately.

Diagnos-Techs, Inc.

Clinical & Research Laboratory
PO BOX 389662, Tukwila, WA 98138-0662
Tel: (425) 251-0596
CLIA License # 50D0630141

DATE 11/10/2006 (1) AMERICAN

Accession # 06-81264

Received : 10/11/2006
Completed: 10/16/2006
Reported : 10/16/2006

THE RED APPLE CLINIC
CAROLINE EDWARDS
26 SUMMERHILL AVE
NEWPORT, GWENT
SOUTH WALES NP19 8FP
UK Tel: 011441633262772

Results For:
EDWARD BARKER
Age:58 Sex:Male Dx Code:Not Provided

Patient's Tel: 07831840086
Specimen Collected:10/04/2006

Test	Description	Result		Ref Values
ASI	**Adrenal Stress Index**			
AP	**Free Cortisol Rhythm**			
	07:00 - 08:00 AM	10	Depressed	13-24 nM
	11:00 - Noon	4	Depressed	5-10 nM
	04:00 - 05:00 PM	2	Depressed	3-8 nM
	11:00 - Midnight	2	Normal	1-4 nM
	Cortisol Burden:	18		*23 - 62*

The cortisol burden reflects the area under the cortisol curve. This is an indicator of overall cortisol exposure, where high values favor a catabolic state, and low values are sign of adrenal deterioration.

Figure 1. Circadian Cortisol Profile

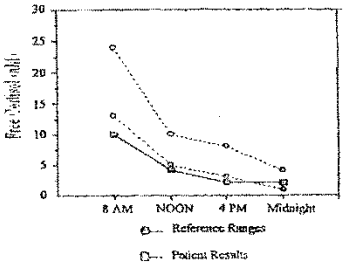

Figure 2.
The Cortisol release inducers fall into 4 broad categories shown in the adjacent flowchart. Long term adrenal axis maintenance and restoration, require optimization of all the cortisol inducers.

Remarks: Depressed morning cortisol, < 13 nM, is suggestive of marginal HPA (Hypothalamic-Pituitary-Adrenal) performance. Normal rhythms exhibit highest cortisol value for the day at 7 - 8 AM.

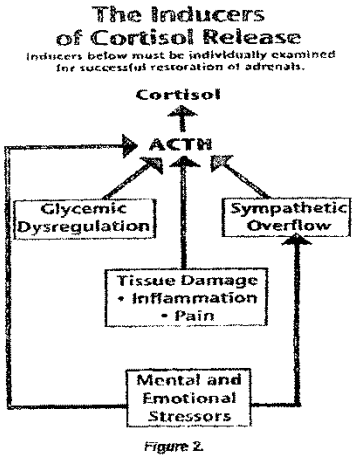

Figure 2.

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Name	BARKER Edward			Source	J5 MED INVEST UNIT NMGH
D.O.B	15 Aug 1948	Sex	M	Con/GP	Dr M W SAVAGE
Address	224 BRADFORD ROAD			Lab No	B0128476G
	MILES PLATTING			Taken	08 Dec 2006
	M40 7BT			Received	08 Dec 2006
NHS No	450 009 1136	CRN	0120061A		
Details					

Short Synacthen Test

Spec No	Time	Serum Cortisol nmol/L
B0128476G	Baseline	402
B0128477P	0.5 Hour	731
B0128478W	1 Hour	816

Normal response

Fairfield 0161 778 2596
Oldham 0161 627 6381
North Man 0161 720 2169
Rochdale 01706 754420

Authorised: KW1C 08 Dec 2006 Printed: 08/12/2006 16:03

Pennine Acute Hospitals NHS Trust
Department of Clinical Chemistry