Crown Health Enterprise

Report on Opinion - Case 98HDC11149

Complaint

The Commissioner received a complaint from the complainant on behalf of his deceased wife, the consumer. The complaint is that:

- *Between mid-May 1997 and late July 1997, the CHE intermittently administered and withheld phenytoin sodium from the consumer. The CHE did not recognise or react appropriately to the consumer's intolerance to phenytoin. The consumer continued to have an unacceptably high level of phenytoin sodium in her system*
- *Further to this, in mid-June 1997 phenytoin was administered to the consumer without her consent or any prior discussion with her husband.*

Investigation

The complaint was received by the Commissioner on 16 January 1998 from the complainant and an investigation was commenced. Information was obtained from:

The Complainant	The deceased consumer's husband
The General Manager	General Manager, Medical and Surgical Services, the Crown Health Enterprise ("CHE"),
The Consultant	Consultant for General Medicine and Medical Specialities at the CHE,

The Senior Medical Officer, at the CHE
The Endocrinologist, at the CHE
The Endocrine Registrar, at the CHE
The Neurologist, at the CHE

The Commissioner obtained the consumer's medical records and also obtained advice from an independent senior neurologist.

Jurisdiction

The Commissioner does not have jurisdiction to consider events which took place prior to July 1996. However, the Commissioner is able to consider the post-July 1996 issues in their context, which includes the consumer's history beginning in March 1996, when she was diagnosed with a cerebral tumour.

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Information Gathered During Investigation

In March 1996 the consumer developed symptoms caused by a cerebral tumour. The surgeon operated late March 1996 and again in early April 1996. The consumer saw the surgeon as a follow-up to her surgery in June 1996. The consumer was subsequently re-admitted to the public hospital in September 1996. It was diagnosed that the tumour had regrown.

In mid-October 1996 the surgeon operated again. This operation caused the consumer to develop diabetes insipidus and suffer a loss of her short-term memory. Following the operation the consumer received a course of radiotherapy to the brain and maintenance steroid drugs to reduce brain swelling. This course of treatment was completed in January 1997.

The consumer began to suffer from seizures in January 1997 that required several hospital admissions during 1997. Details of those admissions are set out below.

In response to the Commissioner's letter outlining the complainant's complaint, the general manager, medical and surgical services, at the CHE, compiled statements from two of the doctors responsible for the consumer's care during 1997 – the consultant for general medicine and medical specialties, and the senior medical officer. The endocrinologist also responded to the Commissioner.

The consumer was admitted to the hospital in late January 1997 following a collapse, which the endocrinologist noted "*sounded as though it may have been a seizure … she was discharged on* [a day in] *February and will continue with her current medications which are prednisone 5mg daily and Intranasal DDVAP 10µg bd.*"

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The consumer was admitted to the hospital again in late March 1997 after she was seen to collapse into a chair with jerking movements of both arms and legs. The discharge letter noted that the diagnosis was "*seizure*? *secondary to hyponatraemia",* and that she had a known grade IV astrocytoma and diabetes insipidus.

The consultant stated that the consumer was first admitted to the hospital under his team in mid-May 1997 following a seizure at home. The consultant stated that the consumer's previous seizures, which had begun in January 1997, had been considered to be caused by hyponaetremia (low sodium levels) secondary to her post-operative diabetes insipidus. However, on this admission her sodium level was 132, which was not consistent with hyponaetremia as the cause of her seizures. The consultant therefore concluded that epilepsy secondary to the previous surgery was more likely.

Following her admission in mid-May 1997 the consumer was started on a dose of 500mg of phenytoin sodium which was reduced to 300mg daily on later in May. The consultant advised that 300mg of phenytoin sodium a day is a normal therapeutic dose. She was discharged in mid-May 1997 with a request to her general practitioner that a blood level check for phenytoin be done in late May 1997. The complainant says that following her discharge, the consumer became drowsy to the point of being totally unresponsive.

The consumer was readmitted to the hospital in late May 1997 with a three day history of increasing drowsiness which was ascribed to phenytoin toxicity and hyponaetremia. A blood test showed her serum phenytoin level was well above the therapeutic range at 118. (The endocrine registrar at the hospital, advised, in a discharge letter dated early June 1997 to the consumer's general practitioner, that the normal range is between 40 and 80). The phenytoin sodium was subsequently withheld from the day the consumer was re-admitted to hospital. The complainant says it took ten days following discharge before she returned to her usual state. She was discharged in late May 1997 without any medication for epilepsy.

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In the discharge letter dated early June 1997 the endocrine registrar wrote that:

> *"She does have a slightly increased ALT but her other liver function tests are normal and this really does not explain why she became toxic on such a low dose. We have elected to leave her off all anti-convulsants in the meantime. Obviously this would have to be reconsidered if she develops further seizures."*

In mid-June 1997 the consumer suffered another seizure and was admitted to the hospital, beginning on an initial dose of *phenytoin sodium* 300mg, reducing thereafter to 200mg daily. In mid-June 1997, the consumer was discharged on *phenytoin sodium* and the endocrine registrar wrote the following note in the discharge summary:

> *"Previous discussions with some medical staff have led to some family concern about the use of phenytoin. We have brought this up with the department of neurology who agree that phenytoin (is) the most appropriate drug in this case. It would seem unlikely that hyponaetremia in the past was a response to phenytoin. She should be maintained on this in the long term. The advice from the Neurologists is that valproate is a less preferable medication under these circumstances."*

The consumer's *phenytoin* level in late June 1997 was 80, and in early July 1997 was 69. The consultant advised that there is no record that the consumer's family required the hospital to discuss specific drug therapy with them before it was introduced, and that he has no recollection of any such requirements.

In early July 1997 the complainant spoke with the endocrinologist in the endocrinology department at the hospital. The complainant expressed his concern about *phenytoin* having been restarted and said that he would rather put up with the risk of the consumer having further seizures than beginning her anti-convulsant treatment again. The endocrinologist wrote in a letter dated early July 1997 to the consumer's GP:

> *"I guess it would be worthwhile discussing the situation with the neurologists but my own thought is that possibly epilim would be appropriate in this situation. I will leave that decision up to you."*

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The complainant said that after early July 1997 the consumer became drowsy once more and he telephoned the hospital. In mid-July 1997, the medical registrar ordered the *phenytoin* to be withheld.

The consumer suffered another seizure in late July 1997 and she was admitted to the hospital once again. She was started this time on *sodium valproate* at a lower than usual dose. In the discharge letter dated early August 1997, the medical registrar noted that, *"*[a]*s the family do not want to start the phenytoin again, her case was discussed with a neurology registrar who suggested a trial with sodium valproate. She was commenced on sodium valproate 200mg bd and according to the blood levels she needs to increase her dose gradually over the next few weeks."* A referral note dated late July 1997 reads: *"*[f]*amily very much against phenytoin".*

The consumer was discharged in early August 1997. The complainant says that the dosage of *sodium valproate* was so low it was ineffective.

The consumer continued to suffer further seizures and died of an infection at a hospice in early September 1997.

Informed Consent

The complainant advised the Commissioner that he was not consulted about the consumer being prescribed *phenytoin sodium* again in mid-June 1997. However, the general manager advised that staff were guided by a statement in the notes of that admission which said: "[t]*he family requests that initiation of further medication be done on an inpatient basis."*

The consultant stated he did not believe that the issue of consent or prior discussion with the family was required because it was clearly stated in the notes that they wanted initiation of any new therapy done in the hospital.

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Neurologist's Advice to the Commissioner

With respect to the diagnosis of the cause of the consumer's seizures, the neurologist advising the Commissioner made the following comments:

> *"Although epilepsy is one of the most common symptoms of malignant cerebral tumours,* [the consumer's] *seizures were neither recognised initially as properly epileptic nor treated as such. Thus, the first seizure in January 1997 was attributed to deranged sodium metabolism. She had a further seizure in March 1997 and this was again managed as an electrolyte disorder. ... It was not until her third or possibly fourth seizure, in May 1997, that epilepsy was recognised and appropriately treated. The delay in diagnosis of her epilepsy was partially understandable, as* [the consumer] *had a significant impairment of her electrolyte balance following the post-operative complication of diabetes insipidus, ...* [however] *epilepsy should have at least been considered as an equally likely if not more likely explanation of her seizures. In a patient who has undergone surgery for a malignant cerebral tumour subsequent seizures are usually epileptic and not caused by metabolic disorders, regardless of whether there is diabetes insipidus or not."*

The neurologist further stated that:

- Prior to May 1997, the consumer's doctors should have seriously considered empirical treatment with anticonvulsant drugs or should have sought the opinion of a specialist, such as a neurologist, who is an expert in the diagnosis and management of epilepsy
- An electroencephalogram ("EEG") could have been helpful with the diagnosis and there did not appear to be *"a significant and on-going contribution from a specialist neurologist"*
- The consumer's doctors should have insisted upon a substantive neurological input.

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The endocrinologist stated:

> *"The initial collapse/seizures leading to her first two admissions were probably due to her documented low sodium levels. Without a history of other seizures when the serum sodium was normal, it was in my opinion reasonable to attribute these episodes to the electrolyte problem."*

A neurologist at the CHE, stated:

> "*The appropriate treatment* [for the first two seizures] *was to treat the diabetes insipidus – this was done. It was possible that anti-epileptic drug therapy could have masked further episodes of low serum sodium, leading to more serious complications."*

Another neurologist from the CHE who was consulted on this matter by the CHE, was of a different opinion. The chief executive stated:

> "*From this difference in opinion I would suggest to you that there is no certainty as to the appropriateness of the delay in introduction of treatment."*

Treatment of epilepsy

The neurologist advised that the management of the consumer's epilepsy was technically deficient.

- The initial treatment for epilepsy in May 1997 when it was diagnosed was appropriate but it should not have been withdrawn without the introduction of either a substitute drug or a lowered dose of *phenytoin sodium* because of the *"unacceptably high risk of recurrent convulsions."*
- Epilepsy caused by active brain diseases is not likely to cease spontaneously.
- The correct treatment for dose-related toxicity from *phenytoin* is to either introduce a new anti-convulsant drug or, alternatively withdraw the drug for a time *"predicated by the kinetics of the drug, and then to introduce the drug once more at a lower dose."*
- In many patients this is preferable to introducing an alternative anticonvulsant drug.
- To withhold treatment completely is hard to justify and as a result, the consumer's epilepsy, not unexpectedly, returned.
- *Phenytoin* should have been given again within days after the initial treatment.

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The endocrinologist stated:

"The phenytoin was stopped at the time of her admission with phenytoin toxicity and not recommenced at this time because:

- [The complainant] *was opposed to his wife being restarted on anticonvulsant medication.*
- [The consumer's] *initial two seizures were thought to be due to low sodium levels and the introduction of an anticonvulsant agent may prevent a seizure from occurring if the serum sodium levels again fell to unsafe levels. In that situation, if the patient developed low sodium levels again, the patient may not have presented until there was severe cerebral oedema, which could be life threatening. This potentially grave risk was a very real concern as this patient's serum sodium levels were extremely labile.*
- [The consumer] *had been significantly unwell as a result of its toxicity*
- [The consumer] *had abnormal haematology results which could be exacerbated by continuing phenytoin. There was also concern that giving sodium valproate may exacerbate her abnormal blood tests. These issues were discussed with the neurologists.*
- *At this point she had only had one seizure that had not been associated with a low sodium level.*

For these reasons we felt it was reasonable not to substitute an alternative anticonvulsant at that time, but to wait and see if she developed further seizures at which time an appropriate agent could be considered."

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The neurologist advising the Commissioner noted from his reading of the consumer's medical records that there was a reluctance on the part of her doctors to change her treatment from *phenytoin* to *sodium valproate* and stated such reluctance was understandable initially, but:

> "[C]*ertainly not after difficulties occurred with her second trial of phenytoin therapy. Sodium valproate, phenytoin, and carbamazepine (the commonly employed anti convulsant drugs) are equally effective for the secondarily generalised type of epilepsy which* [the consumer] *had. The properties of these anti convulsants, which lead to the choice of one over the other, relate primarily to mode of administration, side effects, personal preferences, and so on – rather than individual effectiveness.*
>
> *The initial choice of phenytoin was desirable, as this drug can be given in a loading dose intravenously or orally to control seizures rapidly. Subsequently phenytoin is administered in an oral maintenance dose. These attributes of phenytoin make it a drug of choice for the initial treatment of acute recurrent seizures, particularly in a hospital setting."*

Sodium Valproate

The neurologist advised that when the decision was made to treat the consumer with another anti-convulsant drug, s*odium valproate*, it was employed incorrectly. In early August 1997, the medical registrar, wrote in a note to the consumer's general practitioner that she had been commenced on *sodium valproate* at a dose of 200mg twice daily which was "*to be increased according to blood levels*".

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Information Gathered During Investigation, *continued*

The Commissioner's advisor noted that:

> *"Although one may wish to introduce sodium valproate gradually, the effective dose for adults is 1000mg or 2000mg per day and not 400mg or 600mg per day. The decision to use an unusually low dose of sodium valproate may have been influenced by the mistaken belief that phenytoin toxicity from the commonly employed doses of phenytoin (200mg to 400mg per day) would mean that toxicity would also occur from the conventional doses of sodium valproate (1000mg to 2000mg a day). In fact, the metabolism of sodium valproate is via a different pathway than that of phenytoin, and phenytoin toxicity at recommended doses of phenytoin therapy should not be translated as a restriction to the usual doses of therapy with sodium valproate. The reliance on sodium valproate blood levels, as recommended in her management, is erroneous. Sodium valproate blood levels do not adequately reflect the therapeutic or toxic properties of this drug. As the dose of sodium valproate was inadequate, a recurrency of* [the consumer's] *seizures was again predictable."*

Continuity of Care

The neurologist advised the Commissioner that:

> *"*[The consumer's] *medical care lacked the continuity it deserved. Her case was of such complexity that one could not expect the general practitioner to assume her comprehensive care. In this setting, the expectant plan of action would have been for* [the hospital] *based management by one specialist, be it a neurosurgeon, a neurologist, a radiation oncologist, an endocrinologist, or a general physician to assume overall responsibility for her treatment, while maintaining the partnership with her general practitioner."*

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Information Gathered During Investigation, *continued*

And further stated that:

> *"A relatively young woman who has undergone three major intracranial surgical procedures for a malignant tumour, who has a mortal illness, diabetes insipidus, epilepsy and inability to care for herself needs* [the hospital] *based medical management which ideally should be under the responsibility of one* [hospital] *specialist with the added help of her own general practitioner."*

In response to my provisional Report, the CHE stated it considered the consumer's GP was an appropriate lead-carer in this particular patient's circumstances. The endocrinologist stated:

> *"It was my understanding that* [the consumer's] *general practitioner was the lead carer (with back-up from the endocrinology service and the hospice) given that the patient was at home and he had the most constant contact with* [the consumer]. *He is a very able GP and did an excellent job in this regard. Any other management regime would have been impractical given the circumstances. This enabled only minimal disruption to the support mechanisms that had been put in place ... Endocrinology service support was considerable with frequent telephone calls to the GP and the consumer and her husband and in my opinion there was excellent communication between the parties involved."*

The endocrinologist submitted a letter from the endocrine registrar who confirmed the endocrinologist's statements that much effort went into ensuring the consumer could be managed safely at home. The endocrinologist registrar stated:

> *"This included group meetings to coordinate her management, action plans for readmission so that any potential delays could be avoided, regular blood tests (with results coming to the endocrine service and to the GP), regular phone calls with the complainant and her GP* [sic]. *Phone calls were two to three weekly at times and at least weekly at other times. If at any stage there were problems at home,* [the complainant] *and the GP knew* [the consumer] *could be admitted directly to hospital."*

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Code of Health and Disability Services Consumers' Rights

RIGHT 4
Right to Services of an Appropriate Standard

...

2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.

...

4) Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer.

5) Every consumer has the right to co-operation among providers to ensure quality and continuity of services.

RIGHT 7
Right to Make an Informed Choice and Give Informed Consent

1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.

...

4) Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where-

a) It is in the best interests of the consumer; and

b) Reasonable steps have been taken to ascertain the views of the consumer; and

c) Either-

i. If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or

ii. If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.

...

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Opinion: Breach

Right 4(2) and Right 4(4)

In my opinion the CHE breached Right 4(2) and Right 4(4) of the Code of Health and Disability Services Consumers' Rights. The doctors responsible for treating the consumer when she was admitted to the CHE in late July 1997 failed to treat her epileptic condition appropriately and did not seek sufficient input from a neurologist.

The *sodium valproate* was not administered appropriately according to correct dose levels. The medical registrar showed a lack of knowledge when initiating a dose that was lower than the therapeutic range, and also when instructing the consumer's general practitioner to increase the drug according to blood levels. I am advised that the dose of *sodium valproate* should be adjusted according to the clinical picture of the patient rather than blood levels.

The consumer had the right to services that minimised her symptoms and provided for as high a degree of comfort as possible in the last months of her life.

Right 4(5)

In my opinion the CHE breached Right 4(5) of the Code. The consumer's case was complex and required hospital-based management by one specialist. The consumer's medical care lacked continuity as a result. The CHE should have appointed an in-house specialist to assume overall responsibility for the consumer's care.

I do not accept the CHE's advice that the GP was the lead-carer. The services within the hospital required one responsible professional to co-ordinate services within that environment. This could not be expected from an external medical practitioner, nor would it have been appropriate. I do accept that the hospital worked co-operatively with the general practitioner and family to assist the consumer while bearing in mind the family's concerns. However, in my opinion, a hospital-based carer could have ensured input from a specialist neurologist at the appropriate times and worked in partnership with the consumer's general practitioner to ensure continuity of care between the consumer's many other providers. The absence of this lead-carer reduced the consumer's quality of care.

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Opinion: No Breach

Rights 7(1) and 7(4)

In my opinion the CHE did not breach Right 7(1) or 7(4) of the Code. There is insufficient evidence that the CHE did not consult with the complainant over the consumer's care. Documentation in the clinical notes indicates that discussion on the choice of medication did take place.

Actions

I recommend the CHE takes the following actions:

- Provides a written apology to the complainant for its failure to provide the late consumer with appropriate, co-ordinated care. The apology is to be sent to the Commissioner who will forward it to the complainant.
- Submits copies of policies and protocols that demonstrate correct post-operative management of patients with malignant astrocytomas.
- Ensures all those involved in the consumer's care are sent a copy of the Report and that the lessons to be learnt from the case discussed with them.
- Establishes a policy to ensure consumers are appointed a lead-carer who is responsible for co-ordinating care, including referring to other specialists and team management.
- Uses this Report as a clinical study to improve the quality of care provided to consumers in future.
- Distributes this Report to the senior clinicians involved in the consumer's care to demonstrate the need for co-ordinated care and remind them of their responsibilities to ensure this occurs.

Other Actions

A copy of this Report will also be sent to the consumer's general practitioner for his information and for placement onto her medical records.

A copy of the Report will be forwarded to the Medical Council of New Zealand.