
Specialist Physician, Senior Lecturer in Medicine / Research Nurse / University / Hospital and Health Service

Report on Opinion - Case 98HDC20078

Complaint

The complainant complained about the standard of service his daughter, the consumer, received from a specialist physician and a research nurse of the department of medicine at a university. His complaint was that:

- *The complainant's daughter (the consumer), aged 26, was admitted to a public hospital in early May 1998 with community acquired pneumonia.*
 - *The consumer was entered into the specialist physician's trial using a new macrolide for the treatment of chest infection, but had to withdraw after a couple of tablets because of the side effects from this treatment.*
 - *The complainant telephoned the specialist physician the morning after his daughter's admission. It was agreed that the consumer continue on the trial on discharge from hospital, but that she would be convalescing with her family in Wairoa.*
 - *The consumer's brother, a medical practitioner, spoke to the medical registrar prior to the consumer's discharge two days after her admission. The registrar agreed that as the consumer had only had two tablets, her further involvement in the study would probably not be advantageous.*
 - *The consumer's condition improved at home, but she was not well enough to travel to the hospital by the review date.*
 - *The day following the review date the research nurse telephoned the consumer at home and berated her for not being present for the review.*
 - *The research nurse told the consumer that people all over the world were in this trial, and that she should have made more effort to present for the review. The consumer was upset by the call and had to hang up the telephone.*
 - *The consumer's brother overheard part of the conversation, and telephoned the research nurse back. He was subjected to the same abuse by the research nurse.*
 - *The specialist physician (also the senior lecturer in medicine) has not responded to the complainant's letter of mid-June 1998 or to a letter from the complaints co-ordinator at the Hospital and Health Service dated mid-September 1998.*
-

Specialist Physician, Senior Lecturer in Medicine / Research Nurse / University / Hospital and Health Service

Report on Opinion – Case 98HDC20078, continued

Investigation Process The complaint was received on 2 November 1998 and an investigation was undertaken on 11 May 1999. Information was obtained from:

Complainant / consumer's father
Consumer
Provider / Specialist Physician / Senior Lecturer in Medicine
Provider / Research Nurse
Head of Department of Medicine, Faculty of Medicine and Health Science, University
Vice-Chancellor, University
Quality of Service Manager, Hospital and Health Service

The consumer's medical records were obtained from the hospital and the university.

Information Gathered During Investigation The consumer was admitted to a public hospital in early May 1998 having been diagnosed with community acquired pneumonia (CAP). The consumer was informed by the admitting registrar that the department of medicine, Faculty of Medicine and Health Science, at a local university was conducting a study into the efficacy of a new antibiotic HMR 3647 in treating CAP.

HMR 3647 is an antibiotic similar to erythromycin, but has a wider spectrum of antibiotic activity and it is thought that it will prove to be more effective in treating CAP than treatments presently available.

After the study had been explained to her by a member of the research team and she had read the information sheet regarding the study protocols the consumer agreed to take part in the study and she signed a consent form. The first dose of the trial antibiotic HMR 3647 was given to the consumer on that day.

Continued on next page

**Specialist Physician, Senior Lecturer in Medicine /
Research Nurse / University / Hospital and Health Service**

Report on Opinion – Case 98HDC20078, continued

**Information
Gathered
During
Investigation
*continued***

The consumer's father, the complainant, informed the Commissioner that he telephoned the specialist physician and research team leader the following day to discuss his daughter's condition. He said that they agreed during the conversation that the consumer would continue on the trial and would travel to her parents' home in another town to convalesce following her discharge. During this conversation, the consumer's father expressed the view that his daughter may not be sufficiently well to travel back to the hospital to participate in the trial follow-up reviews.

That day (while still in hospital) the consumer developed diarrhoea which was thought to be an adverse reaction to the trial antibiotic. This antibiotic was discontinued by the specialist physician.

The research nurse informed the Commissioner that the next day she spoke by telephone to the consumer's father to explain the consumer's current health status. The research nurse stated that she informed the consumer's father that as the consumer had developed diarrhoea which was thought to be an adverse reaction to the trial medication, the consumer's treatment had been amended. The study medicine had been stopped after two doses and the consumer commenced on amoxicillin, another antibiotic used in the treatment of pneumonia.

The consumer's brother spoke to the medical registrar prior to the consumer's discharge on three days after being admitted about continuing treatment for the consumer. The medical registrar expressed the opinion that as the consumer had taken only two tablets of HMR 3647, her further involvement in the study would not be advantageous.

The consumer was discharged to her parents' home that day.

The trial protocol for the clinical trial on HMR 3647 and the guidelines for Good Clinical Practice (GCP) issued by the Ministry of Health required that wherever possible a subject who has an adverse event during a trial is followed up to make sure that there were no ongoing problems.

Continued on next page

**Specialist Physician, Senior Lecturer in Medicine /
Research Nurse / University / Hospital and Health Service**

Report on Opinion – Case 98HDC20078, continued

**Information
Gathered
During
Investigation
*continued***

The consumer was given a date for a follow-up interview by the research nurse. She was informed of the necessity of the follow-up interviews and that the follow-up appointment was required as part of the study protocols established by the Ministry of Health to ensure patient safety and to monitor the adverse event until resolution. The first follow-up appointment was made for mid-May 1998.

The medical records show that when the consumer did not attend on the first of the two possible dates she had been given for review, the research nurse contacted her at her parents' home the following day to inquire about her non-attendance at the follow-up review interview.

The consumer informed the Commissioner that she advised the research nurse that she was suffering from a number of other medical problems and would not be attending for a follow-up interview. The consumer stated that she was unhappy with the care that she had received at the hospital, and that she would be withdrawing from the clinical trial.

Immediately following the research nurse's conversation with the consumer, the consumer's brother telephoned. He discussed the information sheet supplied to the consumer by the research team regarding voluntary withdrawal from the trial with the research nurse, and accused the nurse of pressurising his sister to attend a follow-up interview. The research nurse informed the Commissioner that the consumer's brother claimed that she was acting unprofessionally. The research nurse stated that she attempted to explain her position to the consumer's brother but was unable to continue the conversation. The research nurse recorded these conversations in the consumer's notes and reported the incidents to the specialist physician and her supervisor.

The consumer's father wrote to the specialist in mid-June 1998 complaining about the standard of service that his daughter had received from the research nurse. The consumer's father wrote a further letter in early September 1998 to the Chief Executive Officer of the hospital and health service (HHS), expressing concern that the specialist physician had not acknowledged his letter of mid-June 1998.

Continued on next page

Specialist Physician, Senior Lecturer in Medicine / Research Nurse / University / Hospital and Health Service

Report on Opinion – Case 98HDC20078, continued

**Information
Gathered
During
Investigation
*continued***

The complaints co-ordinator from the HHS wrote to the consumer's father in mid-September 1998 acknowledging his letter and informing him that his concerns had been forwarded to the specialist physician for investigation and comment. The complaints co-ordinator informed the consumer's father that the specialist physician and research nurse were employed by the university, not the HHS.

The specialist physician did not respond to either of the complainant's letters of complaint.

The Head of Department of Medicine, Faculty of Medicine and Health Science at the university telephoned the Commissioner's office in mid-May 1999 and offered to speak to the complainant to identify the areas of concern in an attempt to resolve the complaint.

In his letter to the Commissioner of early June 1999, the specialist physician stated that he accepted that he should have responded to the complainant's letter of complaint.

In early May 1999, the Commissioner notified the head of the Department of Medicine of the complaint, who replied:

"I have been Head of the Department of Medicine for [more than ten] years, during which time we have been involved in very many clinical trials in many different areas, involving literally thousands of patients. Our clinical research staff are dedicated and fastidious with patient care. This is the first complaint I have received during this time. It is certainly disappointing that professional efforts at proper trial conduct and communication have led to this. An early response from [the specialist physician] may have avoided this progression. I apologise for this also, as Head of Department."

Continued on next page

**Specialist Physician, Senior Lecturer in Medicine /
Research Nurse / University / Hospital and Health Service**

Report on Opinion – Case 98HDC20078, continued

**Information
Gathered
During
Investigation
*continued***

Enquiries were made by the Commissioner of the registrar at the university as to whether there is a complaints policy for staff to follow in the event of a complaint being made against them as health care providers. The registrar advised the Commissioner that all investigations into university staff actions should be conducted through the Vice-Chancellor's Office.

An investigation letter was sent to the Vice-Chancellor of the university in late July 1999, advising him of the complaint against the specialist physician and the research nurse.

In late August 1999 the registrar responded to the Commissioner on behalf of the Vice-Chancellor, stating that the Vice-Chancellor endorsed the head of the department of medicine's response of early June 1999 to the Commissioner. No details were given to the Commissioner about the university's complaints protocol.

There has been no response to a further letter from the Commissioner to the registrar, dated early September 1999, requesting details of a complaint procedure.

**Specialist Physician, Senior Lecturer in Medicine /
Research Nurse / University / Hospital and Health Service**

Report on Opinion – Case 98HDC20078, continued

**Response to
Commissioner's
Provisional
Opinion**

The specialist physician informed the Commissioner that:

“... I did not respond to [the complainant's] letter (even if in retrospect this was inappropriate) because it is never easy to tell a colleague that they have fallen short of the behaviour expected of a fellow health professional. ...

I will apologise for not responding to [the complainant's] letter. I will forward a letter to you addressed to [the consumer] on my return from overseas.

... It is not correct to say that the University has no complaints procedure although this procedure is not specifically for participants in research. A copy of the complaint from [the complainant] to the Commissioner was sent to [the] Head of the Department of Medicine, and he investigated this. I was interviewed by [the head of department] as was [the research nurse]. He also reviewed all the documentation before responding to Ms Stent. [The head of department] furnished an account of his enquiry to the Registrar and Vice – Chancellor who confirmed the actions he had taken. ...”

Another staff member responded to the Commissioner on behalf of the Vice-Chancellor. The staff member stated that:

“The University accepts that employers may be vicariously liable for actions of their employees. However, the University suggests that the facts of the matter are not as set out in the report and requests that the Commissioner review the way in which the information is presented.

Continued on next page

Specialist Physician, Senior Lecturer in Medicine / Research Nurse / University / Hospital and Health Service

Report on Opinion – Case 98HDC20078, continued

**Response to
Commissioner's
Provisional
Opinion
*continued***

At the time of the incidents that led to the complaint, [the specialist physician] was a senior lecturer in the Department of Medicine of the University. That Department, like most others in the School of Medicine, was contracted to provide certain clinical services to [the HHS]. [The specialist physician] provided such patient healthcare services under the contract. In such circumstances it is not immediately obvious whether the University is in fact a health care provider as the report suggest, since the clinical services delivered by University staff like [the specialist physician] are typically provided under the contract to [the HHS] and are subject to the latter's control.

The University notes that the research project in question was a clinical trial designed to test the efficacy of a new drug.

The Commissioner's attention is drawn to the fact that, regardless of whether University staff are conducting research, all research involving healthcare delivery must be submitted to and approved by the Human Subjects Ethics Committees set up by the Regional Health Funding Authority. Therefore, it is not the University which sets the requirements for such research, but the RHA Ethics Committees.

On Participant Information Sheets which the [university's] Human Subjects Ethics Committee would approve, participants are given the choice of raising any concerns with the Chair of the University's Ethics Committee, or with the Deputy Vice Chancellor (Research). If a participant complains to either of these University officers that complaint will initiate an appropriate complaints procedure.

Continued on next page

**Specialist Physician, Senior Lecturer in Medicine /
Research Nurse / University / Hospital and Health Service**

Report on Opinion – Case 98HDC20078, continued

**Response to
Commissioner's
Provisional
Opinion
continued**

The words 'an appropriate complaints procedure' are deliberately chosen because of the huge range of human subjects ethics committee applications in force in the University at any one time. These range across all faculties and nearly all subjects from Engineering to Religion and from Education to Commerce. While our Ethics Committee has established a process for dealing with complaints, our experience is the process needs to be tailored to the particular situation to ensure the complainant has every opportunity to discuss and detail the crucial issues relating to their complaint.

Further details are on our Website [...] All staff conducting research under University policies have to be familiar with the University's policies to have their application approved. The University's Human Subjects Ethics Committee provides training in compliance and policies compliance with those policies.

Thus, contrary to the impression you gained, the University has a complaints process in place and this would be activated by a complaint directed through one of the appropriate channels. In this case, however, the process was not activated because the research was not under the direct control of the University. Rather, [the complainant's] complaint fell under the RHA Ethics Committee procedures that differ from those of the University.

Also, the University notes [the consumer] was receiving treatment for an illness and the complaint referred to her dissatisfaction 'with the care she had received at [the] Hospital' In such circumstances it is arguable that, notwithstanding the research element, the complaint should have been dealt with under [the HHS'] Complaints procedures.

Continued on next page

Specialist Physician, Senior Lecturer in Medicine / Research Nurse / University / Hospital and Health Service

Report on Opinion – Case 98HDC20078, continued

**Response to
Commissioner's
Provisional
Opinion
*continued***

The University does not dispute the fact that [the specialist physician] should have promptly acknowledged the correspondence and/or appropriately redirected it. That applies whether he was acting as a researcher conducting research, or was involved as one of the physicians providing treatment to [the HHS'] patients. Without repeating your investigations we cannot be sure which complaints procedure was appropriate in the circumstances, but it does seem apparent that the facts outlined in your provisional opinion do not quite match the situation outlined above.

To the extent that the University contributed to this incident, the University offers its sincere apologies to [the consumer]. The University believes, however, that the problems identified in the investigation do not suggest any failure of University processes. Rather, they underline the difficulties patients face in understanding the present arrangements for delivering health care and undertaking medical research.

The University has worked co-operatively with [the HHS] to build quality healthcare services in [the area] and does not wish to see this response viewed as a criticism of [the HHS]. Instead, the University believes that this case underlines the difficulties members of the public may have when they wish to pursue a matter where the authority to proceed may lie with several distinct and very different entities. In such circumstances high levels of understanding are called for and it seems apparent that many of those involved were not aware of the various factors which might have speedily resolved the issues and contributed to an improved understanding of the situation by the [consumer's] family.”

Continued on next page

**Specialist Physician, Senior Lecturer in Medicine /
Research Nurse / University / Hospital and Health Service**

Report on Opinion – Case 98HDC20078, continued

**Response to
Commissioner's
Provisional
Opinion
*continued***

The quality of service manager for the HHS responded to the Commissioner on behalf of the Chief Executive Officer. The quality of service manager stated that:

“ ...

The issue that had arisen in regard to this complaint is whether it is the University or [the HHS] who is the provider when the complaint is centred around research.

In the [consumer's] case, as I understand it, the research was by [the specialist physician] who works for the University and [the HHS].

Correspondence from our complaints co-ordinator on receipt of the complaint in September 1998 redirects the complaint to the University on the grounds that [the specialist physician] was doing research for the University. Rationale for that decision is not documented

The facts are that [the consumer] was a patient of [the HHS] and the research was carried out by joint appointed staff.

I accept, therefore, that [the HHS] is the provider of health services and takes responsibility for the care and treatment of its patient which includes any research activity in which the patient is involved.

... [The HHS] does have a complaints process and it should have been followed in this case and we regret that it wasn't.

I have spoken with [the specialist physician] and clarified that this should be the case for all research activities such as this. He has undertaken to advise the University that this is the accepted practice and there should be no confusion in future cases.

...”

**Specialist Physician, Senior Lecturer in Medicine /
Research Nurse / University / Hospital and Health Service**

Report on Opinion – Case 98HDC20078, continued

**Code of Health
and Disability
Services
Consumers'
Rights**

The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:

RIGHT 2

Right to Freedom from Discrimination, Coercion, Harassment, and Exploitation

Every consumer has the right to be free from discrimination, coercion, harassment, and sexual, financial or other exploitation.

RIGHT 10

Right to Complain

- 3) *Every provider must facilitate the fair, simple, speedy, and efficient resolution of complaints.*
 - 4) *Every provider must inform a consumer about progress on the consumer's complaint at intervals of not more than 1 month.*
 - 6) *Every provider, unless an employee of a provider, must have a complaints procedure that ensures that -*
 - a) *The complaint is acknowledged in writing within 5 working days of receipt, unless it has been resolved to the satisfaction of the consumer within that period; and*
 - b) *The consumer is informed of any relevant internal and external complaints procedures, including the availability of -*
 - i. *Independent advocates provided under the Health and Disability Commissioner Act 1994; and*
 - ii. *The Health and Disability Commissioner; and*
 - c) *The consumer's complaint and the actions of the provider regarding that complaint are documented; and*
 - d) *The consumer receives all information held by the provider that is or may be relevant to the complaint.*
-

**Specialist Physician, Senior Lecturer in Medicine /
Research Nurse / University / Hospital and Health Service**

Report on Opinion – Case 98HDC20078, continued

**Opinion:
No Breach
Research
Nurse**

In my opinion the research nurse did not breach the Code of Health and Disability Services Consumers' Rights.

Right 2

The research nurse telephoned the consumer in mid-May 1998 to check on her health and to enquire about her non-attendance at the follow-up interview the day before. The nurse's actions were guided by the trial protocols established by the Ministry of Health that required follow-up when a patient experienced an adverse drug reaction during a trial.

The consumer informed the nurse that she was unable to attend the follow-up interview as she was experiencing further health problems. The consumer also informed the nurse that she was unhappy with the care she received at the hospital. The nurse questioned the consumer in an attempt to clarify these issues and obtain information to complete the study documentation.

The nurse reported her conversation with the consumer to her supervisor and the specialist physician. The nurse documented the details of the conversation with the consumer and her brother, in the consumer's clinical notes.

It is noted that the guidelines for Good Clinical Practice issued by the Ministry of Health specify that research participants may indicate their wish to withdraw from the clinical trial at any time. The consumer had been informed of this option.

There is no evidence that the research nurse acted inappropriately, or coerced the consumer, when she telephoned her in mid-May 1998. In my opinion the research nurse did not breach Right 2.

**Specialist Physician, Senior Lecturer in Medicine /
Research Nurse / University / Hospital and Health Service**

Report on Opinion – Case 98HDC20078, continued

**Opinion:
Breach
Specialist
Physician**

In my opinion the specialist physician breached Rights 10(3) and 10(4) of the Code of Rights as follows:

Rights 10(3) and 10(4)

The complainant attempted to resolve his complaint about the research nurse's treatment of his daughter directly by writing to the specialist, also the research team leader, in mid-June 1998. The complainant received no acknowledgement from the specialist physician that his letter had been received or that the complaint had been addressed.

When his initial letter was not responded to, the complainant wrote to the chief executive officer of the HHS in early September 1998 expressing concern that his complaint had not been acknowledged by the specialist physician.

The HHS responded in mid-September 1998 advising the complainant that the specialist physician and research nurse were employed by the university and that his concerns had been forwarded to the specialist physician for investigation and comment.

The specialist physician did not respond to this further letter of complaint from the complainant.

By failing to respond to the complainant's letters, the specialist physician did not facilitate a fair, simple, speedy and efficient resolution of the complainant's complaint. The specialist physician failed to meet the timeframe of one month specified as the interval for informing the consumer about progress of a complaint investigation. In my opinion the specialist physician breached Rights 10(3) and 10(4).

Specialist Physician, Senior Lecturer in Medicine / Research Nurse / University / Hospital and Health Service

Report on Opinion – Case 98HDC20078, continued

**Opinion:
Breach
Hospital and
Health Service**

In my opinion the HHS failed to take reasonable actions to prevent a breach of the Code of Rights by the specialist physician.

Employers may be vicariously liable for any breach of the Code of Rights by an employee, under section 72(2) of the Health and Disability Commissioner Act 1994. Under section 72(5) it is a defence for an employing authority to prove that it took such steps as were reasonably practicable to prevent the employee from doing or omitting to do the thing that breached the Code.

An employing authority is defined in section 72(1) of the Act to mean a health care provider or a disability services provider. "Health care provider" is defined in section 3(k) of the Act to include:

"Any other person who provides, or holds himself or herself or itself out as providing, health services to the public or to any section of the public, whether or not any charge is made for the services."

The HHS in providing health services to, and undertaking research on, the consumer was a 'health care provider' and an 'employing authority' under the Health and Disability Commissioner Act.

The university, in undertaking health research on human participants, was also a 'health care provider' and an 'employing authority' for the purposes of the Health and Disability Commissioner Act.

The HHS and the university have clarified that the research and the consumer's care was carried out by joint appointed staff.

The university and the HHS have a complaints procedure in place for staff to follow in the event of a complaint being made.

Continued on next page

**Specialist Physician, Senior Lecturer in Medicine /
Research Nurse / University / Hospital and Health Service**

Report on Opinion – Case 98HDC20078, continued

**Opinion:
Breach
Hospital and
Health Service
*continued***

The HHS has acknowledged an error occurred in early September 1998, when the complainant complained to the HHS about the specialist physician and the complaint was forwarded to the university. The HHS should have informed the specialist physician that the correct procedure to be followed was the HHS complaint process.

In these circumstances, the HHS is vicariously liable for the specialist physician's breaches of Rights 10(3) and 10(4).

**Opinion:
No Breach
The University**

In my opinion the university took reasonable actions to prevent a breach of the Code of Rights by the specialist physician.

The university has a complaints process, which would be activated by a complaint being directed through one of the appropriate channels at the university. The HHS referred the complainant's complaint directly to the specialist physician in error. When the head of the department of medicine was notified of the complaint he took reasonable actions to resolve the complaint and apologised to the complainant.

The university has proved that it took reasonable steps to prevent the specialist physician from breaching the Code, and is not vicariously liable for the specialist physician's breaches of Rights 10(3) and 10(4).

**Specialist Physician, Senior Lecturer in Medicine /
Research Nurse / University / Hospital and Health Service**

Report on Opinion – Case 98HDC20078, continued

Actions

I recommend that the following actions are taken:

- The specialist physician is to apologise in writing to the consumer for breaching the Code of Rights. This apology is to be sent to the Commissioner who will forward it to the consumer.
 - The university ensure that all staff involved in health research involving human participants receive training on the Code of Rights, including how to respond to complaints.
 - The HHS remind complaints co-ordinators of the correct process to be followed when complaints are received from consumers participating in research undertaken by staff jointly employed by the HHS and the university.
-

Other Actions

- A copy of this opinion will be forwarded to the Medical Council of New Zealand.
 - A copy of this opinion, with identifying information removed, will be forwarded to another university.
 - A copy of this opinion will be forwarded to the ethics committee of the provider university and to another ethics committee in the region.
-