Report on Opinion - Case 98HDC11100

Complaint

The Commissioner received a complaint from a parent about treatment his daughter, the consumer, received from the provider, a general practitioner. The complaint is that:

- In early January 1998, the provider vaccinated the complainant's daughter without the complainant's permission.
- The provider did not discuss the nature of the injections and the reason for them before vaccinating the consumer.
- The provider gave the consumer, who was 2 weeks old, vaccinations appropriate for a 6-week-old baby.

Investigation

The complaint was received by the Commissioner on 15 January 1998. An investigation was commenced and information obtained from:

The Complainant The Provider / General Practitioner

Relevant medical records were requested and viewed. The Commissioner obtained advice from a General Practitioner.

Details of Investigation

In early January 1998, the complainant took his two-week-old daughter, ("the consumer"), to the provider, a General Practitioner, as he was concerned about the consumer's jaundice and health. The complainant consulted the provider as he does not speak English well and a doctor who could speak his language was important. The consumer's grandmother, who was present throughout the consultation, does not speak any English at all.

The complainant showed the provider the Well Child Health booklet ("the booklet") produced by Plunket. The complainant said he felt very comfortable conversing with the provider, as she answered quite fluently and there seemed to be no problem with the choice of language.

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Details of Investigation, continued

In his letter to the Commissioner, the complainant stated, "She checked [my daughter], then she injected medicine to [her] on both sides of her legs. (I didn't ask her to inject medicine to my baby). Unfortunately she didn't give me any questions (for example baby's age) and give any explanation to me before she gave injection to [my baby], even she didn't answer my question and check document when I asked her what she injected to [her]. (Both of us can communicate in the same language -Mandarin, I am sure she understood me)."

An hour and a half later, the consumer appeared lethargic and sleepy and the complainant checked the booklet and found the vaccinations the provider gave the consumer were those appropriate for a 6 week old child. The complainant took the consumer to Hospital. The following day at 3.45am the Hospital's consultation note records the diagnosis as, "Accidental early vaccination, mild febrile reaction secondary to vaccination, mild jaundice and raised white cell count." The consumer was discharged with instructions that she should be taken back to Hospital for review at 12 noon.

At 12.10pm the same day, the consumer was reviewed at the Hospital, noted to be sleeping and eating well and was discharged.

The provider's native tongue is Singaporean Chinese and she said she was not fluent in Mandarin. The provider's recollection of events differs from the complainant in that the provider said, "The baby was examined in the presence of father and grandmother. I explained that at 6 weeks, baby usually will have immunisation as per protocol in well child book. There was difficulty in communication as I do not speak or understand Mainland Chinese fluently. However, as I explained the findings of the examination and routine immunisation to the father and grandmother, they did not express any difficulty in understanding me and did not refuse immunisation. The injections were done in the presence of both adults. They did not question why the immunisations were given at that stage. They did not contact me after the event."

On the page of the booklet headed "Six weeks", the provider recorded the consumer's progress as, "Fully alert, feeding, slow weight gain," and "Nothing abnormal detected, slightly jaundiced, for MSU."

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Details of Investigation, continued

The immunisation record page of the booklet comprises five sections based on age. Each section specifies the appropriate vaccinations for that age. The section labelled "6 weeks" and signed by the provider, records she vaccinated the consumer with OPV1 and DTPH1 into the right leg and HepB1 into the left leg.

The provider's patient details record the consumer's date of birth (late December 1997).

On the day of the consultation, (early January 1998), the provider's consultation note records, "For 6 week check. BW=3060 grams. Now 2995 grams slightly jaundiced fully breast fed. No murmurs. Hips no abnormality detected. Abdomen No abnormality detected. For MSU to lab. Immunisation given."

Under the heading 'Immunisations' in the consumer's Medical Record printout is recorded, "[January/98]: imms ok to 6 w, [January/98]: imm 6w (Hep B1, DTPH1, OPV1." During the investigation the provider explained the reference to "immunisations OK to 6 weeks" is an automatic response by the computer when an immunisation has been done.

A month later, in early February 1998, the provider records, "Had too early immunisation. Question re future course of immunisation. To repeat whole course. One injection at a time" and "Baby not seen mother came to tell me." Three days after that, the provider records, "rung parents several times - father not at home."

During the investigation, the provider advised the Commissioner that, "the choice for immunisation was ascertained by asking the guardians for consent after explaining to the guardians what the immunisations were for. Options to refuse or delay immunisations are offered." The provider stated she "checked the baby and advised the father and grandmother that it was routine for a child to receive vaccinations at 6 weeks. They said if this needs to be done, then go ahead and give the baby the immunisation."

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Details of Investigation, continued

General Practice Advice to the Commissioner

The Commissioner was advised that in certain areas of the world, where it is difficult to ensure children will return to be immunised, many injections are actually given at birth. "Thus both Hep B and Polio can both be quite safely given from birth onwards. With HIB there is not specific data easily accessible but the only problem would be that the immunisation did not take as well as it could. However it is most likely that the baby would 'catch up' with subsequent immunisations. The impact therefore on [this baby] is likely to be negligible."

"With Triple vaccination (tetanus, diphtheria and pertussis or whooping cough) there would be no sequellae from either the tetanus or diphtheria components but there is a very slight possibility that the pertussis component might not 'take' as well and this could effect immunity later in The risk however is certainly less than the risk of not being immunised at all. There is no evidence that [this baby] would need a repeat immunisation at 6 weeks."

"Thus there would be no long term sequellae from 5 of the 6 vaccinations given and only a very slight possibility of and from the 6th. Neither should there be any short term consequences. [This baby] would not react any differently to receiving the immunisation whether they were given at 2 or 6 weeks. She would not require an additional vaccination series so there would be no additional discomfort from immunisations."

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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.

RIGHT 5 Right to Effective Communication

1) Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided. Where necessary and reasonably practicable, this includes the right to a competent interpreter.

RIGHT 6 Right to be Fully Informed

- 1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including
 - a) An explanation of his or her condition; and
 - b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option;

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.

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

Provider Compliance

- 1) A provider is not in breach of this Code if the provider has taken reasonable actions in the circumstances to give effect to the rights, and comply with the duties, in this Code.
- 2) The onus is on the provider to prove that it took reasonable actions.
- 3) For the purposes of this clause, "the circumstances" means all the circumstances. the including consumer's circumstances and the provider's resource constraints.

Opinion: Breach

Right 4(2)

In my opinion, the provider breached Right 4(2) of the Code of Rights. This is because by administering vaccinations recommended for a sixweek-old baby when the consumer was only two weeks old, the provider did not follow the recommended protocols for immunisation.

Age is a basic and necessary piece of information to be established in order to properly assess and treat any child. Vaccination protocols for children in New Zealand are laid down in the Well Child Health booklet and are based on age. The onus was on the provider to correctly establish the consumer's age as part of her assessment and to determine what, if any, vaccination was required.

The provider said there were communication difficulties, however even if there were communication barriers, the provider correctly recorded the consumer's date of birth and so should have known her correct age. The complainant said there was no problem with communication, yet the provider did not enquire about the consumer's age nor inform him she was going to vaccinate her. The provider said the complainant brought the consumer to her for the purpose of a six-week-old check and she advised the complainant it was routine for a child to receive a vaccination at six weeks. However the consumer was not six weeks old and it was up to the provider to establish this.

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Opinion: Breach, continued

Informed Consent

The informed consent of the consumer is essential before any procedure is provided to him or her. In terms of the Code of Rights, informed consent is not a one-off event, but a process containing three essential ingredients, namely,

- effective communication between the parties,
- provision of all necessary information to the consumer (including information about options, risks and benefits), and
- the consumer's freely given and competent consent.

These ingredients work together and are represented in the Code by Rights 5, 6 and 7 respectively. In my opinion, the process of obtaining informed consent from the complainant (on the consumer's behalf) was not followed by the provider so as to meet the standard required by the Code of Rights. For the sake of clarity, I have referred below to breaches of Rights 5, 6 and 7 separately.

Right 5(1)

There is conflicting evidence as to whether there were communication problems posed by the use of Mandarin during the consultation. The onus was on the provider to ensure effective communication took place and if she could not communicate adequately with the complainant then she could not ensure he understood the information she was providing.

Right 5(1) of the Code provides that where necessary and reasonably practicable a consumer has the right to a competent interpreter. However I note that even if there were communication difficulties, the provider knew the consumer's date of birth and any communication difficulties did not compromise her ability to calculate the consumer's correct age.

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Opinion: Breach, continued

Right 5(1)

The provider has not shown that she communicated effectively with the complainant to establish the clinical treatment required and to enable the complainant to understand the information provided. In my opinion the provider breached Right 5(1) of the Code.

Right 6(1)(b)

The complainant said the provider did not explain why she was going to inject the consumer. The provider said she did but the explanation was in a language in which she was not fluent. However the provider has not explained the need to give a vaccination to a two-week-old child who did not require that vaccination until she was six weeks old. If there were communication difficulties, the provider could not ensure she fully informed the complainant as to options available, assessment of expected risks and any side effects of the treatment he was consenting to on behalf of the consumer. By not fully informing the complainant why his daughter required vaccinating at that time in her life, the provider breached Right 6(1)(b) of the Code.

Right 7(1)

The provider has not shown she informed the complainant of the reasons why the consumer required vaccinating. In terms of the immunisation protocol, the consumer did not require vaccinating at 2 weeks old. The complainant could not make an informed choice on behalf of his daughter in order to give his informed consent to any vaccination. By not obtaining the complainant's informed consent, the provider breached Right 7(1) of the Code.

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Actions

I recommend the provider take the following actions:

- Provides a written apology to the complainant for her breach of the Code of Rights. This is to be sent to the Commissioner's office and will be forwarded to the complainant.
- Refunds the cost of the consultation. This cheque is to be made out to the complainant and the Commissioner will forward it to the complainant.
- Reads the Code of Health and Disability Services Consumers' Rights and views a copy of the provider video available from this office.
- Provides a written assurance that recommended protocols for immunisation treatment will be followed in future.

A copy of this opinion will be sent to the Medical Council of New Zealand.