Practice Nurse / Medical Centre

Report on Opinion - Case 98HDC16189

Complaint

The consumer complained to the Commissioner about services provided to her on a day in early March 1998 by a practice nurse. The consumer said that the practice nurse dispensed an incorrect dose of emergency contraception to her. The emergency contraception failed and after a pregnancy test two weeks later the consumer discovered she was pregnant. The complaint is summarised as follows:

- *The practice nurse administered the morning after pill to the consumer. It was given in the form of two contraceptive pills and two anti-nausea pills, all given to the consumer in tissue paper.*
- *Instructions were given to the consumer that one contraceptive pill and one anti-nausea pill were to be "taken together as soon as possible at a time determined by the consumer and the remaining contraceptive pill and anti-nausea pill to be taken as close to 12 hours later as possible".*
- *Subsequently the consumer learned that the correct dosage should have been two contraceptive pills and one anti-nausea pill taken at one time and the remaining two contraceptive pills and one anti-nausea pill to be taken 12 hours later.*
- *The outcome of a meeting with the staff of the medical centre, and the explanation given for the event, proved unsatisfactory for the consumer.*

Investigation Process

The complaint was received by the Commissioner on 15 July 1998 and an investigation commenced on 13 November 1998. Information was obtained from:

The consumer
The provider/registered nurse
The consumer's general practitioner
First practice nurse
Second practice nurse
Medical centre/provider's employer
A pharmaceutical company

During the investigation the consumer's medical records were obtained.

Practice Nurse / Medical Centre

Report on Opinion – Case 98HDC16189, continued

Information Gathered During Investigation

The consumer had unprotected sexual intercourse during the early hours of a day in early March 1998. Later that day she telephoned her general practitioner (GP) and told her what had happened. The consumer advised her GP that she did not wish to become pregnant. The GP told the consumer to come into the surgery, see a practice nurse and obtain the "morning after pill", an emergency contraceptive. The GP did not record this telephone consultation in the consumer's records nor did she tell any of the practice nurses of her consultation with the consumer.

The medical centre advised the Commissioner that the GP was fully aware of the consumer's medical history and current status when she recommended that the consumer come and get emergency contraception. Further, the medical centre advised that the consumer's blood pressure had been normal when checked two months earlier.

The consumer remembers arriving at the medical centre shortly before 5pm that evening. The practice nurse (the provider) recalls that the consumer arrived at 5:15pm. The provider was the only practice nurse in attendance and there were no medical staff at the centre. The consumer had not had any previous contact with the provider, as she usually dealt with the GP's two practice nurses. The provider worked with another doctor in the same practice.

The provider stated that the consumer arrived at the medical centre at 5:15pm, and that the computers had been turned off at that point. The consumer stated that she arrived at the medical centre at 4:55pm and that two receptionists were working on the computers. The consumer stated that the computers were definitely still turned on when she arrived.

The consumer is certain that she arrived at the medical centre at 4:55pm. Her daughter's jazz class finished at 4:40pm, and she rushed to get to the medical centre before it closed at 5:00pm. The consumer pointed out that she told the provider that she didn't want to set her alarm for 5:00am (12 hours later) in order to take the second "morning after pill". The consumer said that this confirms that her discussion with the provider took place at 5:00pm, not 5:15pm.

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Practice Nurse / Medical Centre

Report on Opinion – Case 98HDC16189, continued

Information Gathered During Investigation *continued*

The consumer stated to the Commissioner that when she arrived at the medical centre the provider told her that she could see her briefly as she had to be somewhere else at 5:00pm. The consumer said that the provider was in a hurry.

The provider informed the Commissioner that she was not in a hurry and was prepared to give the consumer as much time as necessary for a consultation. The provider stated that the consumer requested the "morning after pill", informing the provider that she did not want any counselling, she just wanted to obtain the pill as quickly as possible. The provider took the consumer into a consulting room and prepared to have a full consultation with her. A full consultation would have included a patient assessment and provision of the medication.

The consumer stated that she told the provider that she had spoken with her GP about how to obtain a "morning after pill" and that the GP had told her either to come to the medical centre before it closed at 5:00pm or to another medical centre which closed at 7:00pm. She was told that she had to "*pop in and see the nurse*". The consumer said that the GP did not tell her that a long or proper consultation would be necessary, nor that the nurse would need a doctor's permission to dispense the "morning after pill". If she had been told that there was not enough time for a proper consultation, the consumer said that she would happily have gone to the other medical centre instead.

The consumer stated that the provider told her that they really needed more time, as some counselling was involved with administering the "morning after pill", and that it would be desirable for her to have a full consultation. The consumer said she explained that she had just had her second unplanned child and definitely did not want a third. The consumer said that she did not need counselling to decide that she did not want any more children, and told the provider that she was currently on Prozac for postnatal depression following the birth of her second unplanned child.

The consumer also explained that, after the birth of her second unplanned child, she had discussed with her GP whether to have her tubes tied. Records of these discussions should be in her notes. However, she had insufficient points to obtain a publicly funded tubal ligation.

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Practice Nurse / Medical Centre

Report on Opinion – Case 98HDC16189, continued

Information Gathered During Investigation *continued*

The provider responded that the consumer seemed to know how she felt, so she would give her the "morning after pill". The provider went to get the pills, and returned with a glass of water for the consumer to take the first dose. She explained to the consumer that the second dose needed to be taken exactly twelve hours later. The consumer said that she thought it was too dangerous for her to rely on setting the alarm for 5:00am to take the second dose, as there was a strong possibility that she would sleep through the alarm and miss the dose. The consumer told the provider that she would prefer to take the pills later that evening, so that she could take the second dose at 7:00am or 8:00am, when she would definitely be awake.

The usual practice at the medical centre is that nurses do not provide emergency contraception without the involvement and approval of a doctor. Usually the woman is seen first by a practice nurse to discuss the two forms of emergency contraception (oral contraceptives and the Intrauterine Contraceptive Device – IUCD). The practice nurse will discuss the risks associated with the treatment, including the risk of failure. The risk of ectopic pregnancy and vomiting if hormone therapy is used was also discussed. It is standard practice for a doctor to see the patient and to authorise the provision of the medication. The consumer insisted that she did not want a full consultation. The provider informed the Commissioner that because of the consumer's very anxious state, and to avoid a dangerous treatment delay, she "*reluctantly acceded*" to the consumer's demands.

The provider advised the Commissioner that:

> "*while a full consultation was desirable, in the circumstances of the case, not to provide the emergency contraception as requested by the patient would have placed her at greater risk. Provision of emergency contraception is not a complicated matter from a clinical perspective and it was not unsafe to provide medication without the normal consultation.*"

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Practice Nurse / Medical Centre

Report on Opinion – Case 98HDC16189, continued

Information Gathered During Investigation *continued*

The medical centre stated that:

> "*At the time of the consultation with* [the provider], [the consumer] *made much of the fact that she had already discussed the situation with* [her GP] *and that* [the GP] *had advised her to come to the surgery for emergency contraception. Arguably therefore,* [the provider] *was indeed acting on the instructions of a doctor, albeit instructions delivered indirectly and communicated to her by the patient.*"

The consumer advised the Commissioner that she did not "make much" of her conversation with her GP, when discussing her situation with the provider, and that she was not anxious when she went to the medical centre. If she had been told that there was not enough time for a proper consultation, the consumer would happily have gone to the other medical centre instead.

The provider provided the consumer with Ovral contraceptive tablets and Stemitil anti nausea medication. The provider advised that she gave the consumer 4 Ovral tablets and 2 Stemitil tablets, with instructions that 2 Ovral and 1 Stemitil be taken immediately and the other 2 Ovral and 1 Stemitil be taken in exactly 12 hours time. The provider also advised that the consumer told her she did not wish to take the first dose in the surgery because she would have had to set her alarm for early the following morning to take the second dose. The provider advised that she wrapped each dose of 2 hormone tablets and one Stemitil tablet in two separate pieces of tissue paper. She handed the two packages to the consumer and gave her a patient information sheet about emergency contraception. The pamphlet briefly explained how emergency contraceptives work and provided instructions on when to take the tablets.

The consumer said that she left the medical centre at about 5:05pm, and she is sure that she was there for no more than ten minutes. The consumer stated that when she left, the two receptionists were still working on their computers, which had not yet been turned off.

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Practice Nurse / Medical Centre

Report on Opinion – Case 98HDC16189, continued

Information Gathered During Investigation *continued*

The provider advised the consumer to return for a pregnancy check and follow up consultation in two weeks time. The possibility of side effects was discussed with the consumer. No written notes were taken during the consultation and no notes relating to this visit were recorded at the time on the clinic's computer. The provider advised that there are no notes because the consumer refused a proper consultation and the clinic's computers had been switched off for the day.

The medical centre informed the Commissioner that supplying emergency contraception is not a complex medical procedure and is one for which detailed records are not usually kept or required. Further, that even if a record of this consultation had been kept, the outcome in this case would not have been altered substantially. The medical centre also stated that the practice is fully computerised and that the computers were turned off at the time of the consultation. Their position was that these were "*significant mitigating circumstances*" explaining why this consultation was not documented.

The provider's response to the issue of record keeping was as follows:

> "*It is acknowledged that records of the patient visit and the provision of emergency contraception should have been made at the time of the visit or shortly thereafter. But, as previously stated there were circumstances that explain why this was not done* – [the consumer] *had refused a full consultation and the surgery's computers had been shut down. Moreover, it is a small practice, where the practice nurses and general practitioners have a close working relationship*."

The provider did not check the consumer's notes nor did she contact her GP to discuss the matter prior to supplying the contraceptive. Rather, she accepted the consumer's explanation of a telephone conversation between the consumer and the provider earlier that afternoon. The provider submitted that it was reasonable for her to assume this conversation had been recorded by the GP.

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Practice Nurse / Medical Centre

Report on Opinion – Case 98HDC16189, continued

Information Gathered During Investigation *continued*

The consumer agreed with the provider's description of the events during the consultation, however she advised that the provider supplied only 2 Ovral tablets. The consumer stated that the provider folded the napkin containing four pills, and gave it to her. She stated that only one tissue-wrapped package was handed to her by the provider and the package contained only 2 Ovral tablets and 2 Stemitil tablets. She advised that the Stemitil tablets were loose and unwrapped. The two hormone tablets were in individual foil covered packets that appeared to have been cut from a sheet of normal contraceptive pills. The consumer said that she was surprised that the "morning after pill" consisted of two pills, as she had thought there would be only one dose. The consumer explained the instructions she had received to her friend, who was waiting for her in the car.

The consumer advised that she took the first dose of one hormone tablet and one Stemitil tablet at exactly 7:52pm that evening and the second dose at exactly 7:52am the following morning.

The consumer recalls that she contacted the GP within a week of taking the tablets, possibly on the following Monday. She advised the GP that she had experienced no side effects from the medication and expressed concern that perhaps the contraceptive had not worked. The consumer advised that the GP reassured her that some people experience no side effects after taking the morning after pill. There is no record of this conversation in the consumer's clinical notes.

Two weeks after receiving the emergency contraceptive the consumer returned to the clinic for a follow-up check. A pregnancy test was performed and this confirmed that she was pregnant. The consumer stated that she was upset about this but initially believed she had just been "unlucky".

At a later date the consumer approached Presbyterian Support Services for advice about the pregnancy. During the conversation the counsellor asked what dose of emergency contraceptive she had taken. The consumer said that she had received two doses, each containing 1 hormone tablet and 1 anti-nausea tablet. The consumer advised that the counsellor informed her that she did not think this was the correct dose. The counsellor advised the consumer to contact her doctor and check what the normal dose is.

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Practice Nurse / Medical Centre

Report on Opinion – Case 98HDC16189, continued

Information Gathered During Investigation *continued*

The consumer contacted the medical centre and spoke to one of the practice nurses. The consumer advised the Commissioner that the practice nurse confirmed the dose used for the emergency contraceptive regime was 2 doses of 2 Ovral hormone tablets, taken 12 hours apart. The consumer advised the practice nurse that each of the two doses she had been given by the provider contained only 1 hormone tablet.

There were several further conversations between the consumer and staff members of the medical centre in relation to the matter. A meeting between the parties in mid-May 1998 failed to resolve the consumer's concerns about the medication she had received.

At this meeting an advocate, the consumer's GP, the provider and the consumer were present. The GP alleged that the consumer had not read the explanatory letter which accompanied the "morning after pills" she was given. The consumer stated that she did read this letter, and challenged this statement of the GP's. The letter stated that she was to take two pills initially, and the other two pills twelve hours later. The consumer told the GP that the letter should specify two "morning after pills" and one anti-nausea pill initially, then two "morning after pills" and one anti-nausea pill twelve hours later. At this meeting the medical centre agreed to change their procedures with regard to administering the "morning after pill" so that the amounts administered were double checked. They also changed the accompanying information to a Family Planning leaflet instead of the misleading letter. The consumer stated that she was satisfied with this outcome in terms of her complaint about the medical centre. The consumer continued to receive medical care from her GP and in early December 1998 she gave birth to a baby boy.

The consumer said that if the provider had recognised that she had made a mistake with the dosage and admitted that she was capable of human error and apologised, she would not have felt it was necessary to pursue her complaint. After the meeting of mid-May 1998, according to the consumer, the provider just kept repeating "*I'm sorry the pill didn't work for you…*", and offered no apology.

The provider informed the Commissioner that she has worked as a practice nurse for more than 15 years and has extensive experience dispensing the "morning after pill". She also works part-time at the Family Planning Association.

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Practice Nurse / Medical Centre

Report on Opinion – Case 98HDC16189, continued

Information Gathered During Investigation *continued*

The provider stated that she provided the emergency contraception under standing orders, and that the use of standing orders "*is a well-established practice throughout all areas of the health service*".

The medical centre advised that at the time of this incident it did not have written protocols or standing orders covering the provision of emergency contraception although it had a usual practice.

The medical centre advised the Commissioner:

> "*Much has been written about the responsibilities of members of staff of this Medical Centre. There has been little comment about responsibilities for* [the consumer] *herself. She is not an especially vulnerable patient in terms of age, maturity or other medical conditions. She is a mature woman who is not naïve in matters of sexuality and reproduction. She attended a Medical Centre and chose not to have a consultation with a health professional, despite being advised by that person that she should do so. She agrees she was given written instructions about how to take the emergency contraceptive pill, but she chose not to read those instructions.*
>
> *General medical and nursing practice has changed from being authoritarian and paternalistic, in response to changing societal values and requirements. This change assumes much greater involvement in decision-making by patients. Patients themselves are no longer passive recipients of care but are very involved in the care they receive so that in a patient-centred approach the care and management is jointly negotiated. The events with* [the consumer] *can be characterised by her taking considerable responsibility for her behaviours prior to, during, and after her attending our surgery. This is consistent with a patient-centred approach to care. Unfortunately, if* [the consumer] *chooses to be responsible for making decisions then she too needs to take responsibility for the outcomes of those decisions, particularly if her choices include ignoring medical advice. In this case it is unfortunate and unfair that we are expected to be responsible for her unhappy outcome.*"

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Practice Nurse / Medical Centre

Report on Opinion – Case 98HDC16189, continued

Information Gathered During Investigation *continued*

The usual emergency contraceptive regime used at the medical centre is the Yuzpe method. This consists of 2 Ovral contraceptive tablets and a further dose of 2 more tablets twelve hours later. A Stemitil tablet is included with each dose of Ovral in order to reduce side effects such as nausea and vomiting. The required number of Ovral contraceptive tablets are cut from a 21 day Ovral contraceptive blister pack. The medical centre advised that there is a recognised failure rate of approximately 2-5% with this regime.

The pharmaceutical company that manufactures the Ovral contraceptive advised the Commissioner that the Ovral contraceptive is produced in 21 day blister packs with each of the 21 tablets containing 50 ug ethinylestradiol and 500 ug norgestrel. The emergency contraceptive regime is not an approved indication for Ovral and is not recommended by the New Zealand pharmaceutical company, nor by the company globally. Despite this, it recognises that emergency contraception is an off-label use of oral contraceptives. The company advised that it does not have data of its own regarding the failure rate of the emergency contraceptive. However, it referred to the World Health Organisation's 1998 Task Force on Postovulatory Methods of Fertility Regulation, which published the results of a study of the Yuzpe method compared with a progestogen only regimen. The trial found that the proportion of pregnancies prevented by the Yuzpe method, compared with the expected number without the treatment, was 57% but that the earlier the treatment was given, the more effective it seems to be. Other studies have reported varying success rates for the method.

Code of Health and Disability Services Consumers' Rights

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

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.

Practice Nurse / Medical Centre

Report on Opinion – Case 98HDC16189, continued

Other Relevant Standards

Principle 2.9 of the Nursing Council of New Zealand Code of Conduct for Nurses and Midwives states that the nurse or midwife:

> "*accurately maintains required records relating to nursing or midwifery practice*".

Opinion: No Breach The Provider (Practice Nurse)

Right 4(2)

Provision of correct medication

In my opinion there is insufficient evidence to conclude that the provider failed to provide the consumer with the correct dosage of Ovral contraceptive tablets in early March 1998. The consumer's recollection of the matter and the provider's recollection of the same events are inconsistent. I note that the provider, a very experienced practice nurse with expertise in contraception counselling, had administered emergency contraception on hundreds of occasions, and was well aware of the correct dosage. However, even experienced nurses do, on occasion, make mistakes. I note also that there is a high failure rate for emergency contraception even when the right dose has been provided and instructions are followed correctly.

On balance, I am unable to conclude that an incorrect dosage was given to the consumer.

Practice Nurse / Medical Centre

Report on Opinion – Case 98HDC16189, continued

Opinion: Breach

The Provider (Practice Nurse)

In my opinion the provider breached Right 4(2) of the Code of Rights.

Emergency contraception

The medical centre has confirmed that its standard practice for issuing emergency contraception is for the nurse to check the number of tablets with a colleague and for the doctor to see the patient. This was the practice at the time the incident occurred.

I note that the provider did not comply with the medical centre's standard practice for emergency contraception. Although I accept that there were extenuating circumstances, the provider did not conduct a full consultation or patient assessment. Most significantly, she did not check with the consumer's GP whether she had authorised emergency contraception.

The provider was not expressly authorised by a doctor from the medical centre to provide the consumer with emergency contraception. In my view, the GP's general advice to the consumer over the telephone did not amount to a direction or instruction to the provider to provide a prescription medicine to the consumer.

I note that the medical centre stated that the consumer clearly expressed her needs at the time to the provider, and the provider responded to the situation as it was presented to her. In my opinion, providing prescription medication without properly assessing the consumer, without the directions or instructions of a doctor as required under the Medicines Act 1981, and without following standard procedures, cannot be in accordance with a consumer's needs or best interests.

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Practice Nurse / Medical Centre

Report on Opinion – Case 98HDC16189, continued

Opinion: Breach The Provider (Practice Nurse) ***continued***

Record keeping

Principle 2.9 of the Nursing Council Code of Conduct requires nurses and midwives to maintain accurate records relating to nursing or midwifery practice. The provider did not record the consumer's consultation in early March 1998 and kept no record of the provision of emergency contraception. The provider has explained that no notes were made because the consumer refused a proper consultation and requested that she just be provided with the "morning after pill". In addition, the provider stated that the surgery's computers had been shut down for the day by the time the consumer arrived at the clinic.

Despite the consumer's refusal to participate in the standard emergency contraceptive consultation, the provider still provided her with advice and supplied the emergency contraceptive to her. These actions should have been recorded in the consumer's clinical notes.

Conclusion

In their responses to the investigation, the medical centre and the provider referred to their standard practice and acknowledged that standard procedures were not followed in this case. The provider provided information and an explanation of her record keeping on this occasion.

In my opinion the provider breached Right 4(2) of the Code, as she did not follow the medical centre's standard procedure, and check with the GP before supplying emergency contraception to the consumer, or keep adequate records of her consultation with the consumer.

I note that, in response to my provisional opinion, the provider advised that she has read and familiarised herself with the Nursing Council of New Zealand's Code of Conduct for Nurses and Midwives.

Practice Nurse / Medical Centre

Report on Opinion – Case 98HDC16189, continued

Opinion: Breach
Medical Centre

Right 4(2)

In my opinion the medical centre breached Right 4(2) of the Code of Rights.

Policy for supply of emergency contraception
The provider was employed by the medical centre as a practice nurse. Consultations for emergency contraception were among her normal clinical duties. The provider advised that although she understood the medical centre's usual practice for the provision of emergency contraception, she did not adhere to it on this occasion and provided the consumer with a prescription medicine without the involvement or authorisation of a medical practitioner.

However, the medical centre had no written protocols or standing orders covering the provision of emergency contraception. There were no clear guidelines available for the provider to refer to in circumstances that were out of the ordinary, as in the case of the consumer. The medical centre was aware of the constraints on nurses under the Medicines Act 1981 and had developed an informal 'usual practice' to ensure emergency contraception was provided by a person who had authority to do so under the Medicines Act.

In my opinion the medical centre breached Right 4(2) of the Code, as it should have had written procedures which clearly established the circumstances in which a nurse could provide emergency contraception.

I note that, since this incident, the centre has changed its policies regarding the supply of emergency contraception. The pills are now provided in a small plastic bag that is stapled to the Family Planning Association instructions for emergency contraception. An example of this new packaging was included with the centre's response to the Commissioner.

Practice Nurse / Medical Centre

Report on Opinion – Case 98HDC16189, continued

Actions

I recommend that the provider:

- Apologises to the consumer in writing. This apology is to be sent to the Commissioner and will be forwarded to the consumer.
- Reviews her practice in relation to supplying emergency contraception and record keeping.

I recommend that the medical centre:

- Ensure that its new policy regarding the supply of emergency contraception is complied with, and that all staff are trained in its application.

Other Actions

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