29 July 2024

Health New Zealand
Te Whatu Ora

9(2)(a)

Tēnā koe 9(2)(a)

Your request for official information, reference: HNZ00048412

Thank you for your requests to Health New Zealand | Te Whatu Ora under the Official Information Act 1982 (the Act) for information relating to contraceptive devices.

Between 16 May and 24 May 2024, Health NZ received four separate requests for official information from you. Due to the frequency and the similarity of the subject matter forming the basis of the four requests, namely information on intrauterine devices (IUDs), we determined that these requests could be combined into this one response under ref: HNZ00048412.

Firstly, we will response to your questions specific to –the Bayer Mirena IUD devices, see below.

- *How many devices do you insert to NZ women in NZ every year?*
- *What age brackets do these women get these devices?*
- *14. What hospitals in NZ insert the most IUDs?*
- *How many Bayer Mirena IUDs are used in NZ women every year?*

While Health NZ holds information nationally about inpatient procedures performed in public hospitals, this does not include information about specific intrauterine devices. As such, we must refuse this portion of your request under section 18(g) of the Act, as we do not hold information that can answer these questions and have no grounds to believe the information is held by another agency subject to the Act.

For context, the clinical notes from all inpatient and same day patients discharged from public hospitals are clinically coded and recorded in the hospital's patient management system (PMS). Clinically coded summaries of these discharges are forwarded to National Collections held by Health NZ, where the information is loaded and stored in the national collection National Minimum Data Set (NMDS). New Zealand hospitals use international coding practice classifications and standards. There is no requirement in these classifications and standards to include information about specific intrauterine devices.

- *What is the main reason that these devices are used on NZ women?*

Mirena IUD devices are used for contraception reasons or to treat heavy menstrual bleeding.

- *Can you please send the latest brochure about these devices please?*
- *What is the latest information given on this product, brochure please?*

The New Zealand Medicines and Medical Devices Safety Authority (Medsafe) provides information for healthcare consumers and professionals about medicines including medical devices.

Information about the Bayer Mirena IUD and a Data Sheet on the Mirena levonorgestrel delivery system can be found on their website at: www.medsafe.govt.nz/Consumers/CMI/m/Mirena.pdf; and www.medsafe.govt.nz/profs/Datasheet/m/Mirenaius.pdf

As set out in these documents, Mirena may be used as a long term and reversible method of contraception, for the treatment of excessive menstrual bleeding (menorrhagia), or for the protection from endometrial hyperplasia (excessive growth of the lining of the womb) during hormone replacement therapy.

- *What are the reasons women in NZ are coerced onto the product?*

Health NZ is not aware of women being coerced onto this product and is therefore refusing this portion of your request under section 18(e) of the Act, because the information requested is not known to exist.

If you know of anyone who has felt coerced into having an IUD fitted, they should make a complaint to the Health and Disability Commissioner (HDC). Information about how to make a complaint, as well as the complaint process, can be found on their website at: www.hdc.org.nz/making-a-complaint/.

- *How many professional people are trained to insert these devices?*
- *How many professional people are trained to remove these devices?*

The Ministry of Health has issued standards of competency for training health professionals in Mirena IUD insertion and removal to ensure high safety standards. You can read about these standards on the Ministry's website at: www.health.govt.nz/publication/long-acting-reversible-contraception-health-practitioner-training-principles-and-standards.

Health professionals are able to provide Mirena IUD procedures if this falls within their scope of practice as set out by the Medical, Nursing or Midwifery Council. Mirena IUDs are most commonly fitted by doctors, however nurses can fit Mirena IUDs under 'standing orders' and supervised by a doctor. Training usually includes both the insertion and removal of devices.

There are a number of ways clinicians can access Mirena training, including:

a) Auckland and Otago Universities undergraduate medical or post graduate diplomas in gynaecology or sexual and reproductive health,
b) through the NZ College of Sexual and Reproductive Health national training, or
c) by experienced and competent practitioners on the job in a hospital or primary care practice.

Because most IUDs are fitted outside of public health settings, for example by GPs, Health NZ does not hold information on the numbers of those trained to fit IUDs. As such, we are refusing this portion of your request under section 18(g) of the Act, because we do not hold this information and have no grounds to believe it is held by another agency subject to the Act.

- *Does it stay within the uterine wall - the levongestal?*

This information is set out in full within Medsafe's Data Sheet (link provided above).

- *How many surgeries are required in NZ to remove these devices?*
- *If there are surgeries what has happened to most women?*
- *How many haemorrhage after removal?*
- *How many Bayer Mirena IUD devices have to be surgically removed?*

As set out above, while Health NZ holds information nationally about inpatient procedures performed in Health NZ's public hospitals, this does not include information about specific IUDs. Health NZ is therefore refusing your request for this information under section 18(g) of the Act, as we do not hold the information.

- *How many women are suicidal due to the Mirena IUD in NZ? Because the lack of progesterone a happy hormone.*

Health NZ is unable to respond to this portion of your request because we do not information about specific IUDs. We must therefore also refuse this question under section 18(g) of the Act.

- *How many adverse effects are reported? What are the side effects known.*

Health NZ is unable to provide this information as Health NZ does not hold specific information about IUD adverse effects.

However, you may find it helpful to contact Medsafe, as it provides an adverse event reporting system for medical devices. Anyone can report an issue associated with a medical device to Medsafe. An issue may relate to an adverse event, or a quality issue. Patients, caregivers, healthcare professionals and suppliers can lodge an adverse event report if an incident has occurred and there is a concern about the safety of the device or its use. Medsafe may be able to provide you with information about adverse event reports it has received regarding the Beyer Mirena IUD. In addition, ACC may hold information about injury/harm claims related to the device.

- *How many are covered by ACC with harm from IUD device?*

Health NZ is unable to provide you with this information as it is not held by us. However, you may wish to contact ACC directly who may be more closely connected to this part of your request. Information about how to contact ACC can be found at: www.acc.co.nz/contact/official-information-act-requests.

- *How often do women make complaints about the Bayer Mirena IUD.*
- *Out of all the Women's Health Departments in New Zealand, what hospital (Women's Department) in New Zealand has the most complaints laid against it?*
- *Do you take into account any Private Hospital's when complaints are laid? Or do they have no accountability at all?*
- *Out of all the Women's Health Departments in New Zealand, what hospital (Women's Department) in New Zealand has the most complaints laid against it?*

As outlined above, Health NZ is unable to provide information specifically about IUDs.

Health NZ also does not hold information relating to private hospitals. Health NZ is responsible for the care provided in public hospitals; private hospitals and their parent organisations are responsible for the care provided by their hospitals.

As such, we must refuse these questions under section 18(g) of the Act, because we do not hold the information requested.

As mentioned previously, patients may complain about the care they receive (from both public and private hospitals) to the Health and Disability Commissioner (HDC).

- *How many gynaecologist currently practice in New Zealand?*
- *How often are their registrations re-registered? And what do they take into consideration, if complaints made against the professional, how many times before action is taken?*

The Medical Council of New Zealand (MCNZ) is responsible for the registration of health professionals in New Zealand and may consider providing you with the information you have requested. You can contact the MCNZ at: www.mcnz.org.nz/about-us/contact-us/.

As this information is not held by Health NZ, we must also refuse this portion of your request under section 18(g) of the Act.

Please note, the MCNZ is not subject to the Act, and is under no obligation to provide this information.

- *Could you please send me the current hysterectomy brochure from RANZCOG. 12. The hysterectomy brochure used in 2018 with the Hologics Novasure Endometrial Ablation information in a box on the right hand corner about 2inch x 3inch.*

Information published by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) about hysterectomy (March 2018) can be accessed from

RANZCOG's website at: https://ranzcog.edu.au/wp-content/uploads/2022/06/Hysterectomy-pamphlet.pdf.

You also posed the following questions relating to Jadelle IUD devices in New Zealand:

- *How many devices do you insert to NZ women in NZ every year? 2. What age brackets do these women get these devices?*
- *What hospitals in NZ insert the most Jadelles?*
- *How many surgeries are required in NZ to remove these from other places?*
- *If there are surgeries what has happened to most women?*

As mentioned previously, while Health NZ holds information nationally about inpatient procedures performed in public hospitals, this does not include information about specific intrauterine devices. We are therefore again refusing this portion of your request under section 18(g) of the Act.

- *What is the main reason that these devices are used on NZ women?*
- *Can you please send the latest brochure about these devices please?*
- *Does it stay within the arm?*

Medsafe provides information for healthcare consumers and professionals about Jadelle. This information can be accessed at: www.medsafe.govt.nz/Consumers/CMI/j/jadelle.pdf .

As set out in these documents, Jadelle is a contraceptive implant, used to prevent pregnancy. Jadelle is inserted just beneath the skin on the inside of the upper arm.

- *How many surgeries are required in NZ to remove these from other places?*
- *If there are surgeries what has happened to most women?*

Like all surgical procedures Jadelle carries a risk of treatment injury. From 2017 to 2023 the incidence of IUD treatment injury registered with ACC dropped significantly from 5/1000 to 1.2/1000 which is slightly lower than international standards of Mirena treatment injury at 1.4/1000 – 1.7/1000.

However, if there is heavy bleeding and/or severe pain, you should seek and receive immediate medical care. Perforation risk is highest post-partum, and in the first three months of IUD insertion. Most perforations are minor and do not require surgical intervention, but the IUD placement should be identified and if it has caused injury, should be removed. A gynaecologist or experienced women's health professional is the best person to provide this care. ACC funds the care costs for treatment injury if accepted. Healthline can provide advice at: https://info.health.nz/services-support/health-and-disability-providers/healthline

- *How many adverse effects are reported? What are the side effects known.*

As per the above response, Health NZ is unable to provide this information as we do not hold information specifically about adverse effects from Jadelle IUDs.

Again, Medsafe may be able to provide you with information about adverse event reports it has received regarding the Jadelle IUD. ACC may hold information about injury/harm claims related to the device.

- *How many are covered by ACC with harm from IUD device?*

Health NZ is unable to provide you with this information as it is not held by us. However, you may wish to contact ACC directly who may be more closely connected to this part of your request. Information about how to contact ACC can be found at: www.acc.co.nz/contact/official-information-act-requests.

Finally, you also asked about Essure IUD devices, as below.

- *How many Essure victims are there in New Zealand.*

- *How many Essure devices were there placed into New Zealand women?*
- *How many received Essure and Bayer IUD Mirena at the same time?*
- *What hospitals implanted Bayer Essure devices?*
- *How many New Zealand women have ended up with hysterectomies due to the Essure device?*
- *How many women have ended up in hospital due to the Essure device?*

As mentioned previously, while Health NZ holds information nationally about inpatient procedures performed in public hospitals, this does not include information about specific intrauterine devices. We are therefore again refusing these questions under section 18(g) of the Act.

Health NZ is currently undertaking a process to identify women who had an Essure device implanted and or removed in a public hospital setting. We understand the devices were implanted in women in New Zealand up until 2017, then the product was withdrawn from the market. We understand the device has not been used in by our public health system since.

- *How many New Zealand women have been accepted for ACC care with Essure injuries?*

As outlined previously, you may wish to contact ACC directly about this part of your request. Information about how to contact ACC can be found at: www.acc.co.nz/contact/official-information-act-requests.

- *Could you please send us the information leaflet that these women received from the RANZCOG and the Medical departments.*

During the years the Essure device was available in New Zealand, each area's then District Health Board and their clinical teams/clinicians we are responsible for providing information about the Essure device. The information provided was not systematically recorded in a central location which therefore makes it very difficult to identify and collate. As such, we must refuse this portion of your request under section 18(f) of the Act, for reasons of substantial collation.

As suggested previously, you may wish to request this information from RANZCOG directly.

- *Has any gynecologist been prosecuted for misinformed consent?*

Health NZ does not have the power to prosecute gynaecologists. We must therefore refuse this final part of your request under section 18(g) of the Act, because we do not hold this information, and do not believe another agency subject to the Act would.

The HDC, however, may be able to assist with this query and you can contact them directly using the contact information provided earlier.

How to get in touch

If you have any questions, you can contact us at hnzOIA@tewhatuora.govt.nz.

If you are not happy with this response, you have the right to make a complaint to the Ombudsman. Information about how to do this is available at www.ombudsman.parliament.nz or by phoning 0800 802 602.

As this information may be of interest to other members of the public, Health NZ may proactively release a copy of this response on our website. All requester data, including your name and contact details, will be removed prior to release.

Nāku iti noa, nā

Dr Richard Sullivan
Chief Clinical Officer
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