Clinical: Surgical
Proactive release : 01 May 2019

17 April 2019

[redacted]

E-mail: [redacted]

Dear [redacted]

Official Information Act (1982) Request

I write in response to your Official Information Act request, received on transfer from the Ministry of Health under section 14 of the Act, on 22 March 2019.

You requested the following information:

- **I would like a detailed breakdown of any and all incidents relating to equipment not being properly sterilised by District Health Boards in 2018 and 2019.**

This response is for Counties Manukau District Health Board (CMDHB), and our CM Health Central Sterilisation Services Departments (CSSD). We have used our Incident Reporting system to provide the following summary details.

Number of incidents relating to a breach of equipment sterilisation processes at CM Health sites within Sterilisation Services (Middlemore Hospital and Manukau Surgical Centre):
Date range as requested – **1 January 2018 until 31 March 2019**

- Foreign bodies identified in equipment sets (Foreign Bodies includes hair, bone, blood, tape and other unknown/unidentified items)
  - 111 incidents
- Packaging incidents (such as holes in guards, water in equipment sets, or no indicators in equipment sets)
  - 69 incidents

Importantly in all these events, all the items/ faults were identified by CSSD or Operating Theatre staff before the equipment was used in any surgical procedure. The items were removed, cleaned and sterilised/ re-processed and checked before being used for a surgical procedure.

The number of incidents should be considered in the context of the number of surgical packs processed (sterilised) at CM Health per year.

- In 2018, at Middlemore and Manukau sites, **366,804 equipment sets** were processed – the incidents reflect an error rate of 0.09%.
- To end of March 2019, at Middlemore and Manukau sites, **91,568 equipment sets** have been processed - the incidents this year reflect a reduced error rate of just 0.04%.

We are confident our current processes, in line with AS/NZS 4187:2014 – *Standards for reprocessing of reusable medical devices in health service organisations*, are robust and safe.

We have robust checking processes in place in all the CSSD and in Operating Theatres, to identify any such breaches before a surgery commences, and we encourage all staff to complete Incident Forms when sterile items are identified as compromised, so that this is investigated and improvement processes can be completed.

We are continuously checking our CSSD processes and systems, and have applied learning from the recent events identified at Hawke's Bay DHB. As a result of that event, we have added additional checks to our processes this year. These include a second safety check of stock being released at the end of the sterilising process; an audit of all sterile stock processed in all CSSD units across the organisation, and a security review of access to the CSSD areas, to ensure that access is only by authorised personnel.

I trust this information satisfactorily answers your query. If you are not satisfied with this response you are entitled to seek a review of the response by the Ombudsman under section 28(3) of the Official Information Act.

Please note that this response or an edited version of this may be published on the Counties Manukau DHB website.

Yours sincerely,

Fepulea'i Margie Apa
Chief Executive