Retention periods of implants

No. 2019/05, The Hague, May 14, 2019

Executive summary

Health Council of the Netherlands

In the past it has sometimes been difficult to trace people who have implants, after issues were revealed with a specific implant. For that reason, healthcare providers have been obliged since 2019 to record data: they must pass on details about high-risk implants to the National Register of Implants (hereinafter the “LIR”). There is currently a minimum retention period of fifteen years for medical record data that is linked to the implant data from the LIR. Questions have been asked in the Dutch parliament about whether this period is sufficient. That is why the Minister for Medical Care and Sport has asked the Health Council of the Netherlands for advice on the desirable retention period for implant data.

The LIR provides a record of what implants were put in place by which healthcare providers. The register does not contain personal (health) data : to that end, the LIR is linked to medical records. If a problem arises with an implant, the Health and Youth Care Inspectorate informs the healthcare providers, who, in turn, approach the people in question. The Second Chamber has adopted a legislative proposal that would raise the current retention period of the data in the medical records from fifteen to twenty years. If required in order to ensure good care , this period can be extended. That decision is the healthcare provider’s responsibility. Some institutions are required to retain core patient data (discharge letters, operation notes) for 115 years, starting from the patient’s date of birth. These are institutions that are covered by the provisions of the Public Records Act , such as academic centres.

The records in the LIR contain details of what are known as high-risk implants. These are lung implants, joint implants, heart implants, brain and nerve stimulators, medication pumps, hearing implants, vascular implants, implants for plastic surgery, incontinence implants, and urological and gynaecological implants. Implants are being introduced into the body increasingly often and at younger ages. Some implants that are designated as high risk have a limited lifespan, but there are also implants that can, essentially, remain in the body for life. In practice, it has transpired that it is always possible for unforeseen imperfections to come to light. Examples include failing electrodes for pacemakers, leaking breast implants, ingrown pelvic floors and inguinal hernia meshes, and hip prostheses that release metal filings. For some prostheses, the adverse reactions or unwanted side-effects may only come to light some years after the implant is removed. For some implants, the risk of complication increases the longer they remain in the body.

Given the unpredictability of any faults, side-effects and adverse reactions that may occur and the importance of always being able to trace the people with the implants, the committee believes that details of high-risk implants should be retained for the entire lifespan of any carrier. The committee recommends adopting a retention period of 115 years, starting from the date of birth of the person concerned. The advantage of a fixed period is that the LIR does

not have to depend on information from third parties about the death of the person with the implant. That would be the case if the term was specified as ‘for life’, with the concomitant risk of contamination of the register’s content.

Because the data from the LIR is linked to the medical records, the committee recommends that the retention period of 115 years should also be adopted for those parts of the medical records that are related to the implants. This is in line with the existing retention period pursuant to the Public Records Act and its underlying decrees. Adopting a term of 115 years means that the same regimen will apply to all healthcare providers . The committee further recommends legally ensuring that the implant details will be transferred as part of the medical records if a healthcare provider ceases to exist.

The Health Council of the Netherlands, established in 1902, is an independent scientific advisory body. Its remit is “to advise the government and Parliament on the current level of knowledge with respect to public health issues and health (services) research...” (Section 22, Health Act).
The Health Council receives most requests for advice from the Ministers of Health, Welfare and Sport, Infrastructure and Water Management, Social Affairs and Employment, and Agriculture, Nature and Food Quality. The Council can publish advisory reports on its own initiative. It usually does this in order to ask attention for developments or trends that are thought to be relevant to government policy.
Most Health Council reports are prepared by multidisciplinary committees of Dutch or, sometimes, foreign experts, appointed in a personal capacity.
The reports are available to the public.

This publication can be downloaded from www.healthcouncil.nl.

Preferred citation:
Health Council of the Netherlands. Retention periods of implants.
The Hague: Health Council of the Netherlands, 2019; publication no. 2019/05.