QUALITY AND RISK MANAGEMENT IN HOSPITALS: EVALUATION OF IMPLANTABLE MEDICAL DEVICES' TRACEABILITY PROCESS

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Background Medical devices may be at the origin of incidents or risks of incidents due to several deficiencies in their circuit, from their design to their use, passing through their manufacturing and marketing. For implantable medical device (IMD’s), risks are greater, and a quality management system based on rigorous traceability is essential to their management to ensure their quality and the safety of implanted patients.

Purpose To assess overall conformity of the IMD’s traceability process in the operating rooms as part of quality and risk management at our hospital.

Material and methods This was a prospective study of the IMD’s traceability process conformity for all patients admitted for a surgical procedure using IMD’s in gynaecology, urology, thoracic surgery and visceral surgery, over a period of 6 months.

Information was extracted from the individual IMD’s traceability records and from the IMD’s traceability register.

Results During the study period, 365 IMD’s were implanted in 297 patients. The most used IMD’s were parietal reinforcement plates (50%) and implantable staples (28%). The most IMD’s consuming services were visceral surgery (73%) and urology (18%). Traceability anomalies (lack of information about patients and/or IMD’s) were present in 22% of cases, and the service responsible for the majority of discrepancies was the urology service (58%). A total lack of traceability was noted in less than 1% of cases.

Conclusion The traceability procedure remains imperfectly applied, in particular concerning the completeness of recorded information. Efforts must be pursued in terms of observance of this procedure, and continuously evaluated to improve the quality, and to master the risk level, at our establishment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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