

NOCA CALLS FOR NATIONAL IMPLANT REGISTRIES TO ENSURE PATIENT SAFETY

26th November 2018 The National Office of Clinical Audit (NOCA) welcomes the special investigation by the International Consortium of Investigative Journalists (ICIJ) and The Irish Times which highlights the importance of stringent medical device regulation. Colm Keena's article in The Irish Times today (26 November 2018) has put a spotlight on how Irish patients have been impacted.

One of the key findings of the ICIJ investigation, 'Implant Files', highlights that "the device industry, and the regulators that oversee it struggle to quickly identify hazardous implants after they are released, leaving patients exposed". In August 2010, an implant used for hip replacements by DePuy (ASR) was recalled globally due to poor patient outcomes and adverse events. In Ireland, an estimated 3,500 people had received this implant following hip replacement surgery, the higher usage of this implant per capita in the world. As there was no national implant register in place at that time, hospitals had to undertake a lengthy review of all theatre diaries and patient charts to identify patients who may have received these implants. This process took years in some instances.

This global recall highlighted the need in Ireland to have a national register for such implants. In 2014, work commenced on the development of the Irish National Orthopaedic Register (INOR) under the governance of NOCA. Currently INOR is being rolled out across all public hospitals providing elective joint replacement surgery.

INOR aims to improve the quality of services and care provided to patients having joint replacement surgery. By using patient scoring systems and recording on implant performance and patient outcomes, INOR aims to monitor the safety of implants and support hospitals should an implant recall occur. If such an event happened today, this information would be available in minutes rather than months.

In his recent report on the use of polypropylene mesh in the treatment of stress urinary incontinence in women, the Chief Medical Officer has recommended that a national registry should be established for mesh implants. The report suggested that the INOR model should be examined for this registry.

The technology and structures that are in place for INOR for hip and knee implants, with additional funding and support from the government, could be expanded to support all implants providing up to date patient safety and instant recall information.

NOCA was established in 2012 to create sustainable clinical audit programmes at national level. NOCA enables those who manage and deliver healthcare to improve the quality of care through national clinical audit. NOCA is funded by the Health Service Executive Quality Improvement Division, governed by an independent voluntary board and operationally supported by the Royal College of Surgeons in Ireland.

ENDS

Notes to Editor:

- INOR was developed with the support of the Irish Institute of Trauma and Orthopaedic Surgery (IITOS), RCSI and the HSE.
- ICIJ 'Medical Devices Harm Patients Worldwide As Governments Fail On Safety' <https://www.icij.org/investigations/implant-files/medical-devices-harm-patients-worldwide-as-governments-fail-on-safety/>
- The Use Of Uro-Gynaecological Mesh In Surgical Procedures – A report from Dr Tony Holohan, Chief Medical Officer, Department of Health <https://health.gov.ie/wp-content/uploads/2018/11/Mesh-Report-21st-Nov-2018.pdf>

For further information or comment, contact Aisling Connolly, NOCA Communications & Events Lead at 01 402 5162 or auditinfo@noca.ie