Irish National Orthopaedic Register (INOR)

Information Leaflet for Hospital Personnel
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Why do we need a National Orthopaedic Register?

In Ireland around 915,000 people, including 1,100 children, are living with arthritis, making it the single biggest cause of disability (Arthritis Ireland 2013). Joint replacement surgery has been shown to be the most effective intervention in alleviating pain and disability in those who present with osteoarthritis.

In 2010 DePuy recalled its ASR (Articular Surface Replacement) hip prostheses. In the Republic of Ireland, an estimated 3,500 people had this DePuy ASR hip replacement when the manufacturer issued a ‘recall’ notice on 27th of August 2010. Neither the Minister for Health, the Department of Health and Children, nor the Health Service Executive could confidently report on volumes impacted. The HSE had to contact each hospital for details of potentially affected patients. Personnel in each hospital had to manually track all the orthopaedic paper records to identify the recalled devices and then record the contact details for affected patients.

The **Irish National Orthopaedic Register (INOR)** will monitor clinical outcomes for joint replacement surgery nationally and will ensure that Ireland will be better placed to deal will any future recalls or reviews. National joint registers have been shown to result in improved outcomes for orthopaedic patients (Herberts and Malchau 1997, Malchau et al 2002). Such registers enable assessment of variability in implant performance, technological changes in prostheses over time, and monitoring of costs associated with such variables (Serra-Sutton et al 2009).

In the field of hip arthroplasty, data from registers are used to produce reliable estimates of the performance of implant system in terms of effectiveness and safety. (Migliore et al 2009).
What is the Irish National Orthopaedic Register (INOR)?

To date, the majority of Irish hospitals retain detailed records for hip and knee surgery on paper records and there is no national mechanism for the registration of data in relation to joint replacement surgery in Ireland. The INOR is an electronic application which will record and monitor elective arthroplasty surgery.

Through the monitoring of joint replacement surgery and implant devices, INOR aims to reduce the cost of revision surgery in Ireland, to identify risk associated with joint replacement and thereby ensure that Irish patients receive the highest possible standard of orthopaedic care within our hospitals.

The National Office of Clinical Audit (NOCA) provides a framework and governance to INOR and to other existing national audits as part of its role in building clinical audit programmes at national level.

NOCA is an important quality initiative, funded by the HSE Quality Improvement Division and supported by the Royal College of Surgeons in Ireland (RCSI). Through clinical audit, NOCA aims to support the improvement of clinical services and ultimately improve outcomes for Irish patients.

Benefits to the patient
INOR will gather information to help surgeons decide which joint replacements are performing well therefore improving patient safety. The information we gather will help surgeons make decisions on patient care. NOCA will produce annual reports on a variety of factors that affect the success of joint replacement surgery.
What is the INOR ICT Solution?

The INOR will utilise an electronic system to collect and analyse Arthroplasty data.

Benefits of an electronic system include:

1. **Increased Data Availability** — Electronic data can be made available at more than one location at a given time, thus supporting collaboration and reducing paper file search times.

2. **Centralised Data security** — INOR will provide automated and centralised data backup. The data will be suitably encrypted and transmitted over a secure network.

3. **Reduced Administration** — Faster search facilities than available with paper file and manual archiving processes

The INOR system will comprise of two main building blocks for collection of data:

- **PAS System** will manage administrative data. Will provide patient demographics directly to INOR

- **INOR Modules** will provide each site with a modular solution for collection of the MDS. A site may choose to use a combination of the modules (Pre-Operative module, Peri Operative module, Inventory Module, Post-Operative module) or implement the complete INOR solution to capture the INOR MDS. This functionality has been purpose built for INOR.
Additionally the INOR System will include:

- **INOR Reporting** which will provide custom built functions including Analysis & Reporting.

- The INOR Electronic Portal will be designed as a **modular web application** allowing for modules to be enabled or disabled, depending on which modules are required from hospital to hospital, to support the capturing of the INOR MDS from each site.

- If a hospital has an existing **Theatre Information system (which is configurable to collect 100% of the INOR MDS)**, INOR will ‘pull’ data from the Theatre Information system. In this instance the hospital would not require the peri-op data collection module for data input into INOR.

**Project Governance**

Under the Governance Board of NOCA, the Irish National Orthopaedic Register convened a separate INOR Governance Committee. The INOR Governance Committee will ensure clinical objectives are met and confidential processes upheld. Relevant specialties and groups are represented in the committee membership to ensure output is interpreted appropriately. For the purpose of Governance the INOR Clinical Governance Committee will also provide guidance and support to the Irish Hip Fracture Database (IHFD)

The INOR Governance committee will review all reports prior to release and provide contextual comment to aid the interpretation of the reports.
In the future the INOR Governance committee will review and agree which requests for research data extracts will be approved. They will specify what data can be released and will require the deletion of all people identifiers such as names, date of birth, age, specific address, while still retaining sufficient record specifics to allow the research achieve its goal.

**Data Protection and Consent**

NOCA and the Governance Committee of INOR recognises the importance of maintaining privacy and confidentiality at all times, and is committed to the highest standards with regard to the manner in which it collects, stores, accesses, shares and manages personal data.

INOR, its governance committee, clinical lead and coordinator are committed to full compliance with the eight principles of data protection. NOCA has prepared a concise and comprehensive INOR Data Protection Policy.
Why do we need Consent?

**Patient Consent:** The Data Protection Acts of 1988 and 2003 (Irish Statute Book) state that personal information obtained from service users for the purposes of informing care, treatment or service provision should not be disclosed to a third party unless the service user has consented. This has implications for INOR with the transfer of patient data from hospital systems (such as PAS Systems, Theatre Information Systems) to INOR. Although each patient will have a specific INOR number when included on the register, their demographic personal data will also be collated. Therefore patients will be directly identifiable through INOR. Consent is therefore required prior to registration on INOR.

**Obtaining Consent:** The Patient attend the pre–operative assessment clinic, where INOR Specific information (INOR Patient Information Leaflet) will be discussed. The patient will be provided with a Patient Information Leaflet during their OPD visit with the surgeon. Any questions the patient may have regarding the register should be answered at the pre-operative assessment clinic.

Informed consent from the patient will need to include at least: consent for the transfer of data to the Data Controller and consent for additional INOR specific purposes (e.g. PROMs and additional contact to schedule Post-Operative Assessment).

*After the provision of information to the patient at pre-assessment clinic, consent for INOR will be obtained.*
After pre-assessment clinic, and before admission for surgery, all patient identification details are available to INOR for consented patients. Where a Patient does not consent to participation in the INOR only pre-defined, non-personal data will be visible on INOR. The patient should be given an opportunity to explicitly grant or deny consent.

By choosing to deny consent the patient should be secure in the knowledge that refusal would not carry a penalty, whether real or implied, in relation to treatment. If the patient consents to registration on the INOR but at a later date wishes to withdraw from participation, the patient must request to ‘opt-out’ of INOR in writing to the National Office of Clinical Audit.

If a patient undergoes Arthroplasty Surgery in an Independent Hospital, the same principles for obtaining consent must be adhered to. However, the procedure for obtaining consent may vary depending on the patient pathway in each hospital.

It is the responsibility of each individual hospital to obtain patient consent prior to collecting patient data as per INOR Minimum Dataset. NOCA will provide each hospital with the patient and staff information leaflet. Prior to submitting the data to INOR each hospital must first provide an electronic indication of the patient consent for their personal information to be submitted to the INOR.

**Surgeon consent** for surgeon’s data to be shared with hospital management and NOCA will be included in the Terms of participation in INOR – Surgeons will accept and note acceptance of terms at first log in to INOR ICT system
Who will enter and access the Data?

Access to INOR will be controlled by user rights. User rights will enable a certain level of access.

This is limited to practicing surgeons, clinical directors and nurses within participating Irish hospitals – individual usernames and passwords will be provided by INOR to each participant for registration purposes.

The identity of the participants will be protected from all other users except those with administration access rights. In order to participate in INOR, all users will be required to register their details on the INOR system.

Once a user is registered, he/she will have access to data on patients registered under their name within that participating hospital.
## Data Entry

<table>
<thead>
<tr>
<th>DATA</th>
<th>RESPONSIBILITY</th>
<th>SYSTEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operative Patient Demographics Data Capture</td>
<td>Clerical/Administrative</td>
<td>PAS</td>
</tr>
<tr>
<td>Pre-Operative Assessment Clinic Data Capture</td>
<td>Nurse/Arthroplasty Nurse Specialist</td>
<td>INOR</td>
</tr>
<tr>
<td>Peri-Operative Clinical Information Data Collection</td>
<td>Surgical team</td>
<td>INOR+/- Theatre Information System</td>
</tr>
<tr>
<td></td>
<td>Consultant</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Specialist Registrar</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Circulating Nurse</td>
<td></td>
</tr>
<tr>
<td>Post-Operative Assessment Clinic Data Capture</td>
<td>Nurse Arthroplasty Nurse Specialist</td>
<td>INOR</td>
</tr>
</tbody>
</table>
## Minimum Dataset (MDS)

### Clerical

**Pre Admit (PAS)**
- Name
- Date of Birth
- Gender
- Hospital Identifier
- Phone number
- Address
- Health Insurance status
- Procedure code
- TCI & Admission
- Discharge

### ANS/Pre-Operative Assessment Clinic Nurse/Post op Assessment Nurse

**Pre op Assessment (INOR)**
- **Patient Consent to registration on INOR**
- INOR number allocation
- Type of procedure (Description & procedure code)
- Co-morbidities (List)
- BMI
- Withdrawal from surgery
- Pre-op PROM Score

*Additional data for Revision*
- Date of Primary Surgery
- Clinic where primary surgery carried out
- Date of Revision Surgery

**Post op Assessment (INOR)**
- Early Complications (List)
- Incident Recording (List)
- Late Complications (List)
- 6 month/2yr/5yr post-op PROM Score
### Minimum Dataset (MDS)

#### Circulating Nurse

<table>
<thead>
<tr>
<th>Peri op (INOR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical Time record (Start Anaesthetic, Knife to skin, wound closure)</td>
</tr>
<tr>
<td>Implant Device component identifier - Product and lot no (Scan)</td>
</tr>
<tr>
<td>Cement type identifier - Product and lot no (Scan)</td>
</tr>
<tr>
<td>Screws type identifier - Product and lot no (Scan)</td>
</tr>
<tr>
<td>Custom built Prosthesis - Product and lot no (Scan)</td>
</tr>
</tbody>
</table>

*Each component is validated against a National Component Catalogue maintained by NOCA*

#### Orthopaedic Surgeon

<table>
<thead>
<tr>
<th>Peri/Post op (INOR or +/- Theatre Information System)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Surgery</td>
</tr>
<tr>
<td>Type of Surgery (Joint, laterality, procedure)</td>
</tr>
<tr>
<td>Procedure Code (ICD10AM code)</td>
</tr>
<tr>
<td>Diagnosis/Indication for surgery (List)</td>
</tr>
<tr>
<td>Surgical Approach (List)</td>
</tr>
<tr>
<td>ASA Grade (List)</td>
</tr>
<tr>
<td>Anaesthesia Type (List)</td>
</tr>
<tr>
<td>Antibiotics used (List)</td>
</tr>
<tr>
<td>Transexamic Acid Y/N</td>
</tr>
<tr>
<td>Bone Graft Y/N</td>
</tr>
<tr>
<td>Bone Graft Type (List)</td>
</tr>
<tr>
<td>Post-Operative Anti-Coagulation (List)</td>
</tr>
<tr>
<td>Method of skin closure (List)</td>
</tr>
<tr>
<td>Complications/Intra op Incident (List)</td>
</tr>
</tbody>
</table>

*Additional data for Revision*

| Diagnosis/Clinical Indications for revision (List) |
| Revision Technique - Single stage or Two Stage |
| Components Revised |

The detail of the INOR MDS is available by visiting the following link: [www.noca.ie](http://www.noca.ie)
## Users Types — Roles / Permissions

<table>
<thead>
<tr>
<th>User Type</th>
<th>Role and Permissions</th>
</tr>
</thead>
</table>
| ARTHROPLASTY NURSE SPECIALIST (ANS) | • Enters pre op assessment data, pre and post op PROMs, Complications and incidents, consent  
• Can view all procedure details (pre op data, PROMs, peri op data, post op data) on all patients attending own hospital  
• Can only ever see full details of procedure etc. if patient has previously attended their hospital  
• Can enter new data on patient with existing INOR record but cannot view details of previous attendance if attended alternative institution  
• Can print already identified reports (Schedules etc., consent)  
• Cannot delete any information  
• **Can amend/modify data on own data entered into register** (Tracked through register/Audit trail) |

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**Note**: The above information is specific to the context of the National Office of Clinical Audit (NOCA) and the Irish National Orthopaedic Register (INOR). The roles and permissions outlined are subject to change based on the specific requirements and policies of these organizations.
# Users Types — Roles / Permissions

<table>
<thead>
<tr>
<th>User Type</th>
<th>Role and Permissions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NURSE</strong> (Pre-Op Assessment Nurse / Theatre Nurse)</td>
<td>• In the absence of an ANS, Enters pre op assessment data, pre and post op PROMs, Complications and incidents, consent (Pre op assessment Nurse)&lt;br&gt;• In theatre enters surgery times and scans prosthesis components&lt;br&gt;• Can view all procedure details (pre op data, PROMs, peri op data, post op data) on all patients attending own hospital&lt;br&gt;• Print report of components (Theatre Nurse-For chart/theatre diary if required)&lt;br&gt;• Can enter new data on patient with existing INOR record but cannot view details of previous attendance if attended alternative institution&lt;br&gt;• Can only ever see full details of procedure etc. if patient has previously attended their hospital&lt;br&gt;• Cannot delete any information&lt;br&gt;• <strong>Can amend/modify data on own data entered into register</strong> (Tracked through register/Audit trail)</td>
</tr>
</tbody>
</table>
## Users Types — Roles / Permissions

<table>
<thead>
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</thead>
</table>
| **SURGEON**          | • Enters Peri operative data as per MDS  
• Can see all procedure details (pre op data, PROMs, peri op data, post op data) on all patients under their care per site  
• Can only print post op note up until 12mn on day of surgery only in operating hospital  
• Can view identified reports relevant to his/her own patients/procedures  
• For all patients not under his care can see implant, date of surgery, hospital  
• Can **modify/amend** their own data entry on their own patients if required (Tracked through register/Audit trail)  
• **Cannot delete any information**                                                                                                                                 |
| **CLINICAL DIRECTOR**| This user has permission to view reports pertaining to the submitting hospital by virtue of having been sent the report by NOCA. **No Data entry.**                                                                                       |
Reports

A main output for the INOR system will be the production of standard reports based on identified data that has been collated.

These reports are intended to provide meaningful feedback to surgeons and hospitals on their performance and individual practice.

They will also serve to define the epidemiology of joint replacement operations in Ireland through the publication of a National Annual Report. This will allow for orthopaedic surgery in Ireland to be benchmarked against other international registers.

The INOR system will produce standard reports for distribution to hospitals and other reports for NOCA publication annually.

Surgeon Reports - a report will be available to each surgeon. Each report will be the Individual Surgeons statistics against the National Average including but not limited to:

- Number of procedures
- Age and Gender of patient
- Complication rate
- Revision rate
- Average Length of stay per patient
- Number of Patients affected by recall alert
- Number of Patients with procedures pending
**Annual Hospital Reports** - A report will be available to the Clinical Director of each Hospital, Head of Orthopaedics of Hospital and the Individual Hospital Clinical Governance Committee.

Each report will be the Individual Hospital statistics against the National Average including but not limited to:

- Indications for surgery
- Type of components and common combinations
- Incident rates by type, volume, implant, surgeon
- Complication rates by type, volume, implant, surgeon

**Annual National Reports** - National reports collated with aggregate anonymised data. Examples of the National reports include but are not limited to:

- Clinical Activity of Hospitals participating in INOR
- Patient characteristics and procedure based on type of provider for Hip/Knee
- BMI for primary knee replacement patients
- Indications for hip primary procedures based on age groups
INOR Implementation Plan

How?
The INOR National Project Team provides clinical, service and ICT project management expertise. The national project team will work closely with the local implementation team to support each implementation. A 'Local Implementation Team' (LIT) is established in each hospital and works with the National Implementation Team to ensure a successful implementation for their site. The local Project Lead is the link between the national and local teams.

Who?
The proposed Local Implementation Team will consist of the following roles:

- Local Implementation Lead
- Local Clinical Lead - Consultant Surgeon
- Orthopaedic Theatre Nurse Manager
- Orthopaedic Circulating Nurse
- Orthopaedic Scrub Nurse
- Local iPM rep / team
- Admissions rep
- Medical Records rep.
- Local ICT Lead
- Anaesthetist
- Arthroplasty Nurse Specialist/Orthopaedic Clinical Nurse Specialist
- Pre-Operative Assessment Clinic Nurse
The main role of the LIT is to ensure the correct people in authority in a given hospital are involved in the important decisions that need to be taken, the local resource requirements are understood and can be provided, that the inevitable hurdles that arise at a local level are identified early and resolved as quickly as possible and that the project gets the attention of the local management team as required.

INOR will impact on many different organisational entities e.g. Theatre, medical records, clinical risk, ICT etc. As such, each impacted organisational entity should be represented on, or informed by, the LIT.
How can a hospital prepare for INOR Implementation?

1. **Clinical Nurse Specialist (CNS) in Orthopaedics/ Arthroplasty Nurse Specialist (ANS)**

   Mindful of the defined role of the CNS, NOCA have identified the requirement for Arthroplasty Nurse Specialist Nurses (ANS) in participating elective site as an essential component to the successful implementation and maintenance of INOR nationally. Each Hospital will be required to provide sufficient orthopaedic nurse specialists to run both pre-surgery and post-surgery assessments. NOCA is recommending establishment of **1 FTE ANS post per 500 new joint replacement surgeries per hospital per year (Pro rata)**.

   The ANS will coordinate and track the completion of the PROMs surveys by the patient at the pre and post-operative assessment, review the patient post operatively, monitor and review data input from their hospital and ultimately assume ‘super-user’ status of the register within their institution.

2. **Schedule of Clinical Nurse Specialist led Pre and Post-Operative Assessment Clinics**

   INOR will enable patient reported outcome measures (PROMs) to be captured as an additional set of information to allow clinicians assess the effectiveness of the joint replacement for those patients. Following a review of available PROMS tools the INOR Clinical Governance Committee identified the *Oxford Hip and Knee Scores* and the *EQ5DL* as the optimum PROM tools for use within INOR.
How can a hospital prepare for INOR Implementation?

PROMs will be recorded at the pre-operative assessment clinic and through a schedule of Post-Operative assessment clinics (6 months, 2yrs (Revision), 5yrs (Primary)). Fundamental to the management and maintenance of these clinics is the availability of an Arthroplasty Nurse Specialist (ANS) to clinically assess, monitor and educate the patient while recording early/late complications and PROMs. A schedule and process for management of post-operative appointments by the ANS will need to be established prior to a hospital’s ability to participate in the INOR.

3. INOR Local Implementation Team

Fundamental to the Implementation of the INOR is the role of the local implementation lead. The local implementation lead deals with the day to day implementation of INOR at each site. The INOR Implementation Lead will require protected time to ensure successful implementation of INOR. Each hospital will identify a LIL from within the LIT who will deal with the day to day implementation of INOR at each site and co-ordinates and manages all local business process changes (e.g. consent for INOR at Pre Op assessment Clinic, collection of component and cement stickers in theatre etc.)

4. Established Clinical Governance / Quality and Safety Committee - Orthopaedic Representation

Nationally, the INOR/IHFD Clinical Governance Committee will ensure full data interpretation of INOR outputs data is brought to the NOCA Governance Board before publication of any output data or national reports. This committee will also ensure clinical objectives are met and confidential processes upheld.
How can a hospital prepare for INOR Implementation?

If poor performance is identified by NOCA, NOCA require confirmation in writing of immediate remedies taken by the individual Hospital Clinical Governance /Quality and Safety Committees to ensure learning and or remedies are achieved. Concurrently if exceptional performance and expertise is identified through INOR this too will be relayed to Hospitals and where appropriate shared nationally to ensure learning and improve quality and outcomes are achieved.

*Hospital participation on the INOR requires confirmation of an established Clinical Governance / Quality and Safety Committee (with inclusion of representation from Orthopaedic Surgeons) and commitment of data entry from 100% of the Orthopaedic Surgeons performing Arthroplasty surgery.*

5. ICT Hardware

As INOR will be delivered over an electronic portal, implementation of the system will require each Pre- and Post-Operative assessment clinic and Orthopaedic theatres are equipped with PCs, printers, networking and mounting (if required) and scanners. Approximately one PC (Touchscreen for PROMs) will be required per pre op assessment room, one/two PCs per orthopaedic theatre and a printer and barcode scanner per PC and one PC per post op assessment clinic. Through approved NOCA funding HSE ICT will ensure required software and hardware are made available to the 12 HSE hospitals.
INOR contact details
You can contact INOR at:

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Website: www.noca.ie