Surveillance and Medical Devices

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Outline – A focus on Joint Replacement

• What is a medical device?
• Why do we need surveillance?
• What kind of surveillance is required/performed?
• How are medical device procedures defined?
• What outcomes should we monitor?
• What data are required for device surveillance?
What is a medical device?

- any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

  I. diagnosis, prevention, monitoring, treatment or alleviation of disease;
  II. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
  III. investigation, replacement or modification of the anatomy or of a physiological process;
  IV. control of conception;
  V. and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means.
Classes of Medical Devices

- Classified to communicate the consequences of their potential adverse outcomes, taking into account where the device is used, for how long it is used and whether it requires an energy source to function.

<table>
<thead>
<tr>
<th>Class</th>
<th>Risk</th>
<th>Examples</th>
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</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Low</td>
<td>Surgical retractors, tongue depressors</td>
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<tr>
<td>Class IIa</td>
<td>Low-medium</td>
<td>Suction unit, hypodermic needles</td>
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<td>Class IIb</td>
<td>Medium-high</td>
<td>Lung ventilator</td>
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<tr>
<td>Class III</td>
<td>High</td>
<td>Heart valves, <strong>joint replacements</strong></td>
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<tr>
<td>Active Implantable Medical Devices</td>
<td>High</td>
<td>Implantable defibrillator</td>
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</table>
Regulation of medical devices

- Medical devices are regulated based on their inherent risk profile, which conveys the potential for the device to cause an adverse outcome if failure does arise.
Post-market surveillance

- Even though some of their risks have been addressed during the pre-market approval phase, the severity, frequency of risks need to be verified in standard clinical settings
Frame-work for post-market surveillance

- Spontaneous reports
- Device Registries
- Health Claims databases
Spontaneous reports

• Country specific Spontaneous Report databases
  – US the Food and Drug Administration (FDA)
    • Manufacturer and User Facility Device Experience database
  – Canada,
    • Canadian Vigilance Adverse Reaction reporting system
  – Australia
    • DEAN Database

• Issues with SP
  – Passive systems
  – Under reporting,
  – Complex procedures so difficult to identify ‘exposure’ – which part failed?
    • Non-standardised device identification/classification
Device Registries

- **What is a registry?**
  - “…an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes.”

AHRQ. Registries for Evaluating Patient Outcomes: A User’s Guide. 2nd ed. (Prepared by Outcome DEcIDE Center [Outcome Sciences...])
Example: Joint Replacement Registry

• Minimal data (usually)
• How are medical device procedures defined?
  – Unique Device Identifiers for each component used (catalogue and lot numbers)
• What outcomes are monitored?
  – Limited set of ‘outcomes’ collected, eg revision surgery, death
• Patient characteristics
  – Age, gender, etc
• Procedure characteristics
  – Surgical technique, surgeon experience etc
  – Indication/diagnosis for treatment
Exposure – Defining a device

• Prostheses used in the Joint Replacement procedure
  – “Device” is made up of many varied components which can be mix-and-matched
    • Selection individualised for the patient
HIP REPLACEMENT

PARTIAL
- PARTIAL RESURFACING
- UNIPOLAR MONOBLOCK
- UNIPOLAR MODULAR
- BIPOLAR

TOTAL
- TOTAL RESURFACING
- TOTAL CONVENTIONAL
- THRUST PLATE

REVISION
- MAJOR TOTAL
- MAJOR PARTIAL
- MINOR

Source: AOA NJRR Annual Report 2013
Total Hip replacement

Acetabular Component

Femoral Stem
Table TY1: Cumulative Percent Revision of Primary Total Conventional Hip Replacement Combinations with Ten Year Data (Primary Diagnosis OA)

<table>
<thead>
<tr>
<th>Femoral Stem</th>
<th>Acetabular Component</th>
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<th>N Total</th>
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</table>

2097 different stem and acetabular combinations

Source: AOA NJRR Annual Report 2013
Total Hip replacement

Model

Fixation
Cemented/cementless

Material
Metal/poly/ceramic

Size/Length

Acetabular Component

Femoral Stem
“Do you have any coffee?”
What outcomes do we monitor?

• What are the problems we want to identify?
  – Failure
    • But all devices will eventually fail
  – Early failure
    • But how early is ‘early’
  – Earlier than expected failure
    • But what is ‘expected’
  – Earlier than expected failure compared to other similar devices
What is a ‘failure’

• Revision surgery
  – Any re-operation in which a component is removed or replaced
  – Details of the revision surgery must be collected and linked to primary surgery
    • Date of revision
    • Reason for revision
    • Revision prostheses
    • Side of the revision (left or right)
      – Because we have two hips and components can vary between sides we need to link the revision to the correct primary
Analysis: time to revision

- Fixed point in time ‘First exposure carried forward’
  - Unlike medicines there is no issues with compliance
- Time-to-event analysis (survival analysis)
Outcomes of JR - Revision

Figure HT4: Cumulative Percent Revision of Primary Total Conventional Hip Replacement (Primary Diagnosis OA)

8% revised by 12 years

Source: AOA NJRR Annual Report 2013
Reason for revision

Figure HT5: Revision Diagnosis Cumulative Incidence of Primary Total Conventional Hip Replacement (Primary Diagnosis OA)

- Early revisions - Dislocation
- Late revisions – Loosening/Lysis

Source: AOA NJRR Annual Report 2013
Post-market surveillance of JR

• Identify prostheses with higher than expected revision rate
Revision by Individual component

- Each component compared to all others in the class eg other conventional total hips

Source: AOA NJRR Annual Report 2013
Importance of the comparison group

Patients who receive different types of procedures are not the same, outcomes of specific protheses (or models) must be compared to other protheses in the class

Source: AOA NJRR Annual Report 2013
Outcomes of Joint Replacement

• What else could impact the revision rate
Total Hip replacement

Model
Fixation
Material
Size/Length

Patient Demographics
Surgical Approach
Surgeon Experience
Diagnosis/indication
Revision by fixation

Figure HT12: Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Fixation (Primary Diagnosis OA)

Source: AOA NJRR Annual Report 2013
Revision by head size

Figure HT13: Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Fixation (Primary Diagnosis OA, excluding large heads (>32mm) metal/metal bearings)

Source: AOA NJRR Annual Report 2013
Revision by bearing surface

Figure HT25: Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Bearing Surface (Primary Diagnosis OA)
Confounding

– Patients selected to receive particular devices, combination of components, using a particular surgical technique due to specific factors that may also be associated with revision
What other data is required?

- **Confounders**
  - More detailed information regarding patient characteristics, frailty, medications, clinical outcomes etc

- **Outcome**
  - Outcomes other than revision, eg infection, functional outcomes
Complimenting JR Registry data with Electronic Records/Health Claims Data

<table>
<thead>
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<th>Confounders/characteristics</th>
<th>Outcomes</th>
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<td>Age</td>
<td>Death</td>
</tr>
<tr>
<td>Gender</td>
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## Complimenting JR Registry data with Electronic Records/Health Claims Data

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<table>
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<th>Other Data sources</th>
<th>Confounders/characteristics</th>
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<tbody>
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<td>Co-morbidity</td>
<td>Hospitalisation for other events (infection, DVT, heart failure)</td>
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<td>Medications (eg DVT prophylaxis, bisphosphonate use)</td>
<td>Discharge to nursing home</td>
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<td>Prior hospitalisation</td>
<td>Functional Outcomes (Pain)</td>
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<td>Physiotherapy</td>
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</tr>
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<td>Rehabilitation</td>
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Emerging strategies for post-market surveillance of Medical Devices

• Registries are the mainstay of post-market surveillance of medical devices but use of electronic health records or insurance claims data will enhance registry data

• Will require adoption of unique device identifiers and harmonised device classification systems
  • Integrating UDIs into registries to allow for multi-national analyses (ICOR) for more rapid identification of device failures
  • Integrating UDIs into electronic patient health data and health insurance claims data to do more detailed analysis (Sentinel initiative)

• Research collaboratives (MDEpiNet, ICOR, Sentinel)
  • Advance the development of analytic techniques for more rapid identification of safety signals
  • Enhance data-sources for surveillance