



MEDICINE & DEVICE
SURVEILLANCE
CRE

Surveillance and Medical Devices

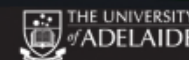
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Outline – A focus on Joint Replacement

- 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

Class	Risk	Examples
Class I	Low	Surgical retractors, tongue depressors
Class IIa	Low-medium	Suction unit, hypodermic needles
Class IIb	Medium-high	Lung ventilator
Class III	High	Heart valves, <u>joint replacements</u>
Active Implantable Medical Devices	High	Implantable defibrillator



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

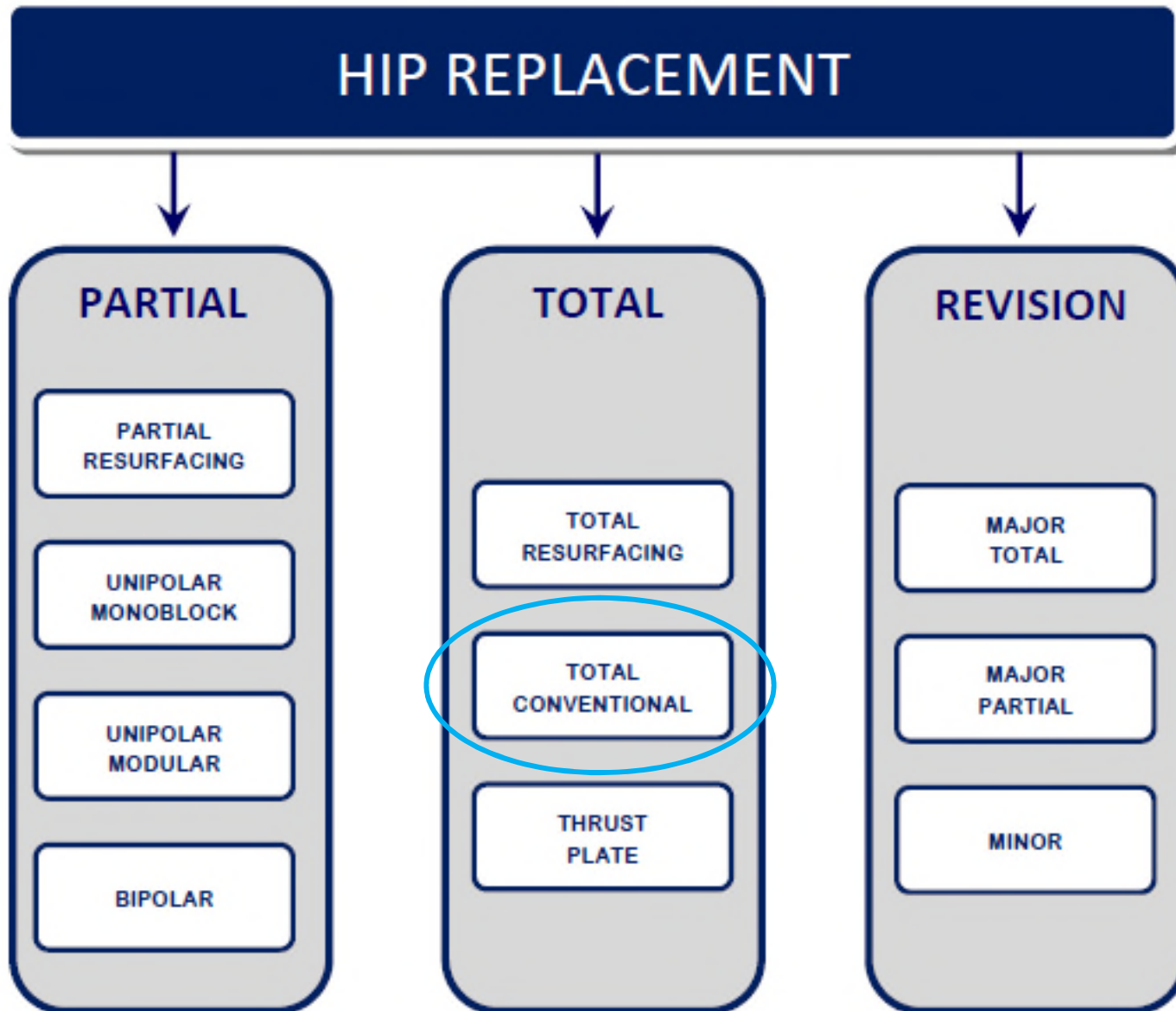
- **What is a registry?**
 - “...an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate **specified outcomes** for a population defined by a **particular disease, condition, or exposure**, and that serves one or more predetermined scientific,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

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

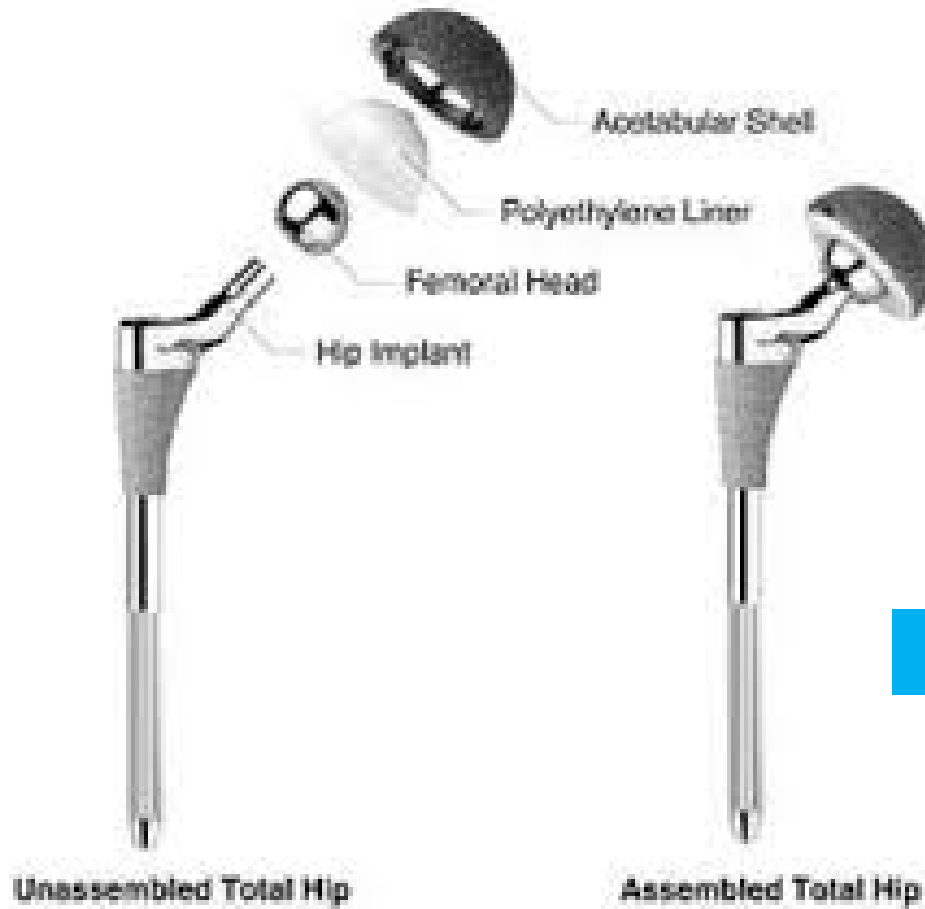
Exposure – Defining a device

- 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





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)

Femoral Stem	Acetabular Component	N Revised	N Total	1 Yr CPR	5 Yrs CPR	10 Yrs CPR
ABGII	ABGII	161	2706	1.7 (1.3, 2.3)	4.1 (3.4, 5.0)	7.0 (6.0, 8.2)
ABGII	ABGII (Shell/Insert)	41	801	1.5 (0.9, 2.6)	3.5 (2.4, 5.1)	8.6 (6.0, 12.2)
ABGII	Trident (Shell)	114	2134	2.3 (1.7, 3.0)	4.9 (4.0, 5.9)	8.5 (6.8, 10.6)
Accolade	Trident (Shell)	277	7973	1.5 (1.3, 1.8)	3.8 (3.4, 4.3)	6.0 (4.4, 8.0)
Alloclassic	Allofit	132	4402	1.2 (0.9, 1.6)	2.8 (2.3, 3.3)	4.5 (3.6, 5.6)
Alloclassic	Fitmore	80	1460	2.9 (2.1, 3.9)	5.1 (4.1, 6.4)	6.8 (5.4, 8.6)
Alloclassic	Metasul*	18	371	0.8 (0.3, 2.5)	3.6 (2.1, 6.1)	4.8 (3.0, 7.8)
C-Stem	Duraloc*	55	894	2.0 (1.3, 3.2)	3.8 (2.7, 5.4)	8.3 (6.1, 11.1)
C-Stem	Elite Plus LPW*	14	367	0.6 (0.1, 0.9)	0.7 (0.1, 5.1)	5.0 (3.4, 10.0)
CLS	Allofit	29	682	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
CLS	Fitmore	28	561	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
CPCS	Reflection (Cup)	19	582	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
CPCS	Reflection (Shell)	44	2185	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
CPT	Trilogy	137	4987	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
CPT	ZCA	19	620	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
Charnley	Charnley Ogee*	47	630	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
Charnley	Charnley*	25	563	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
Charnley	Vitalock*	26	370	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
Citation	Trident (Shell)*	34	1075	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
Citation	Vitalock*	18	508	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
Corail	Duraloc	38	1264	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
Corail	Pinnacle	387	17314	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
Elite Plus	Duraloc*	76	953	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
Epoch	Trilogy	37	990	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
Exeter	Contemporary*	27	426	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
Exeter	Vitalock*	47	1075	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
Exeter V40	ABGII	26	936	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
Exeter V40	Contemporary	138	3870	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
Exeter V40	Exeter Contemporary	78	2554	1.1 (0.7, 1.7)	2.1 (1.5, 2.9)	3.1 (2.3, 4.1)
Exeter V40	Exeter*					

2097 different stem and acetabular combinations



Models



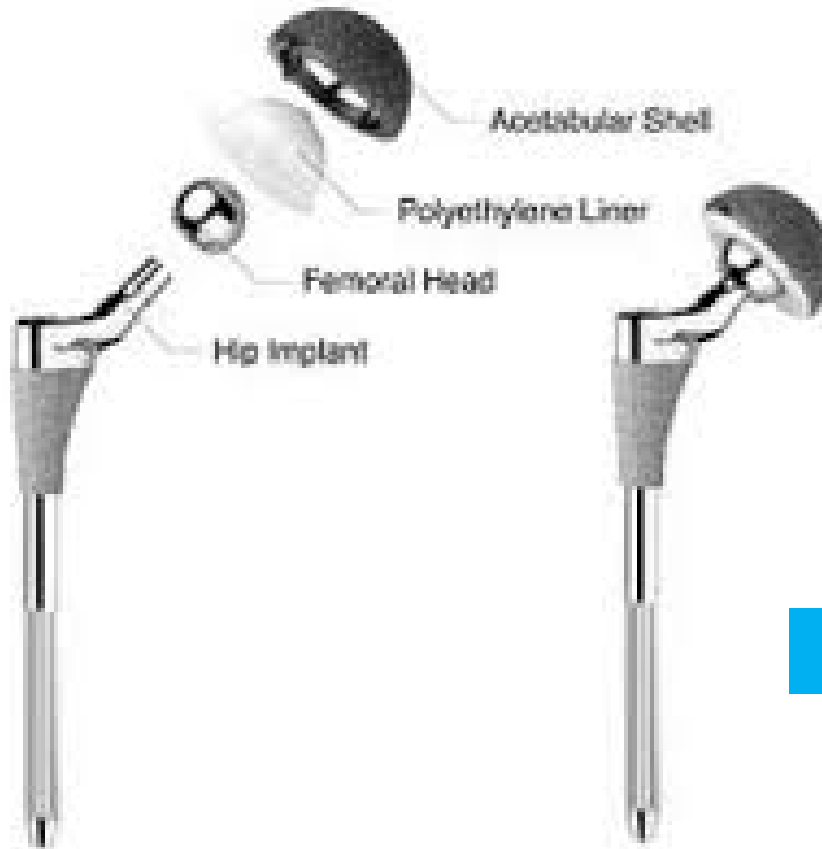
Total Hip replacement

Model

Fixation
Cemented/cementless

Material
Metal/poly/ceramic

Size/Length



Unassembled Total Hip

Assembled Total Hip

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)

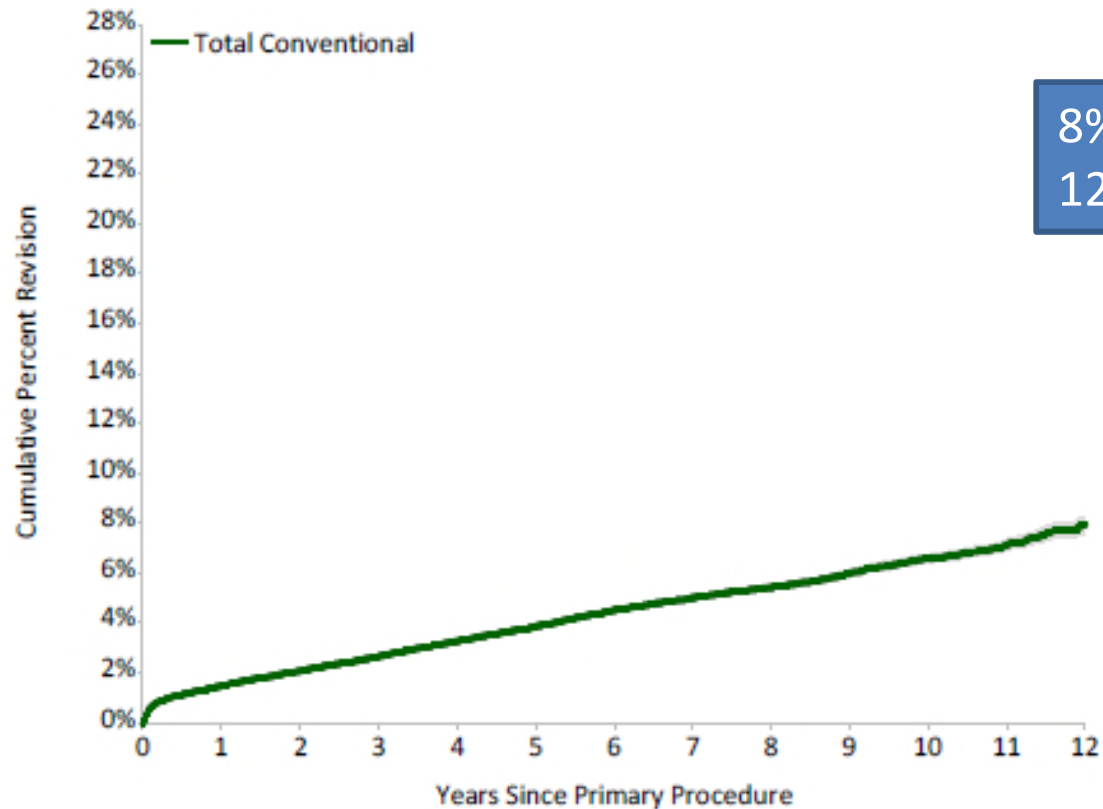
Primary
Procedure



Revision
Procedure

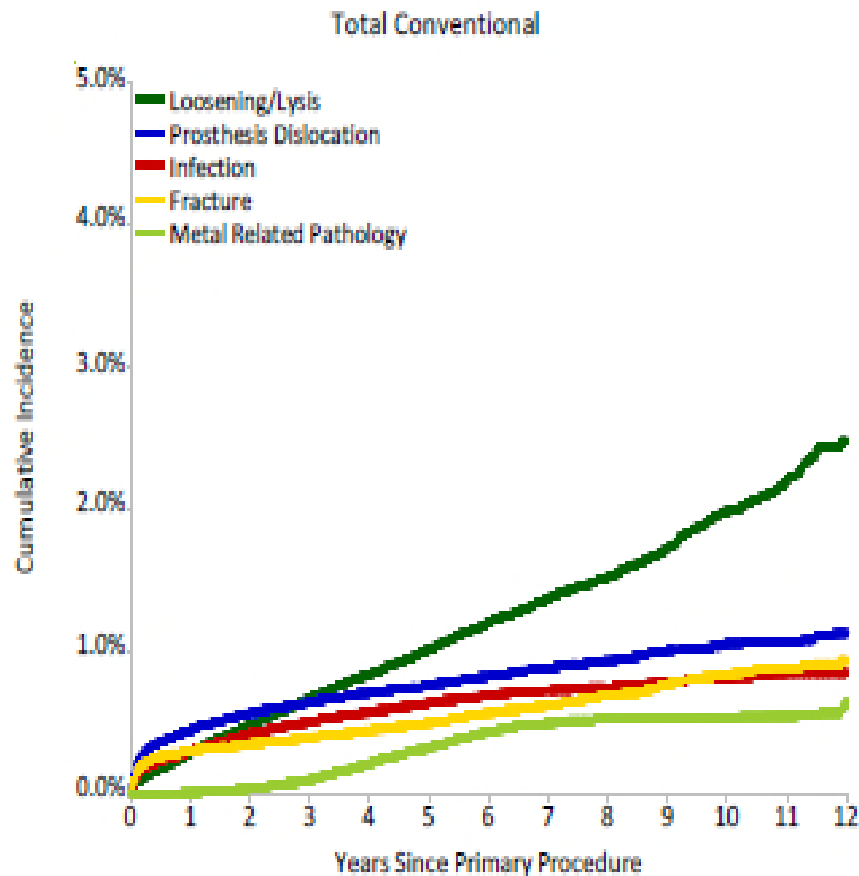
Outcomes of JR - Revision

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



Reason for revision

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



Late revisions –
Loosening/Lysis

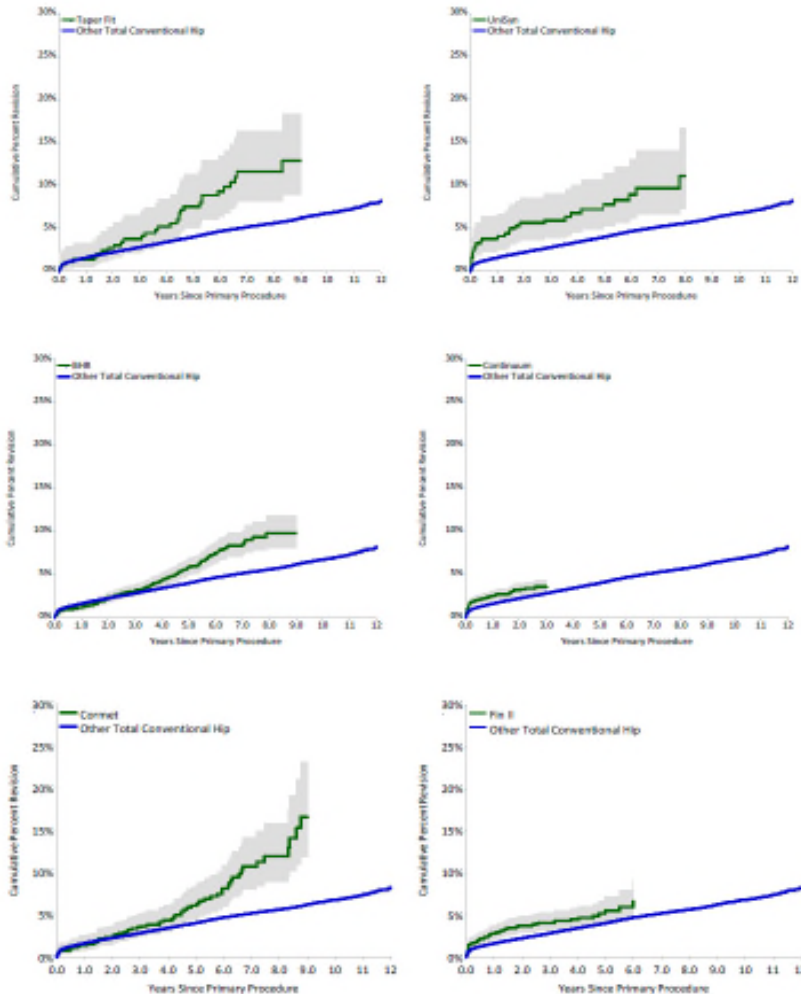
Early revisions -
Dislocation



Post-market surveillance of JR

- Identify prostheses with higher than expected revision rate

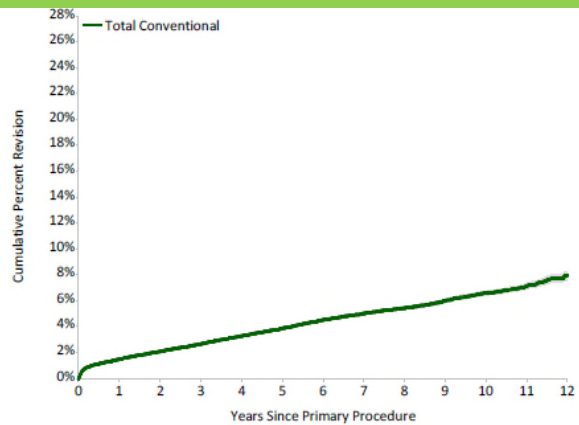
Revision by Individual component



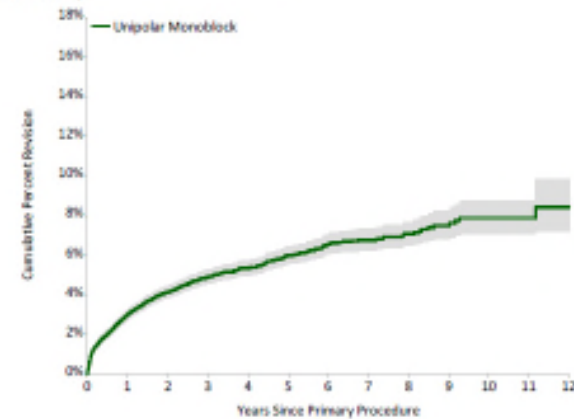
- Each component compared to all others in the class eg other conventional total hips

Importance of the comparison group

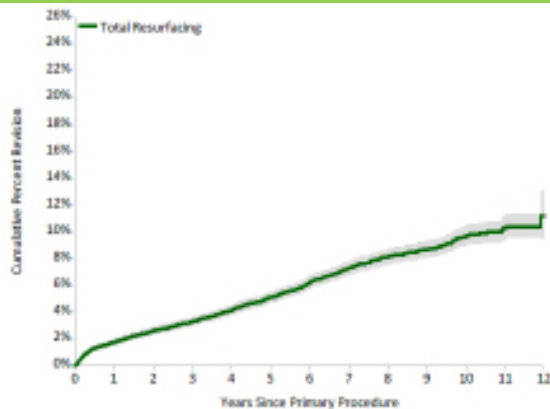
Total Hip



Unipolar Monoblock



Total Resurfacing



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



Outcomes of Joint Replacement

- What else could impact the revision rate



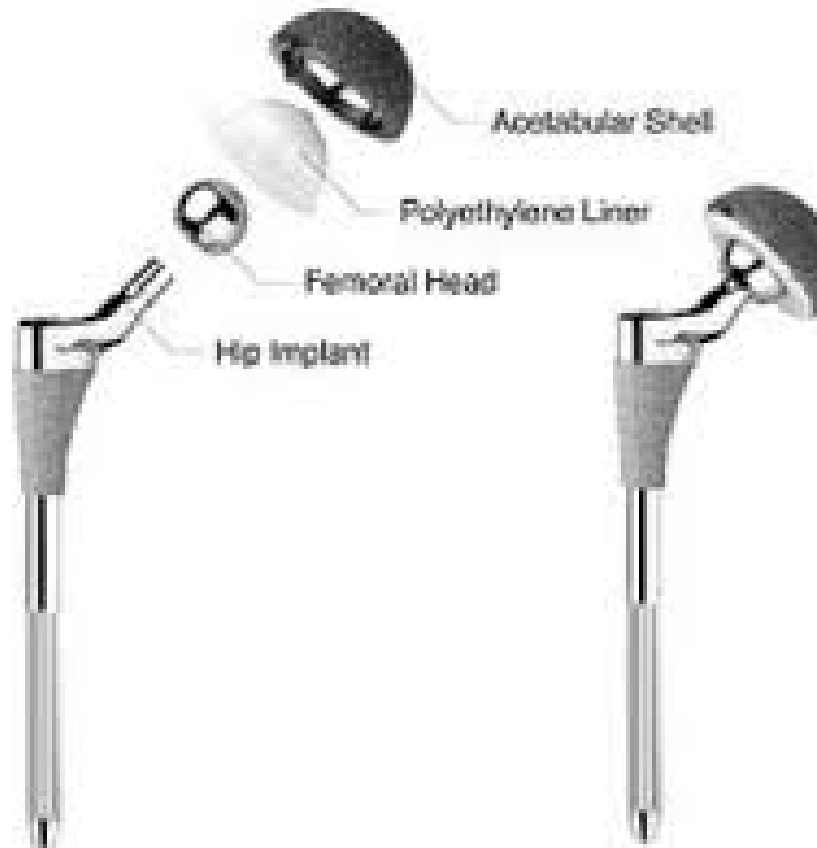
Total Hip replacement

Model

Fixation

Material

Size/Length



Unassembled Total Hip

Assembled Total Hip

Patient Demographics

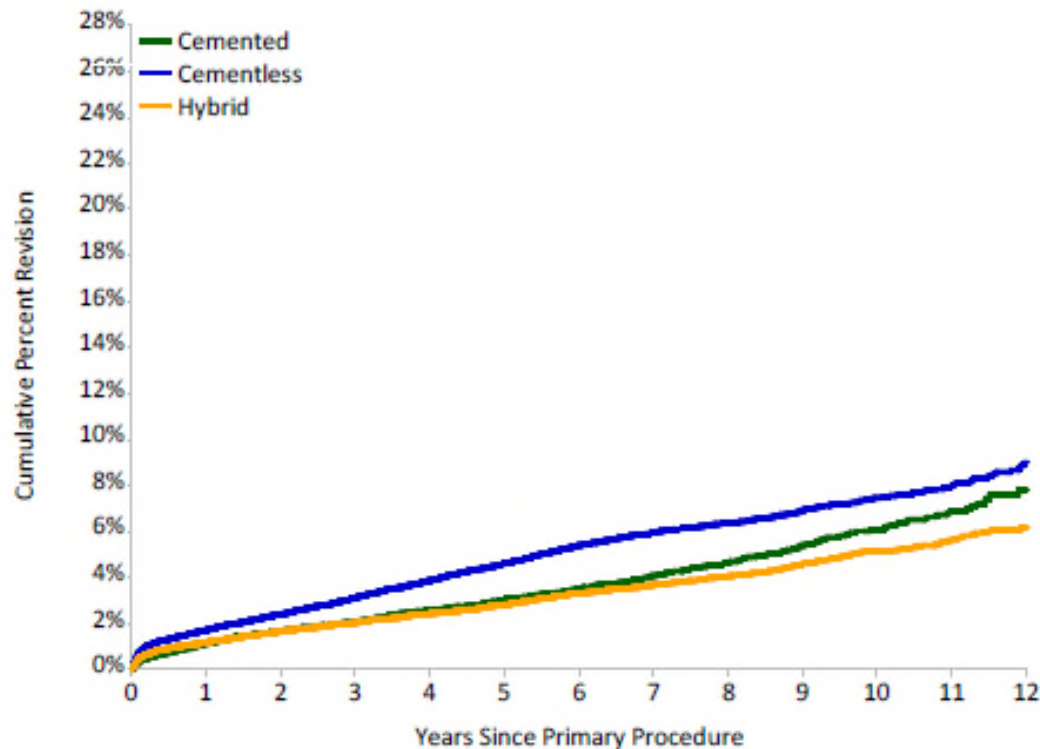
Surgical Approach

Surgeon Experience

Diagnosis/indication

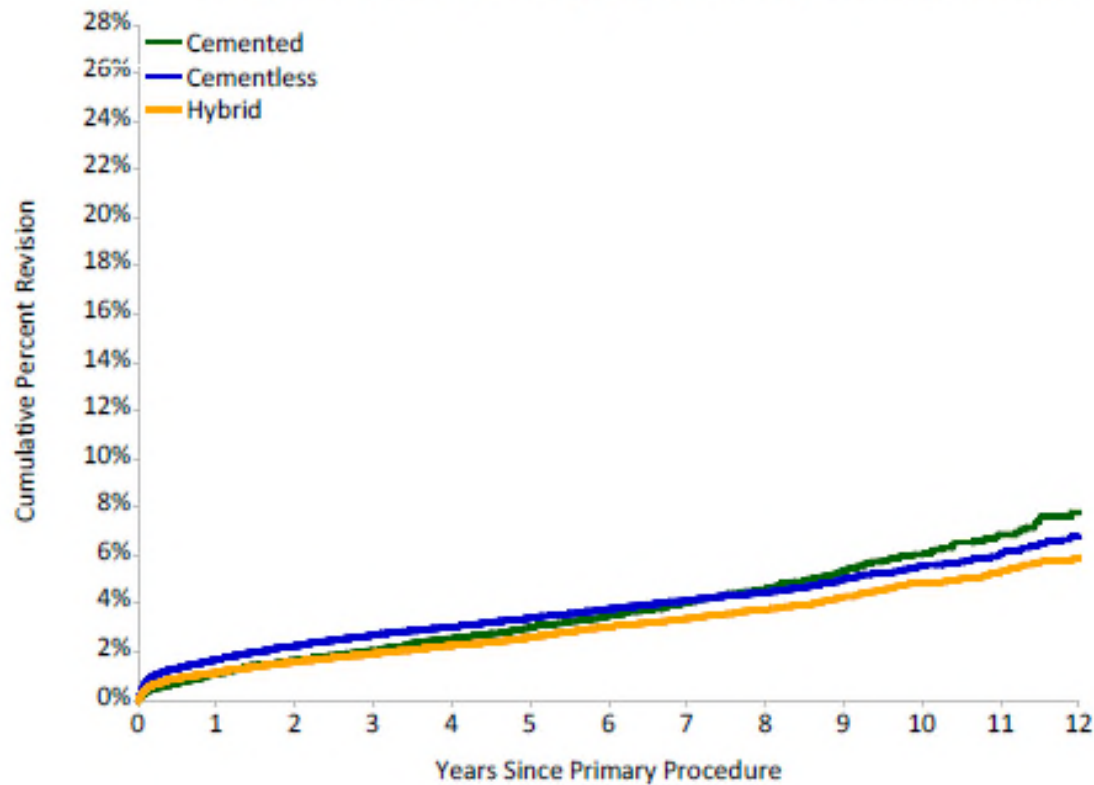
Revision by fixation

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



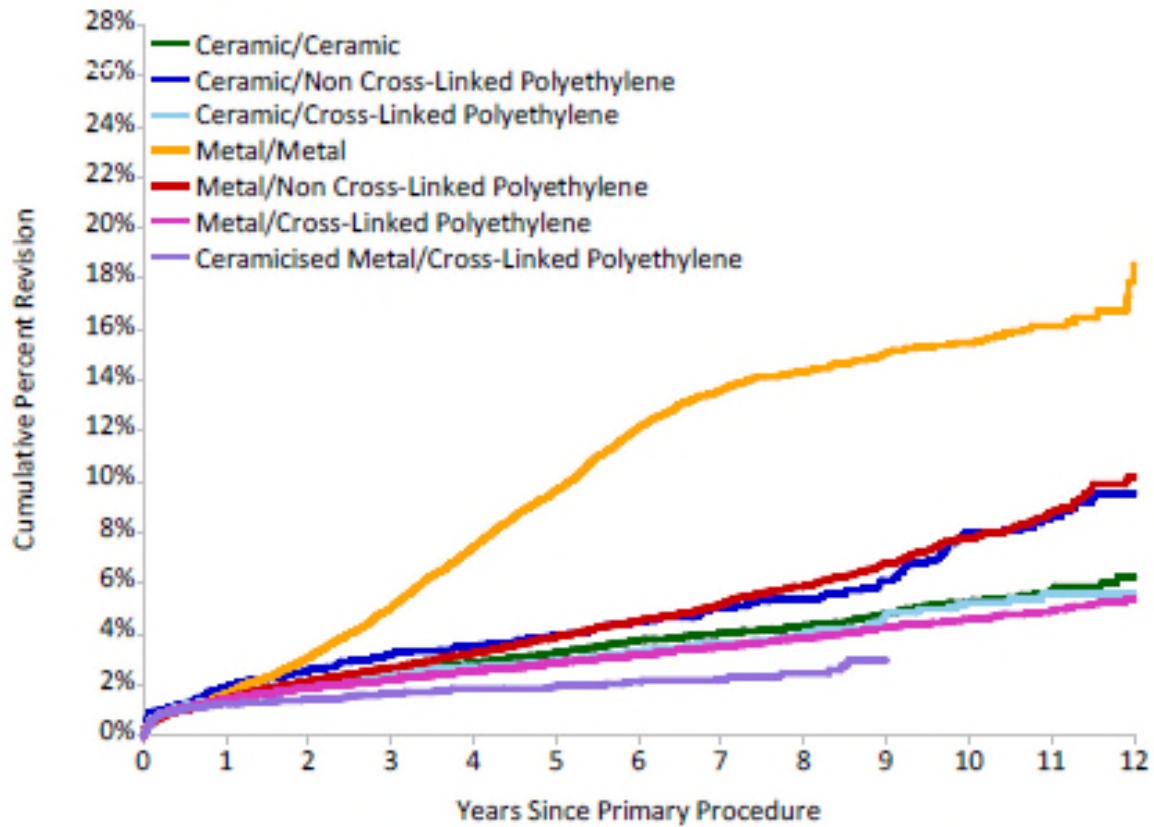
Revision by head size

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



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

Device A v Device B



Revision
Procedure

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

	Confounders/ characteristics	Outcomes
Registry	Age	Death
	Gender	Revision Surgery
	Indication for Surgery	

Complimenting JR Registry data with Electronic Records/Health Claims Data

	Confounders/ characteristics	Outcomes
Registry	Age	Death
	Gender	Revision Surgery
	Indication for Surgery	
Other Data sources	Co-morbidity	Hospitalisation for other events (infection, DVT, heart failure)
	Medications (eg DVT prophylaxis, bisphosphonate use)	Discharge to nursing home
	Prior hospitalisation	Functional Outcomes (Pain)
	Physiotherapy	
	Rehabilitation	

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