Device Evaluation Centre

Delivering Excellence in Evaluating Devices to Transform Patient care

Royal National Orthopaedic Hospital NHS

NHS Trust

Relevance of Post market Surveillance & What the NHS can offer

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Aims

- The importance of Post market Surveillance (PMS)
- The different type of PMS and Post market Clinical Follow up (PMCF) studies
- Key individuals involved in conducting a PMS
- Services that the NHS can offer Device Companies

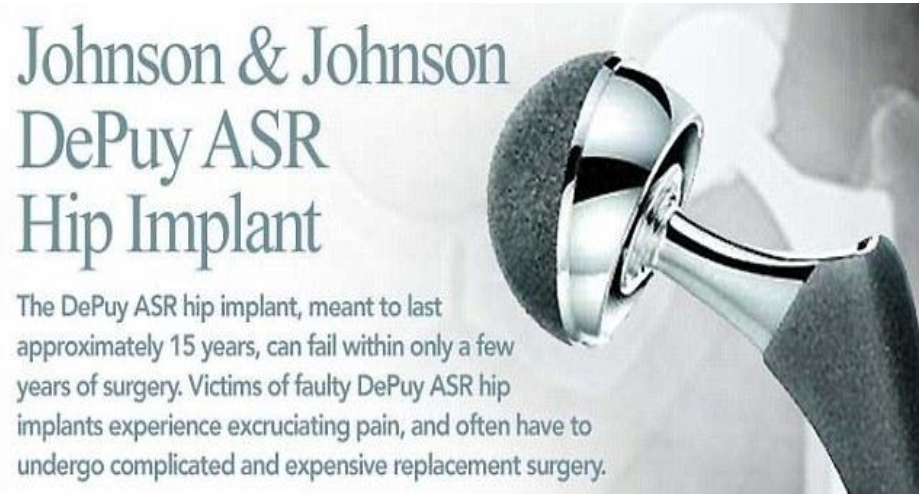
Post market Surveillance (PMS)

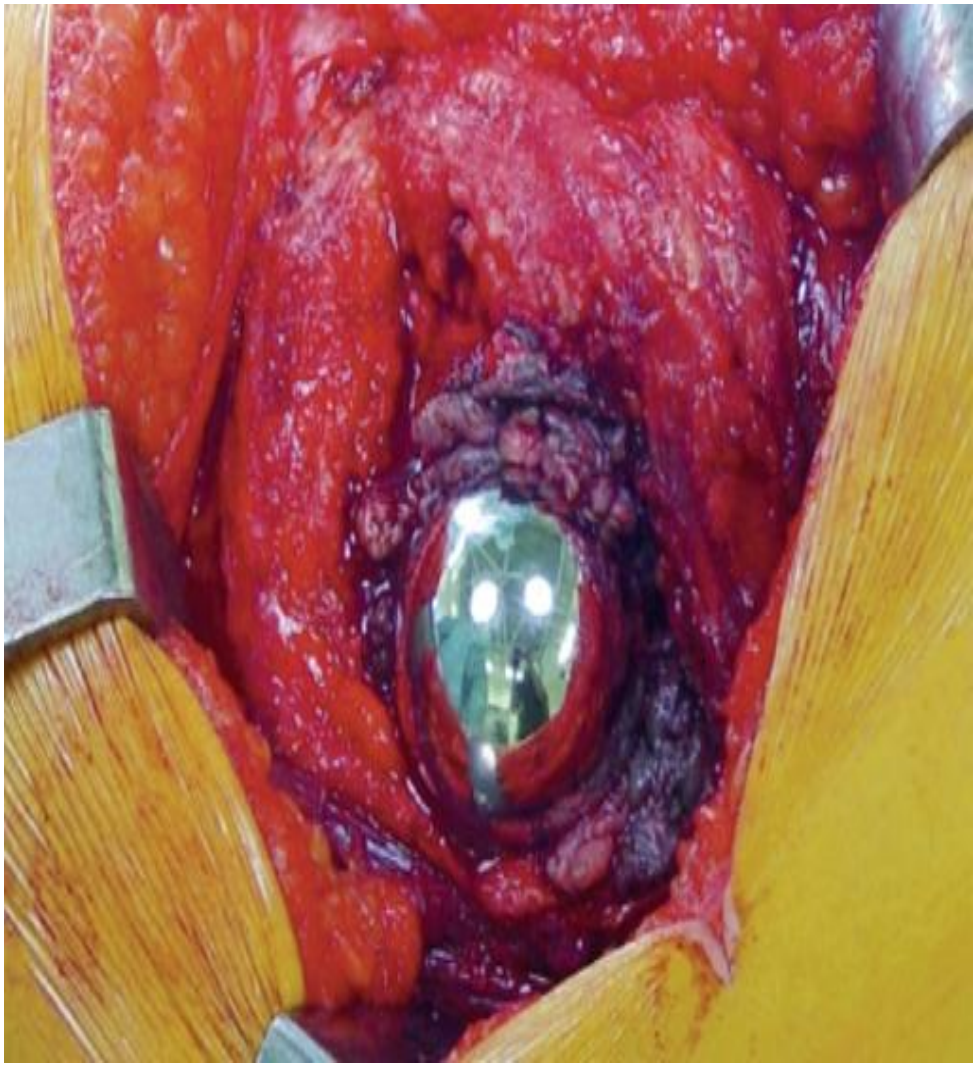
- Post market activities can be divided into 2 groups:

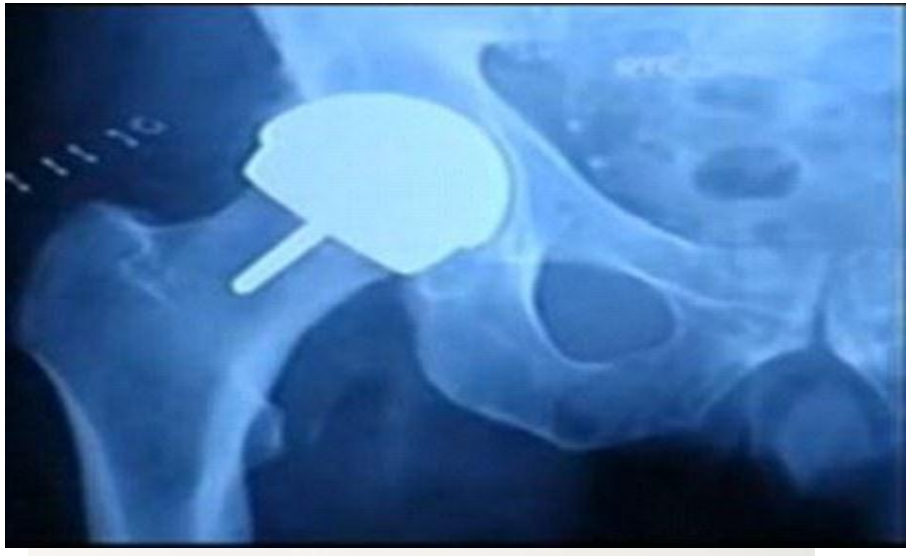
1) PMS- "the pro-active collection of information on quality, safety or performance of medical devices after they have been placed on the market

2)Vigilance-incidents that can occur with medical devices, when they do not perform as intended, thereby leading in the worst case to injury or death.


... YOU'RE RIGHT, MORPHING INTO A HIDEOUS MONSTER IS NOT LISTED AS A POSSIBLE ADVERSE REACTION







Metal on metal hip implants can shed metal particles into the body causing metallosis or metal poisoning.

Why bother?

- Regulatory requirement
- Good Business Sense-to ensure the products are effective in patients
- Patient safety paramount

Post-market Clinical Follow Up Studies (PMCF)

- A study carried out following a CE marking of a device and intended to answer specific questions relating to clinical safety or performance (i.e. residual risks) of a device when used in accordance with it's approved labelling

PMS &PMCF Studies

PMS	PMCF
Compliance data for notified bodies	Focusing on patient outcomes/novel device
ODEP studies-Providing benchmark to 10 years data	Comparative studies with other devices on the market
Retrospective studies-can take the form of registries	Randomised Control Trials

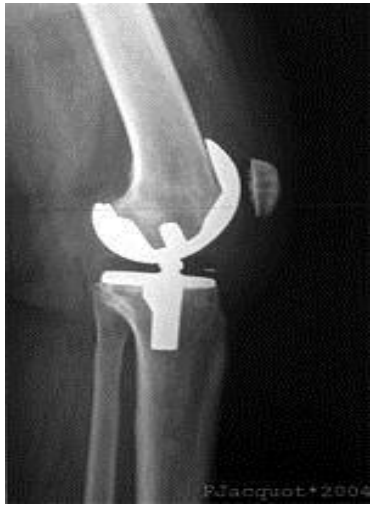
Key Individuals Involved in PMS & PMCF-Trust Level

Industry

- NHS Data rich
- Data which they can utilise to conduct PMS studies on their product

What can the NHS Offer?

- In 2013 in excess of 95,000 knee replacement data was submitted to the National Joint Registry from Hospitals in England and Wales (Registry 2014).
- In 2014, 317 primary total knee replacements were performed at the Royal National Orthopaedic Hospital (RNOH).



Services Provided

To work with commercial companies on Post-market Surveillance (PMS) and Post market clinical follow up (PMCF) studies on devices and assistive healthcare technologies

1. Initial Feasibility

-Initial feasibility & Protocol review (initial input)

-Consultant & study co-ordinator selection

-Key contact point

2. Study development

Protocol design and patient related docs as required

-Ethics & Regulatory submission, if applicable

-Project timeline for study set up to recruitment devised

-Cost Negotiations

3. Approval & Recruitment

-Final Contracts and costs agreed

-Consultants & Study co-ordinator Site initiation visit arranged & compliant with ICH GCP, RGF and/or ISO 14155

-Recruitment to meet Key Performance Indicators

Overseeing the lifecycle of these studies from start to finish

Summary

- PMS is a regulatory requirement and ensures that device is performing and is safe
- Range of PMS and PMCF studies that you may come across
- Need co-operation and engagement from range of stakeholders to ensure these studies are a success
- The NHS R&D department can provide a number of services to companies

Any Questions?