

Questioning the evidence? Bone cement implantation syndrome revisited through the eyes of a national database

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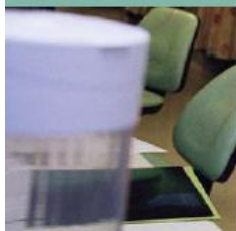


The NPSA – an introduction

- May 2009 = 3,290,848 PSIs reported to the Reporting and Learning System (RLS)
- 10,000 + incidents reported per annum leading to death or patient suffering severe harm
- Self-reporting, voluntary system

Acting on serious risks to patients
February 2009

How the National Patient Safety Agency reviews reports of serious incidents, extracts national learning and shares findings to make the NHS safer for patients.

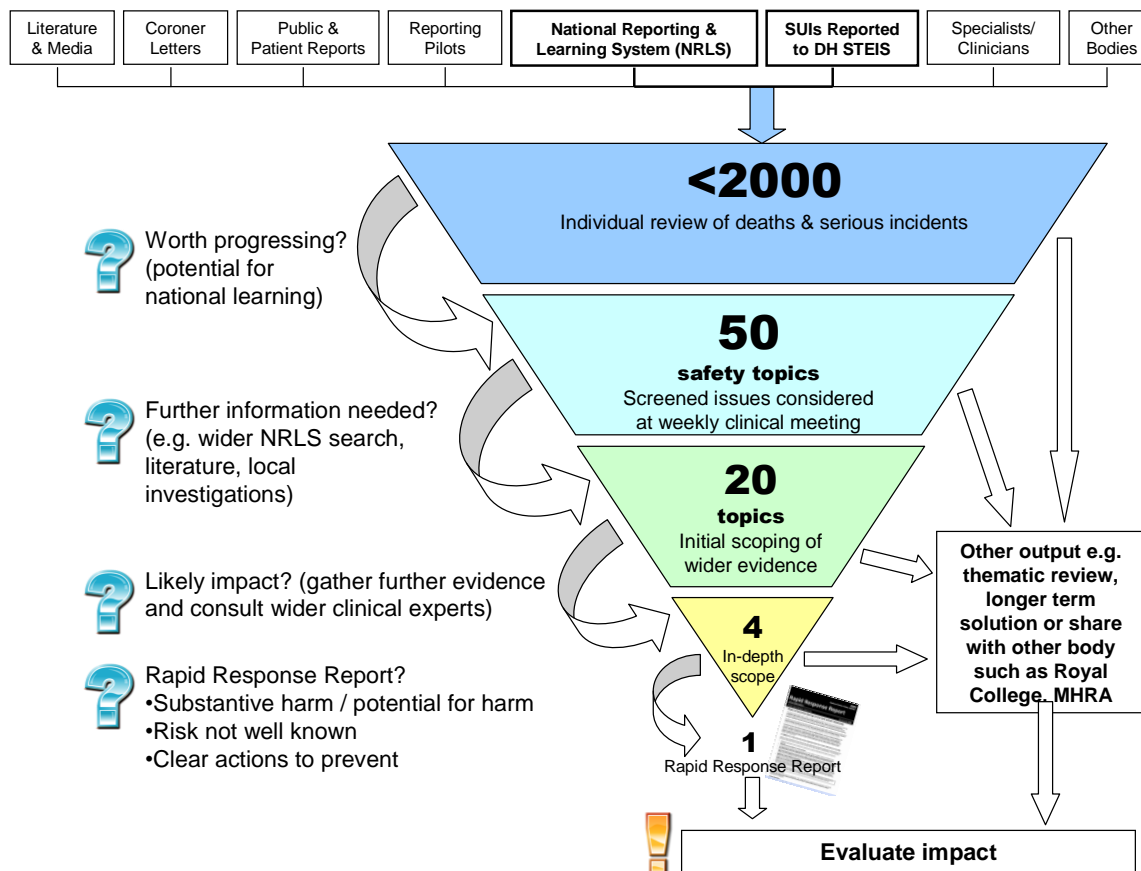


We can only act on the information given – it is vital that doctors, nurses and other staff in the NHS report serious risks to patients promptly so that lessons can be learned and action taken to protect others from harm

Aims

- To develop an understanding of patient safety incidents resulting from the use of hip cement
- Provide solutions to reduce the incidence of these incidents

How do we develop outputs?



Trigger incident

- *“Patient having cemented hip prosthesis inserted for fractured neck of femur. Cement inserted and prosthesis being hammered into place when patient became bradycardiac 40 / min. Unresponsive to atropine. Loss of Palpable pulse with PEA cardiac arrest. CPR commenced and continued for 20 minutes and no response to treatment. Patient died.”*

Revelations from the RLS database

Table 1: Incidents resulting in death or severe harm during a hip procedure, cement use and type of procedure – NPSA data

Base: all incidents involving severe harm or patient death during hip procedures in the RLS up to 31 October 2008

Degree of harm	Procedure	Cement use		Total
		Cemented	Uncemented	
Deaths	Hemiarthroplasty	17	1	18
	Arthroplasty (THR)	3	0	3
	Unknown	4	0	4
	Total	24	1	25
Severe Harm	Hemiarthroplasty	3	0	3
	Arthroplasty (THR)	2	0	2
	Unknown	1	0	1
	Total	6	0	6
Grand Total		30	1	31[‡]

Is this really an issue?

- 1.3 million hip fractures occurred globally in 1990, with predictions of numbers rising to anywhere between 7.3 and 21.3 million by 2050
- The literature on bone cement implantation syndrome – well understood
- Paucity of evidence on whether cement should be used or not
 - Registries
 - EBM - confusing

So what have we done about it?

Rapid Response Report

NPSA/2009/RRR001

From reporting to learning

11 March 2009

Mitigating surgical risk in patients undergoing hip arthroplasty for fractures of the proximal femur

For PRECAUTIONARY ACTION by clinical directors of surgery in the NHS and the independent sector. The deadline date for ACTION COMPLETE is 14 September 2009

Organisations should:

1. Report to the NPSA and MHRA every peri-operative harm or patient death for total hip replacement and hemiarthroplasty, stating use of cemented or uncemented prosthesis and share the results of local investigations with the NPSA.
2. Review local guidelines and audit current activity against best practice including submitting data to the NHFD, and reduce risks as follows:

Patient assessment:

- Identifying patients at risk (e.g. those with pre-existing cardiopulmonary dysfunction), assessing fitness for surgery and most appropriate technique

Anaesthetic technique:

- Maintain normovolemia throughout the procedure, particularly prior to cement insertion
- Maintain particular vigilance during instrumentation and fixation of the implant

Surgical technique:

- Thorough pressurised lavage of the femoral canal before broaching the canal and further instrumentation of the femur
- Consider a suction catheter to reduce the pressure in the intramedullary canal
- Introducing cement into the femur in retrograde fashion via a cement gun
- Communication with the anaesthetist regarding when cement is to be inserted

Limitations

- The RLS is a voluntary, self-reporting system
- Under-reporting
- Large number of case reports – varying quality
- Bias

Future direction

- NICE is reviewing its guidance on femoral fractures
- More engagement from joint registries
- Multi-centred trials
- Further meta-analyses once more data become available

Further information

Panesar SS, Cleary K, Bhandari M, Sheikh A.
To cement or not in hip fracture surgery?

Lancet 2009 (26); 374(9695):1047-9

- NPSA. Mitigating surgical risk in patients undergoing hip arthroplasty for fractures of the proximal femur. 11th March 2009

<http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/?entryid45=59867>