

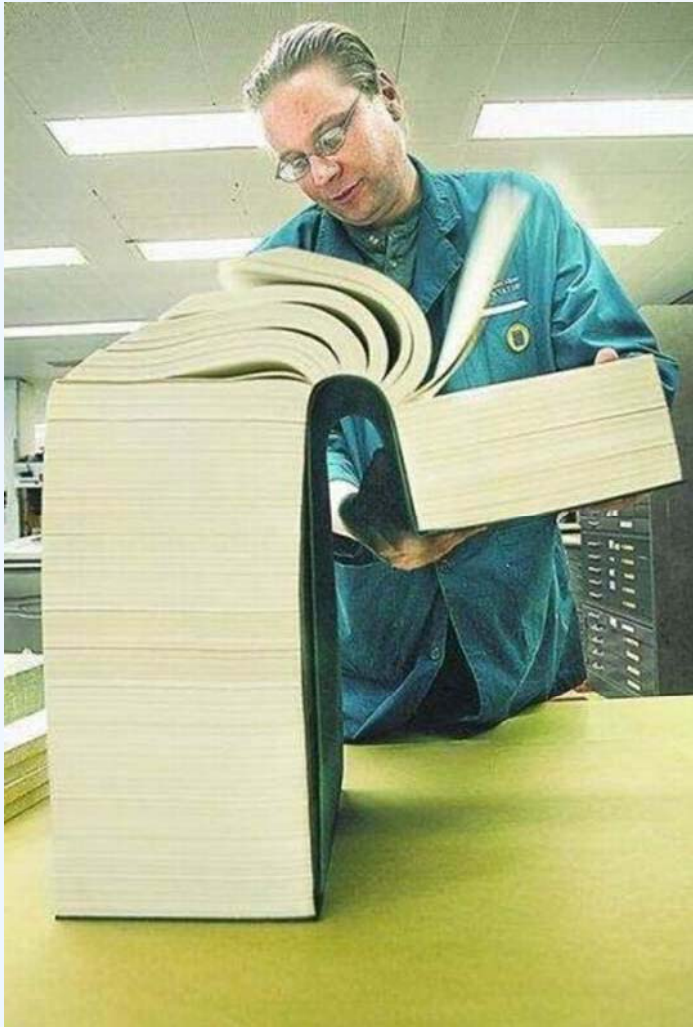
Securing level 3 NHSLA & CQC Compliance

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Introduction

- With considerable financial challenges and efficiency savings over the coming years, can we provide a safe service at a fraction of the cost, or are we gambling with quality?





To establish and maintain quality & safety in the NHS we have regulations/ compliance frameworks; is it becoming too much or is it necessary?

- The key function of the NHS LA, is to contribute to the incentives for reducing the number of negligent or preventable incidents; this is achieved through a risk management programme

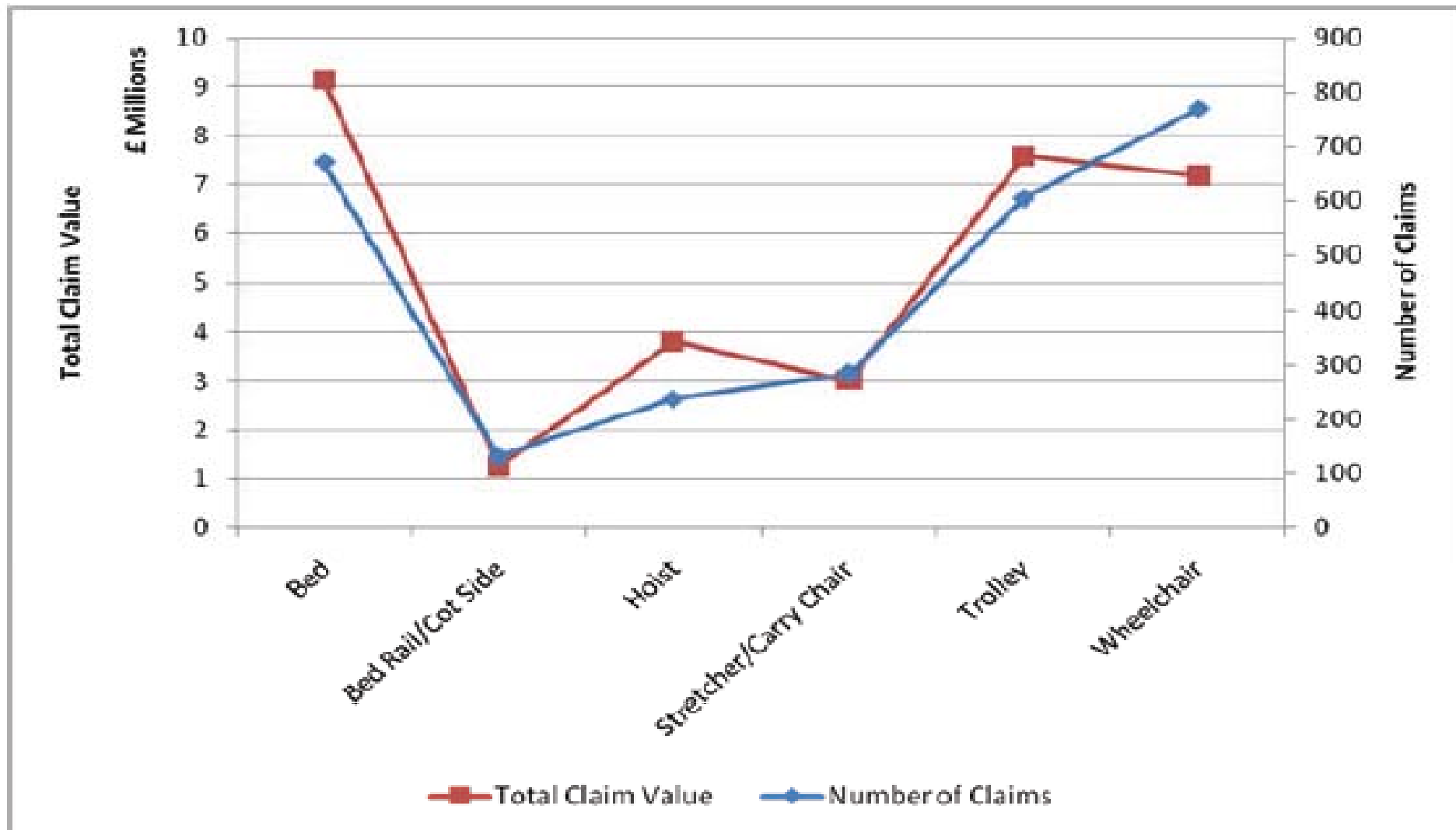
Assessments – discounts

- Level 1 = 10%
 - Level 2 = 20%
 - Level 3 = 30%
- Applied in next financial quarter

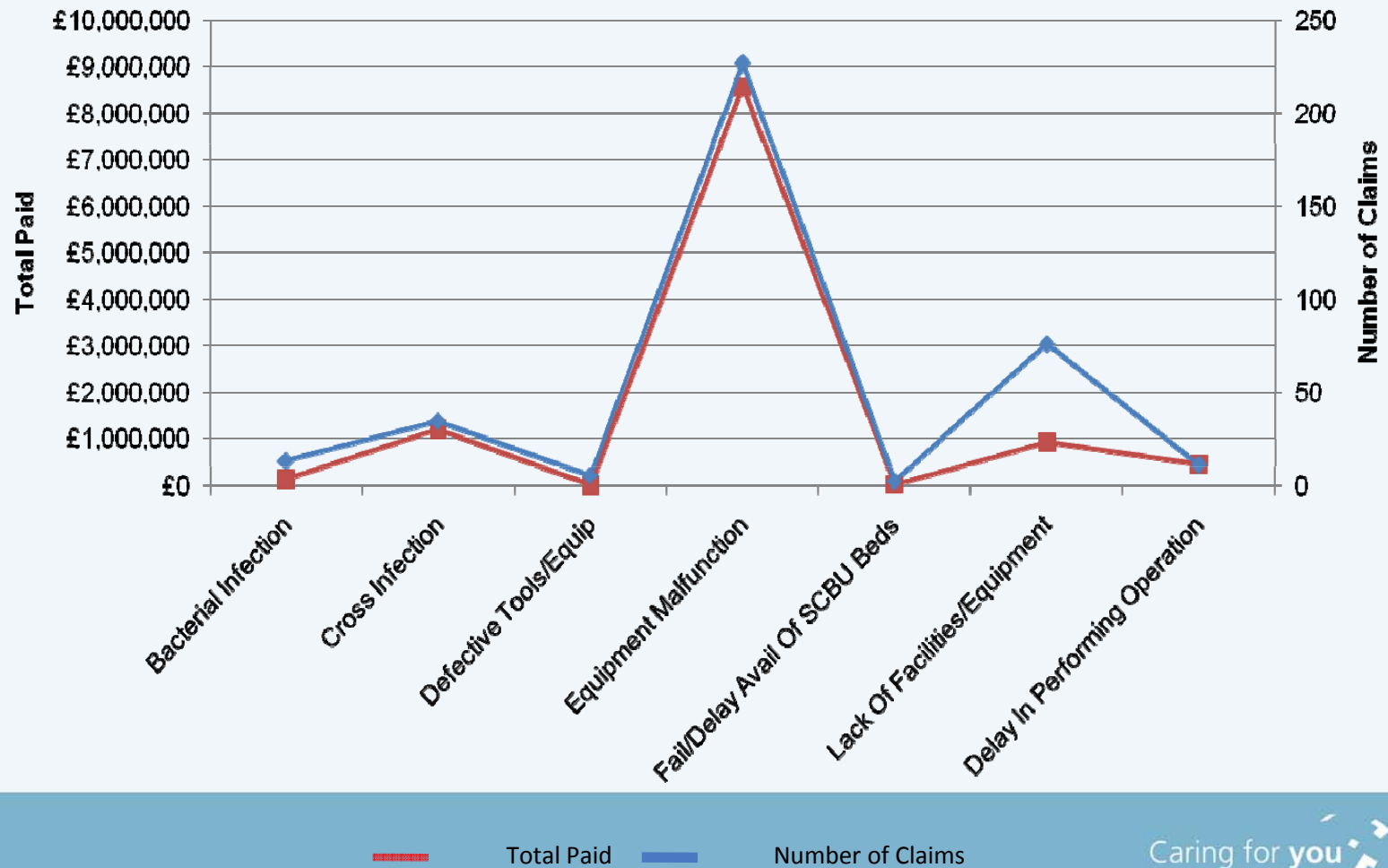
Claims Related to Medical Devices and Equipment

	NUMBER	TOTAL PAID
CNST 1995 - 2010	1,562 (1,303 Closed)	£ 42.4m
RPST 1999 - 2010	2,528 (2,176 Closed)	£ 21.3m
TOTAL	4,090 (3,479 Closed)	£ 63.7m

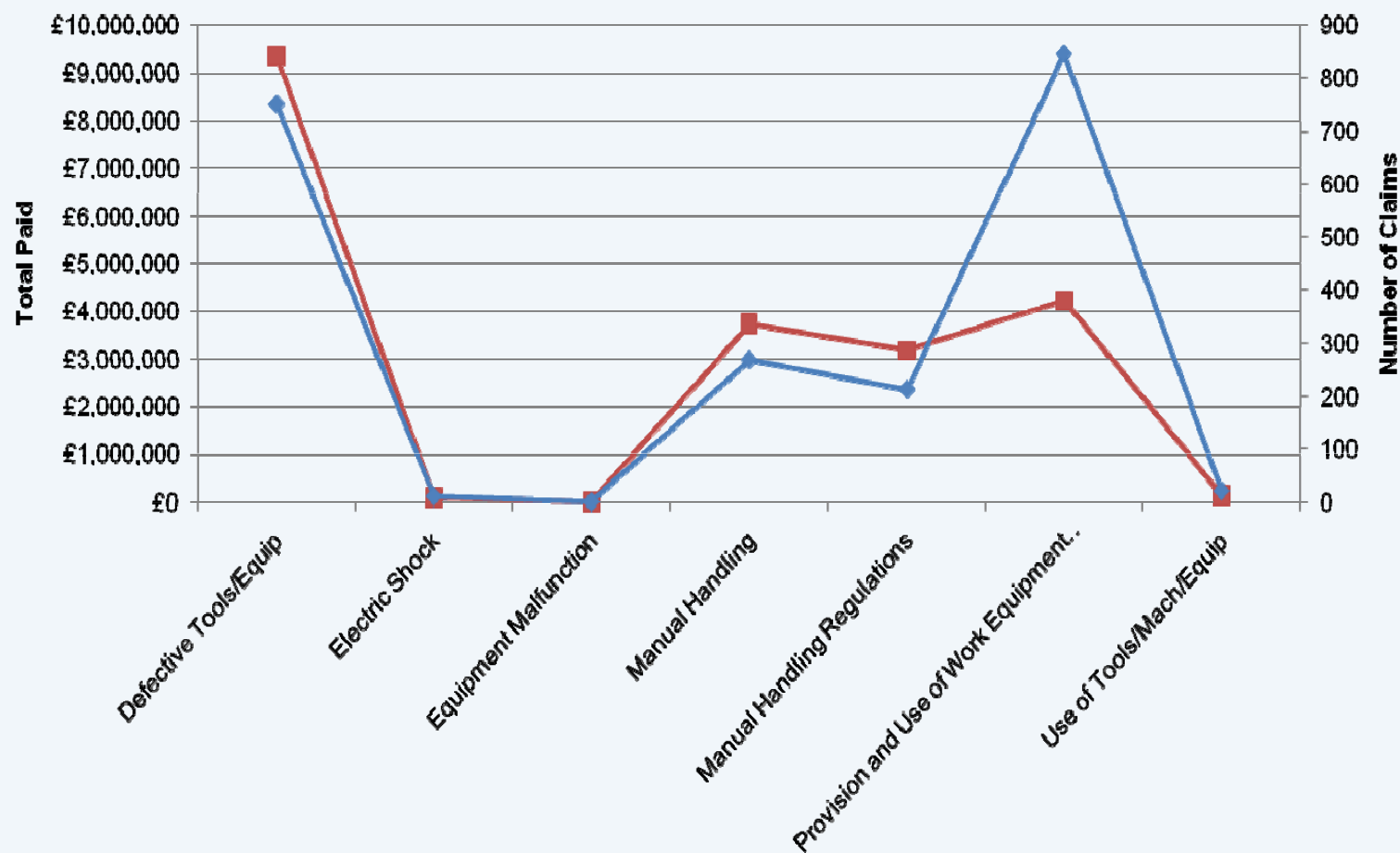
Equipment Types



Relevant Closed CNST Claims



Relevant Closed RPST Claims



— Total Paid

— Number of Claims

What are they looking for?



Standard 2 - Criterion 7: Medical Devices Training

Acute, Community, and Independent Sector organisations: The organisation has an *approved* documented process for ensuring that all *permanent* staff are trained to safely use diagnostic and therapeutic equipment appropriate to their role, that is implemented and monitored.

Level 1	Minimum Requirements
1.2.7	<p>As a minimum, the <i>approved</i> documentation must include a description of the:</p> <ol style="list-style-type: none"> a. <i>duties</i> b. inventory (or links to an inventory) of diagnostic and therapeutic equipment used within the organisation c. process for identifying which <i>permanent</i> staff are authorised to use the equipment identified on the inventory d. process for determining the training required to use the equipment identified on the inventory and the frequency of updates required e. process for ensuring that the identified training needs of all <i>permanent</i> staff are met f. process for <i>monitoring</i> compliance with all of the above.
Level 2	Minimum Requirements
2.2.7	<p>The organisation can demonstrate compliance with the objectives set out within the <i>approved</i> documentation described at Level 1, in relation to the:</p> <ul style="list-style-type: none"> • process for identifying which <i>permanent</i> staff are authorised to use the equipment identified on the inventory • process for determining the training required to use the equipment identified on the inventory and the frequency of updates required • process for ensuring that the identified training needs of all <i>permanent</i> staff are met.
Level 3	Minimum Requirements
3.2.7	<p>The organisation can demonstrate that it is <i>monitoring</i> compliance with the minimum requirements contained within the <i>approved</i> documentation described at Level 1, in relation to the:</p> <ul style="list-style-type: none"> • process for identifying which <i>permanent</i> staff are authorised to use the equipment identified on the inventory • process for determining the training required to use the equipment identified on the inventory and the frequency of updates required • process for ensuring that the identified training needs of all <i>permanent</i> staff are met. <p>Where the <i>monitoring</i> has identified deficiencies, there must be evidence that recommendations and action plans have been developed and changes implemented.</p>

Standard 3 - Criterion 6: Maintenance of Medical Devices & Equipment

Acute, Community, and Independent Sector organisations: The organisation has an *approved* documented process for managing the risks associated with the maintenance of reusable medical devices and equipment that is implemented and monitored.

Level 1

Minimum Requirements

1.3.6

As a minimum, the *approved* documentation must include a description of the:

- a. *duties*
- b. requirement to have a systematic inventory of all reusable medical devices and equipment used within the organisation
- c. process for ensuring that all reusable medical devices and equipment are maintained**
- d. process for ensuring that all reusable medical devices and equipment are repaired**
- e. process for *monitoring* compliance with all of the above.

Level 2

Minimum Requirements

2.3.6

The organisation can demonstrate compliance with the objectives set out within the *approved* documentation described at Level 1, in relation to the:

- process for ensuring that all reusable medical devices and equipment are maintained
- process for ensuring that all reusable medical devices and equipment are repaired.

Level 3

Minimum Requirements

3.3.6

The organisation can demonstrate that it is *monitoring* compliance with the minimum requirements contained within the *approved* documentation described at Level 1, in relation to the:

- process for ensuring that all reusable medical devices and equipment are maintained
- process for ensuring that all reusable medical devices and equipment are repaired.

Where the *monitoring* has identified deficiencies, there must be evidence that recommendations and action plans have been developed and changes implemented.



NHSLA Risk Management Standards for Acute Trusts 2009/2010

Standard 3: Safe Environment

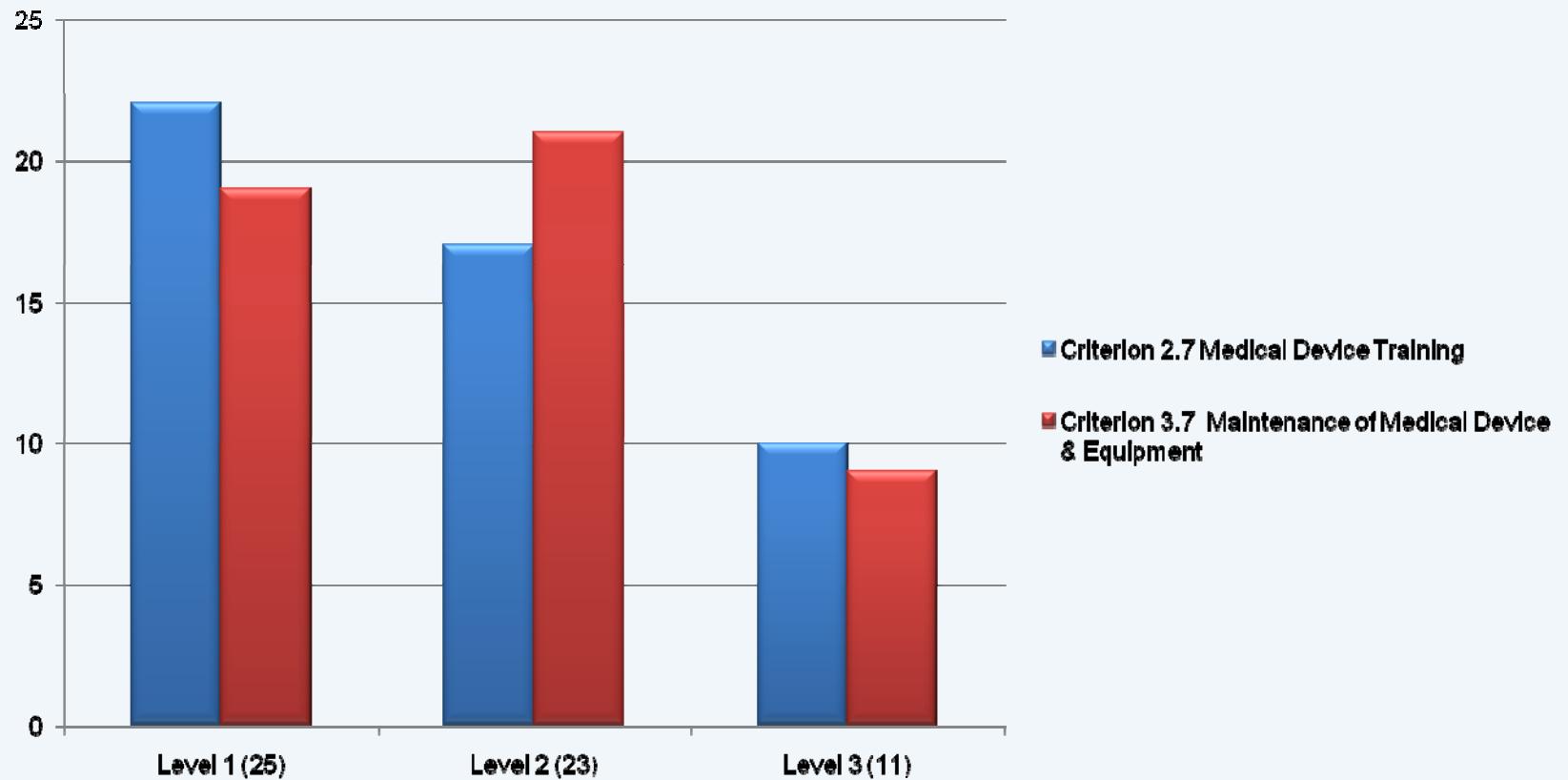
Criterion 7: Maintenance of medical devices & equipment

Level 1				
1.3.7 The organisation has <i>approved</i> documentation which describes the process for managing the risks associated with the maintenance of reusable medical devices and equipment.				
As a minimum, the <i>approved</i> documentation must include a description of:				
c. process for ensuring that all reusable medical devices and equipment are properly maintained and repaired				
Monitoring				
3.3.7 The organisation can demonstrate that there are processes in place to <i>monitor</i> compliance with the <i>approved</i> documentation which describes the process for managing the risks associated with the maintenance of reusable medical devices and equipment.				
Standard	Monitoring and audit			
	Method	By	Committee	Frequency
c. Ensuring that all reusable medical devices and equipment are properly maintained and repaired	Audit of all points of the process for ensuring that all medical devices are properly maintained and repaired. To include all internal and external medical equipment.	Medical Devices Clinical Risk Manager	PQRS	Annual
Evidence				
1.	Policy for the Procurement Management & Use of Medical Devices V 4, July 2009			
2.	Medical Devices Monitoring Report, 11 th January 2010. Includes action plans			
3.	PQRS Committee January 2010 – review of report & action plans			
4.	Ward based action plan page 22			
5.	Trust wide action plan page 30-32			
6.	Printout from <u>Backtraq</u> showing maintenance of equipment from February 2009 to January 2010. Number of devices maintained in compliance with the system/policy has risen from 61% to 70%			
7.	Paper demonstrating all new maintenance contracts added to the <u>Backtraq</u> system			



Identify What You Have And Where You
Need To Go

Acute Organisations - compliance against 2010/11 medical device related criterion

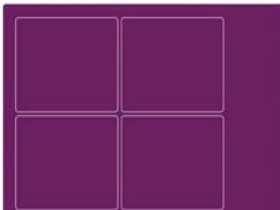


- All health and adult social care providers who provide regulated activities are required by law to be registered with CQC. To do so, providers must show they are meeting new essential standards of quality and safety.
- The CQC's job is to ensure providers meet the essential standards, check that they continue to do so, and take action if they do not

“The CQC has a range of enforcement powers such as **fin**es and **public warnings** - it can **apply conditions** in response to serious risks.”

“...the CQC can issue a fixed penalty of up to **£50,000** for **each serious breach of a standard**”

“It can **demand** that a hospital ward or service is **closed** or **suspended** - it can take a service **off the register** if absolutely necessary...”



Surprise visits



CQC's guidance about compliance: Description of the OUTCOME

Plain English

People focused

Outcome based



Safety, availability and suitability of equipment

OUTCOME 11

What should people who use services experience?

People who use services and people who work in or visit the premises:

- Are not at risk of harm from unsafe or unsuitable equipment (medical and non-medical equipment, furnishings or fittings)
- Benefit from equipment that is comfortable and meets their needs.

That is because providers who are compliant with the law will:

- Make sure that equipment:
 - is suitable for its purpose
 - is available
 - is properly maintained
 - is used correctly and safely
 - promotes independence
 - is comfortable.
- Follow published guidance about how to use medical devices safely

Outcome 11

The lowest proportion of compliance was found in NHS Hospitals

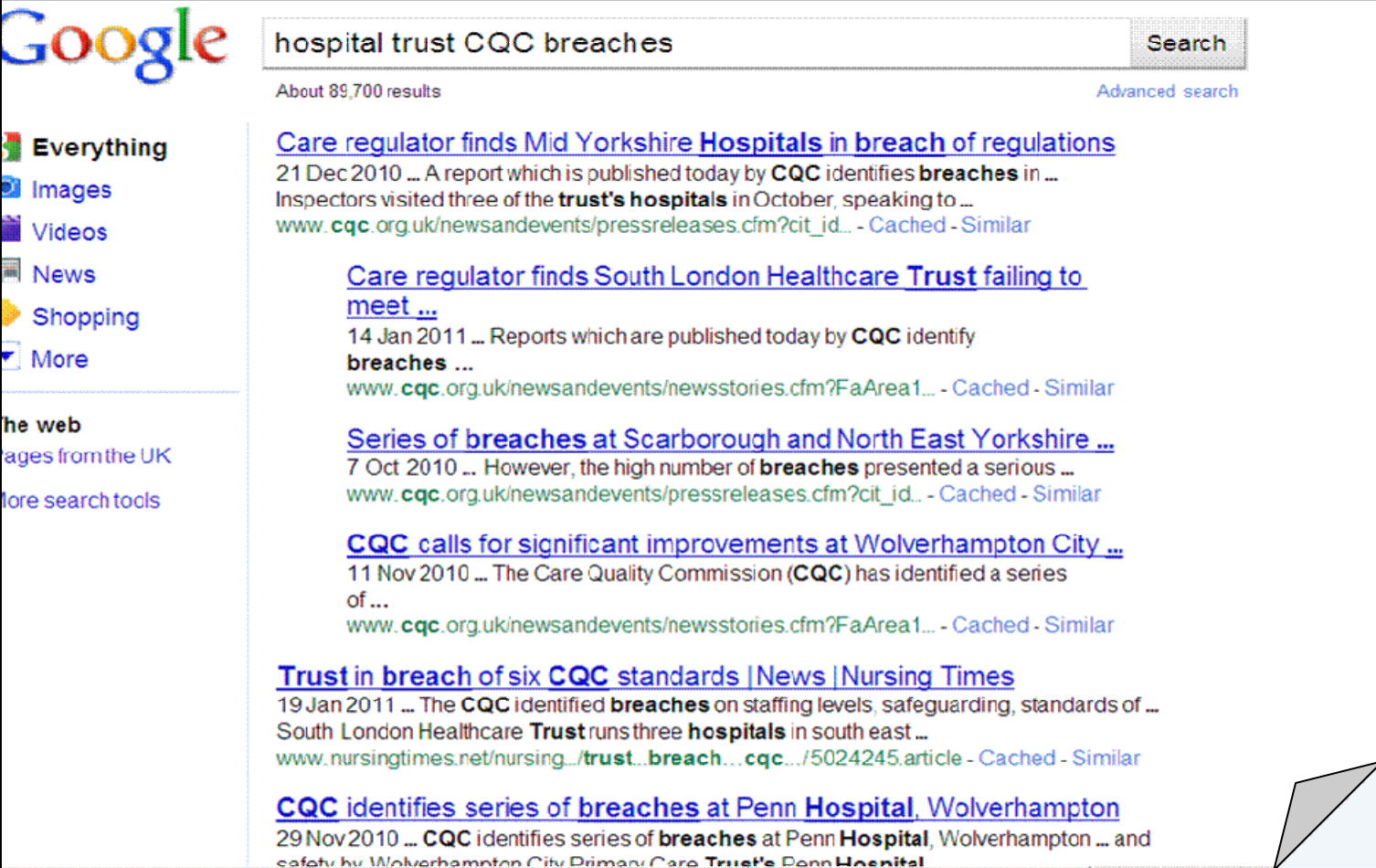
Table 10: CQC reviews of compliance with Outcome 11 on safety, availability and suitability of equipment

	Number of reviews	Review period	Compliant* %	Minor concerns* %	Moderate concerns %	Major concerns %
NHS hospitals	98	April 2010 – July 2011	73	16	10	0
Independent hospitals and clinics	123	Oct 2010 – July 2011	94	4	0.9	2
Care homes with nursing	507	Oct 2010 – July 2011	85	7	5	3
Care homes without nursing	1033	Oct 2010 – July 2011	89	7	3	1
Domiciliary care agencies	253	Oct 2010 – July 2011	94	4	2	0.4

Source CQC: Based on an analysis of approximately 3,500 reviews in total

*Note that a provider with a minor concern would in most cases be judged compliant for that outcome

Assessment Outcomes Are Widely Available



Google hospital trust CQC breaches Search

About 89,700 results Advanced search

Everything
Images
Videos
News
Shopping
More

the web
pages from the UK
more search tools

[Care regulator finds Mid Yorkshire Hospitals in breach of regulations](#)
21 Dec 2010 ... A report which is published today by **CQC** identifies **breaches** in ...
Inspectors visited three of the **trust's hospitals** in October, speaking to ...
[www.cqc.org.uk/newsandevents/pressreleases.cfm?cit_id...](#) - Cached - Similar

[Care regulator finds South London Healthcare Trust failing to meet ...](#)
14 Jan 2011 ... Reports which are published today by **CQC** identify **breaches** ...
[www.cqc.org.uk/newsandevents/newsstories.cfm?FaArea1...](#) - Cached - Similar

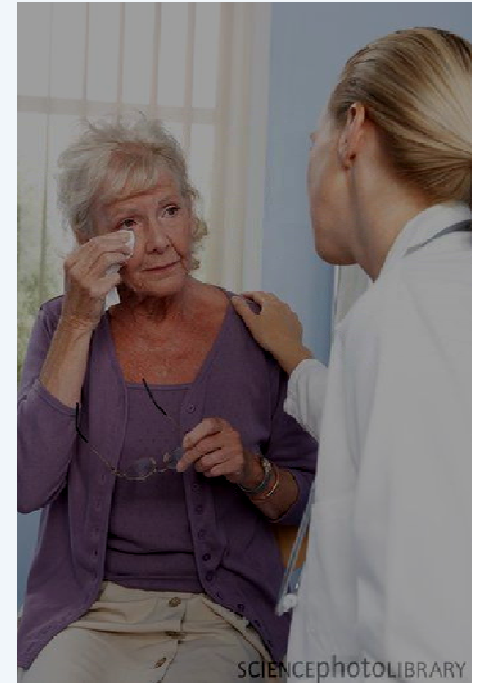
[Series of breaches at Scarborough and North East Yorkshire ...](#)
7 Oct 2010 ... However, the high number of **breaches** presented a serious ...
[www.cqc.org.uk/newsandevents/pressreleases.cfm?cit_id...](#) - Cached - Similar

[CQC calls for significant improvements at Wolverhampton City ...](#)
11 Nov 2010 ... The Care Quality Commission (**CQC**) has identified a series of ...
[www.cqc.org.uk/newsandevents/newsstories.cfm?FaArea1...](#) - Cached - Similar

[Trust in breach of six CQC standards | News | Nursing Times](#)
19 Jan 2011 ... The **CQC** identified **breaches** on staffing levels, safeguarding, standards of ...
South London Healthcare **Trust** runs three **hospitals** in south east ...
[www.nursingtimes.net/nursing.../trust...breach...cqc.../5024245.article](#) - Cached - Similar

[CQC identifies series of breaches at Penn Hospital, Wolverhampton](#)
29 Nov 2010 ... **CQC** identifies series of **breaches** at Penn **Hospital**, Wolverhampton ... and safety by Wolverhampton City Primary Care **Trust's Penn Hospital**

Is it all just a tick box exercise?



Or the difference between patients well being and tragedy

CHALLENGES AHEAD

Gateshead Health **NHS**
NHS Foundation Trust



Caring for you 

Thank you



Any questions?