

professor of cardiothoracic surgery at UCL paediatric cardiothoracic surgeon at GOSH professor of physic at Gresham College



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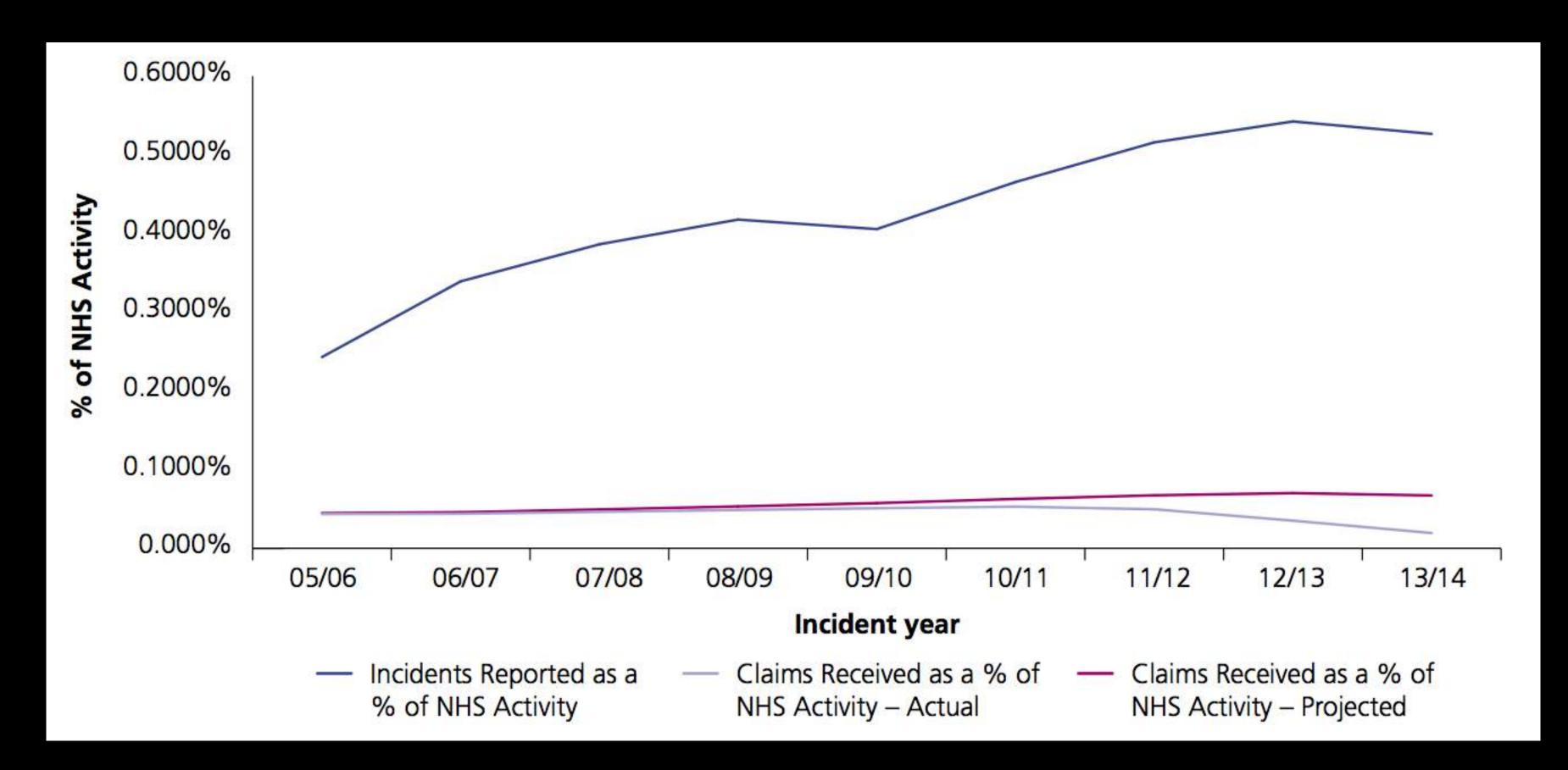
To Blame or Not To Blame





adverse event

serious incident (SI)



serious incidents reported in \approx 0.5% of NHS activity negligence claims made in \approx 0.05% of NHS activity



critical incident



Does our current system of medical litigation:

- help or hinder improvements in safety
- or are there better ways?

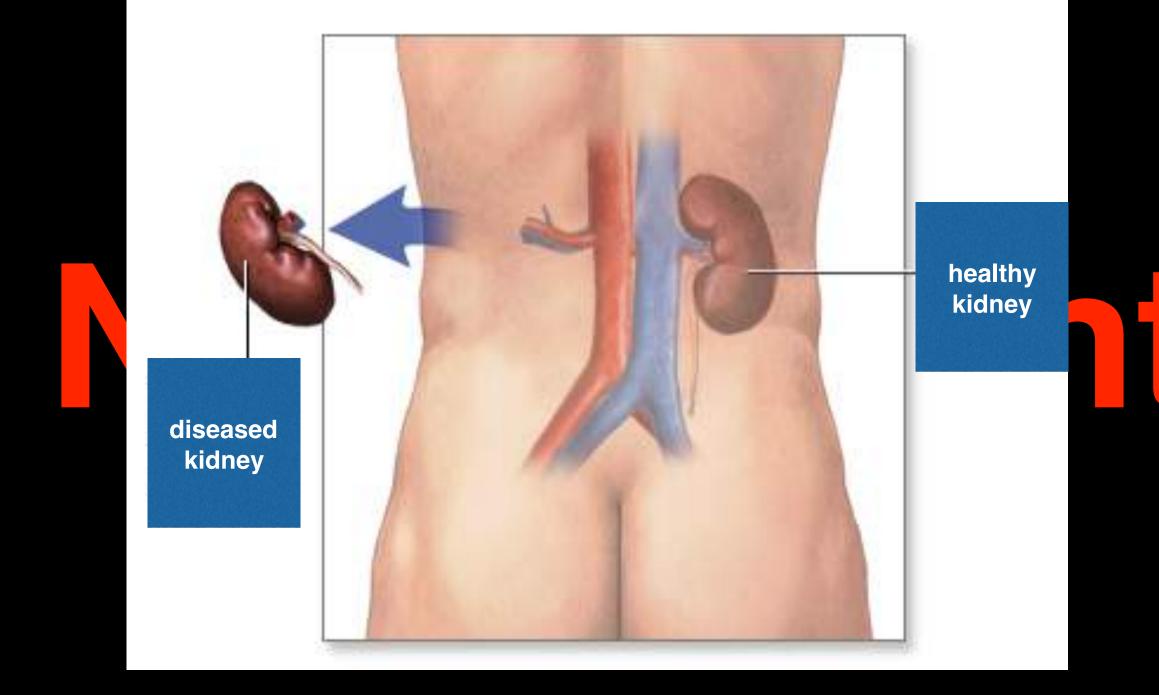
Is the NHS

- capable of learning from adverse events
- spreading that learning for prevention
- able to sustain safe practice?

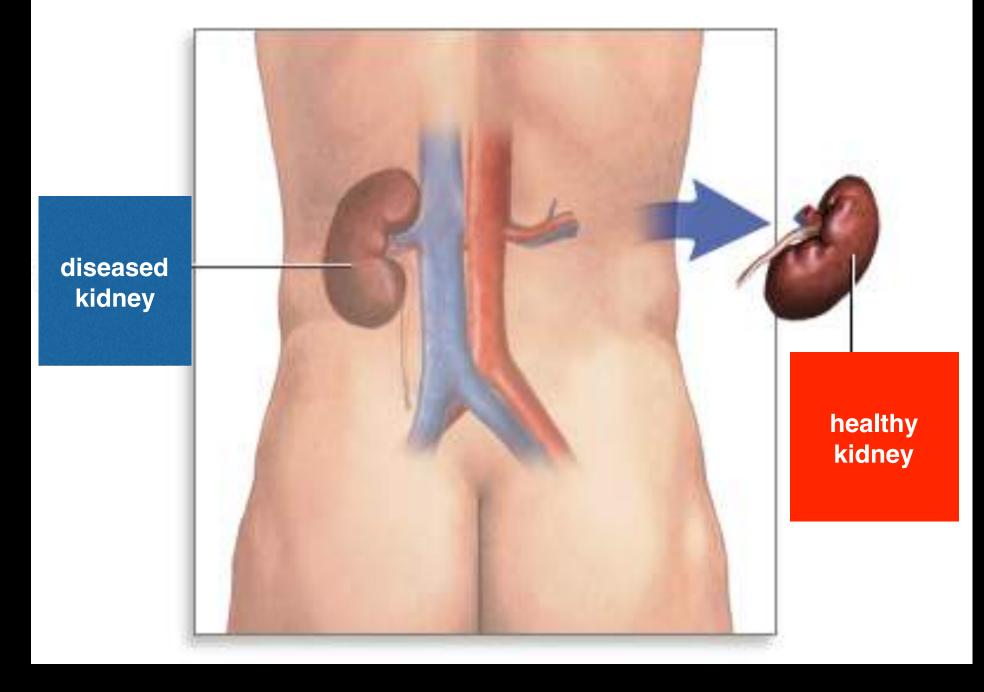


adequately compensate victims of medical error









Oops



compensation it wasn't your fault Investigation what really happened earning it mustn't happen again, anywhere

SUPPORT. for everyone involved



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The duty of CARE The duty of CANDOUR



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long-standing *ethical duty* of doctors

after the Francis Report (2013) a legal obligation for doctors AND organisations



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The Duty of Candour





what was wrong at mid-Staffordshire

- organisation
- a failure to respond to outside pressure
- marginalisation of clinical staff and those who raised issues or complained
- dominance of finance over quality and safety
- poor safety monitoring and failure to deal with early warning signs ullet
- tendency to blame the 'shop-floor' workers, despite them raising issues •



• a repressive, opaque leadership culture and a lack of transparency throughout the

Sadler BL, Stewart K. Leading in a Crisis: the power of transparency. London, 2015



"Whilst there had been a perception that the hospital's staff had been silent, it transpired that the organisation had been deaf"

Vincent C, Burnett S, Carthey J. The measuring and monitoring of safety. London, 2013.





empathy, explanation and an apology may not be enough



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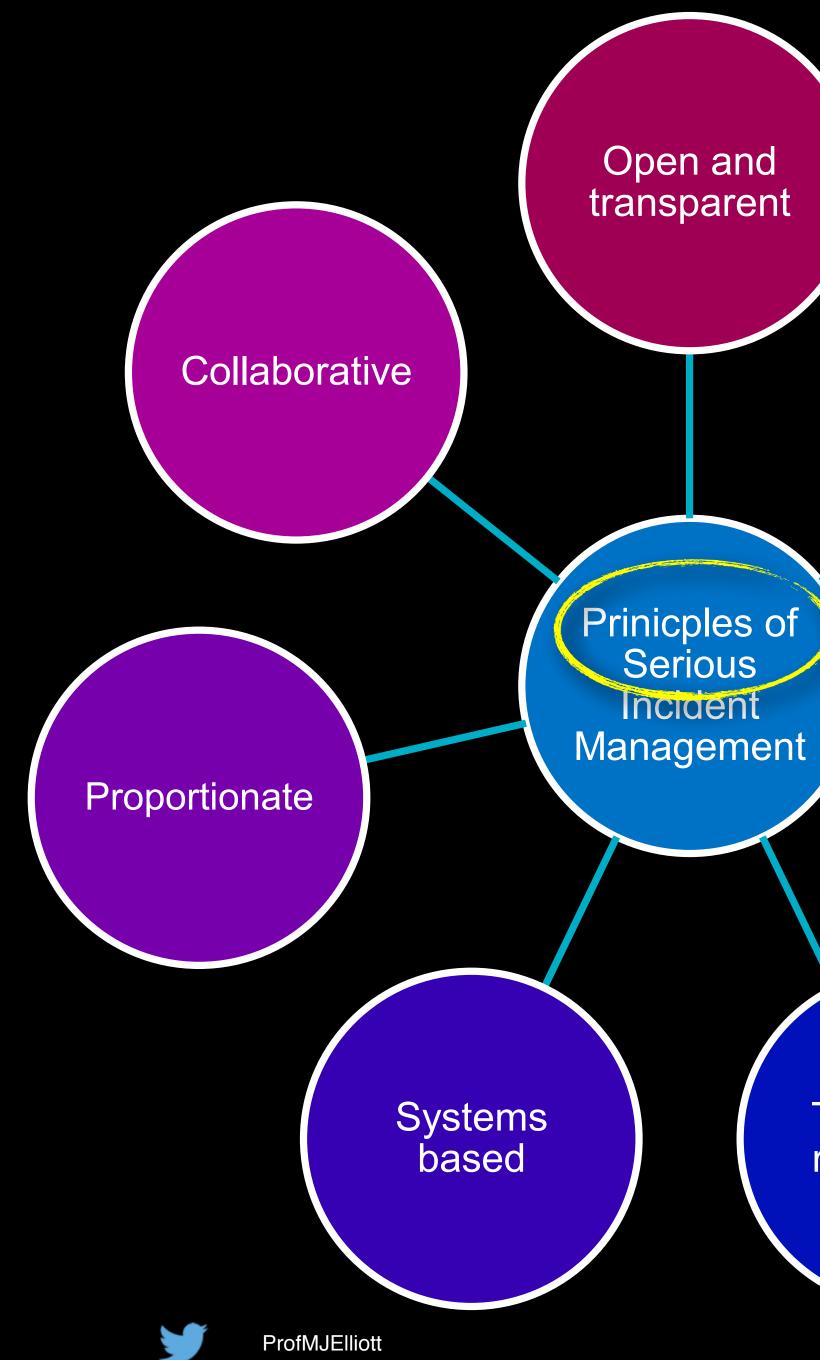


- Acts or Omissions occurring under NHS care that result in:
 - unexpected or avoidable death (including suicide and homicide)
 - unexpected or avoidable injury causing severe harm
 - actual or alleged abuse (sexual, physical or psychological)
- A Never Event
- An incident that threatens continuity of service provision \bullet



Serious incidents





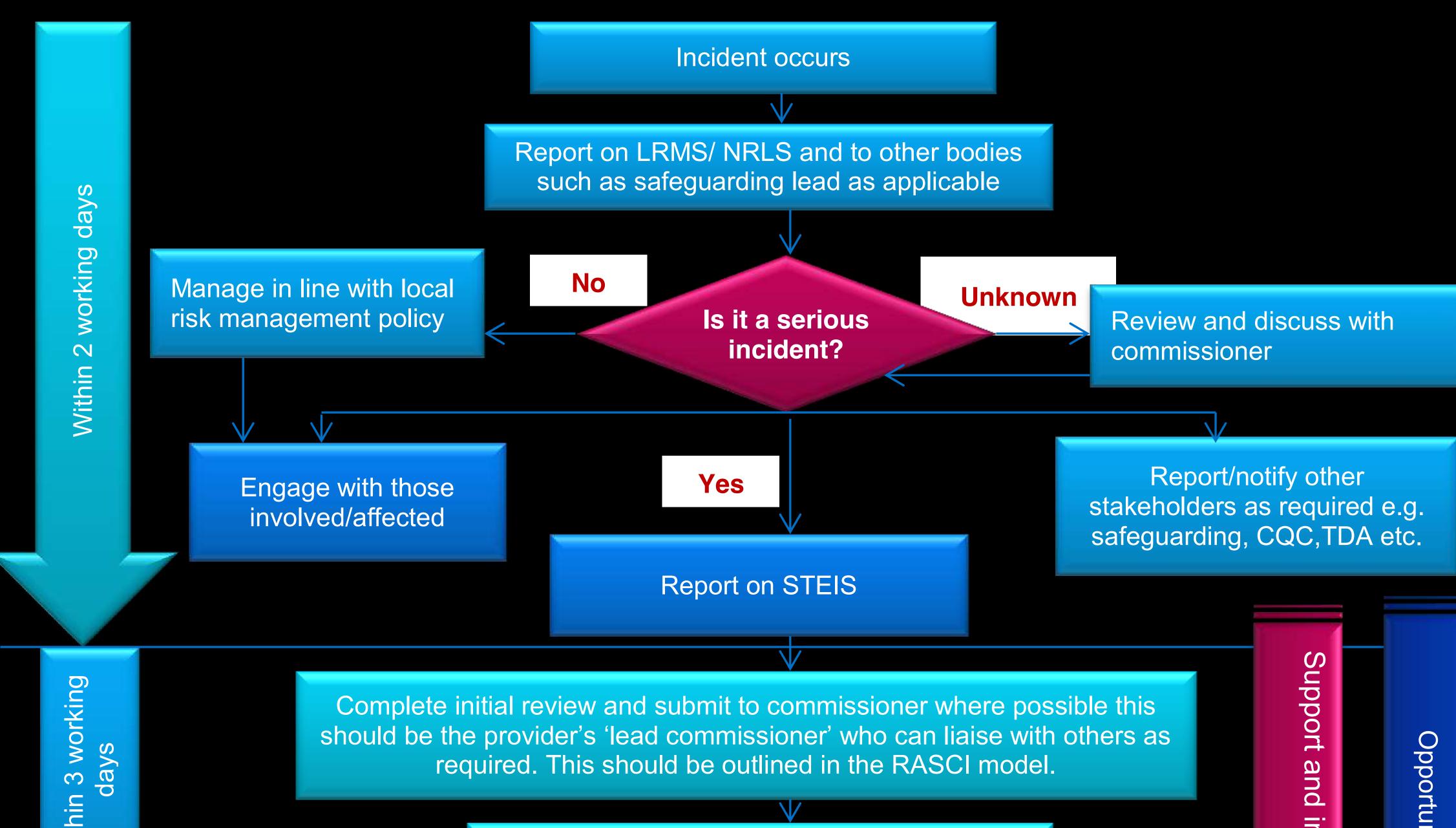
Preventative

Objective

Timely and responsive

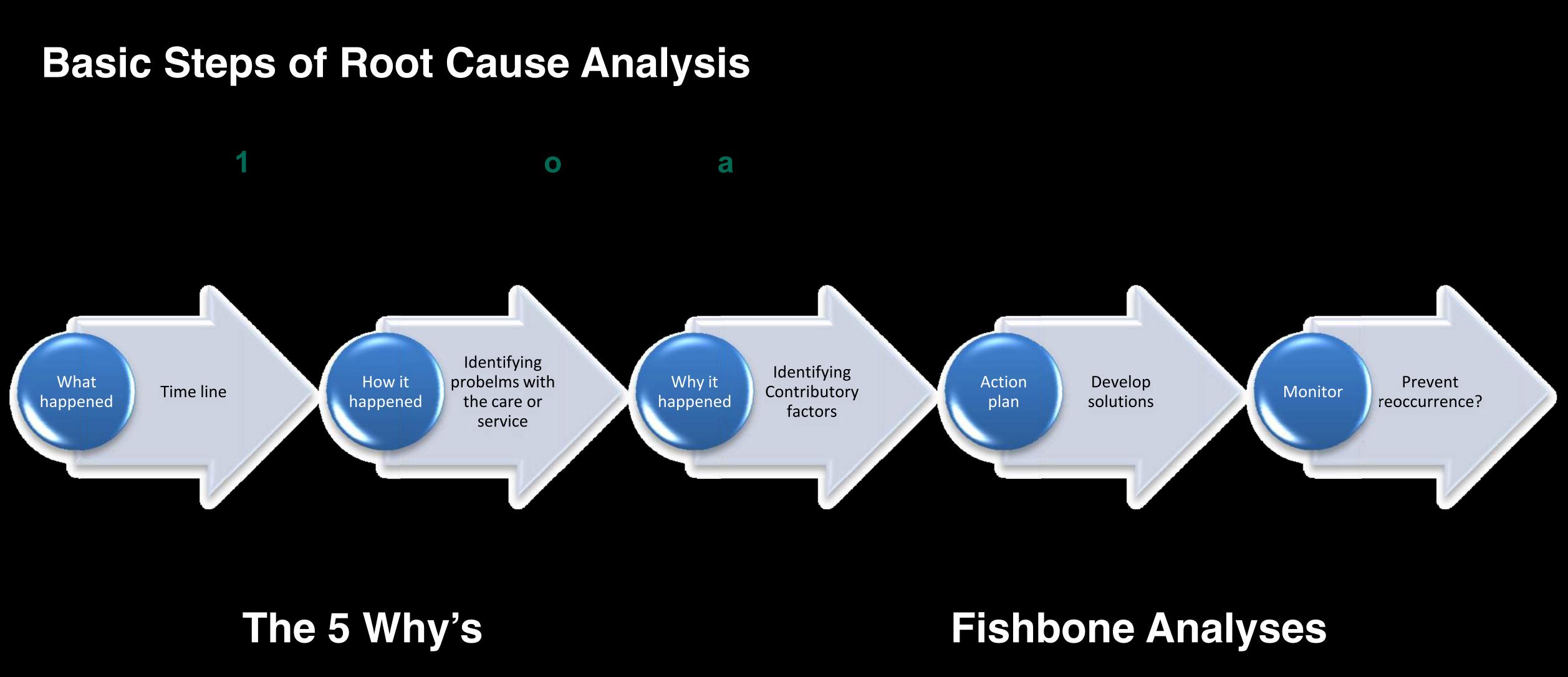
 \boxtimes

1. Overview of the Serious Incident Management Process







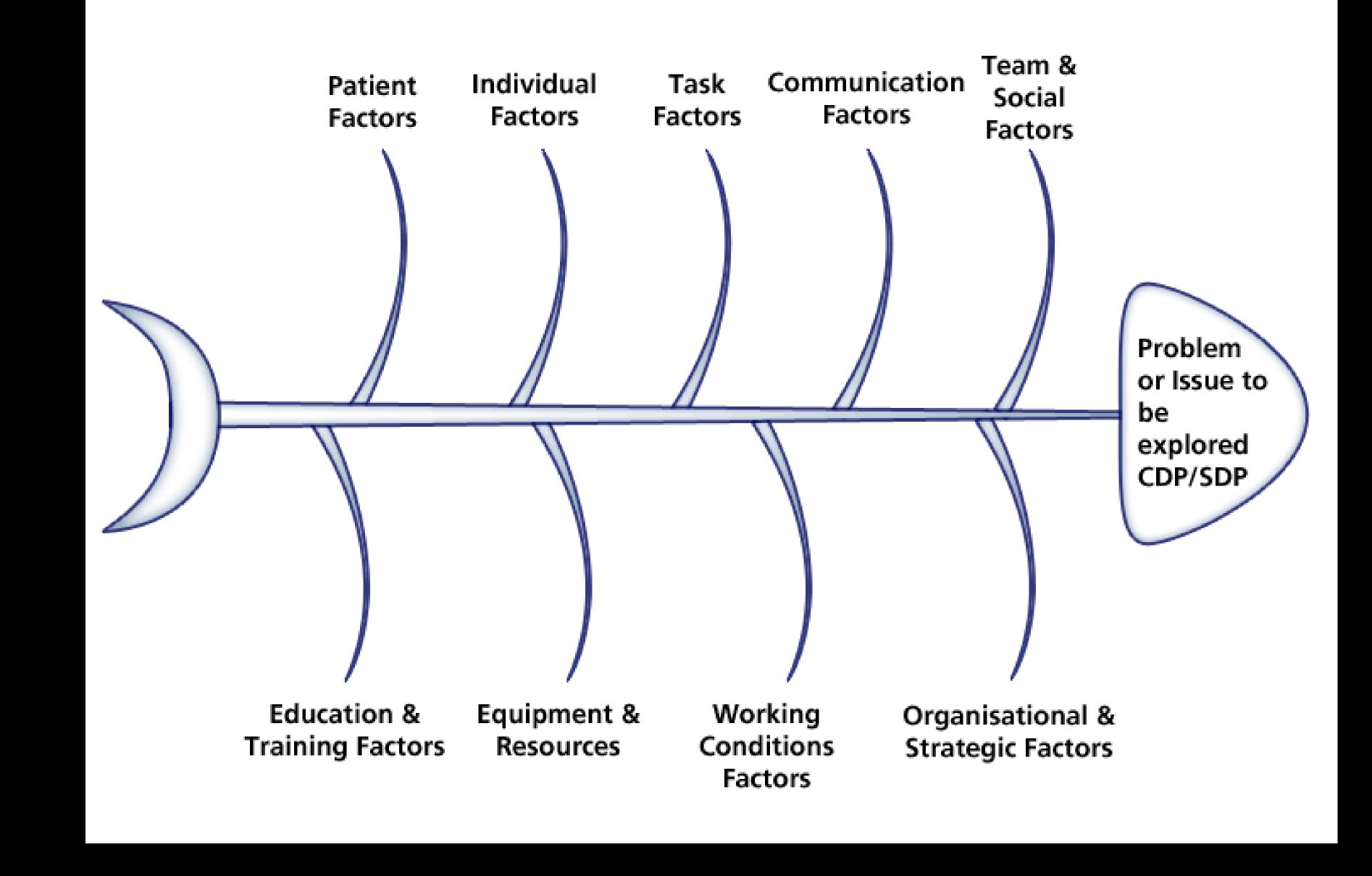


http://www.nrls.npsa.nhs.uk/resources/collections/root- cause-analysis/ .



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a culture that names, shames and blames those who make errors



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Dame cu ture



The Media

Seek to Blame



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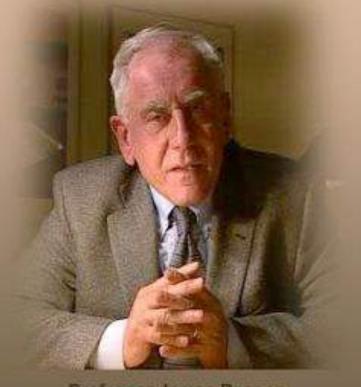
Who's to blame for this?







Reason's Swiss Cheese Theory



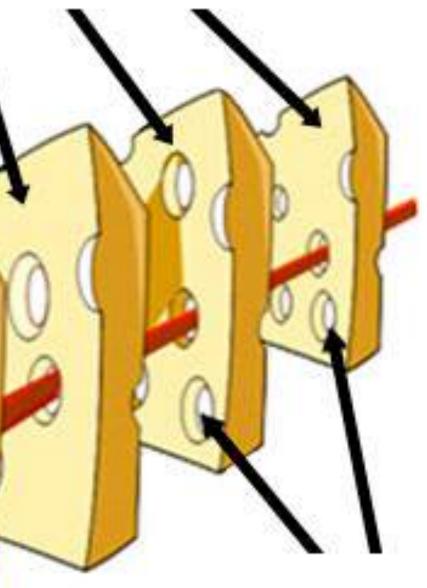
Professor James Reason

Active errors (Patient safety incident)



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Levels of defence



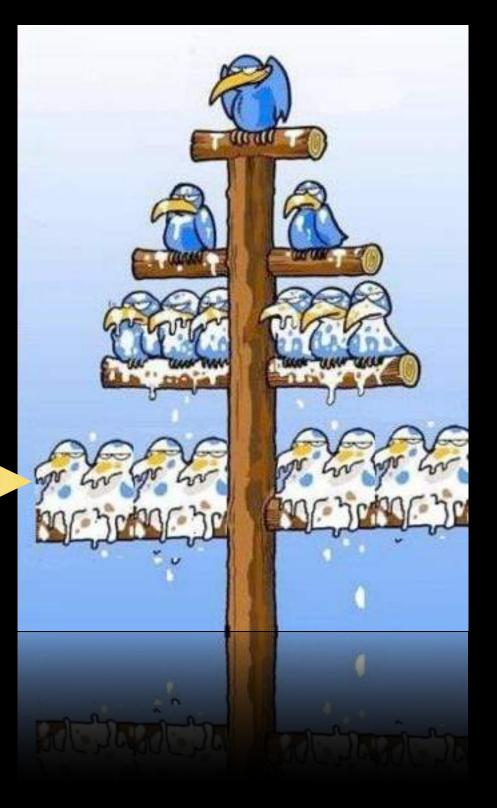
Latent conditions

poor design, procedures, management decisions etc.

(Patient safety incident) management decisions etc.



the surgical trainee





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Feel free to celebrate Boss's Day by blaming me for one of your many mistakes today













* II II + 14 mg



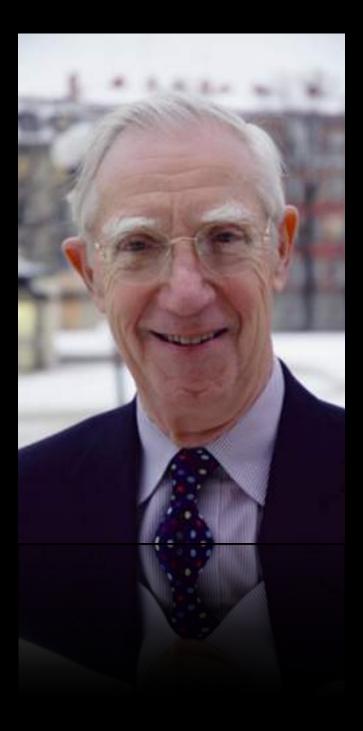
Blame makes people insecure nervous of contr ing over-cautious

Blame can lead to

defensive resistance to reporting errors harm to patients









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"The single greatest impediment to error prevention in the medical industry is that we punish people for making mistakes"

Professor Lucian Leape Testimony to US Congress 2009





Victims 1 St **2nd** 3rc



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initial numbness detachment de-personalisation the confusion confusion grief depression **Contraction Contraction Contract** agitation the flashbacks guilt anger self-doubt PTSD



Table 3. Personal and professional outcomes of an adverse event or a near miss (n=1,463).

Outcome	%	n
Lower confidence in ability as a doctor	63.2	886
Difficulty sleeping	59.9	840
Reduced job satisfaction	48.5	681
Affected relationships with colleagues	25.5	358
Damaged professional reputation	20.1	282
Other personal or professional outcomes	15.8	221
Anxious about potential for future errors	81.5	1,192
Generally distressed (eg depressed, upset or angry)	73.6	1,077
Generally anxious (eg nervous, panicky or tense)	68.0	995
Negative towards yourself (eg shame, guilt or feeling incompetent)	27.3	399
More confident in your abilities (eg feeling effective, efficient or competent)	7.5	110
Determined to improve (eg feeling determined, resourceful or strong)	80.6	1,179



Doctors' experiences of adverse events in secondary care: the professional and personal impact

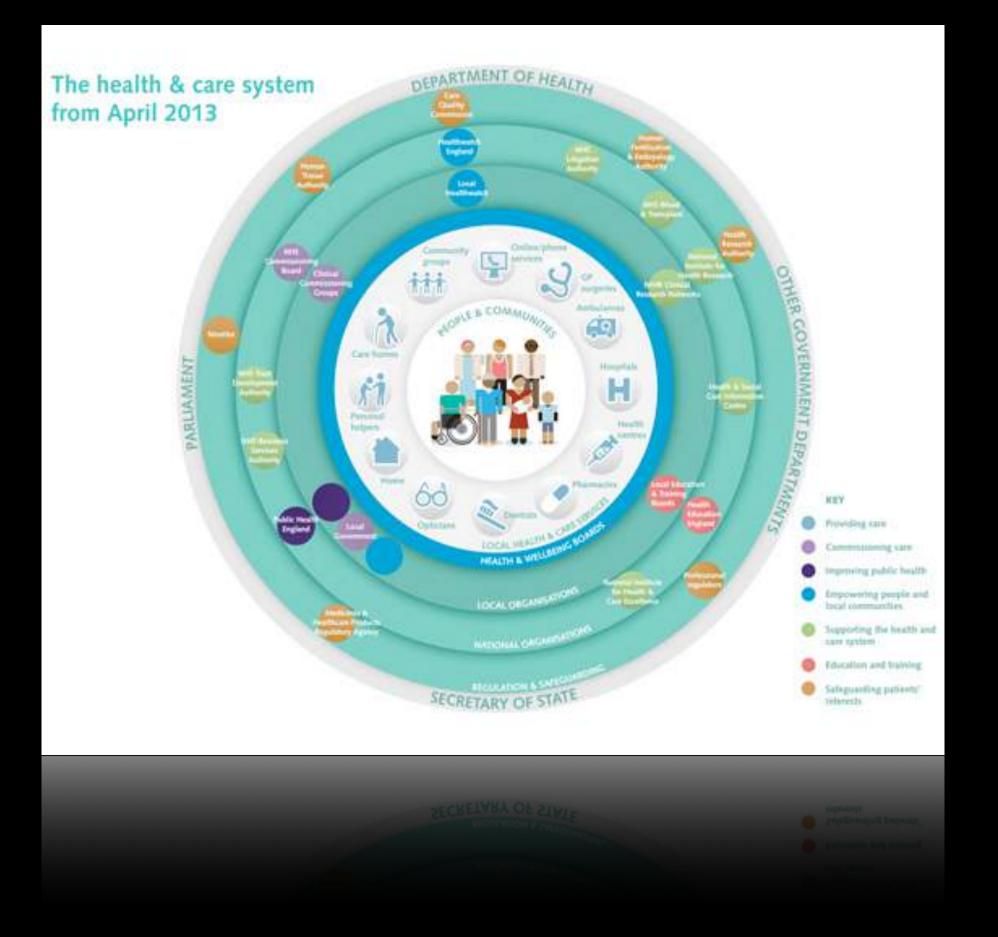
Clinical Medicine 2014 Vol 14, No 6: 585–90



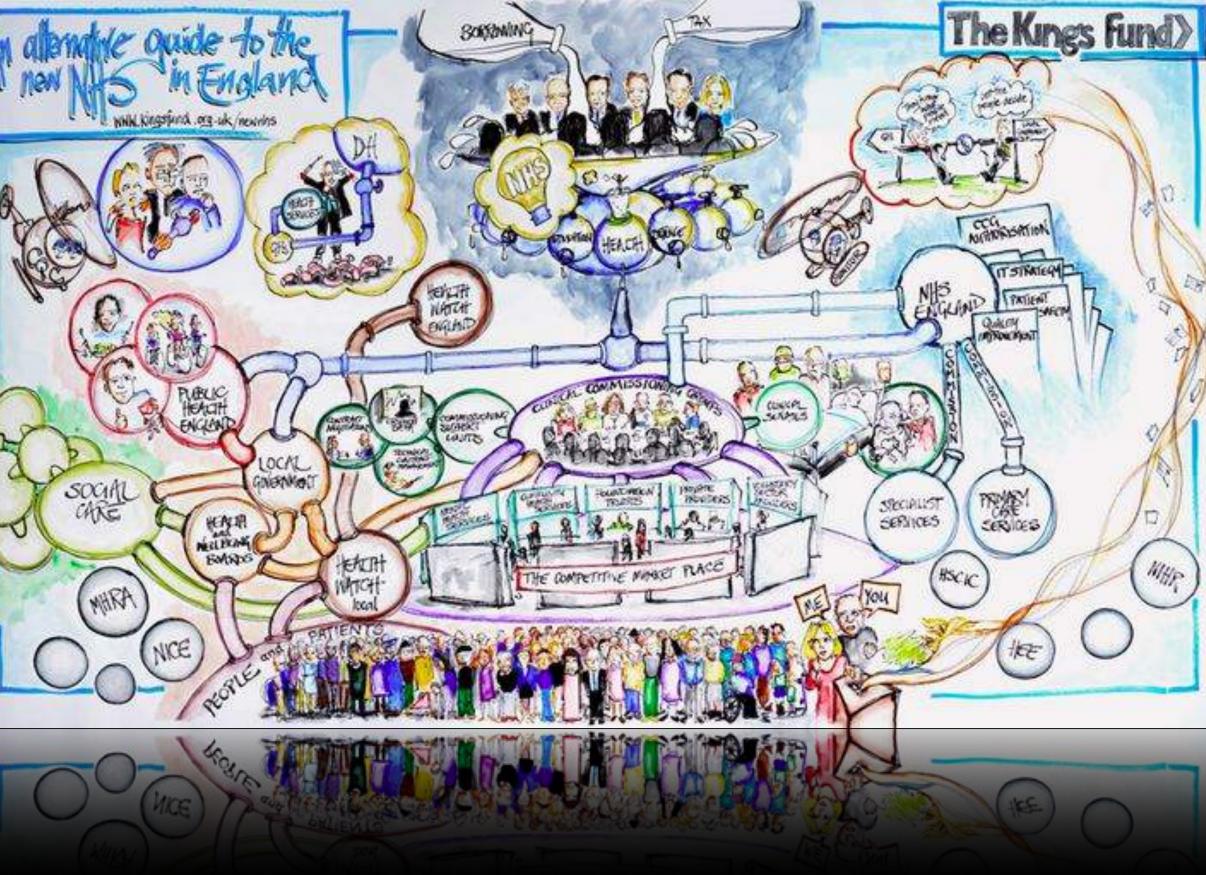




The NHS is extremely Complex











Reporting & Action

local commissioners

investigating trust

> other trust

other trust

other trust

will they change anything? how will we know?



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national commissioners

regulatory authorities

regulatory authorities

regulatory authorities



other

trust

martin.elliott@gosh.nhs.uk

other

trust



"That could never happen here!"



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Investigate Report Recommend ACt



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Compensate?

?



Moind's Fourth Postulate

The degree of certainty in one's level of competence IS

inversely proportional to the actual level.



In the NHS in England the only way you can get compensation is to take legal action by making a claim of medical negligence

Kennedy I, Grubb A. Medical Negligence. In: Kennedy I, Grubb A, eds. Medical Law. London: Butterworths, 2000:273-574.







- **civil rather than criminal proceedings**
- not enforced by police
- one party must sue another
- trials held before a judge, not a jury



a wrong must be done by someone to someone else



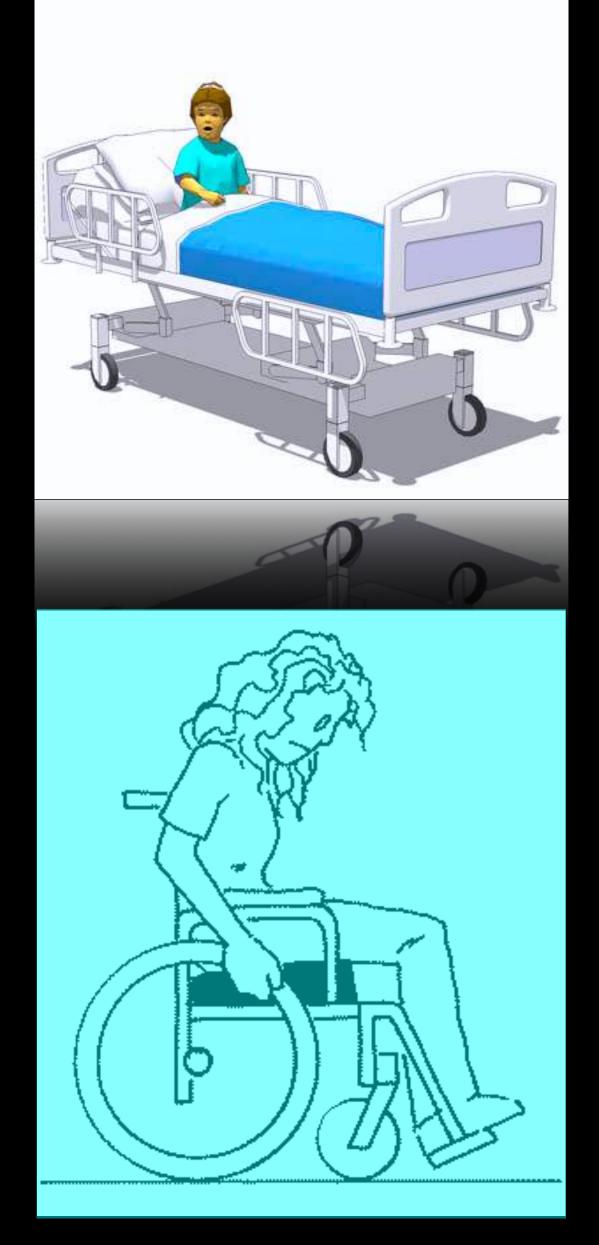
Motivations for Medico-Legal Action

- **RESTORATION,** including financial compensation or other intervention's make the patient whole again'
- CORRECTION, such as system change or competence review to protect future patients
- COMMUNICATION, which may include an explanation, expression of responsibility or apology
- SANCTION, including professional discipline or some other form of punitive action

Bismark M, Dauer E. Motivations for Medico-Legal Action - Lessons from New Zealand. J Legal Med 2006;27:55.





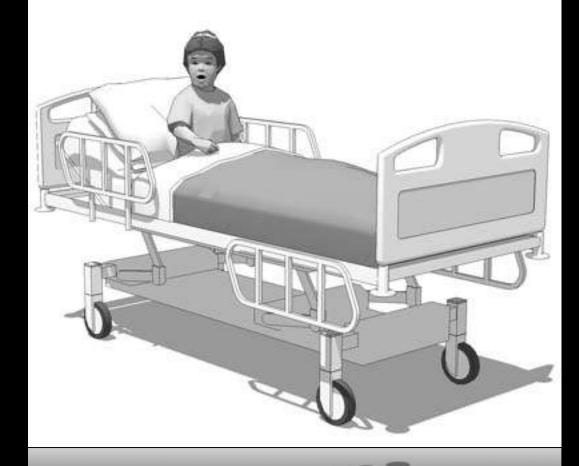


unfairness

negligent act







disease state



000



NHS Litigation Authority (NHSLA)



since 1990 has taken over responsibility for negligence attributable to its medical and dental staff in hospital and community services

NOT GPs, or those in private practice it does not cover referrals to GMC etc or criminal proceedings





for negligence to be proven, the following must exist:

- a duty of care
- a breach of that duty
- that breach causing material harm

Kennedy I, Grubb A. Medical Negligence. In: Kennedy I, Grubb A, eds. Medical Law. London: Butterworths, 2000:273-574.

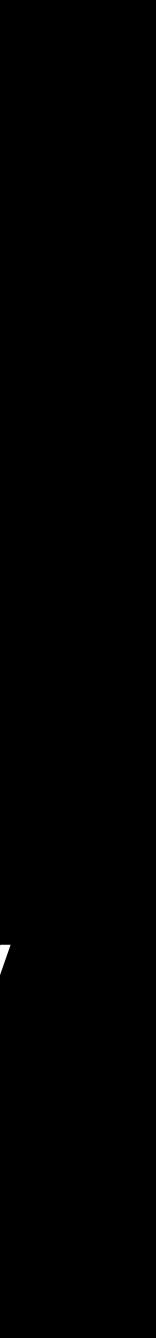


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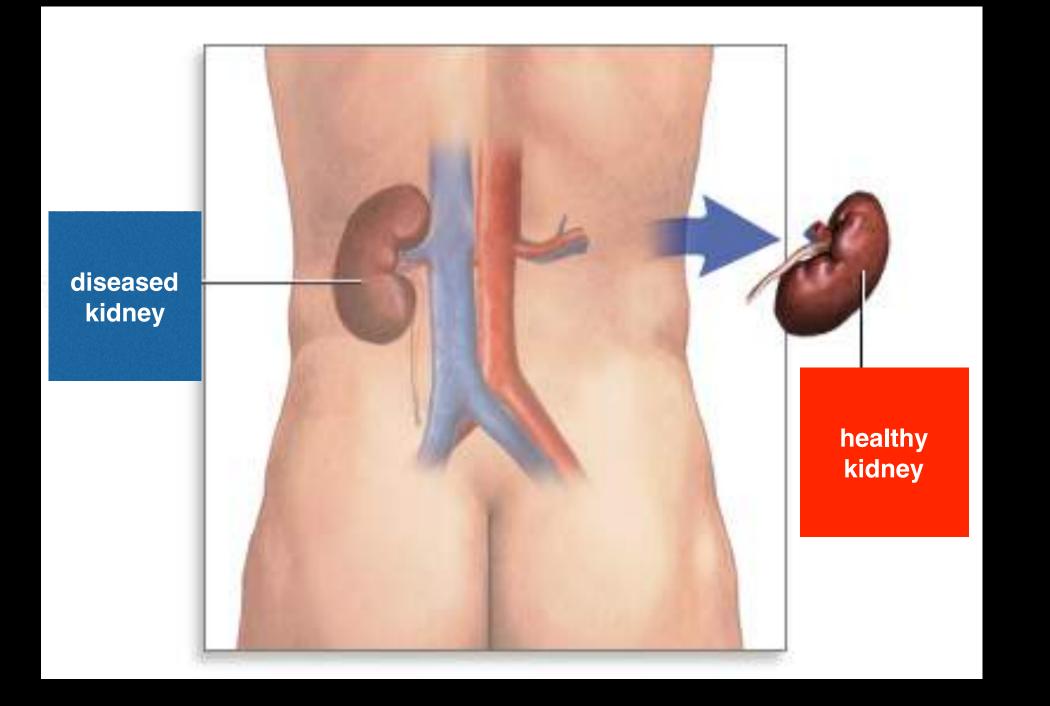
the harm must not be remote (in time) from the breach of duty



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Breach of Duty



the judge's ability to determine if a breach has occurred will depend on the views of expert witnesses



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brain damage after heart surgery





The Bolam Test

Bolam v Friern Hospital Management Committee: 1957, 1 WLR 582, 587

If a doctor reaches the standard of a responsible body of medical opinion, he is not negligent

The Bolitho Case

Bolitho v City and Hackney Health Authority: 1997, 4 All ER 771

The judge should be able to choose between two bodies of expert opinion, and to reject an opinion which was 'logically indefensible"





the evidence





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TYPE 3	THE "EVERY - OTHER - WORD - MAKES - SENSE"
TYPE 4	THE INTOXICATED - OR PROBABLY JUST ON PERCON
TYPE 5	THE DEBONAIR SANSKRIT-OR IS HOPING THE PHAR
TYPE 6	THE DR. HOUSE – HOW CAN I PISS OFF THAT WALGR



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-MEDSCHOOLGUNNER.COM -MEDICALHUMOR.WORDPRESS.COM



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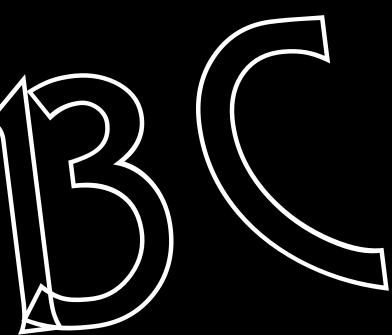
intuitive - pattern recognition



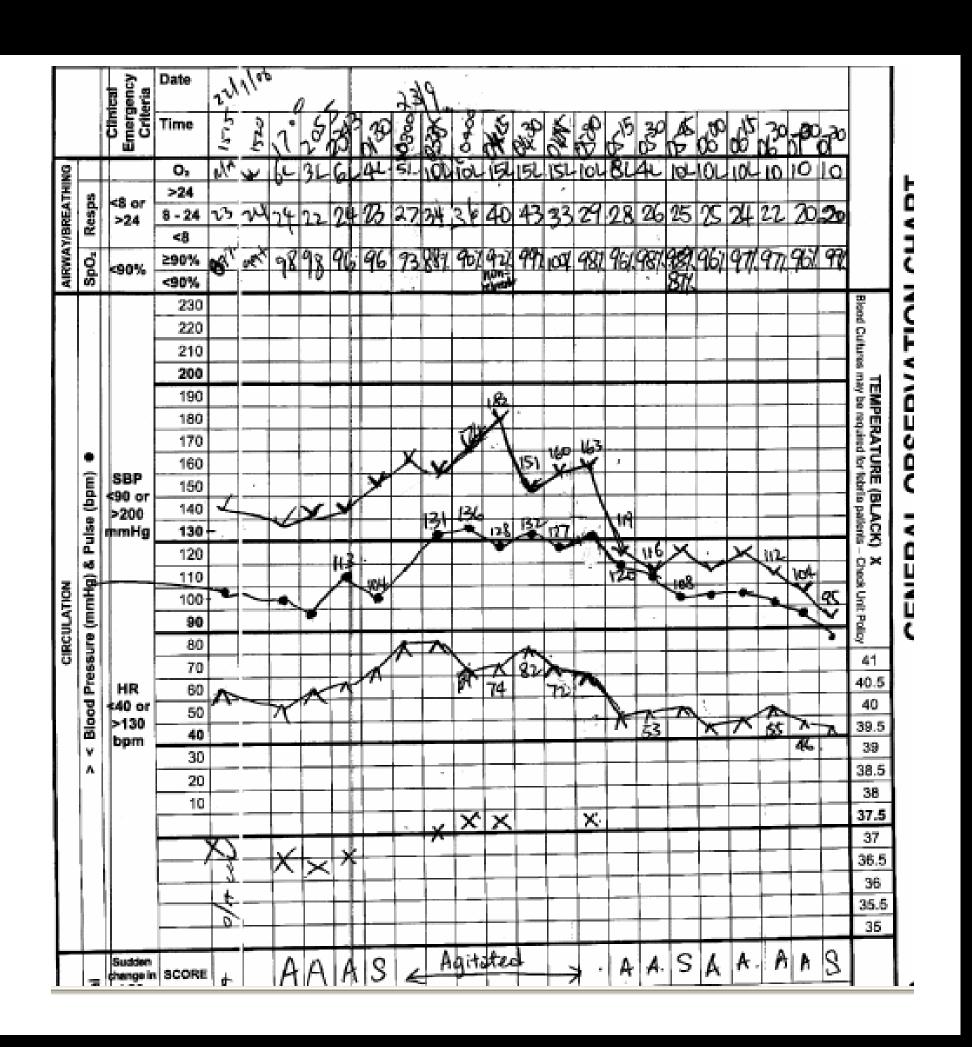




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Copying, on an industrial scale





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Electronic Medical Record

the lost narrative

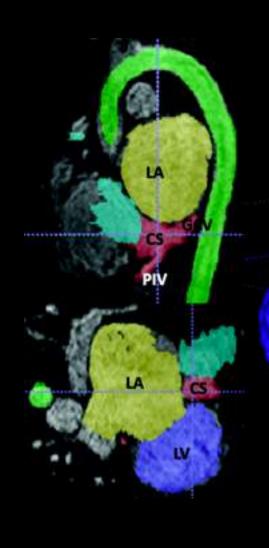
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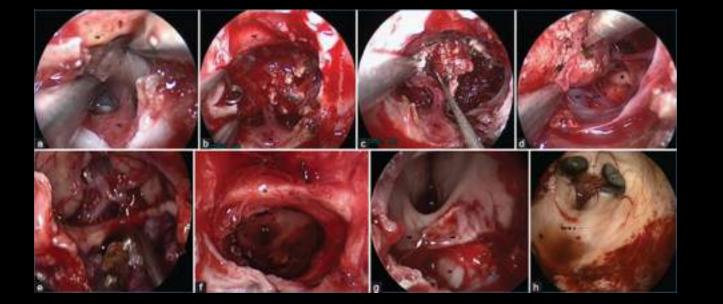




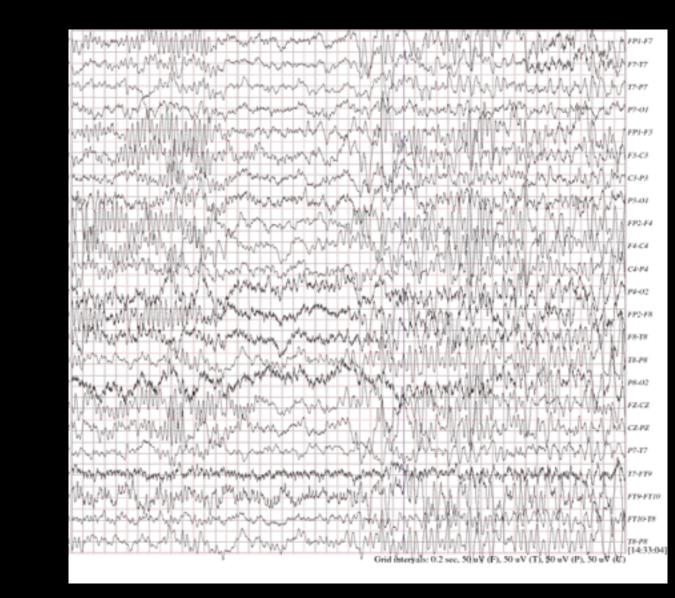


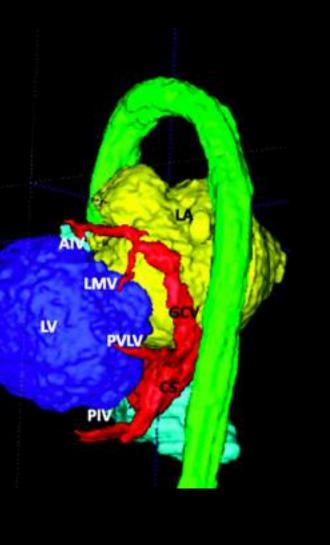


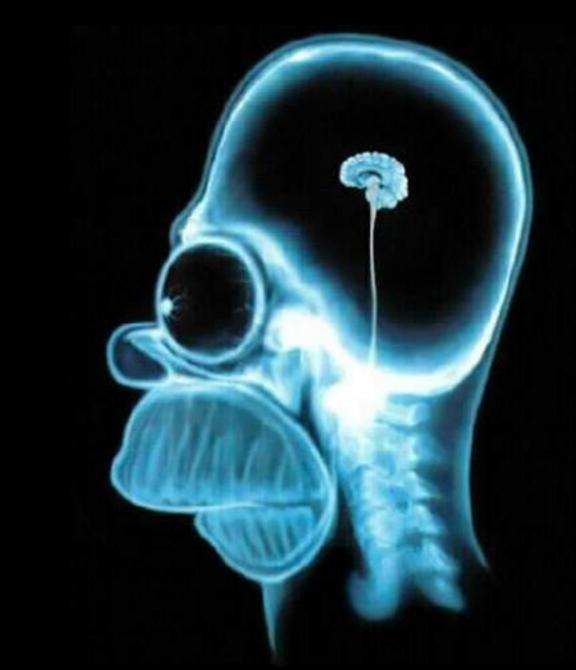
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White blood cell count	8.30	6.70	10.30	11.10	8.70	8.30	8.40	11.70	9.10	8.20	3.8-10.8
Red blood cell count	4.56	4.26	4.39	4.45	4.39	4.62	4.49	4.70	4.40	5.07	4.2-5.8
Hemoglobin	16.20	15.00	15.60	15.60	15.60	16.40	16.00	15.90	15.00	15.50	13.2-17.1
Hematocrit	48.90	45.00	46.60	46.00	45.90	48.70	46.30	47.00	42.30	46.40	38.5-50.0
MOV	107.30	105.60	106.10	103.40	104.50	105.40	103.20	100.00	96.10	91.50	80-100
MCH	35.60	35.30	35.40	35.10	35.50	35.60	35.80	33.80	34.10	30.50	27-33
MCHC	33.20	33.40	33.40	34.00	33.90	33.80	34.60	33.80	35.50	33.30	32-36
RDW	24.00	22.50	21.90	20.80	19.40	18.30	16.50	14.10	15.50	15.30	11.0-15.0
Platelet count	281.00	182.00	302.00	302.00	239.00	242.00	284.00	323.00	386.00	304.00	140-400
Glucose	144.00	103.00	100.00	79.00	93.00	78.00	80.00		94.00	87.00	65-99
Absolute Neutrophils Absolute	6242.00	4945.00	8 106.00	8381.00	5672.00	5212.00	5552.00			01.00	1500-7800
Lymphocytes	1552.00	1253.00	1751.00	1943.00	2445.00	2415.00	2184.00				850-3900
Absolute Monocytes	465.00	482.00	402.00	677.00	479.00	564.00	554.00				200-950
Absolute Eosinophils	25.00	7.00	21.00	78.00	87.00	83.00	76.00				15-500
Absolute Basophils	17.00	13.00	21.00	22.00	17.00	25.00	34.00				0-200
Neutrophils %	75.20	73.80	78.70	75.50	65.20	62.80	65.10		64.00	67.00	
Lymphocytes%	18,70	18 70	17.00	17.50	28,10	29.10	26.00	25.00	25.00	22.00	
Monocytes	5.60	7.20	3.90	6.10	5.50	6.80	6.60	11.00	9.00	8.00	
Ecsinophils %	0.30	0.10	0.20	0.70	1.00	1.00	0.90	1.00	1.00	2.00	
Basophils %	0.20	0.20	0.20	0.20	0.20	0.30	0.40	0.00	1.00	1.00	
Creatinine	0.78	0.66	0.66	0.70	0.88	0.80	0.73		0.80	0.80	0.76-1.46
Sodium	135.00	137.00	137.00	137.00	138.00	140.00	142.00		137.00	140.00	135-146
Potassium	4.10	4.00	420	3.90	3.80	3.70	4.30		4.00	3.80	3.5-5.3
Chloride	96.00	100.00	100.00	100.00	100.00	98.00	101.00		105.00	101.00	98-110
Carbon Dioxide	24.00	24.00	26.00	24.00	26.00	28.00	26.00		29.00	21.00	21-33
Calcium	8.60	8.90	9.00	8.90	9.00	9.20	9.00	9.50	9.20	9.50	8.6-10.2
Protein	6.80	7.00	7.00	6.70	6.60	6.80	7.10		6.90	7.20	6.2-8.3
Albumin	3.90	3.70	4.10	4.10	4,10	4.10	4.00		3.10	3.40	3.6-5.1
Globulin	2.90	3.30	2.90	2.60	2.50	2.70	3.10		3.80	3.80	21-37
AST	22.00	35.00	18.00	27.00	28.00	27.00	34.00		27.00	49.00	10.0-35.00
ALT	42.00	46.00	32.00	25.00	24.00	23.00	23.00		18.00	21.00	9.00-60.00
BUN									5.00	6.00	7.00-25.00



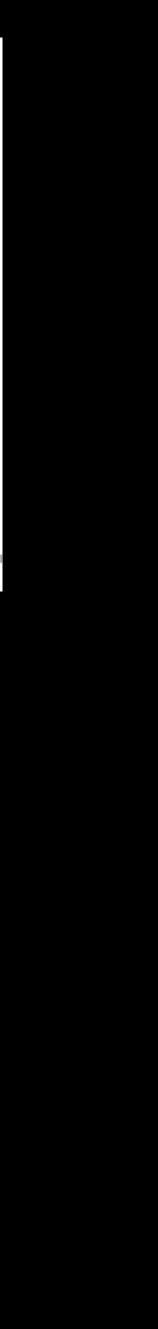


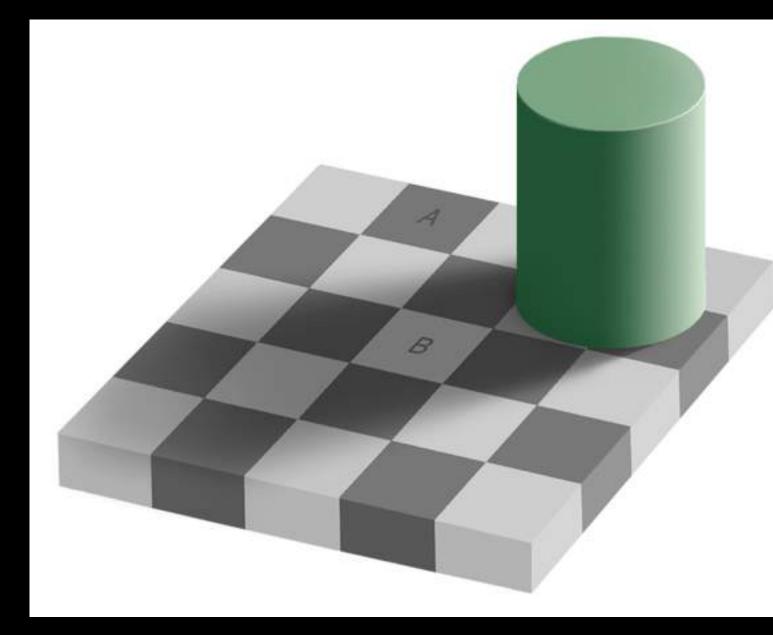








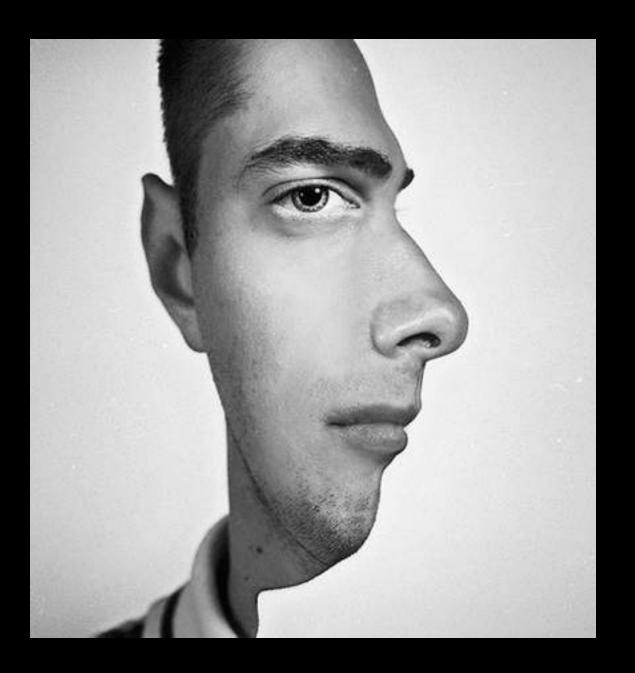




is what we see correct?



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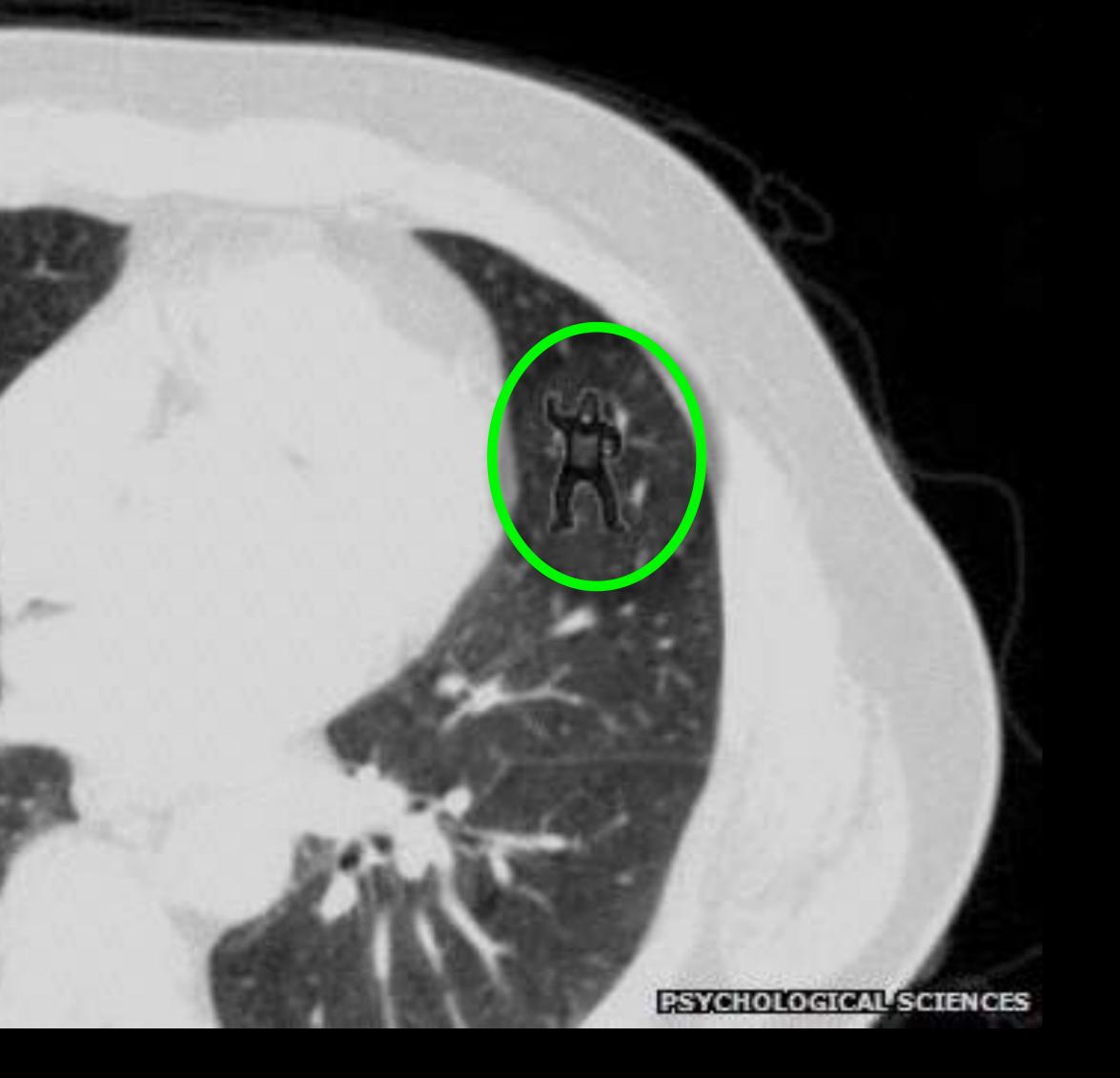




TUMOUR



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a clinician takes risk & makes decisions (many) under pressure

a lawyer analyses risk & decisions at leisure



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Deciding without Data

Jeffrey R. Darst, MD^{1,*}, Jane W. Newburger, MD, MPH¹, Stephen Resch, PhD², Rahul H. Rathod, MD¹, and James E. Lock, MD¹

¹ Department of Cardiology, Children's Hospital Boston and Department of Pediatrics, Harvard Medical School, Boston, Mass, USA

² Department of Health Policy and Management, Harvard School of Public Health, Boston, Mass, USA



Congenit Heart Dis. 2010 ; 5(4): 339–342.



The basis of doctors' decisions

Table 1

Decision Definitions

- 1. Arbitrary/instinct: Multiple options are present, but one is chosen without a clear cut reason in mind; decision not attributable to the 9 categories below.
- 2. Avoid a lawsuit: Done without definable value to the patient; for documentation only.
- 3. Experience/anecdote: Based on a memory of one or more cases; if specific cases cannot be recalled, the decision may be arbitrary.
- 4. Trained to do it: Taught by a more senior or experienced colleague.
- 5. First principles: Things we know to be true, physiology-based.
- 6. Limited study: Case reports, small series.
- 7. General studies: *Can be related* to the question at hand.
- 8. Specific studies: *Expressly addresses* the question at hand.
- 9. For research: Anything done primarily out of curiosity or to learn something about the patient or the disease.
- 10. **Parental preference**: An otherwise arbitrary decision that is swayed by parent input.





Table 2

Basis of Decisions

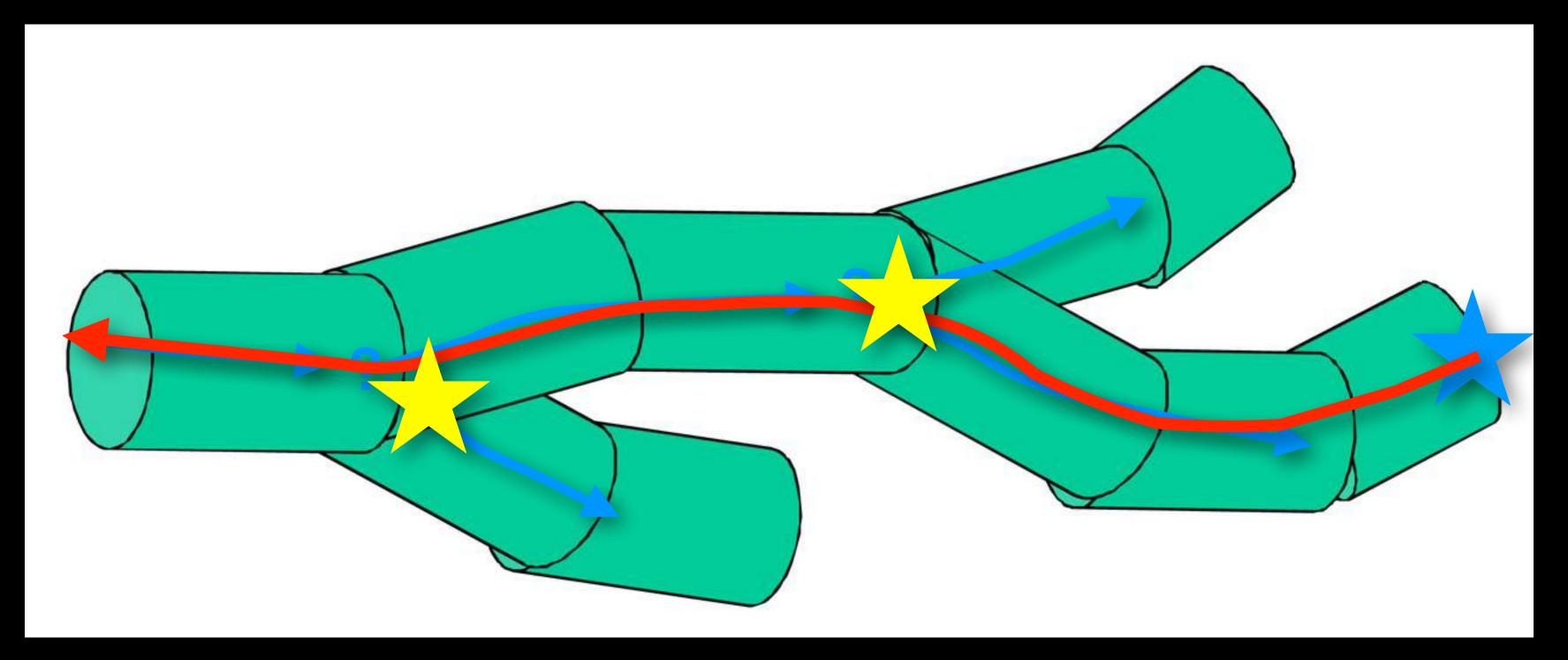
	Number of Decisions [*]	% of Total
Experience/anecdote	441	37.1%
Arbitrary/Instinct	175	14.7%
Trained to do it	173	14.6%
General study	146	12.3%
First principles	146	12.3%
Limited study	61	5.1%
Specific study	34	2.9%
Parental preference	6	0.5%
For research	4	0.3%
Avoid a lawsuit	2	0.2%





Decision Making

The Retrospectoscope





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The Wisdom of the Law

"Judges are the most pragmatic of ethicists, combining law and ethics to arrive at a concrete answer. They cannot sit on the fence.

There is much about practical decision making that doctors and ethicists can learn from them."

"What evidence do I have for this?"

Sokol DK BMJ 2013;347



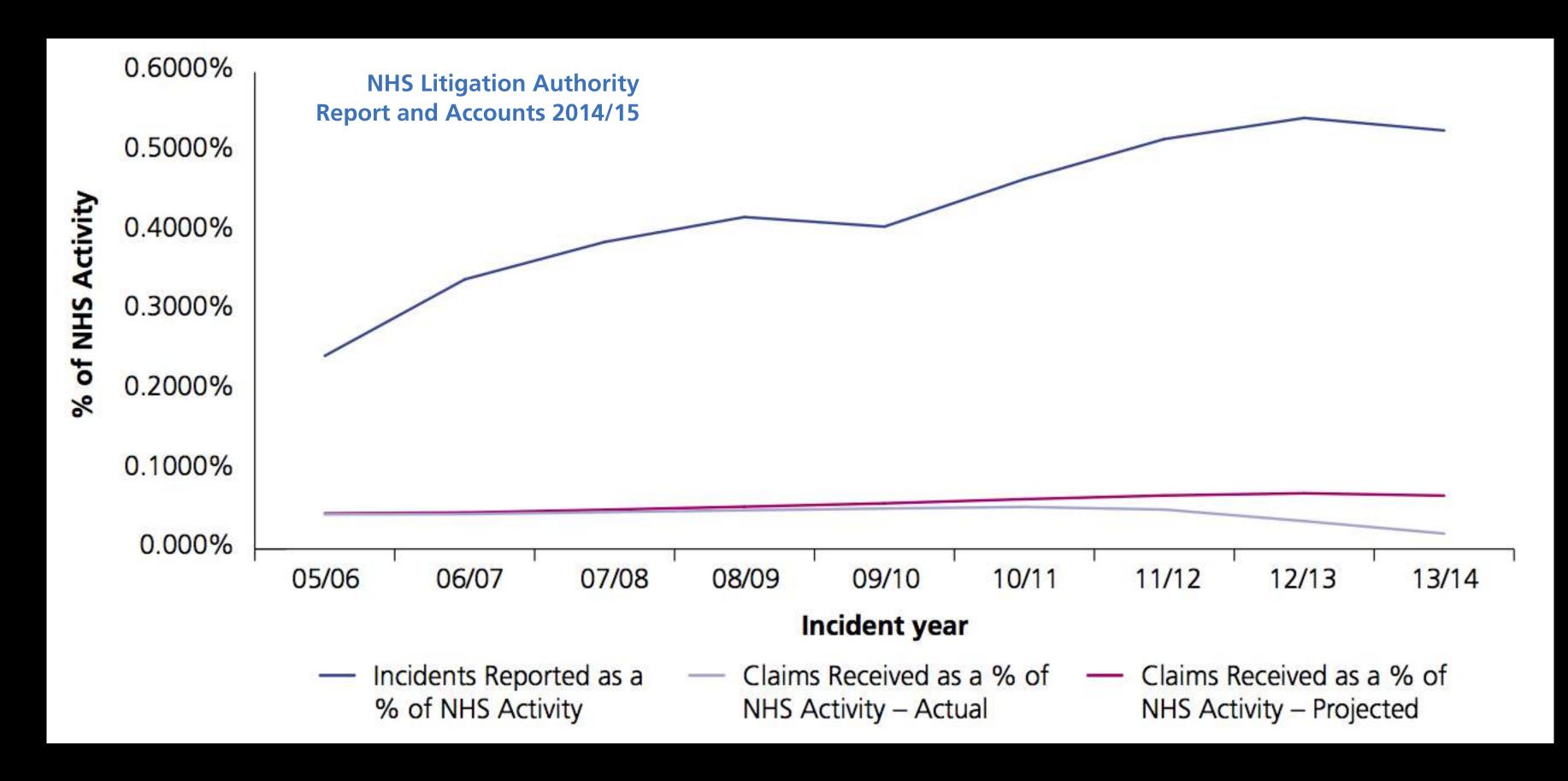




The NHSLA is supposed "to minimise the overall costs of clinical negligence...to the NHS, and thus maximise the resources available for patient care, by defending unjustified actions robustly and settling actions efficiently"





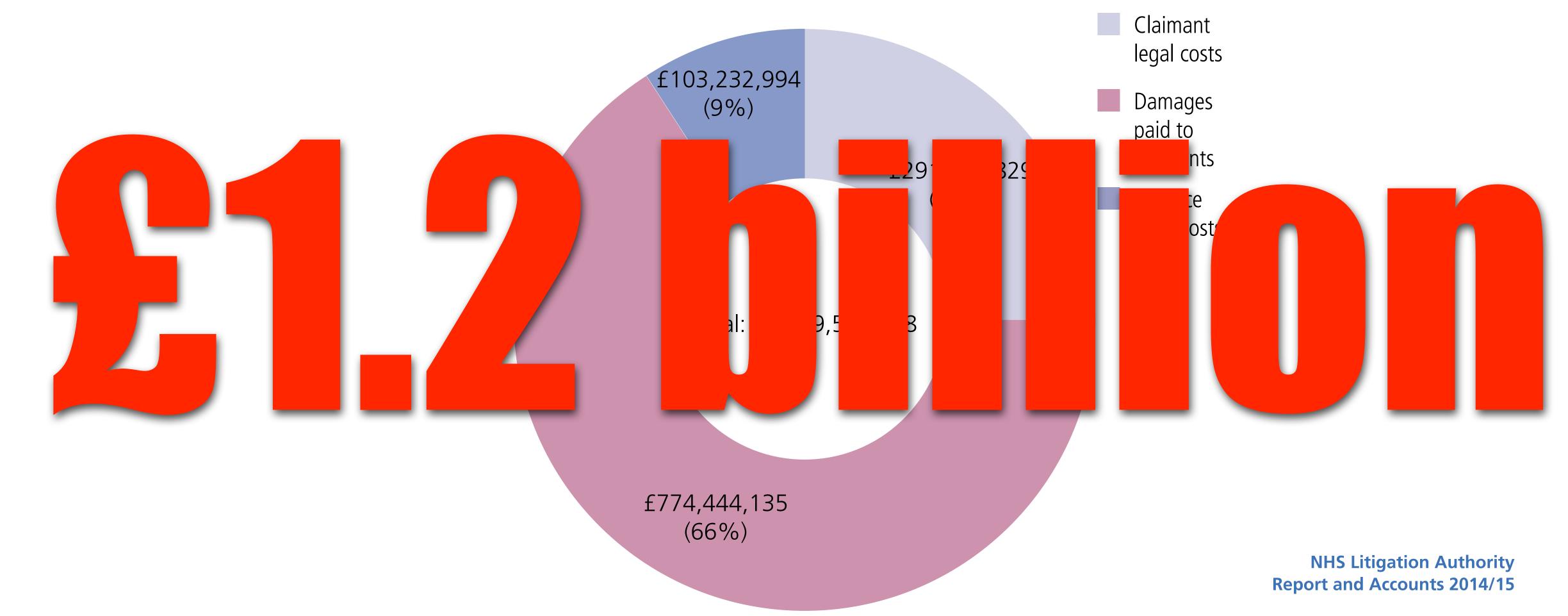


negligence claims made in \approx 0.05% of NHS activity

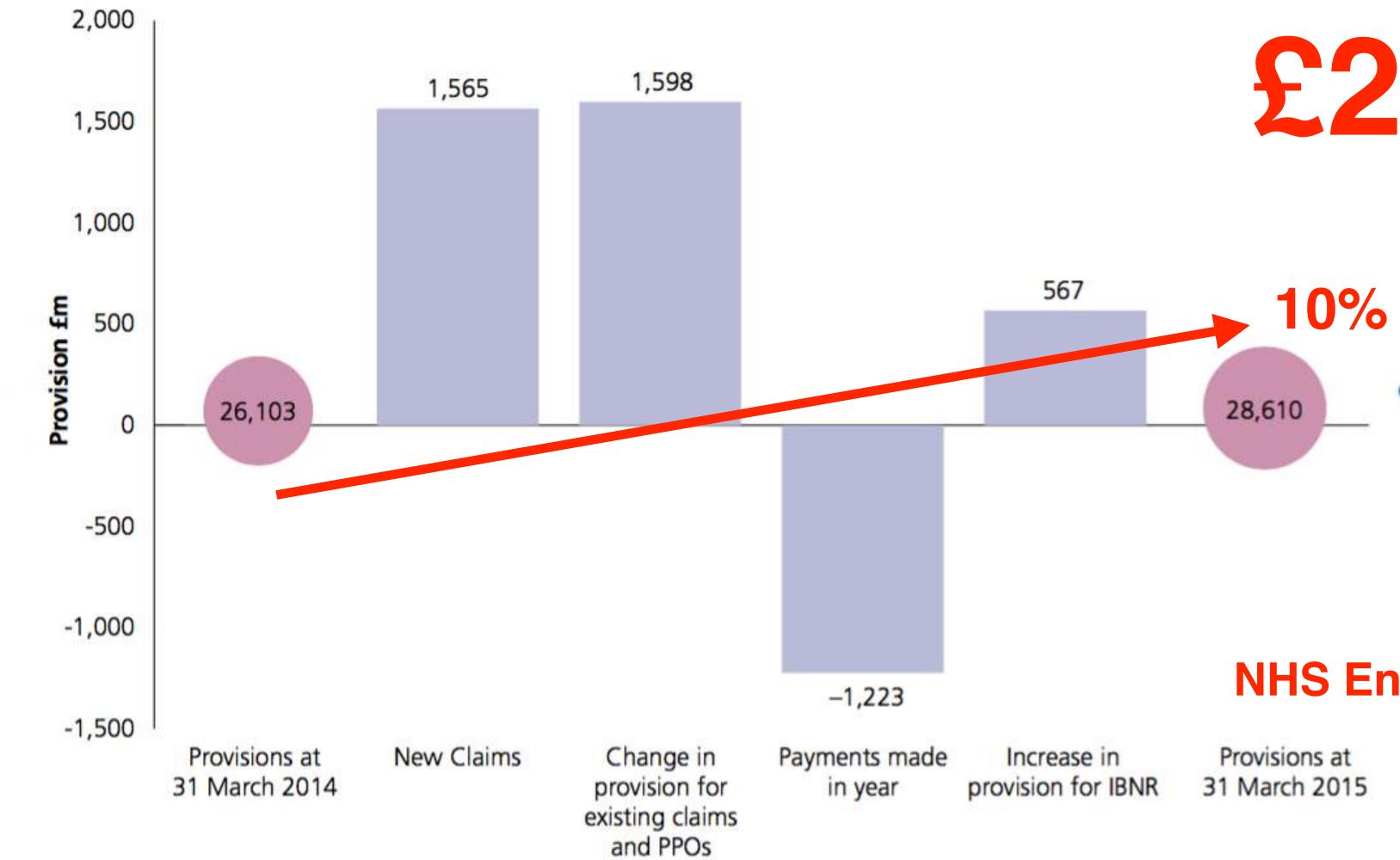




Figure 11: Clinical negligence expenditure including interim payments 2014/15



Amount Set Aside for Claims by NHSLA 2014/15



£28.6 billion



NHS England Commissioning Budget

NHSLA Annual Report 2014-15 NHS England Annual Report 2014-15



Lecal Costs $n_{20}/4/5$ were £300m

excluding costs met by claimants themselves or the Legal Services Commission



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NHS Litigation Authority Report and Accounts 2014/15





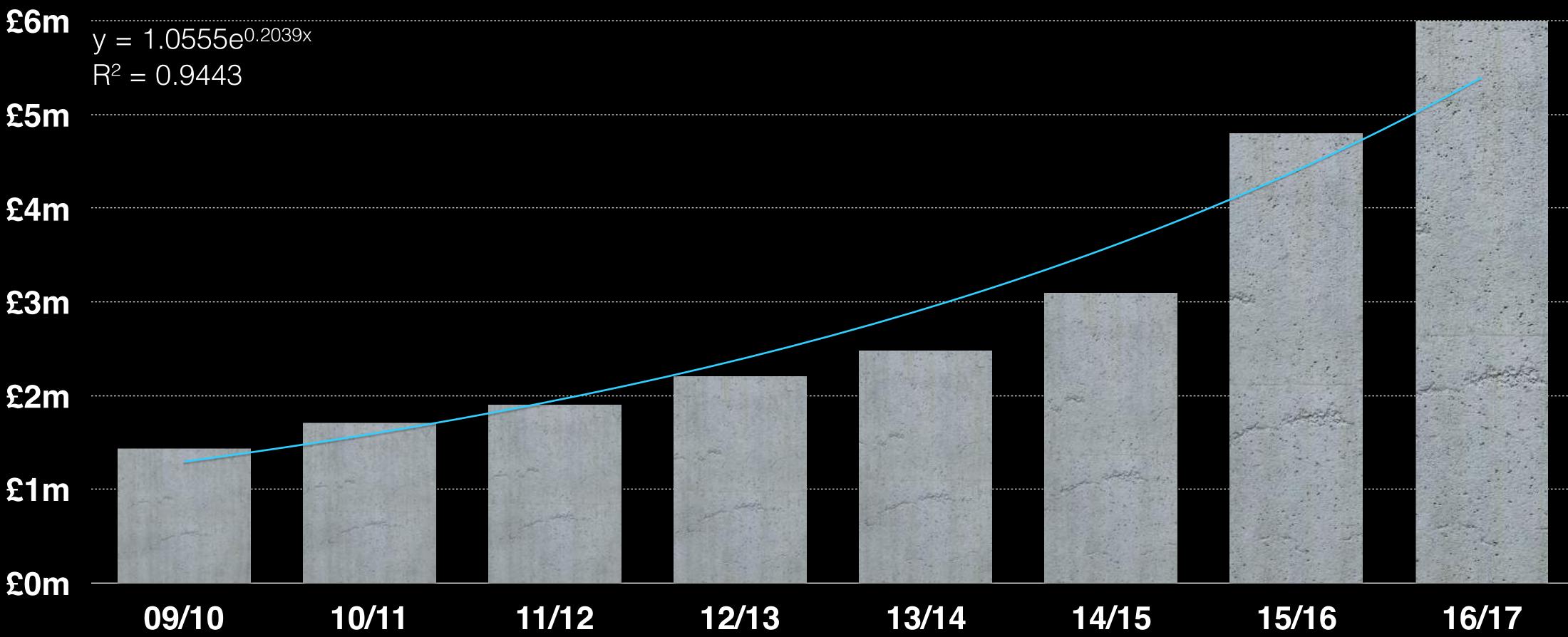
Trusts pay 'contributions' to the Clinical Negligence Scheme for Trusts (CNST), part of the NHSLA

Total to be Collected in CNST scheme for 16/17 is £1,659m a 17% increase on 15/16





Annual Clinical Negligence Cover Premiums at GOSH



CNST contribution calculated as weighted avg of 3 elements: risk based related to staffing and activity levels; previous 5y claims experience; known outstanding claims





Professional Indemnity Schemes





The NHSLA does not cover GPs, or those in private practice. Nor does it cover referrals to GMC etc or criminal proceedings.



Professional Indemnity **Expensive**

£10s of thousands per year out of take home pay in 30 years as a paediatric cardiac surgeon I have paid >£500,000 have yet to need it







14% of doctors appearing before the GMC do not have indemnity cover





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personal communication, Prof Terence Stephenson





Legal Costs for the Claimant are High



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50% of claim value for claims <£100,000

legal aid is no longer available for medical negligence cases





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www.claims.co.uk > ... > Common Medical Negligence Questions -However, most other solicitors in the UK do not offer their services on a no win no fee basis for medical negligence claims. POPULAR QUESTIONS:.



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Medical Malpractice



The life-long costs of harm can be enormous



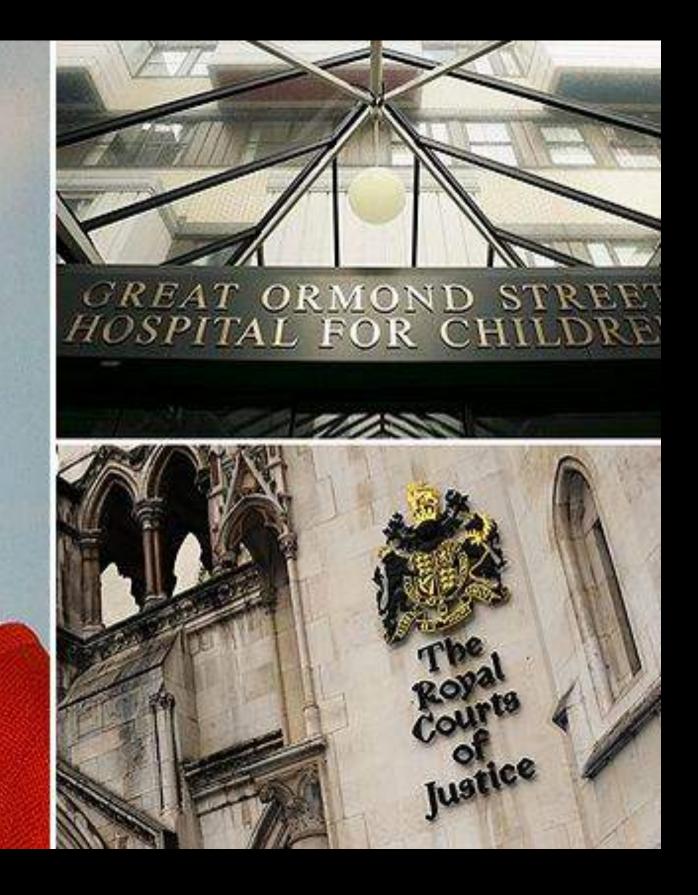
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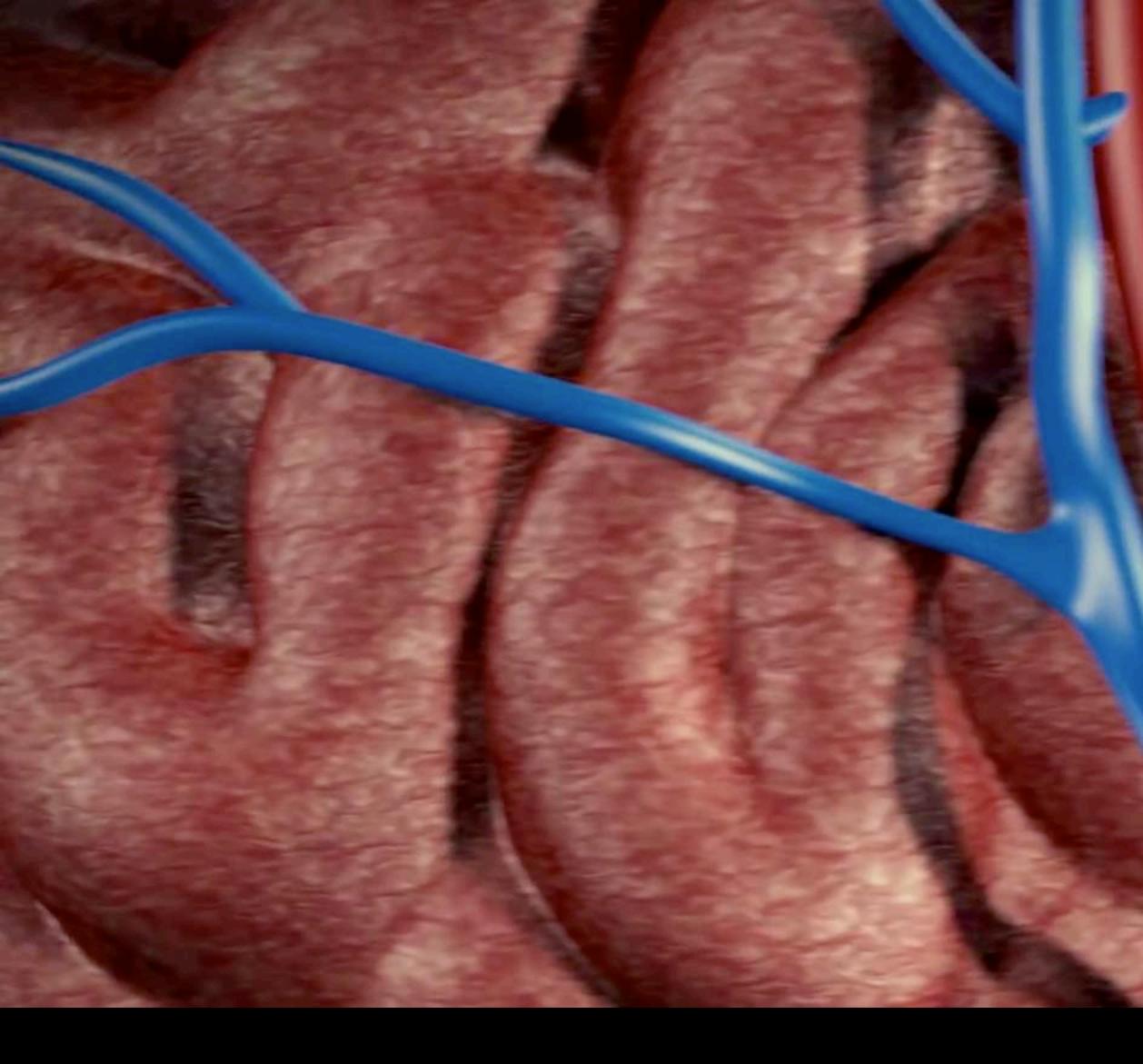




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Dye Glue



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Glue Dye





severe brain damage life-long, 24/7 care



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Cost to NHSLA will be £24,000,000



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the case took four years



the operator





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2003, Liam Donaldson, CMO

complex unfair slow costly unsatisfactory for families encouraging defensiveness and secrecy

"an asymmetric system damaging the doctors and hospitals with out significantly benefitting the patient/victim"

Keren-Paz, Medical Law Review;2010;18(3);363



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Making Amends, proposals to reform clinical negligence in the NHS







- Donaldson proposed a fast-track negligence system
- dealing with compensation, but also correction and communication
- developed into the NHS Redress Act of 2006
 - compensation, explanation, apology & report of action
 - but, waiver of the right to sue
 - consensual, not judicial, process during which legal rights suspended







- secondary legislation not passed
- no political will to introduce it
- left with the 'asymmetric system'
- and a system of litigation which encourages physicians and

Studdert DM, Brennan TA. No-Fault Compensation for Medical Injuries: The prospect for error prevention. JAMA 2001;286:217-23.



Making Amends

institutions "to cloak themselves in confidentiality, forgoing opportunities to learn from problems that lawsuits can sometimes help to illuminate"



No-Fault Compensation

- all schemes have eligibility & threshold criteria
- limitations on extent of cover, & caps on compensation
- lower compensation levels than tort-based systems
- access to courts usually restricted
- comprehensive social welfare/insurance system in place 0



no need to prove negligence to be eligible for compensation



New Zealand Trust in the System

for levy payers for clients



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60% 76%



Why not here in England?



- the size of the population, and its growth rate
- the cost of establishment, and size of, the necessary fund
 - current political drive to reduce size of welfare state
 - lack of belief that 'no-fault' will influence behaviour





If the current system too costly and disliked, & no-fault schemes are unaffordable, what else can we do?



Cap Fees and Compensation

- (MICRA)
 - reduced lawyers 'billable hours' •
 - reduced length of trials •
 - reduced defensive medicine (5-9% reduction in healthcare costs) •
- ullet
- not included in recent Obama-care reforms

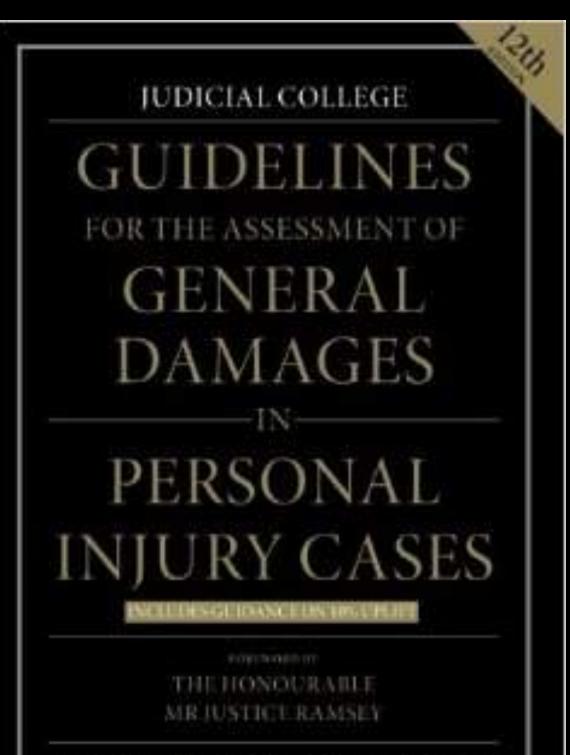


has worked in California (Medical Injury Compensation Reform Act)

proved impossible to spread across USA because of right to jury trial







PUBLISHED BY OXFORD UNIVERSITY PRES

- no punitive damages
- defined categories of payment for specific 'injuries'
- reviewed and published regularly by the Judicial
 - College, as The Guidelines for The Assessment of
- General Damages 'for pain, suffering and 'loss of
- amenity'
- money recoverable from NHSLA or the plaintiff

Tetraplegia \approx £230,000 to £285,000, *in addition* to life-time costs



Caps in England

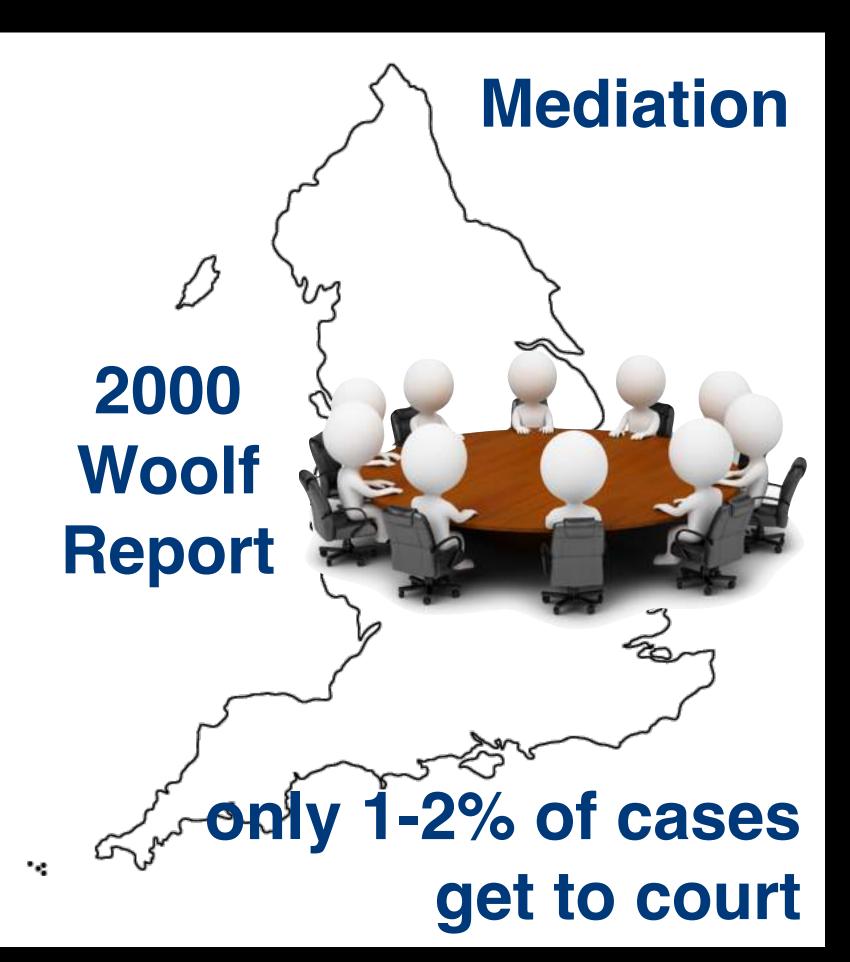


Alternative Dispute Resolution early apology mediation arbitration

mediation worked in Drexel & Pittsburgh, with successful resolution in 85% arbitration cases acrimonious and expensive physicians fear of NPDB









Health Courts

An attempt in the USA to use tribunals before medically 'savvy' judges or tribunals , rather than juries.

Constitutional objections related to right to jury trial

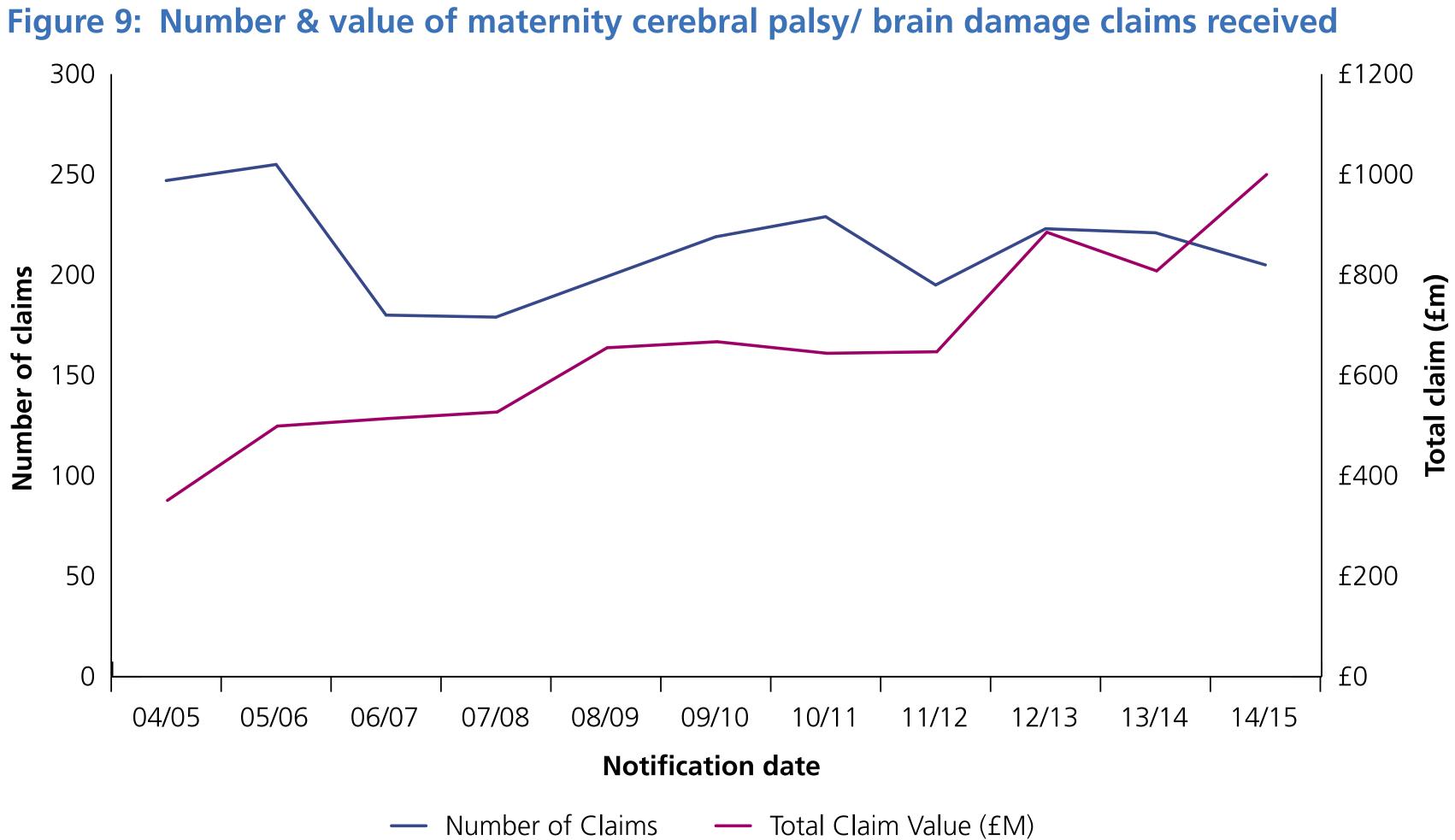
Supreme Court still to adjudicate



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Is Litigation Changing Behaviour?



Maidstone and Tunbridge Wells NHS Trust Caesarean death 'avoidable'

() 13 January 2016 Kent



The death of a woman just hours after a Caesarean birth was wholly avoidable, a court has heard.

Frances Cappuccini, 30, suffered heavy bleeding at Tunbridge Wells Hospital on 9 October 2012 and was operated on but never woke from the anaesthetic.

Inner London Crown Court heard she died after going into cardiac arrest.

Dr Errol Cornish denies manslaughter by gross negligence, while the Maidstone and Tunbridge Wells NHS Trust denies corporate manslaughter.

It is the first time an NHS trust has been charged with corporate manslaughter since the offence was introduced in 2008.



Local Prevention **Reduce Errors at Source**

some things ARE worthy of blame



- Most errors are committed by good, hardworking people trying to do the right thing at the right time
 - Everyone makes errors
- Repeating an error, or allowing errors to escalate is not good





JUST Culture people encouraged (rewarded) for reporting error, but clear accountability

Learning Culture

willingness and competence to use safety data to reform

The Components of Safety Culture: Definitions of Informed, Reporting, Just, Flexible and Learning Cultures



Safety Culture

Informed Culture

those who manage know all the factors (inc.human) which determine safety

Reporting Culture

people are prepared to report their errors and near misses

Flexible Culture ability to reconfigure in face of high tempo events or dangers

Based on *Reason (1997)*



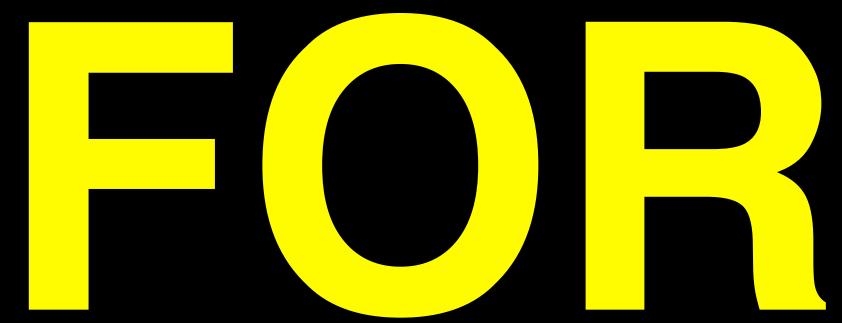
doctors don't like being told what to do



they don't feel 'employed'



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Performance Management of Doctors

- traditionally been 'weak' and peer enforced
- 2012 GMC Revalidation appraisal, 360 deg feedback and limited performance data
- signed of by Responsible Officer at each Trust
- "one of the most comprehensive, and ambitious schemes in the world"
- · BUT





Performance Management of Doctors within Units

- remains weak and lacks detail
- hard to discipline life-long colleague in a small team
- identification of repeat errors poor
- leads to big problems



repeat errors lead to big errors, low grade poor performance









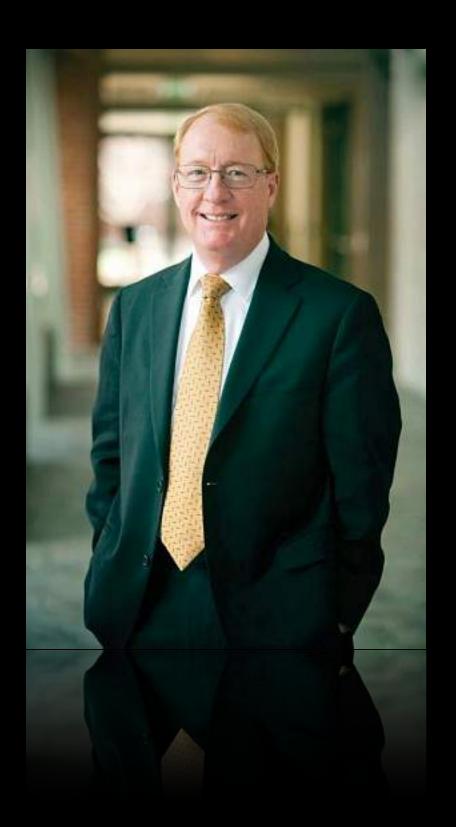
 washing hands reduces infection risk doctors often worst offenders • rarely > 70% hand washing rates

 everyone forgets occasionally • how do we identify the repeat offender? • what do we do about repeat offenders?

Wachter RM, Pronovost PJ. **Balancing "No Blame" with Accountability in Patient Safety.** NEJM 2009;361(14):1401-06.



Dr Gerald Hickson Vanderbilt University



2 to 8% of physicians per discipline are responsible for up to 30% of all malpractice claims

Hickson introduced regular risk assessments, and a series of 'difficult conversations'

"Our goal is to let some of our physician colleagues know 'you're driving 45 in a 30 mph zone, and we thought you'd want to know.""

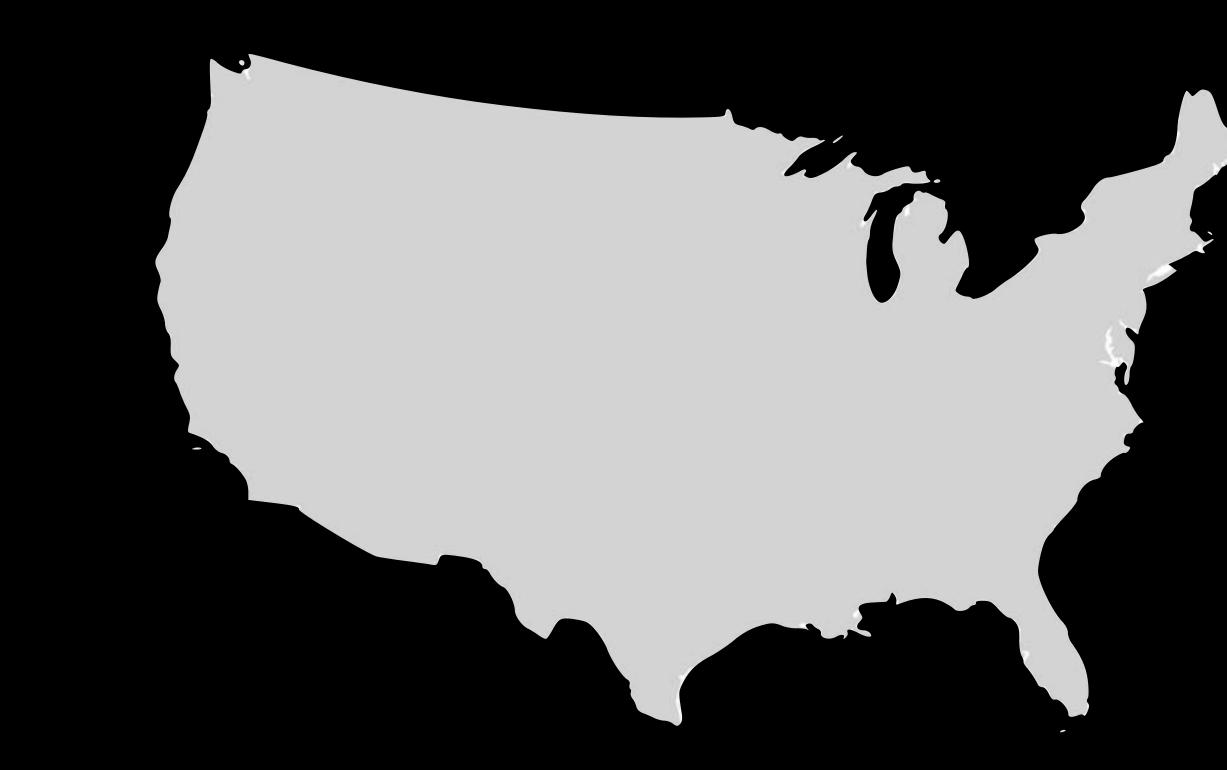
In 13 yr at Vanderbilt, ≈ 100 high-risk physicians have been identified

"70 have done well. 14 have departed, and the rest are getting 'additional assistance'"









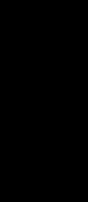
pay for performance (quantity & quality) contracts reviewed regularly tough appointment process





equal pay tenure from year 1 simpler appointment process











Two Tribes

















we all make errors

errors are frequent, negligence is not

harm + negligence = compensation

repeated errors are a warning

litigation is expensive, but 'shines a light'





no-fault compensation is fair and logical

no-fault compensation is ? too expensive

we should concentrate on LOCAL actions to reduce harm, cost and the repetition of error



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Defining the borders of "bad behaviours" (From P. Stastny Sixth GAIN World Conference, Rome, 18-19 June, 2002)



The second secon





A.C. Bradley (1851-1935) in a 1904 lecture on the Tragedies

"It all comes back to consequences."

"The irony of all this is that, ultimately, the tragic consequences of Hamlet's inaction are the multiple unintended deaths he causes."







JM Pressley 2013

