Safe medication practice – what can we learn from root cause analysis and related methods?

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DIA DEVELOP INNOVATE ADVANCE

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NHS Improvement vision for patient safety

Increasing our understanding of what goes wrong in healthcare

Enhancing the capability and capacity of the NHS to improve safety

By tackling the major underlying barriers to widespread safety improvement

Patient Safety in NHS Improvement

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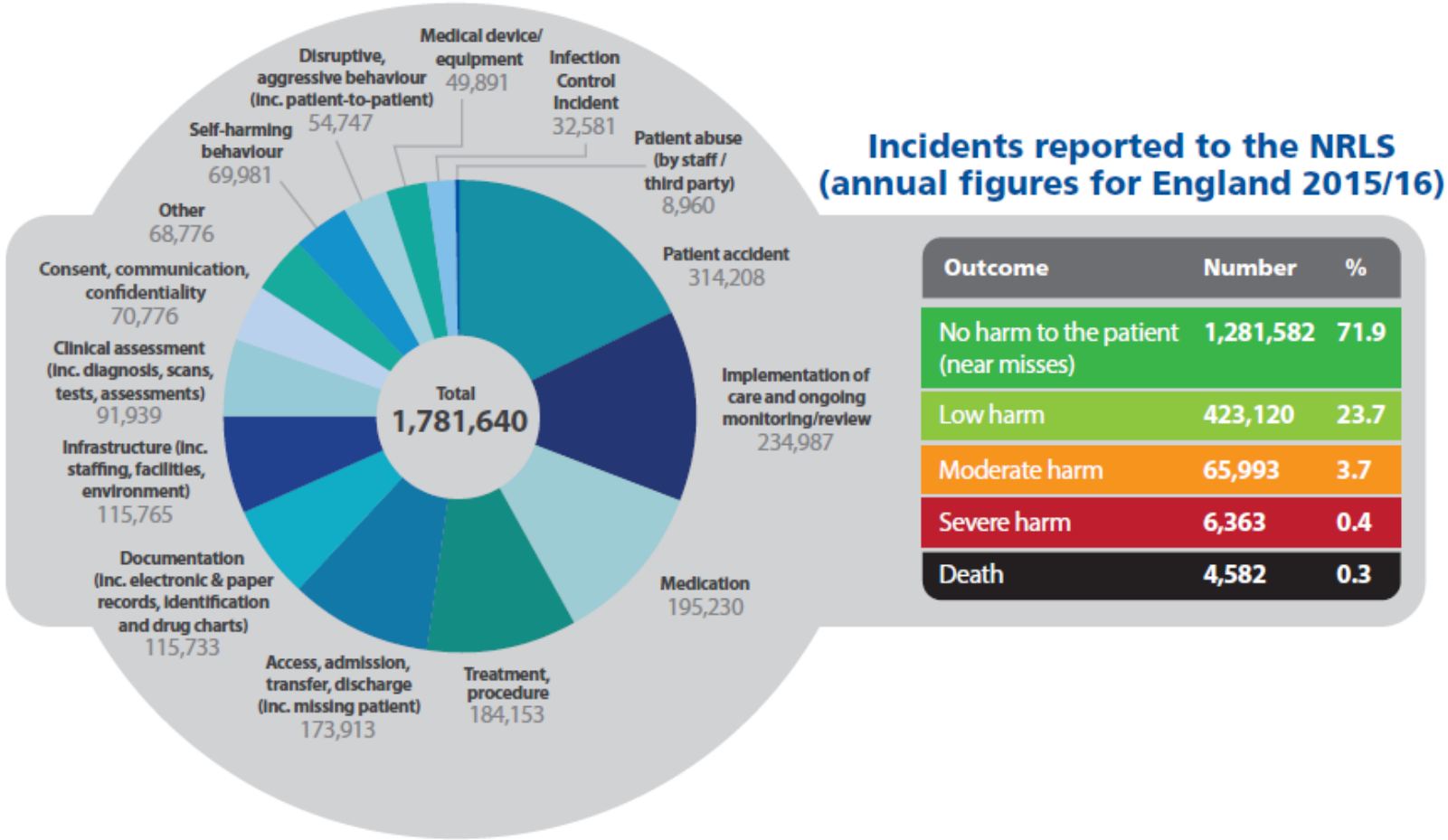
The National Reporting and Learning System (NRLS)



Incidents reported to the NRLS (annual figures for England 2015/16)

Outcome	Number	%
No harm to the patient (near misses)	1,281,582	71.9
Low harm	423,120	23.7
Moderate harm	65,993	3.7
Severe harm	6,363	0.4
Death	4,582	0.3

Medication error, a key point

- What are we up against?

  Fundamentally we can’t do Root Cause Analysis (RCA) or any other analysis measure on all error, its not practically possible

Think scale! We've 'estimated' the error in the NHS

Acknowledgment: Steve Williams, Steve.Williams3@nhs.net

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Actions to improve learning

National Faults	National Remedies
3.3 million **prescribing errors** each year in the community	-National prescribing **competency test** for **medical graduates** -NIHR Greater Manchester Primary Care Patient Safety Translational **Research Centre** including roll out of PINCER study findings to detect **prescribing errors**
26 000 – 2.2 million **dispensing errors** each year in the community	-**Medication Safety Officers network** (including independent pharmacies and large companies) to improve local learning from errors -NIHR Greater Manchester Primary Care Patient Safety Translational **Research Centre** including use of Manchester **Patient Safety** Assessment Framework in **community pharmacies**
45 000 **prescribing errors i**n an average acute hospital each year 40-100 **dispensing errors** in an average acute hospital each year	-National prescribing **competency test** for **medical graduates** -NIHR Imperial Patient Safety Translational **Research Centre** including assessment of **electronic prescribing and administration** systems and providing immediate **feedback to doctors** to reduce errors - Additional **national funding** to implement **electronic prescribing** systems -**Medication Safety Thermometer** to monitor and drive system improvements to reduce patient harms due to high risk medicines -Additional **national funding** to implement safer **dispensing** systems -**Medication Safety Officers** network to improve local learning from errors

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Actions to improve learning

National Faults	National Remedies
215 000 medicines administration errors in an average acute hospital each year	--Medication Safety Thermometer to monitor and drive system improvements to reduce errors e.g. omitted doses -Medication Safety Officers network to improve local learning from errors -Additional national funding to implement safer administration technologies
In hospitals 6500 patients suffer **harm** due to medicines and 167 patients **die avoidably** due to medicines each year	-**Medication Safety Thermometer** to monitor and drive system improvements to reduce patient harms due to high risk medicines **e.g. Anticoagulation ,Insulin, Opioids** -**Medication Safety Officers** network to improve local learning from errors -**Mortality reviews** help identify and drive system improvements to reduce avoidable deaths
40,000 of non elective hospital **admissions** each year are due to medicines	-- **Medication Safety Officers** network to improve **local learning** from avoidable admissions due to **medication errors** -NIHR Imperial and Greater Manchester Primary Care Patient Safety Translational **Research Centres** including roll out of PINCER study findings to detect **prescribing errors** and development and of an Improving Prescribing in the Elderly **medication review tool** -**QOF target** to reduce unavoidable non elective hospital admissions

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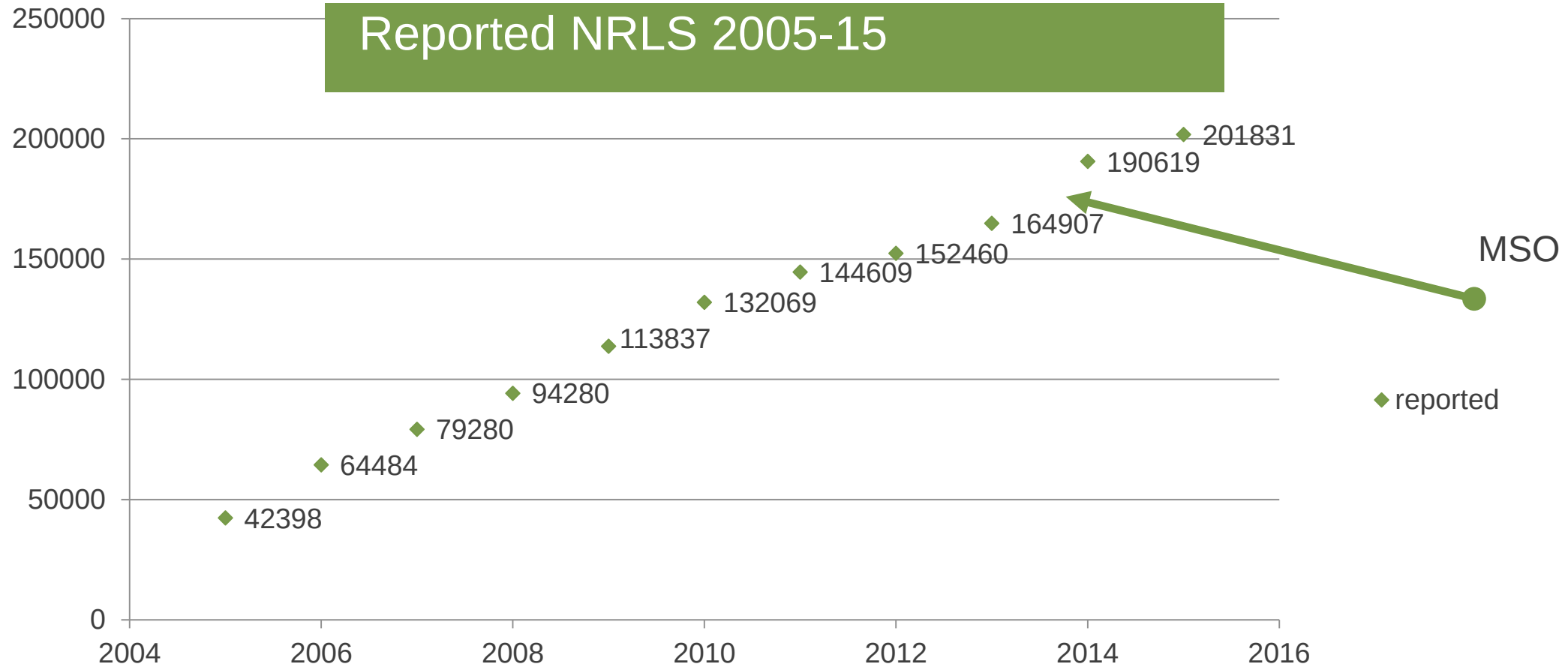
There are a lot of potential investigations!!



In 2014 the absolute number of medication reports to the NRLS increased more than in any previous year, representing a 15.6% increase on the year before.

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Key points

- Too many can’t investigate every error, have to be selective

There are a lot of potential investigators!!

Organisation	count	count aggregate
NHS Acute Medium	46	
NHS Acute Large	41	
NHS Acute Teaching	30	
NHS Acute Small	24	
NHS Acute Specialist	17	
NHS Acute Trust		158
CCG		80
NHS Mental Health Trust		51
Community pharmacy sector		21
Other Independent Sector		21
NHS Community Trusts		18
NHS England Area Team		14
NHS Ambulance Trust		9
Community Interest Company		8
Independent		2
Cosmetic Surgery		1
Mental Health		1
NHS Acute		1
Online Pharmacy		1
Social Care Enterprise		1
Grand Total		387

Registered
Medication Safety Officer
As of August 2016

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It has to be done for the right reason!

- The perfection myth
  - if we try hard enough we will not make any errors
- The punishment myth
  - if we punish people when they make errors they will make fewer of them

Two approaches

Person centred approach

- Individuals who make errors are ‘careless, at fault, reckless’
- Blame and punish
- Remove individual = improve safety

Systems approach

- Poor organisational design sets people up to fail
- Focus on the system rather than the individual
- Change the system = improve safety

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Analysis options

1. Fault Tree Analysis (FTA)
2. Failure Modes Effect Analysis (FMEA)
3. Root Cause Analysis (RCA)

What healthcare practitioner's think

Attendees at workshops said (n=100+, 5 events)

FTA only 5% had ever heard of it

FMEA: needs to be proactive and multidisciplinary and multi-sector, Better alternative (UKMi risk assessment tool). Quantifies and is also Industry recognised. Little published application

RCA: All heard about it. A 'waste of time and money' unless done well, it's a week, it's a big undertaking. Reactive, not proactive. Part of the process, doesn't lead anywhere

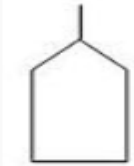
FTA

- Bell Telephone Laboratories developed the concept in 1962 for the US Air Force for use with the Minuteman system.
- Later adopted and extensively applied by the Boeing Company
- Fault tree analysis is one of many symbolic ‘analytical logic techniques’
- little application in Health, but extensively used elsewhere
- mathematically orientated, uses symbols to denote relationships
- Has been assessed for use in healthcare

[1] Cranfield University. Marcus L. Durand. The Evaluation of Methods for the Prospective Patient Safety Hazard Analysis of Ward-Based Oxygen Therapy PhD 2009

Symbols

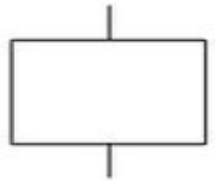
Basic event



External event

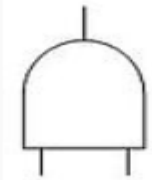
Undeveloped event

Conditioning event



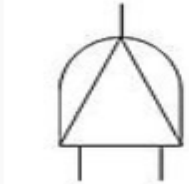
Intermediate event

OR gate

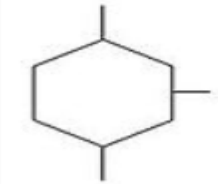


AND gate

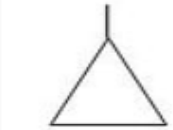
Exclusive OR gate



Priority AND gate



Inhibit gate



Transfer in

Transfer out

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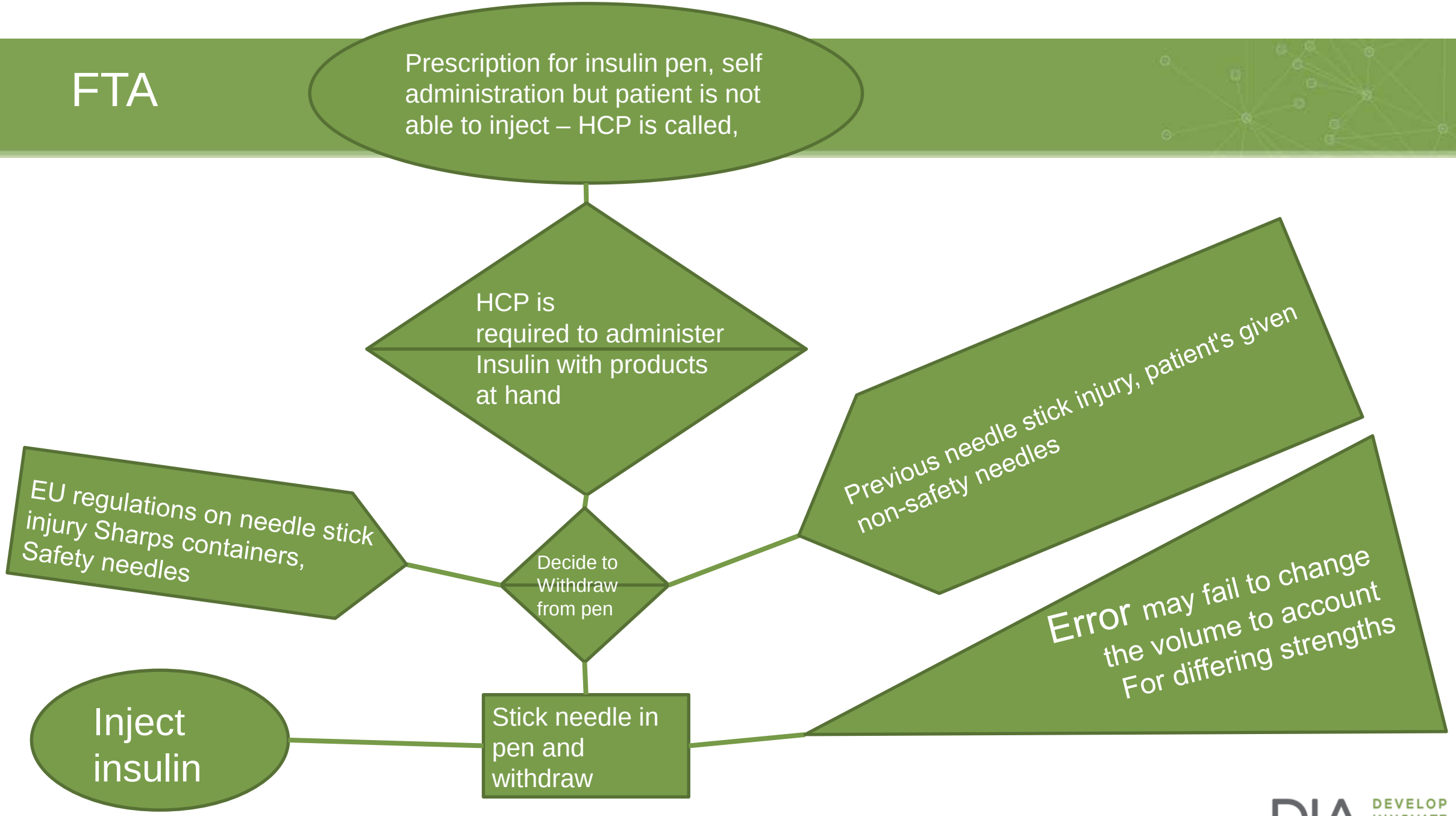
FTA

Often there is a activity and you have to ask…Why?
Consider a genuine, current, patient-safety situation

- ‘nurse drawing up insulin with a syringe out of [insulin Brand] pen.’
- ‘[insulin Brand] was being given by drawing up a dose from an insulin pen - fill cartridge using an insulin needle. These cartridges are only intended for use with a re - usable insulin pen, not for directly drawing up doses’
- ‘In addition the insulin was being drawn up into an insulin syringe from an insulin cartridge designed to be used in a pen - style delivery device’

WHY, WHY, WHY

FTA



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FMEA

- Prospective
- Has a linguistic semantics
- Not comprehensive (holistic) – healthcare is complex
- Has ‘types’ functional, concept design, process
- Has been applied (limited) to medication

http://www.ihi.org/resources/Pages/Tools/FailureModesEffectsAnalysisComparisonFiveMedicationDispensingScenarios.aspx

Think that you know of the perfect storm, insulin pens, EU regulations, multiple strengths.

Could ‘you’ have predicted what HCPs would do?

We asked >100 HCPs

FMEA

What they (100+ HCPs) said

FMEA could have got there with the right people at the table
Predicting human behaviour is challenging
Predict interesting work arounds!
Means different things to different people
Need a National one page description of FMEA and a template.

The UKMi ‘FMEA-like’ assessment -

Tool for assessing the in-use patient safety characteristics of medicines and medicinal products

Product	Assessment completed by	Date

No	Themes	Assessment	Details/ notes
A	Licensing status		
A1	Does the product have a UK marketing authorisation?	Yes ☐ →A2 No ☐ →A3	
A2	Is it only going to be used within that marketing authorisation?	Yes ☐ →B No ☐ →A3	
A3	Is there a suitable product available with a marketing authorisation for the intended use?	Yes ☐ No ☐	
A4	Is the anticipated use supported by a reasonable evidence base?	Yes ☐ No ☐	
A5	Is technical and patient information available in English to support the anticipated use?	Yes ☐ No ☐	
A6	Do you have assurance of pharmaceutical quality? For example, • If the medicine is unlicensed, is the supplier of the medicine suitably licensed? • What type of assurance process does the manufacturer have in place?	Yes ☐ No ☐	
B	Name, packaging and labelling, and other pharmaceutical issues		
B1	Could the medicine's names be confused with those currently in existence? *(Is there risk of sound alike/look-alike errors?)*	Yes ☐ No ☐	
B2	Is the medicine's generic name clearly identifiable in English on the packaging?	Yes ☐ No ☐	
B3	Is other critical information also clearly identifiable in English on the packaging? (e.g. strength, form, any product specific warnings)	Yes ☐ No ☐	
B4	Is the critical information above clear on all sides of the packaging as well as on the primary (e.g. ampoule) and secondary (e.g. carton) packaging	Yes ☐ No ☐	
B4	For branded medicines, is the generic name also suitably prominent?	Yes ☐ No ☐	
B5	Is pharmaceutical information such as the batch number, expiry date, and storage conditions clear and unambiguous on the packaging?	Yes ☐ No ☐	
B8	Where medicines contain more than one active ingredient, are all generic constituents clearly stated on the packaging?	Yes ☐ No ☐	
B7	Is the expression of strength on the packaging consistent with prescribing practice?	Yes ☐ No ☐	
B8	Does the packaging encourage (or at the least not hinder) differentiation between a range of products from a single supplier, or between different products from different suppliers? *(Is there risk of selection errors?)*	Yes ☐ No ☐	
C	Information provided with the product		
C1	Is an English language patient information leaflet available with the product?	Yes ☐ No ☐	
C2	Is English language prescribing information available for the product?	Yes ☐ No ☐	
C3	Is appropriate technical information available in English at the point of care to guide calculations, preparation, and administration?	Yes ☐ No ☐	
C4	Does the product information only contain positive statements about use? For example "for intravenous use only" as opposed to "not for intrathecal use"	Yes ☐ No ☐	
D	Prescribing risks		
D1	Is the product an additional treatment option, or is it replacing another product or drug?		
D2	Are there issues associated with non-familiarity or confusion with existing treatments?	Yes ☐ No ☐	
D3	Is the dosing and prescribing complex?	Yes ☐ No ☐	
D4	Who will prescribe the item? *(consider prescriber's scope of practice and processes involved)*		
D5	Is the prescribed dose consistent with the way the strength, form, and (where applicable) base salt are presented?	Yes ☐ No ☐	
E	Known risks and management		
E1	Has the item (or any similar product) been the subject of any medicines safety alerts? *(e.g. NPSA report, description as a never event, or inclusion in a MHRA drug safety bulletin)*	Yes ☐ No ☐	
E2	Is the medicine under intensive regulatory surveillance?	Yes ☐ No ☐	
E3	Are new or amended clinical or laboratory monitoring requirements associated with the introduction of the medicinal product?	Yes ☐ No ☐	
E4	Is there potential for significant harm in deliberate or inadvertent overdose? If yes, • Are suitable reversibility and antidote strategies available? • Are clinical management strategies in such circumstances defined?	Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐	
E5	Where necessary, is additional patient information available to support safe use of the medicine? For example, are steroid or lithium cards present if necessary?	Yes ☐ No ☐ NA ☐	

F	Preparation, Calculation, Labelling & Information		
F1	Are there current known operator safety issues with the drug? • Is the medicine of a class where operator safety issues might be a concern? • Is the medicine subject to COSHH regulations, for example?	Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐	
F2	Is the medicine supplied to the end user in a presentation that is • ready-to-use (i.e. correct volume and correct strength and is ready to draw up) or • ready-to-administer (i.e. in a final container ready for administration to the patient)?	Yes ☐ No ☐ Yes ☐ No ☐	
F3	In the form presented, are commonly used doses easy to measure?	Yes ☐ No ☐	
F4	If manipulation is required prior to administration, • is it complex (i.e. does it have 5 or more defined steps)? • does it involve any special or unusual complexities (using the contents of part ampoules or vials, complex dilution or mixing with other drugs, or need to crush preparations or make other extemporaneous products prior to administration)?	Yes ☐ No ☐ Yes ☐ No ☐	
F5	Is a complex calculation (i.e. has more than one step) necessary prior to preparation and/or administration?	Yes ☐ No ☐	
F8	Does the product easily enable essential labelling to be in place at point of administration?	Yes ☐ No ☐	
G	Administration		
G1	Is administration of the product in any way complex?	Yes ☐ No ☐	
G2	Is the route of administration of the product intrinsically high risk (such as intrathecal)?	Yes ☐ No ☐	
G3	Does administration require the use of a device and/or disposables? If yes, are there any issues related to their use?	Yes ☐ No ☐ Yes ☐ No ☐	
G4	For injectable medicines, • is the rate of administration safety critical? If yes, what mechanisms are in place to ensure the rate is correct? • is any specific monitoring required during administration? If yes, is it practical & achievable?	Yes ☐ No ☐ Yes ☐ No ☐	
H	Supply chain issues		
H1	Is the product readily and reliably available from a recognised supplier?	Yes ☐ No ☐	
H2	Are expiry dates (both for the product in its original form, and in-use as necessary) available and clear?	Yes ☐ No ☐	
H3	Are there any specific storage requirements? e.g. refrigeration, space (if bulky)	Yes ☐ No ☐	
H4	Are there any issues relating to secure storage? e.g. is there likelihood of misappropriation?	Yes ☐ No ☐	
H5	Overall, consider whether the storage requirements can likely be met?	Yes ☐ No ☐	
I	Disposal		
I1	Does the product pose any special risks during disposal to either the user or staff?	Yes ☐ No ☐	
I2	Are there any specific disposal requirements for the product?	Yes ☐ No ☐	
J	Impact of setting		
J1	Is the product for use in a highly specialist environment? For example in neonates, fluid restricted patients, or those in critical care scenarios. If yes, is there the potential that it will be used outside such an environment? Have issues associated with such use been identified and addressed?	Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐	
J2	Is the medicine one which is likely to be used across other boundaries of care? If yes, have issues associated with such use been identified and addressed?	Yes ☐ No ☐ Yes ☐ No ☐	
J3	Is the medicine one for which self-administration by patients is a possibility? Have any issues associated with such use been identified and addressed?	Yes ☐ No ☐ Yes ☐ No ☐	
J4	Where the manipulation of the product is complex, is the environment in which it is to be prepared conducive to its safe use? That is, will it be as free as possible from distractions and is it an otherwise suitable environment for complex manipulation?	Yes ☐ No ☐	
K	Summary & Outcome (Committees involved; whether or not approved for use in the organisation etc)		
K1	As a consequence of the product's introduction, will any changes to practice occur? If yes, are those changes likely to introduce new risks? Or do they have the potential to address patient safety risks known to be present currently?	Yes ☐ No ☐	
K2	Overall, when considered against the status quo, are the risks identified in relation to the product's introduction reasonable?	Yes ☐ No ☐	
K3	Where it is possible to assess, are any patient safety risks outweighed by the potential clinical benefits the product offers against available alternatives?	Yes ☐ No ☐	
K4	Other comments and actions		

http://www.ukmi.nhs.uk/filestore/ukmiaps/UKMiproductassessmenttool-abbreviatedversion.pdf

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RCA

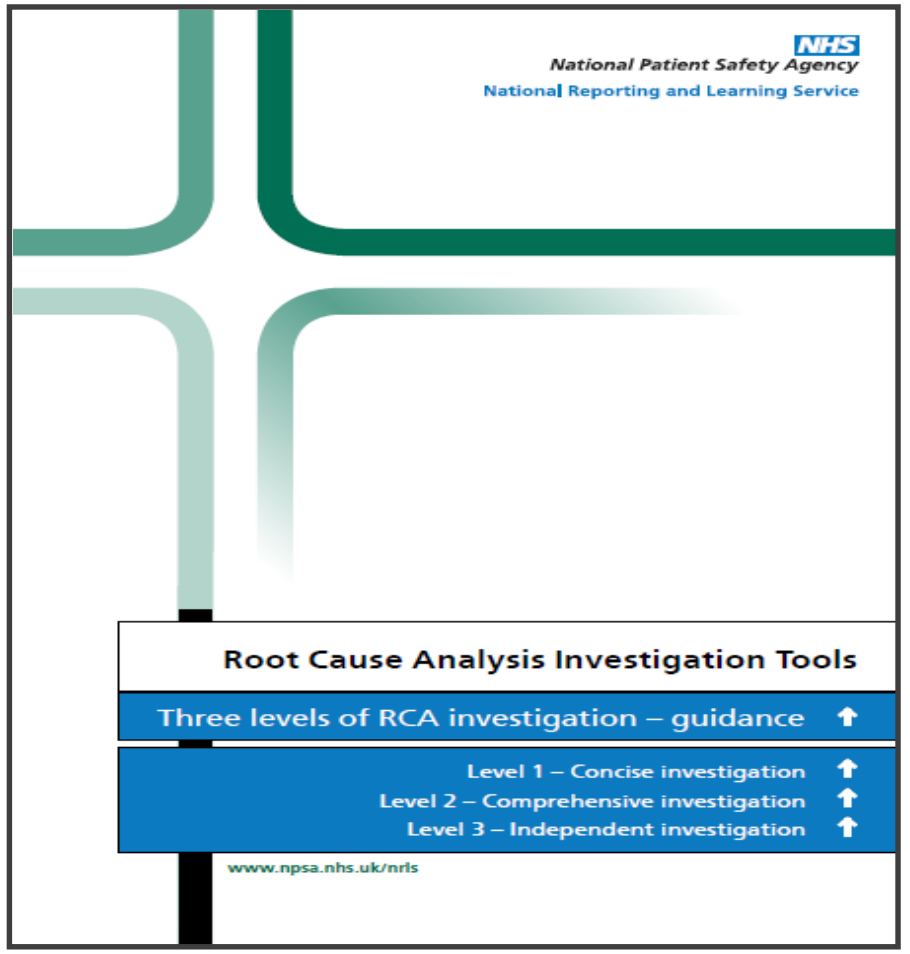
- ….is useful because its ‘holistic’. It enables the structured assessment of human factors (also known as Ergonomics) in a PSI
- Still looks for a ‘root cause’ – but that may be multi-factorial (insulin pens)
- But there are still too many medication errors

RCA

Its critical to understand which incidents to undertake an RCA

Classify according to

- the degree of harm or damage caused at the time
- its realistic future potential for harm if it occurred again
- **Better to do fewer RCAs well than consider it as an ending in its own right**



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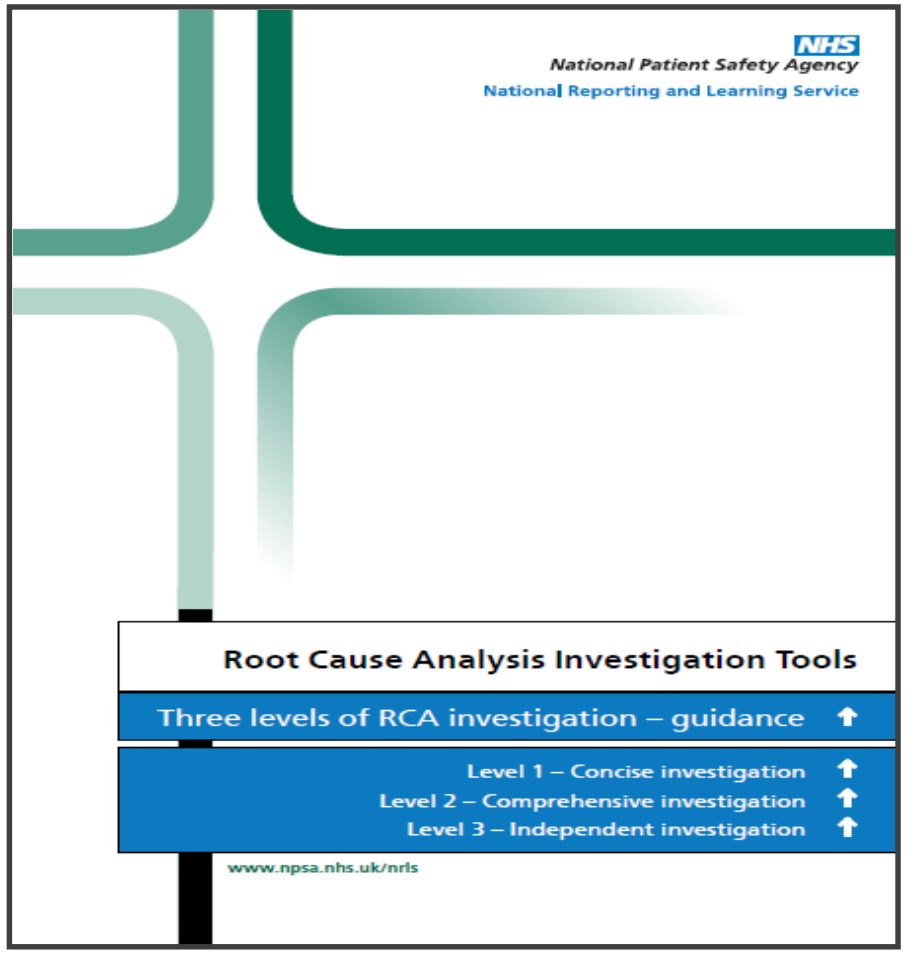
RCA

Its critical to understand which incidents to undertake an RCA

Classify according to

- **Need to accept that RCA is not the automatic ‘turn to’ solution**



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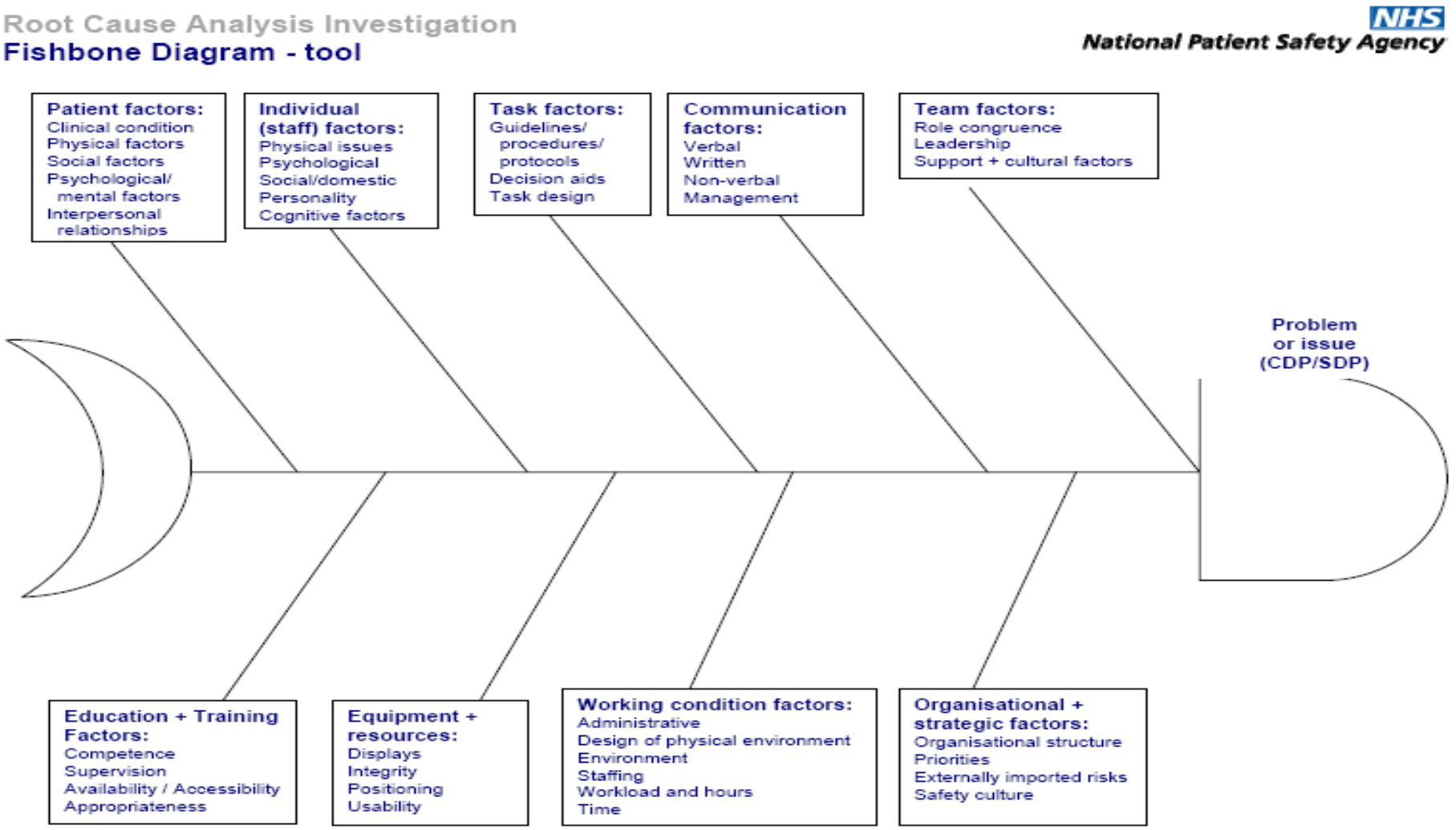
RCA



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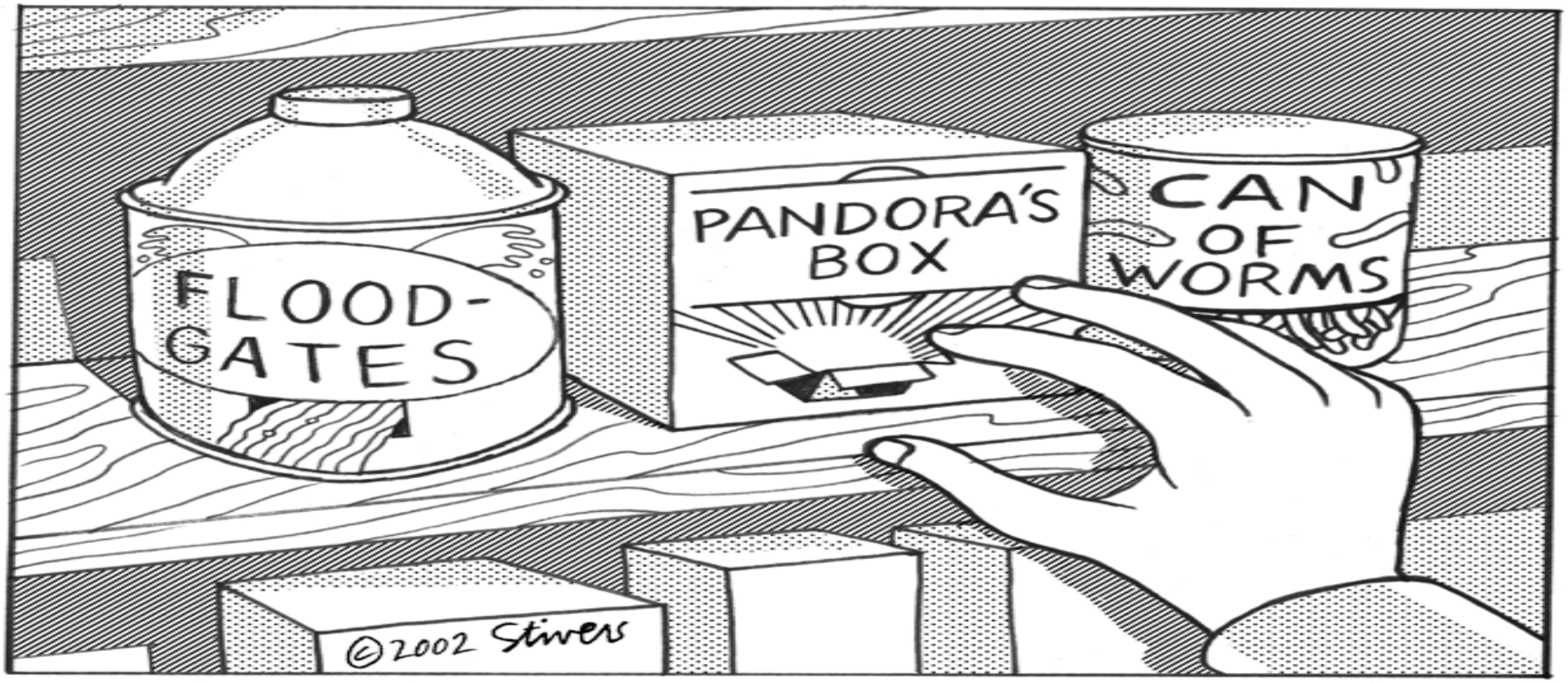
RCA

Analysis – beware of what you find, or think you have found



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Extracts from MSOs RCAs

Process for checking medication prior to spinal injections was not followed

No omissions or errors in care or treatment were identified which would have led to this incident occurring

Failure to follow hospital policies and procedures

It is common practice throughout the NHS to give verbal advice, this is often done without adequate safeguards

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- What was learnt…

Standardisation of practices for handling medication (storage, checking)

''There is no policy within the Trust for the administration of nebulisers and therefore confusion may arise as to how certain drugs should be delivered and whether this can be overridden in an emergency''

''A medication administration error (potential prevented never event) was not reported at the time that it was detected''

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Key points

- Too many can’t investigate every error, have to be selective
- The nature of error may determine the method of analysis

System-wide learning from root cause analysis: a report from the New South Wales Root Cause Analysis Review Committee

Jonny Taitz,[1] Kelvin Genn,[2] Vanessa Brooks,[2] Deborah Ross,[2] Kathleen Ryan,[2] Bronwyn Shumack,[1] Tony Burrell,[1] Peter Kennedy,[1] on behalf of the NSW RCA Review Committee

'**Conclusion** given the number of hours per RCA, it seems a shame that the final output of the process may not in fact achieve the desired patient safety improvements'

2010;**19**:e63. doi:10.1136/qshc.2008.032144

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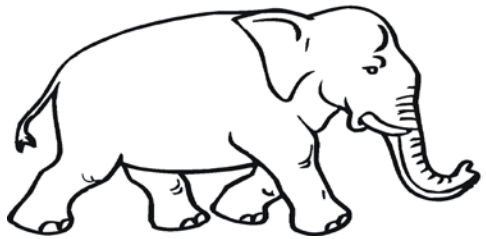
Key points

- Too many can’t investigate every error, have to be selective
- The nature of error may determine the method of analysis

- Investigations to determine the cause of error should be just the start of the undertaking
- We are guilty of failing to learn from the plethora of investigations



What we'd like the audience to remember

- Reserve investigations for things that might make a difference to patient care, and do it properly
- If there are actions, do them
- Share the findings

Ask