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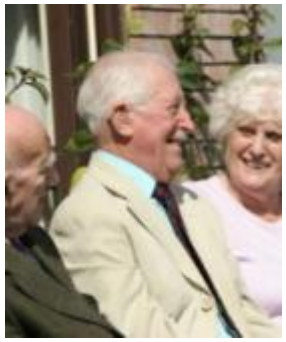
Root cause analysis in context of WHO International Classification for Patient Safety

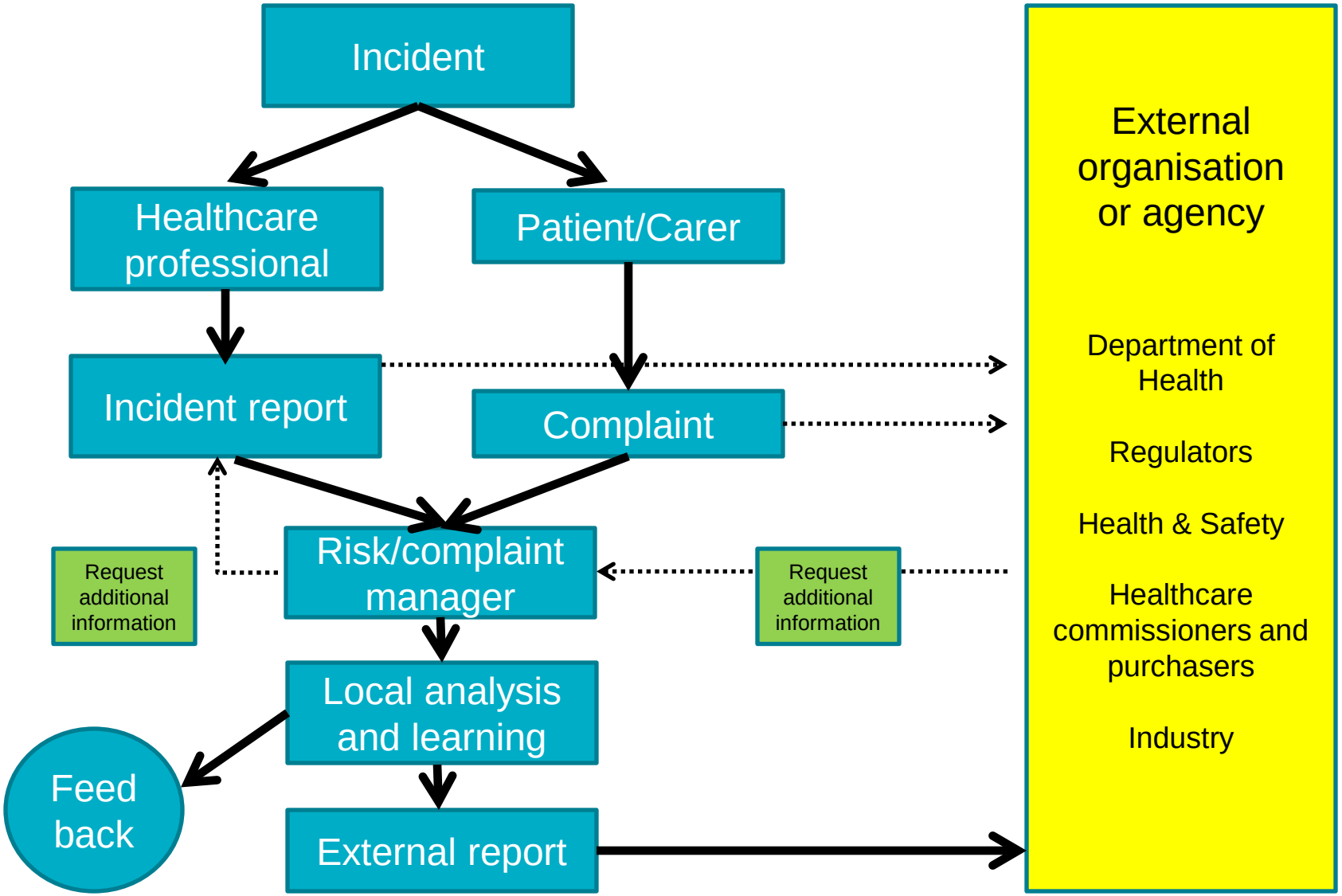
Dr David Cousins

Associate Director

Safe Medication Practice and Medical Devices



How heath care provider organisations manage patient safety incidents



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Root Cause Analysis (RCA)

To identify the root causes and key learning from serious incidents and use this information to significantly reduce the likelihood of future harm to patients

Objectives

To establish the facts i.e. **what** happened (*effect*), to **whom**, **when, where**, **how** and **why**

To establish whether failings occurred in care or treatment

To look for improvements rather than to apportion blame

To establish how recurrence may be reduced or eliminated

To formulate *recommendations and an action plan*

To provide a *report and* record of the investigation process & outcome

To provide a means of *sharing learning* from the incident

To identify routes of *sharing learning* from the incident

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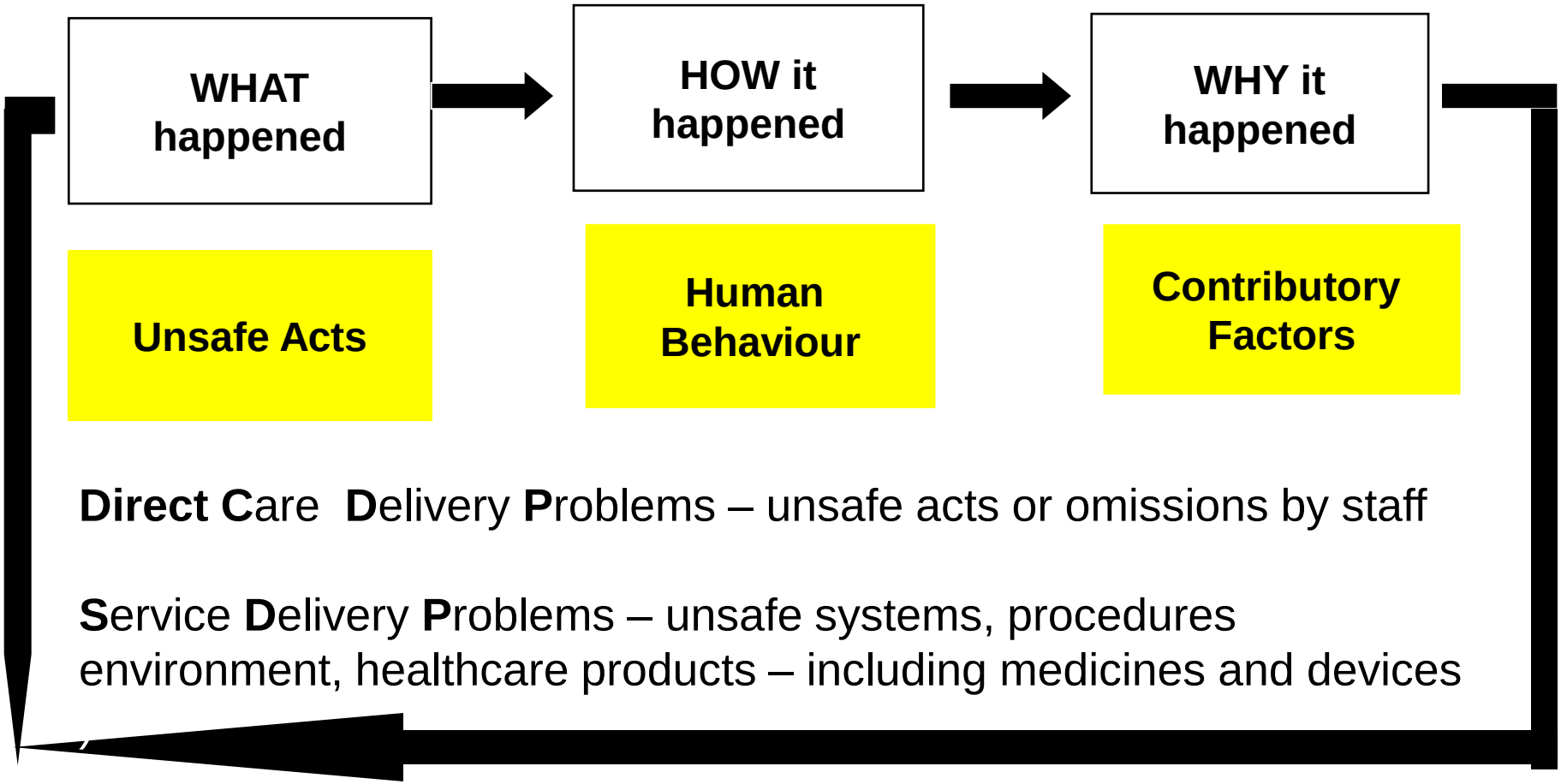
Basic elements of RCA



Direct Care **D**elivery **P**roblems – unsafe acts or omissions by staff

Service **D**elivery **P**roblems – unsafe systems, procedures environment, healthcare products – including medicines and devices

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Human factors (Ergonomics)

- those elements that influence the performance of people operating equipment or systems; they include behavioural, medical, operational, task-load, machine interface and work environment factors
- the environmental, organisational, job factors, human and individual characteristics which influence behaviour at work

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RCA teams in healthcare

- RCA undertaken in the healthcare setting by healthcare staff familiar with the treatments and setting
- Multidisciplinary group of 3-4 persons
- One of which should be fully trained in incident investigation and analysis
- Objective attitude
- Good organisational skills
- Use of experts

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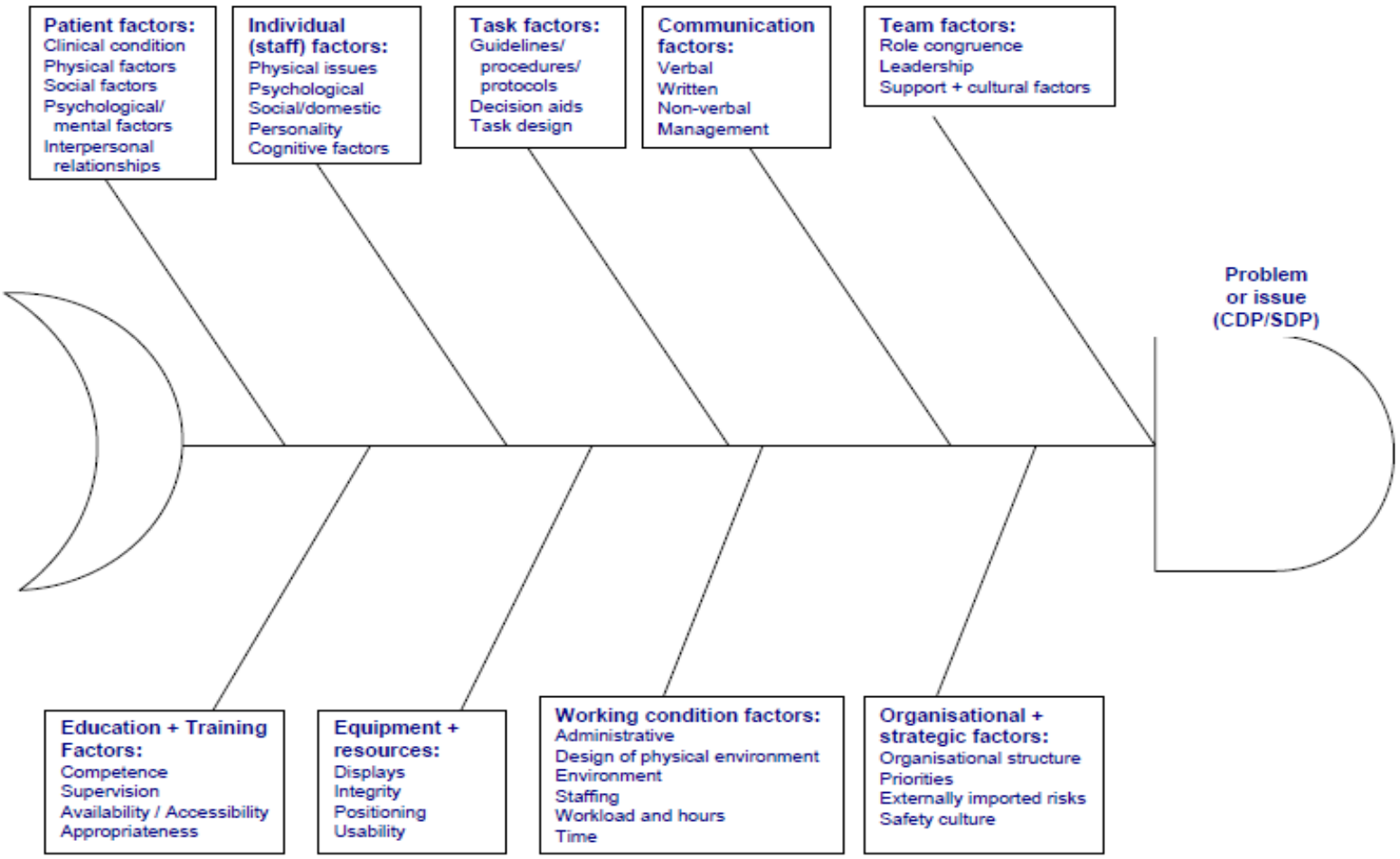
Root Cause Analysis Investigation

Fishbone Diagram - tool

NHS National Patient Safety Agency



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Pre-investigation risk assessment

A Potential Severity (1-5)	B Likelihood of recurrence at that severity (1-5)	C Risk Rating (C = A x B)

Post-investigation risk assessment

A Potential Severity (1-5)	B Likelihood of recurrence at that severity (1-5)	C Risk Rating (C = A x B)

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The Conceptual Framework for the International Classification for Patient Safety

Version 1.1

FINAL TECHNICAL REPORT

January 2009

World Health Organization

www.who.int/patientsafety/implementation/taxonomy

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The conceptual framework for ICPS

The conceptual framework for the ICPS was designed to provide a much needed method of organising patient safety data and information so that it can be aggregated and analyzed to:

- Compare patient safety data across disciplines, between organisations, and across time and borders;
- Examine the roles of system and human factors in patient safety;
- Identify potential patient safety issues; and
- Develop priorities and safety solutions.

- Donaldson L et al. In J Qual Health Care 2009; 21: many articles

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ICPS Drafting Principles

- The classification be based upon concepts as opposed to terms or labels;
- The language used for the definitions of the concepts be culturally and linguistically appropriate;
- The concepts be organised into meaningful and useful categories;
- The categories be applicable to the full spectrum of healthcare settings in developing, transitional and developed countries;
- The classification be complementary to the WHO Family of International Classifications;
- The existing patient safety classifications be used as the basis for developing the international classification's conceptual framework; and
- The conceptual framework be a genuine convergence of international perceptions of the main issues related to patient safety.

Donaldson L et al. In J Qual Health Care 2009; 21:

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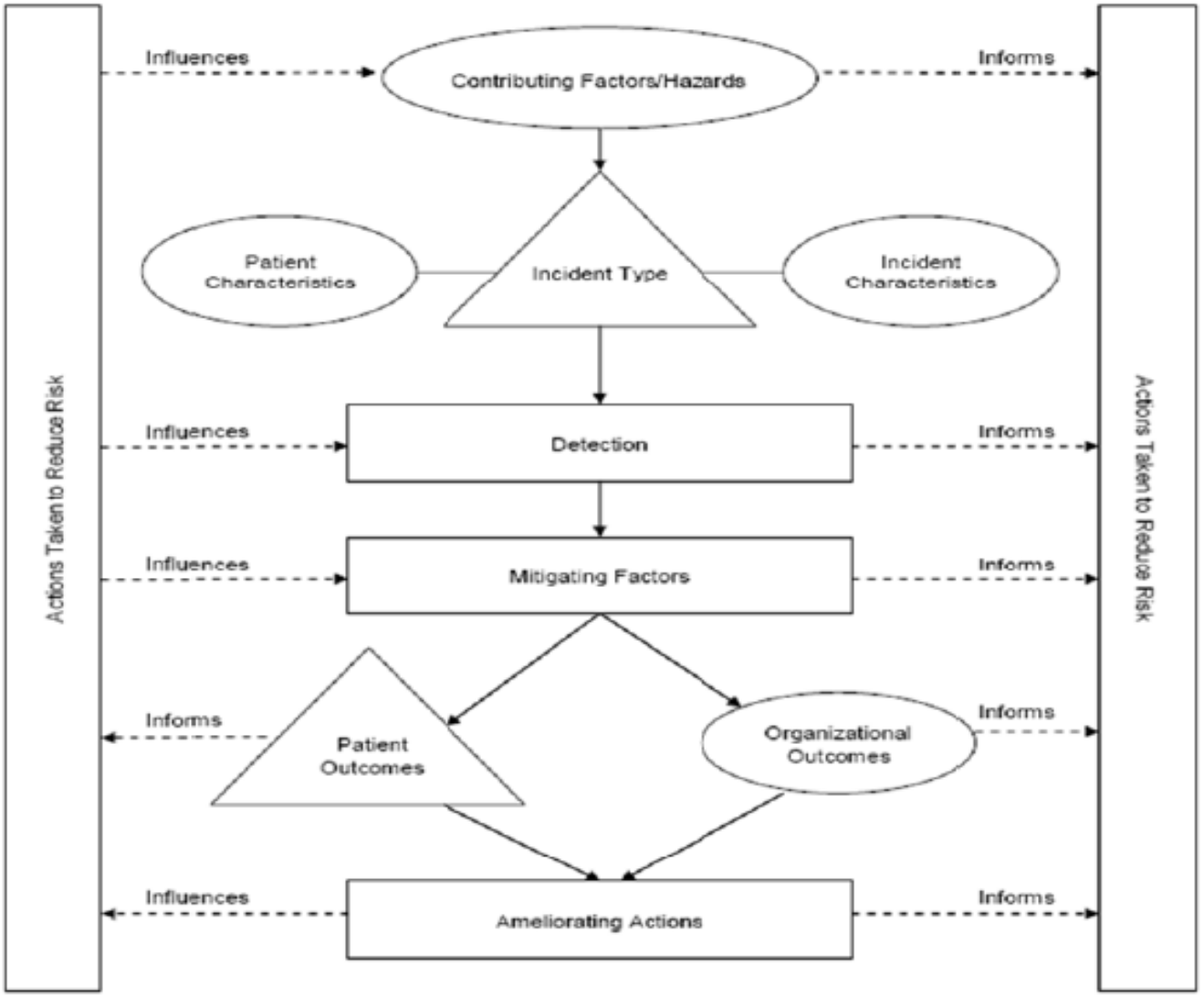
ICPS – Patient safety incident - definition

- Patient safety incident: an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient

- The use of the term ‘unnecessary’ in this definition recognizes that errors, violations, patient abuse and deliberately unsafe acts occur in healthcare and are unnecessary incidents, whereas certain forms of harm, such as an incision for a laparotomy, are necessary. The former are incidents, whereas the latter is not.

Runciman W et al. International Journal for Quality in Health Care 2009; Volume 21, Number 1: pp. 18–26

ICPS Model


Actions Taken to Reduce Risk
Influences
Contributing Factors/Hazards
Informs
Patient Characteristics
Incident Type
Incident Characteristics
Influences
Detection
Informs
Influences
Mitigating Factors
Informs
Informs
Patient Outcomes
Organizational Outcomes
Informs
Influences
Ameliorating Actions
Informs
Actions Taken to Reduce Risk

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ICPS – medicines data fields (examples)

1) Medication incident/error
2) Medicines process (ordinal data)
   - Prescribing
   - Dispensing/preparation
   - Administration
   - Monitoring
3) Type of medicines errors
   - Wrong patient
   - Wrong medicine
   - Wrong formulation
   - Wrong dose
   - Wrong frequency
   - Wrong quantity
   - Wrong rate of administration
   - Known medicine allergy
   - Known clinical contraindication
   - Expired medicine
   - Wrong storage
   - Omitted and delayed medicine

ICPS data fields - general

Detection
Error recognition
Change in patients status
By machine/environmental change/ alarm
By count/audit/review

Pro-active risk assessment

Contributing factors/targets for actions
Patient factors
Staff factors
Work/environmental factors
Organisational / service factors
External factors
Other

Staff and patient factors
Cognitive
Performance
Behaviour
Communication
Pathophysiological/disease related
Emotional
Social factors

Work and environmental factors
Physical environment / infrastructure
Remote / long distance from service
Environmental risk assessment / safety evaluation
Current code specifications/regulation

Organisational and service factors
Protocols/policies/procedures/process
Organisational decisions/culture
Organisation of teams
Resources/workload

External factors
Natural environment
Products, technology and infrastructure
Services, systems and policies

Mitigating factors
Directed to patient
Directed to staff
Directed to organisation
Directed to an agent
Other

Ameliating *actions*
Patient related
Organisation related
Actions to reduce risk

Patient outcome
Type of harm
Degree of harm
Social / economic impact

Organisational outcomes
Media management / public relations
Claims/risk management
Local notification and resolution
Complaint management
Stress debriefing/staff counselling
Reconciliation/mediation

Comparing Terminology 1

WHO Patient safety Terms	MedDRA terms v 15.1	WHO-ART terms
Prescribing	LLT Drug prescribing error	DRUG PRESCRIBING ERROR
No such term	LLT Intercepted prescribing error	No such term
Preparation/dispensing	LLT Drug dispensing error	No such term
No such term	LLT Intercepted drug dispensing error	No such term
Presentation/packaging	HLT Pro*d*uct packaging issue	No such term
Delivery	No such term	No such term
Administration	LLT Drug administration error	DRUG ADMINISTRATION ERROR
No such term	LLT Intercepted drug administration error	No such term
Supply/ordering	No such term	No such term
Storage	LLT Incorrect product storage	No such term
Monitoring	HLT Medication monitoring errors	No such term

Essential term required

Essential term present

Non-essential term

New term for WHO patient safety taxonomy

Comparing Terminology 2

WHO Patient safety Terms	MedDRA terms v 15.1	WHO-ART terms
Wrong patient	LLT Wrong patient received medication	No such term
Wrong drug	LLT Wrong drug administered	Incorrect drug administered
Wrong dose, strength, frequency	LLT Incorrect dose administered	Incorrect dose administered
No such term	LLT Underdose	No such term
No such term	LLT Inappropriate schedule of drug administration	Inappropriate schedule of drug administration
No such term	LLT Accidental overdose	Accidental overdose
No such term	LLT Intentional overdose	Intentional overdose
No such term	LLT Multiple drug overdose	No such term
No such term	LLT Multiple drug overdose-accidental	No such term
No such term	LLT Multiple drug overdose-intentional	No such term
No such term	LLT Overdose	No such term
Wrong formulation or presentation	LLT Product formulation issue	No such term
Wrong route	LLT Incorrect route of drug administration	Incorrect drug administration route
No such term	LLT Drug administered at inappropriate site	Incorrect drug administration site
No such term	LLT Vaccine administered at inappropriate site	No such term

Essential term required

Essential term present

Non-essential term

New term for WHO patient safety taxonomy

Comparing Terminology 3

WHO Patient safety Terms	MedDRA terms v 15.1	WHO-ART terms
Wrong quantity	No such term	No such term
Wrong dispensing label instruction	LLT Wrong directions typed on label	No such term
Contra-indicated	LLT Medical treatment contraindicated	No such term
No such term	LLT Documented hypersensitivity to administered drug	No such term
No such term	LLT Labelled drug disease interaction	No such term
No such term	LLT Labelled drug-drug interaction	No such term
No such term	LLT Labelled drug-food interaction	No such term
Wrong storage	LLT Incorrect product storage	No such term
Omitted medicine or dose	LLT Drug dose omission	No such term
Expired medicine	LLT Expired drug administered	Expired medicine used
Adverse drug reaction	Detailed ADR terminology available	Detailed ADR terminology available

Essential term required

Essential term present

Non-essential term

New term for WHO patient safety taxonomy

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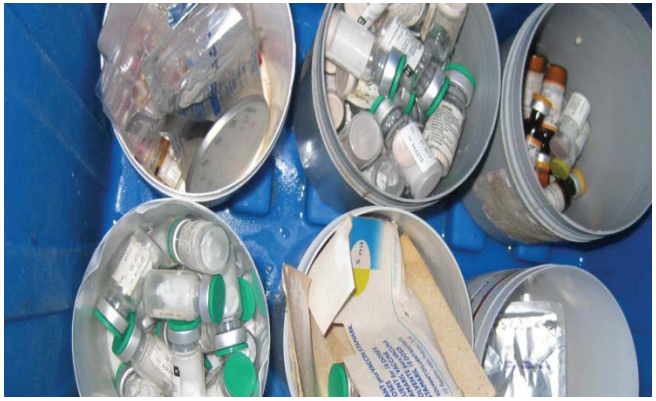
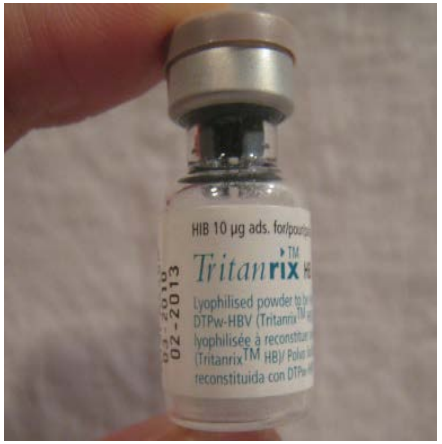
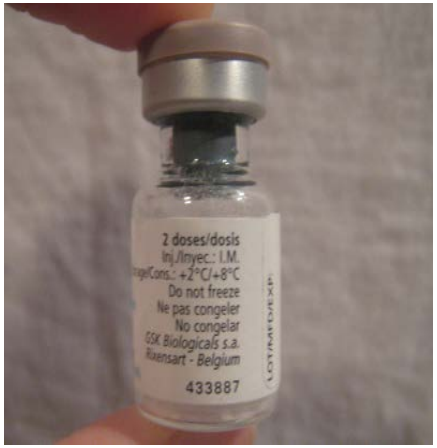
WHO project on vaccine labelling







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Medication error reports involving vaccines reported to the National Reporting and Learning System in the UK January 2005 - December 20011. Types of error

Error type	Incidents	%
Wrong drug / medicine	562	16.1%
Wrong frequency	481	13.8%
Wrong / omitted / passed expiry date	281	8.1%
Omitted medicine / ingredient	274	7.9%
Wrong / unclear dose or strength	258	7.4%
Wrong storage	209	6.0%
Wrong quantity	170	4.9%
Wrong formulation	68	2.0%
Other vaccine incident types	1184	34%
Total	3487	100%

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Medication errors involving vaccines reported to WHO Vigibase by Pharmacovigilance Centres worldwide inception – December 2012

Error Type	Incidents	%
Incorrect vaccine administered	4,238	21.6
Administration error	336	1.7
Incorrect dose administered	1,473	7.5
Accidental overdose	484	2.5
Incorrect form	184	0.9
Expired vaccine	50	0.2
Other vaccine incident types	14,321	73.0
Total vaccine incident reports	19,613	100%

Vaccine Type	Incidents	%
Influenza vaccine	2620	13.4
Tetanus vaccine/Diphtheria vaccine/Pertussis vaccine	2424	12.4
Pneumococcal vaccine	1994	10.2
Varicella zoster vaccine	1953	10.0
Human papilloma vaccine	1232	6.3
Hepatitis a vaccine	1021	5.2
Polio vaccine	955	4.9
Mumps vaccine/Rubella vaccine/Measles vaccine	941	4.8
Rotavirus vaccine	925	4.7
Haemophilus influenza type B vaccine	906	4.6
Hepatitis b vaccine	858	4.4
Other vaccines	3784	19.3
Total	19,613	100

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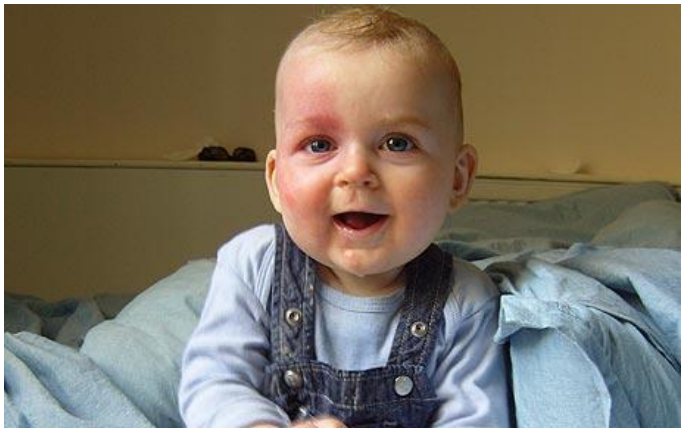

NHS guilty of giving baby fatal overdose

A "GROSS lack of medical attention" by Homerton hospital doctors and nurses directly contributed to a baby accidentally being given a fatal overdose of a toxic drug, an inquest heard last week (June 23).

Seven-month-old Lucas Stachursky was administered with nine to 12 times the amount of anti-seizure drug Phenytoin in six hours he should have received over a day on May 16 last year.

Lucas was brought to Homerton hospital

Lucas given six times too much 'heart slowing' drug

drug for a baby of his size and age," he said.

Lucas was left on the drip containing the high concentration drug, which irreversibly slows the heart, for over six hours.

Ordinarily, a Phenytoin drip feed would last for no longer than an hour.

QC John De Bono, representing Mr Stachursky and Ms Holzscheiter asked Dr Jacqueline Bucknall, who was the consultant paediatrician in charge of Lucas, how long it took to realise that Lucas was on a Phenytoin drip.

"Three hours too late. (When I realised) I

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National Patient Safety Agency

Rapid Response Report

NPSA/2010/RRR018

From reporting to learning

25 November 2010

Preventing fatalities from medication loading doses

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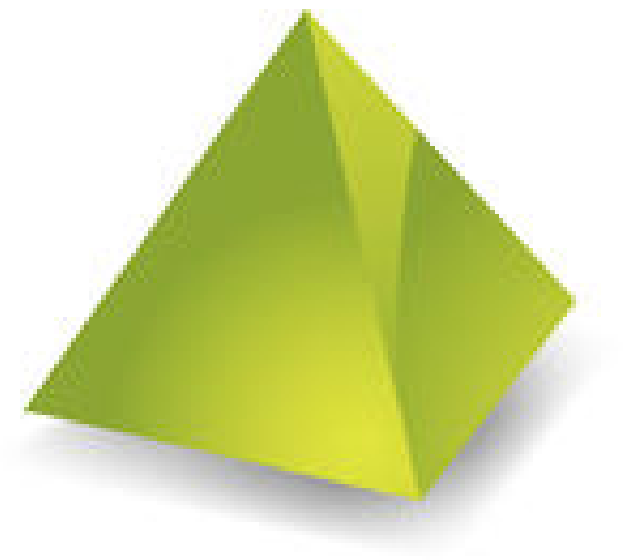
The value of incident reports with low harm



- Death
- Severe harm
- Moderate harm
- Low harm
- No harm

Table 1: Incidents by corrected severity and review of error type

Error type following review	Degree of harm (checked and corrected by clinical review)					TOTAL	
	Death	Severe	Moderate	Low Harm	No Harm	Total (N)	Total (%)*
Incorrect loading dose prescribed or administered	1	1	46	112	313	**473**	**41**
Omitted and delayed administration of loading dose		2	30	71	182	**285**	**24**
Communication and documentation of loading dose and/or subsequent maintenance			6	17	78	**101**	**9**
Maintenance dose prescribed/administered at an incorrect time			5	15	72	**92**	**8**
Loading dose repeated in error			6	23	51	**80**	**7**
Loading dose continued for maintenance without dose change	1	1	5	6	39	**52**	**4**
Maintenance dose not prescribed/administered after loading dose			1	6	21	**28**	**2**
Loading dose given but not required			2	6	20	**28**	**2**
Administration rate of maintenance dose delivered as per loading dose			1	7	18	**26**	**2**
TOTAL	**2**	**4**	**102**	**263**	**794**	**1165**	

Table 2: Medication involved in reported incidents

Name of medication in incident	Degree of harm (checked and corrected by clinical review)					Total
	Death	Severe	Moderate	Low Harm	No Harm	
warfarin		**2**	**13**	**33**	**97**	**145**
amiodarone			**11**	**26**	**75**	**112**
digoxin			**15**	**25**	**59**	**99**
phenytoin	**2**		**13**	**14**	**34**	**63**
metronidazole			1	7	54	62
caffeine			6	13	41	60
aminophylline			6	18	35	59
heparin			4	17	27	48
teicoplanin			1	10	32	43
vancomycin		1	2	12	26	41
trastuzumab				3	36	39
paracetamol				5	28	33
clopidogrel			3	5	20	28
morphine			2	5	18	25
gentamicin			2	3	15	20
tirofiban			2	5	12	19
magnesium sulphate				2	11	13
benzylpenicillin				1	8	9
aspirin				2	6	8
quinine			1	2	3	6
cefotaxime			1	2	3	6
caspofungin			1	3	2	6
phenobarbitone			1	2	3	6
omeprazole				1	5	6
Other medications or unknown (62)						209
Total						**1165**

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For IMMEDIATE ACTION by all organisations in the NHS and independent sector. Deadline for ACTION COMPLETE is 25 November 2011.

An executive director, nominated by the chief executive, working with the lead pharmacist and relevant medical/nursing staff should ensure:

1. All medicines used by the organisation that are likely to cause harm if loading doses and subsequent maintenance doses are not prescribed and administered correctly are risk assessed and used to produce a list of critical medicines (which may contain speciality subsections). This must include warfarin, amiodarone, digoxin, phenytoin and any other medicines identified locally.

2. There is effective communication regarding loading dose and subsequent maintenance dose regimens when prescribing, dispensing or administering critical medicines. This should include handover of patients between healthcare organisations. Tools such as loading dose work sheets, loading dose prescription charts, handover and clinical protocols, and patient-held information should be considered.

3. Clinical checks are performed by medical, nursing and pharmacy staff (when available) so that loading and maintenance doses are correct. Appropriate information should be available to support these checks.

4. Healthcare professionals in the community know when to challenge abnormal doses of the identified critical medicines.

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BNF – dose information for phenytoin inj

Dose

- By slow intravenous injection *or* infusion (with blood pressure and ECG monitoring), 20 mg/kg (max. 2 g) at a rate not exceeding 1 mg/kg/minute (max. 50 mg per minute), as a loading dose (see also notes above); maintenance doses of about 100 mg, by mouth or by intravenous administration, should be given thereafter every 6–8 hours, adjusted according to plasma-phenytoin concentration; CHILD 1 month–12 years, 20 mg/kg at a rate not exceeding 1 mg/kg/minute (max. 50 mg per minute) as a loading dose; maintenance dose of 5–10 mg/kg daily (max. 300 mg daily) in 2 divided doses; NEONATE 20 mg/kg at a rate not exceeding 1 mg/kg/minute, as a loading dose; maintenance dose of 5–10 mg/kg daily in 2 divided doses

  Note To avoid local venous irritation each injection or infusion should be preceded and followed by an injection of sterile physiological saline through the same needle or catheter

  Note Phenytoin sodium doses in BNF may differ from those in product literature

Phenytoin (Non-proprietary) (PoM)

Injection, phenytoin sodium 50 mg/mL, net price 5-

Royal Cornwall Hospitals NHS
NHS Trust

Loading dose worksheet for IV Phenytoin

Dose

Weight (kg)	Dose (mg/ml)
40-49	750mg in 100ml
50-64	1000mg in 100ml
65-78	1250mg in 250ml
79-92	1500mg in 250ml
>92	1750mg in 250ml

Example Prescription—Example 70kg patient

INFUSIONAL THERAPY SHEET

Date	Line	Additive drug (not for blood products) / Fluid or blood product & Batch number	Dose / Volume	Duration	Rate	Loading dose? (✓)	Signature & Bleep	Start time / End time	Device Batch No.	Given by / Added by	Checked by
1/1/ 2011	IV	Phenytoin	1250mg	35 minutes		✓	Doctor (bleep)				
		Sodium Chloride 0.9%	250mL								

Administration

- Dilute in 100-250ml sodium chloride 0.9% and give over 35 minutes
- *must not be diluted in a glucose containing solution*
- Should be delivered via a large gauge cannula in to a large vein. Flush line with sodium chloride 0.9% before and after administration to avoid local venous irritation
- Must be given through a 0.2 micron filter.

Monitoring

Regular monitoring of blood pressure, heart rate and inspection of venflon site

Continuous ECG monitoring throughout phenytoin loading

Inform Medical Staff immediately if patient experiences:

- Hypotension (i.e. marked drop in BP from baseline)
- Arrythmias
- Respiratory depression
- **Any** pain/erythema at venflon site **especially tracking along arm**
- If needed, take levels 18-24 hours after loading dose

Follow up prescription

- 300mg Phenytoin daily oral or intravenous (bio-availability the same)
- Can be as single dose or 100mg TDS

St George's Healthcare NHS
NHS Trust

NHS Commissioning Board

Prescribing Loading Doses in Adult Medicine

Digoxin

Prescribe **LOADING DOSE:**

ONCE ONLY PRESCRIPTIONS

Date	Time to be given	DRUG (APPROVED NAME)	Dose	Route	Prescriber			Administration			
					Initials	Name	Bleep	Date given	Time given	Given by	Pharm

Emergency Loading Dose for Atrial Fibrillation or Atrial Flutter

Adults: 500 to 1,000 micrograms (0.5 to 1.0mg) depending on Age, Lean Body Weight and Renal Function
By intravenous infusion over 2 hours
Maintenance dose by mouth on the following day

Rapid Oral Loading

750 to 1500 micrograms (0.75mg to 1.5mg) as a single dose
The elderly: oral loading dose should be given in divided doses 6 hours apart;
clinical response must be assessed before giving each additional dose

Slow Oral Loading

250 to 750 micrograms (0.25mg to 0.75mg) should be given daily for 1 week,
followed by appropriate maintenance dose
Clinical response should be seen within one week

For information regarding the IV Administration of drugs

Please refer to the Trust IV Drug Administration Prep guides (Adult Ward or Adult critical area depending on you clinical area)
http://stginet/Units%20and%20Departments/IV%20Drug%20Administration/IV%20PUMPS.aspx

St George's Healthcare NHS
NHS Trust

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Prescribing Loading Doses in Adult Medicine

Digoxin

Don't forget to prescribe a **MAINTENANCE DOSE**

REGULAR PRESCRIPTIONS

				Circle / enter times below ↓	↘ Enter dates below					Month:					Year:				
DRUG				06															
				08															
Dose	Route	Freq	Start date	12															
			Review date	16															
Signature		Bleep	Pharmacy	18															
				22															
Additional [illegible]ctions/Indication				New on this admission? ◯ Yes ◯ No						Continue on TTO? ◯ Yes ◯ No				Duration		Date		Signature	

Prescribe Maintenance Dose as a **"REGULAR PRESCRIPTION" in the inside of the drug chart**
Check when this should be prescribed under specific drug entry

Then Prescribe **MAINTENANCE DOSE** on regular side of the drug chart

Standard dose	125 to 250 micrograms daily (IV) (0.125 to 0.25mg) 125 to 750 micrograms daily (Oral) (0.125 to 0.75mg) Some patients may require higher doses
Those with increased sensitivity to the adverse effects of digoxin *(Elderly, Low Body Weight & Impaired Renal Function)*	62.5 micrograms daily

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Use of RCA and the EU Pharmacovigilance system

- Broader view of patient safety
- Not just ‘ product’ focused
- Greater understanding of systems of use and human factors
- Broader and new categories and methods for reporting and learning
- New methods to identify, communicate risks and solutions and implement and sustain safer practice