Improving safety of unlicensed liquid specials in the UK

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What keeps me worried and busy

10-fold medication errors

Repeat prescription of liquid meds

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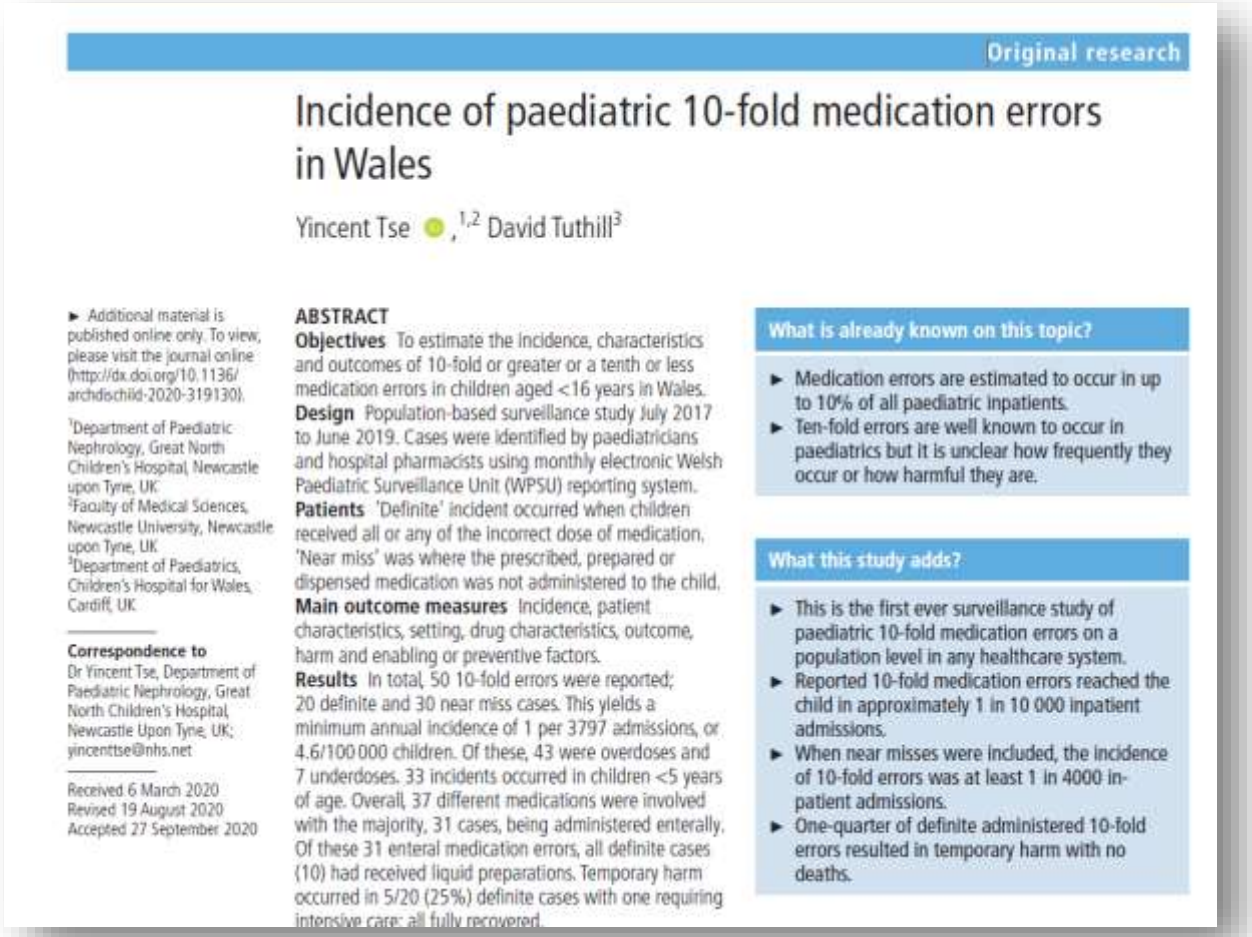

Original research

Incidence of paediatric 10-fold medication errors in Wales

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► Additional material is published online only. To view, please visit the journal online (http://dx.doi.org/10.1136/archdischild-2020-319130).

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ABSTRACT
Objectives To estimate the incidence, characteristics and outcomes of 10-fold or greater or a tenth or less medication errors in children aged <16 years in Wales.
Design Population-based surveillance study July 2017 to June 2019. Cases were identified by paediatricians and hospital pharmacists using monthly electronic Welsh Paediatric Surveillance Unit (WPSU) reporting system.
Patients 'Definite' incident occurred when children received all or any of the incorrect dose of medication. 'Near miss' was where the prescribed, prepared or dispensed medication was not administered to the child.
Main outcome measures Incidence, patient characteristics, setting, drug characteristics, outcome, harm and enabling or preventive factors.
Results In total, 50 10-fold errors were reported; 20 definite and 30 near miss cases. This yields a minimum annual incidence of 1 per 3797 admissions, or 4.6/100 000 children. Of these, 43 were overdoses and 7 underdoses. 33 incidents occurred in children <5 years of age. Overall, 37 different medications were involved with the majority, 31 cases, being administered enterally. Of these 31 enteral medication errors, all definite cases (10) had received liquid preparations. Temporary harm occurred in 5/20 (25%) definite cases with one requiring intensive care; all fully recovered.

What is already known on this topic?

- Medication errors are estimated to occur in up to 10% of all paediatric inpatients.
- Ten-fold errors are well known to occur in paediatrics but it is unclear how frequently they occur or how harmful they are.

What this study adds?

- This is the first ever surveillance study of paediatric 10-fold medication errors on a population level in any healthcare system.
- Reported 10-fold medication errors reached the child in approximately 1 in 10 000 inpatient admissions.
- When near misses were included, the incidence of 10-fold errors was at least 1 in 4000 inpatient admissions.
- One-quarter of definite administered 10-fold errors resulted in temporary harm with no deaths.

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Table 2 Medication involved in 10-fold medication errors

Enteral liquid	Intravenous injection	Intravenous infusion	Enteral tablets	Intraperitoneal
Morphine ×4	Epinephrine ×2	Labetalol	Clonidine	Heparin
Azithromycin ×2	Piperacillin with tazobactam ×2	Morphine	Trimethoprim	
Ranitidine ×2	Benzylpenicillin	Octreotide	Warfarin	
Alfacalcidol	Dexamethasone	Rocuronium		
Azithromycin	Diclofenac			
Cetirizine	Digoxin			
Chlorphenamine	Hydrocortisone			
Clonidine	Lorazepam			
Co-careldopa	Midazolam			
Digoxin	Ondansetron			
Furosemide	Phenobarbitone			
Iodine	Phenytoin			
Lacosamide				
Lamotrigine				
Levacetirazam				
Lorazepam				
Nitrofurantoin				
Oseltamivir				
Phenobarbitone				
Prednisolone				
Propranolol				
Sildenafil				
Vancomycin				

What keeps me worried and busy

10-fold medication errors

Route and form	
Enteral (by mouth or tube) - liquid	28 (56%)
IV bolus	14 (28%)
IV infusion	4 (8%)
Enteral (by mouth) - tablet/capsule	3 (6%)
Intraperitoneal	1 (2%)

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KidzMed – teaching children to swallow pills


How to give medicines through a gastrostomy tube
Share
owly push the plunger into the syringe
MORE VIDEOS
2:03 / 4:53
YouTube

Case 1

Teenager with medical complexity and epilepsy

Clobazam

Community pharmacy

Obtained 10mg / 5ml instead of 5mg / 5ml

Incorrectly labelled as ‘5mg / 5ml: Take 7ml (7mg) daily’

Administer for one month → Unsteady

General Pharmaceutical Council. *Patient safety spotlight: the risks of prescribing and supplying medicines to children*. 2021

Case 2

4 week infant discharged oral morphine 100 micrograms/ml specials solution

Discharge summary:

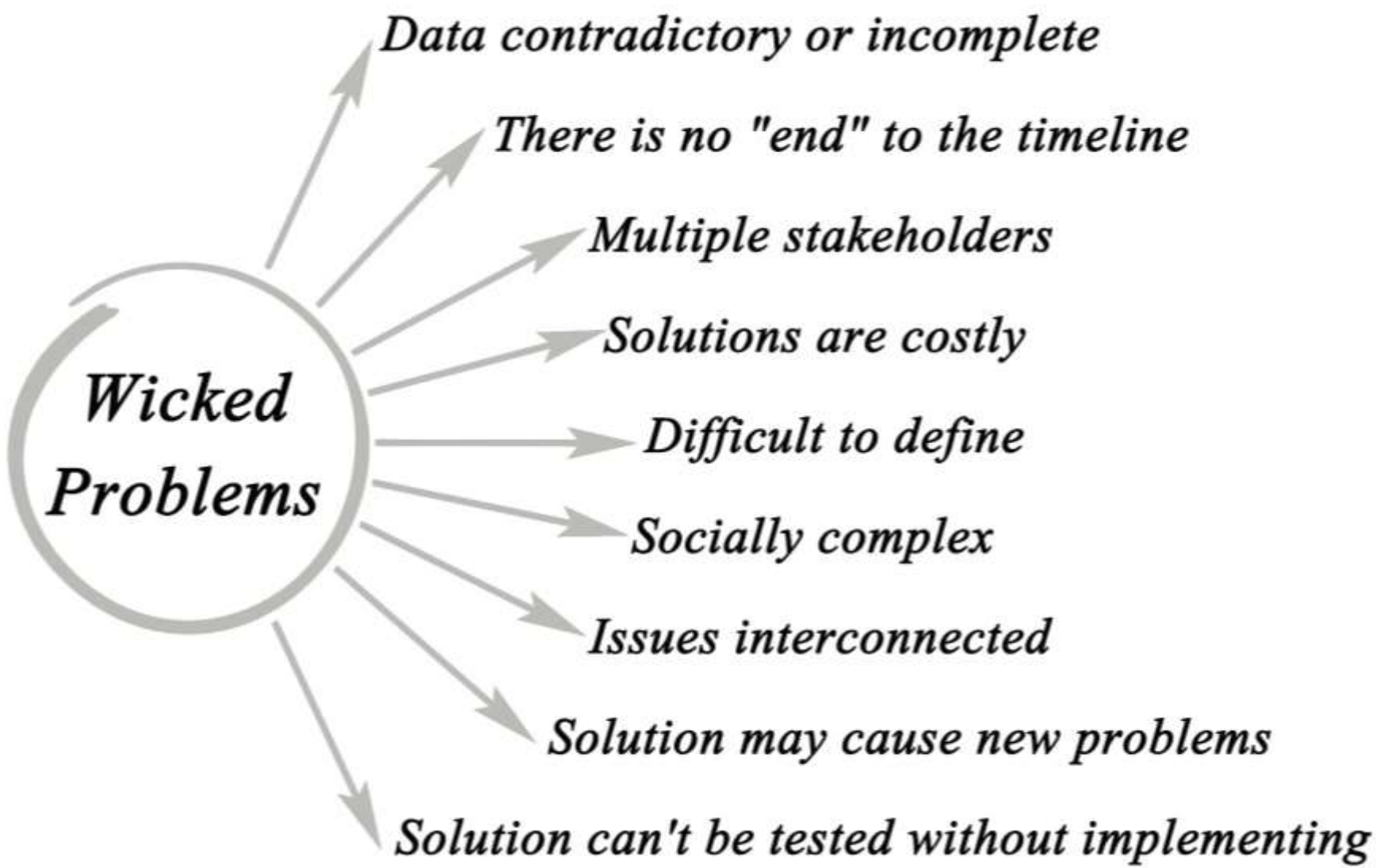
"Oramorph 50mcgs/kg/per dose = 190mcg every 4 hours"

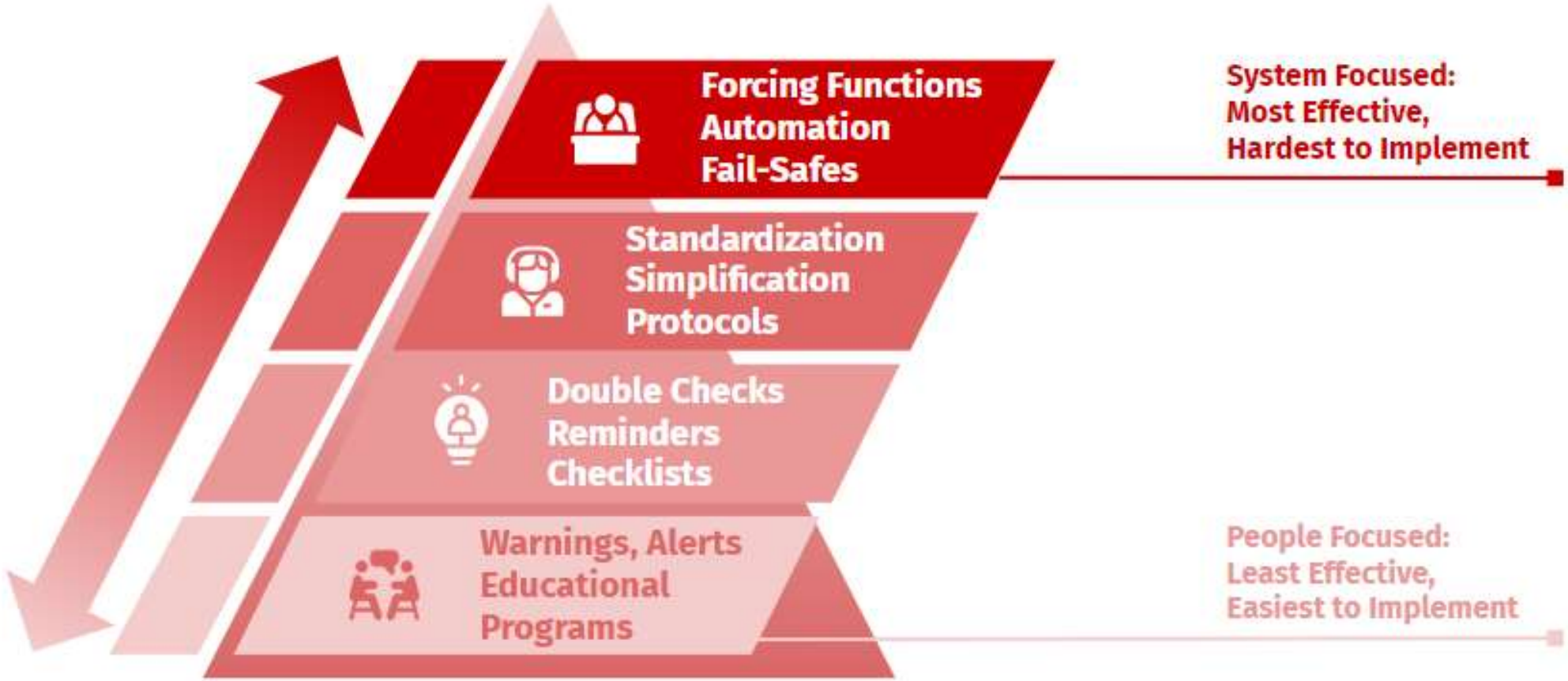
GP prescribed and community pharmacy dispensed Oramorph 10mg / 5ml oral morphine solution

Infant continued to receive 1.9 ml

NHS England NEY. *Serious Incident Case Study: Infant Morphine Overdose Investigation Summary & Learning July 2023*

	REGULATION 28 **REPORT TO PREVENT FUTURE DEATHS**
1.	**CORONER** I am Andrew Harris, Senior Coroner, London Inner South
2.	**CORONER'S LEGAL POWERS** I make these reports under paragraph 7, Schedule 5, Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.
3.	**INQUEST** On 9th September 2020 Miss Juanita Boate Nti (ref 9210617), died aged 4 months, in a Paediatric Intensive Care Unit. A post mortem examination was conducted, indicating an overdose of morphine. An inquest was opened on 10th March 2021 and concluded on 27th July 2023. The medical cause of death was found to be 1a Townes-Brocks syndrome with tracheal stenosis and complex congenital heart disease, following accidental morphine overdose.
4.	**CIRCUMSTANCES OF THE DEATH** Juanita was born on 12th May 2020 and investigations determined that her complex congenital diseases were not treatable. She received palliative care from 1st July and was tenderly cared for by her parents at home with a symptom management plan devised by specialists, which included Morphine solution via her naso-gastric tube as needed. On 3rd September her condition suddenly deteriorated after a dose of morphine and she suffered a respiratory arrest on the way to hospital. She improved with urgent medication to reverse the effect of morphine intoxication, but went on to require intubation. She breathed regularly on pressure support but could not sustain spontaneous ventilation after extubation.


Wicked Problems
Data contradictory or incomplete
There is no "end" to the timeline
Multiple stakeholders
Solutions are costly
Difficult to define
Socially complex
Issues interconnected
Solution may cause new problems
Solution can't be tested without implementing



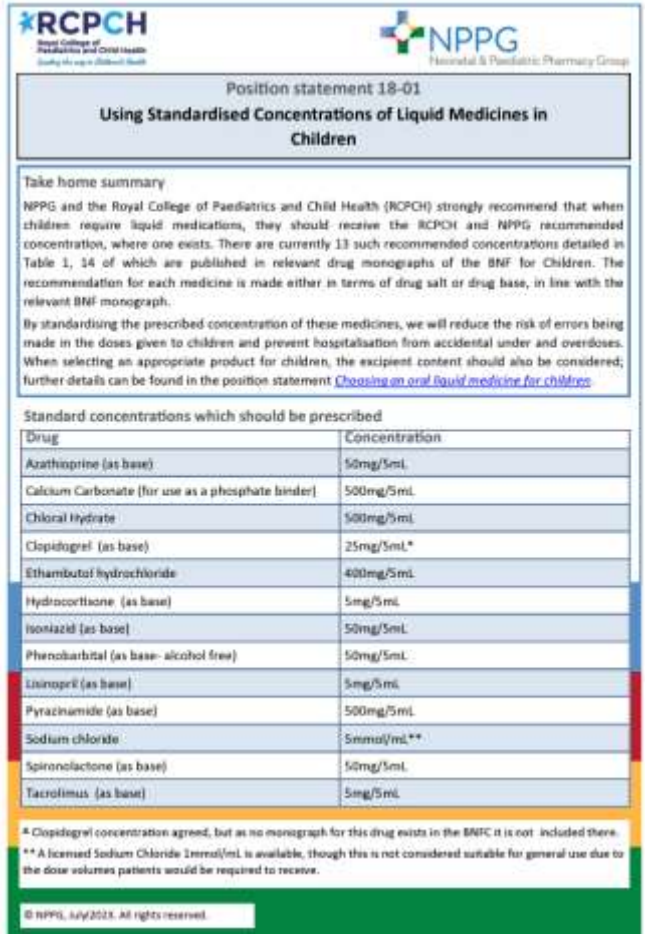
Hierarchy of Effectiveness of Patient Safety Interventions

Change ideas to improve safety of unlicensed liquid specials in the UK

Curated by Joint RCPCH/NPPG Medicines committee

1. National formulary of standard unlicensed liquid specials

- Narrow and standardise strengths available
- Accessible to electronic prescribing systems
- Remove as licensed products become available



RCPCH

NPPG
Neonatal & Paediatric Pharmacy Group

Position statement 18-01

Using Standardised Concentrations of Liquid Medicines in Children

Take home summary

NPPG and the Royal College of Paediatrics and Child Health (RCPCH) strongly recommend that when children require liquid medications, they should receive the RCPCH and NPPG recommended concentration, where one exists. There are currently 13 such recommended concentrations detailed in Table 1, 14 of which are published in relevant drug monographs of the BNF for Children. The recommendation for each medicine is made either in terms of drug salt or drug base, in line with the relevant BNF monograph.

By standardising the prescribed concentration of these medicines, we will reduce the risk of errors being made in the doses given to children and prevent hospitalisation from accidental under and overdoses. When selecting an appropriate product for children, the excipient content should also be considered; further details can be found in the position statement *Choosing an oral liquid medicine for children*

Standard concentrations which should be prescribed

Drug	Concentration
Azathioprine (as base)	50mg/5mL
Calcium Carbonate (for use as a phosphate binder)	500mg/5mL
Chloral Hydrate	500mg/5mL
Clopidogrel (as base)	25mg/5mL*
Ethambutol hydrochloride	400mg/5mL
Hydrocortisone (as base)	5mg/5mL
Isoniazid (as base)	50mg/5mL
Phenobarbital (as base- alcohol free)	50mg/5mL
Lisinopril (as base)	5mg/5mL
Pyrazinamide (as base)	500mg/5mL
Sodium chloride	5mmol/mL**
Spironolactone (as base)	50mg/5mL
Tacrolimus (as base)	5mg/5mL

* Clopidogrel concentration agreed, but as no monograph for this drug exists in the BNFC it is not included there.

** A licensed Sodium Chloride 1mmol/mL is available, though this is not considered suitable for general use due to the dose volumes patients would be required to receive.

2. Standardise pharmacy dispensing labels

- Variation confusion
- May improve carers'/parents' understanding

3. Standardise and embed culture of using generic drug names

- Common brand names refer to specific products and concentrations
- Spoken healthcare culture between staff and families

AS REQUIRED THERAPY

Name: HELEN SMITH			Number: 1006249702		Date of Birth: 10/6/24					
Reason for use: BREAK-THROUGH PAIN	Drug (Approved Name): ORAMORPH		Dose/Sliding Scale Dose: 10–15 mg	Date						
	Frequency & Instruction: 2HOURLY PRN FOR PAIN	Route: ORAL	Max Dose in 24 hours	Time						
Starting Dose & Date: 10mg 8/2/01	Signature & Name: CORMIE		Pharmacy	Dose						
Increased Dose & Date	Signature & Name		Date Discontinued & Initials	Given by						

NHS Trust training material

4. National agreed transitional care prescribing framework for paediatric medicines

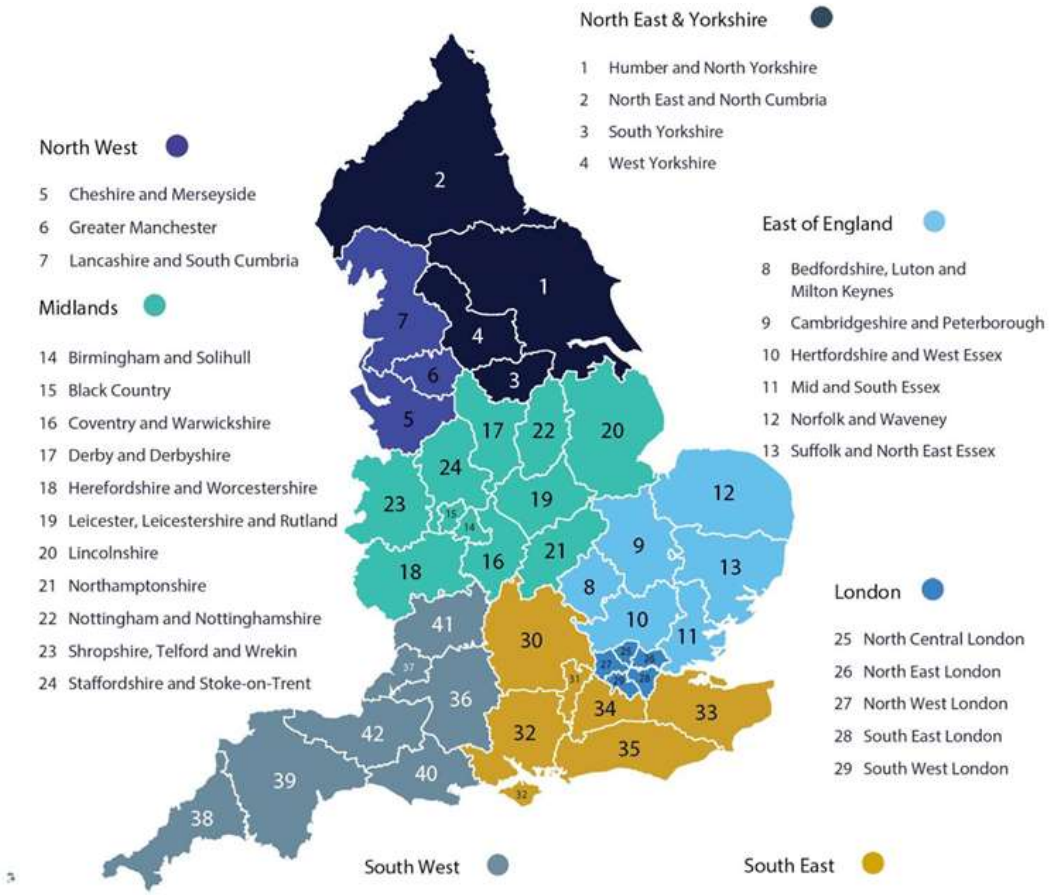
Red Hospital only

(Agreed high risk list)

Amber Shared care

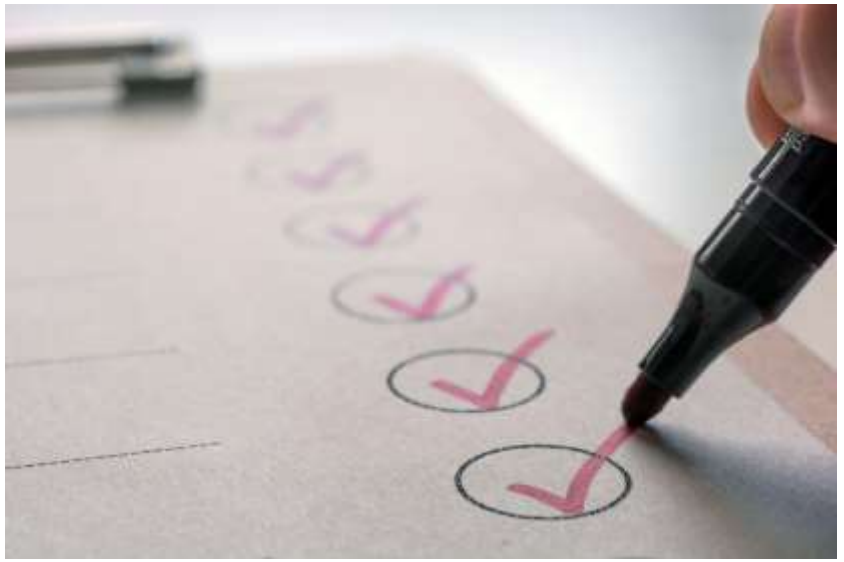
(all unlicenced specials)

Green Primary care



5. Supplies set up before discharge, and communicated with parents / carers

- Direct communication with supplying pharmacy
- RAG rating
- Standardised mechanism e.g. Discharge Management Service
- Health literacy and inclusion



Change ideas to improve safety of unlicensed liquid specials in the UK

Unlicensed liquid specials formulary

Labels

Generic drug names

RAG rating

Supplies set up before discharge