



South Wales and South West
**Congenital Heart
Disease Network**

Formulations-

What you do you need to know?

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Overview

- o Excipients
- o Standardisation of formulations
- o Licensing
- o Medicines Information
- o Cost
- o Challenges
- o What can we do better

What are excipients?

- Substances other than the active pharmaceutical ingredient

ROLES OF EXCIPIENTS

EXCIPIENTS HAVE DIFFERENT ROLES IN A FORMULATION. SOME OF THE MAJOR ONES CAN BE:



Aid in the processing of the drug delivery system during its manufacture.



Protect, support, or enhance stability, bioavailability, or patient acceptability.



Assist in product identification, and enhance any attribute of the overall safety.



Assist in the effectiveness and /or delivery of the drug in use.



Assist in maintaining the integrity of the drug product during storage.

pharma-excipients

IDEAL EXCIPIENT PROPERTIES



pharma-excipients

BUT can lead to adverse or hypersensitivity reactions.....

Problem Excipients



- o Propylene glycol e.g. propranolol liquid
- o Ethanol-intoxication e.g. Furosemide 10%
- o Benzyl alcohol-'gaspings syndrome' in neonates e.g. Clexane multidose vial/amiodarone injection
- o Sorbitol e.g. loperamide liquid



Strengths-can we standardise?

RCPCH and NPPG have strongly recommended the following strengths and documented this in the BNFC under the relevant monographs-

- o Azathioprine 50mg/5mL
- o Chloral hydrate 1g/5mL
- o Clopidogrel 25mg/5mL* (not in BNF-C)
- o Ethambutol 400mg/5mL
- o Hydrocortisone 5mg/5mL
- o Isoniazid 50mg/5mL
- o Melatonin 1mg/mL
- o Omeprazole 20mg/5mL
- o Phenobarbitone (alcohol free) 50mg/5mL
- o Pyrazinamide 500mg/5mL
- o Sertraline 50mg/5mL
- o Sodium chloride 5mmol/mL
- o Spironolactone 50mg/5mL
- o Tacrolimus 5mg/5mL

When it goes wrong...



What if no licensed product exists?

- Use a licensed product within the terms of its license as first choice
- 'Off-label' as a second choice before considering a special
- Could you use a tablet? Could use pill glide to encourage this?
- Can't take tablets...can you crush and disperse?
 - What is the coating on the tablet?
 - Is it soluble in water?
 - Where is it absorbed in GI tract-can it be given down ng/nj tube?
 - Do you need to dilute for going down a tube, so not to block?
- Can't use a tablet or crush?
 - Try and use the same special from the same supplier to minimise product variation



Medicines Information

o If not licensed the information is not always appropriate...based on licensed product specification

o Suitable information is available at;

Medicines for Children leaflets:

<https://www.medicinesforchildren.org.uk/>

But not all drugs have a leaflet yet....

Cost...any ideas???

- o Furosemide 50mg/5ml 150ml
- o Spironolactone 50mg/5ml 125ml
- o Captopril 5mg/5ml 100ml
- o Captopril 25mg/5ml 100ml
- o Enalapril 2.5mg tablets x 28
- o Sildenafil 10mg/ml 100ml
- o Amiodarone 50mg/5ml 250ml
- o Enoxaparin multidose vial 300mg/3ml
- o Warfarin 1mg/ml 100ml
- o Flecainide 25mg/5ml 300ml

Challenges

- o Better information transfer
- o Getting GPs/community pharmacies to provide the same formulation to avoid confusion and potential under/over dosing
- o Communication of medication that will be hospital only requiring local paediatrician to carry on prescribing
- o Supply issues and alternatives and how to communicate this to network and patients

What can we do better?

- o Discharge summaries (workstream)
 - o Formulation strength documented
 - o Better indication of duration for antiplatelets
 - o Who will prescribe GP/local paediatrician-how to communicate this seamlessly
 - o Monitoring clearly documented
- o Standardise formulations used across the network
- o Standardise formulations into primary care (& cost reduction)
- o Review of medication with weight e.g. aspirin and clopidogrel for stents/shunts
- o Is the dose measurable? E.g. enoxaparin multidose vial
- o How do we highlight supply problems to the network/parents?

We have briefly highlighted some of the issues with formulations.....

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Thank You!

