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COLLABORATIVE NETWORK FOR EUROPEAN CLINICAL TRIALS 4 CHILDREN

Risk Mitigation for off-label medicines in children

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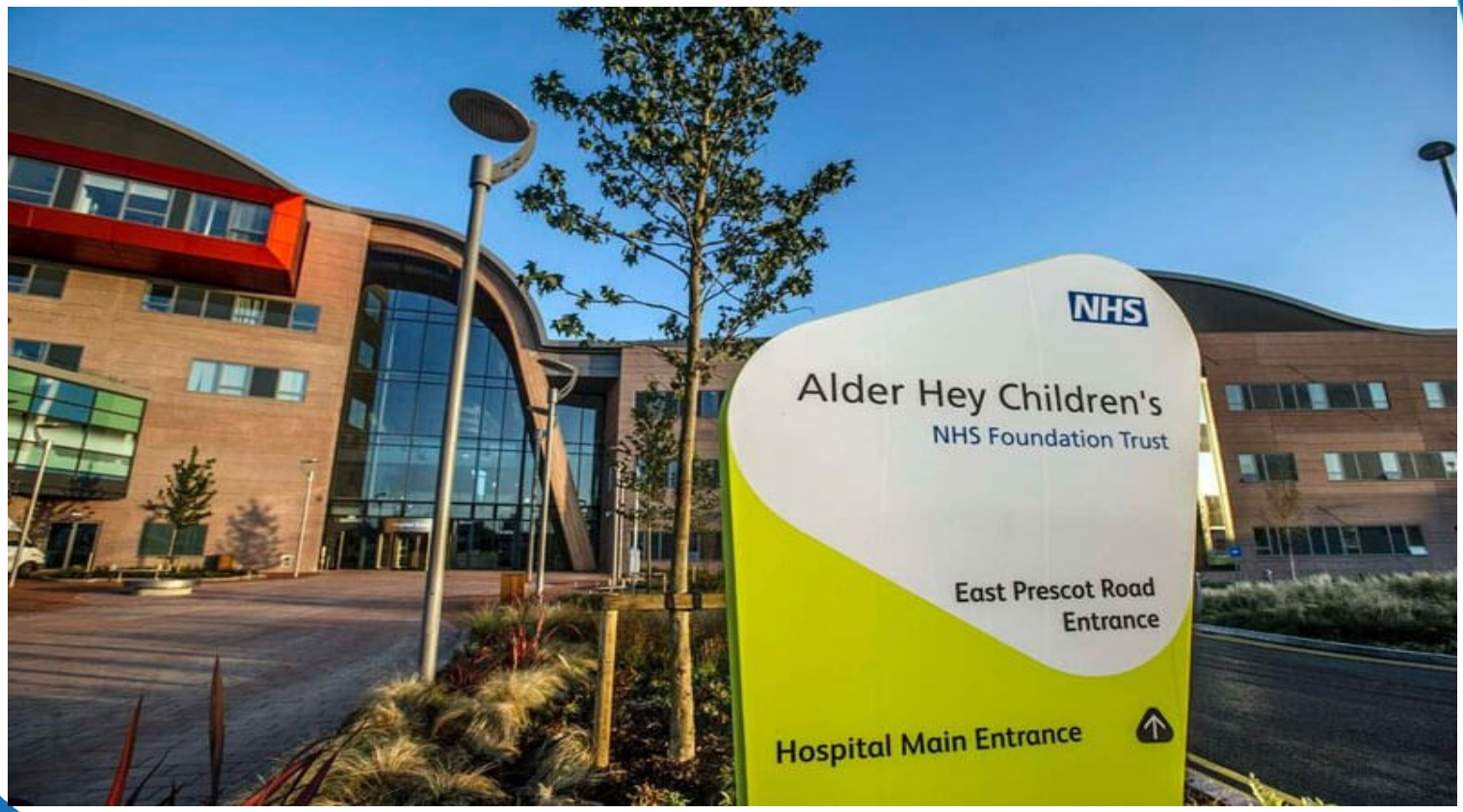
Liverpool Women's

The argument

An integrated approach to risk mitigation is needed

- Goals based on specific intervention(s)
  - Maybe one goal at a time is best
- Team
- Implementation plan
- Evaluation

Alder Hey Children's Hospital



100 YEARS OF ALDER HEY
1914 2014

Paediatric Medicines Research Unit

PMRU
PAEDIATRIC MEDICINES RESEARCH UNIT

Aim:

To improve the health of babies, children and young people by research and development of better and safer medicines and their management.





Examples of Interventions

- Guidelines about manipulations
  - MODRIC project
  - Needs a repository

Examples of Interventions

Alder Hey Children's NHS
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These guidelines were developed as independent research commissioned by the National Institute for Health Research, Research for Patient Benefit (RfPB) Programme (Grant Reference Number PB-PG-0807-13260). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health

A Guide for Health Professionals

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Creating a Pill School – The Kidzmed Project

Creating a pill school to teach children and young people how to take tablet medication.

The Problem

Tablets are safer, more convenient and cheaper than liquid medications. Children and young people (CYP) often remain on liquids due to habit, reluctance to change or staff and parents' lack of knowledge about switching to tablets.

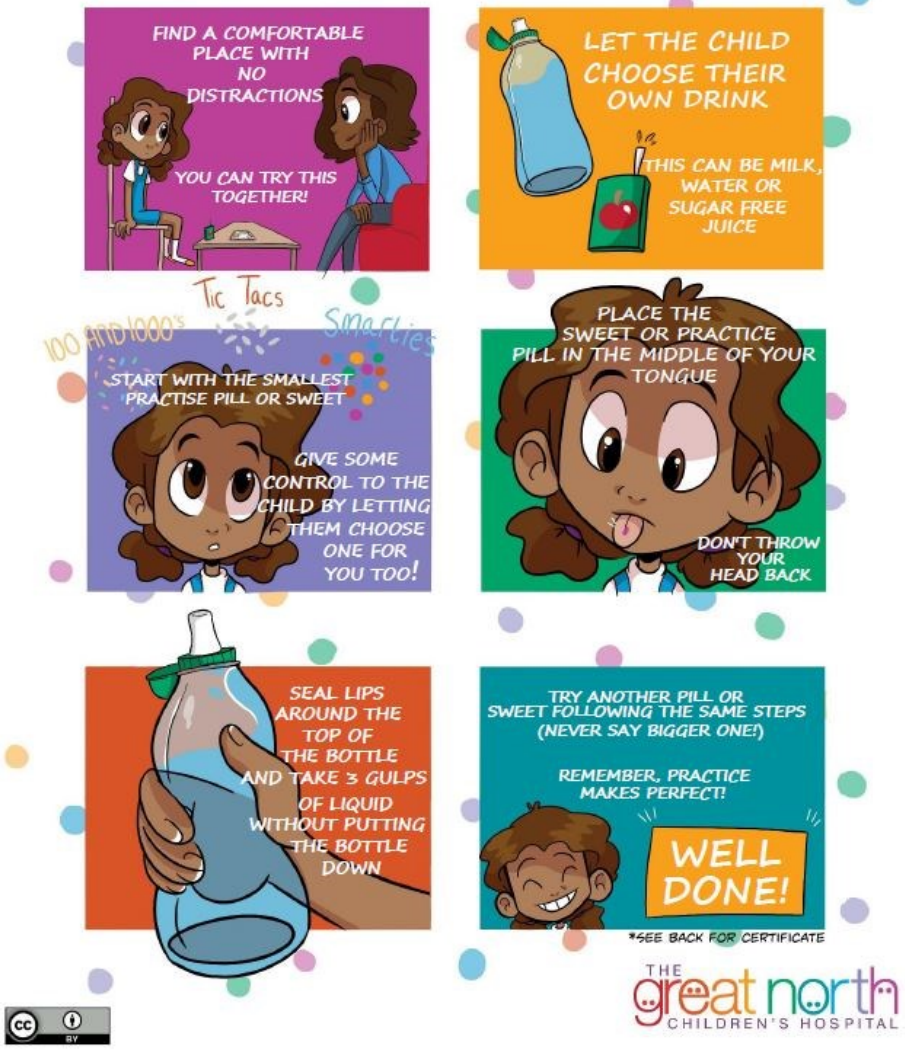
Aims

This initiative started off within one team in our children's hospital to train staff and embed a system of looking for and converting eligible children to tablet medication.

https://qicentral.rcpch.ac.uk/medsiq/patient-support/creating-a-pill-school-the-kidzmed-project/

NHS
The Newcastle upon Tyne Hospitals
NHS Foundation Trust

TODAY WE ARE LEARNING HOW TO SWALLOW PILLS



THE great north CHILDREN'S HOSPITAL

https://qicentral.rcpch.ac.uk/medsiq/patient-support/creating-a-pill-school-the-kidzmed-project/

Learning and Next Steps

- Make learning fun. Learn in teams who normally work together
- Data collection is not difficult but does need close steerage. Once we had enough cost improvement data it opened doors to organisational leaders to help spread the project
- Patient and parents involvement at all stages is really helpful and helps drives the project as the improvement transformed their lives and they are keen to share their experiences

Teaching tablet swallowing is easy. This is not a new idea and we know of individual clinicians who have been teaching their patients how to swallow tablets for many years.

Read the full publication in Archives of Disease in Childhood: Tse Y, Vasey N, Dua D, et al. The KidzMed project: teaching children to swallow tablet medication. Archives of Disease in Childhood. Published Online First: 08 October 2019. doi: 10.1136/archdischild-2019-317512.

Project Lead: Yincent Tse, Consultant Paediatric Nephrologist; Nicola Vasey, Lead Paediatric Pharmacist; Ailsa Pickering, Senior Sister in Paediatric Infectious Disease; Emma Lim, Consultant Paediatrician.

Organisation: Great North Children's Hospital, Newcastle upon Tyne

CAT Study

Open access Original research

BMJ Open

Can children swallow tablets? Outcome data from a feasibility study to assess the acceptability of different-sized placebo tablets in children (creating acceptable tablets (CAT))

Louise Bracken ,[1] Emma McDonough,[1] Samantha Ashleigh,[2] Fiona Wilson,[2] Joanne Shakeshaft,[1] Udeme Ohia,[2] Punam Mistry,[3] Huw Jones,[4] Nazim Kanji,[4] Fang Liu,[5] Matthew Peak[1,2]

To cite: Bracken L, McDonough E, Ashleigh S, *et al*. Can children swallow tablets? Outcome data from a feasibility study to assess the acceptability of different-sized placebo tablets in children (creating acceptable

ABSTRACT

Objective Feasibility study to investigate the acceptability of different-sized placebo tablets in children aged 4–12 years.

Design and setting Clinical Research Facilities, inpatient wards and outpatient clinics within a Regional Paediatric Hospital and/or District General Hospital. Healthy children

Strengths and limitations of this study

- This study was conducted in both inpatients and healthy children to determine the overall acceptability (which includes swallowability, volume of water consumed and taste) of tablets in both children who

https://bmjopen.bmj.com/content/bmjopen/10/10/e036508.full.pdf

NPPG
Neonatal & Paediatric Pharmacists Group

RCSI UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

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NHS
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NHS Foundation Trust

leeds children's hospital
caring about children

NHS
The Leeds Teaching Hospitals
NHS Trust

THE ROTUNDA HOSPITAL
DUBLIN

NHS
Wirral University Teaching Hospital
NHS Foundation Trust

STUDY PROTOCOL

PADDINGToN

Parent co-**D**esigned **D**rug **In**formation for parents and **G**uardians **T**aking **N**eonates home

Paddington

Preparation:

- What do parents want / need?
- What can staff do?
- What are the gaps?

Development of resources with parents:

- Construction
- Evaluation

The impact of paediatric dose range checking software

Table 1 Summary of prescription overdosing error data and severity of reported overdosing-related clinical incidents

	Preintervention	Postintervention
Number of electronic prescriptions completed	131612	136803
Incidence of overdosing errors	12/847 (1.4%)	9/684 (1.3%)
Proportion of overdosing errors classified as minor errors	8/12 (66.7%)	7/9 (77.8%)
Proportion of overdosing errors classified as significant errors	4/12 (33.3%)	2/9 (22.2%)
Total overdosing-related clinical incidents	28	32
Proportion of overdosing incidents resulting in 'No Harm'	7/28 (25.0%)	17/32 (53.1%)
Proportion of overdosing incidents resulting in 'Near Misses'	20/28 (71.4%)	15/32 (46.9%)
Proportion of overdosing incidents resulting in 'Minor Harm'	1/28 (3.6%)	0/32 (0.0 %)

Neame M, et al. Eur J Hosp Pharm 2021;28:e18–e22. doi:10.1136/ejhpharm-2020-002244

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The impact of paediatric dose range checking software

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Proportion of overdosing incidents resulting in 'Minor Harm'	1/28 (3.6%)	0/32 (0.0 %)

"….use of this software does not reliably prevent overdosing errors… appropriate training and prescription checking processes should always continue alongside these interventions"

Neame M, et al. Eur J Hosp Pharm 2021;28:e18–e22. doi:10.1136/ejhpharm-2020-002244

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Examples of "Guidelines"

2022

- ENFit system
- Off Label Use of Chloral Hydrate to sedate neonates and children in critical care
- Administration of Rectal Diazepam to Neonates and Infants to Treat Seizures Prior to Hospital Admission

2021

- Use of Steroid Medication Warning Cards for Children and Young People
- Off label use of Chloral Hydrate in the Management of Intrusive Movement and Motor Disorders in Children and Young People
- The use of chlorhexidine for skin cleansing in neonates

2020

- Alternative parenteral acid suppressants covering main indications of IV rantidine in children
- Choosing an oral liquid medicine for children – December 2020
- Domperidone and ECG monitoring – interim statement January 2020

2019

- The use of unlicensed medicines or licensed medicines for unlicensed applications in paediatric practice – update

2018

- Using Standardised Strengths of Unlicensed Liquid Medicines in Children – updated May 2022

http://nppg.org.uk/position-statements/

Has this research changed practice?

- Publication
- Journal Club
- Grand Round
- Newsletters
- Screensavers…

Has this research changed practice?

NO!!!

What is needed?

Move from research and evaluation into changing clinical practice

- Quality Improvement
- Mandate from health care system
- Accountability to health care system
  - Regular review
  - Consequences of failure and success

Quality Improvement

- an **organised**, multifaceted approach
  - includes teams from multiple healthcare sites
  - coming together to **learn, apply** and share improvement methods, ideas and **data**
- on **service performance** for a given healthcare topic.

Wells S, et al. BMJ Qual Saf 2018;27:226–240. doi:10.1136/bmjqs-2017-006926

Quality Improvement

- Teams are supported by faculty of experts
- Between meetings:
  - Teams are provided with coaching
  - Tasked to apply quality improvement methods, (such as Plan-Do-Study-Act cycles)
- Teams learn faster and are more effective when **collaborating** and **benchmarking** with other teams

Wells S, et al. BMJ Qual Saf 2018;27:226–240. doi:10.1136/bmjqs-2017-006926

Quality Improvement

- An improvement was reported in 83% of the studies (32/39) included in a systematic review
- Collaboratives reporting success generally:
  - addressed relatively straightforward aspects of care,
  - had a strong evidence base
  - noted a clear evidence-practice gap in an accepted clinical pathway or guideline.

Wells S, et al. BMJ Qual Saf 2018;27:226–240. doi:10.1136/bmjqs-2017-006926

Mandate from Health Care System

- Provide resources
- Demonstrate importance
- What do we stop doing to make room for this?
- Hospital
  - Departments
- Region
  - Facilities
- Country
  - Regions
  - Comparable facilities

Accountability

If you don't check it, it doesn't get done

- Who goes to jail if it doesn't happen?
- Who gets a prize if it does happen?

- Not the same as Responsibility
  - Who does the work?
- Accountability and Responsibility need to be described

Conclusion

An integrated approach to risk mitigation is needed

- Goals based on specific intervention(s)
  - Maybe one goal at a time is best
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} Quality Improvement