Why are we here

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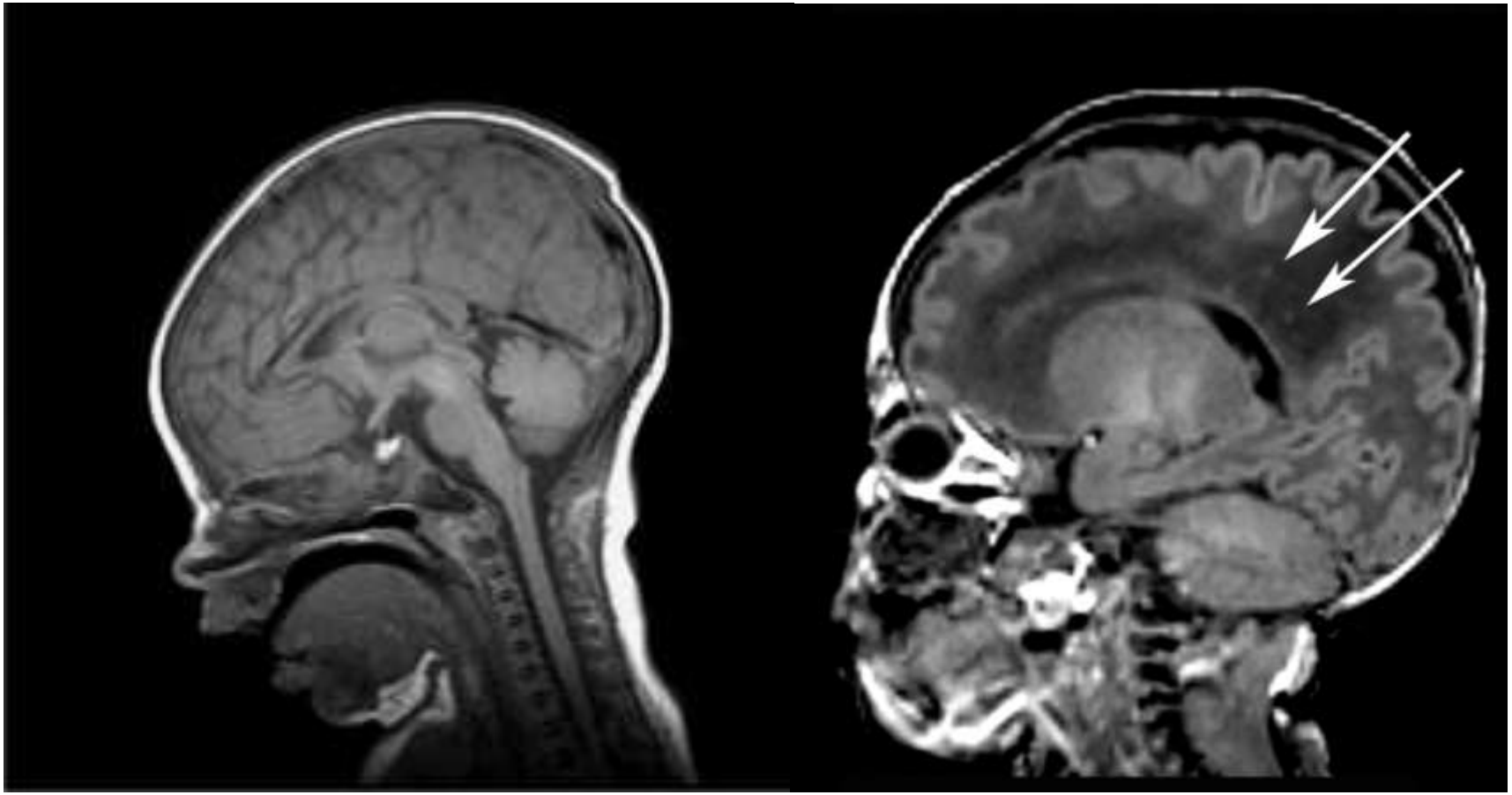
PReCePT – Neonatal Lead

Prevention of Cerebral Palsy in Pre-Term Labour (PReCePT)

Preterm Brain Injury



Clinical Background

- The prevalence of preterm birth is increasing
- While the survival of infants born preterm has improved, the prevalence of cerebral palsy has risen
- The incidence of cerebral palsy decreases significantly with increasing gestational age

  22–27 weeks **14.6%**

  28–31 weeks **6.2%,**

  32–36 weeks **0.7%**

  Full-term - 0.1%

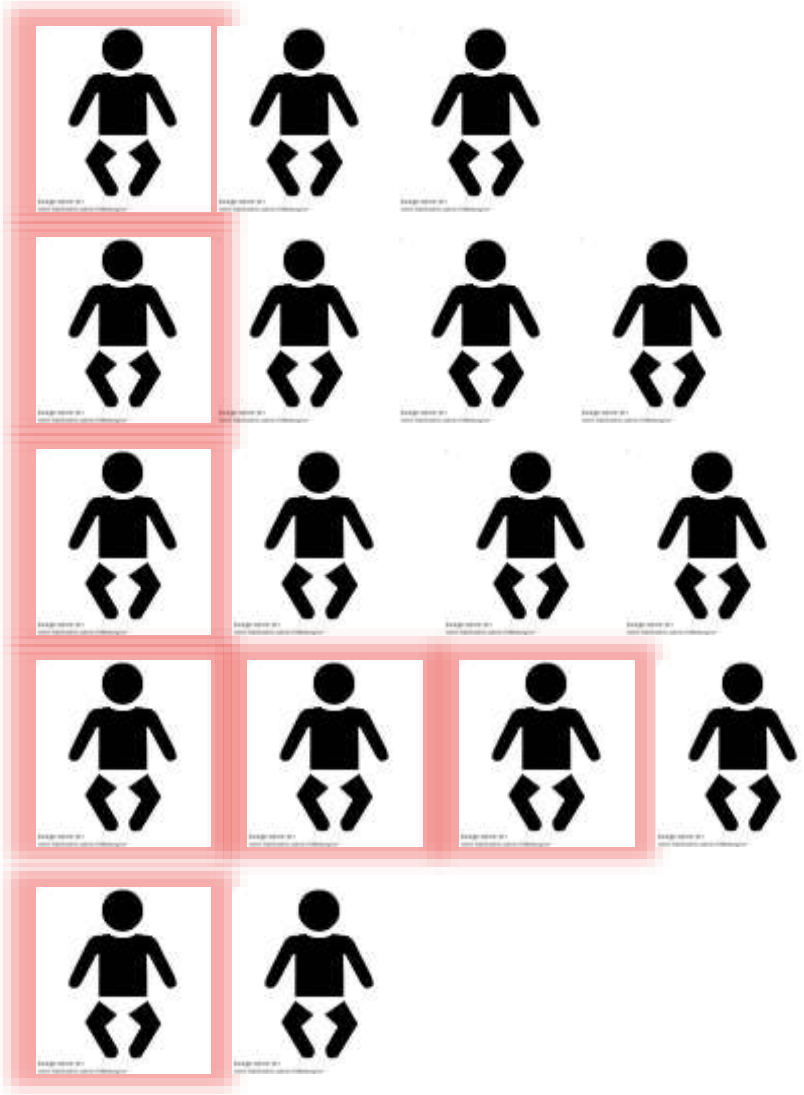
Preterm Birth and Cerebral Palsy

- Preterm birth is the major risk factor for CP
- 10% of very low birth weight babies develop CP
- Estimated 1065 new cases of CP secondary to prematurity each year.

Cerebral Palsy (CP)

- A condition marked by impaired muscle coordination/movement (spastic paralysis) and/or other disabilities, typically caused by damage to the brain before or at birth
- Average lifetime Health Care costs per individual: ~£800,000
- The cost to the individual and their family is unquantifiable
- Until recently no intervention available to prevent CP in preterm babies

Cerebral Palsy



Unable to walk

Unable to talk

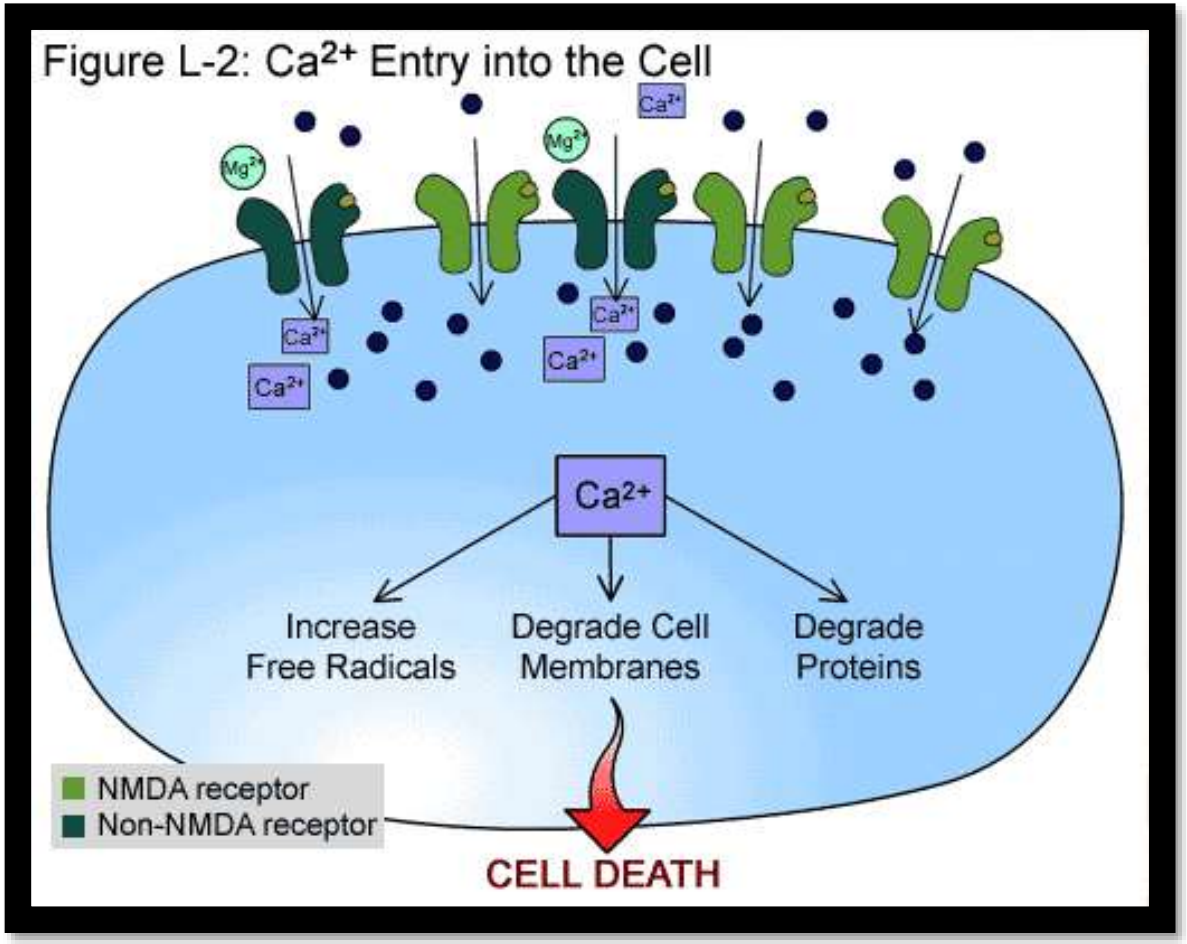
Epilepsy

Experience pain

Intellectual impairment

$MgSO_4$: Mechanism of Action

Rapidly crosses the placenta and enters the fetal brain within minutes



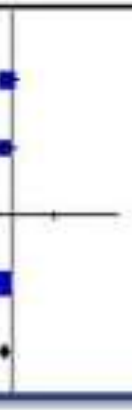
Clinical Evidence

Antenatal magnesium sulphate therapy given to women at risk of preterm birth substantially reduced the risk of cerebral palsy in their child (relative risk (RR) 0.68; 95% Confidence interval (CI) 0.54 to 0.87; five trials; 6145 infants).

MgSO4 : Cerebral Palsy

Outcome: 4 Cerebral palsy

Study or subgroup	Magnesium n/N	No magnesium n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Neuroprotective intent any CP					
Crowther 2003	36/629	42/626		29.0 %	0.85 [0.55, 1.31]
Marret 2006	22/352	30/336		21.1 %	0.70 [0.41, 1.19]
Mittendorf 2002	3/30	0/29		0.3 %	6.77 [0.37, 125.65]
Rouse 2008	41/1188	74/1256		49.5 %	0.59 [0.40, 0.85]
Subtotal (95% CI)	**2199**	**2247**		**100.0 %**	**0.71 [0.55, 0.91]**



Doyle et al. Cochrane Library. 2010

THE COCHRANE COLLABORATION®

Clinical Evidence

NICE 2015 (NG25)

Preterm labour and birth (NG25)

1.10 *Magnesium sulfate for neuroprotection*

1.10.1 Offer intravenous magnesium sulfate for neuroprotection of the baby to women between 24[+0] and 29[+6] weeks of pregnancy who are:

- in established preterm labour **or**
- having a planned preterm birth within 24 hours.

1.10.2 Consider intravenous magnesium sulfate for neuroprotection of the baby for women between 30[+0] and 33[+6] weeks of pregnancy who are:

- in established preterm labour **or**
- having a planned preterm birth within 24 hours.

1.10.3 Give a 4 g intravenous bolus of magnesium sulfate over 15 minutes, followed by an intravenous infusion of 1 g per hour until the birth or for 24 hours (whichever is sooner).

1.10.4 For women on magnesium sulfate, monitor for clinical signs of magnesium toxicity at least every 4 hours by recording pulse, blood pressure, respiratory rate and deep tendon (for example, patellar) reflexes.

1.10.5 If a woman has or develops oliguria or other signs of renal failure:

- monitor more frequently for magnesium toxicity
- think about reducing the dose of magnesium sulfate.

BMJ Open Quality (2017)

BMJ Open Quality

Preventing cerebral palsy in preterm labour: a multiorganisational quality improvement approach to the adoption and spread of magnesium sulphate for neuroprotection

Anna Burhouse,[1] Charlotte Lea,[2] Stephen Ray,[1] Hannah Bailey,[3] Ruth Davies,[4] Hannah Harding,[2] Rachel Howard,[5] Sharon Jordan,[6] Noshin Menzies,[1] Sarah White,[1] Kathryn Phillips,[1] Karent Luyt[7]

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ABSTRACT

Magnesium sulphate has been demonstrated to be an effective neuroprotectant for babies delivered prematurely (under 37 weeks' gestational age). Antenatal administration reduces infant mortality and cerebral palsy (CP); however, uptake in the UK has been significantly lower than other countries. A quality improvement (QI) project (PReventing Cerebral palsy in Pre Term labour (PReCePT)) was carried out in the West of England, UK, to raise awareness of evidence and to improve the uptake of magnesium sulphate as neuroprotectant in preterm deliveries. Five National Health Service (NHS) Trusts and the West of England Academic Health Science Network participated in the QI project. The project was underpinned by a multifaceted QI approach that included: patient and clinical coproduction of resources; recruitment of clinical champions to support the local microsystems and create a stimulating/supporting environment for change; Plan, Do, Study, Act cycles; training for over 600 NHS staff and awareness raising and strategic influencing of key leaders. A baseline audit and regular measurement of the number of eligible women receiving magnesium sulphate was undertaken at each hospital site, and the overall programme was evaluated using data from an international benchmarking organisation for neonatal care outcomes—the Vermont Oxford Network. During the project 664 staff received magnesium sulphate training. The use of magnesium sulphate increased across the West of England from an average baseline of 21% over the 2 years preceding the project to 88% by the conclusion of the project. The project was also able to influence the development of a national data collection process for benchmarking the use of magnesium sulphate for neuroprotection in preterm deliveries in the U.K. PReCePT appears to have had a favourable effect on the uptake of magnesium sulphate across the West of England. The project has also provided learning about how to stimulate adoption and spread of evidence using a QI approach across a network.

PROBLEM

Cerebral palsy (CP) is a significant consequence of preterm birth.[1] Within the West of England, approximately 500 infants are born weighing less than 1500 g each year.[2] These babies are eligible for antenatal magnesium sulphate, which has been proven to reduce the rate of CP.[1] Before the inception of this project, only between 8% and 66% of eligible infants were receiving this treatment across the five sites,[2] potentially resulting in disability that could have been prevented. Significant variation in operational practice was identified both within and between the sites, and we discovered that even where a policy existed that highlighted the need to give antenatal magnesium sulphate, it was not consistently being administered, and a large number of staff and parents were unaware of the need to offer this treatment, often confusing it with the treatment for pre-eclampsia.

The West of England Academic Health Science Network is a membership organisation made up of NHS health and social care providers, clinical commissioning groups, universities and the South West Ambulance Service. It acts to coordinate projects across the member organisations to improve quality and patient safety and speed up the adoption of evidence into practice.

'PReCePT' was codesigned with a range of partners in response to a call asking for local examples of best practice that could be shared with our member organisations and which would benefit from a QI approach to implementation and spread.

Dr Karen Luyt, MBChB, PhD, FRCPCH (Consultant in Neonatal Medicine and Consultant Senior Lecturer Neonatal Neuroscience, University of Bristol), submitted a proposal to share the progress that had been made in University Hospitals Bristol NHS Foundation Trust in the use of magnesium

Assessing the neuroprotective benefits for babies of antenatal magnesium sulphate: An individual participant data meta-analysis

Caroline A. Crowther[1,2*], Philippa F. Middleton[2,3], Merryn Voysey[4], Lisa Askie[5], Lelia Duley[6], Peter G. Pryde[7], Stéphane Marret[8,9], Lex W. Doyle[10,11,12], for the AMICABLE Group[¶]

Key Findings:

Number Needed to Treat = 42 to prevent 1 case of CP

Reduction of moderate/severe (37%) and severe CP (46%)

Effective even if given 0-4 hours before delivery

No risk to mother. No risk of respiratory depression for baby.

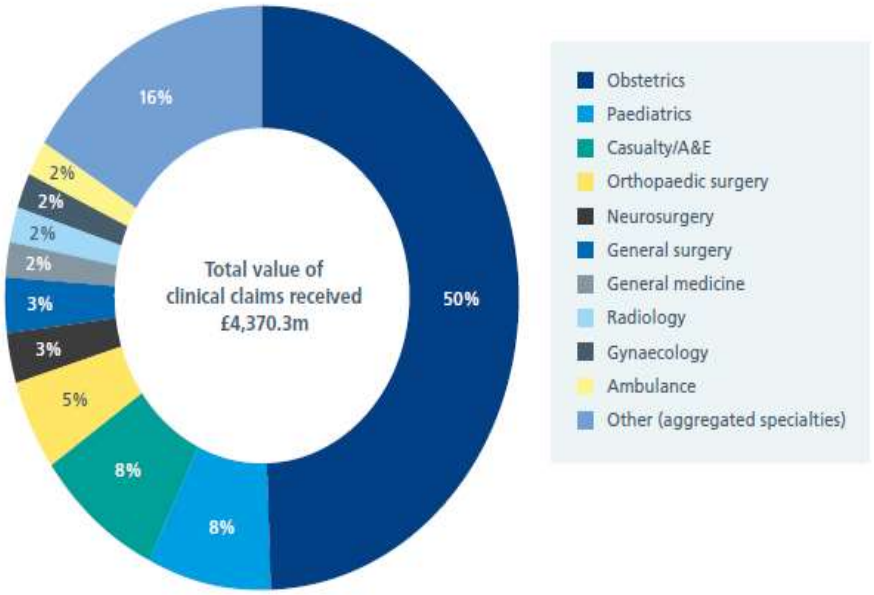
- Antenatal magnesium sulphate for fetal neuroprotection can be recommended to be given close to planned or expected preterm birth using the smallest effective dose of 4g with or without a 1g/hour maintenance dose

The Problem

- Fewer than half of eligible women in planned/unplanned preterm labour are receiving magnesium sulphate (MgSO4) when clinically indicated.

NHS Litigation Cost for CP: £1.9 billion in 2016

Figure 10: Value of clinical negligence claims received in 2016/17 by specialty across all clinical negligence schemes[5]



As in previous years, the greatest value of claims received across all our clinical negligence schemes relate to the obstetrics specialty.

NHS Resolution

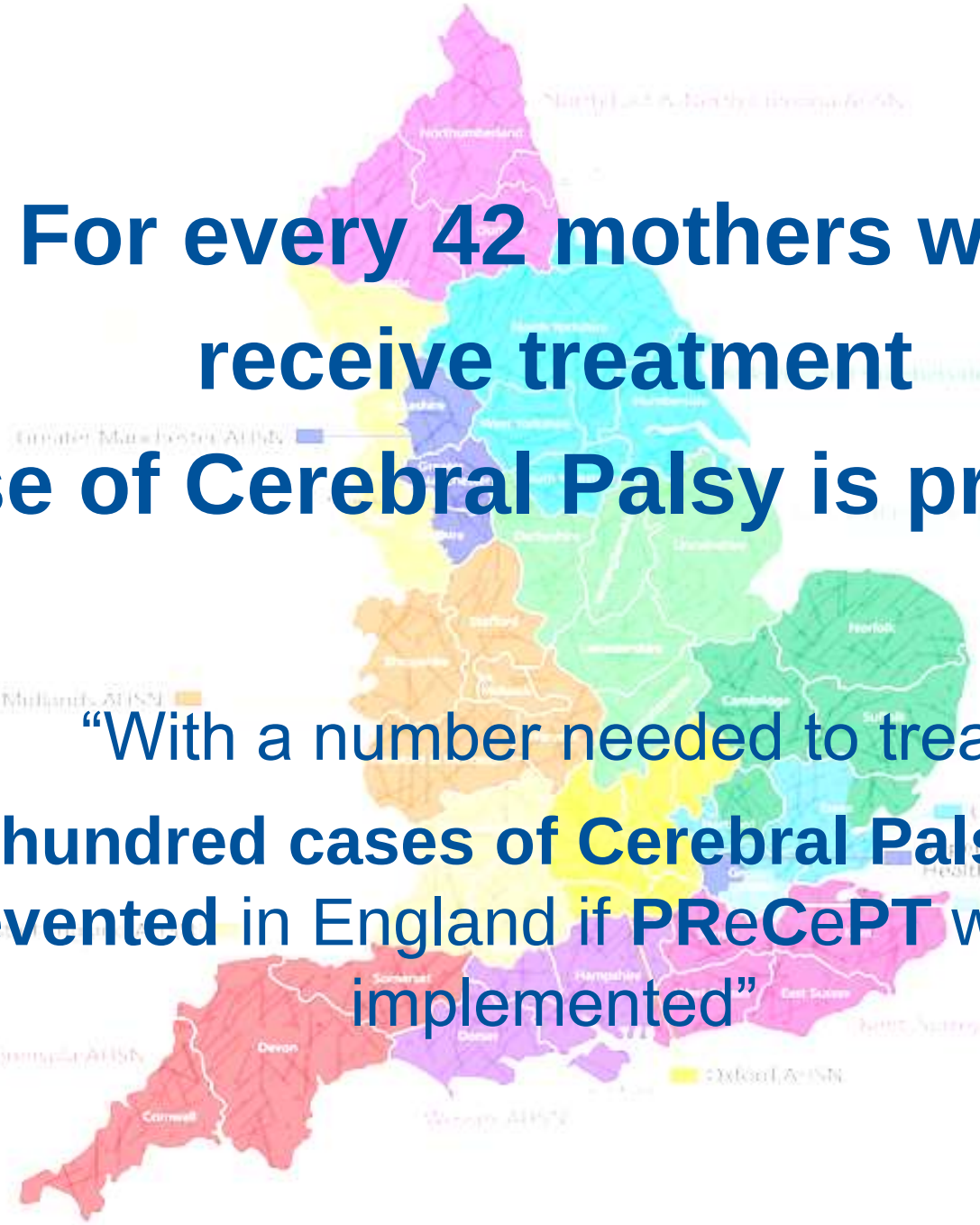
Annual report and accounts 2016/17

188 claims for CP/brain injury to NHS litigation authority in 2015/16

And increasing…….

Figure 19: A comparison of the number and total value of claims for maternity cerebral palsy/brain damage claims over time across all clinical negligence schemes

For every 42 mothers who receive treatment 1 case of Cerebral Palsy is prevented



"With a number needed to treat of 42,

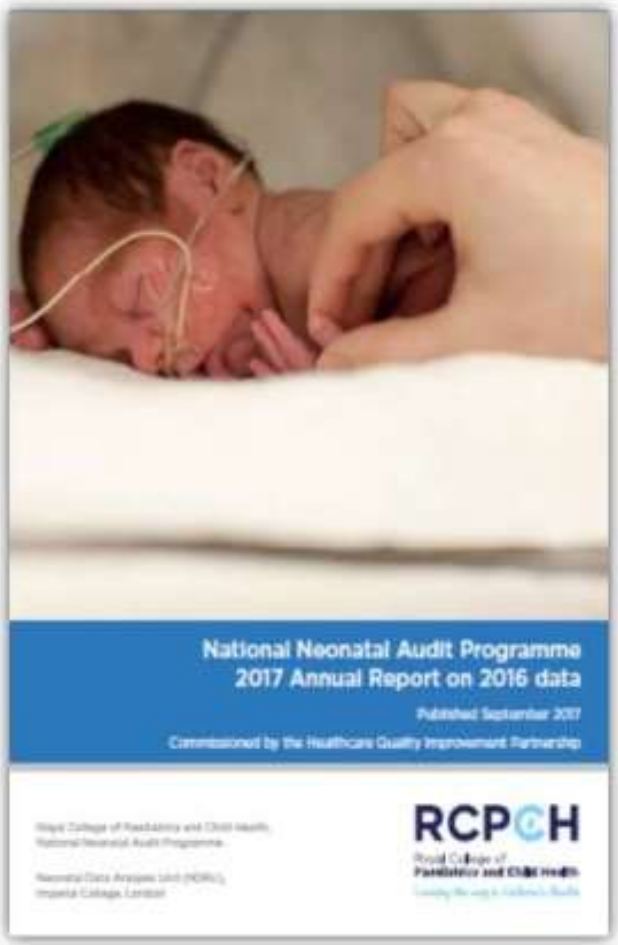
a few hundred cases of Cerebral Palsy may be prevented in England if **PReCePT** was fully implemented"

(Crowther 2017)

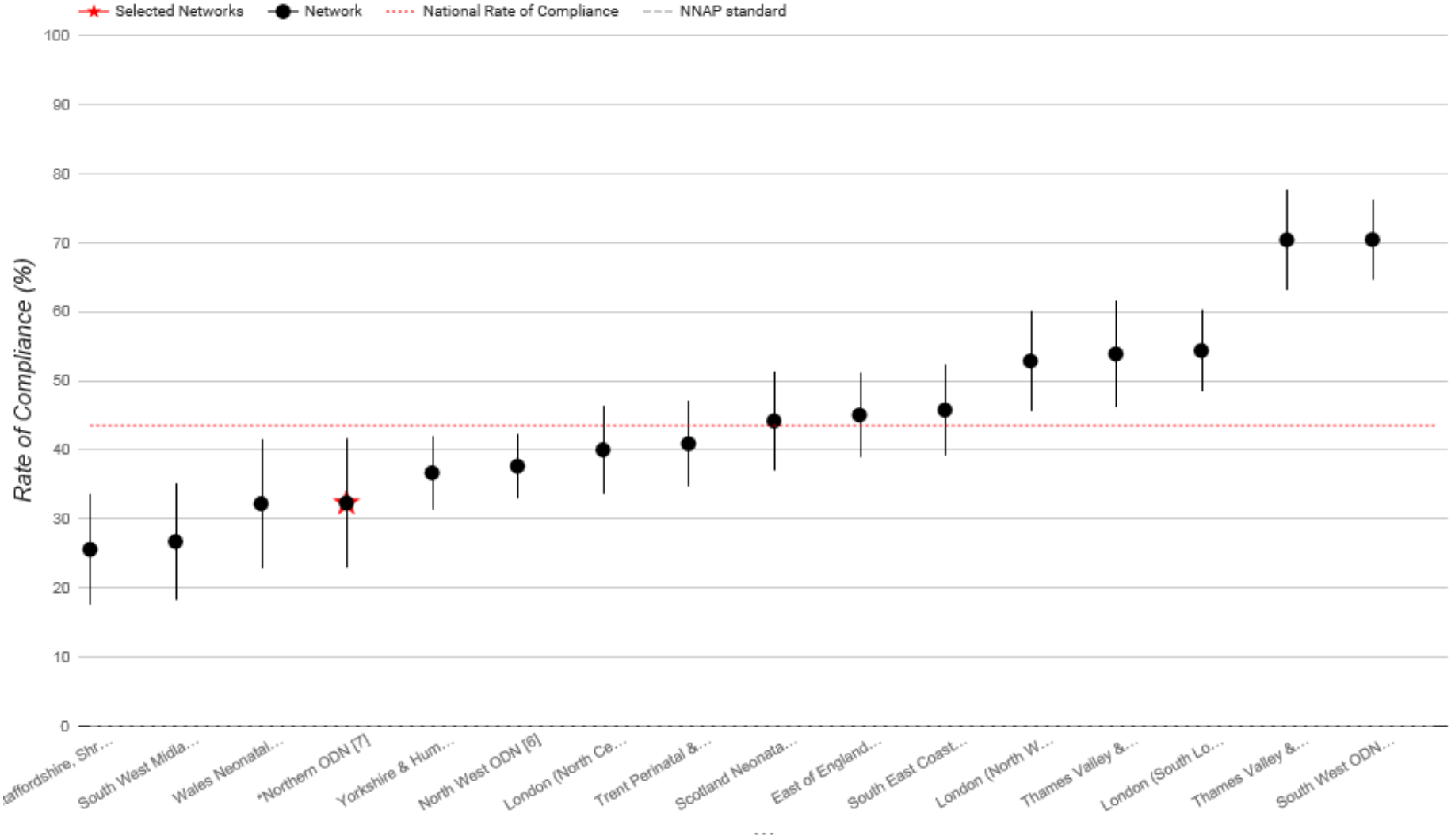
Cost of Magnesium Sulphate

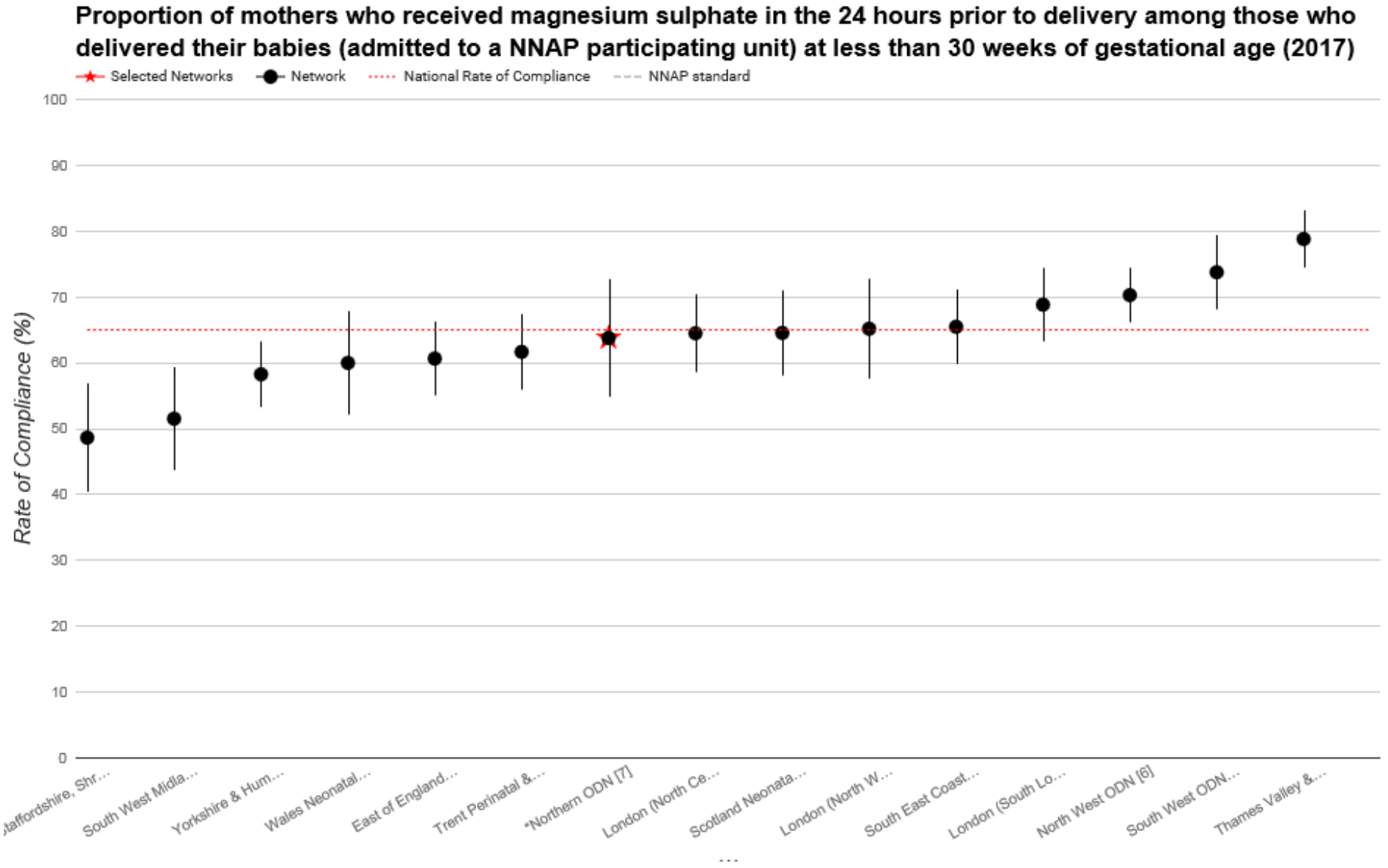
- From £1 per treatment
- MgSO4 ampoule = £1
- 5 x N/Saline Ampoules = £0
- Plus the cost of consumables

National picture



Proportion of mothers who received magnesium sulphate in the 24 hours prior to delivery among those who delivered their babies (admitted to a NNAP participating unit) at less than 30 weeks of gestational age (2016)





National average – 65%

National Benchmarking

Table 5.2.3: Administration of antenatal magnesium sulphate, by NNAP reporting year (2016-2017)*.

NNAP Year	NNU	Mothers	With outcome	Administration of magnesium sulphate		Missing data (%)
				Yes (%)	No (%)	
2016	182	4,242	3,506	1,868 (53.3%)	1,638 (46.7%)	*736 (17.4%)*
2017	176	4,276	3,935	2,522 (64.1%)	1,413 (35.9%)	*341 (8%)*

*Results presented here for 2016 and 2017 are both calculated using the 2017 measure derivation method so that they are directly comparable.

Antenatal Steroids vs. $MgSO_4$

NNAP 2016

Antenatal steroids: Percentage of mothers who delivered their babies between 24 and 34 weeks gestation and received any dose of antenatal steroids.

Magnesium sulphate: Percentage of mothers who delivered their babies at less than 30 weeks gestation and received Magnesium sulphate 24 hours prior to delivery.

Clinical Guideline - Key Points

- Offer MgSO4 to all women less than 30 weeks gestation who are in established preterm labour or having a planned preterm birth within 24 hours
- Consider for women 30^{+0} - 33^{+6} weeks gestation who are in established preterm labour or having a planned preterm birth within 24 hours
- Administer to women prior to transfer to other centres; discontinue infusion during transfer
- Contraindications: patient choice to decline, Myasthenia Gravis and emergency/urgent delivery
- Ideally the earlier before birth the better, (within 24 hours), but even when given immediately (0-4 hours) before birth it will have benefit**.**

NICE NG25 (2015)

Aims

- To improve compliance with NICE Guidance NG25 and increase the proportion of eligible women offered Magnesium Sulphate (MgSO4) in England
- Long Term: Reduction in the incidence of cerebral palsy in babies born preterm.
- Working the AHSN and Maternity Network

PReCePT Programme Timeline

- April 2018: NHSE funding to adopt and spread PReCePT to all maternity units in England using the AHSN network as the supporting vehicle

- June 2018: First tranche of 7 AHSN's work with their local units to implement PReCePT

- April 2020: Achieve target of 85% eligible mothers receive MgSO4 and a stretch target of 95% in high achieving units.

Key elements

A. Understanding the current position through audit of historic notes to ensure accurate data that is reflective of the present clinical picture

B. Designing and implementing a highly reliable process for administering magnesium sulphate

C. Creating awareness through training on why, how and when to give magnesium sulphate to preterm mothers, within maternity units

D. Training staff within the units in quality improvement to support them implement and sustain PReCePT

Drivers for success

- Strong clinical representation from pilot sites
- Strong lay representation
- Fast paced; progress made rapidly
- Strong ‘buy in’ at Trust Executive level

Key members

- Unit Level - Midwives, Midwifery lead, Obstetric lead, Badger lead
- NNN – Mark Green (Data manager)
- Regional project lead – Karen Hooper
- ASHN lead – Julia Wood
- Regional Neonatal Lead – Sundeep Harigopal

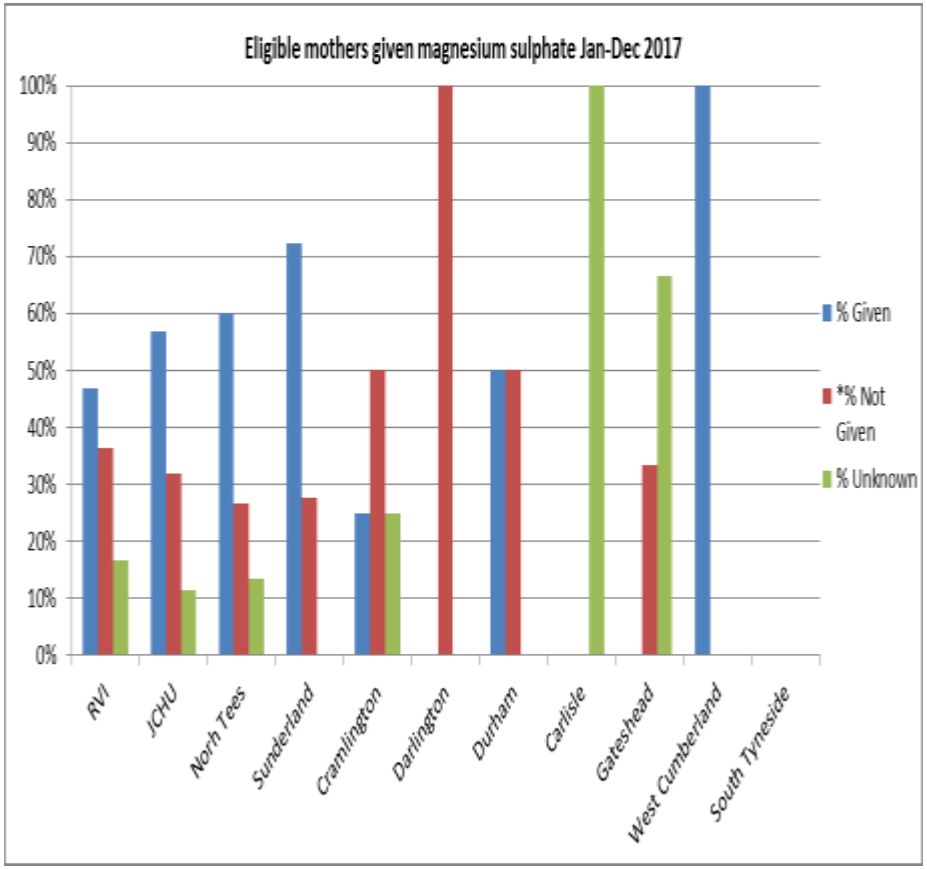
Our challenge

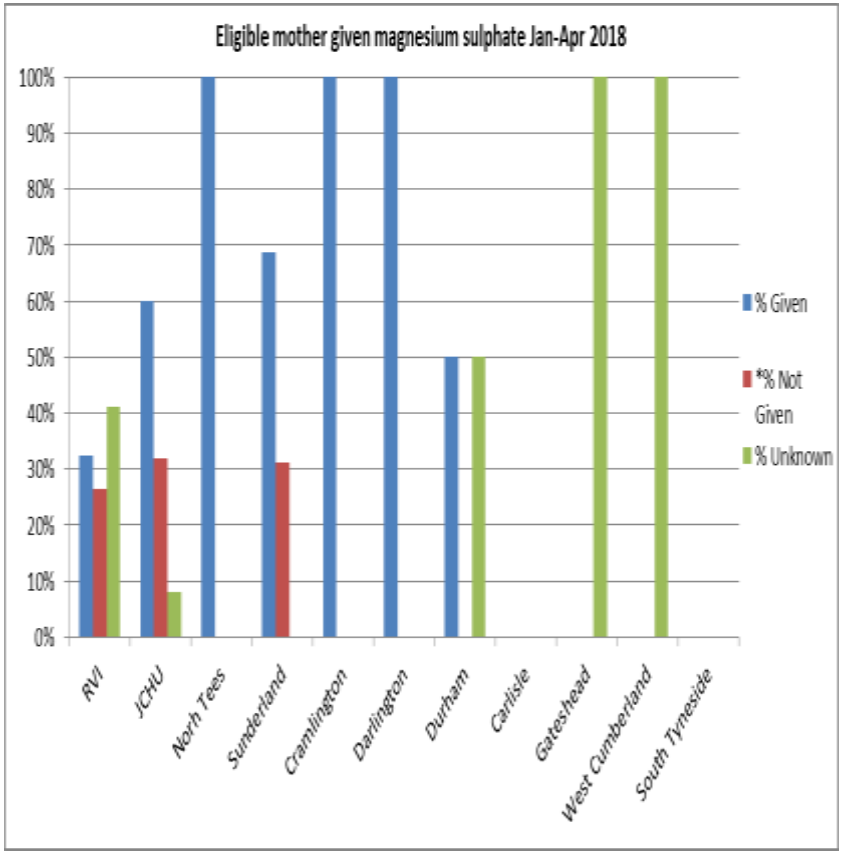
				MAGNESIUM SULPHATE		
		ELIGIBLE MOTHERS	OUTCOME	GIVEN (%)	NOT GIVEN (%)	MISSING DATA (%)
NICU	JAMES COOK UNIVERSITY HOSPITAL	35	33	22 (66.7%)	11 (33.3%)	2 (5.7%)
NICU	ROYAL VICTORIA INFIRMARY	57	41	24 (58.5%)	17 (41.5%)	16 (28.1%)
NICU	SUNDERLAND ROYAL HOSPITAL	21	21	16 (76.2%)	5 (23.8%)	0 (0.0%)
NICU	UNIVERSITY HOSPITAL OF NORTH TEES	15	13	9 (69.2%)	4 (30.8%)	2 (13.3%)
SCU	CUMBERLAND INFIRMARY	4		0 (0.0%)	0 (0.0%)	4 (100.0%)
SCU	DARLINGTON MEMORIAL HOSPITAL	1	1	0 (0.0%)	1 (100.0%)	0 (0.0%)
SCU	NORTHUMBRIA SPECIALIST EMERGENCY CARE HOSPITAL (NSECH)	2	1	1 (100.0%)	0 (0.0%)	1 (50.0%)
SCU	QUEEN ELIZABETH HOSPITAL, GATESHEAD	5	1	0 (0.0%)	1 (100.0%)	4 (80.0%)
SCU	UNIVERSITY HOSPITAL OF NORTH DURHAM	4	4	1 (25.0%)	3 (75.0%)	0 (0.0%)
SCU	WEST CUMBERLAND HOSPITAL	1	1	1 (100.0%)	0 (0.0%)	0 (0.0%)
Network (averages for all units shown)	Northern ODN	145	116	74 (63.8%)	42 (36.2%)	29 (20.0%)
National rate	All participating units	4276	3935	2522 (64.1%)	1413 (35.9%)	341 (8.0%)

NNAP 2017

Our challenge

- Awareness
- Data entry





What does this mean for PReCePT?

If we get this right we can achieve:

- Improved neuroprotection for babies born at less than 30 weeks
- Become innovators & leaders in the national adoption and spread of the project

AND MOST IMPORTANTLY

- Fewer babies with cerebral palsy
- Improved quality of life of preterm babies and their families

PReCePT Study

Prevention of Cerebral Palsy in Preterm Infants

September 2018

The Health Foundation

NHS
University Hospitals Bristol
NHS Foundation Trust

PReCePT Study – the trial

- RCT in 48 maternity/neonatal units in England
- To assess whether an enhanced QI intervention improves the uptake of MgSO4 in preterm deliveries over and above the NPP roll-out
- Compare two support models for implementation of PReCePT QI toolkit:

CONTROL	versus	INTERVENTION
Standard QI support (NPP)		**Enhanced QI support**
(32 units)		**(16 units)**

PReCePT Study - QI support models

Controls (standard support)

- PReCePT QI Toolkit & materials
- Regional level QI training (AHSNs)
- Support funding
  - Regional neonatal lead
  - Local midwife (90 hours)

Intervention (enhanced support)

- Standard support, *plus:*
- Unit level coaching from QI expert
- Learning and celebration events
- Support funding
  - Local Clinical lead (0.5PA)
  - Local midwife (+90 hours)
- Tablet for micro-coaching
- Small fund for study collateral

PReCePT Study - eligibility criteria

Inclusion criteria

- Units in England participating in national PReCePT Programme
- Units with minimum of 10 preterm (<30 weeks GA) births in 2016
- Units with 70% or less MgSO4 uptake in 2016

- ~96 eligible units based on NNAP reports for 2016 (published 2017)