

NIHR ARC West - Written evidence (PRT0056)

1.1. Who we are

We are a group of clinicians and researchers working in implementation science, accelerating evidence-based interventions into clinical practice. We have expertise in perinatal care and evaluation of complex healthcare interventions. We are a multi-disciplinary team of researchers with combined expertise in clinical care, quantitative epidemiological research, health economics, and qualitative research methods, part of the NIHR Applied Research Collaboration West (NIHR ARC West). Our team has been involved in the design, and evaluation of the implementation of the *Prevention of Cerebral Palsy in Preterm Labour* (PReCePT) quality improvement intervention.

Following a pilot evaluation study in 2016, demonstrating effectiveness, PReCePT was allocated “scaling up” funding by NHS England as part of a national improvement programme for the intervention to be implemented in all 155 perinatal units in England. PReCePT was shortlisted for the Health Service Journal (HSJ) Patient Safety Award in the Maternity and Midwifery Services Initiative of the Year category in 2019, and 2020 and was the winner of this category in 2019.

Our findings have been published in peer-reviewed articles, and presented to academic and clinical audiences(1-4).

PReCePT was the National Institute of Health Research (NIHR) making a difference story in March 2023. [Preventing cerebral palsy in premature babies | NIHR](#)

1.2. Reason for submitting evidence

The House of Lords Select committee has placed a call for evidence to support the committees’ inquiry on the prevention, and consequences of preterm birth in England. Among others, the committee is focusing on

the following topics directly aligned with the aims, objectives, and outcomes of PReCePT:

Variation in care and health inequalities

- The implementation of existing NICE and NHS guidance on preterm birth.
- The ethnic and socioeconomic inequalities seen in relation to preterm birth and how these could be reduced.

Below we give an overview of how our work addresses the above issues.

2. The evidence

2.1. Magnesium Sulphate (MgSO₄) as an evidence-based intervention in preterm labour

Magnesium sulphate (MgSO₄) is a medicine recommended for women in preterm labour under 30 weeks gestation, and to be considered for women up to 34 weeks. It protects the preterm babies' brain and reduces the risk of developing cerebral palsy (CP; a lifelong condition affecting movement and co-ordination), and generating major life-time costs, associated with special education and care needs. For every 37 women in preterm labour treated with MgSO₄ one case of CP can be prevented. (5) This recommendation has been part of NICE national clinical guidelines since 2015 but had not been consistently or equitably given to mothers.

2.2. A co-designed quality improvement intervention to improve uptake of MgSO₄

PReCePT is a quality improvement intervention to increase use of this neuroprotective medicine in preterm births. It was co-produced locally in the West of England, supported by the West of England Academic Health Science Network (now Health Innovation West of England) in 2015 and in the form of a downloadable toolkit, subsequently scaled-up and rolled-out

nationally in 2018 as part of the National PReCePT Programme (NPP), delivered by the National Academic Health Science Network (AHSN). Embedded within the NPP, a cluster randomised controlled trial (cRCT) compared the effectiveness of an enhanced support package delivered by QI experts, to that of the standard support delivered by AHSNs in improving MgSO₄ uptake rates. We carried out process, effectiveness, and cost-effectiveness evaluations of the PReCePT programme, and of the PReCePT cRCT study.

PReCePT implementation was led locally by midwifery champions, supported by AHSN quality improvement leads, and clinical (neonatal and/or obstetric) leads.

Improvements in uptake of MgSO₄ were driven by creating commitment to the intervention within organisations, perinatal optimisation stakeholders, clinical teams, and patients; by creating competencies and capacity within teams; and through changes to the way perinatal teams worked. Four improvement drivers were identified by the team:

- (1) Engagement and Awareness raising: setting the ground for implementation through creating commitment to the intervention among stakeholders
- (2) Knowledge mobilisation: creating the conditions for dialogue and co-creating knowledge between stakeholders, implementers, and adopters of the intervention
- (3) Putting in place operational and system enablers
 - a. Building up perinatal staff competencies and understandings of the intervention. This was achieved through PReCePT training and awareness raising activities,
 - b. introducing innovations and improvements to make administration quicker and easier. This was achieved by adopting e.g. Toolkit resources to embed MgSO₄ in clinical

protocols and guidelines, preterm labour proformas, and preterm labour pathways and workflows.

- (4) Embedding knowledge into practice through data monitoring, audit, and using learning to inform future improvement work. This was achieved through better data capture, carrying out missed case analyses and Plan-Do-Study-Act (PDSA) cycles, and feeding back learning into the system.

2.3. Adherence to NICE guidance before and after PReCePT implementation

Effectiveness of PReCePT: In 2017, the year before national roll-out, and two years after publication of NICE guidance, 65% of eligible mothers in England were receiving MgSO₄ treatment. By 2022, this had increased to 85% of eligible mothers. Multivariable statistical modelling, accounting for other factors that could be affecting performance, estimated that around 6 percentage points of this improvement was likely due specifically to the PReCePT programme.

Cost-effective: PReCePT generated around £597,000 net monetary benefit from a lifetime societal perspective. It had 89% probability of being cost-effective for babies under 30 weeks' gestation. The net monetary benefit increased to £4.2M when including babies up to 32 weeks' gestation.

Levelling-up inequalities: Historically there have been regional disparities in the quality of perinatal care between the North and South of England, in this case with mothers in the North of England being 40% less likely to receive MgSO₄ treatment compared to mothers in the South of England. Since PReCePT's implementation, there is no longer any evidence of a North/South divide here, indicating a successful levelling-up of perinatal care quality to prevent avoidable cerebral palsy. By December 2023 over 18,000 babies had benefitted from MgSO₄ brain protection, which translates to 450 to 500 cases of cerebral palsy prevented.

Clinical context: The improvements achieved in magnesium sulphate use in just a few years, with the benefit of the dedicated PReCePT implementation programme, should be compared to the much slower pathway to consistent use of antenatal steroids (another protective treatment for preterm babies). The 'natural course' of getting use of antenatal steroids to become standard practice took decades, illustrating that implementing new clinical evidence in perinatal care practice requires active intervention.

2.4. Lessons learned on how to implement guidance on preterm birth

Removing barriers: Scaling and spreading improvement

Our research highlighted how improvement and delivery of high-quality care is the outcome of a collaborative approach, nurtured by supportive teams, organisations, and institutions. Improvement never results from the actions of a single individual and requires sufficient support and priorities at different levels.

We have identified barriers and enablers related to service users, the clinical teams at the centre of preterm labour care (the perinatal team), the broader multiprofessional and multidisciplinary team caring for women across the perinatal pathway, the health care organisation, the clinical and healthcare improvement meso-systems providing strategic oversight to organisations, and the overarching policy, commissioning, and governance structures shaping organisational and clinical priorities.

Our evaluation highlighted the following drivers, innovations and interventions as enablers for improvement locally:

1. Alignment between clinical and economic evidence, national healthcare policy priorities and guidance, and government investment in patient safety and improvement-promoting mechanisms and structures, data-availability of key quality metrics

(MgSO₄ use and reasons for not given) for local monitoring, national bench-marking (National Neonatal Audit Programme) and evaluation of the impact of the PreCePT quality improvement programme, the Clinical Negligence Scheme for Trusts, quality improvement programmes and regional strategic and capacity-building improvement structures and networks. Our study highlighted how national drivers helped create buy in and commitment from managerial and clinical leadership.

2. Access to networks and communities of practice: Preterm care pathways span settings, clinical teams, and specialties, for example as part of in-utero transfers of care. Within regions, there also tends to be an imbalance between settings in teams' improvement capacity and capability. Knowledge mobilisation and improvement capacity building networks can create supportive conditions for improvement and support units through diffusion and cocreation of knowledge. In our study, in addition to PReCePT communities of practice led by AHSNs and QI coaches, Operational Delivery Networks, MatNEO SIP, and Local Learning Systems among others, helped drive improvement within regions. Knowledge mobilisation and implementation were more successful when strategies created scaffolding for dialogue to flow between implementers, those delivering care, and those involved in strategic and operational decision-making across disciplinary, geographical and hierarchical boundaries.
3. The organisational context is crucial for providing the right conditions for individuals and teams to engage in and successfully implement improvement. Characteristics such as perinatal optimisation culture, information and information technology resources e.g. quality of and interfacing between electronic data systems, middle and senior management commitment and culture e.g. exercising distributed leadership, were found to be important.

For example, our findings showed how in organisations allocating PReCePT champion midwives' backfill funding, and protected time away from clinical duties, champions could dedicate time to improvement activities including involving peers and senior clinicians in improvement. Having funded improvement roles is core to changing local practice and culture.

4. Teamworking culture, shared governance and integrated care pathways were important for PReCePT implementation. Alongside this were cross-disciplinary educational activities, competencies and shared understandings of the intervention among all clinicians and teams involved in preterm labour. At the centre of these, was perinatal communication and teamworking culture. Our research highlighted the ways in which improvement and delivering high quality evidence-based care is reliant on a culture of teamworking and integrated care pathways. This includes data and information communication.
5. MgSO₄ administration is reliant on mothers' timely presentation to the right setting and consent to the intervention being administered. Shared decision-making and patient involvement in their own care requires that mothers are informed of preterm labour, the interventions available to them, and what they need to do if they suspect preterm labour can help achieve these preconditions. Involving patients and the public in care decisions, and quality improvement activities can enhance such efforts. Our research has shown how involving parents in the design and implementation of PReCePT resulted in tools and resources relevant to patient needs i.e. Parent Information Sheets, including in different languages, and communication strategies including parent stories which helped create commitment and participation from all stakeholders.

From our findings, we have developed a blueprint implementation framework for perinatal settings/interventions, that will assist in accelerating implementation of future guidelines in perinatal medicine.

2.5 What next

The evidence base of effective treatments to improve outcomes for preterm babies and reduce NHS costs is constantly expanding. The PReCePT implementation framework can be used to accelerate adoption of national clinical guidelines and consequently equitable access of effective treatments for every mother and preterm baby in our care (Cross reference the Health Innovation West England PERIPrem care bundle evidence submission).

Key references:

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2. Edwards HB, Redaniel MT, Sillero-Rejon C, Pithara-McKeown C, Margelyte R, Stone T, et al. Quality improvement interventions to increase the uptake of magnesium sulphate in preterm deliveries for the prevention of cerebral palsy (PReCePT study): a cluster randomised controlled trial. *BJOG: An International Journal of Obstetrics & Gynaecology*. 2023;n/a(n/a).
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4. Redwood, Sabi, Christalla Pithara-McKeown, Tracey Stone, Emma Treloar, Jenny L. Donovan, and Karen Luyt. Scaling up an intervention to protect preterm infants from neurodevelopmental disabilities—findings from a qualitative process evaluation comparing standard with enhanced quality improvement support packages for maternity units in England. *Implementation Science* 18, no. 1 (2023): 1-11.

5. Crowther CA, Brown J, McKinlay CJD, Middleton P. Magnesium sulphate for preventing preterm birth in threatened preterm labour. *Cochrane Database of Systematic Reviews*. 2014(8).

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