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Please contact the trial /study co-ordinator for general queries and supply of study documentation.

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I) GLOSSARY OF ABBREVIATIONS:

AHSN	Academic Health Science Network
CI	Confidence Interval
CLAHRC	Collaboration for Leadership in Applied Health Research and Care
CP	Cerebral Palsy
CTU	Clinical Trials Unit
FREC	Faculty Research Ethics Committee
GA	Gestational Age
GCP	Good Clinical Practice
HRA	Health Research Authority
ITS	Interrupted Time Series analysis
MgSO4	Magnesium Sulphate
NDAU	Neonatal Data Analysis Unit
NHS R&D	National Health Service Research & Development
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NNAP	National Neonatal Audit programme
NNRD	National Neonatal Research Database
NPP	National PReCePT Programme
ODN	Operational Delivery Networks
OR	Odds Ratio
PReCePT	Prevention of Cerebral Palsy in pre-term labour
RCT	Randomised Control Trial
SAP	Statistical Analysis Plan
SOP	Standard Operating Procedure
WEAHSN	West of England Academic Health Science Network

III) KEYWORDS:

Quality Improvement, Preterm birth, Neuroprotection in preterm deliveries, Magnesium sulphate, Evaluation

INTRODUCTION

BACKGROUND

Preterm birth is the leading cause of brain injury and cerebral palsy (CP) [1]. Progress in perinatal care has led to greater survival rates in infants born preterm [2]. However, while 90% of very preterm infants survive beyond the postpartum period, approximately 35% develop neurodisabilities, including CP, blindness, deafness and cognitive impairment [3]. Around 1.5% of births are very preterm at less than 30 weeks gestational age (GA) [4]. This implies that in the UK, among 750,000 births annually, approximately 11,000 women deliver very preterm, with almost 4,000 babies suffering with some degree of brain injury.

Antenatal magnesium sulphate (MgSO4) therapy given to women at risk of preterm birth substantially reduces the risk of CP in their child by 30% (relative risk 0.68; 95% confidence interval 0.54 to 0.87; five trials; 6145 infants) [5]. At less than 33 weeks gestation the number needed to treat to prevent one case of CP is 42 (95% CI 26–187) [6]. Since 2015 National Institute for Health and Care Excellence (NICE) has recommended administration of MgSO4 in very preterm deliveries as a core part of maternity care, based on accumulating evidence in support of its brain protective potential [7]. Failing to comply with this guideline will now be considered sub-optimal care.

The uptake of MgSO4 in the UK remains relatively low, compared with the rest of the developed world, and this problem applies nationwide with the exception of a few well performing maternity units. For infants below 30 weeks GA, Vermont and Oxford network (VON) reported uptake of 9%, 24% and 38% for 2012, 2013, and 2014 for the UK respectively compared to 46%, 51% and 56% for the international network [8]. The UK National Neonatal Audit reported 43% uptake during 2016, and revealed huge variation across units [9].

Considering the efficacy of MgSO4 [4], approximately 1,400 cases of brain injury among preterm babies could potentially be avoided by consistent administration during labour each year in the UK, including 200 cases of CP annually in England [6]. The impact of CP is significant for individuals and families and can lead to lifelong difficulties [10]. It is estimated that the lifetime cost per patient with CP, including health care, productivity and social costs, is in the region of €830,000 [11]. The annual cost to the public sector in England associated with children born preterm until age 18 is around £1.24 billion. Societal costs (including parental costs/lost productivity) are around £2.48 billion per annum; these costs mainly relate to the effects of neurodisability [12]. The dose of antenatal MgSO4 costs approximately £1. Despite the NICE guideline more than half of preterm infants are not receiving the benefits of this potentially life altering and highly cost-effective treatment. An active Quality Improvement (QI) approach to accelerate uptake could make a major contribution to improve the uptake of MgSO4 and ultimately a reduction in brain injury.

During the original PReCePT project (PReCePT1), resourced by the West of England Academic Health Science Network (WEAHSN), the PReCePT Quality Improvement (QI) toolkit was developed and delivered in 5 maternity units in West of England between September 2014 and March 2015. The PReCePT QI toolkit is a multifaceted approach to increase awareness and knowledge among maternity unit staff about MgSO4 as brain protection in preterm deliveries. It provides practical tools and training to support staff in acute clinical settings to consider MgSO4 in eligible pregnancies. The PReCePT QI toolkit was co-designed by mothers who had experienced preterm birth and clinical teams. The impact was evaluated using routinely collected VON registry data for preterm infants below 30 and 34 weeks GA. Overall, the proportion of women receiving MgSO4 increased from 35% before PReCePT1 intervention to around 60% during and after intervention. Interrupted time series analysis (ITS) showed that at baseline (January 2012), the average uptake of MgSO4 was 8% and this increased significantly every month prior to the PReCePT1 intervention period by 1% (95%CI=0.7 to 1.3%) reflecting a secular trend. In the first month of the intervention (October 2014) uptake

significantly increased by 18% (95%CI = 9.5 to 26.6%); this increase remained constant during and after the intervention period. Improvements were observed for all participating units, although both baseline (before) rates and outcomes (after) varied considerably, between 0% and 30% (before) and between 51% and 89% (after). Infants with below 30 weeks GA were twice as likely to receive MgSO4 as compared to those 30-34 weeks GA. Uptake increased from 21% to 88% in infants below 30 weeks gestation following the 6-month Quality Improvement intervention [13].

Following the implementation of PReCePT1, the NICE Preterm labour and birth guideline (NG25) was published in November 2015 that recommends use of MgSO4 in deliveries below 30 weeks gestation and recommends consideration of MgSO4 in deliveries between 30 and 34 weeks gestation. Cost implications for service provision are modest and medication costs of MgSO4 are low. Despite national guidance, the rate of MgSO4 supplementation in eligible births in 2016 was 43% in the UK, therefore clinical staff (obstetricians/midwives) need to be informed/trained about the evidence for MgSO4 supplementation and the current guidelines.

PReCePT1 has demonstrated the viability of the approach in 5 maternity units in the South West of England, both in terms of making an improvement over baseline and sustainability. Scaling up of this project to other maternity units will be a significant step towards making this life-altering, low cost and effective intervention available for more mothers in England. Nationally around 11,000 infants per year could benefit from this intervention.

Building upon the success of PReCePT1, NHS England are funding a national roll out of a version of the PReCePT QI intervention, delivered by the Academic Health Science Networks (AHSN) via the National PReCePT Programme (NPP). PReCePT is one of seven programmes to have been selected for adoption and spread across the national AHSN Network during 2018-2020. This work will be led by the West of England AHSN and is funded by NHS England.

The NPP is the national adoption and spread of the PReCePT Quality Improvement Toolkit. The NPP aims to support all maternity units in England to increase their average uptake of MgSO4 to eligible mothers (below 30 weeks gestation) during preterm labour, to 85%, with a stretch target of 95% for high performing units, by 2020. The AHSNs will implement the NPP in two tranches, starting in May and September 2018, respectively.

In the NPP, the PReCePT QI toolkit will be implemented using a support model defined by local AHSNs. The PReCePT QI toolkit can be provided at low cost by supporting clinical staff already within the organisation. It has a compelling case for change that can be easily communicated to clinical teams. Furthermore, there is an existing pool of possible clinical champions that can be tapped for a wider intervention roll out.

RESEARCH AIM

This evaluation of the NPP aims to assess whether the AHSN-sponsored roll-out of the standard PReCePT Quality Improvement (QI) intervention improves the uptake of the provision of MgSO4 in preterm babies (<30 weeks G.A.), and to identify the factors that support its implementation and sustainability.

OBJECTIVES

- To assess whether the AHSN-sponsored roll-out of the standard PReCePT Quality Improvement (QI) intervention improves the uptake of the provision of MgSO4 in preterm babies (<30 weeks G.A.).
- To explore issues related to compliance with the intervention and roll-out.
- To explore issues related to effectiveness and sustainability of the intervention and roll-out.

STUDY DESIGN

This study is an evaluation of the roll-out of the NPP using mixed qualitative and quantitative research methods. It is a retrospective observational study using routinely collected patient data and semi-structured qualitative interviews.

The quantitative data will enable us to measure the impact that the QI initiative has had on MgSO4 uptake, and the qualitative interviews will help us understand why the initiative has or has not led to change along with an understanding of how further improvements could be made. The interviews will also give an insight into how positive changes can be sustained going forward.

METHODS; PARTICIPANTS INTERVENTION AND OUTCOMES

STUDY SETTING

All 152 maternity and neonatal units in England are eligible for participation in the NPP and will be included in the evaluation, except for: units that participated in the PReCePT1 study (5 units) and those randomised to receive enhanced support in the Health Foundation funded PReCePT Trial (13 units). 134 units are eligible for inclusion in the evaluation.

STUDY DURATION

The study, including set up, will last for 48 months from December 2018 until December 2022.

ELIGIBILITY CRITERIA

INCLUSION CRITERIA

Maternity units will be included if they meet all the following criteria:

- Maternity unit based in England who are participating in the NPP
- Part of AHSN / ODN network

EXCLUSION CRITERIA

Units will be excluded if they meet any of the following criteria:

- Units that participated in the PReCePT1 study (5 units)
- Units randomized to receive enhanced support in the Health Foundation funded PReCePT Trial (13 units).

INTERVENTION

The NPP implementation, developed by the West of England AHSN and rolled-out to all maternity units in England, involves:

- A Quality Improvement Toolkit containing:
    - Clinical Guidance Pack
    - Pre-term labour pro-forma template
    - Staff training presentations

    - Patient leaflet
    - Infographics for display on the unit to raise staff awareness
    - Posters, magnets, lanyards and other aide-mémoires to promote MgSO4 to unit staff
- Regional AHSN Support
    - AHSN QI lead – funded 0.2 WTE
    - Regional Neonatal Clinical lead - funded 1 PA per week for each Operational Delivery Network (ODN)
- Local Unit Champions
    - Midwife lead – funded 90 hours over 6 months
    - Obstetric lead – not funded
- Learning events – access to national and regional NPP events

The implementation is planned in two tranches with the first wave (c. 80 units) starting between September 2018 and March 2019 and the second wave (c. 72 units) starting between November 2018 and May 2019.

Each AHSN will have its own plan for implementation, and each maternity unit will decide how long the NPP intervention will last. For example, some units may opt for an intensive push over a 3-month period, whereas other units may opt for a steadier approach over a longer period. This will be determined by local units according to their individual teams, culture and resources available. The NPP is expected to end in March 2020, although it is not yet clear whether all interventions will be complete by then.

OUTCOMES

PRIMARY OUTCOME

The primary quantitative outcome will be MgSO4 uptake in pre-term deliveries.

SECONDARY OUTCOMES - QUANTITATIVE

- Sustained uptake of MgSO4
- Reasons for not administering MgSO4 (e.g. mother refused, not enough time, etc)
- Data completeness
- Reported cases of cerebral palsy (assessed at two-year follow-up appointment)

SECONDARY OUTCOMES - QUALITATIVE

- Issues related to compliance with the intervention and roll-out
- Issues related to effectiveness and sustainability of the intervention and roll-out

TIMELINES

NPP WAVE 1

Launched in May 2018
Implementation from September 2018

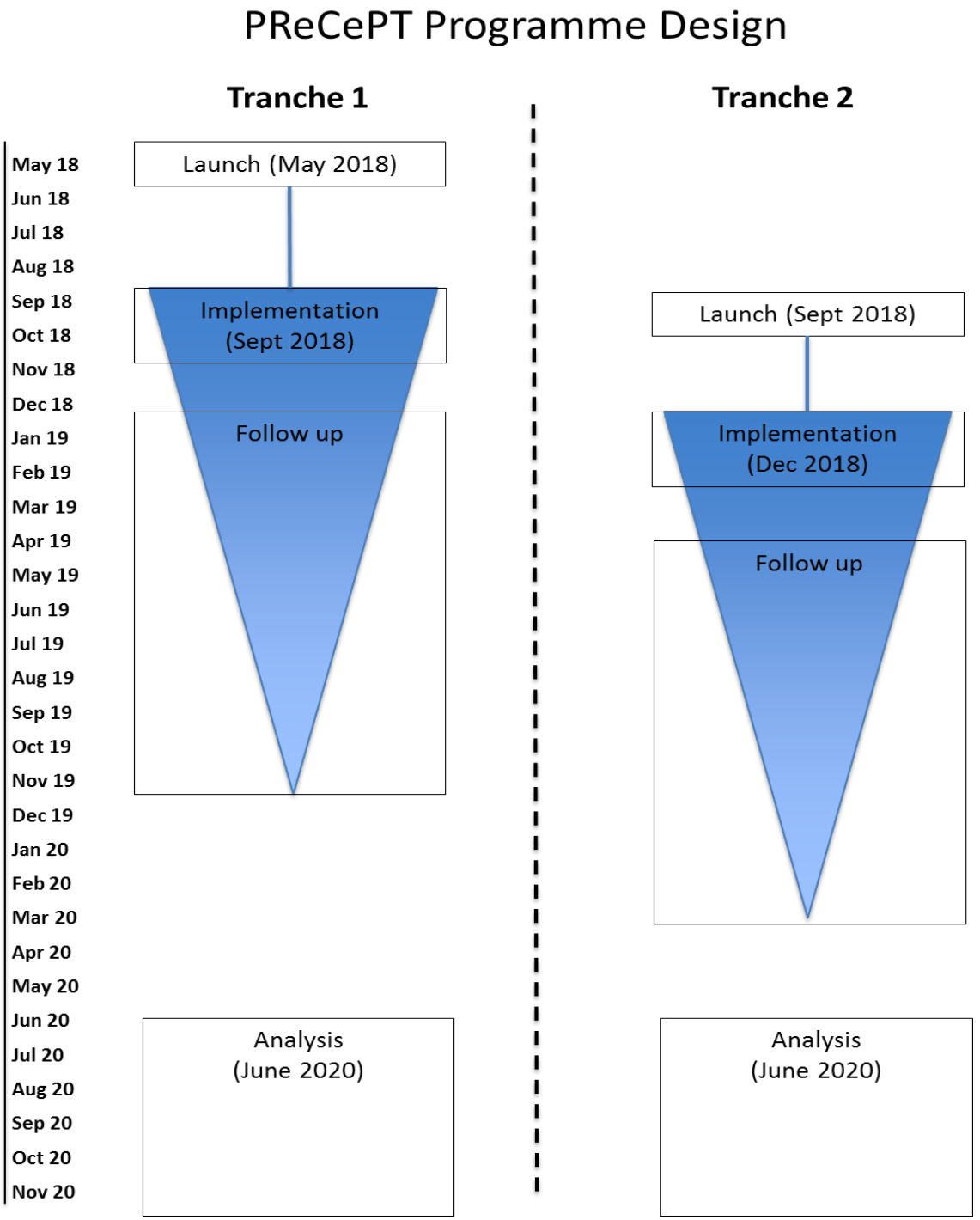
NPP WAVE 2

Launched in September 2018
Implementation from December 2018

(See figure 1 below. See also GANTT Chart for full details)

Preliminary quantitative data analysis will be done at baseline, after implementation has started for all maternity units (estimated June 2019), to determine robustness of data collection and analytical methods. Main quantitative analysis will start in May 2020, after the planned completion of the NPP implementation in the maternity units.

Round 1 interviews with unit Midwife Leads will begin once the implementation completion date has been reached in the individual unit, and continue throughout the follow up period. Round 2 interviews will be carried out during the follow up period, starting approximately 3 months after the implementation completion date to facilitate staff reflection on the sustainability of the intervention.



SAMPLE SIZE

All 152 maternity and neonatal units in England are eligible for participation in the NPP and will be included in the evaluation, except for: units that participated in the PReCePT1 study (5 units) and those randomised to receive enhanced support in the HF-funded PReCePT Trial (13 units). 134 units are eligible for inclusion in the evaluation.

The quantitative analysis will include 134 units taking part in the NPP.

All maternity and neonatal units in England included in the quantitative evaluation will form the sampling framework for the qualitative study.

The unit Midwife Lead and two or three members of staff from approximately 20-30 units involved in the NPP will be selected for in-depth qualitative research to understand implementation and outcomes. We anticipate around 100 interviews in total and criterion-based sampling will be used to ensure inclusion of a range of units according to parameters such as large and small unit (according to number of eligible babies per year), lower and higher MgSO4 uptake at baseline, and geographical spread of units across AHSNs and waves of implementation.

AHSN clinical leads and managers, as well as key stakeholders at the national level who have had a role in the NPP, will also be interviewed to provide data on leadership perspectives. 10-15 of these interviews are anticipated.

RECRUITMENT

PReCePT is one of seven programmes to have been selected for adoption and spread across the national AHSN Network during 2018-2020. This work will be led by the West of England AHSN and is funded by NHS England. The maternity units are being supported through the NPP by their local AHSN. For this evaluation of the NPP, we will approach the units within each AHSN via the AHSN QI lead or the Regional Neonatal Clinical lead for each Operational Delivery Network (ODN) who are in regular contact with the units in their area as part of the NPP.

To recruit staff for interviews, we will ask the AHSN leads to approach the unit Midwife Lead for the NPP on our behalf, and forward the Invitation letter and Participant Information sheet for the round 1 interviews. The Midwife Lead will be asked to suggest other potential interviewees for the round 2 interviews. These will be key members of the team who have been involved in the NPP in their unit, for example the unit champion obstetrician or neonatologist, and unit midwife or junior doctor (snowball sampling).

The AHSN leads will be asked to identify other key leads and stakeholders who have had key roles in the NPP to provide data on leadership perspectives of the roll-out.

METHODS; DATA COLLECTION, MANAGEMENT AND ANALYSIS

DATA COLLECTION METHODS - QUANTITATIVE

Routine anonymous data for the evaluation of the primary outcome and associated clinical data will be obtained from the UK National Neonatal Research Database (NNRD). Consent to use data for each unit will be obtained centrally by the Neonatal Data Analysis Unit (NDAU) on behalf of CLAHRC West (designated evaluation partner for the NPP).

Descriptive data will be obtained from AHSN regional leads/managers for units in their area. Data will include start dates of key staff (AHSN lead, regional clinical lead, unit midwife champion), start

and end dates of the NPP implementation, and unit characteristics such as number of delivery beds and number of unit staff.

DATA COLLECTION METHODS - QUALITATIVE

ROUND 1 DATA COLLECTION – IMPLEMENTATION AND PROCESS

In the first round, a semi-structured interview in the sampled units will be conducted with the unit Midwife Lead once the implementation completion date has been reached (the date the NPP implementation is completed in that individual unit). These interviews will provide data on how the intervention was implemented in each unit; how QI materials and activities were used and if there were any adaptations and tailoring of materials to fit the local context; staff involvement and engagement in the process of implementation; perceived support by unit/ Trust leadership; contextual factors that may have influenced the implementation e.g. organisational changes, staff shortages; capacity issues in maternity units and professional, organisational or cultural issues that may have affected implementation.

ROUND 2 DATA COLLECTION – EFFECTIVENESS AND SUSTAINABILITY

Second round interviews will take place approximately 3 months after the implementation completion date to facilitate staff reflection on the sustainability of the intervention. We will conduct 2-3 semi-structured interviews (in the same sampled units as round 1) with the unit champion obstetrician or neonatologist, and unit midwife or junior doctor. Interviews will provide data on perceived effectiveness of implementation and particularly views on sustainability – is the intervention embedded in everyday practice; what has helped or not helped to sustain the intervention; how have working relationships between obstetricians and neonatologists, and maternity unit and neonatal unit staff been affected; and professional, organisational or cultural issues that may have affected sustainability.

Interviews will also be undertaken with AHSN clinical leads and managers, as well as key stakeholders at the national level, including a sample of directors of AHSNs, and representatives from Mat-Neo and NHS England identified as key leads and stakeholders who have had a role in the NPP, to provide data on leadership perspectives of the roll-out, observations, reflections and views on sustainability, and lessons learned for future roll-outs. 10-15 of these interviews are anticipated.

DATA MANAGEMENT

Interviews will be digitally audio recorded using university approved encrypted digital audio recorders. Digital audio recordings will be transcribed by Bristol Transcription Services, a University of Bristol approved Transcription Company and a confidentiality agreement will be signed prior to this work commencing. The digital data collected will be stored on secure University of Bristol password protected computers. Data in written form will be stored in locked filing cabinets in secure University of Bristol offices. Interview transcripts will be edited to remove identifying details, and participants will be allocated codes in order to prevent linkage of data to participant details except by the qualitative research team. Data will be encrypted in accordance with the University of Bristol Information Security Policies whenever it is transmitted electronically or otherwise conveyed.

Storage of all data will comply with the General Data Protection Regulation (2018) and University of Bristol's data protection policies. Storage will be on secure University computer systems and within a locked office. The electronic audio recordings will be held until the study is finished. After this period electronic audio recordings will be deleted. In accordance with the University of Bristol's Guidance on the retention of research records and data, anonymised, analysed data (e.g. NVIVO database and summaries of data) will be retained for a minimum of ten years on secure password protected University of Bristol servers. The Principal Investigator will act as data custodian.

STATISTICAL METHODS – QUANTITATIVE ANALYSIS

All quantitative data will be analysed using STATA.

PATIENT, MOTHER AND MATERNITY UNIT CHARACTERISTICS

Patient characteristics (e.g. sex and gestational age) and mother characteristics (e.g. age and educational attainment) will be described by implementation period (pre- versus post-implementation). These characteristics will be compared between periods using appropriate tests (e.g. t-tests, chi-squared tests) to identify any key differences. Maternity unit characteristics (e.g. number of beds and number of clinical staff) will also be described.

Continuous variables will be summarised using means and standard deviations (SD) (or medians and interquartile ranges (IQR) if the distribution is highly skewed), and categorical data will be summarised as numbers and percentages.

PRIMARY OUTCOME

The number and percentage of patients receiving MgSO4 in each period (pre- versus post-implementation) will be presented. This will also be presented over time and by baseline MgSO4 group.

The primary analysis will emulate that used in step-wedge randomised controlled trials. Mixed model regression will be used to assess differences in receipt of MgSO4 between implementation periods. Period (pre- versus post-implementation), baseline MgSO4 level in the unit (five categories: 0-19%, 20-39%, 40-59%, 60-79%, 80-100%), multiple pregnancy (single vs. multiple- twin, triplet etc), unit size (quintiles) and calendar time quarters will be fitted as fixed effects. Clustering by AHSN will be taken into account in a multilevel analysis. We do not believe there to be any additional factors which will confound the relationship between implementation period and MgSO4 uptake; however, we will explore this in preliminary analyses and add any factors found to be significant at the 5% level will be added as fixed effects in the model.

The implementation period comparison estimate will be presented as an adjusted odds ratio (OR) with a corresponding 95% confidence interval (CI) and p-value.

A subgroup analysis looking at the effect of baseline MgSO4 will be performed by adding an implementation period by baseline MgSO4 level interaction term in the model. This will highlight any ceiling effects that might be at play.

As a sensitivity analysis, multiple baseline interrupted time series analysis will be used to assess the change in level between pre-and post- implementation periods as well at the change in slopes. In this analysis, units will be grouped by start month. Monthly data will be analysed, and the outcome will be the proportion of preterm babies each month who received MgSO4.

SECONDARY OUTCOME 1: SUSTAINED UPTAKE OF MGSO4

The number and percentage of patients receiving MgSO4 over time (as stated above) will be presented descriptively. The sustained uptake of MgSO4 will be formally tested by replacing the binary period variable in the primary outcome logistic regression mixed model with a categorical period variable with five categories: pre- implementation, and post- implementation months 1-3, 4-6, 7-9 and 10-12.

This will be looked at again up to two years follow-up along with the CP data (see outcome 4 below). For this analysis, post- implementation data will be grouped into six-month categories.

SECONDARY OUTCOME 2: REASONS FOR NOT ADMINISTERING MGSO4

Reasons for not administering MgSO4 will be categorised and presented as numbers and percentages by implementation period. No formal analysis will be performed.

SECONDARY OUTCOME 3: DATA COMPLETENESS

The number and percentage of patients whose MgSO4 status is unknown will be presented over time. No formal analysis will be performed.

SECONDARY OUTCOME 4: REPORTED CASES OF CEREBRAL PALSY

At least two years after the final patient in the primary analysis is born, a new national neonatal research database extract will be requested which includes data back to September 2017 (which will therefore include all patients from the primary analysis along with additional data from babies born after the initial 12-month implementation period). For the patients in the original analysis, this extract will include an indicator variable for Cerebral Palsy (CP), which is assessed at patients' two-year neonatal follow-up visit.

This outcome will not be presented in the main report for this project due to the long follow-up time required; it will be reported as an add on at a later date.

The number and percentage of patients with CP diagnosed at 2 years will be presented by implementation period (pre- versus post- implementation). This will also be presented over time. Note. This analysis will include the same patients as the primary outcome.

Analysis will be the same as that of the primary outcome but with CP as the outcome rather than MgSO4 (logistic regression mixed model).

As a secondary analysis we will add receipt of MgSO4 (binary yes/no) into the model to check whether this is a key mediator for the relationship between implementation period and CP.

Further, CP over time will be formally tested by replacing the binary period variable in the logistic regression mixed model with a categorical period variable with five categories: pre- implementation, and post- implementation months 1-3, 4-6, 7-9, 10-12.

QUALITATIVE ANALYSIS

Interviews will be audio-recorded where possible and transcribed in full.

Analysis will utilise the framework method [14], producing highly structured outputs of summarised data. The matrix output, using rows, columns and 'cells' of summarised data, facilitates analysis by case (for example, unit, professional group, or individual) and by code (summarised data in relation to a particular theme such as intervention fidelity). This allows comparison of data across, as well as within, cases to inform an understanding of factors affecting implementation and observed outcomes. Interviews with senior leaders and stakeholders will be analysed thematically.

In the first instance, two members of the research team will independently review a sample of three transcripts to develop and agree a coding strategy that reflects the research objectives. One researcher will then take responsibility for ongoing coding and categorisation of the data, using the QRS NVivo qualitative data management software. To assure the reliability of the coding and analysis process, codes and categories will be reviewed regularly by the wider team to ensure the accuracy of interpretation and internal consistency of codes. Categories of data and thematic relationships will then be identified and written up as descriptive and interpretive accounts, supported by interview excerpts.

BURDEN TO THE PARTICIPANTS

The main burden will be the time associated with participating in the interview. This has been reduced to a minimum by offering telephone interviews at a time and date convenient to the interviewee. We will aim to keep each interview to 30 minutes in length and only continue for longer at the discretion of participants.

ETHICS, REGULATORY ISSUES AND DISSEMINATION

RESEARCH ETHICS

As the quantitative part of this study uses routine anonymous data (anonymised before transfer to the researchers), no informed consent is sought from individual women delivering in maternity units for their participation in this study, as health care provided is according to current practice, following the clinical practice NICE Preterm labour and birth guideline (NG25) [7], at the discretion of the obstetrician/midwife. Routinely collected anonymised data will be used which are not subject to NHS ethical review.

The following ethical issues are relevant to the conduct of the qualitative part of the study:

1) Informed consent – all interview participants will be asked for verbal informed consent prior to their participation in the telephone interviews. Participants will have at least 72 hours to consider the participant information sheet before being asked to consent. They will be told they are free to withdraw from the study at any time without giving a reason. If participants decide to withdraw from the research after the interview, we ask that they notify us within a week of the interview and the data they have provided will then be destroyed. It will be made clear in the information sheet that if participants notify us after this time, the data may already have been transcribed, analysed and used to inform future interviews.

2) Confidentiality – all audio data will be collected on an encrypted digital recorder and uploaded to a secure server as soon as possible. There is a confidentiality agreement in place with the transcription company, and all transcripts will be anonymised and stored on a secure university server. An anonymised identification code will be assigned to all participants and this is the only way to identify which transcript is attributable to which individual. Where quotes are used in the write up of research, these will be fully anonymised and sufficient contextual detail changed to protect the anonymity of participants. Where it is necessary to store hard copy data (e.g. individual contact details), these will be kept in a locked filing cabinet only accessible to the researchers carrying out the interviews.

3) Harm avoidance - the only potential risk associated with participation in the interview study is psychological distress through being asked to recount decision-making processes or experiences that may have been stressful or caused personal anguish. Every effort will be made to ensure participants are at ease before, during, and after the interviews. They will be reassured that their interview is confidential, that any data will be fully anonymised, and that they have a right to withdraw at any point, without giving reason. If, during interviews, the researcher has reason to believe the participant is in distress, audio recording will be ceased, and support will be offered in situ.

INDEMNITY

The University of Bristol has arranged Public Liability insurance to cover the legal liability of the University as Research Sponsor in the eventuality of harm to a research participant arising from management of the research by the University. This does not in any way affect an NHS Trust's

responsibility for any clinical negligence on the part of its staff (including the Trust's responsibility for University of Bristol employees acting in connection with their NHS honorary appointments).

STUDY SPONSORSHIP

The research is sponsored by the University of Bristol, and is organised and funded by The AHSN Network and The National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care West (NIHR CLAHRC West). This study has been reviewed by University of Bristol Health Sciences Faculty Research Ethics Committee (FREC).

PATIENT AND PUBLIC INVOLVEMENT AND ENGAGEMENT (PPIE)

The original PReCePT1 intervention was developed using a co-design and co-production approach, developing partnerships with BLISS, a support organisation for mothers experiencing pre-term births, and two mothers who had experienced pre-term births.

The two mothers from PReCePT1 have been approached to join the steering group of the PReCePT programme evaluation, enabling the project to benefit from the knowledge and experiences they have developed over the life of PReCePT1. They will feed into the overall design, implementation and progress of the project.

CLAHRC West have a Public Involvement Systems Panel which they use to test out research findings. This is made up of patients, service users and carers. The group will feed into the research process itself, providing a sounding board to test results and findings.

A reference group made up of representatives of relevant stakeholders (BLISS, disability organisations, other) will help guide the dissemination of the findings. This will also be done through the existing networks of our partners and social media.

DISSEMINATION

All outputs from this research will be written and presented according to the NIHR CLAHRC West publication policy.

We plan to publish and share the results of study in relevant professional network publications, including peer reviewed journals, adding to the body of work generated by PReCePT1. We will present the work by disseminating it to a range of influential networks for both clinical and academic audiences.

We will disseminate via:

- AHSN and NHSE networks
- National Patient Safety Collaborative and NHS Improvement (Maternity Transformation Programme/MatNeoQI)
- Healthcare Quality Improvement Partnership through the National Neonatal Audit programme hosted by the Royal College of Paediatrics and Child Health.
- Neonatal/Obstetric networks
- Publication of the results of the evaluation in an academic peer reviewed journal

In addition, we aim to achieve regional and national impact through presentations at national and international scientific conferences, workshops and at local events in the adopting teams' areas.

GANTT CHART

P376 PReCePT Programme evaluation	Project time																															
	Year 1												Year 2																			
Activity	Mon 1	Mon 2	Mon 3	Mon 4	Mon 5	Mon 6	Mon 7	Mon 8	Mon 9	Mon 10	Mon 11	Mon 12	Mon 13	Mon 14	Mon 15	Mon 16	Mon 17	Mon 18	Mon 19	Mon 20	Mon 21	Mon 22	Mon 23	Mon 24	Mon 41	Mon 42	Mon 43	Mon 44	Mon 45	Mon 46	Mon 47	Mon 48
	Jan-19	Feb-19	Mar-19	Apr-19	May-19	Jun-19	Jul-19	Aug-19	Sep-19	Oct-19	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	May-22	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22
Wave 1 implementation																NPP																
Wave 2 implementation																NPP																
Management																																
CLAHRC evaluation group meetings																																
RCA developed and finalised																																
Steering group meetings																																
Qualitative aspect																																
Protocol written																																
Ethics and HRA preparation																																
HRA approval submitted																																
Engage AHSNs / sites for interviews																																
Arrange interviews with participants									Round 1 Wave 1		Round 1 Wave 2				Round 2																	
Conduct interviews									Round 1 Wave 2		Round 1 Wave 2				Round 2																	
Transcription and coding																																
Analysis																																
Write up results																																
Discussion/paper writing																																
Quantitative aspect																																
Discussion / checking Data availability																																
Protocol developed																																
Baseline data collection																																
Analysis									Baselin	Baseline							Main															
Write up findings																																
Discussion/paper writing																																
Dissemination																																
Dissemination workshop of preliminary findings																		Prelim	fdbk													
Partner report writing and approval																																
Paper submission(s)																																
Further dissemination/close																																

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