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

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Abstract

Background

A Quality Improvement strategy (PReCePT) was used in a standard and intensive format to scale up a clinical intervention (administering magnesium sulphate to women in preterm labour) across all maternity units in England to protect prematurely born infants from neurodevelopmental disabilities. Formal evaluations reported the effectiveness of the standard package alone in increasing the administration of magnesium sulphate. In this paper, we focus on the findings of the process evaluations, using Normalisation Process Theory to explain how different implementation contexts generated the observed outcomes relating to normative and relational restructuring, and sustainment.

Methods

Interviews were conducted with key individuals in implementation leadership positions nationally and locally. Interviews were analysed initially using the framework method. We then engaged recursively with NPT constructs to generate generalisable insights with pragmatic applicability in other scenarios.

Results

In total, 72 interviews were conducted with good representation from units across England, and staff from the national Academic Health Science Network. We found that all units irrespective of whether they received a standard or enhanced QI package were successful in the ‘normative restructuring’ of their setting to enable magnesium sulphate to be administered. This suggests that this implementation outcome is necessary to achieve improvements. However, it may not be sufficient to sustain and normalise the changes once additional resources have been withdrawn. Sustainment, our findings suggest, required ‘relational restructuring’ to accommodate altered workflows and facilitate the sharing of responsibilities and tasks in daily practice. Relational restructuring was more likely to have been achieved units receiving enhanced QI support but also happened in units with standard QI support, especially in those where perinatal teamworking was already well established.

Conclusion

Unlike other large QI focused spread-and-scale programmes which failed to show any impact on outcomes, the PReCePT programme in both the enhanced and standard support packages led to improvements in the uptake of magnesium sulphate. The findings suggest that QI programmes interact with the enabling factors, such as strong interprofessional team working, already present in the setting. A standard package with minimal support was therefore sufficient in settings with enabling factors, but enhanced support was required in units where these were absent.
Contributions To Literature

- Normative restructuring, or changes that are produced in the norms, rules and processes as a result of implementing a new intervention, was necessary to make clinical practice improvements. However, it was not sufficient to achieve sustainment and normalisation.

- Relational restructuring, or changes in the way people organised and related to each other, was found to be crucial in maintaining improvements in clinical practice. This was more likely to occur in units with already established perinatal team working, and in those receiving enhanced support to promote changes in behavioural norms.

Background

Learning from different approaches enabling the uptake of evidence-based interventions across organisations and health systems is crucial so that more people can benefit from innovations in healthcare (1). Yet spreading and scaling an intervention, even when it is evidence-based and consistent with clinical practice guidelines, is complex and dependent on implementation contexts and conditions (2-4). The term ‘spread’ refers to replicating a change based on an innovation or new intervention in a different setting from that in which it was originally developed. Scaling up, which is part of spread, means the use of a guided process enabling the new practice to be adopted, usually through involvement of a ‘higher-level’ entity such as a professional body or government agency (1, 2). Despite efforts to generate systematic methodologies for implementation, spread and scale-up of interventions and evidence-based clinical practice guidelines to optimise care across health systems (5), there are no universally replicable methods, because of the complex networks of interactions and articulated tasks in healthcare delivery (4). Instead, learning and insights into how successful changes were accomplished and sustained will be developed through an accumulation of fine-grained accounts describing what was done to implement, spread and scale up an innovation, what changed as a result, and crucially, why and how it changed. This allows comparisons to be made between the contexts, mechanisms and outcomes of implementation processes which change over time and between different settings (6) and how processes and their contexts shape each other in the complex adaptive systems of healthcare delivery (7).

In this paper, we describe how a perinatal Quality Improvement (QI) strategy was used in a standard and an enhanced format to scale up a clinical intervention to protect prematurely born infants from cerebral palsy and other neurodevelopmental disabilities which cannot be cured. Since 2015, the United Kingdom governmental body the National Institute For Health and Care Excellence has recommended that women presenting in preterm labour are given an intravenous infusion of an inexpensive drug, magnesium sulphate (8). Yet despite the evidence that magnesium sulphate (MgSO4) significantly reduces the risk of disabilities to premature infants under 30 weeks’ gestation, by 2017 only 64% of eligible women were receiving it, while high regional variation in uptake suggested serious inequalities in perinatal care (9).
In order to raise awareness and increase MgSO4 administration to all eligible women during preterm labour, the West of England Academic Health Science Network (AHSN) in collaboration with University Hospitals Bristol and Weston NHS Foundation Trust used QI methodology and coproduction principles to develop a perinatal QI intervention, the Prevention of Cerebral Palsy in PreTerm Labour (PReCePT) programme (10). PReCePT was piloted and refined in five maternity units before being selected for adoption and spread across the national AHSN Network during 2018-2020. The aim of the National PReCePT Programme (NPP) was to support maternity units to increase their average uptake of MgSO4 to eligible mothers to 85% by 2020. A randomised controlled trial (the PReCePT QI study) was embedded in the NPP to assess whether a standard QI support package[1] (used in the NPP) was sufficient for a national scale-up of the QI intervention, or whether a more resource-intensive, enhanced support package[2] was needed for successful scale-up. See (11) for a detailed descriptions of both QI packages. Evaluations of the NPP, and the PReCePT study have reported the effectiveness of the standard package alone in increasing the uptake of MgSO4 across all units in England (12, 13). The qualitative process evaluation of the PReCePT QI study also suggested that the standard package alone may be adequate for units delivering care within an implementation-enabling environment, but a more intensive support package may be needed to enable meaningful and sustained change in maternity units with less enabling environments (12). In this paper, we focus on the findings of the process evaluations of the NPP and PReCePT QI study, using Normalisation Process Theory (6, 14) to further our understanding of what needs to happen to incorporate and scale up a new activity (administering MgSO4 to eligible women in preterm labour) into routine clinical practice across an entire healthcare system.

[1] This included provision of PReCePT QI materials (pre-term labour proforma, staff training presentations, parent leaflet, posters for the unit, learning log 3), regional level QI training and support, and up to 90 hours funded backfill per unit for the midwife champion. Implementation is led by local midwives and an obstetrician champion in each unit. The materials are downloadable from the AHSN Network PReCePT webpages: (https://www.ahsnnetwork.com/about-academic-health-science-networks/national-programmes-priorities/PReCePT/PReCePT-resources)

[2] This included provision of the PReCePT QI toolkit as for the standard support group, plus individual unit-level coaching by an experienced QI coach (a first in-person visit, a final in-person visit, and regular telephone coaching during the nine months implementation phase), a computer tablet for micro-coaching staff, access to learning and celebration events, an additional 90 hours backfill funding for the local midwife champion, and 2 hours per week of funded backfill for the local neonatologist champion. At each unit’s discretion this 2 hour backfill can be shared between the neonatologist and obstetrician champion.

Methods
The overall design and methods have been described (12, 13). Following an inductive analysis using the framework method (15), we used in NPT abductively\[1\] (16) to generate insights into the implementation, spread and scale-up processes and then related our data back to the mechanisms and outcomes explained by NPT to understand variation within and between elements of the data, and differences between the QI support packages (6, 14). The aim was to capture how different implementation contexts and perinatal team\[2\] dynamics - frequently lost in accounts of barriers and facilitators (17) - generated the observed outcomes.

Setting

One hundred and fifty maternity\[3\] units in England were enrolled in the NPP, funded by NHS England, and roll-out was overseen and managed by the regional AHSNs who were responsible for providing implementation support to individual units. Funding was allocated to AHSNs for the recruitment of regional clinical leads (either obstetricians or neonatologists) who provided clinical oversight and support to units. Embedded in the NPP was the PReCEPT study, which randomised 40 units to the standard support package (SSP) i.e. aligned with the NPP, or to the enhanced support package (ESP). ESP teams had access to NPP support resources and AHSN support, but in addition received intensive QI coaching tailored to individual units’ needs and implementation readiness.

Data collection and analysis

Interviews were conducted with key individuals in leadership positions in the AHSNs (those providing QI and implementation-related leadership and regional clinical leads providing clinical leadership to units in their region) and in the maternity units (midwifery, neonatal and obstetric ‘champions’ or leads who provided clinical leadership for implementation). Our recruitment strategy was guided by the principles of information power (18) so that sample size was driven by the relevance and extent of the knowledge and experience held by participants rather than predetermined numbers. Interview guides for both groups were developed in collaboration with the project steering groups to ensure all relevant aspects of implementation were addressed. A question relating to the role of COVID-19 pandemic in the uptake of MgSO4 was added in 2020. Interviews were analysed initially using the framework method (15) producing a matrix output, enabling comparison of data across sites to inform an understanding of factors affecting implementation and observed outcomes. The analysis of these data preceded the publication of NPT coding manual (14).

We used NPT to conceptualise how the strategic intention of the AHSN network (to increase the number of eligible women who actually receive MgSO4 thus protecting their premature infants from neurodevelopmental disorders) is translated into the everyday practices of others (staff working in all English maternity units). The national AHSN network and the regional AHSNs acted as the ‘higher-level entity’ (1) or support-system level organisation (19) which coordinated and supported local implementation. The translational activities were rooted in QI methodology but delivered in two different ways: the standard package that was supported by the regional AHSNs, and the enhanced package which included, in addition to the SSP, intensive engagement with QI coaches, backfill funds for local
clinical champions on top of those offered in the SSP, and national networking and celebration events. These support activities affected and shaped the implementation context, defined in NPT as the patterns of social relations and structures that unfold over time, make up the implementation environment and promote or inhibit the mobilisation of resources for implementation (7). We sought to bring to the surface some of the mechanisms that motivated and shaped implementation processes, how they were used to achieve the strategic intention, and how individual and collective action led to the implementation outcomes. The outcomes refer to the effects of the mechanisms at work in producing changes in practice and social relationships and how these became embedded in routine clinical practice, in this case to achieve a MgSO4 administration rate of 85%.

[1] Abduction involves recursively moving back and forth between observations and theoretical generalizations.
[3] There are 155 maternity units in England. The 5 units that were PReCePT pilot sites in the West of England were not included in the evaluations.

Results

In total, 72 interviews were conducted with good representation from units across England, and staff from the national AHSN network. Eighteen interviews were conducted with staff from units receiving ESP, comprising nine midwives, four obstetricians and five neonatologists; 33 interviews were conducted with staff from units receiving SSP, comprising 13 midwives, 10 obstetricians and 10 neonatologists. In addition, we interviewed nine regional AHSN leads responsible for the roll-out of the NPP, and 12 AHSN staff who worked with clinicians in local maternity units.

The clinical intervention to be scaled up involved the administration of an intravenous loading bolus dose of MgSO4, a relatively inexpensive drug, followed by a maintenance infusion. The treatment used for neuroprotection of the infant was similar to that used for the prevention of eclampsia in women. Thus, the use of MgSO4 was relatively straightforward once pre-term labour had been diagnosed, and in terms of complexity and side effects, it was well understood and predictable, necessitating some additional steps in the care pathway, but overall was minimally disruptive to workflows. It is therefore surprising that it took more than a decade for the use of MgSO4 to be incorporated into clinical guidelines when its protective effects were first observed in 1995 (20) and proven in a large RCT in 2003 (21). There was a similar timeline for the clinical adoption of corticosteroid treatment for pregnant women at risk of premature birth to reduce respiratory distress and early neonatal mortality and disability in premature infants (22). This evidence first emerged in 1972. Yet it was not until nearly 20 years later, following the publication of Crowley’s meta-analysis (23) that practice began to change. The evidence review conducted in 2006 (24) confirmed that antenatal corticosteroids should be part of routine clinical care for women in preterm labour.
A possible reason for this time lag may be the destabilisation of the conventional professional organisation, or normative structure, of care for women in labour and preterm infants that resulted from introducing the treatment. The care of women was the responsibility of obstetricians and midwives whereas the care of the infant was that of neonatologists and neonatal nurses. Preventing neurological damage to the preterm infant meant that MgSO4 (and corticosteroids) had to be administered to women before birth - the responsibility of obstetric teams for the benefit of preterm infants who are the responsibility of neonatal teams. This structuring of responsibilities had practical implications because maternity and neonatal units were not always co-located at hospital sites and this physical distance led to fewer opportunities for communication among staff. Other structural barriers included regulations about who can prescribe and administer medications, and access to medical notes which are separate for mother and baby and held in separate physical locations or databases. ‘Ownership’ of PReCePT was therefore initially contested, but it was a crucial aspect of its success. The following interview excerpts illustrate the discussions around which professional group should provide leadership for implementing the required changes in clinical practice:

[Before the PReCePT intervention] it [was] the neonatologists trying to tell the obstetricians what to do and how to look after their patients. [...] And that was quite frustrating that people weren't implementing it and then when PReCePT came in, they suddenly were. And nothing new really, there wasn't new data that came on board, it was just someone different telling them [obstetricians] should do it. (P26, Neonatologist, ESP Unit31)

It makes sense that actually this is an obstetric project really rather than sit with neonatology which was the original thinking [...] It sits better with maternity because [they] are the ones who have to administer it [...] with an obstetrician who has actually been doing degrees in pre-term deliveries so it made sense for that person to [to lead]. (P46, Neonatologist, SSP Unit12)

What this shift in responsibility for leading the change signals is that it is not the technical complexity of the clinical intervention that needed to be addressed in implementation and spread, although it did require additional steps in workflows and time, mainly for midwives. Rather, it was the work of integrating the change into the wider ecology of clinical practice including the policy/regulatory context, and the organisational, team and individual practitioner levels that required considerable thought and effort (25). In the following sections we focus on three of the NPT constructs relating to outcomes that explain how this work was accomplished: normative restructuring, relational restructuring, and sustainment/normalisation (14).

Normative restructuring

Normative restructuring refers to the changes that were required to increase MgSO4 uptake: changes to the norms, rules and resources that govern the actions of maternity and neonatal teams. An important pre-condition for starting the work was an acknowledgement that the change in clinical practice was necessary. Some clinicians assumed that the administration of MgSO4 was already routine and were surprised to learn that following the collection of baseline data for all maternity units, the actual recorded
rates of administration did not align with their expectation, highlighting the value of real-time and
accurate data collection, as suggested below:

Everyone’s first response is, ‘we already give it and it is a normal part of our everyday care when we are
caring for women in prem labour’. But actually the data didn’t support that. (…) One of the first things we
did when the project came in [was to feed back their administration data] because everybody was so
adamant that they did do it already. (NPP support, AHSN6)

The restructuring activities observed in all SSP and ESP units included modifications to the professional
organisation of care for women in labour and preterm infants, to clinical guidelines and processes, and to
procedures for documentation and communication across the perinatal team and with other members of
the multidisciplinary team involved in care of women in preterm labour. These included anaesthetists and
pharmacists, and settings outside the labour ward, for example in community care, Emergency
Departments and triage. Some of these changes had already been identified during the initial PReCePT
pilot phase and been codified in the QI toolkit and implementation guide. For example, one of the first
actions taken by implementers was to compare their hospital clinical guidelines with the PReCePT QI
clinical guideline included in the toolkit. All units reported their unit to already have MgSO4 guidelines in
place, but amendments were needed for these to reflect national policy and PReCePT QI protocols.
Changing existing guidelines was the most often reported change implemented in units. Guideline
updates included administration of MgSO4 for neuroprotection, addressing repeat doses, and most units
had adjusted the gestational threshold of eligible pregnancies to include women up to 34 weeks, as
described below:

*We've changed, a hundred percent. We chose, in our unit, to offer [MgSO4] to everyone up to 33 weeks and
6 days because our numbers are so small […] so it's become the norm really to give it. […] We've probably
gone the other way as we've over-treated so that we don't miss any but I think now we're not so scared of
missing [a dose] so we're able to balance that out a little bit.* (P15, Midwife, ESP unit23)

Others structural impacts were ‘discovered’ and addressed during the implementation process, as the
following interview excerpts illustrate:

*You need an extra person (…) to go and do the magnesium sulphate because of all the other things that
need to be done if somebody is in pre-term labour. Somebody else needs to go away to do it and we've
appreciated that more I think.* (P01, Midwife, ESP unit31).

*What we had to do was to drill it into our registrars [doctors-in-training] that if somebody comes in, in
preterm labour you don’t just write up magnesium and walk away, because then the poor midwife (…) she's
got to monitor the baby, she's got to get a resuscitaire[1] ready, she's got to give her dexamethasone,
she's got to cannulate her, and then you expect her to give her the dose of magnesium as well, and then
you wonder why when she delivers one hour later she's not had the magnesium. So we drilled it into our
registrars that you have to cannulate [the woman], you just give them magnesium straight away, you do
it.* (P27, Obstetrician, SSP unit15)
Workflows were actively restructured to remove barriers to women receiving MgSO4 in preterm labour, but they also restructured staff’s prioritising and decision-making. This is highlighted in the following excerpt describing the introduction of ‘PReCePT QI grab boxes’, resembling the ‘steroid boxes’ already in use. This was a box containing all the equipment and documentation needed when administering MgSO4. It was easily accessible in all places where MgSO4 needed to be administered such as in labour wards and operating theatres. These boxes helped make MgSO4 visible and act as a reminder, making administration as easy and quick as possible:

The biggest changes were essentially people’s mind-set, the thinking, just whenever somebody thinks of preterm labour, they not only have to think of transferring the baby, […] so in-utero transfers, steroids and magnesium sulphate. So we kept what we called grab box, so magnesium sulphate is available. This particular client comes through the door, we can just get hold of the whole bag, it’s all ready to go. (P43, Obstetrician, ESP unit23)

The ‘grab box’ was not only of practical value in reducing delays but also signalled the unit’s commitment to neonatal safety. Other normative restructuring changes included modifications to the way information was documented in patient notes: mainly clinical proformas and stickers to facilitate better recording of MgSO4 administration in maternity notes, and easier transfer of information from maternity to neonatal databases. A powerful tool to improve uptake were the reviews of missed cases where audits revealed that women who should have received MgSO4 but did not, with findings being fed back into the system (through training, communication of results during meetings and handovers, and one-to-one discussions). All units, irrespective of the level of implementation support they received, achieved some or most of the normative restructuring needed to increase their unit’s MgSO4 administration rate through use of the QI toolkit, implementation guide and ongoing QI support. This partly explains why there were no significant differences in MgSO4 administration rates between the ESP and SSP unit in the clinical trial results.

Relational restructuring

Relational restructuring refers to how professional relationships and communication between different hospital units changed as a result of working with PReCePT to implement the new practice. Professional silo-working was one of the greatest challenges for implementers who needed to promote perinatal teamwork, as the following excerpt highlights:

Obstetricians and neonatologists sometimes have a default tendency to operate in silos (…) the most optimistic interpretation I think I can give you is that the perinatal team is starting to form. (AHSN Clinical Lead 1)

Participants’ accounts suggest that poor teamwork was especially risky for perinatal teams for the structural reasons explained above: vital information was not shared because it was stored in different locations and communication was therefore suboptimal. The geographical distance between some
maternity and neonatal units frequently exacerbated communication problems. Yet the care of women in preterm labour and the timely administration of MgSO4 required new routines that needed to be aligned with established responsibilities and a vision for joint working across perinatal teams across maternity and neonatal unit staff. PReCePT activities (such as joint workshops and meetings, awareness training in different settings) enabled the perinatal team to engage in conversations about MgSO4 away from pressurised clinical environments, develop networks across units, and to raise and discuss concerns. They also enabled midwives to initiate conversations with obstetricians about when the administration of MgSO4 would be appropriate. These conversations facilitated a coming-together of the perinatal team and the opening of opportunities for developing creative solutions to structural problems and for learning and improving practice, as illustrated below:

_I think it did have an impact as a joint project that (...) gets people involved together and I think it gave the neonatal team the permission to say, is the mag sulph going up? It gave the midwifery team permission to say, shall we start mag sulph? And I think it was good that everybody was trying to do the same thing._ (P01, Midwife, ESP unit31)

These outcomes were achieved more easily in ESP units that benefitted from additional backfill time for implementers drawn from all three professions (midwifery, obstetrics and neonatology) as well as additional events and meetings, focused training and coaching in QI methodology. Overall, there was more engagement from all three professions in the ESP units while in the SSP units most of the implementation activities were carried out by midwives, as the excerpt below indicates:

_It's good having a midwife with dedicated time to go around doing some teaching [...] To be honest a lot of that stuff I was doing I was juggling with other stuff, so I wasn't doing it very well. [...] At least now we've got a midwife there and she's on labour ward all the time, whereas I'm all over the place._ (P27, Obstetrician, SSP15)

However, one of the most notable differences between the two types of support was the way that PReCePT was viewed: in the ESP units it was understood as a perinatal team project, involving all professions equally, whereas SSP units relied heavily on the lead midwives to support what was seen as either an obstetric or neonatal project. There was also less active involvement of obstetricians and neonatologists in SSP units. The strength and quality of these horizontal relationships had implications for the implementation process in ESP and SSP units. ESP units focused on collaboration, commitment and shared learning among participating units and invested in opportunities for this to happen. Regional and national support networks with which implementers engaged throughout the life of the study, helped form ‘communities of practice’ within which knowledge was created and shared (26), and helped increase MgSO4 uptake in individual units, further enabling spread and scale-up of PReCePT QI. Another corollary of the enhanced QI support was the creation of ‘networks of networks’ where those participating in the PReCePT network also acted as links and access points to other networks, such as Quality and Safety Collaboratives and Local Learning Systems. This generated synergies which allowed the PReCePT
message to be embedded within the wider system, raising the profile of MgSO4 as an important aspect of neonatal safety, transcending professional boundaries of responsibility.

These networks were facilitated by the national PReCePT team for ESP units, but were lacking in SSP units resulting in fewer opportunities for implementers to be part of these mutually supportive, interprofessional collaborations. Nevertheless, clinicians and AHSN staff with QI and coordination roles also organised opportunities for local and regional meetings for training and exchanging knowledge and learning, replicating some but not all of the functions of the collaborative support received by ESP units. The AHSN support tended to focus on the SSP unit lead midwives who were seen as the main implementers. The SSP unit lead midwives were also highly proactive and creative in connecting with each other and seeking solutions to commonly experienced barriers and problems. For example, early in the implementation period, they formed a ‘WhatsApp’ group as a peer support and information sharing tool, and as a mechanism for spreading improvement ideas developed in local units. Inevitably there was contact between ESP and SSP units and while it may have been preferable to avoid cross-study arm contacts for the clinical trial to test the effectiveness of the enhanced intervention, in reality this was impossible. Wider support networks encouraged commitment, motivation, exchanging ideas and networking which increased awareness and spread of MgSO4 administration.

Overall, relational restructuring was more challenging for SSP units. Midwives reported that it was often difficult to protect their time from clinical pressures, despite the funded backfill. This also had an impact on their capacity to attend training and meetings and complete tasks related to PReCePT such as training and awareness raising among staff in their units and hospitals, accurate data collection, data auditing and the investigation of missed doses and follow-up actions. These tasks were often carried out in their own time. Although ESP unit midwives were also called on to provide clinical support during their dedicated ‘PReCePT time’, they were better supported by their fellow implementers, and momentum was less likely to be lost during times of high pressure.

One way of securing more support for their efforts involved SSP unit midwives forging alliances with other members of the multidisciplinary obstetric and neonatal teams. For example, advanced neonatal nurse practitioners were enthusiastic supporters of MgSO4 uptake as the following excerpt illustrates:

*It’s now become a sort of midwife-advance neonatal nurse practitioner led project [...] It’s become us two sort of leading it [...] Our plans are to carry on the monthly meetings even once the PReCePT support has finished so we can maintain that.* (P14, Midwife, SSP unit36)

Vertical relationship with the senior hospital leadership were not explicitly restructured as a result of implementation. However, they formed an important part of the context because explicit leadership support meant that structural and practical barriers with bureaucratic systems and policies could be overcome. Where that support was missing, implementers had difficulties in accessing PReCePT funds, and some hospital policies prevented the use of some parts of the PReCePT toolkit. However, this was not related to whether units received the SSP or ESP.
**Sustainment/normalisation**

This refers to how changes have become incorporated into routine practice following the ending of QI support backfill funding. This coincided with the beginning of the COVID-19 pandemic. Sustainment and normalisation required work including the continued (re)evaluation of performance, dissemination and review of audit results and subsequent action to promote MgSO4 administration and address barriers. Improvements in data collection introduced in the implementation phase, regular training updates for existing staff, and incorporating PReCePT training into mandatory staff inductions continued into the post-implementation phase although some participant accounts suggested that clinical pressures and the impact of the COVID-19 pandemic led to falls in their administration rates. Reasons included staff shortages and reliance on untrained and agency staff while opportunities for training were also reduced. Evaluation data suggested that ESP units were more likely to sustain their administration rates and that this was related to stronger perinatal teamworking. Furthermore, participants’ accounts from both ESP and SSP units suggest that enhancing QI capacity in the workforce also had positive impacts on teams and individuals. Being a lead midwife led to an increase in confidence and opened up opportunities as some alumni went on to continue their connection with their AHSN, collaborate on research projects for the first time, write for professional publications or develop QI activities at their hospital.

[1] A resuscitare is a piece of equipment for the resuscitation and warming of new-born babies.

**Discussion**

The evaluations of the National PReCePT Programme and the embedded randomised controlled trial (the PReCePT QI study) showed that increases in the uptake of MgSO4 were achieved across all units in England irrespective of whether they received a standard or enhanced QI package (12, 13). The qualitative process evaluations provided some explanation. The findings are limited insofar as data were only collected from individuals in implementation roles. The views from other staff members were not included. Ethnographic observations would have also enhanced the richness of the data and may have yielded finer-grained interpretations. However, what our data may have lost in depth, it gained in breadth due to the number of units participating in the process evaluation, also adding to the development of NPT outcome constructs.

One reason for the lack of difference between ESP and SSP units may be the relative straightforward nature of the implementation's 'hard core' (27), the element that carries the key benefit, in this case simply giving a drug to a women with diagnosed premature labour. On the other hand, the implementation's 'soft periphery', including the changes in structures and relationships involved in delivering the 'hard core', was highly complex. The multidisciplinary steering group carefully considered the soft periphery and produced the comprehensive QI toolkit and implementation guide following piloting and refinement so that it could be used flexibly by implementers and tailored to conditions in their own unit (10). The piloting in a small number of maternity units, and integrating and codifying the learning had been a crucial stage in the
process (28). The resultant QI toolkit and guide were available to all units. Similarly, all units received QI support although in different ‘doses’. As Dixon-Woods suggests (29) QI without targeted contextual support is likely to have limited impact. Given the inevitable social contacts and knowledge sharing between the ESP and SSP units during the evaluation period, there were very few differences. Indeed, the qualitative accounts indicated that all units were successful in the normative restructuring of their setting to enable MgSO4 to be administered which suggests that this implementation outcome is necessary to achieve improvements. However, it may not be sufficient to sustain and normalise the changes once additional support and resources have been withdrawn. Sustainment, our findings suggest, requires the restructuring of relationships and behavioural norms (30) to accommodate altered workflows and facilitate the sharing of responsibilities and tasks in daily working practices. The relational restructuring was more likely to have been achieved by ESP units but also happened in SSP units especially in those where perinatal teamworking was already established.

The emergence of professional coalitions through the PReCePT programme at local, regional and national levels also supported relational restructuring. Clinicians worked as advocates for the improvements, legitimised changes, provided training and contributed their expertise to secure commitment and drive motivation (29, 31). Indeed, peer pressure through comparing performance via data dashboards was an important way of influencing peers’ behaviours to make improvements. It also afforded the PReCePT programme a moral authority in addition to the ethical demand to avoid harm to premature infants by intervening while still in utero. While lead obstetricians and neonatologists worked predominantly through their peers, the lead midwives’ implementation role was more complex. They acted as boundary spanners, a bridge between professional silos (32), engaged in relationship building (33), taking on multiple roles, navigating boundaries and accelerating change (34). They bore the burden of driving the normative restructuring, often at a high cost to themselves. They were more likely to have been supported in implementation activities by the other clinical leads if they worked in ESP units. The lack of difference in the programme outcomes across all units can therefore be said to be largely down to their efforts in bringing about the improvements and their regional AHSNs who enabled the formation of peer support and communities of practice.

**Conclusion**

Unlike other large QI focused spread and scale programmes which failed to show any impact on outcomes (25, 35, 36), the PReCePT programme in both the enhanced and standard support packages led to improvements in the uptake of MgSO4. An important insight of the qualitative components of the evaluation was that QI programmes require careful development with input from all people affected by the changes; attending to the normative and relational restructuring required to bring about improvements; and piloting and codification of learning through accessible and flexible materials. But however well materials may have been designed, local implementers needed to be supported to translate the changes into their own context, giving them the opportunity to experiment, discover and be creative with material, financial and team resources. Changes were much more likely to occur in settings where interprofessional relationships were already strong and where there was a history of improvements,
participation in research and QI projects, openness and a commitment to high standards of clinical practice. The findings suggest that QI capacity building irrespective of formal, nationally driven programmes might be useful given that QI interventions and clinical contexts are co-constitutive and that QI programmes interacted with the enabling factors already present in the setting (37). A standard package with minimal support was therefore sufficient in settings with these enabling factors, but enhanced support was required in units where these were absent.

References

2. WHO. Nine steps for developing a scaling-up strategy. 2010.


28. &lt;/number&gt


**Abbreviations**

ESP  Enhanced Support Package

MgSO4  Magnesium Sulphate

NPP  National PReCePT Programme

NPT  Normalisation Process Theory

PReCePT  Prevention of Cerebral Palsy in PreTerm Labour

QI  Quality Improvement

SSP  Standard Support Package

**Declarations**

*Ethics approval and consent to participate*

The PReCePT Study – A cluster randomised trial evaluating the impact of an enhanced support implementation of the PReCePT quality improvement toolkit to increase the uptake of magnesium sulphate in pre-term deliveries for the prevention of neurodisabilities was granted a favourable ethical
opinion by the National Research Ethics Service (REC reference: 19/HRA/0323). The PReCePT Programme Evaluation was granted a favourable ethical opinion by the Faculty of Health Sciences Research Ethics Committee at the University of Bristol (FREC ID: 84582).

Consent for publication

Interview excerpts are presented anonymously.

Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available due to protect the anonymity of staff and their employers, but are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors’ contributions

SR, JLD, ET and KL contributed to the conception of this work; SR and JLD designed the process evaluations; CP-K and TS collected the data; SR, CP-K, TS, JLD, ET and KL contributed to the interpretation of the data; SR drafted the manuscript with contributions from all authors. All authors have approved the submitted version of the manuscript.

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**Supplementary Files**

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- [PReCePTCOREQTable.docx](#)