A rapid improvement event: progesterone prescribing in prevention of miscarriage

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ABSTRACT
A rapid improvement event (RIE) is a standard operational excellence technique that uses team-based problem solving to improve processes. In this study, a RIE was undertaken to improve progesterone prescribing rates for those with a history of miscarriage experiencing vaginal bleeding in early pregnancy. This was on the basis of a recent change in guidelines regarding prescribing in these instances. NICE guidelines changed in November 2021 after Cochrane meta-analysis and the PRISM (Progesterone in Spontaneous Miscarriage) randomised control trial demonstrated a higher incidence of live births in those prescribed vaginal micronised progesterone for threatened miscarriage, when compared with those not prescribed it.

A RIE involves a team approach and a standard sequence of events allowing analysis and improvement of a process. Analysis in the form of audit revealed a low progesterone prescribing rate for eligible patients in our unit. Dissection of this problem into its elements revealed a low level of staff knowledge regarding the change in guidelines and a lack of confidence in prescription of progesterone. A plan of actionable events to improve prescribing rates was devised. The updated guidance and local recommendations on appropriate micronised progesterone formulations were presented at hospital Grand Rounds with multidisciplinary attendance. Infographics were displayed in areas visible to stakeholders within the hospital and on the hospital’s social media pages. The validity of these educational measures to improve the process was reaudited after 3 months.

Progesterone prescribing improved by 48%. Those comfortable with prescribing as per the new guidelines improved from 43% to 78%. A RIE proved to be an effective and efficient approach to collaboration, decision-making and action.

PROBLEM
Bleeding in early pregnancy (threatened miscarriage) is a very common presentation to maternity units and can be very distressing for the patient especially when there is a history of pregnancy loss. Prior to 2019, the use of supplemented progesterone in threatened miscarriage was lacking conclusive evidence but following the PRISM (Progesterone in Spontaneous Miscarriage) randomised control trial, NICE guidance has been updated to recommend offering progesterone to those with a history of miscarriage experiencing bleeding in early pregnancy.12

WHAT IS ALREADY KNOWN ON THIS TOPIC
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⇒ NICE now recommends progesterone in these instances.
⇒ Prescribing rates in our unit were low due to the recent change in the guidelines.

WHAT THIS STUDY ADDS
⇒ We used a rapid improvement event model to improve progesterone prescribing rates and staff knowledge on the potential benefits of progesterone in threatened miscarriage.
⇒ A 48% increase in prescribing was achieved.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY
⇒ A rapid improvement event proved to be an effective and efficient approach to collaboration, decision-making and action.
⇒ A similar approach could be used by those seeking to conduct a swift but effective quality improvement.

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also provide a comprehensive bereavement service which offer patients support during pregnancy loss as well as in pregnancies after loss. Initial audit over a 1-month period demonstrated that there was 158 patients presenting to the emergency department with bleeding in early pregnancy, of whom 41% had a history of at least one previous miscarriage.

Given that this hospital strives for excellence in miscarriage and pregnancy after loss care, it was imperative that staff encountering these patients in the ED were aware of the updated guidance on progesterone prescribing in threatened miscarriage.

This project aimed to increase staff knowledge on the updated guidance to at least 75% and progesterone prescribing to eligible patients in the ED to 50% within a 6-month intervention time period. An RIE model, which is a standard operational excellence technique that uses team-based problem solving to improve processes, was used to fulfil the goals set out in this project.

**BACKGROUND**

It is well recognised that endogenous progesterone is essential in maintaining a pregnancy. The value of supplemented progesterone in the prevention of miscarriage has been the subject of numerous studies. Coomarasamy et al first investigated the role of supplemented progesterone in asymptomatic women with a history of recurrent miscarriages and found no benefit. They subsequently carried out the PRISM trial which was a multicentre randomised, double blind, placebo controlled trial evaluating the use of vaginal progesterone in women with threatened miscarriage. The trial did not demonstrate that supplementing progesterone in threatened miscarriage results in a higher incidence of live births overall; however, it did demonstrate some benefit in those with a history of one to two miscarriages and substantial benefit in those with a history of three or more miscarriages.

The results of the PRISM trial led to a Cochrane review which concluded that there is ‘high quality evidence’ for supplementing progesterone in threatened miscarriage for those with a history of one to two miscarriages and ‘high certainty evidence’ for those with a history of three or more miscarriages. Subsequently, NICE guidance on the management of threatened miscarriage was updated to include offering vaginal micronised progesterone 400 mg two times per day to those with a history of miscarriage presenting with threatened miscarriage and a confirmed intrauterine pregnancy on ultrasound. It is recommended that the progesterone is continued up to 16 weeks where a viable pregnancy is continuing.

**MEASUREMENT**

To establish an understanding of the current practice of progesterone prescribing in our unit, an audit was carried out in the ED where most patients with threatened miscarriage present. It was a retrospective chart review of all presentations to the ED with vaginal bleeding in the first trimester over a 1-month period (November 2021). The aims were to assess the current practice of progesterone prescribing and identify the number of patients who may be eligible for vaginal progesterone based on the new guidance. There were 158 presentations with threatened miscarriage in the first trimester (up to 12 weeks and 6 days), of which 41% had a history of at least one previous miscarriage. No patient was offered progesterone. Forty patients were eligible to be offered progesterone based on the updated guidance. This accounted for 25% of all presentations (figure 1).

To gain a deeper insight of the issue, staff knowledge was also evaluated. A Survey Monkey was issued to all non-consultant hospital doctors who work in the ED, of which 43% demonstrated an understanding of the criteria for prescribing progesterone based on the updated guidance, 28% could identify the correct dose and formulation and 24% were aware of the allergy restrictions associated with vaginal micronised progesterone.

The findings of the initial ED audit and the evaluation of staff knowledge confirmed that quality improvement in this area was necessary; thus, a series of interventions were planned. The ED audit and staff knowledge survey were scheduled to be repeated 3 months after the interventions.

**DESIGN**

The core team in this improvement event consisted of two non-consultant hospital doctors (NCHDs) and a consultant obstetrician/gynaecologist and reproductive medicine specialist with a special interest in recurring miscarriage. A key principle of rapid improvement events is using multidomain collaboration to implement change in a short-term to medium-term timeframe. During the planning stages of the interventions, the hospital pharmacy department was approached to research the most appropriate brand and formulation of micronised progesterone to use in our unit considering patient acceptability.
cost-effectiveness and availability on the medical card or drug payment scheme.

The authors felt that all stakeholders should be educated on the updated guidance during the improvement event. The hospital bereavement midwives created infographics to display to patients outlining the change in NICE guidance.

The updated guidance and local recommendations on appropriate micronised progesterone formulations were presented at hospital grand rounds which is attended by doctors, midwives and allied health professionals.

Infographics briefly outlining the updated guidance were displayed in areas visible to stakeholders and shared on the hospital social media pages. This served as a visual reminder to staff to offer progesterone to eligible patients and to patients to ask about progesterone in their situation. Another infographic outlining the most appropriate formulation and the allergy restrictions was displayed in the office in the ED which is used by doctors and midwives.

**STRATEGY**

Our aim was to increase both staff and patient knowledge on the potential benefit of progesterone supplementation in threatened miscarriage and increase progesterone being offered to the correct patients as per the updated NICE guidance. As this was an RIE, only one PDSA (plan-do-study-act) quality improvement cycle was carried out.

We hypothesised that staff knowledge on the update to NICE guidance and the role of supplemented progesterone in threatened miscarriage was lacking due to the evidence and guidance being relatively new (figure 2). After assembling our core team and gaining ethical approval from the hospital research committee, we audited the current practice and tested staff knowledge which confirmed our hypothesis that improvement in the area was needed.

Although the prescribing practices of doctors was the main focus of this RIE, we acknowledged that multidisciplinary education was paramount to the sustainability of our improvement project given that NCHDs in training rotate to different units on a regular basis and midwives in particular play an important role in orientating doctors who are new to both the unit and the specialty and reminding them of best practice for our patients. Thus, it was decided that it was best that the information was presented at hospital grand rounds which can be attended by all disciplines.

In addition, we recognised the role that patients play in advocating for themselves, particularly in our specialty, so we felt it was important that patients are made aware of the potential role of supplemented progesterone in certain instances. We therefore made infographics directed towards patients which were displayed in the ED and on the hospital social media pages (figure 3).

During the initial audit and planning stages, we were made aware that certain brands of micronised progesterone are not suitable for those with certain food allergies as well as a safety concern with a sound alike drug. Infographics alerting staff to the allergies and safety concerns were displayed in the ED office (figure 4).

While the test of staff knowledge through a survey was done to collect data prior to implementing the change, it also served to spark staff interest in the new guidance prior to the teaching session at grand rounds and the rollout of the infographics. The staff knowledge survey and ED audit were repeated in the same format 3 months after the interventions.

**BLEEDING IN EARLY PREGNANCY (EP)**

This can be scary but it doesn’t always mean you will have a miscarriage.

Research has shown that progesterone is an effective treatment in women who have bleeding AND have had one or more previous miscarriages.

- **Bleeding in EP is very common but the majority of women with bleeding will continue their pregnancy.**
- **Progesterone is a natural hormone, important in pregnancy. It is a safe treatment to use in pregnancy.**
- **If you are bleeding at any stage in pregnancy, please contact the hospital on 016373100 or attend the NMH ED.**

![Figure 2](http://bmjopenquality.bmj.com/)

Figure 2  Rapid Improvement Event Fishbone analysis.

![Figure 3](http://bmjopenquality.bmj.com/)

Figure 3  Infographic displayed to patients & shared on hospital social media.
RESULTS

Initial audit had demonstrated a 0% progesterone prescribing rate of progesterone for patients who were eligible based on the updated NICE guidance. When the audit was repeated 3 months after our interventions, this had increased to 48% (figure 5). Our unit uses electronic health records (Maternal and Newborn Clinical Management System, Cerner, Missouri, USA) and therefore audit in the form of chart review is likely to be very accurate as prescribing is all done through this electronic system. Our goal of at least 50% of eligible patients being prescribed progesterone was not quite achieved, although it is possible that more patients were offered progesterone but decided not to take it and the conversation was not reflected in the clinical notes.

The staff knowledge survey was reproduced using the same questions and was issued to the same group of NCHDs. This demonstrated that 78% could identify the correct patients to offer progesterone, an increase from 43% in our initial survey (figure 6).

LESSONS AND LIMITATIONS

The aim of this improvement event was to increase awareness of an updated change in NICE guidance in the care of patients with threatened miscarriage. Staff knowledge and progesterone prescribing was low due to the guidance being relatively new and a lack of hospital policy.

A strength of this improvement event was the different disciplines such as pharmacy that were consulted in the planning stages to create interventions that contained information that was relevant to our unit. Targeting patients’ awareness of the role of progesterone in certain instances through the display of our infographics in areas visible to them and on social media was also reflective of the increasing role that patients play in their own care in our specialty today.

A limitation to this RIE is that both the educational interventions and reaudit were conducted within the same 12-month period, within which staff remained constant. ‘Changeover’ of junior doctors on an annual basis presents a risk for relapse to low progesterone prescribing rates within our institution therefore training the new cohort of junior doctors after changeover has been identified as a future imperative educational intervention.

The knowledge that our existing junior doctors accrued through our RIE will however carry over to their new units thus improving the calibre of care for patients experiencing threatened miscarriage in Ireland overall.

CONCLUSION

Vaginal micronised progesterone may increase live birth rates in those with a history of miscarriage experiencing threatened miscarriage without increasing the risk of adverse events.2 6  NICE guidance now recommends offering vaginal micronised progesterone 400 mg two times per day to women with a history of miscarriage experiencing threatened miscarriage where an intrauterine pregnancy has been confirmed.1
Evidence and recommendations were relatively new, thus progesterone prescribing rates and staff knowledge on the subject was low. Experiencing threatened miscarriage after a previous loss can be extremely distressing. Furthermore, it is likely that patients attending our unit were aware of the potential benefit of progesterone through the publication of the updated guidance on patient support groups and mainstream media, yet it was not routinely being offered. Thus, an RIE was initiated.

An RIE is a standard operational excellence technique that uses team-based problem solving to improve processes. After establishing the core team, information was collected which confirmed that staff knowledge was low, and progesterone was not being offered where appropriate. The team set out a goal of improving staff knowledge to 75% and progesterone prescribing to 50%.

A multidisciplinary approach was taken when formulating actionable events to improve progesterone prescribing rates. Pharmacists were consulted to advise the best brand and formulation to offer considering patient acceptability, cost-effectiveness and availability on the medical card. The updated guidance and local recommendations were presented at a meeting attended by various disciplines. The authors also recognised the value of patients advocating for their own care so infographics outlining the updated guidance were made available to patients.

The success of the RIE was measured 3 months after the interventions by repeating the audit and staff knowledge survey. Progesterone prescribing for eligible patients had increased from 0% to 48% and staff knowledge increased from 43% to 78%.

Staying up to date with new evidence and guidance updates is imperative and improves patient care. This is particularly important in pregnancy after loss given that it is a worrying time. A collaborative multidisciplinary approach as demonstrated in this RIE is an efficient and effective way to increase knowledge and change practice in a single unit and further afield. While we expect that the improvements achieved in this project will be sustainable due to the multidomain education carried out, we recognise that continuing education and audit is necessary for continuing improvement in addition to changing practice as new evidence and guidance in the area emerges.

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Acknowledgements: We would like to acknowledge the bereavement team at the National Maternity Hospital in particular, Sarah Cullen, clinical midwife specialist in bereavement. We would also like to acknowledge David Fitzgerald and Sarah Cullen from the pharmacy department at the National Maternity Hospital as well as the Emergency Department staff who all played a vital role in making this RIE a success. This work was presented at the 2022 British Maternal Fetal Medicine Society meeting 2022 (poster presentation) and Fertility 2023 (oral presentation).

Contributors: LAB (guarantor) was responsible for the running of the project, data collection, implementation of the interventions and the writing of the report. NO’R was responsible for the design of the rapid improvement event, data collection and critical review of the study proposal and report. CA is a subspecialist in reproductive medicine with a special interest in recurrent miscarriage who was the supervising consultant for this project. She oversaw and critically reviewed the project design, implementation and report.

Funding: The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests: None declared.

Patient and public involvement: Patients and/or the public were not involved in the design, conduct, or reporting or dissemination plans of this research.

Patient consent for publication: Not applicable.

Ethics approval: Not applicable.

Provenance and peer review: Not commissioned; externally peer reviewed.

Data availability statement: All data relevant to the study are included in the article or uploaded as supplemental information.

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Provenance and peer review: Not commissioned; externally peer reviewed.

Data availability statement: All data relevant to the study are included in the article or uploaded as supplemental information.

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