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Woman-Centred Induction of Labour (the WOCIL project)

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ABSTRACT

Induction of labour (IOL) is a common obstetric intervention. 32% of women are induced per year in our obstetric unit. We were experiencing delays in starting IOLs due to unit activity, protracted inpatient stay and dissatisfaction among staff and service users. We used quality improvement (QI) methodology to identify inefficiencies and root causes and used a bottom-up approach in planning improvements. After optimising our IOL processes, we introduced misoprostol vaginal insert (MVI) as it was faster acting than traditional dinoprostone. We compared 207 women who had MVI with 172 women who had dinoprostone prior to MVI introduction. There was a reduction of IOL start to delivery time, from a mean of 30 hours to 21 hours. Fewer women required oxytocin and of those who did, required oxytocin for fewer hours. We also found a reduction in caesarean section rates in women undergoing IOL, statistically significant in nulliparous women (41%–25%, p=0.03).
There was a higher uterine tachysystole and hyperstimulation rate with MVI use and introduction should be accompanied by education of staff. We did not find any increase in neonatal admissions, maternal haemorrhage or other serious adverse events. In summary, MVI is a useful drug in helping high volume units with high IOL rates, reduced bed occupancy and improved flow of women. We would recommend a holistic QI approach to change management, as safe use of the drug requires optimisation of the IOL processes as well as staff engagement, due to rapid flow of women through the IOL pathway and increased hyperstimulation rates.

PROBLEM

Induction of labour (IOL) rates in the UK are currently the highest they have ever been, at 29.4% in 2016–2017.[1] This is likely due to factors such as higher rates of obesity, hypertension and gestational diabetes and an increase in maternal age.[2] In addition, the Saving Babies' Lives Care Bundle to reduce stillbirth rates[3] will continue to drive up IOL rates. The IOL rate in our unit, a tertiary-level obstetric and neonatal regional referral centre, has also risen and is currently at 32% with a delivery rate of 5800 births per year.

We carried out a process mapping exercise and hosted a series of staff engagement events. We found:

- IOL booking process is not robust in evenly distributing workload.
- Low uptake of outpatient IOL.
- Frequent delays.
- Potential for delayed and protracted IOLs resulting in adverse outcomes such as intrapartum sepsis and caesarean section (CS).
- Frustration from staff, women and partners.

The Woman-Centred Induction of Labour (WOCIL) project wanted to reduce the amount of time women spent in hospital during IOL and make the experience more efficient and woman centred. We commenced the work in October 2016 and the project was initially approved to carry on for 18 months. Our primary objective was to reduce overall length of inpatient stay by:

- Starting IOL soon after a woman's arrival to the unit.
- Reducing the amount of time taken from starting the IOL to delivery.
- Increasing use of outpatient IOL.

BACKGROUND

The practice of IOL can vary widely between countries and units, due to obstetric culture and practitioner preferences.[4–6] The focus of IOL-related quality improvement (QI) projects in reported literature largely fall into two categories—the reduction of 'inappropriate IOLs' and 'elective delivery before 39 weeks'[5 7 8] and second, the reduction of inefficiencies in the IOL process.[9]

There is evidence that the following measures can be effective in achieving the above aims:

- Bottom-up approach, multidisciplinary staff engagement in guideline development and staff education.[7–9]
- Standardisation of processes for booking IOLs.[5 7 8]
- Ongoing feedback to staff regarding project outcomes and data.[8 9]

Outpatient IOL has been adopted in maternity units in order to reduce costs and bed occupancy.[9 10] There is also evidence that it increases maternal satisfaction when compared with inpatient IOL.[11] Serious adverse events are rare when used in the low-risk maternity population, and thus most

studies are not adequately powered to detect any potential safety concerns when compared with inpatient IOL.[12] There is some cohort data showing no difference in serious maternal and fetal adverse outcomes.[13] Current national guidelines for outpatient IOL state that adequate 'safety and support procedures' should be in place.[14]

There are two main classes of pharmacological methods for induction of labour: dinoprostone (available in a gel or tablet formulation, requiring 6 hourly administration, and a slow release vaginal insert, where the drug is released over 24 hours) and misoprostol. Misoprostol is also available in two different delivery methods—tablets for vaginal or oral use and a slow release vaginal insert.

When compared with the dinoprostone gel/tablet in the randomised controlled trial (RCT) setting, dinoprostone vaginal insert (DVI) has no difference in efficacy or time to delivery.[15] However, DVI has the benefit of requiring fewer vaginal examinations in women requiring more than one gel/tablet dose. DVI has the potential to reduce total IOL time in the real-life setting, as subsequent doses of the gel/tablet are reliant on midwifery time.[9]

With regard to misoprostol, UK national guidance has stated that it should only be used in cases of intrauterine fetal death or in the context of a clinical trial.[14] At the time of release of the guideline (2008), the only available formulation of misoprostol was in tablets, which required dividing either into quarters or eighths (depending on the regime used), prior to oral or vaginal administration. This technical problem in ensuring accurate concentrations and reliable drug delivery, as well as the fact that use in IOL is off-license, means that misoprostol in tablet form is rarely used for IOL in the UK, as suggested by the national guideline. In the international setting, oral or vaginal misoprostol is a common IOL agent due to low drug cost and stability at room temperature. Efficacy of misoprostol in labour induction is well established.[16] It is a recommended IOL agent by the WHO and International Federation of Gynaecology and Obstetrics.[17 18]

In 2014, a misoprostol vaginal insert (MVI) obtained a UK license. When compared with DVI in the RCT setting in the Efficacy & Safety Study Comparing Misoprostol Vaginal Insert (MVI) Versus Dinoprostone Vaginal Insert (DVI) for Reducing Time to Vaginal Delivery (EXPEDITE) trial, the induction to delivery interval is significantly reduced, with fewer women requiring oxytocin in the MVI group. Incidence of uterine tachysystole and uterine hyperstimulation was increased with MVI; however, there was no difference in mode of delivery and adverse maternal or fetal outcome.[19]

MEASUREMENT

We selected the following outcome measures:

- Time from arrival to commencing IOL.
- Time from commencing IOL to delivery.
- Percentage of women undergoing outpatient IOL.

Process measures included:

- Number of women requiring oxytocin.
- Time from starting oxytocin to delivery.

In order to ensure that our interventions maintained a good safety profile and that women had access to labour analgesia, we collected data on the following balancing measures:

- Mode of delivery (normal vaginal, instrumental or CS).
- Number of women receiving epidural labour analgesia.
- Neonatal safety outcomes (number of babies requiring postnatal antibiotics, being admitted to intensive care, cord pH <7.1).
- Maternal safety outcomes (maternal fever, postpartum haemorrhage).

We collected baseline data from 20 IOLs carried out between November and December 2016. Seven out of 20 waited >12 hour to commence IOL; 0/20 had outpatient IOL. The mean time from start of IOL to delivery was 31 hours, ranging from 2 hours to 63 hours. The CS rate was 45% (9/20).

We obtained quantitative data through structured interview of seven women on the postnatal ward who had IOL. We identified that many women had unrealistic expectations of the IOL process, 4/7 stating that they expected IOL to last 8–24 hour. The most common complaint was that the process had many delays, in particular with drug administration, awaiting review from medical staff and in transfer to the delivery suite.

DESIGN

The WOCIL team comprised two consultant obstetricians (obstetric head of service and the antenatal service lead), who worked closely with the clinical director and general manager for maternity. An IOL Champion Midwife was recruited and given 2.5 days per week to work specifically on the project for the first 4 months. The team also recruited junior medical staff and worked closely with midwifery managers.

We took a bottom-up approach and held engagement events where all staff from all areas of maternity was invited to discuss root causes, as well as change ideas. These discussions formed the basis of our driver diagram and there was ownership by the wider team.

We registered the project as a trust audit. We devised an IOL booking system to limit planned IOLs to four per day. IOLs overcapacity were booked at our other maternity site. We also wrote a new IOL guideline, in response to comments from staff that the existing guideline was not universally adhered to due to ambiguities. In using a 'Quality Improvement IOL Project Guideline', we were able to respond to feedback in implementation, and from ongoing plan, do, study, act (PDSA) cycles. When we reached a good working version, we then submitted it for ratification through the trust guidelines committee.

In initial stages, we were not considering changing our main IOL agent from dinoprostone. We concentrated on

improving and standardising our existing processes and booking systems. After 6 months, we decided to try using MVI due to continued problems of long IOL duration. It was estimated that 50%–70% of our IOLs would be appropriate for MVI. We anticipated that concerns with safety and lack of clinician confidence would be the main barrier to uptake.

STRATEGY

PDSA cycle 1: moving outpatient IOL from the antenatal ward to day unit

Plan— Outpatient IOL uptake was low (0/20 in baseline audit) due to starting IOLs late on the antenatal ward, as midwives are often busy with other ward duties. Women were also not informed in advance that they were eligible for outpatient IOL.

Do— We moved the location of outpatient IOL from the inpatient ward setting to the outpatient day unit, publicised outpatient IOL with posters in the antenatal clinic, and the clinic manager was put in charge of booking all IOLs and thus she would offer outpatient IOL to suitable women.

Study— Day unit staff was engaged in the planning phase and were well supported by their lead midwife, so they felt comfortable with carrying out IOLs. Our outpatient IOL rate increased to 10% (22/223 women) on subsequent data collection. The main barrier to further increase outpatient IOL rate is the high-risk profile of our population and preferential booking of low risk IOLs to the alternate maternity site due to capacity problems (see the PDSA cycle 3 section below).

Act— We initially started with only offering outpatient IOL to nulliparous low risk women. After 6 months, the processes were well established and staff was confident with the process, with no adverse outcomes reported. We then extended outpatient IOL to multiparous women as well.

PDSA cycle 2: starting balloon IOLs for women with previous CS on the antenatal ward

Plan— Women with previous CS were traditionally induced on the delivery suite, either with amniotomy and oxytocin or with an intracervical Foley catheter if the cervix was unfavourable. Women would attend in the morning and usually be diverted to the antenatal ward, where they would occupy an inpatient bed until a bed was available on delivery suite to start the IOL.

Do— We started asking women to present directly to the antenatal ward for IOL, where a registrar or consultant would insert the intracervical Foley's catheter on the antenatal ward. It was anticipated that she could then move to delivery suite and be ready for amniotomy some hours later.

Study— We found the Foley's catheters very difficult to insert on the antenatal ward due to the soft mattress beds with no lithotomy poles and poor lighting. Women were finding the procedure uncomfortable and distressing.

Act— We abandoned this idea. Instead, we asked women to phone the delivery suite midwife coordinator on the day of the IOL, who would advise a suitable time to attend depending on the bed status each day.

PDSA cycle 3: introduction of an IOL booking 'gatekeeper' and booking of overcapacity IOLs to the alternate maternity site

Plan— We found that clinicians would often overbook the IOL booking diary, resulting in too many IOLs booked for a given day.

Do— The clinic manager was assigned the role of 'gatekeeper' to the IOL booking diary.

Study— Women would sometimes resist having their IOLs carried out at a different maternity site.

Act— We put posters up in the clinic explaining to women that both our maternity sites were under the same management of the same trust.

PDSA cycle 4: asking women to phone the antenatal ward or delivery suite prior to attending for IOL

Plan— Women were attending for IOL and waiting many hours to start their IOL due to the unit being too busy.

Do— Success from PDSA 2 and asking women to phone prior to attending on their IOL day encouraged us to scale this intervention up to apply to all women.

Study—t The system was more responsive to changing needs depending on workload and staffing on each day.

Act— Staff felt that they had better control of their workload with this system and run charts showed a reduction in time taken to start IOL after arrival.

PDSA cycle 5: introduction of MVI as an IOL agent for eligible women (as defined by product license)

Plan— Data collected from 223 women undergoing IOL from February 2017–May 2017 showed that in spite of our changes detailed above, there was no change in total IOL time since the start of the project, though there was a reduction in the time taken to start IOL. We reviewed available evidence of MVI and decided we would try this IOL agent, as it was faster acting than DVI.

Do— We drew up a trial QI guideline on use of MVI, based on the inclusion criteria in from the EXPEDITE trial.[19] We offered MVI to all women Para 0–3, undergoing inpatient IOL. We held education sessions for midwives and doctors about the recognition and management of tachysystole and uterine hyperstimulation. Our data was circulated weekly by email and publicised monthly via posters in the department.

Study— We found that use of MVI resulted in a shorter IOL-delivery interval, reduction in use of oxytocin and reduction in CS rates. Conversely, there were also higher hyperstimulation and tachysystole rates, meconium staining of liquor and increase in the use of tocolysis. There was no increase in neonatal adverse outcome. These findings were in keeping with findings from the EXPEDITE trial. More details on our findings are available in the Results section below. There was a learning

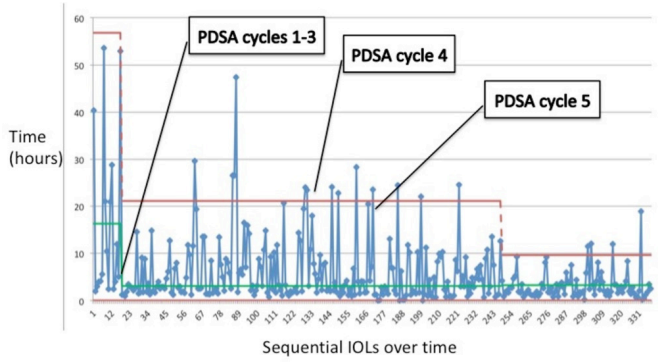

Figure 1 Time taken (hours) from arrival in hospital to start of induction. PDSA, plan, do, study, act.

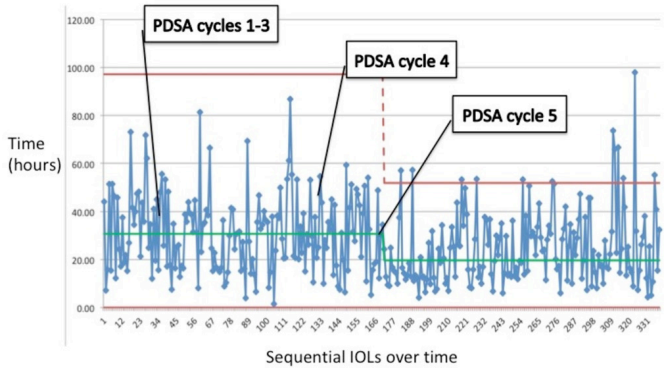

Figure 2 Time taken (hours) from start of induction to delivery. PDSA, plan, do, study, act.

curve with regard to our unit's adoption of MVI. Midwives and doctors developed a lower threshold for removing the MVI as our experience went on. MVI IOLs meant that more women needed urgent transfer to delivery suite due to onset of labour. This created faster flow of women through the IOL process, but also meant that delivery suite could feel more pressured to provide staff and beds on an urgent basis.

Act— We collected data from 207 women using MVI from July 2017 to December 2017. After 2 weeks of use, we changed our inclusion criteria to exclude women who were Para 3 and above, we did not have many women in this category and staff felt it was more cost effective to use DVI in these women, who would not usually be at risk of a long IOL. We also excluded women with fetal growth restriction, abnormal fetal dopplers, pre-eclampsia and antepartum haemorrhage. This was due to one case where it was used in a woman with an undiagnosed small baby, where hyperstimulation occurred and the baby required delivery by urgent CS. Though no harm resulted from this incident, we restricted the use of MVI to exclude babies who were thought to have potentially lower intrapartum reserve. We plan to continue using MVI in women undergoing inpatient IOL due to the improved flow and reduction in length of IOL time.

RESULTS

Time taken to commence IOL after arrival

We plotted data points in sequential order into a statistical process control (SPC) chart (figure 1) and found that compared with baseline, there was a reduction in mean time taken to commence IOL after our initial changes in process design. There were further reductions in upper control limits, as variation in practice reduced with further PDSA cycles. Upper control limits was recalculated again after introduction of MVI due to a shift in 15 points within one sigma of the mean. The mean remained at 3 hours while the upper control limit has reduced from 21 hours to 10 hours, representing a significant reduction in variation between patients in time to commence IOL. We hypothesised that as the unit learnt how to effectively use MVI, we improved overall flow of women through the IOL process. The reduction of bottleneck formation downstream enabled the process to start efficiently upstream.

Time from start of IOL to delivery

As above, we plotted sequential IOLs into a SPC (figure 2) and demonstrated a reduction in total IOL time after introduction of MVI and a large reduction in the amount of variation experienced as demonstrated by the upper control limit. Mean time induction to delivery reduced from 31 to 20 hours. There was a reduction in time from start of IOL to delivery in all groups (multiparous, nulliparous and women starting IOL with intact or ruptured membranes).

Other process and balancing measures

When comparing women receiving MVI with women receiving dinoprostone:

- Fewer women required oxytocin.
- Women who did have oxytocin required it for fewer hours before delivery.

The reduction in oxytocin use reached statistical significance (80%–61% in nulliparous women, p=0.002% and 50%–20% in multiparous woman, p=0.0001). The overall reduction in oxytocin use was 66%–46% (p=0.0001).

With regard to mode of delivery, we compared women receiving MVI to those receiving dinoprostone and divided the groups down into multiparous versus nulliparous, as well as women starting IOL with intact or ruptured membranes. In all groups, there was a trend towards a reduction in CS rates, with the reduction in CS for nulliparous women reaching statistical significance (41%–25%, p=0.03).

We found a higher incidence of uterine tachysystole and hyperstimulation with MVI compared with dinoprostone. Fifty per cent of our women received tocolysis during the course of their MVI IOL, compared with none in the dinoprostone series. However, ongoing data collection from IOLs done 3 months following PDSA cycle 5 showed tocolysis use in 35% of women receiving MVI and 10% of women receiving dinoprostone. This suggests that better education of midwives and doctors in prompt management of women experiencing hyperstimulation

has resulted in identification of more cases in the dinoprostone group, and that with ongoing experience in MVI use, tocolysis rates have fallen since initial introduction of the drug.

We did not find any difference in the uptake of regional anaesthetic, adverse neonatal outcome or adverse maternal outcome, when comparing MVI with dinoprostone. We identified two cases in our series where MVI use may have contributed to fetal heart rate abnormalities and emergency CS. The first was in the first week of use, where the baby was growth restricted but not identified as such before IOL, as described in PDSA cycle 5. The second was following delayed recognition of ongoing uterine hyperstimulation following onset of labour and appropriate removal of MVI. Both cases were fed back to staff as learning opportunities for future practice.

We identified 16 babies receiving MVI who were born with cord pH <7.1 and case notes were reviewed. We found that in each case MVI was unlikely to have contributed to the low cord pH due to the presence of other significant intrapartum factors.

Finally, we collected satisfaction questionnaires from women undergoing IOL periodically and collected qualitative feedback through structured interviews. We received fewer complaints from women on the ward concerning delayed transfers. Staff reported this to be a significant improvement following MVI introduction, although they then raised new concerns about more women needing urgent transfer to delivery suite for pain relief and needing to wait for bed preparation in some cases.

Lessons and limitations

The project strengths included:

- Use of validated QI methodology from the outset.
- Collection of high-quality data with good numbers over the course of 12 months.
- Several PDSA cycles.
- Ownership of the project interventions by the wider maternity team following engagement efforts.

Limitations included:

- Lack of data for IOLs on women with a previous uterine scar.
- Lack of quantitative data for satisfaction of women.
- Lack of detailed comparative data for the characteristics of the women receiving MVI and DVI.

The team anticipated resistance to MVI introduction and hence focused initially on improving the surrounding processes and building a case for change. Only after other aspects of the IOL process were optimised, could we see that we were unable to significantly reduce the overall IOL time. Thus, we were able to get support for MVI from the wider maternity team. MVI use represents a significant change in practice and requires vigilance in the management of uterine hyperstimulation. Following introduction, we reported findings and learning from case reports on a weekly basis in a staff email newsletter so that we could rapidly feed back practice concerns and gain confidence in the use of MVI.

We realise that we are unable to report on details of the women undergoing IOL in the MVI and the DVI groups. Our data was manually collected and our data proforma was designed to enable collection of only our outcome, process and balancing measures. We were satisfied that the data we collected in our 'real-life' setting confirmed the RCT data that MVI results in a faster IOL-to-delivery time than DVI.

Our experience of using MVI mirrored the results from the EXPEDITE trial apart from two aspects. First, our results showed a reduction in CS rate in women using MVI compared with DVI. We hypothesise that this is due to the reduction in protracted delays and women getting frustrated with the IOL process.

Second, our results showed a higher use of tocolysis than in the EXPEDITE trial, which quoted a 10.3% versus 2.6% hyperstimulation rate (MVI vs DVI) and a 12.2% versus 4.1% tocolysis rate. We believe that in our setting, our focus was on safety in the introduction of a new drug and we encouraged a low threshold to use tocolysis in the presence of suspected excessive uterine activity. We found that with continued experience and appropriate MVI retrieval, the tocolysis rate went down from 50% initially to 35% after 3 months.

CONCLUSION

In high-volume maternity units in the UK, IOL is often conducted outside of the delivery suite. With traditional IOL agents like dinoprostone, women are often waiting for midwifery care and a bed on the delivery suite to be available before amniotomy and oxytocin augmentation can begin. This waiting period can often be protracted and can explain why the total length of IOL in a real-life setting is often longer than in the RCT setting.

Following implementation of simple process measures in PDSA cycles 1–4, we found that while we were able to reduce the waiting time, women experienced prior to starting their IOLs, we were unable to significantly impact on overall IOL duration. Our project took a drug that had potential to reduce IOL duration, as shown in the RCT setting[19] and implemented its use in the real-life setting.

The faster IOL process has created new challenges as flow issues have been highlighted in the postnatal and discharge pathways, but the team are confident that in employing QI methodology, we can continue to achieve improvements and benefits for staff and women.

We conducted an analysis of potential financial savings through the faster flow of women undergoing IOL. We calculated an annual saving of 4445 hours of midwifery time and 9904 hours reduced length of stay for our unit. This worked out to be an annual saving of £73 308. See figure 3 for assumptions made in these calculations. While we realise that this figure may not represent an actual financial saving, as we have not been able to cut midwifery

Total number of births per year	5694
% IOL rate	32
% Multiparous	45
% Primiparous	55
% Multiparous women eligible for MVI	60
% Primiparous women eligible for MVI	70
Cost of Midwife per hour	£16
Average cost of an in-patient bed (24h)	£178.84
Cost of MVI – single dose	£93
Cost of DVI – single dose	£33
Number of days per week IOLs carried out	7

Figure 3 Assumptions used in financial impact calculations. DVI, dinoprostone vaginal insert; IOL, induction of labour, MVI, misoprostol vaginal insert.

numbers or close wards due to bed days saved. However, 413 bed days unblocked in 1 year would certainly make a positive impact to the service midwives and doctors can provide to women on a daily basis.

We are very confident that the changes we have implemented and the positive results will be sustained as time goes on, as practice has already been embedded over the past 15 months and MVI has been in use for the past 9 months. We are carrying on with data collection and QI work concerning IOL but focusing on other aspects, such as:

- IOL for women with prolonged rupture of membranes, as delayed IOL could result in higher risk of chorioamnionitis for these women and babies.
- IOL for women with a prior uterine scar.
- Monitoring hyperstimulation rates and use of tocolysis with MVI compared with DVI.
- Women's experience of pain relief administration with MVI.

In conclusion, our experience with using QI methodology in improving a complex maternity pathway has been successful, as demonstrated by the qualitative and quantitative data collected. In promoting and sharing its success, the department has been energised to embrace QI in other aspects of care.

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