TITLE

Implementing routinely discussing and offering of local anaesthesia for intrauterine device insertions.

Short title: LA implementation project

KEY WORDS

intrauterine device (IUD), pain, local anaesthesia (LA), quality improvement, implementation

MAIN TEXT

Dear Editor,

The procedure for intrauterine device (IUD) insertion could cause pain or discomfort. The Faculty of Sexual and Reproductive Healthcare recommends discussing and offering pain relief for IUD insertions to all women.[1, 2] The use of local anaesthesia (LA) is one of the ways to avoid or manage pain during IUD insertion. However, not all clinicians routinely offer LA for IUD insertions.

There were differences in the uptake of IUD insertion appointments in our service between clinicians related to LA. Appointments with clinicians who routinely offered LA for IUD insertions were fully booked weeks in advance compared to appointments with clinicians who did not. To support timely equitable patient-centred care and eliminate this disparity, the service created a project and team to explore ways to ensure LA for IUD procedures was routinely discussed, offered and provided by all IUD inserting clinicians.

Our service was the largest in North East England with over 32,000 attendances and 1600 IUD insertions a year. IUD insertion appointments at the time were booked in person or via telephone with either doctor (*n*=10) or nurse (*n*=5) IUD inserting clinicians, of whom 87% (*n*=13) participated in the project surveys.

For this project, the team choose the Model for Improvement approach.[3] This involved an iterative process of planning, doing, studying, acting, and then repeating based on the evaluation and outcome(s) from the previous cycle (figure).

Topical gel and injectable LA were available in the service, but many clinicians were not trained or confident with injectable LA. Clinicians who were unable to confidently provide injectable LA were trained during the first improvement cycle. An evaluation some months later showed no increase in the number of clinicians who routinely offered or provided injectable LA. This was reported to be due to persisting challenges of ease (including equipment needed, time for assembly and administration, and having to seek a medical colleague to prescribe the injectable LA), lack of clinician confidence to routinely offer an injectable, and patients declining injectable LA. Further meetings led to incorporating another LA option, LA spray, for the second improvement cycle. (See figure and supplemental material LA guidance for clinicians)

A trial of LA spray use was done over a period of 6 months (March 2021 – August 2021). The second cycle evaluation showed that uptake of appointments between clinicians had levelled out, with the proportion routinely offering and using LA for IUD insertions increasing from 83% (*n*=10) to 100% (*n*=13). LA spray was reportedly easy to use, quick

acting, effective, less expensive and more environmentally friendly from the survey (see supplemental material table) and team meetings, as well as more acceptable to patients compared to LA injectable.

Our project aim, for clinicians to routinely discuss and offer LA pain relief and eliminate a potential disparity in care, was achieved but in a different way to that anticipated at the outset, and led to the successful implementation of change that incorporated LA spray.

Advice to others considering change

Implementing this improvement required team discussions as well as considerations of motivators for and against LA options. The initial assumption that it was a lack of injectable LA training that was the primary inhibitor proved inaccurate. It is therefore important to be mindful that a simple intervention may constitute part of a complex system within healthcare provision when it comes to implementation.

Another FSRH resource to support improving IUD pain management is the National Patient Group Directions (PGD) template to support LA use by non- prescriber clinicians.[4] Incorporating knowledge or evidence into practice can however be unique to local contexts. In addition to team effort and time, also consider patient input or representation for a project team.[5]

ACKNOWLEDGEMENTS

We are grateful to the clinicians who anonymously participated in the surveys, the service team, and to other staff who supported this project.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available upon reasonable request.

COMPETING INTERESTS AND FUNDING STATEMENTS

The authors have no competing interests or funding to disclose.

SUPPLEMENTARY MATERIAL AVAILABLE

1. LA spray user guidance
2. Reporting statement checklist
3. Table - Surveyed clinicians and their responses

REFERENCES

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3. Associates in Process Improvement. *Model for Improvement [home page]*. Available from: https://www.apiweb.org/index.php [Accessed 19 May 2024].
4. Specialist Pharmacy Service & Faculty of Sexual and Reproductive Healthcare. *Patient Group Direction Template: Lidocaine 10mg/ml spray for IUC insertion or removal*. Published 19 January 2023, Last updated 22 May 2023; Available from: https://www.sps.nhs.uk/articles/lidocaine-10mg-ml-spray-for-iuc-insertion-or-removal/ [Accessed 29 July 2024].
5. Goldthwaite LM and Brown-Johnson CG. *You're invited: welcome to the dynamic world of quality improvement and implementation science.* BMJ Sexual & Reproductive Health. 2023; **49**(4): p. 231-233.

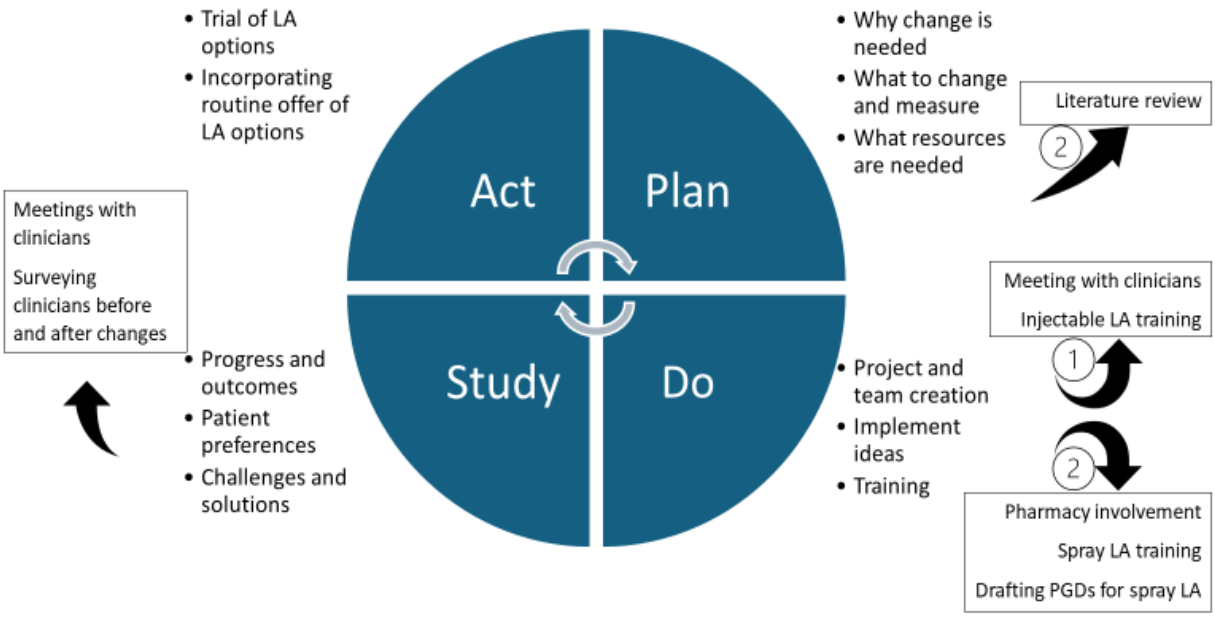

Figure – Model for improvement for project including details during first ① and second ② cycles. LA, local anaesthesia; PGDs, Patient group directions.

Lidocaine 10% Spray for IUC[1,2]

Lidocaine hydrochloride is effectively absorbed from mucous membranes and is a useful surface anaesthetic in concentrations up to 10%. It is generally safe hence available over-the-counter from pharmacies. The effect duration of lidocaine spray is estimated to last less than one hour. Systemic absorption can follow topical application of lidocaine, so the possibility of interactions should be borne in mind.

Severe interactions occur with beta-blockers, cimetidine and noradrenaline (synergistic) and antiretrovirals (they increase exposure to lidocaine); lidocaine increases cardiovascular risks in those with heart disease and risks of convulsions in diazepam users; lidocaine should be used with caution in patients receiving other local anaesthetics or agents structurally related to amide-type local anaesthetics e.g. anti-arrhythmics such as mexiletine, and anti-arrhythmic class III e.g. amiodarone. Avoid lidocaine in cardiac, hepatic and renal impairment; use plain mepivacaine (Scandonest®) instead.

Mode of administration

Lidocaine 10 mg per 1 actuation (depression of the spray nozzle of the pump spray canister)

Dose and site of administration

Up to 4 sprays (40mg) is recommended for application to the cervix prior to IUC fitting
Maximum dose is 20 sprays (200mg).

Recommended procedure for administration

Visualise the cervix using a speculum and wipe clean with gauze if required. Wearing a new pair of non-sterile gloves, assemble the local anaesthetic (LA) spray unit by attaching a new nozzle to the Lidocaine 10% spray bottle. Apply up to 4 actuations/sprays of LA to the anterior cervical lip. It may take a few depressions of the head of the spray nozzle before the LA begins to come out, and the nozzle held ~10cm away from the cervix tends to achieve farther reach and wider spread. Allow 3 minutes for the applied LA to take effect. Detach the nozzle and remove gloves, discard these in clinical waste. Wear a new pair non-sterile gloves to clean the spray bottle using wipes and place aside away from the procedural area to air dry. Lidocaine 10% spray is a non-sterile solution and one study reported vaginitis in half of recipients. So it is recommended to wipe the cervical os clean and vagina dry with wool before continuing with the IUC procedure. After handwashing post procedure, the spray bottle should be put back in its box and returned to pharmacy.

<table>
<tr>
<td>Potential side effects and patient information
Lidocaine (Xylocaine©) Spray has minor influence on the ability to drive and use machines, a dose dependent very mild effect on mental function and may temporarily impair locomotion and co-ordination. When used for surface anaesthesia rapid and extensive absorption may result in systemic side effects. Systemic adverse reactions may result from hypersensitivity, allergic reactions, idiosyncrasy or reduced tolerance on the part of the patient. Reactions involve the central nervous system (CNS) and/or the cardiovascular system. CNS effects include nervousness, dizziness, drowsiness, convulsions, unconsciousness and respiratory arrest.
Cardiovascular reactions are depressant and may be characterised by hypotension, myocardial depression, bradycardia, cardiac arrhythmias, myocardial depression and possibly cardiac arrest</td>
<td>Actions in the case of severe side effect(s) or adverse reaction(s)
Seek appropriate emergency advice and assistance.
Follow routine practice for managing allergic and anaphylactic reactions as appropriate
Document in the individual’s clinical record and inform duty doctor
Complete incident procedure if adverse reaction is severe (refer to Trust policy)
Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at www.yellowcard.mrha.gov.uk.</td>
</tr>
<tr>
<td>Precautions
Adrenaline and oxygen must be available in case of any severe side effect(s) or adverse reaction(s)
Avoid contact with eyes
Avoid in patients with a history of local/topical lidocaine use affecting their mental function, locomotion or coordination if they will be driving afterwards or their return journey is long and to be done alone. Alternatively, they could avoid such activity for one hour after lidocaine use.
Individual to return to clinic if she has any concerns</td>
<td>Documentation in records
Local anaesthesia used and patient advice (including possible side effects) given beforehand
Dose and form administered
Batch and expiry date details
Signature/name of staff who administered the medication
Details of any adverse drug reaction and actions taken if applicable</td>
</tr>
<tr>
<td>Contraindications
Known hypersensitivity to Lidocaine Hydrochloride or other anaesthetics of the amide type
Individual who has received a previous maximum dose of local anaesthetic within 4 hours
Under 16 years of age and assessed as not competent using Fraser guidelines
The threads of an existing intrauterine contraceptive cannot be seen (for replacements)
Complete heart block or heart rate below 60 bpm or hypovolaemia
Porphyria
Inflammation or infection of the tissues where the spray is to be applied - the effect of local anaesthetics maybe increased or reduced if the spray is applied to traumatised, inflamed, damaged or infected area(s). Increased local anaesthetic absorption increases the possibility of systemic side effects, and local anaesthetic effect may also be reduced by altered local pH.</td>
<td>Use with caution in patients with:
Epilepsy
Impaired hepatic function
Impaired respiratory function
Severe renal dysfunction
Cardiac conduction disturbances, congestive heart failure, cardiovascular disease or heart failure, post cardiac surgery, bradycardia
Severe shock
Myasthenia gravis
Patients in poor health or who are debilitated.
Taking antiarrhythmic drugs class III (e.g. amiodarone) should be closely monitored.
Anticoagulated patients who are not within their desired INR range
Bleeding disorders</td>
</tr>
</table>

1. BMJ Group and the Royal Pharmaceutical Society of Great Britain. *British National Formulary.*
2. Xylocaine 10mg Spray Summary of Product Characteristics.

Table – Surveyed clinicians and their responses

	Before introduction of LA spray (*N* = 13)				**After** introduction of LA spray (*N* = 13)			
Questions	**Responses**	***n***	**%**	**Comments**	**Responses**	***n***	**%**	**Comments**
Clinical group	Doctor	9	69		Doctor	8	62	
	Nurse	4	31		Nurse	5	38	
Fitting experience	>5 years	9	69		>5 years	8	62	
	2-5 years	1	8		2-5 years	3	23	
	<2 years	3	23		<2 years	2	15	
LA options currently confident with offering and providing	topical gel only	0			topical gel only	0	0	
	injectable only	1	8		injectable only	0	0	
					spray only	0	0	
	both gel and injectable	9	69		both gel and injectable	0	0	
					both topical gel and spray	5		
					both injectable and spray	2		
					gel, injectable and spray	7		
	none	3	23		none	0		
Preferred LA option and why*	topical gel	0			topical gel	0		
	injectable	10	83	**More/most** effective [3] **It's** effective and quick acting **More** effective than topical gel **It** provides anaesthetic effect required **Remains** local, not as messy **Never** been taught [to perform IUC insertions] with [topical] gel, unsure how effective it is **More** experience and evidence base for its use [x2] **I had** a patient who had a vasovagal episode with [topical] gel - no episodes with injectable and [injectable] is good if cervical os is small	injectable	3	23	**I think** it is the most effective, achieves best pain relief [I] **Usually** fit more difficult ones in gynae that require dilation or pipelles, so would feel this more appropriate in these circumstances [It is the] **One** I am most familiar with

					spray	8	62	**Easy** to use [x6] **Appears** to ... works well [x3] **Ease** of use, quick..., patients tolerate well, no sharp sensation for patient Its quick [x2] **Easy** to use, quick acting, cheapest option and environmentally friendly! **Patients** seem to prefer the idea of a spray to injectable as it is a less invasive procedure than inserting a needle **It** works very well if you wait 3-4mins, especially if you can get the nozzle in the [cervical] os for 2 pumps
	none	2	17	**I do** not use any [LA] **Don't** know the efficacy of either [topical gel or injectable LA]	none	2	15	**I ... advise** to take analgesia 1hour before appointment; sometimes just talking them through the procedure as you're doing it is enough... **Patient choice**
Do you think having an LA spray pain relief option in the service for coil fittings will be useful?	yes	8	62	**LA spray** is easier to administer, and does not bleed like injectable, and quick acting compared to gel **I think** it is useful for patients to be given increased choice/options for pain relief during IUC insertion but would like to see more evidence for its efficacy **Spray** has advantage of being quick and pain free so I think I would offer it more and would make patients feel less anxious **Don't** tend to use much anyway - patients seem to tolerate [IUC insertions] without [LA] or don't like idea of extra injection (risk of extra discomfort)	yes	12	92	**Allows** patients to have LA when having devices fitted by clinicians who aren't comfortable or trained with giving cervical blocks, allows pts to have LA who might fear the idea of a needle **I just** routinely use it now on all pts unless they specifically object. Excellent work on getting it in our pharmacy!
	may be' or 'depends'	5	38	**No** one has explained the benefits of LA spray as well as disadvantages	may be' or 'depends'	1	8	**I offer** LA to all but feel it is not required for most patients
	no	0	0		no	0	0	

LA – local anaesthesia. Percentages rounded up to the nearest whole. *One participant did not answer this question before the introduction of LA spray.