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MEETING ABSTRACTS

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P40.
OASI2: a hybrid effectiveness implementation RCT to inform scale up of care bundle to reduce obstetric anal sphincter injury (OASI) caused during childbirth

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Background
Obstetric anal sphincter injuries (OASI) can have severe debilitating consequences for women. A large-scale quality improvement study (OASI1; 2017-18) implemented a care bundle (antenatal information to women, manual perineal protection and mediolateral episiotomy when indicated) in 16 maternity units in Britain [1] which reduced OASI rates. OASI2 (2021-22) is a scale-up study, which examines strategies used to introduce, implement and sustain implementation.

Method
OASI2 is a cluster-randomised control trial with two arms. Arm 1 (peer-to-peer implementation, n=10) is supported by peer units. Arm 2 (lean implementation, n=10) does not receive any active implementation support. A parallel nonrandomised study group (sustainability arm) consisting of original OASI1 units, allows study of the care bundle's sustainability over time. An estimated 2,750 singleton live births/unit will be eligible for the care bundle. All three study groups receive an implementation toolkit including training resources. Table 1 details the expected implementation strategies across the three arms. Clinical outcomes (OASI rates) are collated from maternity information systems; implementation outcomes (acceptability, feasibility, appropriateness, sustainability) are collected through validated surveys [2,3] administered to women and clinicians, supplemented by qualitative research. Quantitative data are analysed using regression modelling and descriptive statistics.

Results
The trial will identify the effect of the applied implementation strategies [4] on implementation success, and link that to the clinical effectiveness of the bundle. Successful sustainability strategies will be identified.

Conclusion
The study will generate insights into how to effectively scale-up and sustain uptake and coverage of similar interventions in maternity units. A locally adaptable 'implementation blueprint', will be produced to inform development of future guidelines to prevent perineal trauma.

Acknowledgements

Trial Registration
Trial registration pending completion of research protocol.

References
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Table 1 (abstract P40). Discrete implementation strategies to be used in each group of participating units

Discrete Implementation Strategy / group of strategies [4]		Sustainability group	Peer implementation	Lean implementation
Implementation requirements	Identify and prepare champions/ Facilitation/ Clinical supervision	x	x	x
	Develop and organize quality monitoring systems/ change record systems/ Audit & provide feedback / facilitate relay of clinical data to providers	x	x	x
	Develop a formal implementation blueprint/ develop an implementation glossary	x	x	x
	Conduct educational meetings (clinicians)	x	x	x
	Use educational materials (toolkit resources)	x	x	x
	Remind clinicians: pens, posters, stickers (care bundle launch day and promote the care bundle continuously)	x	x	x
	Obtain and use patient feedback/ Prepare patients/ consumers to be active participants (engage local PPI group)	x	x	x
Strategies exclusive to external facilitation	Centralise technical assistance/ Provide local technical assistance/ Use an implementation advisor/ Provide ongoing consultation	Centralised technical assistance	Local technical assistance	
	Organize clinician implementation team meetings (skills development days led by external facilitators)	x	x	
	Create a learning collaborative/ Promote network weaving	x	x	
	Use train the trainer strategies	Project Team > clinicians through cascade	External facilitators > clinicians through cascade	
Strategies related to sustainability efforts	Conduct educational outreach visits	Site visits from Project Team		
	Involve executive boards	Ensure senior-buy in		
	Mandate change/ Create or change credentialing and/or licensure standards	Bundle introduced into mandatory training/ induction packages		
	Fund & contract for the clinical innovation	Protected time or champions		
	Revise professional roles	Formal titles for champions		
	Recruit, designate, train for leadership	Champions trained for external facilitator role		

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