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Ease of use and accuracy of a perineal measuring device (Episiometer) to ensure correct angle and length of a mediolateral episiotomy: a mixed-methods study

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**Introduction** To guide clinicians in performing mediolateral episiotomies (MLEs) at 60-degrees, a new clinical innovation called the 'Episiometer' was developed. The aim of this study was to assess the usability and accuracy of the Episiometer in guiding clinicians to perform a safe episiotomy in both low- and high-resource settings.

Design A prospective, multi-site Phase-I clinical trial was conducted between January 2017 and July 2018, involving three international study sites: Australia; Papua New Guinea; and India. The study design was mixed-methods, incorporating an explanatory sequential design using surveys, clinician interviews and patient chart review to determine the usability and accuracy of the Episiometer. The patient chart review and results of this are discussed in an accompanying article.

## Abstracts

**Methods** The 'Episiometer' is the clinical innovation designed to attain an episiotomy cutting angle of 60-degrees. The instrument is designed to assist clinicians to make an accurate and consistent episiotomy cutting angle within a 'safe' green zone between 45-60 degrees and length of at least 4 cm. The instrument also improves the visibility of the 60-degree line to clinicians, and provides an exact measurement for length (located on the 60-degree angle line). Clinicians from all three sites were recruited to provide feedback and measurements of incisions performed using the Episiometer (n = 135) following attendance at a minimum of at least one training session with site coordinators. Twenty of these clinicians were then recruited randomly from the sample who responded in the surveys and interviewed face-to-face. Patients were followed up 6-weeks postpartum to monitor potential complications (n = 120).

**Results** Overall, the Episiometer was well received by clinicians – particularly by more junior staff members who were significantly more likely to report the Episiometer as being beneficial in guiding a safe MLE compared to their more senior counterparts (P=0.003 and P=0.011, respectively). In addition, 89% of incisions (107/120) were within the 'safe zone' between 45-60 degrees, and 40% (48/120) were made at exactly 60-degrees. No patient had any degree of perineal tear at follow up. **Conclusion** The Episiometer is a well-received clinical innovation in both high-resource and lower resource settings. When used as directed, the Episiometer produces an accurate and safe incision,

and reduces variation in clinicians' performance of episiotomy.