

Table 3 Details of device use standardisation for components of ventouse interventions: flexible (F), mandatory (M) and optional (O)

Component	Verbatim description of standardisation	
Choice of device (F)	'...the exact type of cup to be used (i.e. whether silastic, metal, etc.), was at the discretion of the obstetrician performing the delivery...' ³³	
	'...range of metal cups was used (40-60mm), Malmström, anterior, posterior Bird & 'New Generation' cups) depending on availability & operator preferences.' ⁵⁷	
	'The choice of which conventional cup [comparator] to use was then made by each individual clinician according to clinical judgement for each case.' ²³	
	'Three sizes of metal cups were used, 40, 50 and 60 mm in diameter. The rubber cups...were 50 and 60 mm in diameter.' ⁵⁸	
	'Decision for forceps delivery or ventouse extraction was of consultant and the choice of method was dependent entirely on his/her judgement.' ²⁸	
Creating vacuum (M)	'Negative pressure gradients were those suggested by the manufacturers...-0.2kg/cm ² between contractions and -0.7kg/cm ² for pulls...during contractions' ⁵⁵	
Descent should be achieved with each contraction (M)	'abandoned if station was not gained with traction or if any scalp trauma was noted...' ²⁶	
	'Descent should be seen with each traction...' ²³ and similar text ⁴⁵	
Delivery should be achieved with 3-4 contractions (M)	'...without regard to the number of extraction attempts ("pulls")...' ²⁶	'...traction efforts to deliver the baby were kept to less than three...' ³⁰
	'...three 'pulls' (one 'pull' being traction during a single maternal contraction) ...)' ⁵⁷ and similar text ⁵⁵	'According to departmental policy, a "freshman" is asked to stop the procedure after 3 to 4 pulls have failed to complete the ventouse delivery...' ⁵⁰
	'...4 pulls.' ⁴³	
Cup displacement (M)	'...vacuum extractor was considered to have failed when the cup fell more than twice...' ⁴⁹ and similar text ⁵⁷	
	'Three cup disengagements ("pop offs") mandated abandonment of the vacuum procedure.' ²⁶	
	'...one loss of suction...' ⁵⁵	
	'...the procedure should be abandoned if the cup detaches twice.' ²³	
Cup reapplication (M)	'one reapplication of the cup was permitted with further detachment indicating...a change in mode of delivery.' ⁵⁹	
	'Only two reapplications of the cup were allowed.' ²⁶	'If a cup slipped off, it was replaced once...' ⁴¹
	'...only three reapplications of the cup were allowed.' ³⁰	
Delivery should be achieved within 15 minutes of cup application (M)	'The time limit of application was 15 min' ⁴⁴ and similar text ⁵²	'restriction on the...duration of the extraction.' ⁵⁰
	'...no longer than 20 minutes...' ²⁶	'...30 minutes after the beginning of traction attempts.' ⁴¹
Instrument failure (O)	'If delivery with the selected instrument was not successful, the subsequent course of action (i.e. delivery with another instrument or caesarean section) was at the discretion of the obstetrician conducting the delivery.' ³³ and similar text ⁶⁰	